"A Comparison of Different Community Models of ART Delivery Amongst Stable HIV+ Patients in two Urban Settings in Zambia"

(DAIDS-ES ID: 38191)

A sub-study of

HPTN 071: Population Effects of Antiretroviral Therapy to Reduce HIV Transmission (PopART): A cluster-randomized trial of the impact of a combination prevention package on population-level HIV incidence in Zambia and South Africa (DAIDS ID: 11865)

A Non-IND Study of the HIV Prevention Trials Network

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PROTOCOL SUMMARY

Purpose: The purpose of this study is to compare the virological and clinical outcomes of patients participating in community models of ART delivery to the standard of care in an urban setting in Zambia.

Design: A three-arm cluster-randomized non-inferiority trial to be implemented in two urban communities. Randomization will be at the level of community health worker (CHiP), stratified by community

Study population: A prospective cohort of adult patients enrolled into ART care in two urban communities participating in the HPTN 071 (PopART) trial. The intervention packages will be implemented throughout the two communities.

Study Size: Intervention will be implemented in 2 communities (Chipata and Kanyama), which have a total of 104 community health worker (CHiP) zones. Within each community, the CHiP zones will be randomized to one of the 3 trial arms. In the community with 54 zones, 18 zones will be randomized to each of the 3 trial arms. In the community with 50 zones, 17 zones will be randomized to the two "intervention" arms and 16 zones will be randomized to the "standard-of-care" arm.
Based on data from the first annual round of the CHiP intervention, the number of adults who are known by the CHiP teams to be HIV-positive and to be taking ART at the time of the most recent CHiP follow-up visit averages 50 per zone, with a harmonic mean of 36 per zone. Assuming that 80% of such adults agree to participate in the study and have not moved out of the community within 12 months after enrolment, the number of study participants per zone who can contribute to the primary endpoint measurement will have a harmonic mean of 30.

Study Arms/Interventions:

Arm 1: Adherence Clubs

- Patients living in these zones will be offered the choice of either being part of an adherence club or to continue receiving care at the clinic. In this model, adherence clubs will consist of a group of 20-25 stable patients who receive care in the community. Members of the club will meet every 3 months at an agreed communal venue where they will receive adherence support, symptom screening and pre-packed medications. Club members will be required two have 2 clinical visits (every 6 months) in a year for their routine clinical review and laboratory monitoring.

Arm 2: Home-Based ART delivery

- Patients living in these zones will be offered the choice of home ART delivery by the CHiP or to continue receiving care at the clinic. This model will provide ART to clinically stable patients in their homes. The CHiPs will visit the participant's homes once every 3 months to provide adherence support, symptom screening and dispense pre-packed drugs to the participant. The participant will only be required to visit the clinic twice in a year for routine clinical review and laboratory monitoring.

Arm 3: Control Arm

- Patients will continue receiving care at the local clinic.

Study Duration: The planned duration of the entire study will be approximately 24 months after implementation of the models. Assessment of the primary outcome is planned to be collected at 12 and 24 months after recruitment whereas secondary outcomes are planned to be collected at 6, 12 and 24 months after recruitment.

Primary Objective: To compare virological suppression at 12 months in HIV + patients receiving care via community ART models with those receiving care in the clinic (standard of care).

Secondary Objectives:

1. To compare the proportion of patients with virological suppression at 24 months in patients receiving care via community ART models with those receiving care in the clinic (standard of care).

2. To compare Loss to Follow-up (LTFU) rates and missed dispensation of ARVs among individuals receiving care via community ART models with those receiving care in the clinic (standard of care)., measured using routine health centre data

3.To compare HIV disease progression, and death among individuals receiving care via community ART models with those receiving care in the clinic (standard of care), measured using:

- CD4 cell count, WHO staging events, death from routine health centre data.

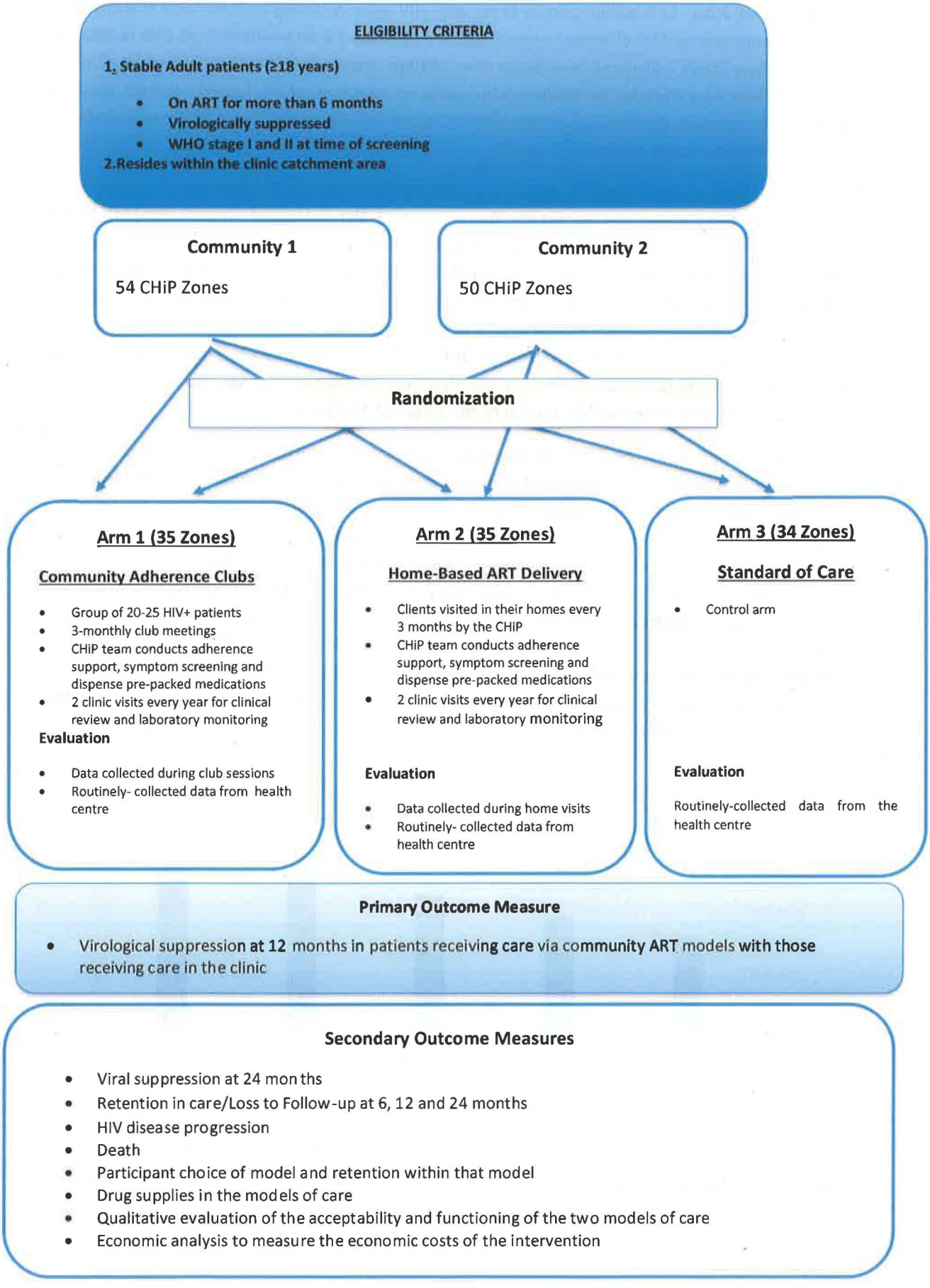
4. To qualitatively assess how health staff (including CHiPs) and PLWH on treatment experience the two models of care. This would be achieved through:

- Documenting treatment, adherence and retention experiences of PLWH accessing treatment through adherence club and home delivery models;
- Exploring the impact of the two models of care on access to treatment, adherence and retention according to the experience and perspectives of CHiPs and health facility staff;
- Qualitatively comparing how participant (PLWH and health staff) experience the models of care and experiences with the routine standard of care at the local health facilities;
- Qualitatively assessing participant (PLWH and health staff) perceptions about and experiences with the impact of the models of care on HIV services at the local health facilities.

5. To measure the health system costs of delivering the different community ART models

Study Sites: This study will be implemented in two Lusaka communities – Chipata and Kanyama.

OVERVIEW OF THE STUDY DESIGN AND RANDOMIZATION SCHEME



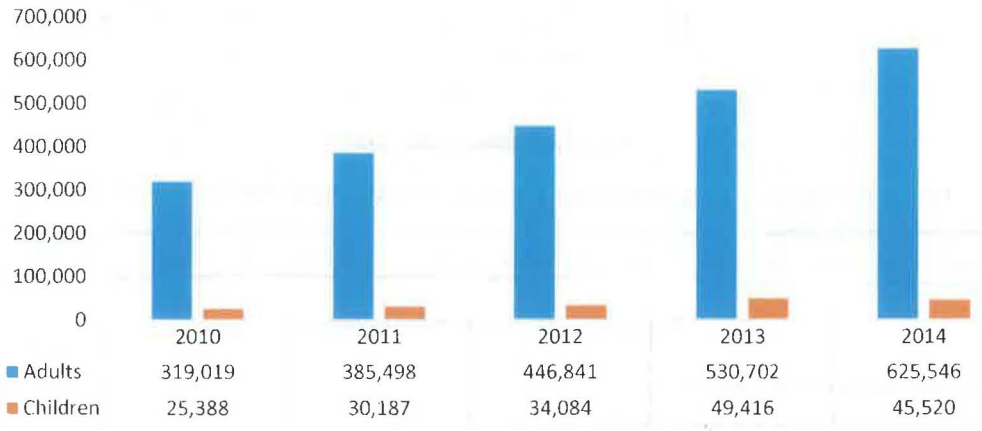
1.0 Background

By the end of 2013, 12.9 million people living with HIV were receiving antiretroviral therapy (ART) globally, representing 37% of those in need. This is a significant improvement from 10% in 2006 (1). The majority of these individuals in resource poor settings receive their ART from primary health care facilities which have done an incredible job in scaling up treatment of HIV infected individuals in the last decade, however, the growing cohort of HIV infected individuals needing ART poses a significant challenge to often fragile health services (2).

In Zambia, 13.3% of adults aged 15-49 years are infected with HIV (11.3% among adult males, 15.1% females). The HIV prevalence is highest in urban settings (18.2%) and lowest in rural settings (9.1%)(3). Significant progress has been made over the last decade in increasing and improving access to and the use of HIV treatment services. Implementation of the 2013 WHO Consolidated Treatment guidelines which increased the eligibility criteria for ART initiation and option B+ resulted in more individuals accessing ART services. In 2014, a total of 671,066 adults and children (267, 092 males and 403,974 female) were receiving antiretroviral therapy. Of these, 108,334 were newly initaited in 2014 alone. 625, 546 were adults 15 years and above, exceeding the national target of 569,567. In the same year 45,520 children were receiving ART exceeding the target of 42,115(4).

The recent introduction the 2015 World Health organization (WHO) guidelines recommend ART initiation to all adults irrespective of WHO clinical staging and CD4 threshold(5) means that even more individuals are eligible for ART. Adherence to treatment and virological suppression will be critical factors for survival and prevention of onward transmission and without a change in the current delivery model of ART in countries such as Zambia; lifelong ART for all PLHIV is unsustainable. Overcrowding of health facilities and overburdening of the health systems may lead to interruptions of therapy and incomplete adherence leading to increased mortality, on-going transmission and development of drug resistance(6). Models for decentralizing ART services through community ART delivery may be important and innovative strategies for maintaining the continuum of care as we strive towards universal treatment to meet the ambitious joint United Nations Program on HIV/AIDS (UNAIDS) 90-90-90 targets by 2020.

Fig 1: Number of Children and Adults recieving ART 2010-2014 in Zambia



Source: GARPR Zambia Country Report

The fragile health systems, as is the case in most sub-African countries, the human resource crisis is the result of many macroeconomic and governance factors. The crisis is further compounded by the impact of the HIV/AIDS pandemic. The human resource crisis is multifactorial but reasons include excessive workload and burnout, high attrition rates of trained professionals; difficult working conditions and poor salaries; low motivation and high burden of infectious diseases, particularly HIV/AIDS, among the workforce. The scale up of ART services and move towards universal test and treat in sub-Saharan Africa has highlighted the human resource challenge on the existing fragile human resource base (7-9). The World Health Organization (WHO) estimates that there is a global deficit of more than 4 million trained health workers and these shortages are critical mostly in sub-Saharan African Countries and parts of Asia. In European countries, there were nearly two doctors per person living with HIV/AIDS as compared to low resource settings where an average of 2000 HIV/AIDS infected individuals per doctor(10).

Fig 2: Number of Doctors, Nurses and People living with HIV/AIDS in Selected Countries

Country	Doctors per 100,000 Population	Nurses per 100,000 population	People living with HIV/AIDS	People living with HIV/AIDS per Doctor	People living with HIV/AIDS per Nurse
Malawi	1	26	900,000	7435	286
Zambia	7	113	920,000	1216	75
Zimbabwe	6	54	1800,000	2337	260
South Africa	69	388	5300,000	171	30
Cambodia	16	61	170,000	75	20
Brazil	206	52	660,000	2	7
USA	256	937	477,000	0.6	0.1
United Kingdom	230	1212	83,000	0.6	0.1

Source: N Engl J Med 2007

Despite significant progress in scaling up ART, Zambia faces significant shortages of HCWs with staffing deficits estimated at over 70% for doctors, clinical officers and nurses(11, 12). The World Health organization /Ministry of Health establishment recommends a staff to population ratio of 1:1500, 1:1700, and 1:8000 for doctors, nurses and pharmacists, respectively. The existing human resource capacity in Zambia is below the recommended cadre-to-population ratios with existing levels of 1:17589, 1:8064 and 1:473 450 for doctors, nurses and pharmacists respectively(7).In trying to cope with demand, there has been decentralization of ART services from hospitals to primary health care facilities and task shifting from doctors to nurses and community health workers (CHWs)(13). A number of ART programs have already begun re-assigning tasks as a result of shortages in specific classes of personnel, such as using nurses to evaluate patients for ART and prescribe for uncomplicated patients and shifting counselling and education to lay counsellors as a way of stretching the resources. As we move towards the 2015 WHO universal test and treat guidelines, HIV programs

will increase and to avoid overwhelming the entire health system, innovative ART care delivery models need to be considered.(7)

The 2015 WHO guidelines recommends that provision of ART services can be maintained in the community, but operational guidance and further evidence is needed for this to happen in practice. Decentralizing ART services into the communities may ease the burden of routine management on other parts of the health systems and improve equity by promoting access to ART in rural and urban areas. In low resource settings with a high burden of HIV, transport cost to the health facilities and long waiting times for patients are significant barriers to access and retention in care. Thus decentralizing of ART care could reduce the workload for the health care workers, thereby reducing waiting times, strengthen community engagement and optimizing access to services and retention in care(14). On the other hand, the risks of decentralizing ART services include supply chain weaknesses resulting in ART stock outs, pilfering of drugs, inequity towards patients not involved in community ART delivery, patients in community based models not viewed as the responsibility of the health system, timely referral of complicated patients to the facility and risk of treatment failure despite lack of clinical symptoms(15, 16).

Community based delivery of HIV care is one example of decentralizing HIV services from the health facilities to the community. This reduces the distance for patients to have to travel to access care and also supports retention in care (15, 16). It is designed to make ART more efficient for health systems and provide appropriate support to encourage long-term patient retention. Models of community-based delivery of ART have been developed in various settings and hold the promise of improving the continuum of care by decongesting the clinics and reduce the burden on healthcare workers. These models of care aim to make it easier for patients to access care and adhere to long term ART, however, further research is needed to evaluate them to ensure that outcomes are equivalent such as how to support long term retention in care while expanding ART provision, patients are virologically suppressed and logistics surrounding these models are not weakened by drug pilfering etc.

1.1 Literature Review

The scale-up of ART services has been rapidly implemented as a life- saving public health intervention and has resulted in averting an estimated 4.2 million deaths(17). Since 2013, evidence and programmatic experience have continued to favour earlier ART initiation among adults living with HIV regardless of WHO clinical stage or at any CD4 cell count. There has been increasing evidence from systemic reviews and cohort analysis indicating that initiating ART earlier reduces mortality, morbidity and HIV transmission outcomes. Recent evidence from the HIV Prevention Trial Network 052, a large randomized clinical trial also demonstrated that early HIV treatment reduced the risk of HIV transmission by 96% (18, 19).

Several studies have shown the potential for ART to prevent transmission of HIV by suppression of community viral loads (20, 21). Data from pilot projects suggest that universal test and treat has the potential to suppress community viral load resulting in reduction of HIV incidence(22) but this has yet to be confirmed in a well conducted randomised experiment. The World Health Organization (WHO)

recommendations on the use of ARVs has recently been revised in favour of immediate treatment regardless of CD4 count and clinical staging due to benefit to the patient(5). In addition, the Strategic Timing of Antiretroviral Treatment (START) study provided concrete scientific evidence that immediate initiation of ART in patients with HIV infection regardless of CD4 count reduced the risk of a combination of AIDS-related illness and death by more than half compared to deferring treatment. These results align benefits for individual patients with the public health benefit of antiretroviral therapy in reducing the risk of viral transmission and thus reinforce the need for universal test and treatment(23).

All benefits from ART are dependent on patients being retained in care and adherent to treatment. As national ART programs move towards these recommendations, it will be crucial to ensure that loss-to-follow up (LTFU) is reduced and retention in care is improved. Systemic reviews from sub-Saharan Africa estimate that approximately(18) a third of patients are lost to follow up in ART programs within the first two years on treatment(24-26). In the same region, retention in care was estimated at 79%, 75% and 62% at 6, 12, and 24 months respectively(24). An updated review in 2010 in a cohort of more than 200,000 patients, the program retention was 86%, 80%, 77% and 72% at 6, 12, 24 and 36 months respectively(25, 27). Therefore, the key challenges that national programs will face in the expansion of ART services will no longer be the access to services but ensuring that patients are not loss to follow-up and retention is improved.

Over the last few years, there have been many interventions suggested to improve LTFU and retention and these include task shifting and decentralization of ART services. Models of care for ART delivery have considerably evolved in resource limited settings. Services have been decentralized from hospitals to primary care facilities and recently into the communities. Community-based models of ART delivery offer a further level of decentralization, which includes shifting of tasks to the community health workers (CHW) and the patient themselves. These models of care are directed towards stable adult patients. While there is no agreed definition of "stable" in this context, patients generally are considered stable if they have been taking ART successfully from a minimum period of time, have no concurrent illness, have a degree of immune recovery (or are virologically suppressed), and are able to adhere to ART(28). These models allow patients to receive care within the communities by allowing community health workers to provide on-going adherence support and dispensation of pre-packed medications thus reducing the frequency of clinic visits. Patients were only expected to go to the clinic twice annually for their routine clinical review and laboratory monitoring. In these models, patients were initiated on ART at the facility and once stable are down referred to models of care. The health facilities and hospital services served as back-up for complicated clinical care needs (44, 45).

Several studies have assessed the feasibility of community models of ART delivery in sub-Saharan Africa where the health facilities serve as referral sites (Table 1). A recent Cochrane review of decentralization included two studies of community ART delivery, one in Uganda and one in Kenya, which provided home-based ART delivery and reported favourable outcomes compared to facility-based models(29-37). In Uganda, a cluster-randomized controlled trial in Jinja evaluated the impact of home-based ART delivery and facility based care where the primary endpoint was virologic failure over 3 years of follow-up(32). ART was initiated in the facility and community health care workers conducted monthly visits to patient's homes where symptom screening for toxicity and disease progression, adherence support and ART delivery was done. After 12 months on therapy, no difference in the mortality, LTFU and virologic failure was observed between the two models of care. Kipp et al. assessed the effectiveness of rural community-based ART program in Uganda and compared the treatment outcomes and mortality with a well-established hospital based program(38). In this

model of care, community health workers conducted weekly visits to patient's homes and provided ART and adherence support. After 2 years, all- cause mortality was similar in both cohorts but community based model patients were twice more likely to achieve viral suppression and good adherence to treatment(39). A similar study in Kenya, where stable patients were randomized to either receive standard of care within the clinic or a model where CHW provided home –based ART delivery, showed that community-based care by PLWH resulted in similar outcomes as standard of care but with half the number of clinic visits suggesting that task shifting into the community can deliver safe and effective community based care, expediting ART roll-out and increasing access to treatment in resource limited settings(35, 40).

Other models of care have also been recently piloted in sub-Saharan Africa as a way to decentralize HIV care into the communities. These include:

1. Adherence clubs

In this approach, a group of clinically stable patients meet once every 2 or 3 months at a health facility or a community venue. This model allows for peer support and health education among its members. Essential tasks such as weighing patients, symptom screening, adherence support and pre-packed ART distribution are carried out by a peer educator and/or lay counsellor who acts as a club facilitator. This enables patients to visit the clinic once or twice a year for their clinical consultation and routine laboratory monitoring. Patients reporting symptoms or found to be missing their club appointments are referred back to the clinic for assessment. This model is well adapted in urban settings where time spent at the clinic is an issue for patients (41, 42). Adherence clubs were piloted in Khayelitsha, South Africa in 2007 as a way to decongest the clinics. These clubs comprised of approximately 30 stable patients and met every second month with a CHW or a nurse for the club session. Data from this pilot showed that 97% of patients were retained in care and the risk of LTFU was reduced to 57% (43, 44). Since 2012, Medicines' Sans Frontiers' (MSF) piloted an extension of this model into the community and by 2013, have collaborated with the Provincial Government of the Western Cape in implementing 776 adherence clubs representing 19% of all ART patients in care in the metropolitan area(42). The implementation of these community-based adherence clubs (CACs) at a large, public sector facility in peri-urban Cape Town had more than 2000 stable patients down referred from primary health care facilities to CACs and overall retention was 97% at 6 months and 94% at 12 months (46). These findings support the continued expansion of community-based models of ART delivery in high prevalence resource settings.

2. Community ART Groups (CAGs)

In this model, stable patients organize themselves into a group of six, taking turns to collect ARVs every month for each of the group members. The group members attend the facility every month to pick up ART for the whole group and dispense drugs to other members in a patient's home. Whilst the group member picks up the drugs for the group, s/he also gets his 6 monthly or yearly clinic consultation and routine laboratory tests. This model was found to be well adapted in rural settings where distance to the clinics are the major barrier and where there is a tight sense of community(2).CAGs were piloted in the Tete province in Mozambique since 2008. Results from this pilot study found high levels of acceptance among patients as CAGs reduced the cost and time burden on patients and strengthened adherence support(42). This model showed low rates of LTFU and

retention rates among the CAG members were 98%, 96% and 93% after 12,24 and 36 months on ART(45, 46). The results of this pilot model enabled the CAG model to be incorporated into the National HIV care strategy of Mozambique and by the end of 2013, more than 17,000 patients were receiving ART in a CAG (42).

Table 1. Publications on community models of care

Publication	Location	Study design `& Objective	Findings
Jaffar 2009	Uganda	Cluster RCT comparing home-based ART to facility based care	No difference in mortality after 12 months or virological failure (1% vs 2%) between the two.
Kipp 2012	Uganda	Prospective cohort study assessing the effectiveness of rural HC/community – based ART program and compare the treatment outcome (VL)of home based ART to hospital-based ART	There was no difference in viral suppression at 6 months (90% vs. 89%) or mortality in the home-based vs. hospital based cohorts
Selke 2010	Kenya	Prospective cluster RCCT comparing the outcomes of stable patients managed by CHWs in home-based care vs. clinic based care	Clinical outcomes were similar as that of standard of care but with half the number of clinic visit.
Luque-Fernandez 2013	South Africa	Cohort study to evaluate the effectiveness of adherence clubs compared to clinic based care in maintaining or improving retention	After 18 months, 97% of club patients remained in care compared to 85% in the clinic. LTFU was reduced by 57% [HR 0.43]
Decroo 2014	Mozambique	Outcomes of Community Adherence Group (CAG) patients	98% retention at 12, 24 months.
Humpreys 2010	Swaziland	prospective cohort to compare the outcomes of stable patients referred to CHC	No differences in LTFU noted

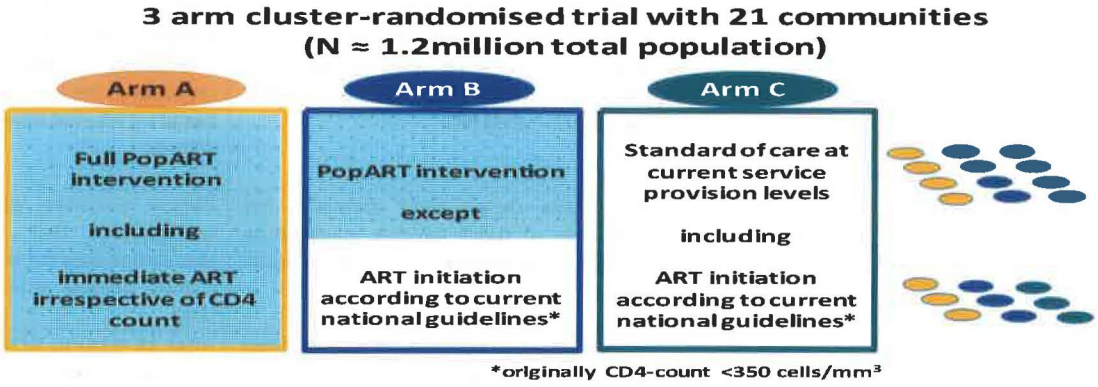
A systemic review and meta-analysis of literature to assess the effect of home-based interventions on virologic outcomes in adults receiving ART in Africa showed insufficient data to know whether there is a difference in virological suppression at 12 months in home-based interventions as compared with the standard of care. Given the few trials conducted in Africa, there is need for further research that measures the effects of home-based models on virological suppression in African populations(47).

1.2 Study Justification

Although community-based models of ART delivery have shown promising outcomes in relation to retention in care and adherence to treatment, (48) additional data is required from innovative community-based models of care to support long term retention as ART cohorts in resource limited settings continue to expand in the context of universal test and treatment. The lessons learnt will be needed to improve the efficacy and effectiveness of the HIV continuum of care and enable programs to redesign delivery systems and focus on less centralized treatment delivery points that often require

patients to travel long distances to health centre and also allow decentralization of health systems to meet scale-up targets and sustain treatment gains. Studies show that ART can be delivered through different routes but there is a lack of evidence about which model provides the most cost-effective strategy and how this can be integrated into other community-based programmes. This study will nest the evaluation of 2 different models of community ART delivery into an on-going cluster-randomised trial. The HPTN 071 (PopART) trial is currently evaluating the impact of community level combination prevention package, which includes universal HIV testing, active linkage to care and intensified provision of ART, on population level HIV incidence. This is a three-arm, cluster randomized, trial being implemented in 21 communities in of which 12 are in Zambia and 9 in South Africa. Arm A includes universal testing with immediate ART, Arm B includes universal testing with ART eligibility according to the current national guidelines and Arm C is the standard of care (control arm).

Fig 2. Schematic Diagram of the HPTN 071 trial



These interventions are being delivered by Community HIV Providers (CHiPs). The CHiPs are members of the community, appointed to provide a package of basic services at a household level, particularly HIV counselling and testing and linkage to care for those who are HIV positive. Their responsibilities include conducting HIV counselling and testing, condom distribution, screening for TB and linking household members for appropriate HIV prevention, treatment and care services. This study will utilise these existing community health care providers to implement 2 models of community-ART delivery:

1. CHiPs delivering ART packages to their clients on a regular basis
2. CHiPs facilitating Community ART clubs

It is not known whether these models of ART delivery will be feasible in urban low resource settings, or whether the care will be as good as the standard quality of care provided by the health systems, therefore this study is timely and innovative:

(1). This will be a first study in an urban setting in Zambia to rigorously evaluate different models of community ART delivery. This information will be critical for the continued scale up of universal test and treatment and may have cost efficient synergies utilising community HIV test providers.

(2). This study will be a randomized head to head non-inferiority comparison. To this date no studies have shown a comparison in clinical outcomes between the different Community ART models and between them and the current standard of care.

(3). This study will provide policy makers with evidence on operational feasibility, acceptability and cost effectiveness of two models and guide policy on the best models to roll out in the context of UTT.

The Zambian Ministry of Health has identified community models of ART delivery as a way of expanding treatment in the context of universal test and treat. The government, through the National AIDS Council, has engaged several in-country partners and researchers to pilot different community models of ART delivery in order to generate information required to inform model standardization at national level for wider roll-out. These models of care will only include stable adult ART patients, defined as patients on ART for more than 6 months who are virologically supressed.

In addition to providing policy makers with evidence for community ART models, this study will also enhance the objectives of the HPTN071 trial where linkage to care and retention in care are essential for the outcome of the trial. This study will also increase local scientific capacity to conduct implementation research in order to sustain national ART and PEPFAR targets as well as build collaborations between indigenous Zambian non-profit organizations, the University of Zambia (UNZA) and Ministry of Health, drawing expertise that will ultimately strengthen Zambian research capabilities.

2.0 Study Objectives and Strategy

2.1 Hypothesis

Overall clinical, immunological and virological outcomes in patients receiving care via community ART delivery models are not inferior to those receiving care in the clinic (standard of care) in urban poor resource settings.

2.2 Primary Objective

To compare virological suppression at 12 months in HIV + patients receiving care via community ART models with those receiving care in the clinic (standard of care).

2.2.1 Secondary Objectives

1. To compare the proportion of patients with virological suppression at 24 months in patients receiving care via community ART models with those receiving care in the clinic (standard of care).

2. To compare Loss to Follow-up (LTFU) rates and missed dispensation of ARVs among individuals receiving care via community ART models with those receiving care in the clinic (standard of care)., measured using routine health centre data

3.To compare HIV disease progression, and death among individuals receiving care via community ART models with those receiving care in the clinic (standard of care), measured using:

- CD4 cell count, WHO staging events, death from routine health centre data.

4. To qualitatively assess how health staff (including CHiPs) and PLWH on treatment experience the two models of care. This would be achieved through:

- Documenting treatment, adherence and retention experiences of PLWH accessing treatment through adherence club and home delivery models;

- Exploring the impact of the two models of care on access to treatment, adherence and retention according to the experience and perspectives of CHiPs and health facility staff;
- Qualitatively comparing how participant (PLWH and health staff) experience the models of care and experiences with the routine standard of care at the local health facilities;
- Qualitatively assessing participant (PLWH and health staff) perceptions about and experiences with the impact of the models of care on HIV services at the local health facilities.

5. To measure the health system costs of delivering the different community ART models.

In addition, we will measure the effect of the combined models on health facility crowding and waiting times as well as time to ART initiation of new patients in the 2 facilities (non- randomised comparison as both facilities have all models of care).

3.0 Methods

3.1 Study Design and Setting

The study will be a cluster-randomized non-inferiority trial in a prospective cohort of adults enrolled in to ART care at two urban primary health care facilities that serve two of the HPTN 071 trial communities in Lusaka, Zambia. These two communities include Chipata and Kanyama, which are the Lusaka arms A and B communities of the parent trial (HPTN 071) respectively. The reason for conducting the study in these two communities is that they are located in an urban setting where there is a high number of HIV patients in care, thus overburdening the clinics and an ideal setting to determine if these community models of ART delivery benefit the health care system in urban Zambia by decongesting clinics and making treatment easier to access.

The HPTN 071 (PopART) trial is evaluating the impact of community level combination prevention package, which includes universal HIV testing, active linkage to care and intensified provision of ART, on population level HIV incidence. This is a three-arm cluster randomized trial being implemented in 21 communities of which 12 are in Zambia and 9 in South Africa. These interventions are being delivered by Community HIV Providers (CHiPs) who are members of the community, appointed to provide a package of basic services at household level particularly HIV counselling and testing, linkage to care for those who are HIV infected, HIV/TB education, adherence support, distribution of condoms, screening household members for TB and STI and linking household members for appropriate HIV prevention, treatment and care services.

Before the start of the main trial, mapping of the households and non-residential buildings, with a census to count the number of adults (≥ 16 years old) and children (≤16 years old) was done and the map of the communities was created based on global positioning system (GPS) coordinates of all households and non-residential buildings. Following the mapping the data was used to define the catchment area of the clinic and to divide it into "CHiP zones" with one CHiP team being responsible for a zone. Each zone within these communities has approximately 400-450 households served by the CHiPs. Table 2 shows the number of CHiPs teams/zones in the 2 communities with the population each CHiP teams covers and the number of HIV positive adults being cared for in each zone

Table 2: Total number of zones in the communities served by the CHiP teams

	CHIPATA (54 Zones)			KANYAMA (50 Zones)		
	HIV+ clients	Total in care in the clinic	On ART in the clinic	HIV+ clients	Total in care in the clinic	On ART in the clinic
Average per zone	99.3	56	51.3	98.6	56.38	46.7
Range in the zone Min-max	33-234	14-155	18 - 143	48 - 213	4 – 143	3 – 102

Each zone is served by 2 CHiPs, therefore 1 CHiP will have an average of 23-25 clients on ART who may need to be provided with ART within the community.

3.1.1 Study Population

The eligible study population will include all stable HIV infected adult patients (≥ 18 years) on first-line ART residing in the 2 HPTN 071 communities and enrolled in the two primary health centres within the community. Stable patients are defined as those who are on first-line therapy, are on treatment and consistently retained in care for more than 6 months, virologically suppressed and have no other health conditions (e.g. TB, pregnancy and other opportunistic infections) requiring attention of a clinician.

3.1.2 Interventions

For this study, the two models of community ART will be either Adherence Clubs or Home Based ART Delivery.

A. Adherence Clubs

Adherence clubs will consist of a group of at least 20-25 stable patients who receive care from the community health care facility. Members of the club will meet every 3 months at an agreed communal venue where they will receive adherence support, symptom screening and pre-packed medications. Club members will be required two have 2 clinical/club visits (every 6 months) in a year for their routine clinical review and laboratory monitoring. The table below provides a broad overview of an ART Adherence Club.

Table 3. Broad overview of the ART Adherence club

Membership	1. Group of no more than 25 HIV positive stable patients 2. Should be residing in the clinic catchment area and accessing services within the facility
Club Meetings	Members will meet every third month (4 club meetings in a year – 2 at community level and 2 at facility level
Clinic/Club Visits	Members will have a clinic visit once every 6 months Members will visit the clinic if the CHiPs refer them.
Process	1. During club meetings: • Members will be assessed (symptom screen) • Adherence support • Group education and provision of condoms • Pre-packed drugs will be dispensed by the CHiPs 2. Clinical/Club visit • Every 6 months the club visit will take place in the facility (either a particular afternoon or a weekend) • Clinical review by the clinician for all the club members • Routine laboratory monitoring for all the club members • Provision of pre packed drugs
Data collection	Data collected during the club meetings will be collected in a hand-held device integrated with current smart care system.

A common place within a particular zone will be identified as a club venue provided it is conducive for all members. These venues will be consistent and easily identified by the facility and club members. The club venues could be in schools, churches, communal clubs etc. and these can also change with time as long as this is agreeable with the club members and the health facility. In preparation of each club session, the facility in charge, CHiP supervisor and the CHiP should ensure that a few days prior to a club meeting:

- Club registers are reviewed to determine which club session will be taking place and in which community zone
- Identify and inform the CHiPs about the upcoming club meeting
- Collect members files from the facility registry and deliver to pharmacy for pre-packaging of drugs
- Send a reminder via phone call to members of their club meeting and venue.

The first club meeting will include registration and norms of the club. Thereafter, the first and successive club meetings will include:

- Club roster and registration of new members
- Updating contact details of all members
- Signing a charter of agreement about the club rules and norms
- Symptom screen checklist to determine if members have any symptoms
- Weight
- Group education on adherence and risk reduction counselling
- Dispensing the pre-pack medications upon receiving the prescription slip
- Distribution of condoms

For members who are symptomatic and show poor adherence, a referral slip will be given to them to refer to the clinician. During the club visits, all data will be entered into an electronic device that is programmed to refer a client back to the clinic if s/he has symptoms or abnormal findings.

At the end of the visit, members will be reminded of their next club meeting which will be indicated on their club card and their bi-annual clinic visits which will be indicated in their ART card.

If a member is absent during the club visit, this will be recorded in the register and the pre-packed drugs will be returned to the clinic. Attempts will be made to call the member to return to the clinic to collect his medicine from the pharmacy.

At the end of the club session, unissued pre-packed drugs will be returned to the pharmacy and registers will be updated before handing them over to the facility staff for ensuring completeness of the registers. All the data that was collected for each participant in the electronic device will then by synced with the clinic database.

Every 6 months, the club meeting will be conducted at the facility to coincide with their clinical review and laboratory monitoring. Club members will be informed to meet on a particular day and time at the health facility (this could be an afternoon during the weekdays or a Saturday morning as decided by the clinic staff). The club meeting will be conducted as above and in addition all members will be reviewed by the clinician and have their routine laboratory tests for monitoring. Drugs will also be pre-packed prior to this meeting and dispensed to the club members. A 1 x 3 monthly script will also be provided.

B. Home-Based ART Delivery

This model will provide ART care to clinically stable patients in their homes. The CHiPs will visit the participant's homes once every 3 months to provide adherence support, symptom screening and dispense pre-packed drugs to the participant. The participant will only be required to visit the clinic twice in a year for routine clinical review and laboratory monitoring. The table below provides a broad overview of the home-based ART delivery model.

Table 4: Broad Overview of the Home-Based ART delivery model.

Membership	1. Should be residing in the clinic catchment area and accessing services within the facility 2. Clinical stable patient 3. Can include 1-2 members of the same household
Home visits	Clients will be visited once every 3 months at their homes
Clinic Visits	Clients will have a clinic visit once every 6 months Clients will visit the clinic if the CHiPs refer them.
Process	1. During home visits: • Clients will be assessed (symptom screen) • Adherence support provided • Health education and provision of condoms • Pre-packed drugs will be dispensed 2. Clinical visit – every 6 months • Clinical review by the clinician • Routine laboratory monitoring • Provision of drug scripts • Drug dispensation
Data collection	Data collected during the home visits will be collected in a hand-held device integrated with current smart care system.

The client's physical address and contact details will be entered in a home-based register, which will be updated at every home visit to ensure contact with the client, is maintained. Home and clinic visit dates will be provided to the client at each visit and clients will also be reminded they will be called at least two days prior to their home visit to schedule the appropriate visit times.

Once a client has been enrolled into home based ART delivery model, the client will be provided with 3 monthly prescription slips for the current drug regimen they are on. On the day of registration into the model of care, the client will be required to collect a 3 months prescription of drugs to last before the first home visit. The facility nurse will ensure that the client has been provided with 1x3 monthly scripts.

All clients receiving home-based ART service will be recorded in a register for use at the facility and their clinic folders will be kept in a separate filing cabinet specific for home based ART delivery.

It will be the responsibility of the facility, CHiP supervisor and the CHiP to review the registers on a weekly basis to determine the number of home visits scheduled for the week. 2-3 days prior to a home visit, the Facility-in-charge and the CHiPs supervisor should ensure:

- Registers are reviewed to see where home visits will take place and in which zone
- Identify and inform the CHiPs about the upcoming home visits and the physical address
- Collect members files from the registry and deliver to pharmacy for pre-packaging of the drugs
- Notify members of their upcoming visits

The first home visit will include registration and norms of the visits. Thereafter, the first and successive home visits will include the following:

- Updating contact details in the register
- Weighing of client
- Symptom screen checklist
- Health education on adherence and risk reduction counselling
- Dispensing pre-packed drugs and condoms
- Date of next visit
- Reminding clients of their bi-annual clinical visit
- Refer clients who are symptomatic

For participant's who are symptomatic and show poor adherence, a referral slip will be given to them to refer to the clinician. During the home visits, all data will be entered into an electronic device that is programmed to refer a client back to the clinic if s/he has symptoms or abnormal findings.

At the end of the visit, client will be reminded of the next home visit and clinic visit. These reminders will be indicated on their home visit and ART cards.

If a participant is not found at home during the visit, s/he will be called or anyone present at home will be given the message to ask the client to return to clinic to collect drugs. If a participant is contacted and agrees to schedule a home visit within 7 days of the missed visit, then the CHiP will reschedule the visit. This will be recorded in the register as missed visit and the pre-packed drugs will be returned to the clinic. Should a client continue to be absent during home visits on more than 2 scheduled home visits, s/he will be followed up and transitioned to mainstream care.

In a household where a couple or two members are both part of this models of care, and one member is absent, all efforts must be made to ensure the absent member is followed up for another unscheduled visit.

All the data that was collected for each participant in the electronic device will then by synced with the clinic database.

Every 6 months, the client will be required to visit the health facility for their clinical review and laboratory monitoring. In addition they will be given a 3-monthly drug supply and provided with a 1x3 monthly drug script. All clients in home based care will be required to visit the facility on a certain day to ensure that they are fast tracked and received their pre-packed drugs within the facility.

SCHEDULE OF VISITS FOR BOTH ADHERENCE CLUBS AND HOME-BASED DELIVERY

Stable patients in both models of care will follow the visit schedule below:

1. Home or club visits every 3 months (depending on the models of care)

2. Clinical visit every 6 months

Clinic visit for enrolment	1st visit	2nd Visit at the Clinic	3rd visit	4th visit at Clinic
0 month Clinic Level	Month 3 Community Level	Month 6 Clinic level	Month 9 Community Level	Month 12 Clinic level
Enrolment into club or home based visit Norms of the models of ART delivery 3-month drug supply	Introductory and standard session in both clubs and home based care Adherence support Symptom screening Dispense 3-monthly pre-packed drugs	**1. Adherence Clubs:** Meet at the facility on a particular day or weekend Conduct the usual club meeting at the facility Clinical and laboratory review 3 months pre-packed drugs provided 1x3 month drug script issued **2. Home Based ART Delivery** Clients in this model meet at the clinic on a particular day or weekend. Adherence support by the CHiPs Clinical review and Laboratory Monitoring Pre-packed drugs dispensed Issuing of 1x3 month drug script	Standard session Review of results Adherence support Symptom screening Dispense 3-monthly pre-packed drug	Same procedure as in month 6

CLINICAL MANAGEMENT OF CLIENTS IN BOTH MODELS OF CARE

Clients in both models of care will need to be followed up closely to ensure that they are stable and this will be done every 6 months at the facility. The 6 month clinical visit will ensure clients receive a complete clinical review and routine laboratory tests are conducted. When a client is reviewed by the clinician, it will be the clinician's decision to determine if s/he remains as part of the community models of care or return to mainstream care. The criteria for returning to mainstream care include:

1. Presence of an opportunistic infection (TB)

2. Detectable viral load

3. Routine blood results significantly abnormal

4. Poor adherence to home visits

5. Patient request

6. Patient has moved out of the community zone where home-based ART delivery services are not available

Members who belong to the adherence club will be informed that this particular club session will take place in the clinic where the Health care workers will conduct a clinical review and laboratory monitoring. The standard session of the clubs will also take place during this time and pre-packed

drugs will be dispensed to them. In order to expedite this club session, the health care workers and club members will agree on a particular day and time when to have the session every 6 months.

For clients in the home based ART model, they will also be expected to visit the clinic every 6 months on a particular day or weekend where their clinical review and laboratory monitoring is fast tracked by the community ART nurse. 3 monthly pre-packed drugs will also be provided.

Once a client has had his clinical visit, the club and home ART register will be updated as having had a clinical visit and laboratory results will also be updated.

If a client has abnormal lab results, s/he will be called to the clinic for review by the clinician.

All laboratory results should be reviewed by the Facility ART in charge and any abnormal results should be discussed with the clinician and the research team. Management of such clients will be according to standard practice.

3.1.3 Inclusion Criteria

All HIV adult patient (≥ 18 years) on first-line ART will be screened for eligibility at the health care facility serving the two communities. The eligibility criteria will include:

- All adult patients who are stable. To be considered "stable" a patient must:
  1. Be on first line treatment for more than 6 months and retained in care
  2. Must be virologically suppressed (according to the current standard of care definition of viral suppression)
  3. WHO stage I and II at the time of screening
- Patient resides within the clinic catchment area
- Willing to provide written informed consent and accept CHiPs intervention.

3.1.4 Randomization

The community zones will be randomized by the research team to one of the three arms:

1. Arm 1 – Patients residing in these zones will be offered a choice of being part of an Adherence club or to continue to receive care at the clinic

2. Arm 2 – Patients residing in these zones will be offered a choice of Home ART delivery by the CHiP or to continue receiving care at the clinic
3. Arm 3- Patients residing in these zones will continue receiving care at the clinic (control arm).

Across the two communities (Chipata and Kanyama), there are 104 community zones that will be randomized to one of the three arms above.

Community	Total number of zones	Arm 1	Arm 2	Arm 3
1	54	18 zones	18 zones	18 zones
2	50	17 zones	17 zones	16
Total	104	35	35	34

3.1.5 Study Procedures

Once the community zones have been randomized, the research team and clinic staff will screen participants for eligibility at the health facility. This includes patients who are taking ART for at least 6 months or more and are clinically stable. If found to be eligible, the research team will explain the study and ask for written consent to take part in the study. The research team will then inform eligible participants which model they have been allocated to or whether they will continue to receive care at the facility. Participants allocated to one of the two community ART models will be offered a choice of whether they would prefer to receive this model or continue receiving care within the health facility. Participant choice will be recorded and participants opting for community ART delivery will be linked up with their respective CHiP teams to either register for a club or to start home delivery. Participants in these intervention arms may change their mind at any time either opting to move to the community model or to move back to the clinic model. Again this information will be recorded as an outcome measure

4.0 Study Outcomes

The primary and secondary objectives for this study are listed in Section 2.2. The outcome measures for these objectives are listed below and will be measured in all study arms unless otherwise noted.

A. Primary Outcome – viral suppression at 12 months measured using the standard of care viral load testing equipment currently in place. Viral suppression will be defined according to National guidelines

B. Secondary Outcomes - these will include:

1. ***Viral suppression at 24 months*** – undetectable HIV viral load 24 months after entry into the models of care. This will be done as part of routine laboratory monitoring and measured using routine programmatic data.

2. ***Retention in care / Loss to Follow-up*** -Loss to follow-up from ART programmes describes all patients who are no longer in care and have an unknown outcome. A most useful definition of "loss to follow-up" should refer to patients with unknown outcomes(49). For this study, LTFU will be defined as *"no patient contact for 90 days or longer after the last given appointment".*

Retention in care refers to *all patients retained in the HIV program*. Patients who are no longer retained in care with unknown outcomes will be classified as LTFU.

- In this study, retention will be defined as the number (%) of clients who are retained in the program at 6, 12 and 24 months after implementation of the intervention.
- The time to Lost to follow-up will be calculated in months according to the time interval between the dates of entry into the intervention to drop out, as recorded in the routine programmatic data.
- Proportion of patients that returned to mainstream care at 6, 12 and 24 months.

3. HIV disease progression – defined as having a new or recurrent WHO stage 3 or 4 condition after 6 months of ART, or a fall in CD4 count, (1). For patients with baseline CD4 count of < 200 cells/ul a fall of CD4 count to baseline or below after 6 months of ART; or persistent CD4 count < 100 cells/ul after 6 months of ART. (2). For patients with baseline CD4 count ≥ 200 cells/ul, a persistent decline in CD4 count after two or more tests. For this study we will determine the following using routine health centre data:

- Proportion of patients who have had their CD4 count tests done at 6, 12 and 24 months after entering the models of care
- Proportion patients who developed a WHO stage 3 or 4 condition at 6, 12 and 24 months
- Proportion of patients with CD4 count below 200 at 6, 12 and 24 months despite on treatment.

4. Death – defined as death at any point during the intervention due to any HIV related cause after enrolment into the study.

5. Participant choice of model and retention within that model. The following outcomes will be measured using programmatic and routine health centre data:

- Proportion of patients who enrolled into the models of care by sex
- Proportion (%) of eligible patients but refused to enter the model of care at baseline
- Proportion of patients who switched back to mainstream care at 6, 12 and 24 months and reasons for switching
- Number of club sessions and home visits that took place at 12 and 24 months after start of intervention

6. Drug Supplies –using routine health centre and programmatic data, we will determine:

- Number of groups/individuals missing at least one refill in the last 12 and 24 months (ART, Cotrimoxazole)
- Missed dispensations of ARVS at 6, 12 and 24 months.
- Proportion of pre-packed drugs returned to the clinic after a club session or home-based visit.
- Number of reported cases of ART drugs being pilfered after the start of the intervention.

7. Qualitative evaluation- of the acceptability and functioning of the two models of community ART delivery based on systematic structured observations of delivery, in-depth interviews and focus group discussions with key-informants (CHiPs, health facility staff) and longitudinal interviews with PLWH.

8. Economic Analysis – this will include:

- Measuring and comparing the incremental costs of the two intervention packages. The economic analysis will focus on measuring economic costs of the interventions from provider's perspective. The main focus will be on costs to the health services, including personnel, equipment and materials. The incremental cost of the interventions will be estimated by comparing costs of service provision and healthcare utilization with non-intervention healthcare facilities.
- Measure the impact of implementing the community ART delivery models on health systems and service delivery at local health centres in terms of technical and allocative efficiency of available HIV resource.

5.0 Data Collection and Tools

Data will be collected at the following points:

Baseline

Three (3) months

Six (6) months

Twelve (12) months

Twenty four (24) months

Routine data will be collected using the national HMIS system and patient clinic records. At baseline, the following variables will be collected from patients to determine their influence on the outcomes:

- Age, sex, weight
- Recent CD4 count before enrolling into the models of care
- Viral load
- WHO stage at enrolment
- Date of starting ART
- Current drug regimen.

To maximize the validity of this information, the study team will work closely with the health centres to improve the collection and management of these routine data.

Data captured from the community models of ART delivery will be collected using the same hand held collection device being used in the main HPTN trial. A specific programme for this model will be installed in the device. This program is designed to maximize the quality of data collection using drop down lists and incorporating checks to avoid simple data entry errors. The CHiPs will undergo formal training on how to use the software to capture data at community level and sync it with the facility database and this training will be documented and retained in the site files.

Under the leadership of the Zambian Ministry of Health, the community ART steering committee has agreed upon a set of core indicators to be used to monitor and evaluate the community ART service delivery models being piloted by different partners. To facilitate the collection of the key indicators across both models, a list of common indicators will be used and this will be captured from both smart care and routine programmatic data.

Appendix 2 gives a detailed description of the data captured by the Chips in both Adherence clubs and home-based visits. The EDC program will capture data as required by the National ART community module for stable on care patients which has been developed by EGPAF and implementing partners. The following data will be captured in the device during the community ART model visits:

At clinic level:

- Patient ART registration details- Name, Sex, Age, ART number

At community Level (Adherence Clubs and Home based Visits)

- Date of visit
- Symptom Screen (fever, weight loss, cough, headache)
- Pregnancy screening for females
- Adherence counselling and types of counselling
- Pre-packed drugs dispensed
- Services referred for PMTCT, ART, STI, VMMC, etc.
- Next community and clinic visit appointment

Data captured electronically during community visits will be linked to the HIV care databases at the health centre. The study team will work closely with the Ministry of Health and implementing partners

supporting the sites to collect relevant data from both the supply and demand side. Data that will be captured electronically during the club and home visits will be synced at the end of the day with the health care centre database. This is to ensure that indicators used for routine monitoring and follow-up will be entered in the current smart care system at facility level. The table below summarizes the core indicators that will be collected at both facility and community levels for the purpose of monitoring and evaluation.

Table 6: Common indicators for community ART models

Common Indicators for Community ART Models of Care		
Main	**Core Indicator**	**Data Source**
1. Recruitment	Proportion of patients enrolled into Home-Based ART models by sex	Smart care / HMIS
	Proportion eligible but refused	Consenting register
	Proportion of patients dropping out (within 1,3,6 and 12 months)	Routine data/ Programmatic data
	CD4 count at enrolment	Smart care
	Time on ART before enrolment	Smart care
2. Retention	Number (%) of clients retained at 1,3,6,12 and 24 months	Smart care
	Loss to follow up by reason: • Dead • Transfer • Lost	Smart care
	Number of patients returned to mainstream care (@ 3, 6. 12, 24 months)	Smart care
	% of clients who developed an OI @ 3, 6, 12 and 24 months	Smart care and routine programmatic data
3. Laboratory	Proportion of patients who have had viral loads within the last 6 months	Smart care and routine programmatic data
	Proportion of patients who have had CD4 count in the last 6 months	Smart care and routine programmatic data
	Proportion of patients with viral suppression at 12 and 24months	Smart care and routine programmatic data
	Proportion of patients with CD4 count below 500 in the last 12 months despite treatment	Smart care and routine programmatic data
4. Drug Supplies	Number of individuals missing at least one refill in the last 6 and 12 months	Smart care and routine programmatic data

Additional data collected for measuring the outcomes of the study objectives will be collected from patient clinical records. The key clinical indicators will be collected from smart care and HMIS and these includes:

- Proportion of patients with continuous immunologic/virologic suppression
- Proportion of patients who develop opportunistic infections in the models of care
- Transition rates of newly eligible patients into the community models
- Transition rates of patients from community models back to facility care

Data Security

Data will be securely stored according to Ministry of Health and Smart Care guidelines that are already in place for all health care centres providing HIV care. All CHiPs involved in community of ART model delivery will have to sign a consent form as per smart care National Guidelines which explicitly explains data confidentiality and respect of clients. Data captured electronically in the device is encrypted and once it is synced with the health centre database, protected by Microsoft SQL security. Access of all data in the health centre database will be based on user right and every user in the facility has to agree to terms of use, which is currently in place. The Audit Trail in Smart Care that is currently in place in all ART health centres logs key events, which occur in the system. It logs information such as who logged into the system, which patient reports they run, changes to inventory and who created a back up. Every single interaction has the identifier of whoever entered the data as well. This trail will be used for security and audit purposes.

In order to obtain the data for monitoring and evaluation as well as for research purposes both by implementing partners and Zambart research teams, permission will be sought from the Ministry of Health. The study team will then periodically extract this data for measuring the outcomes of the study.

Investigators will also allow inspection of all study-related documentation by authorized representatives of the HPTN LOC, SDMC, LC, NIAID, US and in-country government and regulatory authorities and IRBs/ECs. A site visit log will also be maintained at the study site to document all visits.

Qualitative Data Collection

Participants will include CHiPs and health facility staff involved in the models of care and based at the two urban health facilities and PLWH will be selected based on their qualitative representation of particular gender, age, experience and (for PLWH) household groups. Participant numbers will be relatively small. We estimate that participants will include approximately four CHiPs and four health facility staff in each of the two sites and 12 PLWH in each of the two sites.

Semi-structured key informant in-depth interviews (IDI) with health facility staff and CHiPs will be conducted at the two facilities. In addition, one focus group discussion in each site with CHIPs will also be conducted. These two data collections activities (FGDs and IDIs) will only be conducted once after one year and six months into the intervention.

For PLWH, data will be collected through focus group discussions (FGD) as well as in-depth interviews (IDI) for those that will not be comfortable with participating in FGDs. These activities will also be conducted once after one year and six months into the intervention. Moreover, Structured observations of the two delivery models and routine care will be carried out intermittently (Quarterly from the start) by Zambart social scientists in the two mentioned sites.

In addition, other existing social science data collected as a component of the wider PopART trial will be reviewed to help develop the research tools to be used (IDIs, structured observations and FGDs) and for comparative interpretation. For example, drawing on data on PLWH involved in other longitudinal enquiry in other PopART communities who are continuing to go to the health facility for care.

Key themes would include: the impact of the models of care on livelihood options, HIV related stigma and social relations; satisfaction with the modes of delivery; and comparison with routine ART delivery at the public health facility.

The data from this study will be transcribed, coded and managed using ATLAS ti and analysed using key themes and interdisciplinary discussion about key outcomes.

Economic Analysis

This will be embedded in the community models of ART delivery to compare the incremental of delivering the two models. Patient specific resource utilization data will be collected prospectively alongside the main study. We will generate estimates of the costs to the health care system of providing the interventions, such as packaging of drugs for the models, stationary used and trainings. We will also consider recurrent costs for personnel (wages and related costs), laboratory tests, materials, equipment and supplies etc. Direct health benefits will also be measured by triangulating HIV disease progression and death data, and secondary data on quality of life and disability. Data sources will include case report forms and study records. Secondary sources such as peer reviewed publications and grey literature will be reviewed to complement primary data.

6.0 Process Evaluation

For the purpose of this study, we will largely follow the indicators currently used in the national smart care system and the community ART model core indicators in section 5. Standard reports documenting this will be generated and reviewed by the study team and discussed with field teams at monthly management meetings and appropriate corrective actions implemented.

A consolidated report will be generated monthly which will be reviewed by the entire study leadership team on regular scheduled calls. A quarterly report will be developed to share with the national community ART steering committee, Ministry of Health and other implementing partners. This is to ensure transparency, accountability of patient clinical management, antiretroviral therapy management, adherence support and logistic supplies.

Site visits will be conducted by the in-country leadership to review procedures on the ground and implement any corrective action.

7.0 Statistical Analysis

The analysis will compare each of the two trial intervention arms with the "standard-of-care" (control arm), and the primary endpoint is viral suppression at 12 months after study enrolment. The analysis will be done using standard methods for a cluster- randomized trial with a non-inferiority design.

The study has been designed to a study power of between 73 -94% to demonstrate that a trial intervention arm is not inferior to the "standard-of-care" arm for the percentage of participants who are virologically suppressed at 12 months after study enrolment. The definition of "not inferior" is that the percentage of study participants who have died, or are alive but not virally suppressed, at 12 months after enrolment in a trial intervention arm is ≤ 5% higher than in the standard-of-care arm.

Based on the data from the annual first round of the CHiP intervention in the main trial, the number of adults who are known by the CHiP teams to be HIV-positive and to be taking ART at the time of the most recent CHiPs follow-up visit averages approximately 50 per zone, with a harmonic mean of approximately 36 per zone. Assuming that 80% of such adults agree to participate in the study and have not moved out of the community within 12 months after enrolment, the number of study participants per zone who can contribute to the primary endpoint measurement will have a harmonic mean of approximately 30.

Study power calculations have been done with the assumption that an average of 30 study participants per zone will contribute to the measurement of the primary endpoint; that 35 zones are randomized to the 2 intervention arms and 34 zones to the "standard-of-care" arm; and that among study participants in the "standard-of-care" the percentage who have died, or are alive but *not* virally suppressed, 12 months after enrolment to the study is in the range 10-15%. It is also assumed that the coefficient of variation k, of the variation across zones in the percentage of study participants who have either died or are alive but *not* virally suppressed at 12 months after study enrolment, is in the range 0.25 to 0.3. If the percentage of participants who have died or are alive but are *not* virally suppressed at 12 months after study enrolment is 10% in the "standard-of-care" arm, and k=0.25 or k=0.3, study power is 93% and 91% respectively to show that a trial intervention arm is not inferior to "standard-of-care". The corresponding study power figures are 78% and 74% if the percentage of participants who have died or are alive but are *not* virally suppressed at 12 months after study enrolment is 15% in the "standard-of-care arm".

Table summarising study power to show that community ART provision is not inferior to standard-of-care, in terms of patient viral suppression 12 months after either enrolling into community ART or continuing with standard-of-care at the clinic

Standard of care, % not virally suppressed at 12 months after enrolment	Intervention, % not virally suppressed at 12 months after enrolment	Coefficient of variation k	Number of participants per cluster	Study power (%)
5%	≤10%	0.25	30	99%
10%	≤15%	0.25	30	93%
15%	≤20%	0.25	30	78%
5%	≤10%	0.30	30	99%
10%	≤15%	0.30	30	91%
15%	≤20%	0.30	30	74%

We will also use qualitative and quantitative methods to evaluate the acceptability and feasibility of the two models of ART delivery and the barriers to access in care. Interviews would look at the trajectory of linking to care, reflecting on the HIV pathways and care choices prior to the intervention and after and exploring their comparative experience with satisfaction of care and

patient rights, HIV related stigma, household and other social relationships, livelihood pursuits and wellbeing.

The main focus of the economic analysis will be the cost of the models including equipment, materials, laboratory tests and personnel. Cost estimates will be collected for each of the resource items identified from the case report forms and study records. All cost data will be presented in Zambian Kwacha and in US$. Data will be entered and cleaned in excel. Patient specific resource use data will be coupled with the unit cost estimates to generate a patient specific cost estimate. Mean patient costs will be calculated separately for study intervention arms and standard statistical analysis undertaken. Data analysis will be performed in both Microsoft (MS) excel and Stata-version 13.0.

A cohort model will be developed combining the costs and benefits from the intervention. This approach will provide a conservative estimate of the cost-effectiveness of the intervention, as it will only consider the direct health benefits of the trial participants and not account for the indirect health benefits (such as QALY gains or DALYs averted from the secondary infections avoided).

8.0 Ethical Consideration

8.1 Ethical Review

Researchers will obtain ethical clearance from the relevant authorities at the University of Zambia, Biomedical Research Ethics Committee. Permission will also be sought from the Ministry of Health, Lusaka District Health Management Team (DHMT) to conduct the study in Chipata and Kanyama communities.

Participants will be approached to obtain written consent for taking part in the study. A standardized consent form will be reviewed by the Biomedical Research Ethics Committee of the University of Zambia between researchers and study participants prior to any intervention, interview and / or discussions. By and large, researchers will provide enough information about the study to the study participants to help them comprehend the purpose of this study, study benefits and risks to enable them make well informed decisions to either participate or not.

8.2 Participant Withdrawal

All study participants will retain the right to withdraw at any stage from the study interventions. Participants who withdraw from the intervention arms will be transitioned to continue care at the clinic whilst remaining in the study.

Participants will also be withdrawn from the study and transitioned to continue care at the clinic if the study may be discontinued at any time by the National Institute of Allergy and Infectious Diseases (NIAID), the HPTN, other government or regulatory authorities and/or site Institutional Review boards (IRB)/ Ethics Committee (EC).

8.3 Anticipated Risks

Researchers recognize the fact that there might be breach of confidentiality among health workers and CHiPs as a result of the study. The interaction of the CHiPs and research staff with various health workers within the study sites may disclose participant's personal and confidential information to

researchers. For this reason, all research staff will receive good clinical practice/research ethics training at the beginning of the study. All research staff and CHiPs will be counselled to observe maximum confidentiality of any information revealed to then during and after the study.

8.4 Benefits to the Study Participants

There will be no direct and immediate benefit in terms of monetary and/or material benefit during and/or at the end of the study. For this reason the participants will be well informed that their participation is purely voluntary and that they have the right to withdraw at any time.

Benefits anticipated to the participants include less frequent travel to the clinics for their pharmacy refill; reduce waiting time and privacy within the clubs and their homes.

8.5 Dissemination of research findings and final report

Preliminary findings of the study will be shared with our Ministry of Health and implementing partners during the technical working group meetings. We will continue providing progress reports every 6 months and final report at the end of the study will be shared with different partners including the Ethics Committee, Lusaka DHMT and Ministry of Health. Research findings will also be made available to the Ministry of health and in country implementing partners in order to inform policy guidelines regarding scaling up of community ART models. Based on these findings, researchers will make recommendations to all stake holders on how to improve community ART models for the country.

Additionally peer- reviewed research publications will be submitted under the auspice of Zambart intended for both local and international information users.

9.0 Administrative Procedures

Prior to implementation of this protocol, and any subsequent full version amendments, each site must have the protocol and the protocol informed consent form(s) approved, as appropriate, by their local institutional review board (IRB)/ethics committee (EC) and any other applicable regulatory entity (RE). Upon receiving final approval, sites will submit all required protocol registration documents to the DAIDS Protocol Registration Office (DAIDS PRO) at the Regulatory Support Center (RSC). The DAIDS PRO will review the submitted protocol registration packet to ensure that all of the required documents have been received.

Site-specific informed consent forms (ICFs) WILL NOT be reviewed or approved by the DAIDS PRO, and sites will receive an Initial Registration Notification when the DAIDS PRO receives a complete registration packet. Receipt of an Initial Registration Notification indicates successful completion of the protocol registration process. Sites will not receive any additional notifications from the DAIDS PRO for the initial protocol registration. A copy of the Initial Registration Notification should be retained in the site's regulatory files.

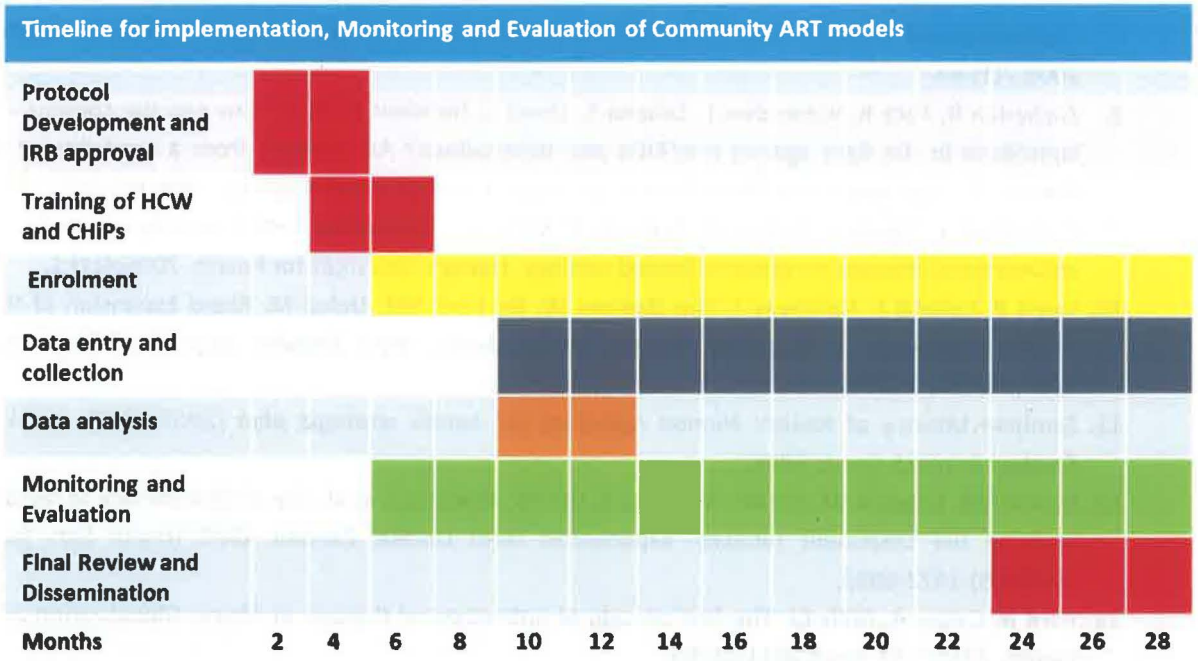
Upon receiving final IRB/EC and any other applicable RE approval(s) for an amendment, sites should implement the amendment immediately. Sites are required to submit an amendment registration packet to the DAIDS PRO at the RSC. The DAIDS PRO will review the submitted protocol registration packet to ensure that all the required documents have been received. Site-specific ICF(s) WILL NOT be reviewed and approved by the DAIDS PRO and sites will receive an Amendment Registration Notification when the DAIDS PRO receives a complete registration packet. A copy of the Amendment Registration Notification should be retained in the site's regulatory files.

For additional information on the protocol registration process and specific documents required for initial and amendment registrations, refer to the current version of the DAIDS Protocol Registration Manual.

10.0 Budget

There will be small costs associated with this ancillary study. Most activities will be carried out by staff already in position in the main HPTN -071 (PopART) trial. Some additional budget lines are needed to support additional requirements for data; pharmacy and field staff and these funds will be covered by the revised PopART budget. This is currently in place through research and PEPFAR COP 2016.

11. Study Timeline



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Appendix 1. INFORMATION SHEET AND INFORMED CONSENT FORM FOR COMMUNITY ANTIRETROVIRAL THERAPY DELIVERY

INFORMATION SHEET

You are being invited to take part in a new type of Anti-Retroviral Therapy (ART)service delivery for HIV stable patients. This is called "Community Models of ART care" and these models include the following:

1. Adherence club
2. Home-Based ART delivery
3. Continue care at the local facility

Adherence Club

The ART adherence club will consist of a group of 20-25 clinically stable HIV patients from this clinic. The members will meet every 3 months at a communal venue in your community where HIV adherence support, a symptom screening and pre-packed drugs will be provided. Community HIV Care Providers (CHiPs) that work in your community will conduct these activities and members will be required to visit the clinic once every 6 months for the next 2 years till the end of the study

Home-Based ART delivery

In this model, the Community HIV Providers (CHiPs) will visit people at home once every 3 months to provide them with adherence support, carry out a symptom screening and dispense pre-packed ART drugs. People who will be part of this model, will only visit the clinic once every 6 months for the next two years till the end of the study.

Continued Access of care at the local clinic

In this model, people will continue to receive care at the local clinic and follow the routine clinic visits that they have been following ever since they started Antiretroviral Therapy (ART).

We are therefore inviting you to participate in this study to see which model works best for the community. Within your community there are several zones and each zone will either have an adherence club, a home based ART delivery or continue receiving care at your local clinic.

Information about the study is supplied in this document. Please make sure that you understand everything described in this document. If you decide to participate, you will be asked to give written consent before you take part. If you sign this form, you will be giving your permission to take part in the study.

This form describes reasons for doing the study, how we will conduct the study and the benefits and risks of the study.

Your participation is voluntary

You do not have to take part in these models of ART service delivery. If you decide today to take part in this study, you may stop at any time without reducing or affecting any care that you receive at this clinic or anywhere else. If we learn any new information during the course of the study that might make you concerned about continuing, we share that information with you.

If you are offered community-based ART, but decide today to continue care at the clinic, you may change your mind later and if you are still living in the same area, you will then begin receiving ART in your community. If you accept community-based ART at any time, you can always decide later to go back to receiving ART at the clinic.

Who is doing the study?

Researchers from the Zambia AIDS Related Tuberculosis (ZAMBART) Project in conjunction with Ministry of Health will be conducting this pilot model in your community.

The study has been approved by the Medical Ethics Committees of the University of Zambia and the London School of Hygiene and Tropical Medicine.

What is the purpose of this study?

The purpose of the study is to compare HIV care and support delivered in your community by two different ways to the care that you would receive normally in the clinic. The two community delivery methods that are being studied are an adherence club where you would be in a group of 20-25 patients receiving care in a club within this community or a program where you would receive care at your home. The other option is that you will continue receiving care in the clinic.

In both the adherence club and home based ART delivery, you will receive adherence support, screening for symptoms and collect your medications rather than travelling to the clinic to collect the drugs.

This is meant to reduce long waiting times at the clinic and also reduce the number of visits you make to the clinic every year to collect your medications.

It will also allow the clinic to attend to patients who clinically unwell to be monitored closely.

The models will be monitored closely by the Zambart research team to determine if it will be successful in retaining HIV patients in care and allow us to roll it out wide in all communities.

What will happen during this study?

For you to be part of this study, we will need to check if you:

- Have been on ART for more than 6 months
- Have an undetectable viral load
- Have no underlying infections such as Tuberculosis (TB) etc
- Have maintained your clinic visits in the last 12 months.

We will review your ART file to see what drug regimens you are and whether you live in this community. If you did not have a viral load done as part of your routine care, we will have the clinic staff collect blood from you to measure your viral load. Once we confirm that you are stable by meeting the above requirements, we will determine which community zone you are living in. if the community zone you are living in has an adherence club, you will be asked to join the club and if you are not willing to then you are free to continue receiving care at the local clinic. If your zone provides Home based ART service, you will be asked to join this model where HIV care will be provided in your home. If you are not willing to join this model you can continue receiving care at the clinic. If the zone you are living in has no clubs or home based delivery, you will continue coming to the clinic for your care. In all these models we will ask you for your physical address and enter you in either a home ART register or club register which will be kept in this clinic. The research team will also look at your clinic records to determine if you are doing well whilst receiving most of the HIV care in your community and if you did have your 6 monthly laboratory tests as part of your care.

What happens if I am in an Adherence club?

If you belong to an adherence club, you will be asked to meet at a common venue in your community with other members of the club who are also receiving care at this clinic. You will be asked to meet once every 3 months and a trained community HIV provider (CHiP) who works within your community zone will visit your club and do the following:

1. Screen you to determine if you have any symptoms
2. Record your weight
3. Adherence counseling
4. Provide you with 3 monthly supplies of ARVs and Septrin

During these meetings, you will also have an opportunity to discuss any concerns or problems in a private setting with the CHiP.
A Clinic nurse will also accompany the CHiP during one or two meetings to provide support.

The CHiP will also remind when to next go to the clinic for your laboratory tests as well clinical review by the health care worker. You will be required to visit the clinic every 6 months and during this clinical visit, the club meeting will take place in the clinic where we will provide you with adherence support, have the clinician review you and a nurse collects blood for your laboratory tests. We will also give you your 3 months supply of drugs that should last you until we meet you in 3 months' time at the next club meeting in the community.

When you attend a clinic visit for your laboratory tests and clinical review every 6 months, the results will be entered in your clinic file and the CHiP will also give the results to you.

If you are unwell or the CHiP discovers you have a symptom that requires medical attention, you will be referred to the clinic to be seen by a clinician who will then decide if you are healthy to continue receiving care at the club or should resume care at the clinic.

All the information collected during the club visit will be entered in an electronic tablet. The information collected will then be entered into the clinic register and your care card at the clinic.

The information provided during the meetings will also be used to determine if you will be clinically stable at the end of the study and also if the model works. These results are important to determine if you will be adherent and help us to roll these clubs in other communities in Zambia.

At the end of the study, which is after 2 years, we will then refer you back to the clinic where you will continue your care.

What happens if I am in a Home Based ART delivery model?

If you belong to a zone where home based ART delivery will be provided, we will ask you for your physical address and a CHiP team that works in your community zone will visit you once every 3 months to do the following:

1. Screen you to determine if you have any symptoms
2. Record your weight
3. Adherence counseling
4. Provide you with 3 monthly supplies of ARVs and Septrin

During these home visits, you will also have an opportunity to discuss any concerns or problems in a private setting with the CHiP.
A Clinic nurse will also accompany the CHiP during one or two meetings to provide support.

The CHiP will also remind when to next go to the clinic for your laboratory tests as well clinical review by the health care worker. This will be every 6 months where you will come to the clinic. We will discuss the best date and time for you to go to the clinic so that you can be quickly seen by the clinician and nurse who will collect blood for laboratory tests. During this visit, we will also provide you with adherence counselling and a 3 month supply of drugs that will last you until the next home visit.

When you attend a clinic visit for your laboratory tests and clinical review every 6 months, the results will be entered in your clinic file and the CHiP will also give the results to you.

If you are unwell or the CHiP discovers you have a symptom that requires medical attention, you will be referred to the clinic to be seen by a clinician who will then decide if you are healthy to continue receiving care at home or should resume care at the clinic.

All the information collected during the home visit will be entered in an electronic tablet. The information collected will then be entered into the clinic register and your care card at the clinic.

The information provided during the home visits will also be used to determine if you will be clinically stable at the end of the study and also if this type of model works. These results are important to determine if you will be adherent and help us to roll out this type of service in other communities in Zambia.

At the end of the study that is after 2 years, we will then refer you back to the clinic where you will continue your care.

What if I am not in a club or home based ART model?

If you live in a zone that has no adherence club or home ART delivery services, you will continue receiving care at your local clinic like you have always done. The fact that you will be receiving care at the clinic will help us understand whether continuing receiving care in the clinic is better than the two models we are offering. Even if you continue receiving care at the clinic you will still be part of the study as we will monitor you at the local clinic and use the clinic data to determine if your care is no different from the other two models.

Regardless of whichever models of care you are in, you may be selected to participate in a set in-depth interviews and a focus group discussion that will be conducted by a group of social scientists from Zambart. The interviews will be held 4 times during the duration of the study while the focus group discussion will be held once. You are free not to participate in these interviews and focus group discussions if you are selected. If you choose not to participate in the interviews or focus groups, will still be allowed to remain in the study and to remain in the model of care you participate in.

What are the potential benefits?

There are no direct clinical benefits as a result of participating in the study. However: If you chose to participate in any of the two ART delivery models, it could reduce the amount of time you have to spend at the clinic. When you are referred to the clinic, you will be received and fast tracked through the queues.

Belonging to these types of models will provide a safe venue with whom you can share and get emotional support. When attending the clinic for a clinical review and laboratory tests, you will not need to queue up for drugs as this will be given to you at the club or at home.

What are the possible risks or discomforts?

There are no foreseen risks to being part of the additional study. However, if there were a breach of confidentiality, there is a risk that someone could learn of your status or other personal information. The study team will do everything to ensure confidentiality is maintained and the staffs who will be running these models of care are trained in maintaining confidentiality.

Adherence Clubs - if you are part of an adherence club, it would mean that other members of the club know that you are on ART. The other members in the club will also be from the same clinic that you have been receiving HIV care from. All members of the club should be able and willing to sign a "club charter of rights and responsibilities" in the presence of all club members, which include commitment to maintaining confidentiality. You will need to respect for one another's privacy during and after the club meetings - i.e. don't talk outside the group, ever, about who is in the group and their personal information. Should a member be found to breach this, s/he will be disqualified from the club and returned to mainstream care.

Home-Based Visits - there is a possibility that family, friends and people in your community may find out that you are participating in health related study if they see the CHiPs coming to your home and you may experience stigma but we will do everything we can to protect your privacy. During home-visits, everything discussed between your and the CHiPs will be done in private.

In both of these models you may end up feeling embarrassed or anxious when sensitive questions are being asked. You are free to skip questions you may deem personal or otherwise.

What are my responsibilities?
If you chose to participate in this study, you are agreeing to share the data or information captured with the clinic staff and researchers who will use the results to see if this type of service is ideal for stable patients.
If you choose to participate, you are agreeing to be responsible for visiting the clinic ONCE every 6 months. However, the CHiP will provide you with the date of the clinic visit and also remind you of the appointment.

You are also agreeing to ensure that you receive your drug supply during these home visits and sign off an appropriate form that you have received the drugs.

How will my confidentiality and privacy be protected?
The only people who have access to the information you have provided during these meetings are the clinic staff and Zambart researchers conducting this study.

People who may review the study records include: Biomedical Research Ethics Committee, local regulatory agencies, US National Institutes of Health (NIH), study staff, and study monitors. Institutional Review Boards (IRBs) or Ethics Committees (ECs) are committees that watch over the safety and rights of research participants. Provincial and/or national public health officials may be given community-wide results but not individual results

What are some reasons why I may be withdrawn from this activity without my consent?
You may be withdrawn from the study without your consent if the research study, or part of this study, is stopped or cancelled.

What happens if I am injured by participating in this study?
It is very unlikely that you could be injured as a result of participating in this study. However, if you are injured while participating in this study, you will be given immediate treatment for your injuries. You will not have to pay for this care. There is no program for compensation either through this institution or the United States NIH. You will not be giving up any of your legal rights by signing this Subject Information and Consent Form.

Persons to Contact for Problems or Questions
If you have any questions about your participation in this research study, your rights as a research Participant, or if you feel that you have experienced a research-related injury, contact:

Site Research Staff: DR MOHAMMED LIMBADA

Research Site Address (es): ZAMBART Project, School of Medicine, Ridgeway campus, P.O. Box 50697, Lusaka, Zambia.

Daytime Telephone Number (s): +260 211 254710
Email: Mohammed@zambart.org.zm

If you have any questions or concerns about your rights as a research Participant or want to discuss a problem, get information or offer input, you may contact:

Independent Review Board/Ethics Committee: Biomedical Research Ethics Committee

Address of Independent Review Board: School of Medicine, Ridgeway campus, P.O. Box 50110, Lusaka, Zambia

Daytime Telephone Number: + 260 211-256067

Thank you for reading this information sheet. If you have any questions, please ask them now. If you have either read or have heard the information in this Participant Information and Consent Form, if all of your questions have been answered, and if you agree to take part in the study, please print and sign your name and write the date on the line below.

_____ _____
Participant's Name (print) **Participant's Signature (or fingerprint)**

Date: _____
I certify that the information provided was given in a language that was understandable to the participant.

_____	_____
Name of Study Staff	**Study Staff Signature**

Conducting Consent Discussion (print)

Date: _____

_____	_____
Witness' Name (print) **(As appropriate)**	**Witness' Signature and Date**

Date: _____

Appendix II. INFORMATION SHEET AND INFORMED CONSENT FORM FOR QUALITATIVE STUDY PARTICIPANTS.

A Comparison of Different Community Models of ART Delivery amongst Stable HIV + Patients in Two Urban Settings in Zambia".

You are invited to take part in this research study because you are a health care worker, a Community HIV Provider (CHiP) or a person taking part in the community models of ART delivery at your health facility. Please ask the study staff to explain any words or procedures that you do not clearly understand.

This form is called a Participant's Information and Consent Form. The purpose of this form is to give you information about the research study you are being asked to take part in. The form describes the purpose, procedures, benefits, and risks of the research study. You may choose not to join the research project or withdraw from this study at any time. If you choose not to take part in this study, it will not in any way affect your employment, participation in community models of ART delivery or access to health care. Please read this Participant's Information and Consent Form and ask as many questions as needed. You should not sign this form if you have any questions that have not been answered to your satisfaction. If you sign this form, you will be giving your agreement to take part in the study.

There are several key points that you should be aware of before signing the consent form.
These key points have been separated into sections under **bold headings** below.

What will happen during this study and why am I being asked to take part?

Zambart is conducting a study on two different community models (adherence *clubs and home delivery model*) of delivering ART services in your community. The purpose of this study is to compare whether people who are participating in these community models will have better health outcomes at the end of the study compared to others who are accessing treatment from the health facility. Understanding how health staff (including CHiPs) and people living with HIV who are on treatment experience the two models of care will help us interpret the results of this study better. Because you are either a health worker or a patient receiving ART, we would like to know your experience with these models of care by having you participate in a Focus Group Discussion or Individual Interview. If you agree to participate in a Focus Group Discussion, you will be put in a group of 8-10 people and two researchers from Zambart social science will we will discuss with the whole group a number of question related to how you or other people in the community have experienced the two models of ART. If you agree to participate in an Individual Interview on the other hand, you will have a one on one discussion with one researcher from Zambart social science who will ask you a number of questions related to how you experience the two models of ART. The focus group discussions (FGDS) and in-depth inter views (IDIs) will be conducted once 18 months into the intervention.

What are the possible risks or discomforts?
Some of the questions that we will ask you will be of a sensitive nature. You may become embarrassed, worried or anxious when asked questions about HIV, sexual risk behavior and other topics. Should this occur, or if you are otherwise upset by the study, the research staff can refer you to an appropriately trained person in this area for assistance.

Another possible risk of participating in this study may be the loss of confidentiality of the information you give as it may find its way to people you work with or people in the community may hear of what you will tell us.

Your participation is voluntary
You do not have to be part of this study. Taking part in this study is your own decision. If you feel you have been forced or unfairly pressured into participating either by us (the research team) or by your employer or line manager, then you are welcome to decline to participate now and this will not affect your employment, or care you receive at the health care facility or your ability to continue participating in the main study or community model of ART. If you decide today to take part in this research project, you may refuse to take part in any portion of the study or stop at any time and that also will not affect your employment, healthcare or main study participation or ART delivery.

Who is doing the Study?
Social science researchers from the Zambia AIDS Related Tuberculosis (Zambart) Project and the London School of Hygiene and Tropical Medicine (LSHTM) and partners including Imperial College London, will work closely on this study with colleagues from the HIV Prevention Trials Network (HPTN).

What are the potential benefits?
There are no direct benefits associated with participation in the group discussions or individual interviews, but there may be indirect benefits for your community in the future. The information gained from this study may help organizations to design future intervention and programs that will help improve ART service delivery. This is also another benefit for policy-makers and intervention implementers to understand the impact of these models on service delivery as well as access to HIV services.

Are there any alternatives to participation?
There may be other studies going on here or in the community that you may be eligible for. If you wish, we will tell you about other studies we know about. You also have an alternative of not participating in this study.

How will my confidentiality and privacy be protected?
Confidentiality means we (the research team) will protect your identity and take steps to make sure that all the information you provide is separated from your identity (name, address, phone number

or any audio recording) as a person. We do this so that someone reading one of our reports or seeing our presentations will not know your identity.
However, we cannot guarantee absolute confidentiality but every effort will be made to protect your confidential information. For example, none of the information you give will be kept in the same place as your name or other personal identifiers. Your name and any other information that may identify you or your household will be kept confidential. Although we will record the interviews and focus groups with your permission the discussions, information will not be linked or traced back to you. Data collected using the audio recorder will be downloaded to password protected secure computers under the management of the HIV Prevention Trial Network -HPTN 071 (PopART) data team. When this discussion or interview is fully transcribed (written up), the recordings will be destroyed and data will be checked and cleaned centrally so as to remove any identifiers. Any publication of this study will not mention your name or identify you personally. Your records however may be reviewed by the U.S. National Institute of Health, the US Office of Human Research Protection, and the Bio-medical Research Ethics Committee from the University of Zambia, HIV Prevention Trial Network personnel, study staff, monitors and others who are responsible for the conduct of safety for this study.
However, if we identify any serious health or welfare problems during the course of this research, we are obligated to refer you to others who are trained to help and will still keep all the information you will give about your problem confidential.

What happens if I am injured by participating in this study?
It is very unlikely that you could be injured as a result of participating in this study. Nothing that we will be asking of you will place you at risk of injury. However, if you are injured while participating in this study, you will be given immediate treatment for your injuries. You will not have to pay for this treatment. There is no program for compensation through the United States National Institutes of Health. However, in case of any research related injury, the London School of Hygiene and Tropical Medicine would provide compensation. You will not have to pay for this treatment. Social harms (that is, things like negative impacts on your employment or harassment by your neighbors, friends, or family due to participating in this study) are expected to be minimal, but if they occur, they will be monitored closely throughout the duration of the study. We encourage you to report any social harm that you experience, as and when they occur. If you do experience negative social harms every effort will be made by study staff to provide appropriate care and counselling to you, and/or to refer you to appropriate resources and care.

You will not be giving up any of your legal rights by signing this Participant's Information and Consent Form.

Costs to you
There is no cost to you for being in this study. If you are taking part in a Focus group discussion or an interview, we try by all means to conduct the activity at your own convenient time and location in the community or at the health facility. All Focus Group Discussions will approximately be one

hour and thirty minutes while interviews will most likely be within an hour. Refreshments for both activities will be provided.

What are some reasons why I may be withdrawn from this activity without my consent?
You may be withdrawn from the study without your consent for the following reasons:

- The research study, or this part of the study, is stopped or cancelled
- The study staff feels that completing the study or this part of the study would be harmful to you or others.
- If you as a participant are unable or unwilling to participate in the study in a way that is in compliance with the necessary study procedures

Persons to Contact for Problems or Questions
If you have any questions about your participation in this research study, your rights as a research participant, or if you feel that you have experienced a research-related injury, contact:

CONTACTS FOR QUESTIONS (Names, addresses and phone numbers of the following):

1. **Principal Investigator:** Dr. MOHAMMED LIMBADA ZAMBART Project PO Box 50697, Ridgeway Campus, School of Medicine Lusaka. Telephone: +260 211 254710
   Email: Mohammed@zambart.org.zm
2. **Co-Investigators:** Bwalya Chiti, Dr. Virginia Bond, Dr. Helen Ayles, ZAMBART Project PO Box 50697, Ridgeway Campus, School of Medicine Lusaka.
   Telephone: +260 211 254710

Chairperson, Bio-medical Research Ethics Committee, School of Medicine, Ridgeway Campus, University of Zambia, P.O. Box 50110, Lusaka, Zambia.
Telephone: 260 211 256067

INFORMED CONSENT FORM FOR HEALTH CARE WORKERS AND People Living with HIV QUALITATIVE STUDY PARTICIPANTS

A comparison of different community models of ART delivery amongst stable HIV+ patients in two urban Setting in Zambia.

1. I have been given sufficient time to consider whether to take part in this study.

2. My taking part in this research study is voluntary. I may decide not to take part or to withdraw from the research study at any time without penalty or loss of benefits or treatment to which I am entitled.

3. The research study may be stopped at any time without my consent.

4. I have had an opportunity to ask the study staff questions about this research study. My questions so far have been answered to my satisfaction.

5. I have been told how long I may be in the research study.

6. I have been informed of the procedures that may be performed during the research study.

7. I have been told what the possible risks and benefits are from taking part in this research study. I may not benefit if I take part in this research study.

8. I do not give up my legal rights by signing this form.

9. I have been told that before any study related procedures being performed, I will be asked to voluntarily sign this Participant Information and Consent Form.

10. I will receive a signed and dated copy of this Participant Information and Consent Form.

If you have either read or have heard the information in this Participant Information and Consent Form, if all of your questions have been answered, and if you agree to take part in the study, please print and sign your name and write the date on the line below.

_____ _____

Participant's Name (print) **Participant's Signature (or fingerprint)**

Date: _____

I certify that the information provided was given in a language that was understandable to the participant.

Name of Study Staff	**Study Staff Signature**

Conducting Consent Discussion (print)

Date: _____

Witness' Name (print) **(As appropriate)**	**Witness' Signature and Date**

Date: _____

Appendix III. Community ART Smart Care module for Stable ART Patients

Registration:

Last Name

First Name

Gender

Date of Birth

NRC

Auxiliary ID (optional... can be phone number, safe motherhood number or any other unique ID)

1 Stable on Care

1.1 Health History

Do you have a fever? [Yes] [No]

Do you have Cough for more than 2 weeks? [Yes] [No]

Are you losing weight? [Yes] [No]

Do you have headache? [Yes] [No]

1.2 Health Screening LMP (if female)

1.2.1 Still Having menstrual periods? [Yes] [No]

1.2.2 (If 1.2.1 is Yes) Last menstrual period [Enter date]

1.2.3 (If 1.2.1 is No) Reason for not having menstrual period?

[Pregnancy]

[Menopause]

[Premenarche]

[Breast feeding]

[Contraceptives]

[Don't Know]

1.3 Physical Exam (OPTIONAL –only by HCW conducting the visit)

1.3.1 Blood Pressure [diastolic][systolic].....OPTIONAL

1.3.2 Temperature [value].....OPTIONAL

1.3.3 Weight [value].....OPTIONAL

1.3.4 Urine Protein [Negative] [Trace] [+] [++] [+++].....OPTIONAL

1.3.5 Urine Glucose [Negative] [Trace] [+] [++] [+++].....OPTIONAL

1.4 Adherence Counselling

1.4.1 Does the patient ever have trouble taking the pills? [Never] [Rarely] [Sometimes] [Often] [Very Often]

1.4.2 Since the last visit has client missed more than 3 doses? [Yes] [No]

1.4.3 Reasons for missing doses? [Forgot] [Felt Ill] [Away from home/travel] [Meds finished]

1.5 Counseiiing Given

1.5.1 Type of Counselling Given?

[Adherence Counselling]

[Safer sex]

[Family planning]

[Disclosure]

[STI/TB counselling]

[Partner testing] [Nutrition]

1.6 Drugs Dispensed

1.6.1 Pre-packed drugs dispensed to Patient? [Yes] [No]

1.7 Next Appointment Date [value]

1.8 Next Six Month Visit Date [value]

1.9 Facility Referral

1.9.1 **Please select the Type of Referral**

[Partner Referral to Facility for ART]

[Male Circumcision]

[Family Planning]

[HTC Appointment]

[ANC Appointment]

[OPD]

1.9.2 **Specify Facility referred to**

2.7.2.1 Province [value]

2.7.2.2 District [value]

2.7.2.3 Facility [value]

1.9.3 Appointment Date [value]

1.10 Save

1.10.1 Confirm Save [Yes] [No]

Appendix IV: INVESTIGATORS CVs

CURRICULUM VITAE FOR MOHAMMED LIMBADA, BSc, MBCHB, MScID

General Information

Holds a Bachelor of Science, Human Biology and Bachelor of Medicine and Bachelor Surgery from the University of Zambia

Has a MSc in Infectious Diseases from the London School of Hygiene and Tropical Medicine

Current Appointment:

- Phylogenetic Study Manager under the HPTN 071 study
- Population Cohort Coordinator HPTN071

Qualifications

BSc	Human Biology, University of Zambia	1995-1999
MBCHB	Bachelor of Medicine and Bachelor of Surgery, University of Zambia	2000-2002
Msc	(Infectious Diseases) London School of Hygiene and Tropical Medicine	*2011*

Courses attended

Good Clinical Practice (GCP), Responsible conduct of Research and Human subject protection- CITI	2013
	2012
Brown International Advanced Research Institute, Browns University, Providence, USA	2007
	2007

ASPIRE HIV/AIDS Professional Development Program- San Francisco General Hospital, University of California.	2007
Clinical Training Skills – Ministry of Health/JHPIEGO	2006
Management of Adult HIV/AIDS in Zambia. (John Hopkins Centre for Clinical Global Health education and JHPIEGO)	2006
Pediatric HIV Management – Trainer of trainers; MOH/Clinton Foundation	2005
Principles of STI/HIV –University of Washington, Seattle	2005
Trainer of Trainers Course (Adult HIV Management), Ministry of Health	2003
Management of Adult HIV Training Course, South- Africa Foundation of Professional Development (FPD), South African Medical Association	
The Care and Treatment of HIV- infected Children, Baylor College of Medicine- Texas	

Research Experience

Overview

I have over 5 years' experience conducting research in the field of HIV/AIDS in high burden settings. I have served as a local Principal investigator for the HPTN 063 Study and Investigator of records of a clinical study funded by EGPAF.

Recently I have been part of the HPTN 071 intervention working group and Population Cohort group. I am currently the study manager of the HPTN 071 Phylogenetic study.

My research interests focuses on finding novel approaches surrounding HIV prevention and treatment, including mother-to-child transmission and sexually transmitted infections.

Major Research Studies

2014-current HPTN 071 and Phylogenetic Study
Funder: NIH/Gates
Role : Study Manager

2011- 2014 HPTN 063
Funder: NIH/FHI 360
Role: Principle Investigator

2009-2011 Non – Virologic Methods to predict HIV infections among HIV-exposed infants less than 12 weeks
Funder: EGPAF
Role: Investigator of Records

Other

Previous posts held

2004-2005 Senior House Officer – **Monze Mission Hospital**
2002-2004 Resident Doctor, **University Teaching Hospital**

Other professional activities

2007-2014 **Member,** National ART Technical Working Group

Presentations at Conferences

2011 Early Immunologic response and subsequent survival among malnourished adults receiving antiretroviral therapy in urban Lusaka. Croi 2011, Boston USA
2012 Retention in care among HIV infected patients in rural areas of Zambia – National ART update, Lusaka
2013 Clinical, Virologic and Pharmokinetic Response to Acyclovir among African women with Genital Ulcer Disease – National Research Conference, Lusaka, Zambia

Accepted Abstracts

1. Chi BH, **Limbada MI**, Giganti MJ, Li MS, Bweupe M, Musonda P, Bubala P, Mubiana-Mbewe M, Chintu NT, Bolton-Moore C, Stringer JS. **Non-virologic algorithms for predicting HIV infection among HIV-exposed Infants less than 12 weeks of age. : http://www.ncbi.nlm.nih.gov/pubmed?term=22935865**

2. Koethe JR, **Limbada MI**, Giganti MJ, Nyirenda CK, Mulenga L, Wester CW, Chi BH, Stringer JS.AIDS. **Early immunologic response and subsequent survival among malnourished adults receiving antiretroviral therapy in Urban Zambia. 2010 Aug 24; 24(13): 2117-21. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2919155/**

3. Chi BH, Cantrell RA, Mwango A, Westfall AO, Mutale W, **Limbada M**, Mulenga LB, Vermund SH, Stringer JS. **An empirical approach to defining loss to follow-up among patients enrolled in antiretroviral treatment programs. Am J Epidemiol. 2010 Apr 15; 171(8): 924-31. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2850972/**

4. Baeten JM, Reid SE, Delany-Moretlwe S, Hughes JP, Wang RS, Wilcox E, **Limbada M**, Akpomiemie G, Corey L, Wald A, Celum C. **Clinical and virologic response to episodic acyclovir for genital ulcers among HIV-1 seronegative, herpes simplex virus type 2 seropositive African women: a randomized, placebo-controlled trial. Sex Transm Dis. 2012 Jan; 39(1): 21-4. http://www.ncbi.nlm.nih.gov/pubmed?term=22183840**

5. Koethe JR, Lukusa A, Giganti MJ, Chi BH, Nyirenda CK, **Limbada M**, Banda Y, Stringer JS. Association between Weight Gain and Clinical Outcomes among Malnourished Adults Initiating Antiretroviral Therapy in Lusaka, Zambia. **PMID:19730111 [PubMed-as supplied by publisher]**

6. Chi BH, Giganti M, Mulenga PL, **Limbada M**, Reid SE, Mutale W, Stinger JS. **CD4+ Response and Subsequent Risk of Death among Patients on Antiretroviral Therapy in Lusaka, Zambia. J Acquir Immune Defic Syndr. 2009 Sep 1; 52(1): 125-31. PMID: 19546812 [PubMed- indexed for MEDLINE.**

7. Goldman JD, Cantrell RA, Mulenga LB, Tambatamba BC, Reid SE, Levy JW, **Limbada M**, Taylor A, Saag MS, Vermund SH, Stringer JS, Chi BH. **Simple adherence assessments to predict virologic failure among HIV-infected adults with discordant immunologic and clinical responses to antiretroviral therapy. AIDS Res Hum Retroviruses. 2008 Aug; 24(8): 1031-5. PMID: 18724803 [PubMed-indexed for MEDLINE**

Peer Reviewed Publications

8. Chi BH, **Limbada MI**, Giganti MJ, Li MS, Bweupe M, Musonda P, Bubala P, Mubiana-Mbewe M, Chintu NT, Bolton-Moore C, Stringer JS. **Non-virologic algorithms for predicting HIV infection among HIV-exposed Infants less than 12 weeks of age. : http://www.ncbi.nlm.nih.gov/pubmed?term=22935865**

9. Koethe JR, **Limbada MI,** Giganti MJ, Nyirenda CK, Mulenga L, Wester CW, Chi BH, Stringer JS.AIDS. **Early immunologic response and subsequent survival among malnourished adults receiving antiretroviral therapy in Urban Zambia. 2010 Aug 24; 24(13): 2117-21.**
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2919155/

10. Chi BH, Cantrell RA, Mwango A, Westfall AO, Mutale W, **Limbada M,** Mulenga LB, Vermund SH, Stringer JS. **An empirical approach to defining loss to follow-up among patients enrolled in antiretroviral treatment programs. Am J Epidemiol. 2010 Apr 15; 171(8): 924-31.**
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2850972/

11. Baeten JM, Reid SE, Delany-Moretlwe S, Hughes JP, Wang RS, Wilcox E, **Limbada M**, Akpomiemie G, Corey L, Wald A, Celum C. **Clinical and virologic response to episodic acyclovir for genital ulcers among HIV-1 seronegative, herpes simplex virus type 2 seropositive African women: a randomized, placebo-controlled trial. Sex Transm Dis. 2012 Jan; 39(1): 21-4.**
http://www.ncbi.nlm.nih.gov/pubmed?term=22183840

12. Koethe JR, Lukusa A, Giganti MJ, Chi BH, Nyirenda CK, **Limbada M**, Banda Y, Stringer JS. Association between Weight Gain and Clinical Outcomes among Malnourished Adults Initiating Antiretroviral Therapy in Lusaka, Zambia. **PMID:19730111 [PubMed-as supplied by publisher]**

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: **Kwame Shanaube**

eRA COMMONS USER NAME (credential, e.g., agency login): NA

POSITION TITLE: **Site Coordinator-HPTN 071/PopART- Zambia**

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Zambia	BScHB	06/1988	Bachelor of Human Biology
University of Zambia	MBChB	07/1999	Bachelor of Medicine & Bachelor of Surgery
University of Witwatersrand, South Africa	MPH	11/06	Public Health
London School of Hygiene and Tropical Medicine	PhD	1/14	TB/HIV Clinical epidemiology

NOTE: The Biographical Sketch may not exceed five pages. Follow the formats and instructions below.

A. Personal Statement

I am a clinician with a Master's degree in Public Health and PhD in TB clinical epidemiology. I have worked in the field of TB and HIV for the past 12 years as a researcher. Having worked in TB/HIV public health research for the past 12 years my confidence has an investigator has enormously grown. I have managed four large studies; two of which are community randomized trials; other two have been operational research and I am currently PI for an adolescent study looking at uptake and acceptability of Universal HIV testing and treatment (UTT). My experience has ranged from providing technical assistance to the ministry of health for the implementation, roll out and evaluation of integrated TB/HIV activities; conducting a tuberculin skin test surveys and designing mechanisms of follow up; designing and implementing monitoring and evaluation tools for household based integrated TB/HIV

interventions as well as evaluating Quantiferon TB- Gold priority research questions in a developing country.

I am currently site coordinator for one of the largest HIV prevention trials, the HPTN 071/PopART. I am hard working, result-oriented and extremely dedicated to my work. I have published papers in the international medical literature and several more are in preparation. Apart from leading multi-disciplinary teams, I have held key decision making responsibilities which included managing study finances. I have experience of working with international development program and extensive exposure to global health systems. I am involved in teaching Master of Science in Epidemiology students in the school of Public Health as well as mentoring them.

My vision: To contribute towards efforts of improving the lives of individuals infected with TB and HIV at individual, family, and community levels; to promote strengthening of health systems in countries where TB and HIV is rampant. I believe I have a role to play to make the world a better place.

B. Positions and Honor

AWARDS

- Study Manger for the "best overall performing team-Tuberculin skin test survey, 2009", Zambart
- Scholarship by WHO to attend advanced Course on Diagnostics, 29th August to 2 September 2011, France

HONORS

- Honorary lecturer- University of Zambia, School of medicine; 2014-date

POSITIONS AND EMPLOYMENT

- 01/12-present Study Manager/ Site Coordinator, HPTN 071/PopART, Zambart, Lusaka Zambia
- 04/15-present Principal Investigator, Adolescent in HPTN 071/PopART study
- 06/07-12/11 Study Manager, Quantiferon-TB GOLD Cohort, ZAMSTAR, Zambart, Lusaka Zambia
- 01/06-12/08 TB prevalence survey Manager, copperbelt site ZAMSTAR, Zambart, Lusaka Zambia
- 06/09-06/10 Monitoring and Evaluation Manager, ZAMSTAR, Zambart, Lusaka Zambia
- 01/05-12/09 Tuberculin skin test survey manager, ZAMSTAR, Zambart, Lusaka
- 10/03-12/04 Study Manager, Integrated TB/HIV activities (ProTEST), Study Manager, Lusaka Zambia.
- 05/01-01/02 Resident Doctor, St Johns Medical Center, Lusaka Zambia)
- 12/97-01/02 Junior and Senior Medical officer, University Teaching Hospital (UTH), Lusaka, Zambia

C. Contribution to Science

1. TB/HIV integration- "ProTEST Project- Zambia"
The name "ProTEST" is derived from the "Promotion of voluntary HIV testing" as an entry point for access to the core interventions of intensified TB case-finding and isoniazid preventive treatment. The ProTEST initiative was established in 1997 by WHO to develop a more coherent response to TB in settings with high HIV prevalence through collaboration between TB and HIV/AIDS control programmes. HIV counselling and testing services were developed as the entry point to a package of prevention, care and support services. This paved the way for large-scale operationalization of the comprehensive range of interventions needed to control TB in settings with high HIV prevalence. My specific role in this initiative was that of study manager and I spearheaded the provision of technical assistance to the Ministry of Health; was involved in national roll out of collaborative TB/HIV activities and pioneered strategies to bring TB & HIV programmes together- now the basis of international policy-WHO framework for TB/HIV collaborative activities. To test whether TB/HIV integration, including community level implementation combined with enhanced case finding for TB, can impact the TB epidemic at community level we conducted the ZAMSTAR trial of which my roles were as follows: study manager for the tuberculin skin test survey and TB prevalence survey; in charge of monitoring and evaluation of the intervention. The ZAMSTAR trial has informed the implementation of community level HIV/TB integration and also the role of TB case finding which both have been included in WHO policies.

Published papers/reports

1. Ayles H, Muyoyeta M, Du Toit E, Schaap A, Floyd S, Simwinga M, Shanaube K, Chishinga N, Bond V, Dunbar R, De Haas P, James A, Gey van Pittius NC, Claassens M, Fielding K, Fenty J, Sismanidis C, Hayes RJ, Beyers N, Godfrey-Faussett P. Effect of household and community interventions on the burden of tuberculosis in southern Africa: the ZAMSTAR community-randomised trial. Lancet. 2013 Oct 5; 382(9899):1183-94.
2. Report of a Lesson's Learnt Workshop on the 6 ProTEST pilot projects in Malawi, South Africa and Zambia 3-6 Feb 2004. WHO 2004. WHO/HTM/TB/2004.336

Presentations I have made at international meetings and conferences

1. 42nd UNION conference on Lung Health, Lille, France, "Impact of ZAMSTAR interventions on transmission of tuberculosis", 30th October 2011.
2. Global TB/HIV working group on the stop TB Partnership; " Integration of TB/HIV with PMTCT: field experience from Zambia", Toronto, August 2006
3. TSRU meeting," ProTEST expansion in Zambia", Geneva, April 2004
4. 35th Union World Conference on Lung Health, Paris," ProTEST expansion in Zambia" October 2004
5. WHO meeting "Scaling up TB/HIV collaborative activities in Zambia", Ethiopia, 2004

2. **TB diagnostics**
I have contributed to the TB diagnostics knowledge gaps in testing new tools for TB infection and disease (see other sections for details) as well HIV self-testing tools in a

resource limited setting. I was part of a team that pilot tested the feasibility and uptake of HIV self-testing using OraQuick® ADVANCE in a resource limited setting. In addition in line with WHO policy, I have been involved in field testing and ministry of health implementation and roll-out of gene Xpert.

Published papers

1. Dalila Zachary, Lawrence Mwenge, Monde Muyoyeta, Kwame Shanaube, Albertus Schaap , Virginia Bond, Barry Kosloff, Petra de Haas, Helen Ayles. Field comparison of OraQuick® ADVANCE Rapid HIV-1/2 antibody test and two blood-based rapid HIV antibody tests in Zambia; July 2012.

3. ***Diagnosis of latent tuberculous infection and use of tools to predict disease in HIV infected populations***

Tuberculin skin test (TST) has been traditionally used to identify tuberculous infected individuals; however, its use is limited by several factors. QuantiFERON-TB Gold In-Tube (QFT-GIT) provide an alternative to TST and its use is included in the guidelines of many countries in low TB incidence settings although its use in high-burden settings remains unclear. This led to my PhD training at the LSHTM in TB/HIV clinical epidemiology funded by FIND which focused on the use of IGRAs within prospective, large scale studies of households exposed to tuberculosis and to determine whether they would be used to predict individuals most likely to develop disease. This study also served as a pilot field demonstration study comparing the performance and operational characteristics of QFT-GIT and TST in a resource limited setting with a high prevalence of TB and HIV. My specific role was that of study manager and Co-PI. Findings from this study contributed towards the formulation of WHO policy which recommended that neither IGRAs nor the TST should be used in low- and middle-income countries for the identification of individuals at risk of developing active TB.

Published papers

1. WHO. Use of interferon-gamma release assays (IGRAs) in TB control in low- and middle-income settings. 2011. Expert Group Meeting Report 20-21 July 2010; WHO/HTM/TB/2011.17
2. Shanaube K, Hargreaves J, Fielding K, Schaap A, Lawrence K-A, Hensen B, et al. Risk Factors Associated with Positive QuantiFERON-TB Gold In-Tube and Tuberculin Skin Tests Results in Zambia and South Africa. PLoS ONE. 2011;6(4):e18206
3. Shanaube K, De Haas P, Schaap A, Moyo M, Kosloff B, et al. (2010). "Intra-assay Reliability and Robustness of QuantiFERON-TB Gold In-Tube Test in Zambia." Int J Tuberc Lung Dis 14: 828 - 833.
4. Shanaube K, Sismanidis C, Ayles H, Beyers N, Schaap A, Lawrence K-A, et al. Annual Risk of Tuberculous Infection Using Different Methods in Communities with a High Prevalence of TB and HIV in Zambia and South Africa. PLoS ONE. 2009;4(11):e7749.

Presentations I have made at international meetings and conferences

1. UNION meeting, CDC late breaker session, Berlin, "Prognostic value of Quantiferon-TB Gold test in household contacts in Zambia and South Africa", Nov 2010
2. CREATE meeting, "QuantiFERON-TB Gold responses in TB patients and contacts" Cape town, Sept 2009
3. 4th National Health Research Conference, " Tuberculin Skin Test Survey in Zambia and South Africa"; Lusaka; January 2007

4. HPTN 071/PopART study

The Population Effects of Antiretroviral Therapy to Reduce HIV Transmission (PopART) study is based on the principle of evaluating UTT using operational research within existing systems. PopART (HPTN 071) is a research study that aims to determine the impact of a package of HIV prevention interventions on community-level HIV incidence. My specific role in this study is that of PopART study manager include involves provision of technical and administrative leadership for a large multi-disciplinary team; development of the study protocol and other priority research questions; designing intervention and research SOPs as well as spearheading training and implementation; working in close cooperation with the PEPFAR implementing agencies, CDC and USAID, and other stakeholders in the preparation, implementation, monitoring and evaluation of the study and managing study budget resources. Although the study is currently ongoing implementation lessons learnt so far especially on the feasibility of rolling out UTT have been invaluable to policy makers, other health professionals and international policy.

Published papers

1. Shanaube K, Bock P. Innovative Strategies for Scale up of Effective Combination HIV Prevention Interventions in Sub-Saharan Africa. Curr HIV/AIDS Rep. 2015;12(2):231-7.
2. Hayes R, Ayles H, Beyers N, Sabapathy K, Floyd S, Shanaube K, et al. HPTN 071 (PopART): Rationale and design of a cluster-randomised trial of the population impact of an HIV combination prevention intervention including universal testing and treatment - a study protocol for a cluster randomised trial. Trials. 2014;15 (1):57.

Presentations I have made at international meetings and conferences

1. HPTN Annual Meeting, "Overview of PopART intervention", June 2014, Lusaka, Zambia.
2. INTEREST Meeting, "Overview of the PopART study", May 2014, Lusaka, Zambia
3. East and Southern Regional Consultation on the Strategic use of ARVs, "An overview of the PopART study" Harare, Zimbabwe, March 2013.

D. Research Support

1. **Uptake and acceptability of a combination HIV prevention package among young people in Zambia and South Africa (Adolescents in PopART) the nested study will be a**

community randomized comparison of a combination prevention approach, combined with youth targeted interventions where necessary, in adolescents aged 15-20 years.
Roles: Principal Investigator
Date: 2015-2018
Funding: **DFID and SIDA as part of the EPHSA research funds- Contract in process 2.**

2. **PopART/HPTN 071 Population Impact of antiretroviral therapy to reduce HIV transmission**
   Role: Study Manager
   Dates: 2011-2018
   Funding: **NIH/NIAID/BMGF/NIMH/NIDA $70,000,000, OGAC funding for implementation $57,000,000 (Total being directly managed through Zambart $36,500,000)**

Completed Research Support

1. **ZAMSTAR: Community randomised trial of two interventions to reduce the prevalence of tuberculosis at community level**
   Role: Tuberculin skin test survey manager/TB survey Prevalence managers for Copperbelt sites
   Dates: 2004-2014
   Funding: **Bill and Melinda Gates Foundation via CREATE consortium $30,000,000 of which $13,150,995 was managed by Zambart**

2. **Quantiferon Gold In Tube for diagnosis of M. tuberculosis infection demonstration project and cohort study**
   Dates: 2007-2010
   Role: Study Manager
   Funding: **Work was supported by the Foundation for Innovative New Diagnostics (FIND). Further support was provided by a subcontract from Johns Hopkins University with funds provided (Grant No. 19790.01) from the Bill and Melinda Gates Foundation via the CREATE (Consortium to Respond Effectively to AIDS and Tuberculosis Epidemic) consortium.**

4. **Promotion of voluntary Testing as an entry point for access to the core interventions of intensified TB case-finding and isoniazid preventive treatment.**
   Role: ProTEST study manager
   Dates: 2001-2004
   Funding: **WHO**

1. **Surname:** Simwinga **Nationality:** Zambian

   First name (s): Musonda **Sex:** Male

2. **Contact Details:** Musonda Simwinga

   C/o Zambia AIDS Related Project. University of Zambia School of Medicine, Ridgeway Campus. P.O. Box 50697, Lusaka, Zambia. Email: musonda@zambart.org.zm, musondasimwinga@yahoo.co.uk

3. **Summary**

I hold a Bachelor of Arts (BA), Master of Arts (MA) and I recently obtained a research degree PhD from the London School of Hygiene and Tropical Medicine (LHTM). I have 10 years' experience conducting research in TB and HIV in high burden settings using mixed methods approaches. My previous experience was in managing development and HIV/AIDS oriented projects including Monitoring and Evaluation. Recently, my research interests have been to assess and develop better ways of engaging the community in research. I have been involved in various studies including the ZAMSTAR study, a large two country randomised control trial of community level interventions aimed at reducing the burden of TB and HIV.As an employee of the ZAMBART Project, I has been instrumental in building capacity for all research staff in conducting ethical research through facilitating research ethics as well as Good Clinical Practice (GCP) training.

4. **Degree(s)** ***(subjects, university or school, year)***

- 2015: PhD (research degree) with the London School of Hygiene and Tropical Medicines
- 2007: Research Ethics fellowship with Fogarty African Bioethics Training Programme attainable at John Hopkins University
- 1996-1997: Master in Policy Studies with Fort Hare University
- 1989-1993: Bachelor of Arts degree with the University of Zambia

5. **Posts held** ***(type of post, Institution/Faculty/department, date for the Last 10 years)***

- 200-2004: Field Operations Manager and the Microcredit and Income Generation Manager for the Microprojects Unit (MPU) which was the largest EU funded project in the country
- May-2004 November 2004 : Monitoring and Evaluation office/ Social scientist for the Microbicide Development Programme (MDP) Zambia

- December 2004 – April 2005: Monitoring and Evaluation Manager and Acting Programme Manager for the Reaching HIV/AIDS Affected People with Integrated Development and Support (RAPIDS) programme funded through PEPFAR
- May 2005 to 2011: Study Manager for the Zambia and South Africa TB and AIDS Reduction (ZAMSTAR) in Zambia. ZAMSTAR was a large multi-country randomized trial of 2 innovative interventions to reduce the burden of TB and HIV at community level. The study covered a population of approximately 1.2million people in Zambia and South Africa in 24 communities (16 ZA, 8 SA).
- December 2011 to date: Community Engagement Manager

4. Publications

1. **Simwinga, M.** and C. Kabero, *Community Engagement* in *Research Ethics in Africa: A Resource for Research Ethics Committees*, M. Krugger, P. Ndebele, and L. Horn, Editors. 2014, Sun Press: South Africa.
2. Nancy E. Kass, Andrea N. DeLuca, Leonie Coetzee, **Musonda Simwinga**, et al., *Applying Ethical Principles to International Community-Based Research: A Case Study from the Consortium to Respond Effectively to the AIDS-TB Epidemic (CREATE).* IRB: Ethics & Human Research, 2014. **36**(3)
3. Ayles H, Muyoyeta M, Du Toit E, Schaap A, Floyd S, **Simwinga M**, Shanaube K, Chishinga N, Bond V, Dunbar R, De Haas P, James A, Gey van Pittius NC, Claassens M, Fielding K, Fenty J, Sismanidis C, Hayes RJ, Beyers N, Godfrey-Faussett P; ZAMSTAR team, *Effect of household and community interventions on the burden of tuberculosis in southern Africa: the ZAMSTAR community-randomised trial.* Lancet. 2013 Oct 5;382(9899):1183-94. doi: 10.1016/S0140-6736(13)61131-9. Epub 2013 Aug 1
4. Bond V, Chilikwela L, **Simwinga M**, et al., *Children's role in enhanced case finding in Zambia.* Int J Tuberc Lung Dis 2010. **Oct: 14**(10): p. 1280-7.
5. Boccia D, Hargreaves J, **Simwinga M**, et al., Tuberculosis infection in Zambia: the association with relative wealth. Am J Trop Med Hyg., 2009. **Jun; 80**(6): p. 1004-11.

L A W R E N C E M W E N G E

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PROFILE: HEALTH ECONOMIST

I'm an enthusiastic, adaptive and fast-learning economist with an acute interest and experience in health economics and health systems research. My major areas of interest are health care financing, economic evaluation and health policy analysis.

Specialties: Economic analysis, cost tracking, Policy analysis, project management, and econometrics and modelling, Project Appraisal, health systems research and health care evaluation.

PROFESSIONAL EXPERIENCE

Zambia AIDS Related TB (ZAMBART) Project, Zambia, 2006-present, Health Economist

Main Roles:

- Lead Health Economist; Managing and coordinating all health economics projects, 2014-present.
- Principle investigator on Economic Evaluation of the Better Health Outcomes through Mentoring and Assessment (BHOMA) interventions, Zambia, 2010-2014.
- Assistant Programme manager; Community TB case finding Programme, 2009-2011.
- Co-Principle investigator on Economic Evaluation of the Zambia South Africa TB and AIDS Reduction (ZAMSTAR) community randomized Trial, Zambia and South Africa, 2006-2010.
- Co-Principle investigator on Economic Evaluation of TB diagnostics; solid and liquid TB culture, Zambia, 2006-2007.

Consultancy Work

- **Institution of Medical Research and Training (IMReT);** Zambia, 2013-present, Health Economics Consultant (Co-principal Investigator).

- **London School of Hygiene & Tropical Medicine (LSHTM);** Health Economics Consultant on economic evaluation of eye health services in Zambia, 2011.
- **AIDS Alliance;** Health Economics Consultant on cost analysis of Home-based care services in Zambia, 2008.

EDUCATION

2012 **MSc in Public Health**, London School of Hygiene and Tropical Medicine; London, UK. **Thesis title:** The Cost of Eye Care Treatment from the Societal Perspective in Zambia.

2006 **BSc in Agricultural Economics**, University of Zambia; Lusaka, Zambia.

1997 **School Certificate ('O' level)**, Mungwi Technical Secondary School; Mungwi, Zambia.

SKILLS TRAINING WORKSHOPS

2012: **Evaluating the costs of public health interventions**: A short-course in applied economic evaluation organised by Boston University and University of Zambia; Lusaka, Zambia.

2011: **Health Care Evaluation**, London School of Hygiene & Tropical Medicine; London, UK.

2009: **Economic Evaluation of health care,** London School of Hygiene & Tropical Medicine; London, UK.

AWARDS

2009 Commonwealth scholarship for distance learning studies to pursue a Master's of Science (MSc) course in Public Health with London School of Hygiene and Tropical Medicine, London, UK.

1999 Best Student award, Community Health workers Training organized by Ministry of Health & JICA at Chawama clinic; Lusaka, Zambia.

1995 Best Student award in Mathematics Olympiads organized by JICA at Mungwi Technical Secondary School; Mungwi District, Zambia.

RESEARCH EXPERIENCE

1. Investigator; *HPTN 071 Population Effects of Antiretroviral Therapy to Reduce HIV Transmission (HPTN 071-PopART): A Cluster-Randomized Trial of the Impact of a Combination Prevention Package on Population-Level HIV Incidence in Zambia and South Africa*, Zambart, 2013-2017.
2. Consulting Economist; *Economic Evaluation of Cryptococcus Meningitis at UTH, Lusaka Zambia*, IMReT, 2012-2014.

3. Principle Investigator; *Cost analysis of better health outcomes through mentoring and assessment (BHOMA) interventions*, CIDRZ and Zambart, 2011-2014.

4. Consulting Economist; Cost-effectiveness analysis of eye services in Zambia, LSHTM, 2011

5. Co-Principle Investigator; *A comparative economic evaluation of TB/HIV community randomized interventions in Zambia and South Africa*, Zambart 2008 to 2009.

6. Consulting Economist; *Cost analysis of home-base care programmes in the era of antiretroviral therapy (HIV): assessing the cost of providing home-based care services in Zambia from provider's perspective*, AIDS Alliance, 2009.

7. Health Economics Research Assistant; *A comparative economic evaluation of MGIT and LJ TB culture techniques in Zambia. Lusaka, Zambia (published)*; Zambart 2007.

8. Health Economics Research Assistant; *assessing costs of tuberculosis (TB) diagnosis and treatment from the patient's PERSPECTIVE in Zambia. Lusaka, Zambia (published)*, Zambart, 2007.

9. Student; *Assessing the relationship between Migration and rural Agriculture in Mungwi district*, UNZA, 2005 (BSc. Thesis).

CONFERENCE PRESENTATIONS

1. Poster: *Cost analysis of TB/HIV reduction models; Enhance Case Finding and Household interventions.* 41st World Conference on Lung health of the International Union Against Tuberculosis and Lung Disease, Cape Town, South Africa, November 2010.

2. Paper: *Cost Analysis of ZAMSTAR TB/HIV Reduction Models*. CREATE Meeting; Cape Town; 2009.

3. Poster: *cost-effectiveness analysis of TB culturing using solid media versus liquid media to diagnose TB in Zambia*. 38th World Conference on Lung health of the International Union Against Tuberculosis and Lung Disease, Cape Town, South Africa, November 2007.

4. Paper: *why Satanism is linked to HIV testing and HIV prevention activities in Zambia (co-presenter)*, Lusaka, Zambia, 2005.Paper: *HIV-related Stigma (Literature review)*. 1st International Conference on HIV/AIDS conference, Dar e salaam, Tanzania, 2004.

6. Poster: *Community Awareness Campaign and the Misconceptions surrounding HIV/TB*. 13th International Conference on AIDS and STIs in Africa, Nairobi, Kenya, 2003.

SELECTED PUBLICATIONS

1. Ulla K Griffiths, Fiammetta M Bozzani, Adrian Gheorghe, **Lawrence Mwenge**, Clare Gilbert. Cost-effectiveness of Eye Care Services in Zambia. Cost Effectiveness and Resource Allocation 2014.

2. **D. Zachary, L. Mwenge, M. Muyoyeta, K. Shanaube, A. Schaap, V. Bond, B. Kosloff, P. de Haas, H. Ayles.** *Field comparison of OraQuick® ADVANCE Rapid HIV-1/2 antibody test and two blood-based rapid HIV antibody tests in Zambia. BMC Infectious Diseases* 2012.

3. M. Muyoyeta, P. E. W. de Haas, D.H. Mueller, P. D. van Helden, **L. Mwenge**, A. Schaap, C. Kruger, N. C. Gey van Pittius, K. Lawrence, N. Beyers, P. Godfrey-Faussett, and H. Ayles. *Evaluation of the Capilia TB assay for culture confirmation of Mycobacterium tuberculosis in Zambia and South Africa.* J Clin Microbiol. 2010 Aug 4.

4. A. Aspler, D. Menzie, O. Oxlade, J. Banda, **L. Mwenge**, P. Godfrey-Faussett, H. Ayles. *Costs of tuberculosis diagnosis and treatment from the patient perspective in Lusaka, Zambia.* Int J Tuberc Lung Dis 2008.

5. D.H. Mueller, **L. Mwenge**, M. Muyoyeta, M.W. Muvwimi, R. Tembwe, R. McNerney, P. Godfrey-Faussett, H. Ayles. *Costs and cost-effectiveness of tuberculosis cultures using solid media in a developing country.* Int J Tuberc Lung Dis 2008.

CURRICULUM VITAE

PERSONAL DETAILS

- Name: James Mwanza
- Sex: Male
- Age: 38years
- Tribe: Ngoni
- Nationality: Zambian
- Marital status: Married
- Religion: Christian

CONTACTS

- Cell:+ 260 968 335460
- Email : jamesmwanza@gmail.com
  : james@zambart.org.zm.
- Postal add: C/O Zambart Project. P.O. Box 50697 Lusaka-Zambia

PERSONAL ATTIBUTES

- Highly motivated individual.
- Requires minimum supervision.
- Ability to meet deadlines.
- Able to work under extreme pressure.
- Result oriented.

SKILLS

- Good communication skills; written, verbal and listening skills
- Well-developed interpersonal skills and ability to interact with other staff
- Good computer skills, especially Ms Excel, Ms PowerPoint and some Data Base knowledge

ACADEMIC QUALIFICATIONS

- **2015**- Masters of clinical Pharmacy Degree (McPharm clin).university of Zambia.
- **2005**- Bachelors of Pharmacy Degree (B. Pharm) University of Zambia
- **2005**- Certificate in pharmaceutical care, communication, counseling skills and health promotions. Robert Gordon University.

PROFESSIONAL QUALIFICATIONS

- **2011-2013**-Various trainings in logistics management/supply chain for pharmaceuticals and laboratory commodities. MOH/JSI Inc.
- **June 2013**-Training in basic financial management for public funds. ZSSIP
- **January, 2008**- Certificate in Logistics for Health Commodities, Global Health e Leaning Centre, USAID

- **1996** – Grade 12 General Certificate of Education, Exams Council of Zambia
- **1992** – Grade 9 Junior Secondary School Leaving Exams. Examinations Council Of Zambia
- **1990**-Grade 7 School Certificate Examinations Council of Zambia.

- **February, 2008** – Certificate In Monitoring and Evaluation, Global e Leaning centre, USAID
- **February, 2007**-Good Clinical Practice. (G.C.P)- Certificate in Human Subject Protection, Supported by DAIDS, USA.
- **June, 2005** – Certificate in Antiretroviral Therapy And Opportunistic Infections and Neoplasm Management, MOH / ZPCT
- **August 2005**- Certificate in Tuberculosis Management, Drug use and Reporting. WHO/Ministry of Health

WORK EXPERIENCE AND RESPONSIBILITIES

1. **Zambart Project.**
   Currently working as PHARMACIST OF RECORDS at Zambart Headquarters.
2. **Ministry Of Health- Pharmacist Logistics.**

➢ **Responsibilities**

- Monitoring all the Logistics Management systems/supply chain avenues.
- Analyzing supply chain constraints and possibly coming up with long lasting solution for the continuous supply of commodities to the community
- Trainer of trainers in supply chain for EMLIP, ARV's, TB, Essential medicines and vaccines to facility in-charges and dispensers
- Validation of Fridges for cold chain storage
- Ensuring that Bulk storage facilities and product handling procedures comply with Good Ware Housing Practicing.
- Procurement Planning for Medical and surgical supplies
- Storage Control Procedure Management
- Training Pharmacy In charges in DILSAT.
- Liaisons officer between Ministry of Health and Zambia Revenue Authority-Nakonde Boarder.
- Monitoring of distribution Patterns of all supplies to various Health Centres
- Preparing orders for ARV,PMTCT and HIV test kits
- Vaccine management for Child immunization.

3. **Zambia Emory-HIV Research Project (ZEHRP) Ndola, (2007-2009)**

   A USAID/ IAVI Funded Organization

   Position: Project Pharmacist (Pharmacist of Record) /Archivist.

   Responsibilities:

   1. Managing available resources in conformity with standards of good pharmacy practice and planning for expansion of pharmaceutical services.
   2. Management of study drug in the P.I.P study (Partners In Prevention) A phase II double blind study. Suppression of H.S.V type II using Acyclovir tablets to reduce HIV transmission.
   3. Management of study Vaccine/Placebo in the PAVE 100 vaccine trial.
   4. Management of storage conditions for study drugs, vaccines/placebos for various clinical trials.
   5. Inventory control for all clinical trial drugs, medicines, surgical supplies and contraceptives
   6. Implementation of drug/vaccine related study protocols.
   7. Meeting pharmaceutical needs and requirements of I.A.V.I – sponsored clinical trials
   8. Establishing policies and procedures to ensure safe use of study products
   9. Liason officer between Pharmaceutical Regulatory Authority (PRA) of Zambia and the Project (Pharmacist of Records)
   10. Prudent management finances and asserts of the organizations
   11. Monitoring and evaluating the procurement and utilization systems and procedures for their effectiveness.

4. **Kasama General Hospital (2005-2007)**

   Position: Pharmacy Manager

   Responsibilities:

   1. Dispensing of anti-retroviral drugs to patients

2. Forecasting health commodity requirement (essential drugs) for the hospital
3. Procurement planning and pipeline monitoring and support for all essential drug security programs
4. Participating in performance audits both at hospital and provincial level.
5. Trainer of trainers in adherence counseling to ARV medication
6. Monthly ordering of ARV's for the ministry of health and submitting monthly consumption reports.
7. Using robust logistics management information systems (LMIS) to fuel activities that support essential drug security by focusing on, the four pillars of logistic management which are **Forecast, Finance, Procurement and Delivery.**
8. Constant monitoring of inventories, usage rates of essential drugs at hospital, clinic and district levels of care.
9. Ordering of essential drugs from the medical stores and submission of monthly consumption report
10. Supervising the procurement of surplus medicines by hospital tender committees.
11. Participating in Quantification Exercise at District/Hospital/ Provincial and National level for the planning of acquisition of essential drugs in the Ministry of Health
12. Training other health staff on district integrated logistical self-assessment tools (DILSAT) to promote commodity security.

PROFESSIONAL MEMBERSHIP

1. Health Professions Council of Zambia.
2. Pharmaceutical Society of Zambia,
3. Hospital Pharmacists Association of Zambia.

REFEREES

- Dr Chiluba Mwila, PhD.
  Lecturer department of Pharmacy
  Email:mwilachiluba@gmail.com
  Cell: +260 969 314492.

- Dr Ravi Paul.MD PhD.
  Consultant Psychiatrist University Teaching Hospital.
  Email:ravipaul35@gmail.com.
  Cell: +260 976 744654.

- Prof. Pierre Yassa.MD.
  Lecturer of Dermatology.
  School of medicine, University of Zambia.
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