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Re-engagement at Discharge 2:
Improving post-hospital outcomes for adults with HIV in Zambia (ReCharge 2)

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1. Protocol Synopsis

Full Title	Re-engagement at Discharge 2: Improving post-hospital outcomes for adults with HIV in Zambia (ReCharge 2)
Clinical Trial Phase	N/A
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Sample Size	N = 100
Study Population	Eligible patients living with HIV hospitalized at University Teaching Hospital or Levy Mwanawasa Hospital, Lusaka, Zambia
Accrual Period	1/1/2023-6/1/2024
Study Design	Single Arm Pre/Post Pilot Study
Study Duration	2 years
Study Agent/ Intervention Description	Community health worker (CHW) follow-up after discharge from hospital
Primary Objective	1. To assess the feasibility and acceptability of CHW follow-up following hospitalization
Secondary Objectives	1. To estimate the potential impact of the pilot program on the proportion who are alive and virally suppressed at 6 months post-discharge 2. To understand implementation factors related to pilot program
Exploratory Objectives	1. To investigate barriers and facilitators to ART adherence for PLHIV following hospitalization 2. To investigate barriers and facilitators to community-based support for PLHIV following hospitalization
Primary Endpoints	1. The proportion of discharged patients who are successfully visited after discharge. 2. The proportion of discharge follow-up visits by a CHW that are comprehensive 3. The proportion of initial post-discharge visits to the ART clinic that are attended by the participant's CHW supporter.
Secondary Endpoints	1. HIV viral load at 6 months post-discharge. 2. Mortality within 6 months of discharge. 3. Retention in HIV care after discharge defined by no gap of >28 days off ART from discharge date to 6 months post-discharge date. 4. ART clinic visit within 1 month of discharge 5. Transition back to ART care at original (pre-admission) clinic

2. Background Information and Scientific Rationale

2.1 Background Information

Hospitalization presents a potential opportunity to alter the long-term outcomes of persons living with HIV (PLHIV) in sub-Saharan Africa (SSA).[1] HIV-related hospital admissions remain common despite mature antiretroviral therapy (ART) programs,[2] and while inpatient mortality rates are 10-30%, an additional 20-40% die within 1 year of discharge.[3,4] Most hospitalized PLHIV are ART-experienced and had history of poor retention in care and viral suppression.[3,5,6] For example, at a central hospital in Zambia, ~90% of hospitalized PLHIV had prior/current ART use (median of 30 months) and 50% of ART-experienced individuals were not virally suppressed, many of whom had disengaged from care. Current inpatient care focuses on stabilization and neglects to understand and intervene on the underlying reasons for suboptimal care engagement that contributed to the hospitalization. Discharge transition of care models for hospitalized PLHIV are virtually non-existent.[7]

2.2 Rationale

Many PLHIV have poor outcomes following hospitalization, including high mortality, readmission, and gaps in HIV care engagement. This is likely multi-factorial and not all etiologies may be modifiable. While high mortality may be due to incurable cancer, the majority of deaths in PLHIV are thought to be caused by infectious diseases for which treatments exist. However, succumbing to these life-threatening infections after discharge may be due to poor understanding of discharge instructions, lack of post hospital care, and poor understanding of required follow up. Psychosocial support also plays a role in the mental and physical health of these sick patients.

In ReCharge 1, we gathered formative data and identified at least three major factors that undermine HIV clinical outcomes after hospital discharge. First, there are gaps in continuity of care between the discharging facility and outpatient. Second, support from family is often suboptimal due to lack of understanding on the cause of illness, lack of HIV status disclosure, and the cost of care. Third, HIV comorbidities may underpin or complicate the immediate reason for discharge or the post-discharge engagement in care. These data were disseminated to local experts in Zambia including from the Ministry of Health and used to create a new care model for post-discharge HIV care. The care model draws from other successful programs in Zambia. In ReCharge 2 we now propose to pilot the program and assess feasibility, acceptability, and potential for clinical impact.

3. Literature Review

It is estimated that 1.2 million people are currently living with HIV in Zambia, representing between 11-12% of the adult population.[8,9] Urban areas have had a consistently higher percentage of infected people than in rural areas. HIV infection is also higher among females than among males. Of the 1.2 million adults living with HIV, 700,000 (58.3%) were women.[8] The number of AIDS-related deaths since 2010 has reduced by 37%, from 26,000 deaths to 17,000 deaths in 2018,[8] a reduction due to the concerted efforts of the Zambian Government and its global partners in improving access to antiretroviral therapy. Over the past decade, there has been a rapid scale-up of antiretroviral therapy (ART) in Zambia as in other high HIV prevalence settings in Africa.[8,10] As scale-up programs continue, accessibility to ART has increased tremendously.

Despite the improved access, the number of patients failing therapy with increasing duration of exposure to ART remains high. Factors leading to treatment failure include poor adherence to treatment, prior exposure to antiretroviral treatment with the development of resistance from single dose nevirapine, primary viral resistance, inadequate drug absorption, suboptimal dosing, the complexity of the regimen, inadequate or inconsistent drug supply to mention but a few ; the mortality in such patients failing therapy is usually high.[11-13] Inpatient settings in Zambia continue to have a high burden of HIV, with prevalence of >50% among admitted people.

Hospitalization presents a potential opportunity to alter the long-term outcomes of persons living with HIV (PLHIV) in sub-Saharan Africa (SSA).[1] HIV-related hospital admissions remain common despite mature antiretroviral therapy (ART) programs,[2] and while inpatient mortality rates are 10-30%, most survive to be discharged home. Unfortunately, our team and others in East and Southern Africa have documented that an additional 20-40% of hospitalized people with HIV die within 1 year of discharge.[3,4] Most hospitalized PLHIV are ART-experienced and had history of poor retention in care and viral suppression.[3,5,6] For example, at University Teaching Hospital in Zambia, ~90% of hospitalized PLHIV had prior/current ART use (median of 30 months) and 50% of ART-experienced individuals were not virally suppressed, many of whom had disengaged from care. Current inpatient care focuses on stabilization and neglects to understand and intervene on the underlying reasons for suboptimal care engagement that contributed to the hospitalization. Discharge transition of care models for hospitalized PLHIV are virtually non-existent.[7] Causes of death both during and after hospitalization are not well-understood because of the rarity of post-mortem examinations (especially in out of hospital death); however, most deaths are likely due to common HIV-related opportunistic infections.

Re-engaging patients in HIV care and ART after a period of suboptimal retention has been termed 'using the side door'.[14,15] 'Side door' patients are underrepresented in HIV program evaluations as their data are censored at initial disengagement. These patients represent a unique population with distinct barriers to reconnect and to re-initiate on treatment,[16,17] as compared to those using the 'front door' (i.e., proceeding with optimal retention from testing to ART initiation to long-term viral suppression). After hospitalization, long-standing barriers to ART may be exacerbated and new challenges (such as reduced functional status) may arise.[18-20] These patients need differentiated care models to intensify and optimize their treatment.

4. Study objectives

4.1 Primary objective

1. To assess feasibility and acceptability of a post-discharge CHW follow-up program for adults with HIV

4.2 Secondary objectives

1. To estimate the potential impact of the pilot program on the proportion who are alive and virally suppressed at 6 months post-discharge
2. To understand implementation factors related to pilot program

4.3 Exploratory objectives

1. To explore barriers and facilitators to the HIV care cascade for PLHIV following hospitalization
2. Describe the prevalence of behavioral health comorbidities after hospital discharge among people with HIV
3. To investigate the impact of HIV-associated coinfections and comorbidities on post-hospital outcomes.
4. To explore experiences of community health workers with the delivery of a post-discharge community based CHW follow-up model for adults with HIV
5. To characterize the prevalence of mental health co-morbidities such as depression among PLHIV during and following hospitalization

4.4 Primary Endpoints – Program Feasibility

1. The proportion of discharged patients whose discharge summary is completed
2. The proportion of discharged patients who undergo a home/community visit from a CHW within 1 week of discharge
3. The proportion of discharged patients that attend their recommended hospital follow-up appointment
4. The proportion of discharged patients that carry their discharge summary to their recommended hospital follow-up appointment
5. The proportion of discharged patients who have disclosed their HIV status at least one treatment supporter
6. The proportion of discharged patients who are currently taking the recommended medications for HIV, coinfections, and comorbidities at 1-month post-discharge
7. The proportion of discharged patients who seek relevant services (behavioral health, mental health) following screening and referral

4.5 Secondary Endpoints – HIV cascade and clinical outcomes

1. HIV viral load at 6 months post-discharge.
2. Readmission to hospital within 6 months of discharge
3. Mortality within 6 months of discharge.
4. Retention in HIV care after discharge defined by no gap of >28 days off ART from discharge date to 6 months post-discharge date.
5. Engaged in ART care at a community (non-referral site) clinic at 6 months post-discharge
6. Mental health outcomes (i.e. depression level) post intervention

5. Study design

This is a pilot implementation study with a mixed methods evaluation. The primary outcomes are feasibility and acceptability, which will be assessed among participants, CHWs, and other health workers involved in the pilot. Surveys and in-depth interviews (IDIs) will be used as means of collecting data. Secondary HIV care cascade and clinical outcomes, such as mortality, readmission, HIV VL, retention, etc. will also be assessed. Secondary outcomes will be compared, via a single-arm pre/post pilot study, with a comparator group recruited in the recent past (pre-intervention).

5.1 ReCharge CHW intervention description

The ReCharge intervention is package of services designed to address major barriers to post discharge engagement identified through the ReCharge 1 formative research and based on reflective discussion and engagement with local expertise.

The package will be overseen by a physician working at the discharging hospital and will be supported and managed by a Community Liaison Officer. This package will consist of enhanced discharge planning, made possibly by a discharge card that physicians will complete. The card will capture a summary of the discharge plan and follow-up appointment schedule for the discharged patient. At the time of discharge, the CLO get will get involved to inform the patient about the program and if willing to be enrolled, the patient will be recruited into the programme.

After discharge, the package for the enrolled patients will include home delivery of HIV support services to be provided a by community health worker (CHW) with support and coordination provided by the CLO based at the hospital. Additional technical support will also be provided physician based at the hospital. Once the patient has been recruited into the programme, the CHW will provide the first home visit within 7 days of hospital discharge. Several additional homes visits together with phone-based support will occur thereafter. The CHW visits will consist of the following elements:

- ***Vital signs assessment****:* As is currently standard with UMB CHW home visits, the CHW measures the pulse and blood pressure using an electronic cuff and enters these into their tablet. If outside of safe ranges (per WHO ranges), the table prompts immediate escort to nearest health facility
- ***Symptom screen***: in addition to standard warning signs (such as the four TB screening questions), screening questions could be tailored based on discharge information (i.e. confusion following admission for crypto)
- ***Medication check***: The CHW will verify (visually) that patient has filled all medications, both ART, and non-ART (for ATT, hypertension, etc.) prescribed as per the discharge summary, and perform pill counts to verify proper adherence. Patient and caregivers will be counseling on why each medication was prescribed and what are expected side effects. If prescriptions have not been filled, then CHW can assist in facilitating medication dispensation from their outpatient clinic.
- ***Outpatient follow-up verification****:* At the first visit (within one week), the CHW will discuss with patient and care giver the timing and location of follow-up. They will remind the client by phone 1 day before and if the patient misses that visit, the CHW will arrange to

accompany the patient to the clinic at the soonest possible time. In Zambia, the standard post-hospital follow-up at outpatient occurs at 2 weeks.

- ***Identify knowledge gaps among patient and family related to the reason for illness****:* The CHW will document the reason for illness and the family's and patient's understanding of the illness and list any questions they have.
- ***Screening for behavioral health comorbidities****:* The CHW will screen for symptoms of depression and unhealthy alcohol use at ~1 month after discharge and make referrals as feasible.
- Conduct a quick home observation to document the patient home environment to assess barriers existing as well as facilitators to engagement.

To ensure that CHWs are fully supported, they will meet with CLO once per week to discuss their clients. CLOs reinforce adherence to the model. The CHW will also call their CLO supervisor urgently from the client household if certain parameters are outside of range, such as elevated pulse. The CLO can then engage the physician as needed.

The ReCharge CHW intervention holds promise. First, it was designed based on a rigorous local formative project (ReCharge 1) and with inputs from clinical, community, and program experts and MOH. Also, CHW support is both highly feasible and acceptable, but can reduce death in PLWH. In the REMSTART trial, weekly home visits plus testing and treatment of cryptococcal disease among people with low CD4 reduced mortality significantly. Many of our clients will have CD4 >200; however, given their recent hospitalization, they are at high risk of mortality.

5.2 Intervention evaluation: pre/post implementation trial

5.2.1 Study Design

We plan to conduct a prospective pilot study among 100 PLHIV at study sites who will receive the ReCharge CHW intervention model. Although a range of outcomes will be assessed, and comparisons will be made to a historical control group, the main goal is to demonstrate feasibility and acceptability. If these are demonstrated, we will seek approval and resources for a fully-powered evaluation of the program.

5.2.2 Historical control data:

To make inferences around possible impact, which will inform the sample size of a fully-powered future trial, before implementation of the intervention, we will collect historical control data on the outcomes of interest. We acknowledge that our comparison of trial outcomes to those from historical controls will be prone to time trends in patient outcomes and in clinical practices, which could make the intervention appear to have spurious effects. To minimize this bias, we will collect historical control data on discharged patients just prior to implementing the intervention. These will be participants with the same inclusion/exclusion criteria as intervention patients and recruited in the same way.

5.2.3 HIV clinical care:

Participants will receive routine HIV clinical care per national guidelines. For example, participants with high VLs at enrollment or at 6 months will be assumed to have poor

retention/adherence and will be referred for a period of enhanced adherence counseling. If adherence improves but VL remains high, clinicians are recommended to switch the regimen. We expect our participants will be physically ill; therefore, they will likely be referred for a post-discharge appointment within 1-2 weeks of discharge and may have frequent appointments in the post-discharge period. ART dispensations will be per clinician recommendations.

5.2.4 Quantitative outcomes:

Our primary effectiveness outcome will be alive and virally suppressed at 6 months after hospital discharge. Patients who either pass away or have a viral load >60 copies/ml will be considered failures. Patients who are alive but have unknown VL will also be considered failures. Those who transfer care outside of Lusaka District (we expect this to be 2-3%, based on a prior study) will be censored. We will also evaluate numerous secondary outcomes, including retention on ART, defined as possession of ARVs within 30 days of the 6-month post-discharge time point, consistent with PEPFAR TX_CURR definition.[21] We will also assess ARV adherence (based on medication possession ratio), number of visits attended, and the rate of hospital re-admission.

To ascertain these outcomes, our research assistant will contact the client each month post-discharge to check vital status (alive versus dead) and whereabouts. At 6 months after discharge, we will confirm the location of last HIV care and arrange for patient to have HIV VL, either back at the hospital or at their local clinic. The team will extract electronic medical records from the clinic including visit, pharmacy, and laboratory data, including HIV viral load results. Transfers within Lusaka (where there are 30+ ART clinics) are common and this approach will allow us to have complete end-line data for most clients, including historical controls and pilot participants.

We will also collect implementation outcome data during the trial, such as proportion of trial participants who do not receive any CHW services, the number and type (phone calls, home visits, meetings at the facility) of interactions between participants and CHWs. Semi-structured interviews with a subset of patients will be done to check acceptability of the intervention.

To begin to understand and anticipate meaningful patterns in our pilot data, we will also collect socio-demographics and socio-economic data on patients and their households, as well as capturing extent and severity of co-morbidities. We will include the following measures, captured at the following time points:

At enrollment/in hospital:

- Education (highest completed grade attained) for patient and primary caregiver
- Age, marital status, number of children
- Relationship to household head
- Religion and religiosity (affiliation, frequency of church attendance (weekly)
- Distance to referral health clinic and to referring hospital (time takes to get to clinic / mode of transit)

At one month:

- Mental health screening (PHQ)
- Alcohol screening (AUDIT)
- Household food insecurity (HFIES scale)
- Household asset-based wealth index (DHS module)

5.3 Qualitative study: feasibility, acceptability, and implementation factors

5.3.1 Study Design

To characterize feasibility and acceptability, we prospectively enroll up to 100 hospitalized adults with HIV and provide them with the ReCharge CHW intervention. We will measure various indicators of feasibility. We will recruit and follow up longitudinally a cohort of participants (n=24) prospectively through the intervention, interviewing them at the start one or two weeks after being enrolled into the project and after the end of the intervention to understand the determinants of feasibility and acceptability. We will also include participants' primary caregivers in interviews after towards the end of the intervention (n=20). Acceptability and feasibility will also be assessed through IDIs with the CLOs (n=2-4) and CHWs (n=4-8) involved in the pilot implementation as well as up to 6 other healthcare workers that will be based at the hospital and community clinic.

The patient sub-sample will be followed longitudinally using a qualitative study variation of responsive and adaptive design approaches[22] (see Table 2). IDIs will be conducted and transcribed by trained research assistants.

IDIs are best suited to capturing individual experience and perceptions,[23] our main objective with these study populations. The sample size for each study population category anticipates what is required to reach saturation on key themes, but may be supplemented if necessary, particularly likely for patients and caretakers. Data collection tools will be informed by Andersen's Behavioral Model of Health Services Use[24] which emphasizes the multi-level influences on health seeking behavior and related outcomes including enabling resources (e.g. family support, transportation), predisposing characteristics (e.g., self-stigma, knowledge), as well as broader healthcare system and external environmental influences.

Table 2: Sample & methods: qualitative study of CHW pilot

	Enrollment	**1-3 months**	**Endline**	**Total**
Patients IDIs	24		20-24	16*
Caregiver IDIs			12 to 16	16-20
CLOs/CHWs IDIs		6	6	6
Hospital/ Facility- HCWs			6-10 IDIs	6-10
**Reflects total number of patients followed longitudinally*				

5.3.2 Qualitative participants criteria and recruitment

Patients and caregivers: We will begin with an oversample of 24 patients (every 3rd enrollee will be selected, adjusted to ensure a sex-stratified sample) to capture a total of 16 patients and their caregivers, stratified by retention in care, by endline (8 with high retention, 8 with low retention). IDIs at enrollment will establish a relationship, gather key insights toward understanding what led to the patient's hospitalization, gather expectations of post-discharge health, care, and anticipated barriers and enablers to retention in HIV care. As we identified in the formative phase of this work, many of the challenges patients face after discharge stem from concerns that resulted in their hospitalization (e.g., internalized stigma, concerns with disclosure and acceptance of their status, co-morbidities that require complex management in the context of limited household resources). The CHWs assigned to the patient will introduce the patient to a member of the qualitative research team either during hospitalization, or at the first home visit. The participant will then decide if they would be willing to talk with the interviewer either while being admitted or 1 week after discharge, If the patient is too sick or feels more comfortable to be interviewed after discharge, these interviews will take place within a week following the first CHW home-based visit at a time and place convenient for the discharged patient.

At the six-month follow-up, we will re-interview up to 16 of these 24 for a second IDI reflecting on patient experience and capturing their perceptions of whether and how CHW follow-up addressed barriers or enhanced enablers to care to assess feasibility and acceptability. We will work with CLOs, CHWs, and clinic-level data to stratify the endline sample by patient outcome (retained versus not retained), and purposively select patients within strata to capture a range of demographic and facility-level characteristics. The same interviewer who interviewed the patient at time 1 will return to complete the interview at time 2. Again these interviews would take place at a time and place convenient for the patient. The interviewer will then ask the patient for permission to invite their primary caregiver to be interviewed as well. If the patient and the caregiver consent, then the interviewer will also interview the care giver. Caregiver IDIs will address the experience of caring for the discharged patient throughout the intervention and their perceptions of CHW follow-up. When non-retained participant deaths are ascertained, we will try to perform an IDI with the caregiver (after reasonable time elapses for mourning) to understand the barriers to care, co-morbidities and other mortality causes (we estimate up to 4 such cases based on COLAH); we may therefore have more caregiver than patient endline interviews.

In addition to the longitudinal sub-sample of 16 patients stratified by re-engagement in care outcomes; we will also purposively sample up to 8 patients (for a total of up to 24 endline interviews) who showed signs of mental illness or behavioral health concerns (i.e., scored above ≥10 points on the PHQ-9 screening tool for depression and related concerns; or scored above ≥3 on the AUDIT-C), and were referred by the team for mental health services. We will interview these patients to understand experiences of patients with mental health related challenges such as depression and alcohol abuse, and to assess how the referral process and related services were received by such patients. These interviews will be essential toward preparing for future work with patients experiencing similar challenges.

CHWs: We will conduct two repeat IDIs with 2-4 CLOs and 4-8 CHWs (midline and endline), to understand their experience with program delivery both during and at the end of the intervention. The IDIs will focus on individual experiences with specific patients (positive and negative) and can be used to triangulate patient perceptions and programmatic challenges.

Facility-based HCWs: To understand coordination and care continuity from hospital discharge, to community, to an outpatient facility, we will conduct IDIs with 6 HCWs (2 hospital based, 4 clinic based) on their experience with CHWs and discharged patients. These will include inpatient staff, where we will address perceived advantages and disadvantages of CHW follow-up for quality of inpatient and outpatient care following discharge.

6. Study population

6.1 Description of the study site

This study will be conducted at tertiary care hospitals in Lusaka. Lusaka has a high prevalence (~18%) of HIV infection among adults.[9] Lusaka has 36 primary public-sector health centers (25 of which are currently supported by CIRKUITS), six Level 1, and two Level 3 Hospitals, one of which is UTH. UTH outpatient departments, because of their unique capacities in Zambia, provide care for people from all provinces. However, >85% of admitted patients are from Lusaka.

The UTH Department of Medicine is the largest of departments, with 280 inpatient beds and 10,000-12,000 admissions per year (20-30 per day), 50-70% of whom are HIV-positive. Within DOM, a robust counselor-led (lay health worker) opt-out HIV rapid testing program is in place.[25,26] This program reaches >90% of new admissions; the remaining 5-10% are not tested due to severity of illness. The median length of hospital stay is ~7 days. Patients stay in one of four open wards, each with 60-80 beds, and one clinician team (consisting of a Consultant, one senior, and 3-4 junior house officers) is in charge of each ward. Laboratory tests are provided by the UTH central laboratory.

Levy Mwanwasa University Teaching Hospital (LMUTH) was recently upgraded to a level 3 facility, overseen by Lusaka Provincial Health Department. Within just several years its ART department has grown >1,000 patients. The inpatient Department of Medicine includes >100 beds and 40-60% are with HIV. Inpatient and discharge procedures are very similar to UTH and the LMUTH laboratory offers similar testing capacity.

6.2 Description of the study population

This study will be conducted among all adult patients living with HIV who are admitted to 'E Block' medical wards at the University Teaching Hospital and Internal Medicine wards at LMUTH in Lusaka, Zambia between 1 January 2023 and 1 June 2024.

6.3 Participant inclusion and exclusion criteria

- Hospitalized patients living with HIV soon to be discharged (n=100)
    - Inclusion criteria: (i) age 18+ years, (ii) HIV-positive, (iii) hospitalized for at least 1 night at study site, (iv) clinically stable and expected to be discharged according to their clinician, and (v) objective evidence of suboptimal HIV outcome, defined as HIV VL above the lower limit of the assay or CD4 count <=200.
    - Exclusion criteria: (i) unable to provide informed consent, (ii) no phone, (iii) planning to reside outside of Lusaka urban district after discharge

- Health systems leaders for one-on-one key informant interviews (around n=6):
    - Inclusion criteria: (i) age 18+ years old, (ii) experienced administrators and clinical heads in Zambia, and (iii) professional experience at UTH or another health facility in Lusaka
    - Exclusion criteria: (i) declines to participate.

- CHWs providing ReCharge intervention, for interviews (n=4-8):

  - Inclusion criteria: (i) age 18+ years old, (ii) HIV peer educator or psychosocial counselor, and (iii) at least 2 years of experience supporting HIV care uptake at the community-level
  - Exclusion criteria: (i) declines to participate.

- Caretakers of patients living with HIV who received the ReCharge intervention (up to 20)
  - Inclusion Criteria: (i) age 18+ years old, (ii) serves as primary caretaker for participant-patient, (iii) resides with patient the majority of the time
  - Exclusion criteria: (i) patient does not permit inviting caretaker to participate, (ii) declines to participate

6.4 Participant recruitment

1. Hospitalized patients living with HIV being discharged home
   Our team will integrate with the inpatient teams at the Internal medicine units at study sites. We will solicit from the teams patients who may be eligible to enroll. A research team member will assess criteria and if eligible the patient will need to provide written informed consent to enroll. We expect that 30-40% of adults admitted to Internal medicine have HIV, and among them, about 30% will meet criteria to participate. We expect it will take 3-4 months to enroll the needed sample size.

2. Health systems leaders for Key Informant Interviews:
   Health system leaders will be recruited directly through email, phone and in-person introduction to the study from among individuals who are experienced administrators and clinical heads in Zambia, from both UTH and other health facilities in Lusaka.

3. Community health workers (CHWs) for Interviews:
   We will identify a list of eligible CHWs through the CLO coordinator. These will be UMB CHWs recruited to deliver the recharge intervention

4. Caregivers/Supporters of discharged HIV Patients:
   We will seek to conduct in-depth interviews with caregivers of the patients recruited into our qualitative study cohort of patients for the intervention . As explained above, we will first seek the consent of the patient to invite their caregiver to participate in the study and only interview the caregiver's following their provision of their informed consent.

7. Data Collection & Management

7.1 Study Procedures

The research team will consist of a small group of researchers with expertise in qualitative research and fluent in English, Nyanja, and Bemba, the primary languages spoken in Lusaka Province. The research team will be trained and supervised by UMB researchers with expertise in quantitative and qualitative research. The primary methods of research will enrollment in a study register. Qualitative procedures will include one-on-one interviews with participants identified through purposive and convenience sampling. All qualitative interviews will be conducted by trained research assistants. Following participant recruitment, IDIs will take place in a private room with the trained interviewer.

7.2 Data Management and Storage

Quantitative data will be entered on a password-protected laptop and analyzed using Stata 15 (Stata, College Station, TX). Digital recordings from interviews with patients and the resulting transcriptions will be labeled only with a unique study ID and stored at Maryland Global Initiatives Corporation (MGIC) on the secure server. No personal identifiers will be captured to protect confidentiality. The database will be housed on a password-protected laptop computer owned by MGIC and will be backed up periodically to the MGIC server. Data analysis will occur both in Zambia and internationally and analysts will only work with de-identified data to protect confidentiality.

MGIC has a robust ICT department that will provide primary data management services on this study. As a key partner to MoH in the HIV/AIDS response, MGIC collects and manages HIV program data for MoH at >100 HIV care facilities in Zambia. A 5x3 meter secured room at MGIC headquarters houses central servers and 2 senior data managers plus 2 senior ICT experts are on hand to support data capture, management, and storage. On this study, as mentioned above, our qualitative and quantitative data will be backed up on the server. However, only anonymized data will be backed up.

8. Statistical Considerations

8.1 Sampling frame and Sample Size Calculations

8.1.1 Quantitative sample Size

Our sample size calculation was based on the hypothesis that CHW follow-up will have substantial impact on the proportion who are alive and fully HIV virally suppressed at 6 months. To detect a change in retention from 60% (based on prior studies) to 80% between historical controls and pilot study participants, with a two-sided alpha and 80% power, we would need a sample size of at least 82 pilot participants. We expect that, because of the clinical acuity of participants, some may pass away before discharge occurs, and these would be censored and not included in main analysis. Hence, we will inflate the sample to 100.

8.1.2 Qualitative sample Size

A total of 24 interviews at the start of the project will be conducted with patients recruited and another 16 at the end with some of the patients interviewed at the start. An additional 16 interviews will also be conducted with care givers of the 16 patients who will be interviewed twice. Providers such as CHWs(n=4-10) and CLOs(n=2) and hospital staff(n=6-10) will also be part of the sample for the study.

8.2 Data Analysis

8.2.1 Quantitative analysis

We will describe and compare sociodemographic and clinical characteristics of historical controls and participants. For the primary outcome, we will compare proportions retained in care at 6 months between controls and CHW follow-up recipients, after excluding participants who transferred out. Potential confounders between the intervention and outcome will be adjusted for in multivariable analysis. Sex-stratified models will be fit as secondary analyses, which are important in planning for the follow-on trial. We will compare the proportions who died in each group, as our central hypothesis is that re-engagement in HIV care after hospitalization can lower mortality. We recognize that with a sample size of 100 we will be under-powered for multivariable and sex-stratified analyses (as well as the mortality comparison); however, the point estimates, when interpreted together with feasibility and acceptability data, will be informative and provide support for future use of this intervention.

8.2.2 Qualitative analysis

All qualitative interviews will be digitally recorded, transcribed, and simultaneously translated verbatim from Nyanja or bemba into English and then coded using *Atlas.ti*. Two research team members will conduct thematic analysis, reading and coding the data iteratively.[27] We will first use a set of agreed upon deductive codes based on the domains addressed, followed by discussion and agreement on inductive codes that capture unanticipated and deeper analytic concepts.[28] We will then identify and summarize key themes, with matrices for data reduction and analysis. We will organize findings as applicable, with attention to how our findings inform program development across key actors and institutions. Analyses will focus upon

changes in patient and CHW perceptions of HIV care as a result of CHW follow-up , as well as triangulate perceptions of the feasibility and acceptability of intervention components across patients, caregivers, CHWs, and facility HCWs. Attention will be paid to potential determinants (patient-level, community-level, structural, facility-based) of pilot outcomes, with consideration for modifications toward scale-up. Weekly discussions and simultaneous coding of a subset of transcripts will ensure high interrater reliability throughout; themes and findings will also be vetted through meetings with the fieldwork team. Our Key Personnel feature two Co-Investigators with extensive qualitative experience (Bwalya, Stoebenau).

9. Ethical Considerations

9.1 Permission to Conduct Research at UTH

Prior to seeking IRB approval, we will present this protocol to the UTH and Levy Head of Department and request permission to conduct this study at UTH. See appendices for letters of permission.

9.2 Institutional Review Board (IRB) Review and Informed Consent

This protocol, and any subsequent modifications, will be reviewed and approved by the IRB at the University of Zambia Biomedical Research Ethics Committee (UNZABREC) of the University Teaching Hospital in Lusaka, Zambia before the commencement of the study, as well as the National Health Research Authority (NHRA). This protocol will also be reviewed by the IRB at the University of Maryland Baltimore.

9.3 Potential risks and benefits

9.3.1 Potential risks

There are no more than minimal risks to participation in this study for all participants. Patients and caretakers may be uncomfortable with some of the questions posed to them in one-on-one interviews. The researcher will remind the participant that they do not have to answer any questions that make them feel uncomfortable. Loss of confidentiality is another potential risk; this is minimal and will be minimized by use of unique patient codes and de-identified data.

9.3.2 Potential benefits

There are no known direct benefits for participants in this assessment. We hope that the assessment will serve to inform and improve service provision and that participants will be pleased to know they have contributed to that effort. This information is useful on a societal level for advancing our understanding of the treatment of HIV in a resource-limited setting.

9.3.3 Risk to benefit ratio and minimization of risks

The knowledge gained from this study will be important as an addition to a very limited body of literature about post hospitalization outcomes among PLHIV in sub-Saharan Africa.

9.4 Voluntary participation

During recruitment and implementation of IDIs, we will counsel participants that their participation is voluntary and regardless of the data they provide, their position with MoH, UTH, etc. will not be impacted in any way. Transcripts will be stripped of identifying information. We will approach patients who are eligible to participate in a discrete manner to maintain confidentiality. We are aware that private space is minimal in AMEU and the inpatient units and our staff will be coached on how to discuss sensitive issues in the most discrete ways possible to avoid inadvertent disclosure. If possible, a private space will be used for consenting and collection of data. When interviewees are conducted away from the hospital either at home or any other space, they will be conducted with consultation with the patient.

Potential participants will be counseled that they can refuse to participate in the study and still receive HIV care at the treatment site. Participants will be free to not answer questions

that they deem too personal during the study. Providers will be highly trained and will receive specific training in human subjects research. The study staff obtaining consent and collecting data will be highly trained in human subjects and responsible conduct of research and will have the appropriate certifications (e.g., NIH).

9.5 Informed consent

Informed consent procedures will follow international standards. The consent form will be available in English, Nyanja, and Bemba; consent will occur in the language (among the three) chosen by the participant. If the participant is not literate in one of the three languages, an independent witness (either family member, friend, or clinic staff not working on the study) who is literate in the chosen language will be present and will participate in the consenting process. Study procedures will allow for potential participants to take time (potentially weeks to months if desired) to make a decision about whether or not to participate and a follow-up appointments in the days and weeks after the initial meeting can be scheduled, if desired. The participants will be encouraged to ask questions throughout the consent process and also throughout their entire participation in the study.

9.6 Participant confidentiality

Throughout the study, we will maintain strict participant confidentiality in various ways. We will collect data using an ID number that is only linkable to the patient's name, phone number, and address using a linkage file. Files will be maintained in a locked filing cabinet in a locked office and the linkage file will be locked separately. Only a member of the study team will keep the keys and be able to open the file cabinets containing participant records. Access to the files will be restricted to members of the study team. If necessary, the IRB, MoH, or other regulatory body will be granted access to study files. At the end of the study, linkage files and personal identifying information will be destroyed, leaving only de-identified data for ongoing analysis and dissemination.

9.7 Participant withdrawal

Participants will be allowed to withdraw from the study at any time and for any reason and without stating a reason. Participants will be provided with the PI and other study team members' phone numbers and if the participant informs the study team of her/his wish to leave the study, that wish will be honored. Participant data and records would be destroyed at that point and the ethics committee would be informed of the withdrawal.

9.8 Participant treatment

Participants will receive clinical care and treatment according to the MoH guidelines on HIV management and per the standards of care. A study team member will be available to participants by phone at all times and patients who require hospitalization after discharge or additional medical attention will be referred to the appropriate public sector facility.

10. Study Time Frame

Following IRB approval, we will organize a stakeholder meeting to explain the research and the purpose. We will then begin data collection using IDIs, followed by data analysis. Following completion of data analysis, the results will be disseminated through a variety of channels, including through educational programs at UTH, conference presentations, and publication in a peer-reviewed journal.

Timeline for Major Activities	2022		2023				2024			
	Q3	Q4	Q1	Q1	Q3	Q4	Q1	Q2	Q3	Q4
IRB Approvals		X								
Stakeholder meetings	X									
Pre-implementation data collection			X	X	X					
CHW intervention implementation					X					
Post implementation data collection					X	X				
Data collection: IDIs					X	X				
Data analysis						X	X	X		
Local dissemination of findings							X	X		
Conference presentation								X	X	
Manuscript development & publication									X	X

11. Publication plan

It is expected that the results of the study will be presented at an infectious disease conference (e.g. CROI, IDSA/ICAAC, or IAS/IAC). It is anticipated that the study will generate an abstract. We anticipate that the study will also generate a manuscript that will be submitted to an infectious disease journal such as *Journal of the International AIDS Society*, or other journals of a similar caliber. It is anticipated that a manuscript would be submitted within 6 months of completion of the final analysis of the study data.

12. Budget

Budget (in Kwacha)	**Year 1**
Personnel	
Key personnel salaries	300,000
Other staff salaries	200,000
Travel	
Local travel (Lusaka)	40,000
Other	
Participant costs (such as transport reimbursements)	20,000
Training costs (for study team and UTH staff)	40,000
Meeting costs (for sensitization and dissemination)	35,000
Miscellaneous costs (stationery, office rent, etc.)	20,000
Indirect costs	150,000
Total	800,000

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14. Appendix 1: Patient Interview Guide

IDI Interview Guide for patients, Interview 1 (~1-week post-discharge)

Background information:

(*Objectives: Rapport building, understanding of potential sources of support, assessment of living situation and economic status, understanding of other health-related behaviors as it relates to any leisure activities) (Interests? Ways they earn a living?*)

1. Can you please tell me about yourself and the family members who live here with you?
    a. Tell me about everyone who lives here on a regular basis with you. How are they related to you? (Possible probes: married? Kids? Ages?)
    b. Can you talk about any other close family members who live nearby and who are important to you in your life?
    c. Tell me a bit about how people in this household get by, what are the different kinds of work they do?
    d. When you are feeling well, what are some of the things that you do when you have free time, or for recreation:
        i. Possible probes: Reading, watch TV, do you take alcohol, smoke, what about others in your family?

2. (*Objective: These questions are to understand the role of stigma and whether participant perceives stigma or themselves as burden or source of shame within household/community – in case these factors have played a role in how they are cared for/care for themselves; whether/how they feel their identity as a PLHIV has had any negative impacts on their life within their community*)

    Thank you. Now, if it's okay, I'd like to understand a bit more about your health. To start, would you please tell me in detail how you learned about your status? (NOTE: try to get them to tell this to you as a story, they can set the stage/scene - Age, circumstance- what year was it?)
    a. Can you talk about how you felt after learning about your status at that time? Have your feelings changed since that time and how?
    b. Have you told anyone about your status (or has anyone learned about your status without you telling them? How did they come to know about it?
        i. How was that experience (disclosure) for you?
        ii. Were there any changes in relationships with family over time?

3. *Objective: To understand how the participant has approached treating their HIV, different treatment regiments they may have tried prior to ART, different influences on different ways of getting treatment etc. AND to establish the context around their starting on ART, and how they got it and how they felt about it from the beginning. Also want to see if the mechanisms by which they accessed it have changed at all as this may be part of the problem.*

    Thank you so much for sharing that with me. Now I'd like to understand more about your experience with caring for your health. **NOTE: *Ask these items only if the person reported knowing their status before being hospitalized***.

a. Let's start with right after you learned your status. Can you talk about how you cared for your health during that time? (*Try to figure out when this was – before/after test and treat?*)
b. Now let's talk about any changes more recently in how you have looked after yourself.
c. Let's talk in a bit more detail about ART if you don't mind.
    i. Have you ever been on ART? Can you describe how you started to take ART? (If not already addressed above)
    ii. Who encouraged you to start, when did you start, how did you start taking ART?
    iii. What was your experience with taking ART? (Emotional response to taking it, physical response to taking it in the body).
    iv. Can you talk about where and how you have accessed ART over time and whether or how this changed?

d. **Ask all participants:** Apart from going to the clinic as a way of taking care of your health, have you tried different methods or ways of taking care of your health over time? Can you talk about these?
    i. Can you talk about who encouraged you to take these different approaches (ART? other healing practices? Church/religious influence?)
    ii. **If influenced by church – ask them to talk more about this** – Can you talk more about the guidance you received from your church?
    iii. Can you also tell me a bit more about the church? (What type)
e. Can you talk about any other health challenges you have been facing?

4. *Objective: These questions will help us to understand their perceived barriers to staying on treatment. Hope here is that some of these might be amenable to intervention with CHWs…. So we want to try to identify any of these.*
   Many of us have a difficult time accessing and staying in HIV care or on treatment**(That is accessing the drugs, staying on ART without stopping)**. For many, the challenges they face with staying on ART lead them to be non-adherent (not taking treatment everyday) or even stop taking it. Can you describe any experiences you have had with this?
   For these question, make that you probe on challenges by asking the participants on challenges related to accessing ART, Taking ART, Staying on ART etc.
    a. Can you talk about any challenges you faced with taking ART?
        i. Challenges at home/In household? Community?
        ii. Concerns with taking it because of advice received (from family, friends, church)
        iii. Challenges with clinic / accessing drugs? (Stigma, time, cost, distance, rude staff)
        iv. Challenges/barriers within yourself (acceptance of status, motivation, beliefs, fears, side-effects, what others might think etc.)
    b. Now, among all of the reasons you have just mentioned, which of these reasons would you say mattered the most. What makes you say that? (rank exercise)
    c. Were you able to overcome any of these challenges? (**If yes**, can you talk about how you overcame the challenges? **If no**, what could help you to overcome these challenges?)

5. *(Objective: Understand their support system since diagnosis, changes to that system, and whether they have one or feel they have one and who primarily it consists of – Does their family support them, who in the family – did someone supporting them early on move away, leave, pass away? Etc.*)
   Now I would like to understand more about the people in your life who have supported you since you learned about your status.
   a. Who would you say has helped or supported you the most? In what ways?
   b. Have the people who have cared for you/supported your health changed over time?
      i. Can you talk about this and why was there this change, how did this affect you and your treatment/health? (PROBE to identify role of family members in the household)

Thank you for sharing this with me. Now I'd like to ask you more about your most recent health challenges that took you to the hospital, if you don't mind.

6. Can you talk about your most recent hospitalization, tell me about what happened?
   a. What led to your going to the hospital?
   b. How did you get there? Who helped you realize you needed to go? Who helped you to get there?
   c. Can you just let me know, quickly, about how many other times you have been admitted to the hospital in the past since you learned about your status?
      i. Can you talk about the events that led to your hospitalization in the past?

(Objective: Want to know about the additional concerns they may have been facing with their health that led to their hospitalization; additional questions here on social support/family support)

7. Thinking now about the most recent time you were in the hospital - Can you talk about your experience in the hospital?
   a. What did you learn about the cause of your illness that led to your being hospitalized while you were there?
      i. What other information was shared with you by the doctors/nurses about your medical condition?
      ii. How did that make you feel?
   b. Can you talk about how being in the hospital made you feel?
      i. PROBE on whether those feelings have motivated them to act or lose hope…without saying this directly!

8. Now, can you please tell me about what was the discharge process like for you?
   a. Can you talk about how you learned you were going to be discharged? (PROBE: sudden, knew a few days in advance?)
   b. How did you feel about being discharged when you were? (Early? Late? From their perception)
   c. Can you describe for me in detail everything you were advised to do following discharge?
      i. What exactly do you remember being told to do once you left the hospital?

ii. Did the hospital provide you with any referral to help you get connected to care?
iii. How did you feel about the advice/instructions you were given? (Easy to understand, not feasible, helpful, unhelpful, etc.)

9. Now, let's talk about how it was after you left the hospital. How has it been since you were discharged? Can you talk about that?
    a. How have you been feeling?
    b. What has been worrying you?
    c. What is going well or getting better?
    d. Who has been helping you with your health since discharge? Can you talk about how they have been helping?

10. Now I'd like to ask you more about what you need in order to completely recover.
    a. What do you think are the things that you need in order to get better?
    b. What does your family need in order to be able to support you to get better?
    c. In addition to medical advice and treatment, what additional form of support do you need to stay/get healthy? (e.g., Nutrition , information, psychological, financial, religious)
    d. What are all the challenges you are facing now to stay/get healthy?
        i. With treatment, clinic, or access to healthcare
        ii. With family or support
        iii. With finances following hospital stay
        iv. Within community or its expectations
        v. Others? (Probe on those related to ART and ART use, especially cost of healthcare -transportation, labs, tests, medicines)
        vi. What is it that you think should be done to help you overcome these challenges?
    e. What kinds of support are you receiving? And from where? Whom?

11. Thank you very much for you time. Do you have any question or comments before we close this interview?
    a. Is there anything else that you would like us to talk about that you think is important for me to understand about your problems with your health?
    b. Do you have any additional recommendations you would like to share on whether or how CHWs, or other healthcare workers, could better serve patients after discharge to ensure they recover as best as possible?

15. Appendix 2: Patient Interview Guide (at 6 months)

IDI Interview Guide for patients, Interview 2 (at six months)

Thank you for agreeing to speak with me today. I'd like to talk with you today about your experiences since we spoke together last time.

1. To begin, can you talk about how it was after you left the hospital. If possible, try to remember back to the first few weeks following your return from the hospital in ____ (name month). Tell me how you were feeling just after you returned home.
    a. Can you talk about your energy levels when you first got home?
    b. How about your levels of pain?
    c. Can you talk about the medications you were prescribed? Can you describe what you were prescribed and what you took?
        i. (if prescribed new drugs) Can you talk about how the medications made you feel?
    d. Can you talk about who in your home or community (family, friends/neighbors) helped you with your recovery process after discharge?
        i. How did they help you?

2. Now I'd like to ask you about any healthcare you have received since discharge, if any.
    a. Can you describe in detail any follow-up visits to hospital/clinic you have had since discharge? **(IF they have followed-up, then ask:)**
        i. What? Where? When since discharge? How many? For what purpose? (INTERVIEWER – note how /what compares to the advice they received)
        ii. How have these appointment(s) gone?
        iii. Have you received any support for these follow-ups? (Family, CHWs)
        iv. What has been good about these appointment(s)?
        v. What has been difficult about these follow-ups?
        vi. Are you facing any challenges with continuing to follow-up visits for your care? Can you talk about these? (Probe on logistics, healthcare setting, finances since discharge, family, community)
        vii. Some people are told to take different medications after discharge. Have you had any experience with that and if yes how is that going?
        viii. After being discharged, can you describe where have you been collecting your drugs?
            1. If referred back to your clinic, how has your experience been with that?

    b. **(IF they have not had any interaction with healthcare system since discharge)** Can you talk about the reasons that you have not seen anyone/gone to a clinic since you left the hospital?
        i. (IF mentions any challenges – probe A LOT) Can you talk about any barriers or challenges you experienced with follow-ups after discharge?
            1. ? (Probe on logistics, healthcare setting, finances since discharge, family, community)
        ii. (IF mentions that it is not necessary – probe – this is a misunderstanding)

iii. (If mentions that they have an appointment booked, then ask): Do you think there will be any challenges for you with getting to this appointment? Can you talk about those challenges?
iv. (If they missed the appointment) – Can you talk about the reasons you were unable to make the appointment? (PROBE on what's next)

3. Now I'd like to ask you more about your relationship with the CHW who supported you following discharge.
    a. Can you talk about the different ways the CHW supported your recovery, if at all? Let's list these. Phone calls? Visits? What else?
    b. Can you talk about which of these ways helped you the most?
        i. Are there any things that you were able to do (care you were able to receive, medications you were able to access) that you may not have been able to do/get without support from the CHW?
        ii. How did the CHW support your follow-up visit with the hospital, if at all?
        iii. How did the CHW support your follow-ups with your clinic, if at all?
    c. Which of these things helped you the least, or you would have preferred they had not?
        i. Can you talk about anything the CHW did that you did not appreciate or find useful or helpful?
    d. What else would you have appreciated from the CHW? How else would you have liked them to help you?
        i. If you could go back in time to when you were in the hospital, is there anything you would have liked to have gone differently that you think would have helped you to recover faster or to get better?

4. (for those who screened for mental health/alcohol). I believe we referred you for additional care with (Strong Minds / ___ alcohol care).
    a. Can you talk about what happened after you received the referral?
    b. Can you talk about any visits you had to (Strong minds / ___).
    c. Can you talk about your experience there? What did you learn? How did it make you feel?
    d. Can you talk about what has happened, if anything, since your first visit?

5. What would you say is the biggest change or the most significant and positive thing that has happened for you as a result of this program (support from CHWs)?
    a. What makes you say that?

6. Can you talk about any changes that have taken place for you in the last six months?
    a. Disclosure? – any changes in who knows your status?
    b. Behavioral health – any changes in behaviors that might be risky? (e.g., alcohol)
    c. Relationships – any changes in your personal relationships with family members?
    d. Self-esteem – Any changes in how you feel about yourself?

7. We are going to try to build up this program to support more patients like you who are leaving the hospital to help support them to recover.
    a. Can you think of any recommendations you have for us that could help to make this support program stronger?
    b. What do you think are the things that you need in order to get better?
    c. What does your family need in order to be able to support you to get better?

d. In addition to medical advice and treatment, what additional form of support do you need to stay/get healthy? (e.g., Nutrition , information, psychological, financial, religious)
e. What are all the challenges you are facing now to stay/get healthy?
    i. With treatment, clinic, or access to healthcare
    ii. With family or support
    iii. With finances following hospital stay
    iv. Within community or its expectations
    v. Others? (Probe on those related to ART and ART use, especially cost of healthcare -transportation, labs, tests, medicines)
    vi. What is it that you think should be done to help you overcome these challenges?
f. What kinds of support are you receiving? And from where? Whom?

16. Appendix 3: Caregiver Interview Guide

Interview with Care Giver

IDI Interview Guide for Caretakers of Patients – End line

When appropriate, please make sure you collect this information from the participant.

- Community name:
- Age:
- Gender:
- Education level
- Religion

NOTE: We will need to develop coding scheme to link caretaker to patient for transcription purposes.

1. (Rapport building) First, tell me about yourself and your family in your household.(Children? Dependents?)
    a. Tell me a little bit about how you are related to _____?
    b. Tell me about the role you play in this household?
    c. What kind of work do you do? (If lives in different household from patient, then ask: Tell me a bit about how people in this household get by, what are the different kinds of work they do?)

(Transition to new topic)

We recently talked to _____ and we would like to talk to you about your role since their hospitalization.

2. First could you please talk about the events that led to _____'s hospitalization in _____ [month]?
    a. What, in your mind, were the reasons that ____ got sick and needed to be hospitalized?
    b. Has he/she ever been hospitalized before this? How many times in the past has this happened?
        i. **If yes**, what are the reasons ____ has been hospitalized in the past?

3. What role did you play in looking after ___ when ____ was in the hospital? (**IF bedside, or there often, then ask following**):
    a. What was the discharge process like? Can you talk about how you learned when ____ was going to be discharged? (PROBE: sudden, knew a few days in advance?)
    b. How did you feel about ____being discharged when they were? (Early? Late? From their perception)
    c. Can you talk about the advice the doctors/nurses gave ____ about what he was supposed to do following discharge?
        i. What exactly do you remember about this?

ii. Was _____ given any referral to a local clinic?
iii. How did you feel about the advice/instructions you were given? (easy to understand, not feasible, helpful, unhelpful, etc.)
iv. Was _____ given any medicine from the hospital? Was there any that you were asked to buy because the hospital did not have?

4. Let's talk about what it's been like since ____ returned home after the last hospitalization. How has that been for you?
    a. What is going well for you and for _____ so far?
    b. Can you talk about any follow-up for clinic care, appointments ____ has attended since coming home?
    c. **(if got care)** Can you describe the role you played in getting ____ to the hospital/clinic for their follow-up care appointments?
        i. Can you describe whether ____ received any new medication or treatment recommendations since discharge? If so – how has it been to support ____'s medication/treatment adherence?
    d. **(If has not followed-up)** Can you talk more about the reasons that ___ has not had a follow-up visit yet?
        i. What challenges have you faced with supporting ____ to follow-up with care since leaving the hospital?
            1. Hospitalization can be expensive. Can you talk about any of the impacts of those costs for you and your family?

5. What other challenges have you had in caring for _____ ? (Time, resources, types of treatment).
    a. Challenges
        i. Individual level – lack of emotional support, over burden, lack of information/knowledge, uncooperative patient
        ii. Household level – Relationship dynamics, financial challenges
        iii. Community level – stigma, people in the community asking questions
    b. How do these challenges you face affect/influence how ___takes his/her treatment?

6. How would you like ____ to be getting care? What do you think ___ needs to get better?
    a. What kind of advice do you give(name of the patient) to help him/her stay healthy?
    b. What kind of support do you wish you had to better support(name of the patient)
    c. What would you like to see happen differently that can help ……. To stay healthy?
    d. What else could help you to be able to address those challenges, or what would need to happen to help remove those challenges?

7. Now I'd like to ask you more about your relationship with the CHW who supported ___ following discharge.
    a. Can you talk about the different ways the CHW supported ___ recovery, if at all? Let's list these. Phone calls? Visits? What else?
    b. Can you talk about which of these ways helped ___ and you the most?

i. Are there any things that you were able to do (care you were able to receive, medications you were able to access) that you may not have been able to do/get without support from the CHW?
ii. How did the CHW support ___ follow-up visit with the hospital, if at all?
iii. How did the CHW support ___ follow-ups with your clinic, if at all?

c. Which of these things helped ___ the least, or you would have preferred they had not?
iv. Can you talk about anything the CHW did that you did not appreciate or find useful or helpful?

d. What else would you have appreciated from the CHW? How else would you have liked them to help ____?
v. If you could go back in time to when ____ was in the hospital, is there anything you would have liked to have gone differently that you think would have helped ____ to recover faster or to get better?

8. What would you say is the biggest change or the most significant and positive thing that has happened for ____ as a result of this program (support from CHWs)?
   a. What makes you say that?

9. Can you talk about any changes that have taken place for ____in the last six months?
   a. Disclosure? – any changes in who knows ___status?
   b. Behavioral health – any changes in behaviors that might be risky? (e.g., alcohol)
   c. Relationships – any changes in ____personal relationships with family members?
   d. Self-esteem – Any changes in how ___feels about themselves?

10. We are going to try to build up this program to support more patients like ____who are leaving the hospital to help support them to recover.
    a. Can you think of any recommendations you have for us that could help to make this support program stronger?
    b. What do you think are the things that you need in order to get better?
    c. What does your family need in order to be able to support you to get better?
    d. In addition to medical advice and treatment, what additional form of support do you need to stay/get healthy? (e.g., Nutrition , information, psychological, financial, religious)
    e. What are all the challenges you are facing now to stay/get healthy?
       vi. With treatment, clinic, or access to healthcare
       vii. With family or support
       viii. With finances following hospital stay
       ix. Within community or its expectations
       x. Others? (Probe on those related to ART and ART use, especially cost of healthcare -transportation, labs, tests, medicines)
       xi. What is it that you think should be done to help you overcome these challenges?
    f. What kinds of support are you receiving? And from where? Whom?

ONLY ASK IF STATUS OF PATIENT IS KNOWN

If it's okay, I would like to ask you some questions about _____'s status and your struggles and efforts to support _____ with this.

1. First, can you tell me when/how you learned about ____'s HIV status? How was that experience for you? (Stigma, fear, friends/family response, reaction)
    a. How has ____'s HIV status affected your life in this family?
        i. PROBE: has this had any effect on your relationship within your family?
    b. Can you talk about whether _____'s status has had any impact on your role in the community? What about ____ 's role in the community?

2. What form of treatment has _____ been getting since diagnosis, to your knowledge?
    a. What is it that has worked well for _____ with the treatment he/she is taking?
    b. What has not been working well?(type or combination of drugs, changing from first line to second line treatment, taking tuberculosis treatment too, etc.)

3. Now I would like to talk to you about access to care for (name of the patient).
    a. Where did ____ access his/her care from? Can you talk about any changes in how ____ accessed care over time?
    b. Apart from getting care from the clinic, are there other places and forms of treatment where _____ got care?
        i. Probe about traditional medicine, faith healing.
        ii. How has this affected his/her journey on treatment?
    c. What, if anything, seemed to work well for ____ 's HIV care?
    d. What did you encourage ___ to do? What did others encourage ___ to do?

4. (**If the patient learned their HIV status before hospitalization):** Many people have a difficult time accessing and staying in HIV care or on treatment. For many, the challenges they face with staying on ART lead them to be unable to take treatment every day or even stop taking it. Can you describe any experiences _____ has had with this?
    c. Can you talk about any challenges _____ faced with taking ART?
        i. Challenges at home/In household? Community?
        ii. Concerns with taking it because of advice received (from family, friends, church)
        iii. Challenges with clinic / accessing drugs? (Stigma, time, cost, distance, rude staff)
        iv. Challenges/barriers within yourself (acceptance of status, motivation, beliefs, fears, side-effects, what others might think etc.)
    d. Now, among all of the reasons you have just mentioned, which of these reasons would you say mattered the most. What makes you say that? (rank exercise)
    e. Was ____ about to overcome any of these challenges? If Yes: how? **If no**, what could help you to overcome these challenges?)
    f. Were you able to help ____ overcome any of these challenges? (**If yes**, can you talk about how you were able to support _____ to overcome the challenges?
    g. Are there other resources you would need to help ____ overcome some of these challenges? Can you talk about that?

11. Thank you very much for you time. Do you have any question or comments before we close this interview? Is there anything that you would like us to talk about that which we have not talked about which you think is important for(name of the patient) that can help him get better or do well on his treatment journey?

17. Appendix 4: CHW, CLO, Clinicians Interview Guide

Interview with CHW, CLO, Clinicians

Endline, ReCharge Interview with CHW, CLO, Clinicians (hospital, clinic)

Interviews with providers involved in ReCharge.

1. To help understand more about your involvement in Recharge broadly, tell me your responsibilities in this intervention. What role did you play with caring for patients LHIV who had been hospitalized and then discharged following their discharge?

2. To understand how this program worked and its weaknesses, let's talk more specifically about examples of two patients you worked with. Think of one that worked out well. Think of one that did not. (each question to be asked for both types of patient).
   a. Talk about your first encounter with this patient. How did it go? Where was it? What did you learn? What did you do to help them?
   b. Talk about your first visit with them after discharge? How did it go? Where? What happened?
   c. Talk about other calls, supports you provided? What happened? What did you do, how did they respond?
   d. Talk about what you learned about what the patient needed, how did you support that?
   e. Talk about the patient's involvement in care after discharge? What services did they get? Where? How?
   f. Talk about your role with anyone else in the patient's life – caregiver? Children? Others?
   g. Talk about how you supported the patient's recovery?
   h. Tell me what you think was the most important contribution you made to this patient's recovery?
   i. Tell me what you think enabled / prevented them from recovering?
   j. What else could the program have done to better support this patient?
   k. (for patient that did not go well) What explains, in your mind, why this patient did not do well/recover?
      i. What would the program change to help patients like this one to do better in the future?

3. What are your recommendations for how CHWs should work with hospital to help discharged HIV patients?

4. What are your recommendations for how CHWs should work with clinics to help discharged HIV patients?

5. What are your recommendations for how CHWs should facilitate relationship between hospitals and clinics to help discharged HIV patients?

18. Appendix 5: Information and Consent Forms for ReCharge Patients

THE UNIVERSITY OF ZAMBIA

BIOMEDICAL RESEARCH ETHICS COMMITTEE

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IRB00001131 of IOR G0000774

Ridgeway Campus
P.O. Box 50110
Lusaka, Zambia

Information Sheet and Consent Form for Discharged Patients for Re-Engagement at Discharge 2

Improving post-hospital outcomes for adults with HIV in Zambia (ReCharge 2)

Investigators:

Names	Institutions	Contacts of the Investigators
Dr. Cassidy Claassen	University of Maryland at Baltimore (USA) and University of Zambia School of Medicine	cclaassen@ihv.umaryland.edu
Dr. Michael Vinikoor	University of Alabama at Birmingham (USA) and University of Zambia School of Medicine	mjv3@uab.edu

Background and rationale for the study:
Hello. I am __(name)__ and I work with the University of Maryland team in Zambia. I would like to talk to you about an upcoming study that you may be able to help with. This form explains why we are doing this study and what you will be asked to do if you choose to be in this study. We will read this form with you. Please ask any questions you have about this study at any time to fully understand this information so that you can make an informed choice about being in this study.

Many hospitalized patients at referral hospitals in Zambia are living with HIV. After being stabilized at the hospital and discharged to go home, people living with HIV experience a challenging recovery process, and during this time, the risk of readmission to the hospital and/or death is high. Outcomes are especially poor when the person living with HIV also had a low CD4 count and/or has a high HIV viral load (VL). After discharge, challenges may come from the need to receive follow-up care at multiple health facilities, inconsistent or poor support from family, and behavioral health issues like mental illness and alcohol use.

Purpose:
The purpose of this study is to evaluate a new program that may help people living with HIV after they are discharged from the hospital. If we learn through this study that the program is beneficial to patients, their families, and health workers, we recommend that more patients receive it. You are being asked to participate in the study because you are 18 years or older, were hospitalised and discharged, and we spoke with you at the point of discharge about taking part in the new Recharge programme that is being conducted in your community.

Procedures:
If you say yes, we would like to come and visit you, and have two separate 30–45-minute interviews at different times. If you will allow us and give permission, we would like to audio-record and type out the transcript for analysis. We hope the first interview would take place 3 months into the programme and the second would take place towards the end of the programme (around 6 months).

We will include you in the program from today until 6 months after you are discharged. Before discharge we will ask you questions about where you live, including your contact details, and about your family or community supporters. We will also obtain some information from your medical records about your medical history. If you have not had the needed labs done, we will collect up to 10 ml (2 teaspoons) of blood for these tests and will bring you the results. At discharge, we will give you a card to bring with you to any follow-up appointments. The card has information about your medical history, medications, and appointments.

For up to 3 months after you are discharged, a counsellor working with our team will be assigned to help you recover. The counselor will periodically phone you and/or, if it's ok with you, visit you at home or in the community to provide you with additional support to help meet your mental, emotional, social, and spiritual needs as well as those of your family. We will also provide you with health education to you and your family, help you follow the discharge plan from your doctors, and remind you about follow-up appointments. The first home visit will happen within 1 week of discharge. Thereafter, the counsellor will phone you and/or meet you several more times. S/he may also accompany you to your follow-up appointments. The counsellor will check to see if you are having any negative thoughts or feelings that suggest depression or if you have challenges with heavy alcohol use and will refer you to the clinic if necessary.

At 6 months after you are discharged, you will have a final study visit at the hospital. At the visit, we will obtain information from your medical records, and collect up to 10 ml (2 teaspoons) of blood to check your viral load and bring you the results.

Who will participate in the study?
Up to 100 people meeting the study criteria will participate.

Risks/Discomforts:
One possible risk is that people will find out about your medical information. We will safeguard your confidentiality. We will only discuss your medical information with people you designate. When visiting you at home or in the community, our team will never reveal the reasons for the visit to others. In addition, we will call you and ask if it is okay to visit you. If you don't want us to visit you at home, you can tell us an alternative location where we can meet you. During surveys and interviews, you may feel embarrassed, worried, and/or uncomfortable talking about your medical information and/or experiences. **You do not have to answer any questions you don't want to and you can stop participating at any time.** The blood draw may cause a small amount of pain or discomfort, and could

carry a risk of infection. We will follow all standard sterile procedures to minimize discomfort as well as infection.

Benefits:
Research is designed to benefit society by gaining new knowledge. You may not receive any direct benefit from being in this research study, but we believe it will help us to provide better treatment to people with HIV who are hospitalized.

Alternatives:
You may choose not to take part in this study. Also, you can choose to participate now and decide to stop later at any time.

Confidentiality:
Every effort will be made to keep your personal information confidential. Only the research team and your physicians will have access to your medical records and/or study file. Your study file will not include your name but a study ID number to keep the records anonymous. No names will be used in audio-recorded interviews and after typing out the content, audio recordings will be destroyed. Summary results from this study will be reported on clinicaltrials.gov. However, information from the study that is published for scientific and/or programming purposes will not contain any of your personal identifying information like names, address, etc. Your records may be reviewed by representatives of the University of Zambia Biomedical Research Ethics Committee, the University of Maryland Institutional Review Board, the study sponsor (NIH), the U.S. Office for Human Research Protections (OHRP), the Zambian Ministry of Health, or the Office for Human Research Protections. However, these reviews will only be used to ensure that the study is being conducted properly and that your records are being stored appropriately.

Cost: It will not cost you anything to be in this study.

Reimbursement: We will reimburse you for your time and transportation costs during the study. You will receive K100 today, at discharge from the hospital, and at each home or clinic/hospital visit where our team meets you.

Questions: If you have any questions, concerns, or complaints about this study, you may contact the Principal Investigator, Dr. Cassidy Claassen, at University of Maryland at Baltimore, 31C Bishops Road, Kabulonga Area, Lusaka, Zambia; Phone: +260 971075439; Email: cclaassen@ihv.umaryland.edu

Questions about participants rights:
If you have questions about your rights as a research participant, you may contact the people listed above. You can also contact the UNZABREC Chairperson for the Institutional Review Board (IRB) and/or the UMB Institutional Review Board:

UNZA Biomedical Research Ethics Committee
Ridgeway Campus, Nationalist Road, Lusaka
Landline Phone: 0211 256 067
Other Phones: 0955 155 633, 0955 155 634
Email: unzarec@zamtel.zm

University of Maryland Baltimore IRB
620 W. Lexington St., 2nd Floor
Baltimore, Maryland, USA 21201
Phone: +1 410 706 5037
Email: hrpo@umaryland.edu

Statement of voluntariness:

You are free to withdraw from the study at any time. You are also free to refuse to answer any questions that make you feel uncomfortable or that you deem private or otherwise. Just let the interviewer know that you prefer not to answer that question. Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in the study. You will not lose any benefits you are otherwise owed. Your choice to leave the study will not affect your access to healthcare now or in the future. You will be given any new information gained during the course of the study that might affect your willingness to continue to take part.

The University of Maryland, Baltimore (UMB) is committed to providing participants in its research studies all rights due to them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in this study. This study has been reviewed and approved by an Institutional Review Board (IRB). The IRB is a group of scientists, physicians, experts, and community representatives. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research studies.

If you have questions, concerns, complaints, or believe you have been harmed through participation in this study as a result of researcher negligence, you can contact members of the IRB or the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland, Baltimore
Institutional Review Board Human Research Protections Office
620 W. Lexington Street, Baltimore, MD 21201
410-706-5037

STATEMENT OF CONSENT

..... has described to me what is going to be done, the risks, the benefits involved and my rights regarding this study. I understand that my decision to participate in this study will not alter my usual medical care. In the use of this information, my identity will be concealed. I am aware that I may withdraw at any time. I understand that by signing this form, I do not waive any of my legal rights but merely indicate that I have been informed about the research study in which I am voluntarily agreeing to participate. A copy of this form will be provided to me.

Name of participant: ……..
Signature of participant: ……..
Date (DD/MM/YY): ……..

Name of witness*: ……..
Signature of witness*: ……..
Date (DD/MM/YY): ……..

Name of study staff member: ……..
Signature of study staff member: ……..
Date (DD/MM/YY): ……..

**Note: Witness name, signature and date are required on this consent form only when the consenting volunteer is not able to read and/or is illiterate*

19. Appendix 6: Information and Consent Forms for Hospital and Program Staff

THE UNIVERSITY OF ZAMBIA

BIOMEDICAL RESEARCH ETHICS COMMITTEE

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Assurance No. FWA00000338
IRB00001131 of IOR G0000774

Ridgeway Campus
P.O. Box 50110
Lusaka, Zambia

INFORMATION SHEET AND CONSENT FORM FOR HOSPITAL AND PROGRAMME STAFF

Title of the proposed study: Re-engagement at Discharge 2: Improving post-hospital outcomes for adults with HIV in Zambia (ReCharge 2)

Investigators:

Names	Institutions	Contacts of the Investigators
Dr. Cassidy Claassen	University of Maryland at Baltimore (USA) and University of Zambia School of Medicine	cclaassen@ihv.umaryland.edu
Dr. Michael Vinikoor	University of Alabama at Birmingham (USA) and University of Zambia School of Medicine	mjv3@uab.edu

Background and rationale for the study:
Hello. I am_____ and I work at University of Maryland in partnership with the University of Maryland and Levy Mwanawasa University Teaching Hospital (LMUTH) and University Teaching Hospital (UTH). I would like to talk to you about an upcoming study that you may be able to help with. This form explains why we are doing this study and what you will be asked to do if you choose to be in this study. We will read this form with you. Please ask any questions you have about this study at any time to fully understand this information so that you can make an informed choice about being in this study.

Many hospitalized patients at referral hospitals in Zambia are living with HIV. After being stabilized at the hospital and discharged to go home, people with HIV experience a challenging recovery process, and during this time, the risk of readmission to the hospital and/or death is high. Outcomes are especially poor when the person with HIV also had a low CD4 count and/or has a high HIV viral load (VL). After discharge challenges may come from the need to receive follow-up care at multiple health facilities, inconsistent or poor support from family, and behavioral health issues like mental illness and alcohol use.

Purpose:
The purpose of this study is to evaluate a new program that may help people living with HIV after they are discharged from the hospital. If we learn through this study that the program is beneficial/helpful to patients, their families, and health workers, we recommend that more patients receive it.

You are being asked to be in the study because you are a healthcare worker, a community health worker (CHW), or a community liaison officer (CLO) taking care of or providing support to recently discharged patients from this hospital. You may also be a program administrator who oversees the management of discharged patients.

Procedures:
If you agree to take part, we will invite you to attend a one-on-one interview session at a space/room where there is privacy. If you agree to participate in this interview, the interviewer will ask about your thoughts and perspectives of the programme, and ask your opinion about ways to support patients better after hospital discharge. The interview will be audio-recorded and typed out for analysis. However, the information will not be linked to individual names to provide confidentiality. The interview will take around 1 to 1½ hours to complete.

Who will participate in the study?
Around 100 people will take part in an interview.

Risks/Discomforts:
You may feel embarrassed, worried, and/or uncomfortable talking about your opinions and experiences. You do not have to take part in every discussion or answer every question. You do not have to answer any questions you don't want to and you can stop participating at any time.

Benefits:
Research is designed to benefit society by gaining new knowledge. You may not receive any direct benefit from being in this research study, but we believe it will help us to provide better treatment to people with HIV around the time of hospitalization.

Alternatives:
You may choose not to take part in this study. Also, you can choose to participate now and decide to stop later at any time.

Confidentiality:
Every effort will be made to keep your personal information confidential and only the research team will have access to the audio recording from the interview. Your name will not be revealed to further minimize any breach of confidentiality. Forms or recordings will be given a code. Summary results from this study will be reported on clinicaltrials.gov. However, results published for scientific and programming purposes will not contain any identifying information. Your records may be reviewed by representatives of the University of Zambia Biomedical Research Ethics Committee, the University of Maryland Institutional Review Board, the study sponsor (NIH), the U.S. Office for Human Research Protections (OHRP), the Zambian Ministry of Health, or the Office for Human Research Protections. However, this information will be kept confidential and will only be used to ensure that the study is being conducted properly and that your records are being stored appropriately.

Cost: It will not cost you anything to be in this study.

Reimbursement: We will reimburse your travel costs at K100.00 for an interview.

Questions: If you have any questions, concerns, or complaints about this study, you may contact the Principal Investigator, Dr. Cassidy Claassen, at University of Maryland at Baltimore, 31C Bishops Road, Kabulonga Area, Lusaka, Zambia; Phone: +260 971075439; Email: cclaassen@ihv.umaryland.edu

Questions about participants rights:
If you have questions about your rights as a research participant, you may contact the people listed above. You can also contact the UNZABREC Chairperson for the Institutional Review Board (IRB) and/or the UMB Institutional Review Board:

UNZA Biomedical Research Ethics Committee
Ridgeway Campus, Nationalist Road, Lusaka
Landline Phone: 0211 256 067
Other Phones: 0955 155 633, 0955 155 634
Email: unzarec@zamtel.zm

University of Maryland Baltimore IRB
620 W. Lexington St., 2nd Floor
Baltimore, Maryland, USA 21201
Phone: +1 410 706 5037
Email: hrpo@umaryland.edu

Statement of voluntariness:
You are free to withdraw from the study at any time. You are also free to refuse to answer any questions that make you feel uncomfortable or that you deem private or otherwise. Just let the interviewer know that you prefer not to answer that question. Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in the study. You will not lose any benefits you are otherwise owed. Your choice to leave the study will not affect your access to healthcare now or in the future. You will be given any new information gained during the course of the study that might affect your willingness to continue to take part.

The University of Maryland, Baltimore (UMB) is committed to providing participants in its research studies all rights due to them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in this study. This study has been reviewed and approved by an Institutional Review Board (IRB). The IRB is a group of scientists, physicians, experts, and community representatives. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research studies.

If you have questions, concerns, complaints, or believe you have been harmed through participation in this study as a result of researcher negligence, you can contact members of the IRB or the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland, Baltimore
Institutional Review Board Human Research Protections Office
620 W. Lexington Street, Baltimore, MD 21201
410-706-5037

STATEMENT OF CONSENT

..... has described to me what is going to be done, the risks, the benefits involved and my rights regarding this study. I understand that my decision to participate in this study will not alter my usual medical care. In the use of this information, my identity will be concealed. I am aware that I may withdraw at any time. I understand that by signing this form, I do not waive any of my legal rights but merely indicate that I have been informed about the research study in which I am voluntarily agreeing to participate. A copy of this form will be provided to me.

Name of participant: ……..

Signature of participant: ……..

Date (DD/MM/YY): ……..

Name of witness*: ……..

Signature of witness*: ……..

Date (DD/MM/YY): ……..

Name of study staff member: ……..

Signature of study staff member: ……..

Date (DD/MM/YY): ……..

**Note: Witness name, signature and date are required on this consent form only when the consenting volunteer is not able to read and/or is illiterate*

20. Appendix 7: Information and Consent Forms for Discharged Patients to Enroll into the Qualitative Study

THE UNIVERSITY OF ZAMBIA

BIOMEDICAL RESEARCH ETHICS COMMITTEE

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E-mail: unzarec@unza.zm
Assurance No. FWA00000338
IRB00001131 of IOR G0000774

Ridgeway Campus
P.O. Box 50110
Lusaka, Zambia

INFORMATION SHEET AND CONSENT FORM FOR DISCHARGED PATIENTS ENROLLED INTO THE QUALITATIVE STUDY

Title of the proposed study: Re-engagement at Discharge 2: Improving post-hospital outcomes for adults with HIV in Zambia (ReCharge 2)

Investigators:

Names	Institutions	Contacts of the Investigators
Dr. Cassidy Claassen	University of Maryland at Baltimore (USA) and University of Zambia School of Medicine	cclaassen@ihv.umaryland.edu
Dr. Michael Vinikoor	University of Alabama at Birmingham (USA) and University of Zambia School of Medicine	mjv3@uab.edu

Background and rationale for the study:
Hello. I am (name) and I work with the University of Maryland team in Zambia. I would like to talk to you about an upcoming study that you may be able to help with. This form explains why we are doing this study and what you will be asked to do if you choose to be in this study. We will read this form with you. Please ask any questions you have about this study at any time to fully understand this information so that you can make an informed choice about being in this study.

Many hospitalized patients at referral hospitals in Zambia are living with HIV. After being stabilized at the hospital and discharged to go home, people with HIV experience a challenging recovery process, and during this time, the risk of readmission to the hospital and/or death is high. Outcomes are especially poor when the person with HIV also had a low CD4 count and/or has a high HIV viral load (VL). After discharge challenges may come from the need to receive follow-up care at multiple health facilities, inconsistent or poor support from family, and behavioral health issues like mental illness and alcohol use.

Purpose:
The purpose of this study is to evaluate a new program that may help people living with HIV after being discharged from the hospital. If we learn through this study that the program is beneficial to patients, their families, and health workers, we will recommend that more patients receive it. You are being asked to be in the study because you are 18 years or older, you were hospitalized and after discharge, and you were enrolled into the ReCharge programme.

Procedures:
If you agree to take part in this study, we'll come to your house for two 30- to 45-minute interviews, which we'd like to record and type up for analysis, with your permission. We hope that these two interviews will happen three months into the program and near the end of the programme (around 6 months). If it is okay with you, we would like to have the first interview with you today. If today is not convenient for you, we can reschedule the interview for another day as soon as you are discharged and ready. You will advise us when it is ok for us to conduct this interview with you .During these interviews, we will ask you about your experiences with the ReCharge program and what worked and what didn't. These interviews will take place where you feel most comfortable, which could be at home or anywhere else in the neighborhood.

Once we finish talking to you, we would like to also talk to another family member that has been supporting you after you were discharged from hospital.

Who will participate in the study?
About 40 people with relatives who were admitted and discharged from LMUTH/UTH.

Risks/Discomforts:
You may feel embarrassed, worried, and/or uncomfortable talking about your opinions and experiences. You do not have to take part in every discussion or answer every question. You do not have to answer any questions you don't want to and you may stop participating at any time. Some of the questions in the interviews could be potentially stressful to answer.

Benefits:
Research is designed to benefit society by gaining new knowledge. You may not receive any direct benefit from being in this research study, but we believe it will help us to provide better treatment to people with HIV around the time of hospitalization.

Alternatives:
You may choose not to take part in this study. Also, you can choose to participate now and decide to stop later at any time. The alternative to joining in this study is for you to receive regular care for HIV and any other medical problem that led to your admission to LMTTH/UTH.

Confidentiality:
Every effort will be made to keep your personal information confidential and only the research team will have access to the audio recording from the interview. Your name will not be revealed to further minimize any breach of confidentiality. Forms or recordings will be given a code. Summary results from this study will be reported on clinicaltrials.gov. However, results published for scientific and programming purposes will not contain any identifying information. Your records may be reviewed by representatives of the University of Zambia Biomedical Research Ethics Committee, the University of Maryland Institutional Review Board, the study sponsor (NIH), the U.S. Office for Human Research Protections (OHRP), the Zambian Ministry of Health, or the Office for Human Research Protections.

However, this information will be kept confidential and will only be used to ensure that the study is being conducted properly and that your records are being stored appropriately.

Cost: It will not cost you anything to be in this study but your time.

Reimbursement:
We will reimburse you at K100.00 today, and at the final visit at 6 months.
Questions: If you have any questions, concerns, or complaints about this study, you may contact the Principal Investigator, Dr. Cassidy Claassen, at University of Maryland at Baltimore, 31C Bishops Road, Kabulonga Area, Lusaka, Zambia; Phone: +260 971075439; Email: cclaassen@ihv.umaryland.edu

Questions about participants rights:
If you have questions about your rights as a research participant, you may contact the people listed above. You can also contact the UNZABREC Chairperson for the Institutional Review Board (IRB) and/or the UMB Institutional Review Board:

UNZA Biomedical Research Ethics Committee
Ridgeway Campus, Nationalist Road, Lusaka
Landline Phone: 0211 256 067
Other Phones: 0955 155 633, 0955 155 634
Email: unzarec@zamtel.zm

University of Maryland Baltimore IRB
620 W. Lexington St., 2nd Floor
Baltimore, Maryland, USA 21201
Phone: +1 410 706 5037
Email: hrpo@umaryland.edu

Statement of voluntariness:
You are free to withdraw from the study at any time. You are also free to refuse to answer any questions that make you feel uncomfortable or that you deem private or otherwise. Just let the interviewer know that you prefer not to answer that question. Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in the study. You will not lose any benefits you are otherwise owed. Your choice to leave the study will not affect your access to healthcare now or in the future. You will be given any new information gained during the course of the study that might affect your willingness to continue to take part.

The University of Maryland, Baltimore (UMB) is committed to providing participants in its research studies all rights due to them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in this study. This study has been reviewed and approved by an Institutional Review Board (IRB). The IRB is a group of scientists, physicians, experts, and community representatives. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research studies.

If you have questions, concerns, complaints, or believe you have been harmed through participation in this study as a result of researcher negligence, you can contact members of the IRB or the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland, Baltimore
Institutional Review Board Human Research Protections Office
620 W. Lexington Street, Baltimore, MD 21201
410-706-5037

STATEMENT OF CONSENT

..... has described to me what is going to be done, the risks, the benefits involved and my rights regarding this study. I understand that my decision to participate in this study will not alter my usual medical care. In the use of this information, my identity will be concealed. I am aware that I may withdraw at any time. I understand that by signing this form, I do not waive any of my legal rights but merely indicate that I have been informed about the research study in which I am voluntarily agreeing to participate. A copy of this form will be provided to me.

Name of participant: ……..

Signature of participant: ……..

Date (DD/MM/YY): ……..

Name of witness*: ……..

Signature of witness*: ……..

Date (DD/MM/YY): ……..

Name of study staff member: ……..

Signature of study staff member: ……..

Date (DD/MM/YY): ……..

**Note: Witness name, signature and date are required on this consent form only when the consenting volunteer is not able to read and/or is illiterate*

21. Appendix 8: Information and Consent Forms for Caregivers

THE UNIVERSITY OF ZAMBIA

BIOMEDICAL RESEARCH ETHICS COMMITTEE

Telephone: 256067
Telegrams: UNZA, LUSAKA
Telex: UNZALU ZA 44370
Fax: + 260-1-250753
E-mail: unzarec@unza.zm
Assurance No. FWA00000338
IRB00001131 of IOR G0000774

Ridgeway Campus
P.O. Box 50110
Lusaka, Zambia

IMFORMATION SHEET AND CONSENT FORM FOR CARE GIVERS OF DISCHARGED PATIENTS ENROLLED INTO THE QUALITATIVE STUDY

Title of the proposed study: Re-engagement at Discharge 2: Improving post-hospital outcomes for adult patients in Zambia (ReCharge 2)

Investigators:

Names	Institutions	Contacts of the Investigators
Dr. Cassidy Claassen	University of Maryland at Baltimore (USA) and University of Zambia School of Medicine	cclaassen@ihv.umaryland.edu
Dr. Michael Vinikoor	University of Alabama at Birmingham (USA) and University of Zambia School of Medicine	mjv3@uab.edu

Background and rationale for the study:
Hello. I am _____ and I work with the University of Maryland team in Zambia. I would like to talk to you about an upcoming study that you may be able to help with. This form explains why we are doing this study and what you will be asked to do if you choose to be in this study. We will read this form with you. Please ask any questions you have about this study at any time to fully understand this information so that you can make an informed choice about being in this study.

Many patients hospitalized at referral hospitals in Zambia are hospitalized due to different illness. After being stabilized at the hospital and discharged to go home, some people experience a challenging recovery process, and during this time, the risk of readmission to the hospital and/or death is high. After discharge challenges may come from the need to receive follow-up care at multiple

health facilities, inconsistent or poor support from family, and behavioral health issues like mental illness and alcohol use.

Purpose:
The purpose of this study is to evaluate a new program that may help people after discharge from the hospital. If we learn through this study that the program is beneficial to patients, their families, and health workers, we will recommend that more patients receive it.

You are being asked to be in the study because you are 18 years or older, and you have a relative who was hospitalized and after discharge, they were enrolled into the recharge programme. This relative has identified you as the person who has been supporting them for the past number of months.

Procedures:
If you agree to take part in this study, we'll come to your house for two 30- to 45-minute interviews, which we'd like to record and type up for analysis, if you'll let us. We hope that these two interviews will happen three months into the program and near the end of the programme (around 6 months). If it is okay with you, we would like to have the first interview with you today. If today is not convenient for you, we can reschedule the interview for another day as soon as you are ready. You will advise us when it is ok for us to conduct this interview with you. During these interviews, we will ask you about your experiences with the ReCharge program that has been supporting your relative and what worked and what didn't. These interviews will take place where you feel most comfortable, which could be at home or anywhere else in the neighborhood.

Who will participate in the study?
About 40 people with relatives who were admitted and discharged from LMUTH/UTH.

Risks/Discomforts:
You may feel embarrassed, worried, and/or uncomfortable talking about your opinions and experiences. You do not have to take part in every discussion or answer every question. You do not have to answer any questions you don't want to and you may stop participating at any time. Some of the questions in the interviews could be potentially stressful to answer.

Benefits:
Research is designed to benefit society by gaining new knowledge. You may not receive any direct benefit from being in this research study, but we believe it will help us to provide better treatment around the time of hospitalization.

Alternatives:
You may choose not to take part in this study. Also, you can choose to participate now and decide to stop later at any time. If you choose not to participate in this study, this will not affect how you or your relatives access health services or benefits you receive from this health facility.

Confidentiality:
Every effort will be made to keep your personal information confidential and only the research team will have access to the audio recording from the interview. Your name will not be revealed to further minimize any breach of confidentiality. Forms or recordings will be given a code. Summary results from this study will be reported on clinicaltrials.gov. However, results published for scientific and programming purposes will not contain any identifying information. Your records may be reviewed by representatives of the University of Zambia Biomedical Research Ethics Committee, the University of Maryland Institutional Review Board, the study sponsor (NIH), the U.S. Office for Human Research

Protections (OHRP), the Zambian Ministry of Health, or the Office for Human Research Protections. However, this information will be kept confidential and will only be used to ensure that the study is being conducted properly and that your records are being stored appropriately.

Cost: It will not cost you anything to be in this study but your time.

Reimbursement:
We will reimburse you at K100.00 today, and at the final visit at 6 months.
Questions: If you have any questions, concerns, or complaints about this study, you may contact the Principal Investigator, Dr. Cassidy Claassen, at University of Maryland at Baltimore, 31C Bishops Road, Kabulonga Area, Lusaka, Zambia; Phone: +260 971075439; Email: cclaassen@ihv.umaryland.edu

Questions about participants rights:
If you have questions about your rights as a research participant, you may contact the people listed above. You can also contact the UNZABREC Chairperson for the Institutional Review Board (IRB) and/or the UMB Institutional Review Board:

UNZA Biomedical Research Ethics Committee
Ridgeway Campus, Nationalist Road, Lusaka
Landline Phone: 0211 256 067
Other Phones: 0955 155 633, 0955 155 634
Email: unzarec@unza.zm

University of Maryland Baltimore IRB
620 W. Lexington St., 2nd Floor
Baltimore, Maryland, USA 21201
Phone: +1 410 706 5037
Email: hrpo@umaryland.edu

Statement of voluntariness:
You are free to withdraw from the study at any time. You are also free to refuse to answer any questions that make you feel uncomfortable or that you deem private or otherwise. Just let the interviewer know that you prefer not to answer that question. Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in the study. You will not lose any benefits you are otherwise owed. Your choice to leave the study will not affect your access to healthcare now or in the future. You will be given any new information gained during the course of the study that might affect your willingness to continue to take part.

The University of Maryland, Baltimore (UMB) is committed to providing participants in its research studies all rights due to them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in this study. This study has been reviewed and approved by an Institutional Review Board (IRB). The IRB is a group of scientists, physicians, experts, and community representatives. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research studies.

If you have questions, concerns, complaints, or believe you have been harmed through participation in this study as a result of researcher negligence, you can contact members of the IRB or the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland, Baltimore
Institutional Review Board Human Research Protections Office
620 W. Lexington Street, Baltimore, MD 21201
410-706-5037

STATEMENT OF CONSENT

..... has described to me what is going to be done, the risks, the benefits involved and my rights regarding this study. I understand that my decision to participate in this study will not alter my usual medical care. In the use of this information, my identity will be concealed. I am aware that I may withdraw at any time. I understand that by signing this form, I do not waive any of my legal rights but merely indicate that I have been informed about the research study in which I am voluntarily agreeing to participate. A copy of this form will be provided to me.

Name of participant: ……..

Signature of participant: ……..

Date (DD/MM/YY): ……..

Name of witness*: ……..

Signature of witness*: ……..

Date (DD/MM/YY): ……..

Name of study staff member: ……..

Signature of study staff member: ……..

Date (DD/MM/YY): ……..

**Note: Witness name, signature and date are required on this consent form only when the consenting volunteer is not able to read and/or is illiterate*

22. Appendix 9: Patient Health Questionnaire 9 (PHQ-9): Nyanja

Pa milonga iwiri yapita, kodi ni kangati kamene munavutisidwa ndi yali mavuto aya yokonkapo? **(Chongani mu kabokosi kuti muonese yankho yanu)**		
1	Kukondwera pang'ono kapena kusangalala kung'ono mukuchita zinthu	☐0.Kulibe ngankhale pang'ono ☐1.Masiku angapo ☐2.Kupambana pa hafu ya masiku ☐3.Pafupi-fupi masiku onse
2	Kumvera kuipa, wodidikizidwa mu maganizo, kapena wopanda chiyembekezo	☐0.Kulibe ngankhale pang'ono ☐1.Masiku angapo ☐2.Kupambana pa hafu ya masiku ☐3.Pafupi-fupi masiku onse
3	Kuvutika kugona kapena kusagona, kapena kugona kwambiri	☐0.Kulibe ngankhale pang'ono ☐1.Masiku angapo ☐2.Kupambana pa hafu ya masiku ☐3.Pafupi-fupi masiku onse
4	Kumvera kulema kapena kunkhala ndi mphamvu zing'ono	☐0.Kulibe ngankhale pang'ono ☐1.Masiku angapo ☐2.Kupambana pa hafu ya masiku ☐3.Pafupi-fupi masiku onse
5	Kunkhala ulibe chilakolako chakudya safuna kapena kudya kwambiri	☐0.Kulibe ngankhale pang'ono ☐1.Masiku angapo ☐2.Kupambana pa hafu ya masiku ☐3.Pafupi-fupi masiku onse
6	Kumvera kuipa pa za inu mweka -- kapena kuti munakangiwa kapena munazilekelela kapena kulekelela banja	☐0.Kulibe ngankhale pang'ono ☐1.Masiku angapo ☐2.Kupambana pa hafu ya masiku ☐3.Pafupi-fupi masiku onse
7	Kuvutika kuika maganizo pamodzi pa zinthu, monga kuwerenga nyuzipepa kapena kuonelela TV	☐0.Kulibe ngankhale pang'ono ☐1.Masiku angapo ☐2.Kupambana pa hafu ya masiku ☐3.Pafupi-fupi masiku onse
8	Kuyenda kapena kukamba pang'ono-pang'ono kwambiri Kwamene mwina munaona? Kapena zosiyanako – kunkhala Kusankhazikika kapena kusapumula kuti munali kuyenda-yenda kwambiri kupambana nthawi zonse	☐0.Kulibe ngankhale pang'ono ☐1.Masiku angapo ☐2.Kupambana pa hafu ya masiku ☐3.Pafupi-fupi masiku onse

9	Maganizo yakuti chingankhale bwino kufa kapena Kuzichita mweka mu njira iliyonse	☐ 0.Kulibe ngankhale pang'ono ☐ 1.Masiku angapo ☐ 2.Kupambana pa hafu ya masiku ☐ 3.Pafupi-fupi masiku onse
	Score "Masiku angapo".	
	Score "Kupambana hafu ya masiku":	
	Score "Pafupi-fupi masiku onse":	
	Enter Total Score:	
10	Ngati mwachonga mavuto yali yonse, kodi aya mavuto; Yachipanga bwanji kunkhala chovuta kwa inu kuchita nchito zanu; Kusamalira zinthu pa nyumba kapena kumverana ndi anthu ena? with other	☐ 0.Sichokosa ngankhale pang'ono ☐ 1.Nichokosako ☐ 2.Ni chokosa kwambiri difficult ☐ 3.Nichokosa kwambiri
	Does the hard copy score match the database score?	☐ Yes ☐ No
	If the scores do not match, please comment	_____ _____
	Date form completed: (DD/MM/YYYY)	
	Form Completed by (initials):	

23. Appendix 10: Patient Health Questionnaire 9 (PHQ-9): Bemba

Pa milungu ibili iyapita bushe miku inga iyo mwacushiwapo namafya ayali fyonse ayakonkelepo aya? (Click the circle to indicate your answer)		
1	Ukutemwa ukunono nangu ukusekelamo mukucita ifintu	☐ 0.Awe nelyo panono ☐ 1.Inshiku ishingiko ☐ 2.Ukucila pali hafu ya nshiku ☐ 3.Mupepi na cila bushiku
2	Ukushisansamuka, ukutitikishiwa nangu ukushikwata isubilo	☐ 0.Awe nelyo panono ☐ 1.Inshiku ishingiko ☐ 2.Ukucila pali hafu ya nshiku ☐ 3.Mupepi na cila bushiku
3	Ubwafya bwakulala nangu ukulalisha nangu ukulalisha sana	☐ 0.Awe nelyo panono ☐ 1.Inshiku ishingiko ☐ 2.Ukucila pali hafu ya nshiku ☐ 3.Mupepi na cila bushiku
4	Ukumfwa uwanaka nangu ukukwata amaka ayanono	☐ 0.Awe nelyo panono ☐ 1.Inshiku ishingiko ☐ 2.Ukucila pali hafu ya nshiku ☐ 3.Mupepi na cila bushiku
5	Ukushifwaya ukulya nangu ukulya sana	☐ 0.Awe nelyo panono ☐ 1.Inshiku ishingiko ☐ 2.Ukucila pali hafu ya nshiku ☐ 3.Mupepi na cila bushiku
6	Ukumfwa ububi palwa mwebene mweka – nangu ukuti mwalifilwa nangu mwaliilekelesha nangu mwalilekesha ulupwa	☐ 0.Awe nelyo panono ☐ 1.Inshiku ishingiko ☐ 2.Ukucila pali hafu ya nshiku ☐ 3.Mupepi na cila bushiku
7	Ubwafya bwakubika amaano pa fintu, pamo nga ukubelenga nyunshipepa nangu ukutamba TV	☐ 0.Awe nelyo panono ☐ 1.Inshiku ishingiko ☐ 2.Ukucila pali hafu ya nshiku ☐ 3.Mupepi na cila bushiku
8	Ukwenda nangu ukulanda panono-panono sana icakuti; Bambi kuti baishiba? Nangu ukupilibula – ukuba uushiteka umutima panshi umutima panshi icakuti mwaleenda-enda sana ukucila lyonse	☐ 0.Awe nelyo panono ☐ 1.Inshiku ishingiko ☐ 2.Ukucila pali hafu ya nshiku ☐ 3.Mupepi na cila bushiku
9	Amatontonkanyo ayakuti kuti caba bwino nga mwalifwile nangu ukuicena mwebene munshila imbi	☐ 0.Awe nelyo panono ☐ 1.Inshiku ishingiko ☐ 2.Ukucila pali hafu ya nshiku

		☐ 3.Mupepi na cila bushiku
	Score "Several days"	
	Score "More than half the days"	
	Score "Nearly every day"	
	Enter Total Score:	
10	Nga cakutila mwaconga amafya ayali yonse, bushe aya mafya yalengele ukuba icayafya kuli imwe ukucita imilimo, Ukusakamana ifintu pa ng'anda, nangu ukumfwana nabantu bambi	☐ 0.Sichokosa ngankhale pang'ono ☐ 1.Nichokosako ☐ 2.Ni chokosa kwambiri difficult ☐ 3.Nichokosa kwambiri
	Does the hard copy score match the database score?	☐ Yes ☐ No
	If the scores do not match, please comment	_____ _____
	Date form completed: (DD/MM/YYYY)	
	Form Completed by (initials):	

24. Appendix 11: Patient Health Questionnaire 9 (PHQ-9): English

In the past two weeks, how many times have you been bothered by these problems? (Click the circle to indicate your answer)		
1	A little interest or pleasure in doing things	☐ 0.Not at all ☐ 1.A few days ☐ 2.More than half a day ☐ 3.Almost everyday
2	. Feeling down/bad, depressed, or hopeless	☐ 0.Not at all ☐ 1.A few days ☐ 2.More than half a day ☐ 3.Almost everyday
3	Difficulty falling asleep or staying asleep, or sleeping too much	☐ 0.Not at all ☐ 1.A few days ☐ 2.More than half a day ☐ 3.Almost everyday
4	Feeling tired/weak or having little energy	☐ 0.Not at all ☐ 1.A few days ☐ 2.More than half a day ☐ 3.Almost everyday
5	Poor appetite or overeating	☐ 0.Not at all ☐ 1.A few days ☐ 2.More than half a day ☐ 3.Almost everyday
6	Feeling bad about yourself or that you are a failure or let yourself or your family down	☐ 0.Not at all ☐ 1.A few days ☐ 2.More than half a day ☐ 3.Almost everyday
7	Difficulty/trouble concentrating on things, such as reading or watching TV	☐ 0.Not at all ☐ 1.A few days ☐ 2.More than half a day ☐ 3.Almost everyday
8	Moving or speaking very slowly that other people could have noticed or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	☐ 0.Not at all ☐ 1.A few days ☐ 2.More than half a day ☐ 3.Almost everyday
9	The idea that it would be better to die or to do it yourself in any way	☐ 0.Not at all ☐ 1.A few days ☐ 2.More than half a day

		☐ 3.Almost everyday
	Score "Several days"	
	Score "More than half the days"	
	Score "Nearly every day"	
	Enter Total Score:	
10	If you checked off any problems, how difficult has these problems made it for you to do your job, take care of things at home, or get along with other people?	☐ 0. Not difficult at all ☐ 1. A bit difficult ☐ 2. Difficult ☐ 3. Very difficult
	Does the hard copy score match the database score?	☐ Yes ☐ No
	If the scores do not match, please comment	_____ _____
	Date form completed: (DD/MM/YYYY)	
	Form Completed by (initials):	

25. Appendix 12: English - Modified Alcohol Use Disorders Identification Test-Consumption

Modified Alcohol Use Disorders Identification Test-Consumption (AUDIT-C)					
PART ONE: pre-admission alcohol use					
Questions	0 points	1 point	2 points	3 points	4 points
In the 3 months before you were admitted to the hospital, on average, how often did you have a drink containing alcohol?#	Never	Monthly or less	2-4 times a month	2-3 times a week	4+ times a week
When you were drinking alcohol, on average, how many drinks did you have?*	0-2	3-4	5-6	7-9	10 or more
When you were drinking alcohol, on average, how often did you have 6 or more drinks* in one day?	0	Less than monthly	Monthly	Weekly	Daily or almost daily
PART TWO: post-discharge alcohol use					
Questions	0 points	1 point	2 points	3 points	4 points
Since discharge, on average, how often have you had a drink containing alcohol?	Never	Monthly or less	2-4 times a month	2-3 times a week	4+ times a week
When to refer for counseling for unhealthy alcohol use: • Score of 3 or more pre-admission and 2 or more post-discharge • Score of 3 or more post-discharge, regardless of pre-admission score					

Footnotes:
#If the person reports never drinking (i.e., abstinence), leave next two blank (skip them)
*Standard drink units can be determined as follows:

- 1 **lager** (12-ounce bottle, Mosi/Castle, 3% alcohol) = 1 unit
- 1 glass of **wine** (5-ounce, 10% alcohol) = 1 unit
- 1 container of **opaque beer** (1-liter, Chibuku Shake Shake, etc., 4% alcohol) = 4 units
- 1 bottle of **spirits** including gin, vodka, 'junta', 'twojilijili' (200 ml bottle; 40% alcohol) = 8 units
- 1 bottle of **Cachasu** (200 ml bottle; >40% alcohol) = 10 units

26. Appendix 13: Nyanja - Modified Alcohol Use Disorders Identification Test-Consumption

Kuyesa Kugwiritsa Ntchito Mowa Wosinthidwa (AUDIT-C) *(Modified* Alcohol Use Disorders Identification Test-Consumption (AUDIT-C))					
GAWO LOYAMBA: kumwa mowa musanalowe					
Mafunso	0 points	1 point	2 points	3 points	4 points
M'miyezi itatu musanalowe m'chipatala, pafupifupi, ni kangati pomwe mumamwa chili conse comwe kuli mowa?	Ayi	Mwezi uliwonse kapena kuchepera	2-4 pa mwezi	2-3 pa sabata	4+ pa sabata
Mwenze kumwa mabotolo angati ya mowa ngati muli pa tsiku lakumwa mowa?	0-2	3-4	5-6	7-9	10 kapena kuposa
Ndi nthawi ziti zimene mumwa zakumwa zofikira mabotolo yali 6 kapena zopitilila pa nthawi imodzi?	Ayi	Pasanathe mwezi uliwonse	Mwezi uliwonse	Mlungu uliwonse	Tsiku lililonse kapena pafupifupi tsiku lililonse
GAWO LACHIWIRI: kumwa mowa mutasiya					
Mafunso	0 points	1 point	2 points	3 points	4 points
Kuyambira kumasulidwa, ni kangati pomwe mumamwa chili conse comwe kuli mowa?	Ayi	Mwezi uliwonse kapena kuchepera	2-4 pa mwezi	2-3 pa sabata	4+ pa sabata

Nthawi yolozera upangiri wogwiritsa ntchito mowa mosayenera:

- Zigoli za 3 kapena kupitilira apo alowetsedwa kale ndi 2 kapena kupitilira apo atasiya
- Zigoli zitatu kapena kupitilira apo mutangotulutsidwa, posatengera kuti munalandira bwanji

Mawu a M'munsi:
#Ngati munthuyo anena kuti samamwa (mwachitsanzo, kudziletsa), siyani ziwiri zotsatirazi (zidumphani) Zakumwa zokhazikika zitha kuzindikirika motere:

- 1 lager (botolo la 12-ounce, Mosi / Castle, 3% mowa) = 1 unit
- 1 galasi la vinyo (5-ounce, 10% mowa) = 1 unit
- Chidebe chimodzi cha mowa wosawoneka bwino (1-lita, Chibuku Shake Shake, etc., 4% mowa) = mayunitsi 4
- Botolo limodzi la mizimu kuphatikizapo gin, vodka, 'junta', 'twojilijili' (botolo la 200 ml; 40% mowa) = mayunitsi 8
- 1 botolo la Cachasu (200 ml botolo;> 40% mowa) = mayunitsi 10

27. Appendix 14: Bemba - Modified Alcohol Use Disorders Identification Test-Consumption

Modified Alcohol Use Disorders Identification Test-Consumption (AUDIT-C)					
PART ONE: pre-admission alcohol use					
Questions	0 points	1 point	2 points	3 points	4 points
Mu myeshi shitatu lintu tabalami teka mu chipatala, miku inga mumona ukuti mwina mwenu alenwo bwalwa?	Never	Monthly or less	2-4 times a month	2-3 times a week	4+ times a week
Umwina mwenu, nga cakuti lelo alenwa, miku inga alenwa ifikali ifya bwalwa?	0-2	3-4	5-6	7-9	10 or more
Miku inga mumwene umwina mwenu alenwa imiku 6 no kuya pantanshi mu kulongana kumo kwine?	0	Less than monthly	Monthly	Weekly	Daily or almost daily
PART TWO: post-discharge alcohol use					
Questions	0 points	1 point	2 points	3 points	4 points
Ukufuma epo mwafumine mu chipatala, miku inga mumona ukuti mwina mwenu alenwo bwalwa?	Never	Monthly or less	2-4 times a month	2-3 times a week	4+ times a week

When to refer for counseling for unhealthy alcohol use:

- Score of 3 or more pre-admission and 2 or more post-discharge
- Score of 3 or more post-discharge, regardless of pre-admission score

Footnotes:

#If the person reports never drinking (i.e., abstinence), leave next two blank (skip them)

*Standard drink units can be determined as follows:

- 1 **lager** (12-ounce bottle, Mosi/Castle, 3% alcohol) = 1 unit
- 1 glass of **wine** (5-ounce, 10% alcohol) = 1 unit
- 1 container of **opaque beer** (1-liter, Chibuku Shake Shake, etc., 4% alcohol) = 4 units
- 1 bottle of **spirits** including gin, vodka, 'junta', 'twojilijili' (200 ml bottle; 40% alcohol) = 8 units
- 1 bottle of **Cachasu** (200 ml bottle; >40% alcohol) = 10 units

28. Appendix 15: Letter of Permission to Conduct Research at UTH

REPUBLIC OF ZAMBIA
MINISTRY OF HEALTH
University Teaching Hospitals (Adult)

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DIRECTOR CLINICAL CARE AND DIAGNOSTIC SERVICES

Our Ref:

Your Ref:

5th November, 2020

Dr. Cassidy Claassen
The University of Maryland
School of Medicine
LUSAKA

Dear Sir

RE: REQUEST FOR AUTHORITY TO CONDUCT RESEARCH

Reference is made to your letter dated 29th October, 2020.

I wish to inform you that permission has been granted to you to conduct research entitled **"Qualitative study on barriers and facilitators to health care engagement following hospitalization among patients with HIV at the University Teaching Hospitals, in Lusaka".**

You are advised to liaise with the Head of Department.

Yours faithfully

Dr. Charles Mutemba
Head Clinical Care
UNIVERSITY TEACHING HOSPITALS-ADULT HOSPITAL

Cc: The Head of Department