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Integrated community-based HIV and non-communicable disease care within microfinance groups in Kenya: study protocol for the Harambee cluster randomised trial

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ABSTRACT

Introduction In Kenya, distance to health facilities, inefficient vertical care delivery and limited financial means are barriers to retention in HIV care. Furthermore, the increasing burden of non-communicable diseases (NCDs) among people living with HIV complicates chronic disease treatment and strains traditional care delivery models. Potential strategies for improving HIV/NCD treatment outcomes are differentiated care, community-based care and microfinance (MF).

Methods and analysis We will use a cluster randomised trial to evaluate integrated community-based (ICB) care incorporated into MF groups in medium and high HIV prevalence areas in western Kenya. We will conduct baseline assessments with n=900 HIV positive members of 40 existing MF groups. Group clusters will be randomised to receive either (1) ICB or (2) standard of care (SOC). The ICB intervention will include: (1) clinical care visits during MF group meetings inclusive of medical consultations, NCD management, distribution of antiretroviral therapy (ART) and NCD medications, and point-of-care laboratory testing; (2) peer support for ART adherence and (3) facility referrals as needed. MF groups randomised to SOC will receive regularly scheduled care at a health facility. Findings from the two trial arms will be compared with follow-up data from n=300 matched controls. The primary outcome will be VS at 18 months. Secondary outcomes will be retention in care, absolute mean change in systolic blood pressure and absolute mean change in HbA1c level at 18 months. We will use mediation analysis to evaluate mechanisms through which MF and ICB care impact outcomes and analyse incremental cost-effectiveness of the intervention in terms of cost per HIV suppressed person-time, cost per patient retained in care and cost per disability-adjusted life-year saved.

Ethics and dissemination The Moi University Institutional Research and Ethics Committee approved this study (IREC#0003054). We will share data via the Brown University Digital Repository and disseminate findings via publication.

Trial registration number NCT04417127.

Strengths and limitations of this study

- First randomised controlled trial (RCT) to evaluate the impact of integrating HIV/non-communicable diseases care within group microfinance on viral suppression and retention in care.
- The cluster randomised design allows the effect of integrated community-based care to be differentiated from that of group microfinance and standard of care.
- The study will enrol patients regardless of viral suppression status, thereby reaching some of the highest-risk populations who are often excluded from other differentiated care models.
- The exclusion of HIV-negative participants limits the generalisability of study findings to groups that may otherwise benefit from community-based care and microfinance but protects the privacy and confidentiality of people living with HIV.

INTRODUCTION

Despite considerable advances in expanding access to antiretroviral therapy (ART) in sub-Saharan Africa (SSA) over the past decade, retention in HIV care remains suboptimal: only half of people living with HIV (PLHIV) in SSA are virally suppressed.[1–3] In western Kenya, the primary barriers to retention in HIV care are distance to health facilities, inefficient vertical care delivery and limited means for accessing transportation and food.[4–6] Access barriers are heightened in remote locations where travel is restricted and transportation fees are prohibitively high relative to income.[7] Such barriers lead to gaps in ART adherence and eventual unsuppressed viral load (VL), which allows for disease progression and greater risk of transmission.[8] The

growing burden of non-communicable diseases (NCDs) among PLHIV[9–12] further complicates chronic disease treatment (including ART adherence) for HIV care systems with limited resources.

Differentiated care aims to provide client-centred services that encourage ART adherence and engagement in care while maximising efficiency.[13–16] As health systems implement the WHO 2015 recommendations to 'treat all' with ART,[17] differentiated care models alleviate burden on already-strained health systems expanding to enrol new patients on ART, and bolster adherence for those already in care. In South Africa, community-based ART adherence clubs with quarterly group care for symptom checks and medication refills have increased retention and viral suppression (VS) while decongesting facilities.[18 19] In Kenya, medication adherence clubs[20 21] simultaneously provide HIV, diabetes and hypertensive medications to patients in the community, thereby addressing the increasing burden of NCDs among PLHIV in the community.[9–11] Though promising, the effectiveness of differentiated care models on clinical outcomes has not yet been evaluated in a randomised trial.

The true impact of differentiated and community-based care will hinge on the ability of these models to self-sustain. Microfinance (MF) has shown to be effective for improving economic outcomes for over 170 million poor people worldwide, and provides unparalleled opportunities for delivering health-related services to hard-to-reach populations.[22] MF can address barriers related to economic insecurity through increased income and savings. Delivering health services within MF groups addresses barriers of geographic accessibility and availability,[23] demonstrating improvements in care-seeking behaviours in multiple contexts.[23–26] However, delivering health services within the context of group-based MF has yet to be extended to HIV care.

AIMS

The objective of this study is to address the challenge of improving HIV and NCD outcomes among PLHIV in rural, low-resource settings. The central hypothesis is that integrating HIV and community-based NCD care with group-based MF will improve VS and retention among PLHIV in Kenya via two mechanisms: improved household economic status and easier access to care. Harambee (Kiswahili for 'pulling resources together') is based on strong feasibility and acceptability evidence of community-based care with group MF for NCDs in Kenya.[27 28] Thus, the aims of the Harambee study are:

1. Evaluate the extent to which integrated community-based HIV care with group MF affects versus and retention in care among PLHIV in rural western Kenya by randomising existing MF groups to receive either: (A) integrated community-based HIV and NCD care, or (B) standard of care (SOC). We will augment trial data with medical record and active follow-up data from matched controls who are not involved in MF and receiving standard care (C), comparing outcomes in groups A, B and C.
2. Identify the specific mechanisms through which MF and integrated community-based (ICB) care impact versus using a mixed-methods approach. We will conduct quantitative mediation analysis to examine two main mediating pathways (household economic conditions and easier access to care), as well as exploratory mechanisms (food security, social support, HIV-related stigma). We will use qualitative methods and multistakeholder panels to contextualise implementation of the intervention.
3. Estimate the cost-effectiveness of the intervention relative to SOC with and without MF in terms of (1) cost per HIV suppressed person-time, (2) cost per patient retained in HIV/NCD care and (3) cost per disability-adjusted life-year (DALY) saved.

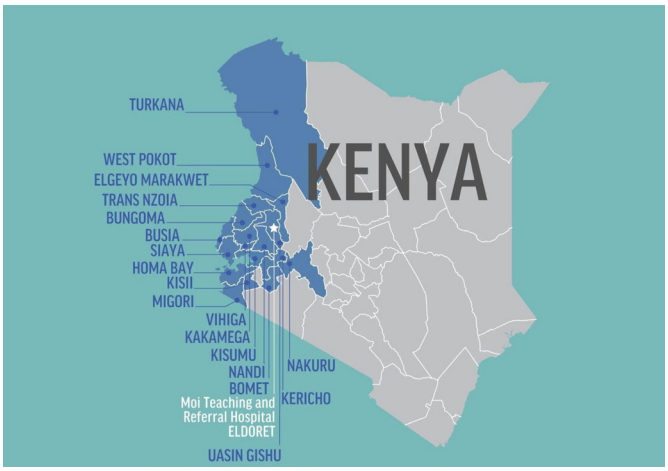

Figure 1 AMPATH catchment area. Harambee study activities will be conducted in Busia county and Trans Nzoia county.

METHODS AND ANALYSIS

Setting

The Academic Model Providing Access to Healthcare (AMPATH) programme is an academic global health partnership between Moi Teaching and Referral Hospital, Moi University, and a consortium of North American universities led by Indiana University.[29 30] Since 2001, AMPATH has grown to provide care to over 165 000 PLHIV across more than 800 clinical sites in western Kenya (figure 1). AMPATH's HIV clinical care protocols follow WHO[31] and Kenyan National AIDS and STI Control Programme guidelines,[32] and entail routine 12-month VL monitoring with more intensive monitoring for unsuppressed patients. Patient data are managed via AMPATH's electronic medical record system (AMRS). In response to the growing burden of diabetes and hypertension, AMPATH formed a Chronic Disease Management (CDM) programme in partnership with the Government of Kenya and local communities.[33] The CDM programme has a robust diabetes and hypertension

management protocol (online supplemental appendix 1) and uses medicines contained in the Kenyan national formulary.[34] AMPATH also runs the Group Integrated Savings for Empowerment (GISE) programme to support income-generating opportunities. The GISE programme follows the Village-Level Savings and Loan Associations model[35 36] to create community-led savings groups. MF group members mobilise and manage their own savings, provide interest-bearing loans to group members, and contribute to a social fund for use in cases of emergency and group welfare issues. More than 6484 HIV-positive AMPATH patients currently participate in GISE.

The present study will be conducted in two counties: Busia and Trans Nzoia. Each county has rural health facilities staffed by physicians, advanced practice practitioners and nurses, while community health workers provide health promotion and disease prevention education in the community. There is a long-standing relationship between AMPATH's HIV, CDM and GISE programmes and the local county healthcare providers and communities.

In Kenya's rural areas, prevalence of hypertension and diabetes mellitus among adults ages 15–64 years is estimated to be 24.7% (95% CI 22.3% to 27.2%)[37] and 1.9% (95% CI 1.3% to 2.5%),[38] respectively. In the counties targeted for study implementation, HIV prevalence in adults is 9.9% in Busia and 4.0% in Trans Nzoia, compared with 4.9% nationally.[39] In both counties, over 90% of adults living with HIV are virally suppressed (VL ≤400 copies/mL).[40]

Conceptual framework

Our research is guided by the Andersen behavioural model of health utilisation and elements of the socioecological model which emphasise the multilevel determinants of retention, ART adherence and VS (figure 2).[41 42] The interwoven relationship between individual characteristics and household and healthcare environments work together to impact health outcomes, including retention in HIV care and VS.[43] It is possible that the intervention will improve retention in care and VS through direct care delivery or through other mediating pathways such as improved household economic conditions, easier access to care, increased social support and reduced HIV-related stigma. Our study will examine the effect of improving the household socioeconomic environment via MF, and the interacting aspects of individual and healthcare environments with community-based care in MF groups.

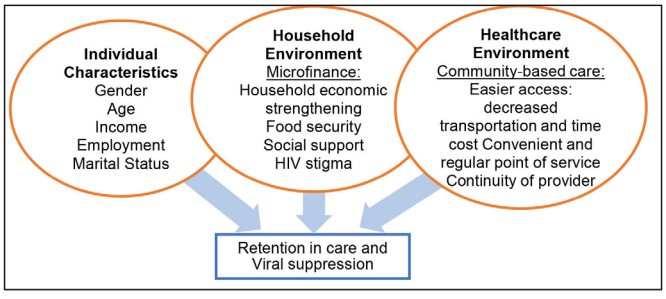

Figure 2 Conceptual framework.

Community mobilisation and baseline assessments

Research personnel and AMPATH outreach staff will conduct initial community mobilisation meetings with MF group leaders. Leaders will in turn inform their members about the study and randomisation process.

MF group members who meet all eligibility criteria (described below) and agree to participate will complete baseline assessments during the first MF group meeting following study start. At baseline, participants will complete informed consent procedures, provide a blood draw for HIV VL testing and complete survey assessments. Surveys will assess the following constructs: household economic status (Demographic & Health Survey, DHS, Wealth Index),[44] food security (Household Food Insecurity Access Scale),[45] barriers to accessing HIV care,[46] social support (Oslo Social Support Scale),[47] internalised HIV stigma,[48] quality of life (adapted MOS-HIV),[49 50] and the Patient Health Questionnaire-2 (PHQ-2),[51] medication adherence (adapted AIDS Clinical Trial Group adherence[52] and Voils DOSE-Nonadherence[53] questionnaire), and patient-reported satisfaction with care.[54] Biological specimens will be processed in AMPATH's research and clinically certified labs. Participants will also consent to have their AMRS data accessed for secondary outcome analysis.

We will recruit as many MF group members as possible and provide the intervention when more than half of the group members consent to participate. We will compare the distribution of cluster-specific rates of consent between treatment arms and, if necessary, adjust for cluster-specific consent rates during statistical analysis. Group members who do not wish to participate will not be excluded from any MF activities.

Cluster randomised trial

We will conduct a two-arm cluster randomised trial, with a matched group of SOC only participants, comparing MF+ICB to MF+SOC to SOC (figure 3).

Randomisation will occur at the level of MF group clusters and be stratified by county to achieve balance across geography and level of pre-existing MF participation. Group cluster randomisation will occur after all consenting participants complete baseline assessments using a computer-generated sequence to randomise MF groups to receive either ICB care or standard care. Randomisation will be conducted centrally by biostatisticians at Brown University.

Study participants

This trial will enrol 1200 participants. Forty existing MF groups with 900 participants will be randomised to receive either the ICB intervention (MF+ICB) or SOC (MF+SOC). We will compare results from the two trial arms to AMRS and active follow-up data from 300 matched patients who are receiving SOC without MF (SOC).

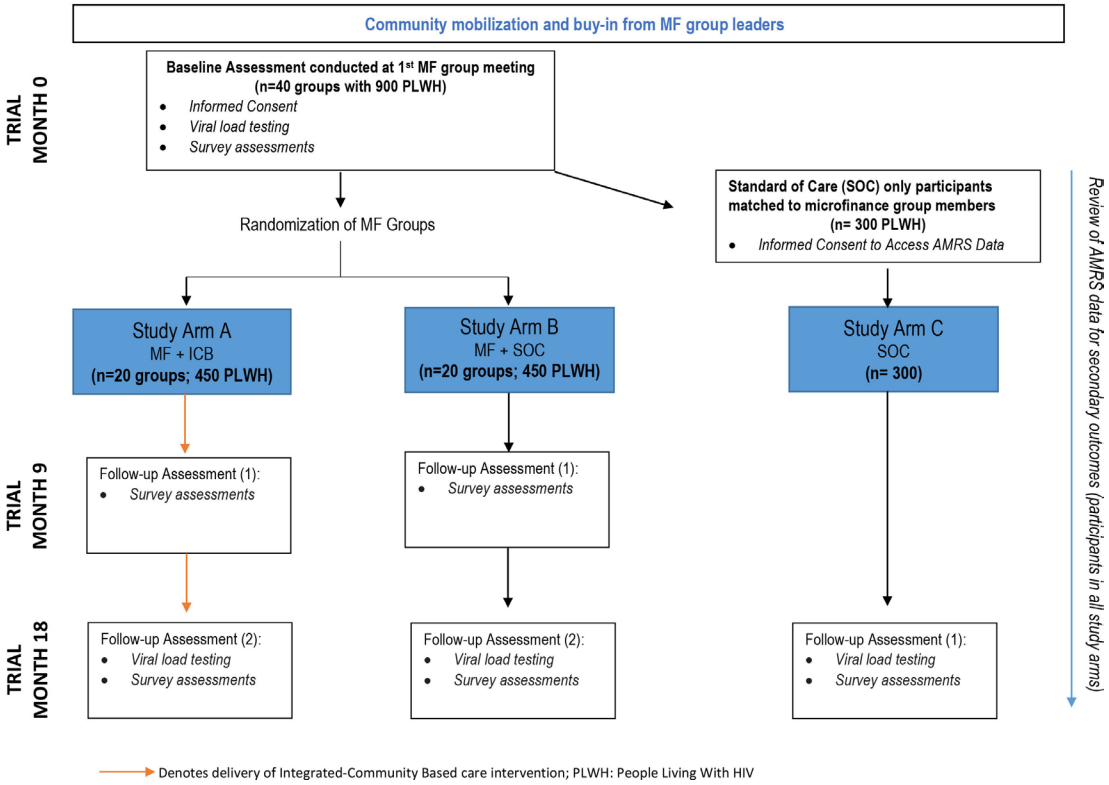

Figure 3 Cluster randomised trial design. ICB, integrated community-based care; MF, microfinance.

A MF group will be eligible for study participation if it meets the following criteria: is an active AMPATH GISE group that was formed at least 6 months prior to study baseline and is consistently meeting and engaging in saving and lending; and is an AMPATH GISE group with a majority of group members who are AMPATH HIV patients who have disclosed their HIV status. Non-AMPATH MF groups and AMPATH Community ART Groups (CARGs) will not be eligible for study inclusion.

Members of eligible MF groups will be invited to participate if they meet the following criteria: at least 18 years of age at study baseline; HIV-positive; have ever received HIV-related care through AMPATH after 2010; initiated ART at least 6 months prior to study baseline; are consistently attending GISE group meetings within the last 6 months and actively engaging in saving and lending; have an AMPATH Medical Record System (AMRS) ID; and are willing and able to provide informed consent. MF group members who participate in an AMPATH CARG or the Bridging Income Generation with Group Integrated Care (BIGPIC) study[28] will not be eligible for study inclusion. During the enrolment visit, research assistants will review eligibility criteria and study procedures and provide sufficient time for MF group members to ask questions. Individuals will provide voluntary written informed consent for study participation (online supplemental appendix 2). Study participation will not be restricted to stable (ie, virally suppressed) patients.

Intervention and control

Microfinance (MF) with Integrated Community-Based (ICB) Care

ICB care will be delivered in intervention groups at monthly MF meetings by a clinical team comprised of the same cadre of workers who deliver care in AMPATH-supported facilities (clinical officer, pharmacy technician, peer navigator, social worker). The intervention will include the following components: (1) integrated care visits by a clinical team occurring monthly during trial months 1–6, and then quarterly for trial months 7–18, which include clinical evaluation, consultation with a clinical officer, medication distribution (ART and other chronic and acute medications), and point-of-care laboratory testing (creatinine, blood glucose, haemoglobin A1C (HbA1c) and VL as it becomes available); (2) peer support for promoting ART adherence during every MF meeting and (3) referrals to facilities for emergency or acute care needs that are not feasible to address in the community.

Care teams will review AMRS to coordinate care delivery with participants' needs at the time of study visits. All patients will have had VL monitoring as part of standard care. Initial intervention group visits (trial months 1–6) will focus on non-HIV-related needs and screening for NCDs. Facilities will be informed that participants will be receiving HIV care outside of clinic for the duration of the study, unless emergency or acute care is required. We will follow AMPATH's established care protocols for handling new opportunistic infections, suspected viral resistance, malignancy screening and diagnosis. These protocols are available via AMPATH's Clinical Protocols

and Standard Operating Procedures directory: https://wiki.ampath.or.ke/display/ACPS.

At each MF group meeting, participants will undergo routine triage and screening and receive health education in a group setting. Each participant will meet with a clinical officer in a privacy tent to review symptoms, ask questions and receive referrals as needed. Participants will receive prescriptions for ART and other medications which will be dispensed by a pharmaceutical technician. Peer navigators and social workers will be available to provide counselling or facilitate referrals.

Microfinance (MF) with Standard of Care (SOC)

An attention-matched control design is inherent in this study. MF groups randomised to receive SOC will meet as usual in their MF groups and continue to receive regular care from an AMPATH-supported rural health facility.

Standard of care

This will be the current SOC delivered by the AMPATH HIV and CDM programmes, in accordance with standard operating procedures for HIV care, diabetes, and hypertension. SOC participants are not involved in MF and will continue to receive regular care from an AMPATH-supported health facility. SOC patients will be invited to enrol as they attend regular HIV care visits and provide voluntary written informed consent for study participation (online supplemental appendix 2).

Data collection

We will conduct assessments for primary and secondary outcomes in all three trial arms at 18 months. This will include VL testing and administration of survey assessments. For intermediary outcomes analysis (aim 2), we will conduct one additional data collection round at 9 months in the two trial arms. For participants who do not attend MF meetings during assessment time points, we will use their contact information to schedule follow-up data collection outside of regular MF meetings.

Clinical data will be collected in the field during intervention visits by clinical officers using mobile tablets with secure data encryption and cloud-based data capture. These tablets are the same devices being used by clinicians delivering care within AMPATH facilities. All clinical encounter forms are currently supported in the field and uploaded to the main AMRS server. Data collected as part of care delivered during the intervention will become part of the patient's electronic medical record. AMRS data will be reviewed for secondary outcomes on an ongoing basis for all study participants.

Outcomes

The primary outcome measure will be VS at 18 months. Secondary outcome measures will be (1) retention in care at 18 months, defined as the proportion of scheduled visits attended during the study period; (2) 18-month absolute mean change in systolic blood pressure (SBP) and (3) 18-month absolute mean change in HbA1c level. Mean changes in SBP and HbA1c level have shown to be associated with longer-term cardiovascular benefit,[27 55–58] even when traditional control thresholds are not met.

Analytical approach

As participants will not be randomised to the SOC arm, we will match individuals from the SOC and the two intervention arms on gender and age using coarsened exact matching.[59 60] After all data are collected, we will check statistical balance of pre-exposure covariates. If substantial differences are seen, we will use causal inference methods to account for those differences (eg, g-computation or doubly robust methods). We have successfully used these and other quasi-experimental methods in Kenya and elsewhere[61 62] to analyse the impact of economic-based interventions on health outcomes.[63–66]

The primary analysis of interest is comparing VS at 18 months between the MF+ICB and MF+SOC arms. As a secondary hypothesis, we will test MF+ICB vs SOC alone and MF+SOC vs SOC alone. We will use a generalised mixed effects model to test the primary and the secondary hypotheses.[67] For the primary outcome, the model we will use is:

$$logit(P(Y_{ij} = 1 | I_j, S_j, VB_{ij}, C_j)) = \beta_0 + \beta_1 I_j + \beta_2 S_j + \beta_3 VB_{ij} + C_j$$

where, Y_{ij} is VS at 18 months for participant i in cluster j, I_j is the indicator if cluster j is randomised to the MF+ICB arm, S_j is an indicator if cluster j comes from the SOC individuals, VB_{ij} is the baseline VL for participant i in cluster j, and c_j is the random effect associated with cluster j. The estimator β_1 estimates the difference between the MF+SOC and MF+ICB arms and positive values indicate higher VS in the MF+ICB arm. To test the primary hypothesis, we will perform a hypothesis test for H0: $\beta_1=0$. To test the secondary hypothesis we will perform a hypothesis test for H_0: $\beta_2=0$ and H_0: $\beta_1 - \beta_2=0$.

For secondary outcomes, we will modify the above model to reflect that retention in care is a proportion and that the absolute mean change in SBP and HbA1c level is a continuous outcome. Dropout from the study will be handled using inverse probability weighting.[68 69] The design, analysis and interpretation of trial results will follow the Consolidated Standards of Reporting Trials (CONSORT) statement on cluster randomised trials.[70] All data will be deidentified prior to analysis.

Power calculation

Forty existing MF group clusters with 900 PLHIV will be randomised in a 1:1 ratio to either MF +ICB or MF +SOC. For the power calculations, the SD of the group size was set to 5, type-1 error rate to 0.05, and the intraclass correlation coefficient to 0.05. Based on studies of the effect of financial interventions we expect at least 15% increase in VS between MF+ICB and MF+SOC, MF+SOC and SOC only, and MF+ICB and SOC only groups.[18 71] The power calculations used VS in MF+SOC ranging from 20% to 50% and accounted for 15% drop-out.[28] For all the different scenarios considered, the power to detect a 15% increase in VS was greater than 80% for testing all three hypotheses.

Mediation analysis

We will conduct quantitative and qualitative mediation analyses to examine the mechanisms by which MF and community-based care operate on VS and retention in HIV care.

Quantitative mediation analysis

We will use causal mediation analysis to evaluate the importance of causal pathways between MF with ICB care and VS and retention.[72] We will use survey assessments[44–46 48–50 54 73] collected at baseline, 9-month and 18-month follow-up visits. The primary analysis will focus on two mediators: household economic conditions[44 45] and access to care.[46] We will estimate the mediation effect of each mediator separately using the difference method and account for multiple comparisons using a Bonferroni correction. The generalised linear models needed to implement the difference method will adjust for key confounders such as education, location, gender and age. We will perform a sensitivity analysis of the assumption of no unmeasured mediator-outcome confounders.[74] Secondary analyses will estimate the mediation effect of food security, social support and HIV-related stigma.

Qualitative mediation analysis

We will conduct qualitative in-depth interviews (IDIs) with 40 MF group participants (n=20 from each trial arm). Participants who participated in at least 2 MF group meetings during the trial will be purposively sampled after completing the 18-month assessment. Semistructured interviews will take place in a private and quiet location to assess the following domains: (1) Experiences related to MF groups; (2) Barriers/facilitators to accessing HIV care, including household economic conditions, food security, geography, social support and HIV-related stigma; (3) How participation in MF and/or community-based care impacts retention in care and ART adherence; (4) Satisfaction with HIV care delivery in the community or facility and (5) Suggested improvements for care delivery models.

Text from the IDIs with trial participants will be coded into a hierarchical, branching structure in which broad concepts are first identified along the domains identified in the interview guides and our conceptual model. Participant's coded data will be compared with identify mechanisms through which MF and community-based care impacted retention in HIV care and ART adherence, and the additive impact of the community-based care delivery in the intervention group.

We will additionally conduct IDIs with 10 staff who delivered the intervention (eg, clinical officers, pharmacy technicians, social workers) to assess domains related to job satisfaction, challenges to delivering community-based HIV/NCD care and context-specific issues with delivering care in this setting. We will analyse qualitative data from clinical staff to identify implementation challenges that would help explain the main study findings and allow for translation of the ICB care model to AMPATH's broader catchment area.

We will triangulate findings from the mediation analyses with trial results to explain the potential mechanisms of action and provide contextual evidence for scaling up and translating the ICB care intervention in future settings.

Cost-effectiveness analysis

We will compare the two trial arms and matched controls using three closely linked analyses: (1) cost per HIV suppressed person-time, (2) cost per patient retained in HIV/NCD care and (3) cost per DALY saved.

For each intervention arm, we will estimate costs from the provider, patient, and government perspective using validated cost-tracking methods that capture all costs required for intervention delivery, as well as cost offsets that may result from improved health. First, we will take the perspective of AMPATH as a care provider. Total costs will represent the sum of fixed and variable costs. Per-patient variable costs will be calculated by multiplying the number of units of each good or service used by the unit cost. ART costs will be obtained from AMPATH/PEPFAR suppliers in Kenya. Unit costs for non-ART drugs will be estimated from invoices and key informant interviews. Clinical care unit costs will be estimated by multiplying the time of the clinical interaction (from time motion logs) by staff salaries. Fixed costs will be allocated to participants proportionally and include those incurred by the project not directly attributable to participants (eg, maintenance, utilities, testing equipment). Capital costs will be discounted at a rate of 7% per year to account for depreciation. Second, we will consider costs from the patient's point of view, which will include time and transport costs to the place where care is administered. Third, we will perform a potential cost-saving estimation from a government perspective where financial outlays are compared into the future to gauge the extent to which the proposed intervention can be financially self-sustained.

Once costs and effectiveness are calculated for each intervention arm, we will generate incremental cost-effectiveness ratios (ICERs) from each costing perspective.[75] We will examine whether ICERs are affected by changes in model parameters by performing one-way (and n-way) sensitivity analyses in which we examine the effect of changing one (or n) of the model parameters, holding all other parameters constant. In addition, we will conduct threshold analysis whereby we will point out the values at which the intervention options may no longer be cost-effective; we will use a probabilistic uncertainty analysis for the variables that have an underlying probability distribution.[76] We will additionally estimate return on investment using a cost–utility approach that we have successfully used for HIV testing[77] and can be adopted for HIV treatment retention interventions.[78]

LIMITATIONS

There are potential limitations to our study design. First, we expect to encounter difficulties prospectively following SOC participants over 18 months of the trial, due to logistical constraints of contacting these patients in the community. To pre-emptively address these difficulties, each SOC observation will be associated with a list of four ordered backup participants that will be used in instances when the original SOC participant cannot be located. Backup participants will be selected using AMRS such that they have the same age and gender as the original SOC participant. If exact matching for ordered backups is not possible, we will ensure gender is identical for all backups and then select each backup whose age is closest to the original SOC participant. Second, we may have some differential dropout and missing data because blinding of study participants and personnel is not possible due to the nature of the community-based intervention. Thus, our investigative team includes seasoned statisticians who are experienced in applying inverse probability weighting methods to address missing data, which will help ensure that analytical objectives are met. Finally, other differentiated care models are already being implemented by lay health workers across SSA exclusively among stable patients.[13] However, we expect that the Harambee ICB model will be able to provide care for unsuppressed patients because of the involvement of a clinical physician rather than reliance on ommunity health workers and/or peer navigators.

Despite these limitations, the Harambee study offers an innovate, culturally relevant, and potentially cost-effective approach to address the growing burden of NCDs among PLHIV in SSA. Evidence from this study will inform the delivery of ICB care to improve outcomes among PLHIV in similar settings.

TRIAL STATUS

For the cluster randomised trial portion of the study (aim 1), participant enrolment and baseline data collection began in November 2020 and is currently ongoing. Qualitative data collection and cost-effectiveness analyses have not yet begun. We anticipate that results from the trial will be available in 2023.

ETHICS AND DISSEMINATION

This protocol (V.1.0) has been approved the Moi University/Moi Teaching and Referral Hospital Institutional Research and Ethics Committee (IREC Approval # 0003054) and Brown University (IAA#18–90). Any changes made to this protocol will be reviewed and approved by the Moi University/Moi Teaching and Referral Hospital Institutional Research and Ethics Committee prior to implementation. The trial will be conducted in compliance with this study protocol and IREC-approved Data and Safety Monitoring Plan, as well as the Declaration of Helsinki and Good Clinical Practice. Results from this study will be reported in accordance with the CONSORT statement for cluster randomised trials.[70]

A manuscript with the results of the cluster randomised trial study will be published in a peer-reviewed journal. Separate manuscripts will be written for each of the secondary aims, and these will also be submitted for publication in peer-reviewed journals.

On completion of the trial, and after publication of the primary manuscript, data requests can be submitted to investigators at Brown University School of Public Health, USA.

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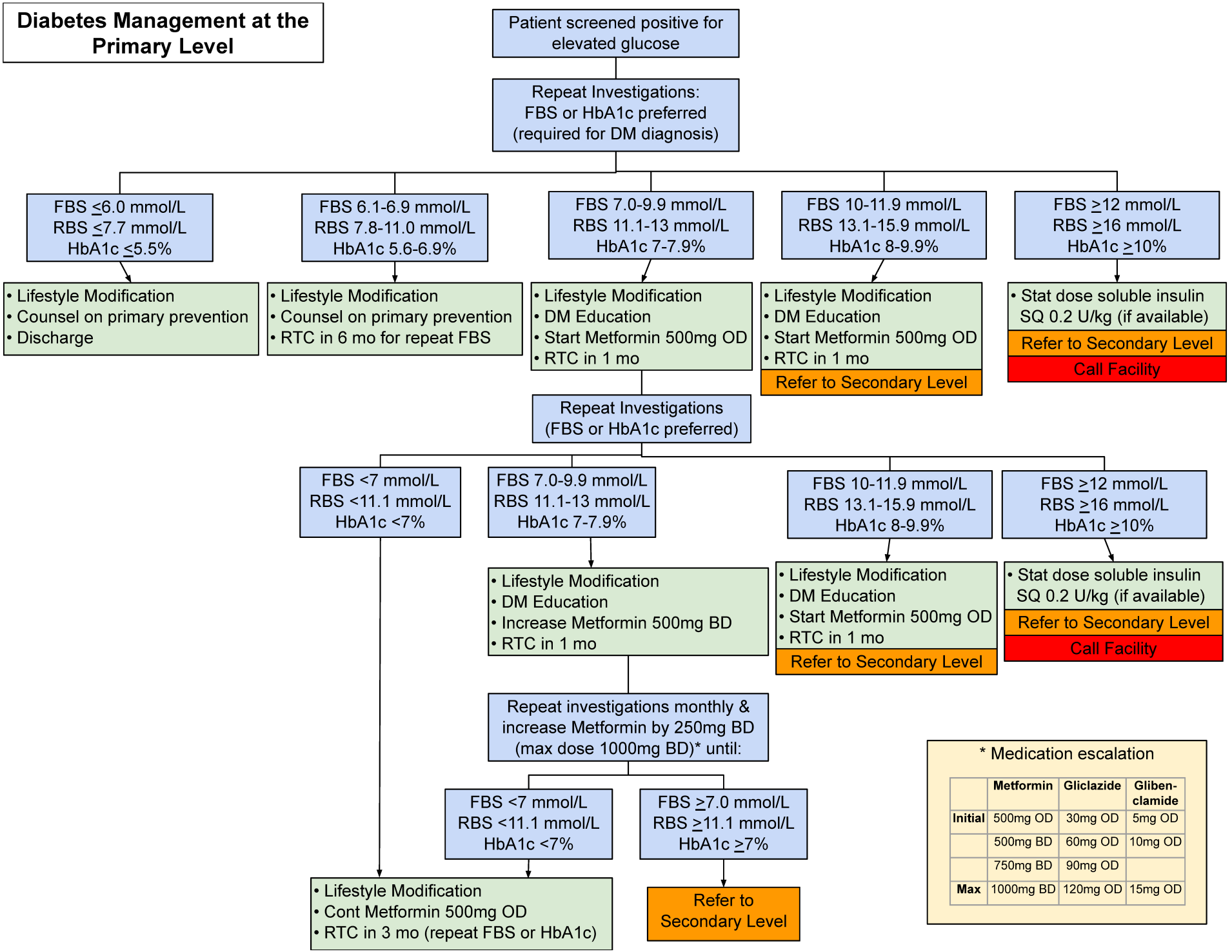
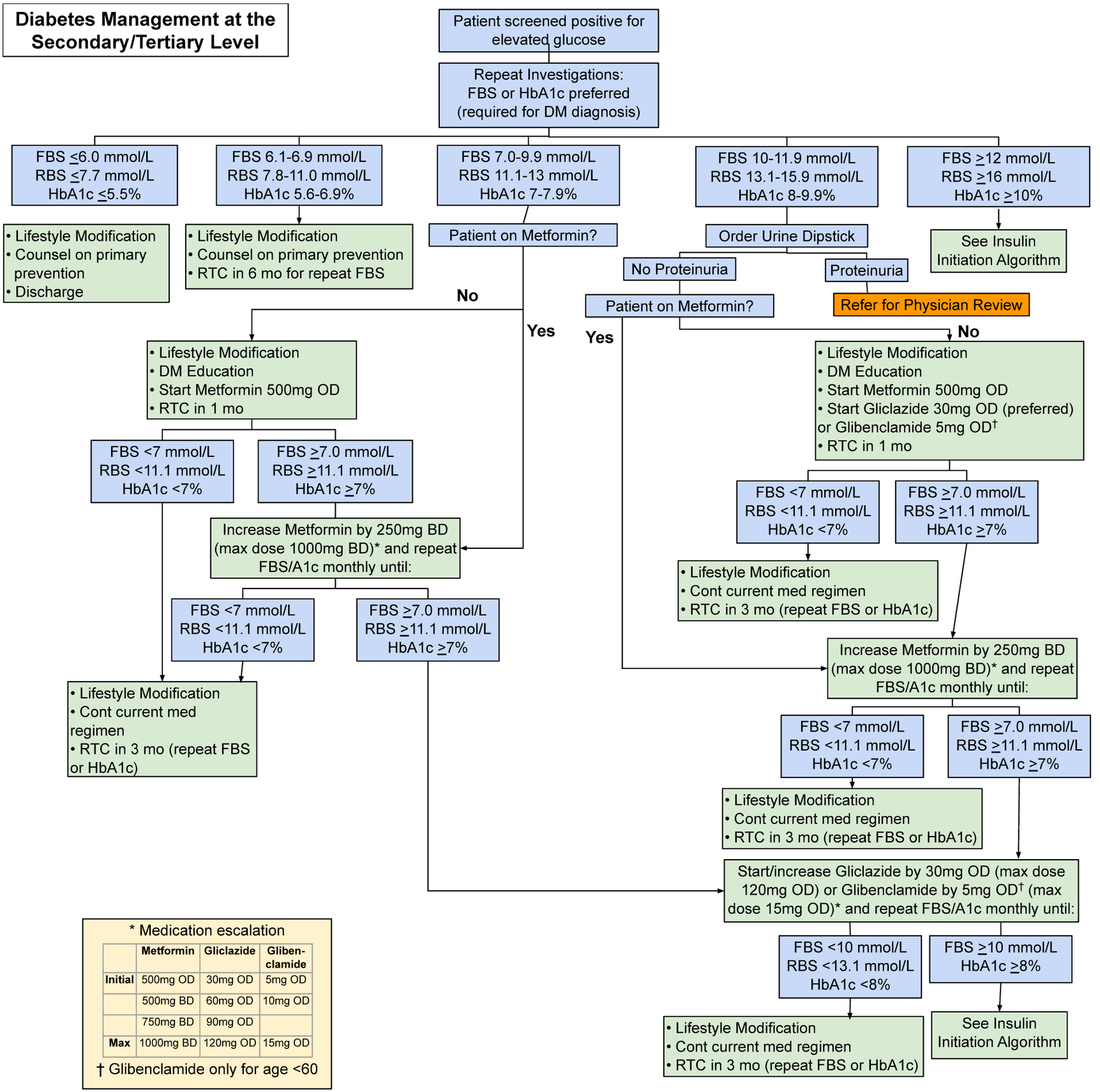
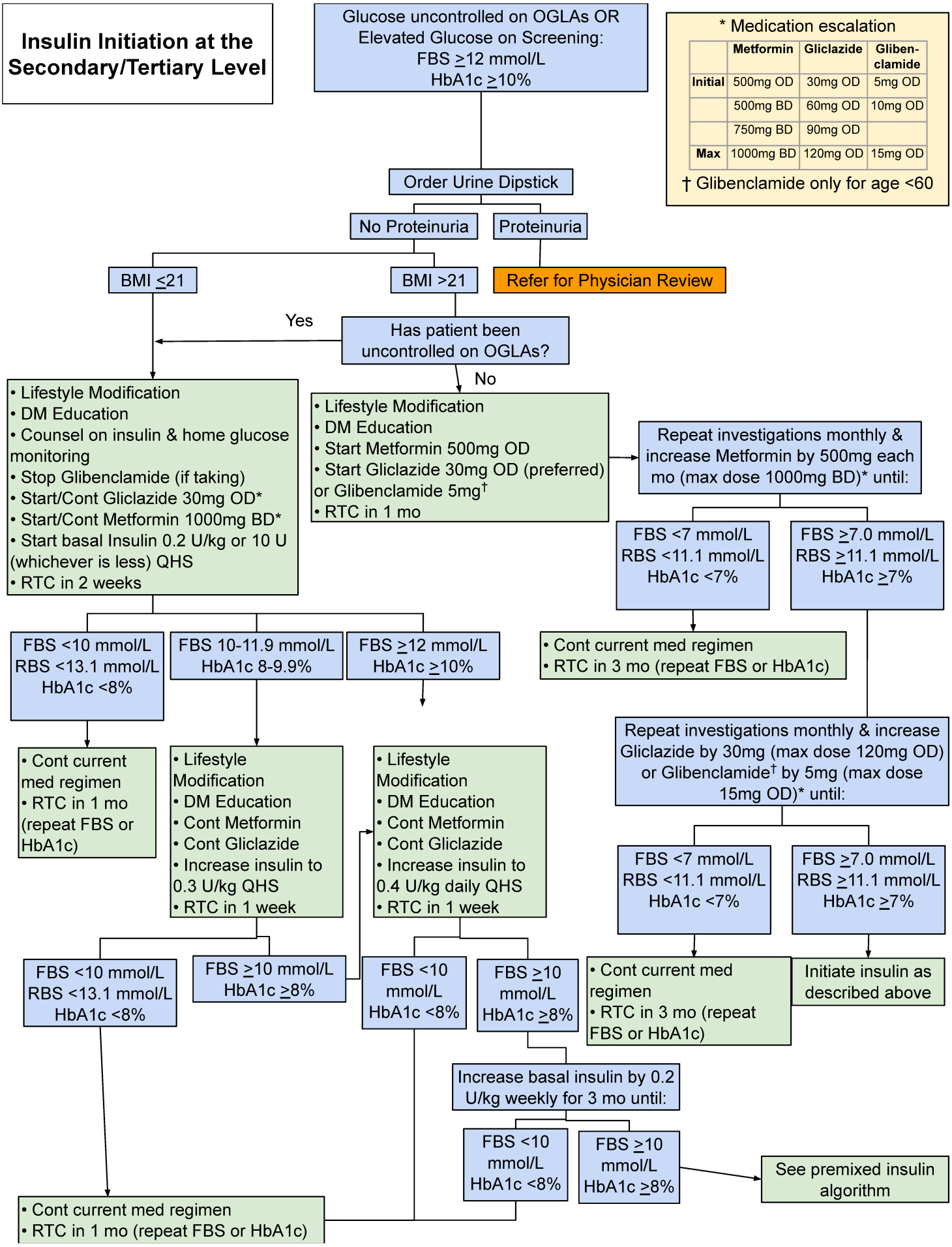
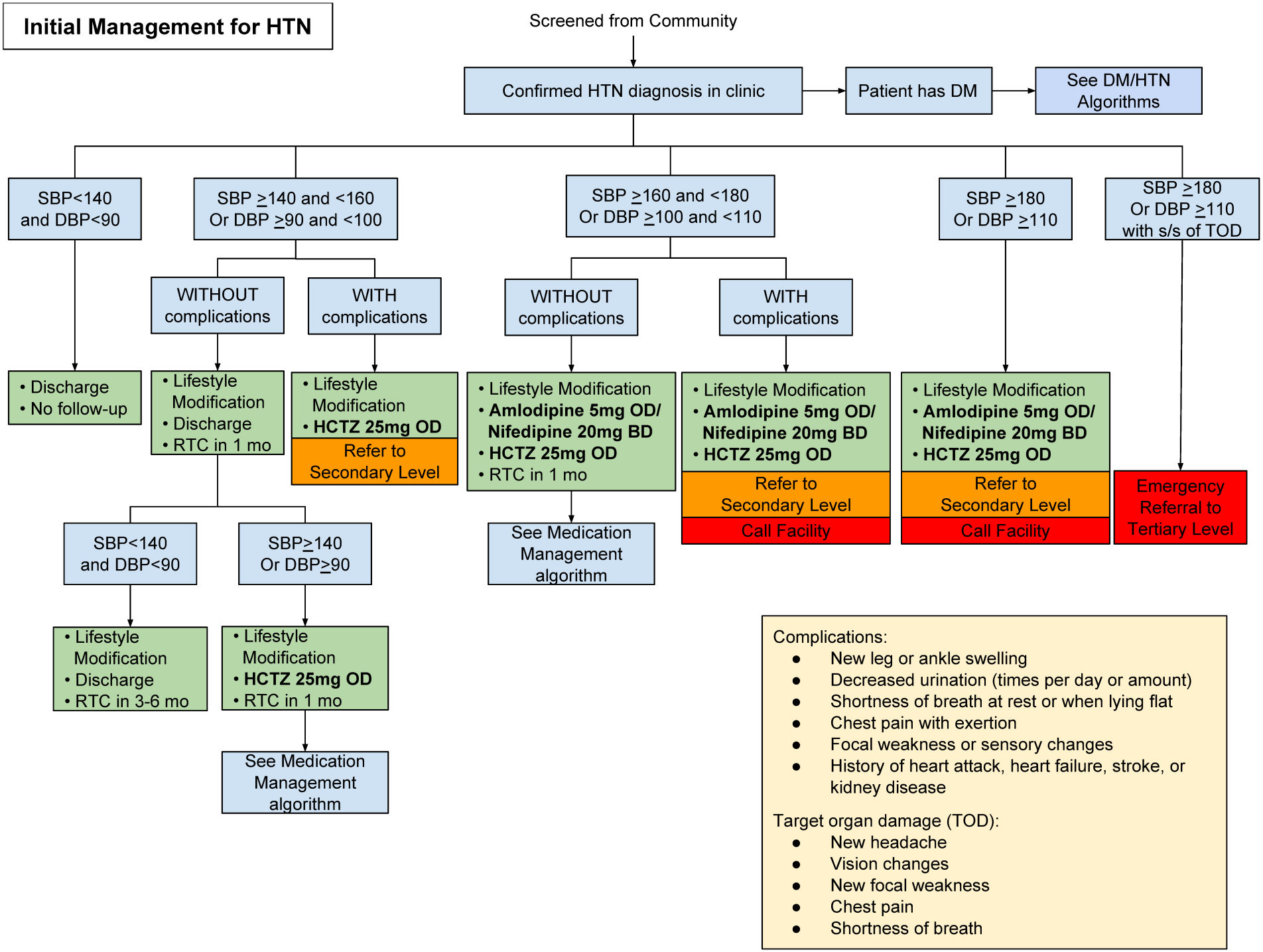
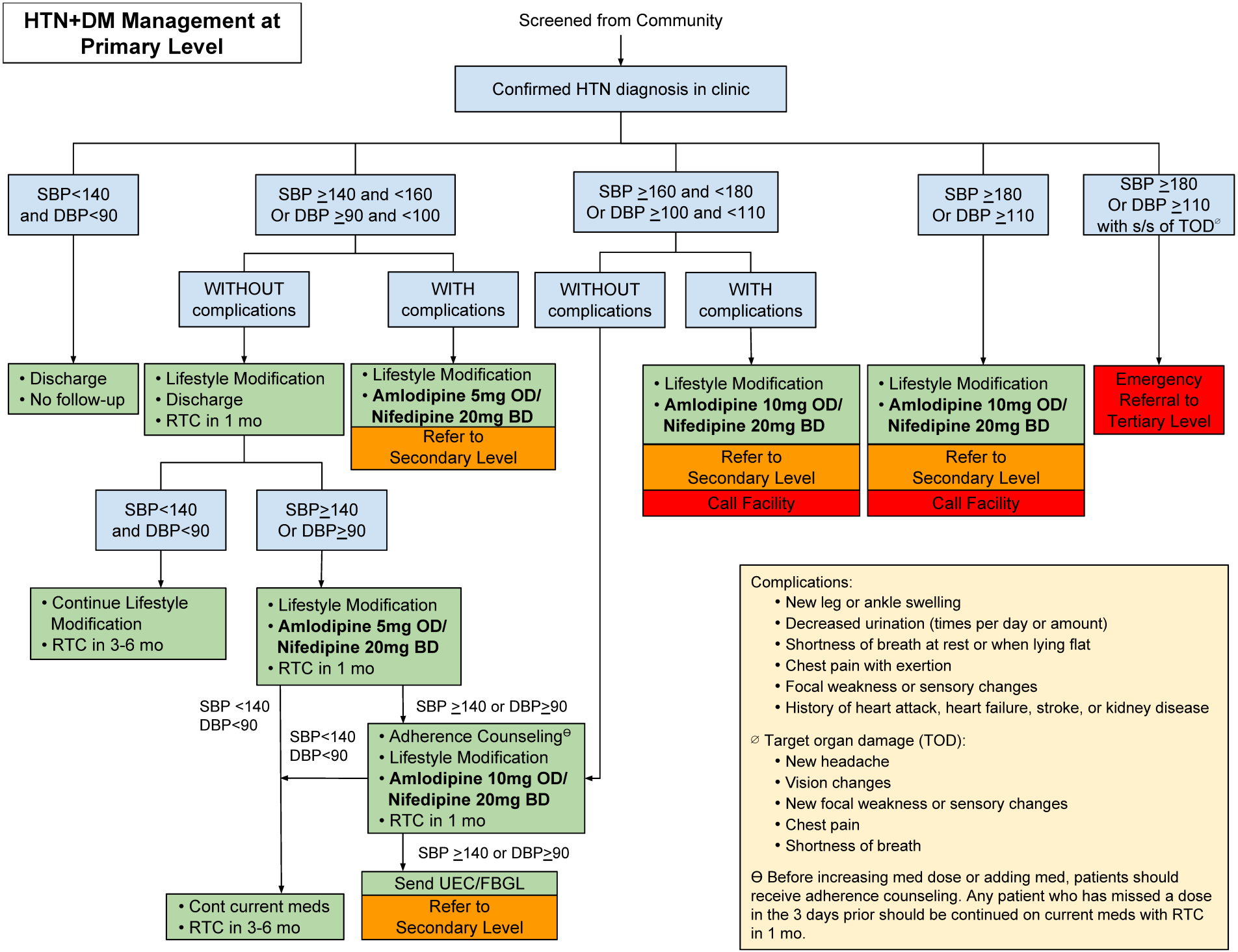
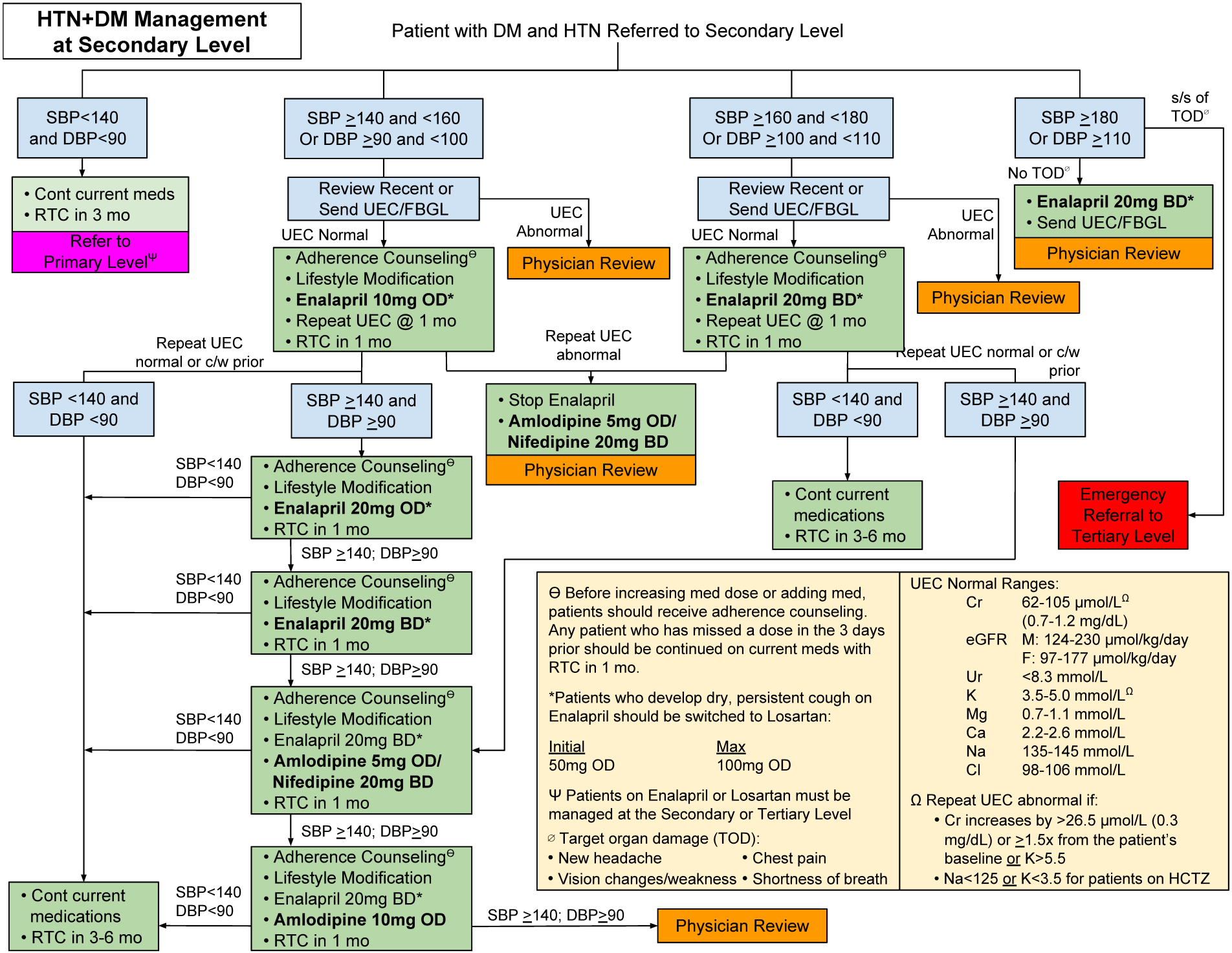

Diabetes Management at the Primary Level
Patient screened positive for elevated glucose
Repeat Investigations: FBS or HbA1c preferred (required for DM diagnosis)
FBS ≤6.0 mmol/L RBS ≤7.7 mmol/L HbA1c ≤5.5%
• Lifestyle Modification • Counsel on primary prevention • Discharge
FBS 6.1-6.9 mmol/L RBS 7.8-11.0 mmol/L HbA1c 5.6-6.9%
• Lifestyle Modification • Counsel on primary prevention • RTC in 6 mo for repeat FBS
FBS 7.0-9.9 mmol/L RBS 11.1-13 mmol/L HbA1c 7-7.9%
• Lifestyle Modification • DM Education • Start Metformin 500mg OD • RTC in 1 mo
FBS 10-11.9 mmol/L RBS 13.1-15.9 mmol/L HbA1c 8-9.9%
• Lifestyle Modification • DM Education • Start Metformin 500mg OD • RTC in 1 mo
Refer to Secondary Level
FBS ≥12 mmol/L RBS ≥16 mmol/L HbA1c ≥10%
• Stat dose soluble insulin SQ 0.2 U/kg (if available)
Refer to Secondary Level
Call Facility
Repeat Investigations (FBS or HbA1c preferred)
FBS <7 mmol/L RBS <11.1 mmol/L HbA1c <7%
FBS 7.0-9.9 mmol/L RBS 11.1-13 mmol/L HbA1c 7-7.9%
• Lifestyle Modification • DM Education • Increase Metformin 500mg BD • RTC in 1 mo
FBS 10-11.9 mmol/L RBS 13.1-15.9 mmol/L HbA1c 8-9.9%
• Lifestyle Modification • DM Education • Start Metformin 500mg OD • RTC in 1 mo
Refer to Secondary Level
FBS ≥12 mmol/L RBS ≥16 mmol/L HbA1c ≥10%
• Stat dose soluble insulin SQ 0.2 U/kg (if available)
Refer to Secondary Level
Call Facility
Repeat investigations monthly & increase Metformin by 250mg BD (max dose 1000mg BD)* until:
FBS <7 mmol/L RBS <11.1 mmol/L HbA1c <7%
FBS ≥7.0 mmol/L RBS ≥11.1 mmol/L HbA1c ≥7%
• Lifestyle Modification • Cont Metformin 500mg OD • RTC in 3 mo (repeat FBS or HbA1c)
Refer to Secondary Level
* Medication escalation
Metformin
Gliclazide
Gliben-clamide
Initial
500mg OD
30mg OD
5mg OD
500mg BD
60mg OD
10mg OD
750mg BD
90mg OD
Max
1000mg BD
120mg OD
15mg OD


Diabetes Management at the Secondary/Tertiary Level
Patient screened positive for elevated glucose
Repeat Investigations: FBS or HbA1c preferred (required for DM diagnosis)
FBS ≤6.0 mmol/L RBS ≤7.7 mmol/L HbA1c ≤5.5%
FBS 6.1-6.9 mmol/L RBS 7.8-11.0 mmol/L HbA1c 5.6-6.9%
FBS 7.0-9.9 mmol/L RBS 11.1-13 mmol/L HbA1c 7-7.9%
FBS 10-11.9 mmol/L RBS 13.1-15.9 mmol/L HbA1c 8-9.9%
FBS ≥12 mmol/L RBS ≥16 mmol/L HbA1c ≥10%
• Lifestyle Modification
• Counsel on primary prevention
• Discharge
• Lifestyle Modification
• Counsel on primary prevention
• RTC in 6 mo for repeat FBS
Patient on Metformin?
Order Urine Dipstick
See Insulin Initiation Algorithm
No Proteinuria
Proteinuria
Refer for Physician Review
No
Yes
Patient on Metformin?
Yes
No
• Lifestyle Modification
• DM Education
• Start Metformin 500mg OD
• RTC in 1 mo
• Lifestyle Modification
• DM Education
• Start Metformin 500mg OD
• Start Gliclazide 30mg OD (preferred) or Glibenclamide 5mg OD†
• RTC in 1 mo
FBS <7 mmol/L RBS <11.1 mmol/L HbA1c <7%
FBS ≥7.0 mmol/L RBS ≥11.1 mmol/L HbA1c ≥7%
FBS <7 mmol/L RBS <11.1 mmol/L HbA1c <7%
FBS ≥7.0 mmol/L RBS ≥11.1 mmol/L HbA1c ≥7%
Increase Metformin by 250mg BD (max dose 1000mg BD)* and repeat FBS/A1c monthly until:
• Lifestyle Modification
• Cont current med regimen
• RTC in 3 mo (repeat FBS or HbA1c)
FBS <7 mmol/L RBS <11.1 mmol/L HbA1c <7%
FBS ≥7.0 mmol/L RBS ≥11.1 mmol/L HbA1c ≥7%
• Lifestyle Modification
• Cont current med regimen
• RTC in 3 mo (repeat FBS or HbA1c)
Increase Metformin by 250mg BD (max dose 1000mg BD)* and repeat FBS/A1c monthly until:
FBS <7 mmol/L RBS <11.1 mmol/L HbA1c <7%
FBS ≥7.0 mmol/L RBS ≥11.1 mmol/L HbA1c ≥7%
• Lifestyle Modification
• Cont current med regimen
• RTC in 3 mo (repeat FBS or HbA1c)
Start/increase Gliclazide by 30mg OD (max dose 120mg OD) or Glibenclamide by 5mg OD† (max dose 15mg OD)* and repeat FBS/A1c monthly until:
FBS <10 mmol/L RBS <13.1 mmol/L HbA1c <8%
FBS ≥10 mmol/L HbA1c ≥8%
• Lifestyle Modification
• Cont current med regimen
• RTC in 3 mo (repeat FBS or HbA1c)
See Insulin Initiation Algorithm
* Medication escalation
Metformin
Gliclazide
Glibenclamide
Initial
500mg OD
30mg OD
5mg OD
500mg BD
60mg OD
10mg OD
750mg BD
90mg OD
Max
1000mg BD
120mg OD
15mg OD
† Glibenclamide only for age <60


Insulin Initiation at the Secondary/Tertiary Level
Glucose uncontrolled on OGLAs OR Elevated Glucose on Screening: FBS ≥12 mmol/L HbA1c ≥10%
* Medication escalation
Metformin | Gliclazide | Gliben-clamide
Initial | 500mg OD | 30mg OD | 5mg OD
500mg BD | 60mg OD | 10mg OD
750mg BD | 90mg OD |
Max | 1000mg BD | 120mg OD | 15mg OD
† Glibenclamide only for age <60
Order Urine Dipstick
No Proteinuria
Proteinuria
BMI ≤21
BMI >21
Refer for Physician Review
Yes
Has patient been uncontrolled on OGLAs?
No
• Lifestyle Modification • DM Education • Counsel on insulin & home glucose monitoring • Stop Glibenclamide (if taking) • Start/Cont Gliclazide 30mg OD* • Start/Cont Metformin 1000mg BD* • Start basal Insulin 0.2 U/kg or 10 U (whichever is less) QHS • RTC in 2 weeks
• Lifestyle Modification • DM Education • Start Metformin 500mg OD • Start Gliclazide 30mg OD (preferred) or Glibenclamide 5mg† • RTC in 1 mo
Repeat investigations monthly & increase Metformin by 500mg each mo (max dose 1000mg BD)* until:
FBS <7 mmol/L RBS <11.1 mmol/L HbA1c <7%
FBS ≥7.0 mmol/L RBS ≥11.1 mmol/L HbA1c ≥7%
• Cont current med regimen • RTC in 3 mo (repeat FBS or HbA1c)
FBS <10 mmol/L RBS <13.1 mmol/L HbA1c <8%
FBS 10-11.9 mmol/L HbA1c 8-9.9%
FBS ≥12 mmol/L HbA1c ≥10%
• Cont current med regimen • RTC in 1 mo (repeat FBS or HbA1c)
• Lifestyle Modification • DM Education • Cont Metformin • Cont Gliclazide • Increase insulin to 0.3 U/kg QHS • RTC in 1 week
• Lifestyle Modification • DM Education • Cont Metformin • Cont Gliclazide • Increase insulin to 0.4 U/kg daily QHS • RTC in 1 week
Repeat investigations monthly & increase Gliclazide by 30mg (max dose 120mg OD) or Glibenclamide† by 5mg (max dose 15mg OD)* until:
FBS <7 mmol/L RBS <11.1 mmol/L HbA1c <7%
FBS ≥7.0 mmol/L RBS ≥11.1 mmol/L HbA1c ≥7%
• Cont current med regimen • RTC in 3 mo (repeat FBS or HbA1c)
Initiate insulin as described above
FBS <10 mmol/L RBS <13.1 mmol/L HbA1c <8%
FBS ≥10 mmol/L HbA1c ≥8%
FBS <10 mmol/L HbA1c <8%
FBS ≥10 mmol/L HbA1c ≥8%
Increase basal insulin by 0.2 U/kg weekly for 3 mo until:
FBS <10 mmol/L HbA1c <8%
FBS ≥10 mmol/L HbA1c ≥8%
See premixed insulin algorithm
• Cont current med regimen • RTC in 1 mo (repeat FBS or HbA1c)


Initial Management for HTN
Screened from Community
Confirmed HTN diagnosis in clinic
Patient has DM
See DM/HTN Algorithms
SBP<140 and DBP<90
SBP ≥140 and <160 Or DBP ≥90 and <100
SBP ≥160 and <180 Or DBP ≥100 and <110
SBP ≥180 Or DBP ≥110
SBP ≥180 Or DBP ≥110 with s/s of TOD
WITHOUT complications
WITH complications
WITHOUT complications
WITH complications
• Discharge
• No follow-up
• Lifestyle Modification
• Discharge
• RTC in 1 mo
• Lifestyle Modification
• HCTZ 25mg OD
Refer to Secondary Level
• Lifestyle Modification
• Amlodipine 5mg OD/ Nifedipine 20mg BD
• HCTZ 25mg OD
• RTC in 1 mo
• Lifestyle Modification
• Amlodipine 5mg OD/ Nifedipine 20mg BD
• HCTZ 25mg OD
Refer to Secondary Level
Call Facility
• Lifestyle Modification
• Amlodipine 5mg OD/ Nifedipine 20mg BD
• HCTZ 25mg OD
Refer to Secondary Level
Call Facility
Emergency Referral to Tertiary Level
SBP<140 and DBP<90
SBP≥140 Or DBP≥90
See Medication Management algorithm
• Lifestyle Modification
• Discharge
• RTC in 3-6 mo
• Lifestyle Modification
• HCTZ 25mg OD
• RTC in 1 mo
See Medication Management algorithm
Complications:
New leg or ankle swelling
Decreased urination (times per day or amount)
Shortness of breath at rest or when lying flat
Chest pain with exertion
Focal weakness or sensory changes
History of heart attack, heart failure, stroke, or kidney disease
Target organ damage (TOD):
New headache
Vision changes
New focal weakness
Chest pain
Shortness of breath


HTN+DM Management at Primary Level
Screened from Community
Confirmed HTN diagnosis in clinic
SBP<140 and DBP<90
SBP ≥140 and <160 Or DBP ≥90 and <100
SBP ≥160 and <180 Or DBP ≥100 and <110
SBP ≥180 Or DBP ≥110
SBP ≥180 Or DBP ≥110 with s/s of TOD⌀
WITHOUT complications
WITH complications
WITHOUT complications
WITH complications
• Discharge • No follow-up
• Lifestyle Modification • Discharge • RTC in 1 mo
• Lifestyle Modification • Amlodipine 5mg OD/ Nifedipine 20mg BD
Refer to Secondary Level
• Lifestyle Modification • Amlodipine 10mg OD/ Nifedipine 20mg BD
Refer to Secondary Level
Call Facility
• Lifestyle Modification • Amlodipine 10mg OD/ Nifedipine 20mg BD
Refer to Secondary Level
Call Facility
Emergency Referral to Tertiary Level
SBP<140 and DBP<90
SBP≥140 Or DBP≥90
• Continue Lifestyle Modification • RTC in 3-6 mo
• Lifestyle Modification • Amlodipine 5mg OD/ Nifedipine 20mg BD • RTC in 1 mo
SBP <140 DBP<90
SBP ≥140 or DBP≥90
SBP<140 DBP<90
• Adherence Counseling⊖ • Lifestyle Modification • Amlodipine 10mg OD/ Nifedipine 20mg BD • RTC in 1 mo
SBP ≥140 or DBP≥90
• Cont current meds • RTC in 3-6 mo
Send UEC/FBGL
Refer to Secondary Level
Complications:
• New leg or ankle swelling
• Decreased urination (times per day or amount)
• Shortness of breath at rest or when lying flat
• Chest pain with exertion
• Focal weakness or sensory changes
• History of heart attack, heart failure, stroke, or kidney disease
⌀ Target organ damage (TOD):
• New headache
• Vision changes
• New focal weakness or sensory changes
• Chest pain
• Shortness of breath
⊖ Before increasing med dose or adding med, patients should receive adherence counseling. Any patient who has missed a dose in the 3 days prior should be continued on current meds with RTC in 1 mo.


HTN+DM Management at Secondary Level
Patient with DM and HTN Referred to Secondary Level
SBP<140 and DBP<90
• Cont current meds
• RTC in 3 mo
Refer to Primary LevelΨ
SBP ≥140 and <160 Or DBP ≥90 and <100
Review Recent or Send UEC/FBGL
UEC Abnormal
Physician Review
UEC Normal
• Adherence CounselingΘ
• Lifestyle Modification
• Enalapril 10mg OD*
• Repeat UEC @ 1 mo
• RTC in 1 mo
SBP ≥160 and <180 Or DBP ≥100 and <110
Review Recent or Send UEC/FBGL
UEC Abnormal
Physician Review
UEC Normal
• Adherence CounselingΘ
• Lifestyle Modification
• Enalapril 20mg BD*
• Repeat UEC @ 1 mo
• RTC in 1 mo
SBP ≥180 Or DBP ≥110
s/s of TODØ
No TODØ
• Enalapril 20mg BD*
• Send UEC/FBGL
Physician Review
Repeat UEC normal or c/w prior
Repeat UEC abnormal
• Stop Enalapril
• Amlodipine 5mg OD/ Nifedipine 20mg BD
Physician Review
SBP <140 and DBP <90
SBP ≥140 and DBP ≥90
SBP<140 DBP<90
• Adherence CounselingΘ
• Lifestyle Modification
• Enalapril 20mg OD*
• RTC in 1 mo
SBP ≥140; DBP≥90
SBP<140 DBP<90
• Adherence CounselingΘ
• Lifestyle Modification
• Enalapril 20mg BD*
• RTC in 1 mo
SBP ≥140; DBP≥90
SBP<140 DBP<90
• Adherence CounselingΘ
• Lifestyle Modification
• Enalapril 20mg BD*
• Amlodipine 5mg OD/ Nifedipine 20mg BD
• RTC in 1 mo
SBP ≥140; DBP≥90
SBP<140 DBP<90
• Adherence CounselingΘ
• Lifestyle Modification
• Enalapril 20mg BD*
• Amlodipine 10mg OD
• RTC in 1 mo
SBP ≥140; DBP≥90
Physician Review
• Cont current medications
• RTC in 3-6 mo
SBP <140 and DBP <90
• Cont current medications
• RTC in 3-6 mo
SBP ≥140 and DBP ≥90
Emergency Referral to Tertiary Level
Θ Before increasing med dose or adding med, patients should receive adherence counseling. Any patient who has missed a dose in the 3 days prior should be continued on current meds with RTC in 1 mo.
*Patients who develop dry, persistent cough on Enalapril should be switched to Losartan:
Initial 50mg OD
Max 100mg OD
Ψ Patients on Enalapril or Losartan must be managed at the Secondary or Tertiary Level
Ø Target organ damage (TOD):
• New headache
• Chest pain
• Vision changes/weakness
• Shortness of breath
UEC Normal Ranges:
Cr 62-105 µmol/LΩ (0.7-1.2 mg/dL)
eGFR M: 124-230 µmol/kg/day F: 97-177 µmol/kg/day
Ur <8.3 mmol/L
K 3.5-5.0 mmol/LΩ
Mg 0.7-1.1 mmol/L
Ca 2.2-2.6 mmol/L
Na 135-145 mmol/L
Cl 98-106 mmol/L
Ω Repeat UEC abnormal if:
• Cr increases by >26.5 µmol/L (0.3 mg/dL) or ≥1.5x from the patient's baseline or K>5.5
• Na<125 or K<3.5 for patients on HCTZ

Harambee: Integrated Community Based HIV/NCD Care and Microfinance Groups in Kenya

Sponsored by:
National Institute of Mental Health (NIMH)
R01MH118075-01A1

Informed Consent Documents

Overview

The following documents will be used to collect written informed consent from participants who enroll in Aims 1-3 of the study. Adult Consent Form 1 will be used to obtain written informed consent from participants who are members of microfinance groups (i.e., MF + ICB and MF + SOC groups) and enroll in Aim 1. Adult Consent Form 2 will be used to obtain written informed consent from participants who receive standard of care at an AMPATH clinic (i.e., SOC group) and enroll in Aim 1. Adult Consent Form 3 will be used to obtain verbal informed consent from enrolled participants or AMPATH staff who participate in key informant interviews.

Adult Consent Form 1
(For microfinance group members who are asked to enroll in Aim 1)

Title of Research:	Harambee: Integrated Community Based HIV/NCD Care and Microfinance Groups in Kenya
Principal Investigators:	Juddy Wachira; Becky Genberg; Omar Galarraga
IREC Approval #:	0003054
Sponsor:	National Institute of Mental Health (NIMH)
Version Date:	11 March 2020

What you should know about this study

- You are being asked to join a research study.
- This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- You are a volunteer. You may choose not to take part in the study at all. If you choose to join the study, you may quit at any time. There will be no penalty if you decide to quit the study.
- During the study, we will tell you right away if we learn any new information that might affect whether you wish to continue to be in the study.

What is the purpose of research study?

The purpose of this research study is to learn if offering HIV care and other health services in the community, instead of at a health facility, will help people who are living with HIV to live healthier lives. This research study also wants to learn if offering HIV care and other health services to people who are members of microfinance groups will help people who are living with HIV to live healthier lives.

Why we are asking you to participate?

You are being asked to participate in this study because:

1) You are at least 18 years old
2) You are an HIV patient
3) You have been taking antiretroviral (ART) medications for the past 6 months or longer
4) You receive care for HIV at an AMPATH HIV clinic
5) You have an AMPATH identification number
6) You have been a member of an active microfinance group for the past 6 months or longer
7) You do not have serious infections or illnesses that require immediate care or hospitalization
8) You are not a member of a community ART group (CARG)
9) You are not pregnant

Initials of Participant_____

What will happen if you agree to participate in the study?

If you agree to participate in the study, your microfinance group will be assigned to Group A or Group B. The chances that you will be in Group A or Group B are equal because they are picked by chance (like tossing a coin – the chances of getting each side are the same).

If you are assigned to Group A, you will attend your regular microfinance group as normal. When you attend your microfinance group, you will also meet with AMPATH staff members and members of this research study. The AMPATH staff will take your vital signs (blood pressure, temperature, heart rate, height, weight, waist circumference, etc.) and give you medicine for your HIV for free. If you have high blood pressure or diabetes, you will receive medicine for a fee. The price you will pay for the blood pressure or diabetes medicines will be similar to prices at the AMPATH pharmacy. During your microfinance group meeting, AMPATH staff will also take samples of your blood to test your HIV levels (viral load) to see how healthy you are. The frequency of this blood test depends on your age and the amount of HIV virus in your body. At a minimum, we will take a blood sample at least three times, once at the beginning of the study, once in the middle (6 months if you are less than 25 years old or 12 months if you are 25 years old or above), and once at the end of the study (18 months). We will also test your blood sugar levels to know if you have diabetes. At a minimum, this will occur two times, one at the beginning (baseline) and another at the end of the study (18 months) at no cost to you. If you are found to have diabetes, you will pay a subsidized fee for any additional tests you may need. You will also speak with an AMPATH counselor. If you have any problems or concerns, the counselor will help you and refer you to the AMPATH clinic if you have an emergency.

If you are assigned to Group B, you will participate in your regular microfinance group as normal and will continue to get HIV care and services for blood pressure and diabetes as normal; either at the AMPATH clinic or any health facilities when you go for your regular appointments.

If you are assigned to Group A or Group B, you will be asked to complete one survey 3 times during the study: once in the beginning, once in the middle (at 9 months), and once at the end of the study (at 18 months). This survey will ask questions your household, access to food, access to HIV care, your community and your general health and well-being. In addition, we will also collect information every three months related to your microfinance activities including your saving and loaning activities.

In addition, the research team will also collect information about you from your AMPATH and other medical records throughout the study. This information will include demographics (e.g. age, gender), diagnoses for HIV, your HIV health, HIV-related infections and other illness like blood pressure and/or diabetes, medication history, the number of times you attend your clinic appointments, the number of times you participate in a study visit, and the dates of these visits and appointments.

We do not know whether receiving care in Group A or in Group B is better, or if they are the same. The purpose of the study is to answer this question. No matter which group you are in, you should continue to take your medicines according to your doctor's instructions.

Explanation of Procedures

The following steps will be followed if you agree to participate in the study:

Step 1: Baseline Assessment

Initials of Participant_____

To be eligible for this study, you must meet our inclusion and exclusion criteria. A member of the research team will speak with you to make sure you can participate in this study.

If you agree to participate in the study today, we will take a blood sample to test your HIV level. We will tell you the results of your blood test as soon as they are available. We will also perform a finger prick to test your blood sugar for diabetes. We may do another finger prick to confirm whether you have diabetes or not. We will tell you the result of the finger prick as soon as they are available. We will also measure your height, weight, temperature, waist circumference, and heart rate. To know if you have high blood pressure, we will measure your upper arm blood pressure as you sit quietly on a chair. If your blood pressure is high, we will measure your upper arm blood pressure again in 2 weeks and tell you the results as soon as they are available.

Lastly, you will also complete a survey today that will ask you questions about your household, access to food, access to HIV care, your community and your general health and well-being.

Step 2: Study Visits

Group A**:** During the study, a clinical officer (CO) and research staff will come to your regular microfinance group meetings every month for the first 6 months of the study and then every 3 months for the last 12 months of the study. On days when the CO and research staff come to your group, they will:

- Attend to your health needs
- Take your vital signs as described above
- For HIV: count your pills and give you free medicines for your HIV
- For high blood pressure, measure your blood pressure at no cost to you and give you medicines at a subsidized fee
- For diabetes, measure your blood sugars and give you medications at a subsidized fee
- Provide peer support if you are feeling unhappy or have any other issues that you want to discuss at no cost to you

If there are any issues with your health that the CO cannot address, s/he will refer you to the nearest health facility so that you can receive the care that you need.

Group B: You will continue to receive care at your usual AMPATH clinic. For hypertension and diabetes management, you will receive that care by a clinician at the nearest AMPATH clinic or any health facilities that is most convenient to you. Our team can make provide you with a list of available clinic locations.

Your microfinance group will continue to meet at the normal time, days and location. Members of the same microfinance group will always be in the same group for this study.

What happens if I decide to stop my treatment?

If you choose to stop receiving care in Group A or B before the end of the study, or if you decide you cannot complete all of the care visits:

- You will be asked to return to your usual clinic care at AMPATH and continue receiving care as you previously did before joining the study
- We will contact you at the end of the study (18 months) to test your HIV viral load and blood sugar levels, measure your blood pressure, and to complete the surveys. Participation in these surveys is voluntary.

Initials of Participant_____

If you choose to leave your microfinance group before the end of the study, or if you decide you cannot complete all of the microfinance visits:

- For Group A, you must decide whether you will want to (1) continue receiving care at the community during microfinance group meetings or (2) be referred back to receiving care at your AMPATH clinic as you previously did before joining the study.
- For Group B, you will continue receiving care at your usual AMPATH clinic.
- For both groups, we will contact you at the end of the study (18 months) to test your HIV viral load and blood sugar levels, measure your blood pressure, and to complete the surveys. Participation in these surveys is voluntary.

What happens if I become pregnant during the study?

Women who are part of study Group A and become pregnant while in the study will be asked to go back to the HIV clinic and attend their scheduled clinic visits. A pregnant woman in Group A will be encouraged to continue coming to her microfinance group, but the CO will not be able to deliver her drugs or attend to her clinical care needs in the community. She must go to the clinic to get her HIV drugs. Women who are part of study Group B who become pregnant during the study will be seen in the HIV clinic. We do not think there will be more risk to the pregnant woman or the unborn baby by participation in the study. However, this study will not directly help pregnant women or their babies.

Risks of taking part in this study

Blood draws

Taking blood may cause some discomfort, bleeding, or bruising where the needle enters the body, light headedness, and in extremely rare cases, fainting or infection. However, the study staff are well trained to perform blood draws and we do not expect any complications to you from the procedure.

Risk of losing confidentiality and increased stigma

For people in Group A, there is a risk of losing confidentiality (privacy) and increased stigma because of the community visits by the CO. This may cause other family members or neighbors to become curious. However, the study team will be as unnoticeable as possible while making community visits. Nobody outside of your group will be told the reason for the visits and only fellow study participants are allowed to be present during this part of the study. For people in Group B, there is also a risk of losing privacy. However, the clinic staff will be sure that your records are kept safe and your personal information is not given to anybody without permission. All of the information you provide and all of your responses to the survey will be coded with a study ID and will never include your name.

Benefits of taking part in the study

There is no direct benefit for participating in this study; however, the information learned from this study may help other people who are living with HIV for two reasons. One, it will help determine if offering HIV care and other health services in the community, instead of at a health facility, will help people who are living with HIV to live healthier lives. Two, it will help determine

Initials of Participant_____

if offering HIV care and other health services to people who are members of microfinance groups will help people who are living with HIV to live healthier lives.

Confidentiality

We will try very hard to keep your records confidential (private). We cannot guarantee absolute privacy. Your medical information could be shared if required by the law. Only a coded number, not your name, will be used to identify your information on study materials. Your name will not be used in any reports that the study may publish. A group of people may look at our records to make sure they are complete and true. A group may also look at our records for data analysis (to see what the information people shared with us means). The groups looking at the records could be study investigators and their research partners, the Moi Institutional Research and Ethics Committee (IREC), the Indiana University Institutional Review Board (IRB), the Brown University IRB, the Purdue University IRB, the Johns Hopkins University IRB, the study staff, or the sponsor (NIH).

Data Sharing

We will not share the data from this study with anyone outside of our study staff team.

Protecting your privacy during data collection

Participation in this study involves multiple visits from AMPATH staff who will include a clinical officer, pharmacy technician, peer navigator, and social worker. Staff will conduct visits during your regular scheduled microfinance group and will meet with you in a location that is private and away from the other group members. Because we want to ensure your privacy during these visits, we will ask anyone nearby, either family members or neighbors, to relocate until after we are finished.

Costs

For HIV, your medications and care services (physical examinations, viral load tests, peer support) will continue to be provided at no cost to you.

For high blood pressure and diabetes, the lab tests at the beginning and end of the study will be free. However, you will pay for additional lab tests (if recommended by the clinician) during the course of the study. The cost for these tests are subsidized. You will also have to pay a small amount for your blood pressure and diabetes medications.

You will not be giving up any of your legal rights by signing this consent form.

Payment/Compensation

This study does not offer any money for taking part.

How long will your part in the study last?

If you enroll in this study, you will in the study for 18 months from the day you enroll.

What will happen if I miss or cannot attend one of my microfinance group meetings?

If you do not attend a microfinance group meeting for any reason on a day that AMPATH staff are scheduled to conduct a visit, the staff will contact you to schedule a follow-up meeting for a time outside of your regularly scheduled group meeting.

Initials of Participant_____

Who is sponsoring this study?

This research is funded by the National Institutes of Health in the United States. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

Your alternatives to joining the study

Your participation in this study is voluntary. You may choose to discontinue your participation at any time without penalty. Refusing to participate will not impact any care you receive from AMPATH or any other provider.

Ending Consent

You may end your consent at any time. Information obtained and used before you end your consent will continue to be used for research. If you wish to end your consent, please let us know.

Who do I call if I have questions or problems related to the study?

- Call the principal investigator: Juddy Wachira at 070-524- 2450
- Call or contact the **Moi University Institutional Research and Ethics Committee (IREC)** if you have questions about your rights as a study participant. Contact IREC if you feel you have not been treated fairly or if you have other concerns. The IREC contact information is:

  Moi Teaching and Referral Hospital
  Institutional Research and Ethics Committee
  2nd floor. Door No. 219,
  P.O. Box. 3-30100
  Eldoret, Kenya
  Office line: 0787723677
  Email: irecmtrh@gmail.com or contact@irec.or.ke

What does your signature on this consent form mean?

Your signature on this form means:

- You have been informed about this study's purpose, procedures, possible benefits and risks.
- You have been given the chance to ask questions before you sign.
- You have voluntarily agreed to be in this study.

_____	_____	_____
Print name of Adult Participant	Signature of Adult Participant	Date

_____	_____	_____
Print name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date

Initials of Participant_____

Adult Consent Form 2
(For standard of care patients who are asked to enroll in Aim 1)

Title of Research:	Harambee: Integrated Community Based HIV/NCD Care and Microfinance Groups in Kenya
Principal Investigators:	Juddy Wachira; Becky Genberg; Omar Galarraga
IREC Approval #:	0003054
Sponsor:	National Institute of Mental Health (NIMH)
Version Date:	11 March 2020

What you should know about this study

- You are being asked to join a research study.
- This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- You are a volunteer. You may choose not to take part in the study at all. If you choose to join the study, you may quit at any time. There will be no penalty if you decide to quit the study.
- During the study, we will tell you right away if we learn any new information that might affect whether you wish to continue to be in the study.

What is the purpose of research study?

The purpose of this research study is to learn if offering HIV care and other health services in the community, instead of at a health facility, will help people who are living with HIV to live healthier lives. This research study also wants to learn if offering HIV care and other health services to people who are members of microfinance groups will help people who are living with HIV to live healthier lives.

Why we are asking you to participate?

1. You are being asked to participate in this study because:
2. You are at least 18 years old
3. You are an HIV patient
4. You have been taking antiretroviral (ART) medications for the past 6 months or longer
5. You receive care for HIV at an AMPATH HIV clinic
6. You have an AMPATH identification number
7. You do not have serious infections or illnesses that require immediate care or hospitalization
8. You are not a member of a community ART group (CARG)
9. You are not pregnant
10. You are not currently participating in a microfinance group

Initials of Participant_____

What will happen if you agree to participate in the study?

If you agree to participate in the study, the research team will ask you to complete a survey at the beginning (baseline) and at the end of the study (18 months). The survey will ask you questions about your household, access to food, access to HIV care, your community and your general health and well-being.

The research team will also collect information about you from your AMPATH and other medical records throughout the study. This information will include information about you like your age and gender, diagnoses for HIV, HIV progression (CD4 cell count, HIV viral load), hypertension and/or diabetes, medication history, the number of times you attend your clinic appointments and the dates of these visits and appointments.

Explanation of Procedures

The following steps will be followed if you agree to participate in the study:

Step 1: Baseline Assessment

To be eligible for this study, you must meet the criteria set by the study. A member of the research team will confirm this information with you.

If you agree to participate in the study today, we will draw blood to test your HIV viral load and see the level of the virus in your body. We will run the test at a laboratory that is designated by your AMPATH clinic and inform you of the results once available. We will also perform a finger prick to test your blood sugar for diabetes. If your blood sugar meets the criteria for possible diabetes, a second finger prick will be conducted to confirm whether you have diabetes or not. This result will be available immediately and you will be informed of the test result once available. We will also take measurements of your height, weight, waist circumference, and heart rate. To determine if you have high blood pressure, we will take a measurement your upper arm blood pressure as you sit quietly on a chair. If your blood pressure is high, we will confirm whether or not you have hypertension through measurements in 2-3 weeks in a second visit. These results will also be communicated to you as soon as they are available.

Lastly, you will also complete a survey that will ask you questions about your household, food security, access to HIV care, your community and your general health and well-being.

Step 2: Follow-up Assessment

At the end of the study (18 months), we will draw blood for HIV viral load testing again. We will run the viral load tests at a laboratory that is designated by your AMPATH clinic and inform you of the results once available. If you were diagnosed with diabetes at the beginning of the study, a finger prick will be conducted to test your blood sugar levels. This result will be available immediately and you will be informed of the test result immediately. If you were diagnosed with high blood pressure, we will also take measurements of your height, weight, waist circumference, pulse rate and measure your upper arm blood pressure as you sit quietly on the chair. You will also be asked to complete a follow-up survey at the end of the study (18 months). The survey will ask you questions about your household, food security, access to HIV care, your community and your general health and well-being.

Initials of Participant_____

What happens if I decide to stop my treatment?

If you choose to stop receiving care in your usual AMPATH clinic or Ministry of Health clinic before the end of the study, or if you decide you cannot complete all of the scheduled care visits:

- As part of your routine care, you may be contacted by your clinic staff to understand why you decided to stop care
- Our research staff will reach out to you at the end of the study (18 months) for follow up assessment (HIV viral load testing, blood sugar level testing if needed, blood pressure measurement if needed, survey)

What happens if I become pregnant during the study?

You cannot join this study if you are currently pregnant. However, it is possible that some female patients might become pregnant during the study. Women who are part of study and become pregnant while in the study will be asked to go back to clinic and attend their scheduled clinic visits. She must go to the clinic to get her HIV drugs as usual. We do not think there will be more risk to the pregnant woman or the unborn baby by participation in the study. However, this study will not directly help pregnant women or their babies.

Risks of taking part in this study

Blood draws

Taking blood may cause some discomfort, bleeding, or bruising where the needle enters the body, light headedness, and in extremely rare cases, fainting or infection. However, the study staff are well trained to perform blood draws and we do not expect any complications to you from the procedure.

Risk of losing confidentiality and increased stigma

There is a risk of losing confidentiality (privacy). However, the clinic staff will be sure that your records are kept safe and your personal information is not given to anybody without permission. All of the information you provide and all of your responses to the survey will coded with a study ID and will never include your name.

Benefits of taking part in the study

We do not know if HIV care in the community keeps HIV-infected people as healthy as HIV-infected people who receive care at a health facility. It is possible that you may receive no benefit from being in this study. However, information learned from this study may help others who are infected with HIV live healthier lives.

Confidentiality

We will try very hard to keep your records confidential (private). We cannot guarantee absolute confidentiality. Your medical information could be shared if required by the law. Only a coded number, not your name, will be used to identify your information on study materials. Your name will not be used in any reports that the study may publish. A group of people may look at our research records to make sure they are complete and true. A group may also look at our records for data analysis (to see what the information people shared with us means). The

Initials of Participant_____

groups looking at the records could be study investigators and their research partners, the Moi Institutional Research and Ethics Committee (IREC), the Indiana University Institutional Review Board (IRB), the Brown University Institutional Review Board (IRB), the Purdue University Institutional Review Board (IRB), the Johns Hopkins University Institutional Review Board (IRB), the study staff, or the sponsor (NIH).

Data Sharing

We will not share the data from this study with anyone outside of our study staff team.

Protecting your privacy during data collection

Participation in this study involves multiple visits from AMPATH staff who will include a clinical officer, pharmacy technician, peer navigator, and social worker. Staff will conduct visits during your regular scheduled microfinance group and will meet with you in a location that is private and away from the other group members. Because we want to ensure your privacy during these visits, we will ask anyone nearby, either family members or neighbors, to relocate until after we are finished.

Costs

For HIV, your viral load tests will continue to be provided at no cost to you.

For high blood pressure and diabetes, the lab tests at the beginning and end of the study will be free. However, you will pay for additional lab tests (if recommended by the clinician) during the course of the study. The cost for these tests are subsidized. You will also have to pay a small amount for your blood pressure and diabetes medications.

You will not be giving up any of your legal rights by signing this consent form.

Payment/Compensation

Participants in standard of care will receive KSh500 as convenience fee each time for participating in research at baseline and the final survey assessments.

How long will your part in the study last?

If you enroll in this study, you will be asked to participate now and in 18 months from now.

Who is sponsoring this study?

This research is funded by the National Institutes of Health in the United States. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

Your alternatives to joining the study

Your participation in this study is voluntary. You may refuse to participate and there will be no penalty for refusing. Refusing to participate will not impact any care you receive from AMPATH, or any other provider. You may choose to discontinue your participation at any time without penalty.

Ending Consent

Initials of Participant_____

You may end your consent at any time. Information obtained and used before you end your consent will continue to be used for research. If you wish to end your consent, please let us know.

Who do I call if I have questions or problems related to the study?

- Call the principal investigator: Juddy Wachira at 070-524- 2450
- Call or contact the **Moi University Institutional Research and Ethics Committee (IREC)** if you have questions about your rights as a study participant. Contact IREC if you feel you have not been treated fairly or if you have other concerns. The IREC contact information is:

  Address: Moi Teaching and Referral Hospital
  Institutional Research and Ethics Committee
  2nd floor. Door No. 219,
  P.O. Box. 3-30100
  Eldoret, Kenya
  Office line: 0787723677
  Email: irecmtrh@gmail.com or contact@irec.or.ke

What does your signature on this consent form mean?

Your signature on this form means:

- You have been informed about this study's purpose, procedures, possible benefits and risks.
- You have been given the chance to ask questions before you sign.
- You have voluntarily agreed to be in this study.

_____ _____ _____

Print name of Adult Participant Signature of Adult Participant Date

_____ _____ _____

Print name of Person Obtaining Consent Signature of Person Obtaining Consent Date

Initials of Participant_____

Moi University
Adult Consent Form 3
(For microfinance group members or AMPATH staff who are asked to participate in Aim 2 in-depth interviews)

Title of Research:	Harambee: Integrated Community Based HIV/NCD Care and Microfinance Groups in Kenya
Principal Investigators:	Juddy Wachira; Becky Genberg; Omar Galarraga
IREC Approval #:	0003054
Sponsor:	National Institute of Mental Health (NIMH)
Version Date:	11 March 2020

What you should know about this study

- You are being asked to join a research study.
- This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- You are a volunteer. You may choose not to take part in the study at all. If you choose to join the study, you may quit at any time. There will be no penalty if you decide to quit the study.
- During the study, we will tell you right away if we learn any new information that might affect whether you wish to continue to be in the study.

What is the purpose of research study?

The purpose of this research study is to learn if offering HIV care and other health services in the community, instead of at a health facility, will help people who are living with HIV to live healthier lives. This research study also wants to learn if offering HIV care and other health services to people who are members of microfinance groups will help people who are living with HIV to live healthier lives.

What will happen if you agree to participate in the study?

If you agree to participate in this study, you will be interviewed by a trained member of our research team. This interview will last approximately one hour and will take place in a private, quiet, and convenient location, off-site of AMPATH. The interview will include a discussion of factors that you believe are important to understand integration of HIV and primary care into microfinance groups. If you agree to participate, the interviewer will record the interview using a digital recording device. The interviewer may also take notes during the interview.

What type of questions will be asked during the interview?

The purpose of the interview is to learn *how* microfinance groups help patients with HIV live healthier lives. The purpose of the interview is also to learn *how* delivering HIV care in the community help patients with HIV live healthier lives.

Initials of Participant_____

Risks of taking part in this study

There are no physical risks associated with participating in this study. You may experience psychological discomfort when sensitive topics are discussed. There is a minimal risk of losing confidentiality (privacy). However, the research staff will be sure that your records are kept safe and your personal information is not given to anybody without permission. All of the information you provide and all of your responses during the interview will be coded with a study ID and will never include your name.

Benefits of taking part in the study

We do not know if HIV care in the community keeps HIV-infected people as healthy as HIV-infected people who receive care at a health facility. It is possible that you may receive no benefit from being in this study. Information learned from this study may help others who are infected with HIV live healthier lives.

Confidentiality

Your name or other information that may identify you will not be associated with your answers during this interview, the recording, transcription, or any other notes made by the interviewer. We will transcribe the interview from the recording and destroy the audio file. The transcribed documents will be stored in secure locations and digital files will be protected with passwords. Only members of the study team will have access to the data. No one at AMPATH, including your physician, AMPATH employees, or other patients, will know your answers to the questions in this interview.

We will try very hard to keep your information confidential (private). We cannot guarantee absolute confidentiality. Your information could be shared if required by the law. A group of people may look at our research records to make sure they are complete and true. A group may also look at our records for data analysis (to see what the information people shared with us means). The groups looking at the records could be study investigators and their research partners, the Moi Institutional Research and Ethics Committee (IREC), the Indiana University Institutional Review Board (IRB), the Brown University Institutional Review Board (IRB), the Purdue University Institutional Review Board (IRB), the Johns Hopkins University Institutional Review Board (IRB), the study staff, or the sponsor (NIH).

Data Sharing

We will not share the data from this study with anyone outside of our study staff team.

Costs

There will be no cost to you to participate in this interview.

Payment/Compensation

This study does not offer any money for taking part.

What will happen if you miss or cannot attend your scheduled interview?

If you do not attend your scheduled interview for any reason, the study staff will contact you to schedule a follow-up interview.

Initials of Participant_____

Who is sponsoring this study?

This research is funded by the National Institutes of Health in the United States. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

Your alternatives to joining the study

Your participation in this study is voluntary. You may refuse to participate and there will be no penalty for refusing. Refusing to participate will not impact any care you receive from AMPATH, or any other provider. You may choose to discontinue your participation at any time without penalty.

Ending Consent

You may end your consent at any time. Information obtained and used before you end your consent will continue to be used for research. If you wish to end your consent, please let us know.

Who do you call if you have questions or problems related to the study?

- Call the principal investigator: Juddy Wachira at 070-524- 2450
- Call or contact the **Moi University Institutional Research and Ethics Committee (IREC)** if you have questions about your rights as a study participant. Contact IREC if you feel you have not been treated fairly or if you have other concerns. The IREC contact information is:

  Address: Moi Teaching and Referral Hospital
  Institutional Research and Ethics Committee
  2nd floor. Door No. 219,
  P.O. Box. 3-30100
  Eldoret, Kenya
  Office line: 0787723677
  Email: irecmtrh@gmail.com or contact@irec.or.ke

What does your signature on this consent form mean?

Your signature on this form means:

- You have been informed about this study's purpose, procedures, possible benefits and risks.
- You have been given the chance to ask questions before you sign.
- You have voluntarily agreed to be in this study.

_____ _____ _____

Print name of Adult Participant Signature of Adult Participant Date

_____ _____ _____

Print name of Person Obtaining Consent Signature of Person Obtaining Consent Date

Initials of Participant_____