Clinical Study Protocol

Study Title:	Impact of Providing Medical Records in a Patient-Centered, Community Pharmacy Based, HIV Care Model (HIV-MOI) of the Community Pharmacy-Based HIV Care Model study
ClinicalTrials.gov Identifier:	NCT03437694
Sponsor:	National Institute on Minority Health and Health Disparities
Sponsor Project Title:	Texas Center for Minority Health, Education, Research and Outreach
FAIN Number:	U54MD006882
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Protocol Version/Date:	Original Approval: 5/24/2019 Most Recent Approval: 10/17/2023

North Texas Regional Institutional Review Board (NTRIRB)

University of North Texas Health Science Center

PROTOCOL INFORMATION

Title of Research Activity: Medical record based versus non-medical record based community pharmacy provided medication therapy management

Name of Principal Investigator: Dr. Crystal Hodge, PharmD, BCIDP, BCPS (formerly known as Crystal Howell)

Institution: UNTHSC

Sponsoring Agency / Company (if applicable): NIMHD

Sponsor's Protocol Number (if applicable): ClinicalTrials.gov Identifier: NCT03437694

Specific Aims –

A. To investigate the change in control of diabetes and/or hypertension in adult African-Americans with HIV, who receive medication therapy management (MTM) from their community pharmacist when the pharmacist is provided the information from the participants' medical records (intervention) or not provided the information from the medical records (control, standard of care is no medical record information is provided). Control will primarily be determined using HgbA1c & plasma glucose from medical records (diabetes), and systolic blood pressure from medical records (hypertension) and these will be compared against nationally accepted standards for each condition. Control of HIV will be monitored (no change anticipated) via medical record provided HIV-RNA viral loads and CD4 counts.

B. Background and Significance

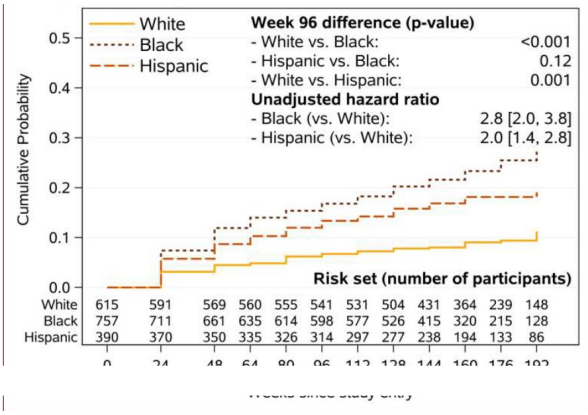

Figure 1: Adapted from Ribaudo 2016

Despite being only 12% of the United States (US) population, African-Americans (AA) represent 45% of all persons with HIV. Rates of new infections nationwide are highest in AA (44.3/100,000 persons) with the next closest race being less than half (16.4/100,000, Hispanics). Texas' 2016 surveillance epidemiology mirrors this disparity in AA with infection rates of 49.8/100,000 compared to 16/100,000 in Hispanic (next highest group). Once diagnosed, standard of care is to immediately initiate a 3-drug combination of antiretrovirals. With the overall effectiveness of current antiretroviral therapies (defined as an HIV plasma viral load (HIV-RNA) of less than 20 copies/mL) at or This disparity is not fully explained by socio-economic factors or adherence. Controlling for many known socioeconomic disparity factors, ACTG A5257 could not explain the low rate of virologic suppression in AA. Controlling for adherence rates, antiretroviral agents used, years diagnosed and use of antiretroviral therapy in 31,055 persons with HIV, a joint NIMH/ NIAID funded study revealed AA odds ratio to achieve virologic suppression was 0.48 compared to whites ($p<0.01$) – the only race with statistical difference. Thus, using adherence to explain outcomes is insufficient. Recent evidence demonstrates even within HIV populations, AA have significantly ($p<0.001$) fewer years of productive life among other races. Specifically, for every 1 year of productive life lost among non-Hispanic and whites, 1.52 and 1.75 years were lost by AA women and men, respectively ($p<0.001$). These deaths often result from cardiovascular disease and DM. It has been known for a decade DM and HTN rates are higher in persons with HIV. A 2016 analysis of >50,000 adults with HIV, AA had higher incidence rates for both DM (RR=1.4-2.0, $p<0.01$) and HTN (RR=1.5-1.8, $p<0.001$) compared to whites with projections of worsening over the next 20 years. With higher

rates, AA with HIV also have poorer control of DM and HTN (both p<0.001). A cohort of persons with HIV (n=23,974, 53.4% AA) found control to be significantly worse for AA compared to whites for DM and HTN (p<0.001, both). Again, adherence differences alone fail to explain these disparities. Therefore, innovative approaches must prove improved control of more than just HIV. Control of HIV, DM and HTN require medications.

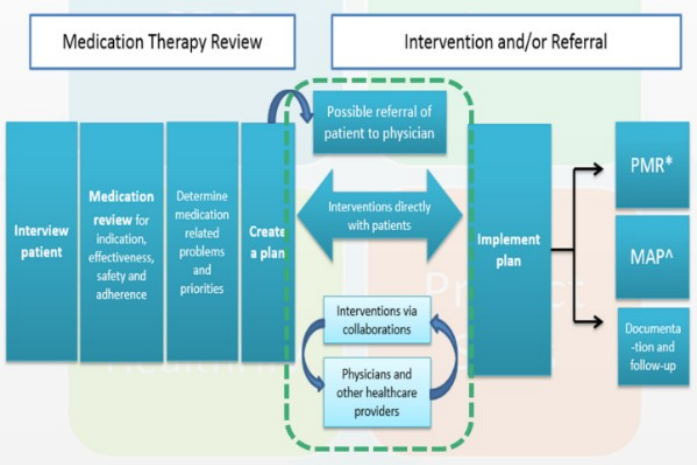

Figure 2: Traditional CMTM (no routine exchange of medical information

What is MTM? In 2003, MTM became a standard of care for all Medicare Part D patients (CFR 423.153(d), www.cms.gov). MTM is substantially more than patient counseling. In MTM, pharmacists comprehensively address modifiable barriers. Pharmacists provide individualized, patient-centered services addressing known domains and levels influencing health disparities in AA. Pharmacists, using the patient's language of choice (due to limited English) in the community pharmacy (due to stigma and/or availability of health services) or via telephone (due to mobility) educate on diagnoses and medications (due to health literacy), assess patient understanding (empowering medical decision making) of medical provider's treatment plan (patient-clinician relationship) while optimizing medications (individual health outcome), adherence and provide medication acquisition assistance (insurance coverage). The consensus definition of MTM is as follows:

> *Medication Therapy Management is a distinct service or group of services that optimize therapeutic outcomes for individual patients. Medication Therapy Management services are independent of, but can occur in conjunction with, the provision of a medication product. Medication Therapy Management encompasses a broad range of professional activities and responsibilities within the licensed pharmacist's, or other qualified health care provider's, scope of practice. A guideline of services that may be provided at each visit are listed below. The list is not prescriptive or all-inclusive. The pharmacist decides what to do according to the individual needs of the patient at the time of the visit:*
>
> - *Performing or obtaining necessary assessments of the patient's health status*
> - *Formulating a medication treatment plan*
> - *Selecting, initiating, modifying, or administering medication therapy*

- *Monitoring and evaluating the patient's response to therapy, including safety and effectiveness*
- *Performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events*
- *Documenting the care delivered and communicating essential information to the patient's other primary care providers*
- *Providing verbal education and training designed to enhance patient understanding and appropriate use of his/her medications*
- *Providing information, support services, and resources designed to enhance patient adherence with his/her therapeutic regimens*
- *Coordinating and integrating medication therapy management services within the broader health care management services being provided to the patient*

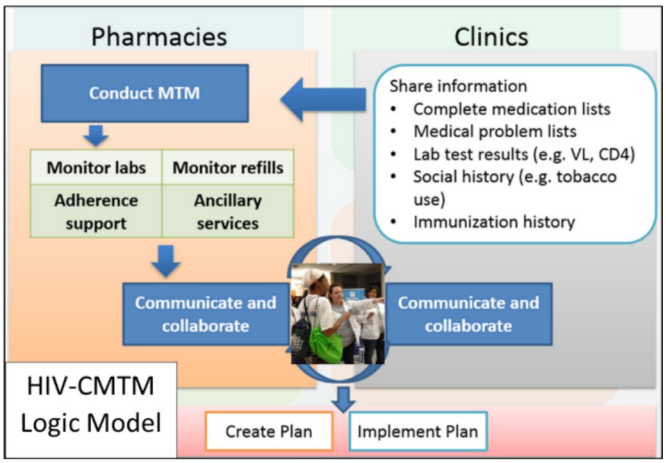

Figure 3: HIV-CMTM Logic Model

Pharmacist provided medication therapy management (MTM) has a proven track record for improving DM and HTN control. MTM is successful in patients with ≥ 3 medical conditions and ≥ 6 medications (K) and AA. (15). In a systematic review of 298 published studies, MTM improved disease clinical and humanistic outcomes. (16). Diabetics with uncontrolled HTN who received MTM were 13 times more likely to gain HTN control ($p<0.001$). (17) A 2nd systematic review involving 14,225 patients showed MTM decreased systolic blood pressures in all patient populations. MTM ideally includes all elements of the Pharmacist Patient Care Process. This 5-steps of this process are: Collect, Assess, Plan, Implement and Follow-up/Monitor. While COLLECT refers to gathering information from both patients and medical records, information typically only consists of prescriptions transmitted and results of patient interview in the pharmacy. MTM (Figure 2) does not requires providers to exchange patient's medical information with the pharmacist. Only in rare or exceptional cases is the community pharmacist ever provided information directly from a patient's medical record. The CDC project's MTM's **innovation** had pharmacists gain access to the patient's medical information, permitting greater knowledge of the medical provider's comprehensive plan as well as the full scope of conditions present and not just those being prescribed therapies. By having access to the medical records, pharmacists were able to: (1) more accurately ask questions, (2) independently determine

the state of each of the patient's medical condition, and (3) make more appropriate recommendations to optimize patient outcomes. The results of this scientifically rigorous study will provide the level of evidence currently missing of MTM's effectiveness in outcomes, make known the domains and levels of influence necessary to address to make it acceptable by the patients (and providers), and create the toolkit to deploy it into other communities where disparities exist.

INNOVATION

The **innovation** of medical record shared MTM is illustrated in the logic model (Figure 3): the sharing of a patient's medical information with the community pharmacist. *Figure 3 is a logic model only and not representative of the actual flow of the study, procedures or study requirements*. This proactive sharing of medical information prior to the pharmacist providing MTM is what is novel. The **impact** of this study is the likely demonstration that MTM improves the health in AA with HIV and discovers influences on MTM acceptability and uptake by patients, their community and providers. Knowledge gained can create a toolkit instructive on expanding MTM into additional communities with healthcare disparities and thereby multiply the impact of this limited measure.

C. Preliminary Studies

UNTHSC recently completed a 4-year demonstration/pilot project that was designed to develop a MTM program for persons with HIV. The demonstration project focus was to assess if MTM could be implemented in a community pharmacy. A secondary goal was to describe the impact on retention in care, viral load suppression and adherence to antiretrovirals. As that project's data analyses are ongoing, only partial results available.

Retention in care: Historical baseline data was that of the 1.2 million people in the US living with HIV, less than half were retained in care (Figure 5). MTM incorporated quarterly visits as a means to engage persons with HIV outside their clinic to see if this impacted retention in care. MTM visits (as compared to returning to medical clinic) permitted a novel approach to maintain engagement with patient. It also provided medical providers routine reports on the safety and effectiveness of the agreed upon medical plan. It worked. Of the 796 participants in the demonstration project, 98% (n=779) were retained in care. However, as a demonstration project, investigators were unable prove causality or assess for domains or levels of influence on why retention improved. This study is designed to demonstrate causality.

Virologic suppression: Preliminary analyses suggest improved outcomes in the 201 AA with HIV with data currently available. In AA with HIV (representing 48% of the CDC project enrolled participants), 85% achieved either virologic suppression (<20 copies/mL) or in those enrolled who already had virologic suppression, these participants CD4 count rose

from below to above 200 cells/mcL. Both strongly suggest clinically significant improvements in control of HIV in AA.

Adherence to medications: these data are not currently available.

Although our CDC-funded demonstration project showed encouraging and promising results, it does not establish causal relationship between intervention and clinical outcomes. There was neither a control group nor random allocation of treatment. The primary critique of demonstration/pilot projects are the lack of scientific rigor to state cause:effect. Therefore, without the evidence this proposal will provide, the population that stands to see the most benefit from such an intervention, i.e., African-Americans, will not.

D. Investigator Experience

In combining post-graduate training and employment after my terminal degree, I have participated in the direct patient care management of a plethora of patient populations with infectious diseases (ID), including HIV. As a clinical pharmacist specialist and board certified in ID, I have a broad understanding of the multidisciplinary team nature of the delivery of HIV care and experience working collaboratively with other health professional disciplines at large academic medical centers, community hospitals, and hybrids of the two. The variety of patient populations and world-class patient care teams I have worked with and continue to work with at the University of Texas Southwestern Medical Center, has provided a solid practice foundation in the field of ID, inclusive of HIV. Correspondingly, prior to finishing my terminal degree, I worked as a pharmacy technician and intern at Walgreens where I personally delivered MTM services.

As pharmacy faculty in ID with a hospital-based clinical practice, I have developed three main pillars of research to stomp out ID focused on outcomes, utilization, and therapy-specific. My primary practice and research interests include multi-drug resistance, scholarship of teaching and learning, and infections in immunocompromised hosts, which include persons living with HIV (PLH). Due to the lack of an immune system, immunocompromised patients are more likely to develop infections not typically seen in immunocompetent patients. This often leads to difficulty in ethically conducting quality research due to available research designs, having an adequate number of patients, or exorbitant numbers of confounding variables. I have particular interests in PLH and am driven to provide more data for both the management of as well as prevention of infection in these patients so that I can better optimize their care. I have provided significant contributions to the literature for transplant recipients, was a CO-I for multiple CDC grants related to latent tuberculosis infection (LTBI), and am a current CO-I of a HRSA grant, “TAKE on HIV for Health Professions Programs” intending to include the National HIV Curriculum into undergraduate education, various health professions education, as well as post-graduation education. I have since joined this project, initially as a CO-I to provide a pharmacist perspective that has conducted MTM and as a subject matter expert on HIV. Starting in July of 2022, I became the PI for this project which will hopefully lead to decreased health disparities for AA living with HIV. My clinical experiences, research skill set, and experience in teaching and education of health professions students

make me well suited for my role in this project.

Dr. Howell has participated in the management of a plethora of patient populations with infectious diseases (ID). These experiences include but are not limited to antimicrobial stewardship for adults and pediatrics, solid organ transplant recipients, bone marrow transplant recipients, patients with cancer, persons living with HIV (PLWH), indigent patient populations in a county hospital, indigent patients at charity clinics, a cystic fibrosis center, a travel medicine clinic, and a leprosy clinic. She has worked for both large academic medical centers, private community hospitals, hybrids of the two, and navigated health systems with several hospitals. The variety of patient populations and world-class patient care teams have provided a solid practice foundation in the field of ID that can be applied to any number of research projects. As such, my respect for the intricacies of the puzzle involving the microorganism (bug), the drug, and the patient has only grown over time.

Dr. Howell received her PharmD from the University of Texas at Austin and completed a PGY-1 Pharmacy Practice Residency at Emory University Hospital followed with a PGY-2 Infectious Diseases Residency at Emory University Hospital Midtown and Emory University Hospital.

E. Experimental Design and Methods

1) Methods and Procedures

Statement of Clinical Trial Conduct:
This trial will be conducted in accordance with the principles and guidance provided by the NIMHD Terms of Award. The Principal Investigator will seek to assure no deviations from, or changes to the protocol will take place without prior agreement from the sponsor and documented approval from the Institutional Review Board (NTRIRB), except where necessary to eliminate an immediate hazard(s) to the trial participants. All personnel involved in the conduct of this study have completed NTRIRB required CITI or UNTHSC mandated trainings prior to being permitted to engage in the study. The PI agrees to ensure that all staff members involved in the conduct of this study are informed about their obligations in meeting the above commitments.

This study is a prospective, randomized (1:1 medical record based MTM, the intervention to non-medical records based MTM, the control or standard of care), clinical trial, comparing disease-specific clinical and humanistic outcomes in 200 adult African-Americans with HIV (1:1 men:women) and either DM and/or HTN. Data will be collected from individual participants for a 2-year period. Potential participants will be identified and recruited as detailed in the recruitment section. A study screen visit will be arranged.

Screening visit (Visit 1)

The screen visit is when the participant will be consented. The screen visit may take place over the phone or in-person. Either the PI or SC will conduct the screening visit. For screening procedures done over the phone, the necessary documents will be sent to the participant's email through Docusign in an encrypted link. The PI or SC will schedule a meeting through zoom to consent the participant and guide them on the pages that requires their signatures. For participants who do not have access to internet the consent form will be mailed out to them. Later the PI or SC will schedule a meeting over the phone to obtain the consenting process and guide the participant on the pages that required their signature. A SCREENING CHECKLIST has been developed and is attached to facilitate the NTRIRB review of the steps being taken by the research team when conducting the screening visit (Visit 1). This (and all) checklists are for use only by research team personnel. Participants will not have to complete the survey at screening visit. Participants are not compensated for completing the screening visit.

Once properly consented, PI/SC will interview participant to learn of any and all healthcare entities who have provided care to the participant. For each of those identified that are, in the opinion of the PI/SC, likely to have meaningful information, a UNTHSC Medical Records Release Form will be completed. Medical records from these identified healthcare provider(s) for the 12 months prior to the most recent visit to that healthcare provider will be requested. These records will be requested to be sent to UNTHSC via (primarily) a secure FTP link using the software program, ACCELLION. This is a HIPAA compliant platform for data sharing/transfer. The record release form instructs the recipient to send an email to the PI to obtain a link. A link is then sent for the records to be securely transferred. The secondary method for transfer will be via certified mail and addressed to PI at UNTHSC. Medical record focus will primarily be those of the participant's primary care and/or HIV care provider. Healthcare facilities will be instructed (on the medical records release form) to contact a research team member to make arrangements to retrieve the medical records if neither of these mechanisms work for that institution. Documents will be transported in locked, secure containers to substantially reduce the likelihood that accidental spillage would occur should the UNTHSC research team personnel be involved in a motor vehicle accident on route between the pharmacy, physical assessment sites (if different) and UNTHSC. If the participant provides the names for non-primary care/HIV providers but whom the participant feels provides or has provided significant care in the past year, these will be sought as well. The 12-month is not an absolute limit and this may be extended back if the participant feels it is appropriate and gives permission. These requests may include ERs (for instance in those participants who use an ER as primary care) or psychiatrists. If it includes prisons, these records will not be sought. The focus of initial and repeated medical record acquisition for the study will be the participant's primary care provider.

Participants will then be asked to provide the information complete a PARTICIPANT CONTACT INFORMATION FORM. This document, maintained in paper form and updated throughout the study, will be securely stored alongside the Case Report Form and the UNTHSC TEAM ASSESSMENT document.

Medical records will be requested using the UNTHSC Medical Records Release Form. See above for details. Billing instructions for costs to provide medical records is provided on the UNTHSC Medical Records Release Form. Instructions to participants regarding any bills received for medical records is provided in the consent form and elsewhere in this document.

This same process to request, attain and securely maintain medical records will be repeated throughout the study every time additional medical records are sought for participants. The participant's responses to questions regarding healthcare provision at each visit will guide need to attain additional records. It is anticipated this would occur every 90 days, maximally. Minimally, we will request medical records every 12 months after enrollment (anticipate to be Visits 4 & 9).

All medical record requests are historical. No medical records will be obtained for dates after a participant has been discontinued or withdrawn. This does not preclude that medical records will be received after a participant has been discontinued. In those instances, where medical records are received after a participant has been discontinued or withdrawn, these records will still be reviewed and information used in the database only. Medical information from this post-discontinuation received medical records will not be provided to the study pharmacist via an updated Case Report Form (CRF) (if the participant was in the intervention group).

If healthcare facility replies that an additional/alternative form(s) is required, PI/SC will contact participants to complete any required elements via the participants preferred and authorized (per contact sheet completed at screening) method. An ADDITIONAL MEDICAL RECORD RELEASE FORM SIGNATURE NEEDED SCRIPT has been developed and is provided for this anticipated need.

Participants will not have to complete the survey at this 'repeat medical record form release signing' visit.

The medical records will be reviewed by the study coordinator and confirmed by a second UNTHSC research team member using the ELIGIBLITY CHECKLIST. Once this is completed and eligibility is confirmed, participant will be contacted (ELIGIBILITY CONFIRMATION CONTACT AND VISIT 1 SCHEDULE SCRIPT) to confirm continued desire to participate and schedule Visit 2. Both will be completed prior to providing a UNIQUE (participant) IDENTIFICATION number (UID) for group assignment.

Medical records for both groups are necessary. As the study is designed to randomize sequentially after medical records are received, medical records will be sought for all those consented. This is a study validity requirement. As the information to determine disease improvement or worsening is only officially determined via medical records of the participant's healthcare provider, medical records must be obtained for both groups to compare groups. This is also why medical records will be sought throughout the study. The information extracted from the medical records and entered into the database will be primarily used to assess for differences between the groups. See the Data Safety Monitoring Plan (provided) for more details.

The layman's description of what specific information will be extracted and used from the medical records is provided in the consent form, following the header, "What information is being used from your medical records?" A more technical description is found in the database section that follows.

Walgreens study pharmacists will not be provided the actual medical records. For those participants randomized to intervention group, the medical records will be used to populate the CASE REPORT FORMS for Pharmacist Use or CRF-Pharmacist. Only the PI, SC (and Dr. Bedimo who is providing physician oversight to ensure accuracy, integrity and meaningfulness of extracted data being provided to the study pharmacist) will see the medical records. Only PI and SC will extract clinical data from the medical records for entry onto intervention group's participant's CRF-Pharmacist. This will occur every time medical records are received for participants randomized to the intervention group. Only the CRF-Pharmacist (not the actual medical records) will be provided to the Walgreens study pharmacist. The CRF-Pharmacist will be provided to the study pharmacist in advance of the MTM visit. CRF-Pharmacist will be hand carried in a secure container and provided to the study pharmacist. For those participants randomized to the control group, a case report form only containing the participant study UID number and other pertinent document header information will be provided to the study pharmacist.

Information from the medical records for all participants will also be used to enter diseases, medications, laboratory results, and vital signs into the study database. More details are contained in the database section below. SCREENSHOTS OF DATABASE entry fields are provided to detail what information from the medical records and CRF is to be entered into the database. To clarify, only the PI/SC will enter data into this database. No study pharmacist or participants will ever engage with this database.

In summary, intervention group participants' initial and all subsequent CRF-Pharmacist given to the study pharmacist will have information extracted from the medical records. During the study, if additional medical records are received and contain information not previously included on the CRF-Pharmacist or update previously included information on the CRF-Pharmacist, this may result in more medical information being added to the CRF-Pharmacist. Control group participants CRF-Pharmacist will never have any information extracted from the medical records included. Recall the standard of care for MTM services is that the pharmacists do not have access to medical records directly from the patient's healthcare providers.

All originals of the CRF-Pharmacist and all medical records will remain at UNTHSC in a secured location (PI/SC offices) between study visits. A copy of the case report form will remain on site at the pharmacy in a secure location accessible only to study authorized Walgreens study pharmacists. Once randomized, the participant will be contacted to arrange an enrollment visit. The participant will be informed which group they were randomized to when contacted to arrange the enrollment visit. A script entitled, "Follow up after consenting, medical records received and eligibility confirmed, to set up an enrollment visit at Walgreens pharmacy" has been developed for this and is attached. If the participant expresses a desire to withdraw upon learning to which group s/he has been randomized, the participant will be reminded of the HIPAA release form and procedures to follow should they wish to no longer participate at that time. Participants will not be compensated for screening visits.

Within the main consent form, the participant will be asked to denote if the participant wishes for their HIV / primary care / specialist medical provider to be notified of their participation in this study.

Visit 2

PI/SC will serve as the visit date and time coordinator between the study pharmacist and participant. At every MTM 'visit', PI/SC will be present. The study pharmacist conducts the MTM based on the information on the case report form as well as that obtained via

participant interview. Upon completion of the interview with the participant, the study pharmacist will develop a prioritized medication problem list and create an action plan. Using sound clinical judgement and following any applicable legal and ethical practice standards, the study pharmacist will discuss/collaborate with the participant and any relevant or applicable medical provider/healthcare team member regarding the plan. Engagement (communication) with a patient's medical provider is part of the standard of care of MTM when deemed appropriate by the pharmacist performing MTM. The study pharmacist will use clinical judgement in deciding when to contact medical providers in the course of providing MTM to the participants. Included in this plan is the recommended next time point when the study pharmacist and the participant should engage for follow up. The preferred interval should not exceed 90 days (this is a data analysis plan and not a participant safety influenced interval). If at this visit (or any future visit), the study pharmacist determines additional medical records are potentially available, the study pharmacist will ensure the PI/SC seeks to attain these. Medical records will be sought for both groups by the PI/SC. If the study pharmacist feels compelled to obtain complete medical records for those randomized to the control group, this is allowed. The study pharmacist would be acting outside of the role of the study pharmacist in this regard and would have to obtain a separate release of medical records using Walgreen's standards to obtain this. Costs associated with this would fall to the study pharmacist or participant. The study pharmacist would be required to communicate this information to the participant. This would impact how that participant's data is managed thereafter but does not require discontinuation from the study. This is detailed later in the protocol, section F.1. This is also provided in the consent in Alternative Treatment section.

PI/SC are present to serve as scribes for the study pharmacist to aid in data acquisition accuracy and completeness. This is communicated in the consent form for telephonic MTM visits. PI/SC will be in compliance with all safety and confidentiality requirements as applicable.

Visit 3 – 9

All visits 3-9 will only take place via telephone or in-person per participant preference.

At the next MTM visit (arranged by the SC and agreed upon by both the participant and the study pharmacist), the study pharmacist will interview the participant to determine progress towards plan desired goals or targets. Upon completion of that interview, the study pharmacist will collaborate / discuss with participant and any or all medical providers as relevant or applicable to the plan and make changes to (update) the plan accordingly.

Once this is completed, the study pharmacist will discuss with the participant when the following MTM visit should take place. PI/SC will be present for each MTM visit they will serve as scribe (note taking on the paper CRF-Pharmacist updated from previous visit) for these follow-up visits and confirm accuracy of information recorded with study pharmacist as soon as possible following completion of the visit. CRF-Pharmacist will not be made available or visible to participant.

This sequence of events will be repeated approximately every 90 days (quarterly) for 2 years after enrollment. At the final visit, participants will be provided information on how to receive MTM visits outside of the study. As MTM is a service that is typically charged to a patient or their insurance company, the study is compensating Walgreens to provide MTM as part of the study. The amount of personal expense to a patient for MTM varies based on how the service is to be billed (cash vs. co-pay). This can also vary based on who provides the service (Walgreens vs. another pharmacy). The study pharmacist will explain anticipated personal cost to the participant at the final visit if MTM is continued at Walgreens only. This is communicated in the consent form in Visit 9. There is additional language in the Alternative to Participation section of the consent form.

UNTHSC team assessments:
A single, qualitative survey assessing barriers to care, health literacy, adherence and other domains will be administered verbally by the UNTHSC research team member at Visit 2-9. A single tool was decided upon after receiving feedback from key stakeholders.

At each visit 2-9, consent to attain the records may be sought from the participant for any medical care received since the previous visit. This will be done for both groups. This process will follow that described in Screening Visit section. Participants will not be discontinued if records are not received. As a reminder as to why medical records are being sought for both groups, if this is not done for both groups, there is a risk that differences in health between the two groups could not be determined. This would not align with data safety monitoring plan.

If a participant withdraws consent to continue at any visit, permission to obtain medical records up until the date of withdrawal or discontinuation will be sought. This represents when information that would be used in the data would be received after discontinuation occurred as the information would have been recorded in the medical records prior to the discontinuation date.

Case report form compilation: CRF-Pharmacist will serve as the cumulative list of clinically meaningful (see further description in Screening Visit section) medical information extracted from the medical records (intervention group) as well as the findings of the study pharmacist performing the MTM (control group and intervention group).

CRF-Pharmacist and CRF-Staff are maintained electronically on the secure LabArchives platform. These are only accessible to UNTHSC research team personnel. Printed versions will be used during the MTM portion of each study visit. The study pharmacist will review and approve PI/SC hand notations made during the MTM portion of the visit. Once approved, PI/SC will update the forms electronically (using Word).

Intervention group Case Report Form updates: Prior to each scheduled MTM visit, PI/SC will update the CRF-Pharmacist and CRF-Staff with information extracted from the medical record (as applicable). The most up-to-date form will be hand carried to the pharmacy for the MTM visit via a secure carrying case by either the PI/SC. The form will be updated during the MTM visit with the information attained of that visit. At the conclusion of the visit, the CRF-Pharmacist will be copied. The copy is stored at the pharmacy in a secure location accessible only to study personnel. The original is (securely) hand carried back to UNTHSC by PI/SC. The information of the visit is used to update the CRF form electronically, then the information is entered into the database and then stored in a secure location. Prior to all future scheduled visits (up to 9), PI/SC will review any newly received medical records (if applicable), update the most recently completed case report form with this information, print the document, then transport it to the pharmacy for the study pharmacist to use at the next scheduled MTM visit.

Control group Case Report Form updates: At the conclusion of each MTM visit for participants in the control group, all CRFs will be updated based on the study pharmacist-participant session. The form will be copied and then the copy stored at the pharmacy in a secure location accessible only to study personnel. Maintaining the historical information will permit the study pharmacist to look back over the course of the study when providing currently providing a MTM intervention. The originals will be hand carried back to UNTHSC by UNTHSC research team member, the form updated electronically (using only the information from the MTM visit), then entered into the database and then stored in a secure location. Only the notes from the previous visit will be used to update the CRF-Pharmacist for control group participants. The updated CRF-Pharmacist will be brought to the pharmacy in advance of the next scheduled MTM visit. This process is repeated after every visit except the final visit where no new updated forms are brought back to the pharmacy.

UNTHSC team assessments: The UNTHSC team assessments will be entered onto the CRF-Staff. This document is not ever shown to the study pharmacist for either group or the participant. The document is also used to update the database.

2) *Data Analysis and Data Monitoring* – Describe plans for statistical analysis of data when appropriate. If a data safety monitoring committee is appropriate to protect the safety and/or welfare of subjects, describe its operation (e.g., membership, stopping rules and frequency of review).

The diseases being used to validate HIV-CMTM effectiveness are HIV, DM and HTN. For HIV, disease control is defined as plasma HIV-RNA of < 20 copies/mL. Standard of care recommends follow-up based on viral load. (19) For DM, self-monitoring of blood glucose is less reliable than quarterly A1c levels (goal of ≤ 7%) which is monitored every 3 months. In HTN, goals vary based on comorbid conditions as follow-up varies with medications. As AA have 2-3 higher incidental rates of stroke compared to whites. (Howard). As a 10 mmHg difference in systolic blood pressure is shown to reduce stroke rate by 24% in AA, a decrease in systolic blood pressure reductions of 10 mmHG [or attainment of blood pressure goal] was selected as the primary measure for effectiveness on HTN. Medical record blood pressure will be the primary source for analyses as ultimately, it is the information collected by the diagnostician that is used for decisions.

Two sample t-test for continuous outcomes (viral loads) and chi-square for categorical outcomes (blood pressure under control or not) would be used to assess significance at the 0.05 level.

DATA AND SAFETY MONITORING PLAN

There are no medical procedures or prescription changes that can occur as part of this study that are not first authorized by the patient's medical provider. A data safety monitoring plan has been presented and approved by the NIMHD Program and Science Officer that reflects the low safety risk to participants, from a medical perspective. The DATA SAFETY PLAN is attached. The risks to participants due to protection of information and how information is safely maintained is addressed elsewhere in the protocol.

3) *Data Storage and Confidentiality*

Data Security, Collection, Entry, Management, and Quality Control: Only authorized study personnel will have access to the data. All HIPAA research safeguards and protocols for protected health information will be observed. All randomized participants will be assigned a unique identification (UID) number for use throughout the project. This number will be

assigned at screening. The UIDs by themselves are randomly generated numbers. These are not linked to any other database's PHI (patient identifiers).

The UID is the first column of the MASTER PATIENT LIST. As the study participants are followed up over time, the main purpose of the master list is for data entry by the study coordinator. All data will be entered based on the UID for each participant as the key. As such, only information necessary to match a participant uniquely to the UID will recorded on the master list. As is on the provided blank MASTER PATIENT LIST, information recorded are: last name, first name, middle initial, gender, date of birth, last 4 digits of the social security number, study arm (intervention/control), and enrollment status (enrolled in the study vs. declined to participate). The enrollment status is necessary because the UID is assigned when the participant is screened. Not everyone assigned a UID will be enrolled in the study. The complete social security numbers are collected for the sole purpose of providing compensations to the participants (a requirement of the UNT BSC). The complete sequence will be contained only on the PARTICIPANT CONTACT INFORMATION FORM. The PARTICIPANT CONTACT INFORMATION FORM will remain in the participant binder that is stored in PI/SC offices. The MASTER PATIENT LIST will be stored in a locked cabinet in the office of the PI or SC. A copy of the MASTER PATIENT LIST will be provided to the study pharmacist for placement in the secure locked cabinet in the study pharmacy that is only accessible by authorized study personnel of Walgreens.

During enrollment period, the master list will be updated and printed after each enrollment, then stored physically in a secured location (as described previously in a secured cabinet only accessible to authorized study personnel at Walgreens or in PI/SC offices). When enrollment ends, a final master list will be stored in the pharmacy accessible only by authorized study personnel. Password encrypted flash drives containing the cumulative patient list will be securely stored at UNTHSC, accessible only by authorized study personnel. As participants are being compensated, their identifying information that is necessary to satisfy UNT BSC requirements for compensation will be provided to finance. Great care has been taken by the PI to remove the word "HIV" from study title and all materials that are required to be handled by non-study related personnel at UNTHSC (finance personnel). Only non-diagnostic PHI will be provided to finance to satisfy policies for study participant compensation.

Medical records will be solicited in accordance with the requirement of the providers or institutions of the potential research participants. The frequency of the solicitation will be contingent on receipt of medical services as disclosed by the participants during the study. If in the course of reviewing medical records, it is discovered there are other providers not

previously disclosed by the study participants (or potential participants during screening), Dr. Bedimo will be consulted on the need to solicit the additional records. In any event, if the records are deemed clinically important by Dr. Bedimo, the participant will be contacted and permission sought to obtain those records. To clarify, if it is discovered medical records exist that represent period of incarceration, these records will not be solicited.

Delivery of medical records is anticipated to be primarily via ACCELLION (encrypted email), certified mail, or fax and if so, addressed to Dr. Howell or the study coordinator. Mail received will be placed in a secure environment (locked cabinet inside a locked office) only accessible to authorized study personnel (PI/SC offices). The study has a dedicated fax machine located inside a locked office and only accessible to study personnel. The fax machine is used to send medical record requests and receive medical records. Healthcare facilities will be instructed (on the medical records release form) to contact Dr. Howell to make arrangements to retrieve the medical records if neither of these mechanisms work for that institution. Documents will be transported in locked, secure containers to substantially reduce the likelihood that accidental spillage would occur should the UNTHSC research team personnel be involved in a motor vehicle accident on route between the pharmacy, physical assessment sites (if different) and UNTHSC. No medical records will be transported outside of the PI/SC offices. Medical records will be scanned and stored into LabArchives and paper copies destroyed (if applicable) after this is completed (maximally 1 year after last study visit is completed for all participants).

Research team has attained ACCELLION secure data transfer capability. This system permits a team member to email a secure link to the institution/individual that has been authorized to release the medical records. ACCELLION uses AES-256 encryption, FIPS 140-2 certified and FedRAMP Authorized, bring your own encryption keys (BYOK) for secure, encrypted transfer of large files as well as a secure email message body whereas only authenticated users can read the message along with a unique digital fingerprint verifies email attachment integrity.

Data on the case report forms are entered into the study database. UNTHSC research team members will enter this data into the study database. The database is created and managed by a project biostatistician. Database only identifies participant UID.

The CRF is a word document. Extracted information will be typed onto the document. This will take place in PI/SC offices (PI & SC offices at UNTHSC). The electronic versions of the CRFs will be stored securely on LabArchives, a password protected, backed-up 12 times daily, HIPAA compliant platform.

UNTHSC research team personnel will be trained extensively on data entry, integrity, rationale, and methods prior to commencement of data entry. Routinely the statistician will meet with PI/SC to provide quality assurance feedback (and if necessary, retraining) during the data collection period. Once data collection begins, the quality and usability of the data will be closely monitored in various ways. For the first two weeks, every single entry (each datum) will be manually verified and validated to ensure correct data entry. Weekly thereafter, descriptive and summary statistics will be computed for data entered during the corresponding week to identify any error trends or anomalies. Beginning in month two (2) of data collection per site, a random sample of patient data (5%, split evenly between male and female participants) will be selected from the prior month's data and also reviewed manually for integrity and quality. Data quality issues will be addressed immediately. All changes to entered data will be logged using a memorandum of odd data and errata (MODE) form (contains UID, data in question, date issue found, issue description, issue remedy, and date completed). MODE forms will be retained securely by biostatistician. All CRF collected data will be stored and backed-up using a platform called LabArchives™. Content placed in LabArchives™ is password-protected, encrypted in transit and at rest, as well as backed up 12 times a day. LabArchives is HIPAA as well as 21 CFR Part 11 compliant. Content owners and administrators can specify who can access or edit each file stored. As the data are collected, the aggregate database will be updated and will be structured to ensure that the study data can be readily retrieved for report generation, statistical analyses, and data transfer. As the data are collected, the aggregate database will be updated and will be structured to ensure that the study data can be readily retrieved for report generation, statistical analyses, and data transfer.

After the final participant final visit is completed, the Master Patient List, Participant Contact Information Form, all remaining medical records and all printed CRF forms will be scanned and uploaded to LabArchives. Once this is completed, all paper copies will be destroyed in accordance with UNTHSC policies for medical record destruction. At the end of the study the master patient list linking specific participants to their UIDs will be destroyed. The study pharmacy will maintain its copies of its documents per its Walgreens policies. See attached Walgreens Authorization for Release of Information to a Third Party for their document retention policy and requirements. The information from this document has been included in the consent form in the section, Terms of Authorization. The form will be provided to potential participants during the consenting process and prior to soliciting any other medical release forms. This will be the first release form provided for the potential participant to sign. If the participant refuses to sign the Walgreens Authorization for Release of Information to a Third Party, then the participant will be a screen failure.

No information generated from this study will be uploaded, stored or retained by Walgreens electronically. The information from this study does not go into Walgreens' MTM system. All MTM information for this study will be on paper until PI/SC enters it into LabArchives (not a Walgreens database). Walgreens personnel will not have access to LabArchives. All elements of this study will be represented in paper form only and stored/housed/secured as described in the protocol. Walgreens retains the materials for legal purposes only.

All data for this study will be maintained for 6 years following the conclusion of the study. At this point, all remaining electronic and paper documents will be handled in accordance with whatever the current UNTHSC policies and procedures for medical record destruction is in effect. The MASTER PATIENT LIST will also be destroyed after 6 years. This will remove all ability of researchers to connect an individual participant's data. Walgreens will store the master patient list, copies of CRF and Walgreens release until 2031.

4) *Setting*

All study visits will take place over the phone or in-person. Participants who request in-person visits will meet with the research coordinator and/or study pharmacist in a room properly suited to accommodate the required distancing per the Center for Disease Control and Prevention's (CDC) recommended COVID-19 safety protocols for the immunocompromised populations. Social distancing will be observed, and the participants will be required to wear a facemask. After the in-person meetings for the consenting process and/or study visits are completed, hand sanitizers will be made available for disinfecting their hands.

5) *Estimated Period of Time to Complete the Study*

MTM sessions typically last up to 90 minutes for the first session then 30-45 minutes for each session thereafter. The UNTHSC assessments and survey are estimated to take 10 minutes or less per visit. Visits are encouraged to not exceed 90-day intervals. There are 8 planned quarterly visits, totaling 9 visits when including the consenting visit.

Due to funding limitations, the last day of study visits will occur on December 15, 2023. A formal memo to be sent via United States Postal Services (or similar university services) and text message verbiage will communicate the study termination to study participants. Participants who have been lost to follow-up, i.e. have not had a study visit in more than six months despite reminder communication, will not receive the physical memo or text message alert. Reimbursement for study visits will only occur for study visits that are

completed by the December 15th deadline.

F. Human Subjects - Describe the characteristics of the research population:

1) Sample Size:

Patient Identification, Recruitment (enrollment rate included in Power Calculation description below), Randomization, and Interim Analysis:
Two hundred adult AA with HIV and either/both DM or HTN will be recruited using NTRIRB approved recruitment materials. Once consented, patient gender and comorbidity stratified randomization (i.e., separate randomization by men/women and by DM/HTN) will be used to randomize them into the intervention group or control. Randomization assignment will be controlled by the biostatistician. This will create eight groups: men with DM receiving intervention (1.a.), men with DM receiving control (2.a.), women with DM receiving intervention (1.b.), etc. (Figure 4). Patients with dual diagnosis of DM and HTN will be randomized into either the intervention or control group. Their data will be used in both DM and HTN analyses (after conducting a sensitivity analysis to determine that the dual diagnosis does not confound or bias the results). A random number generator (range 1 to 10,000) will be used for group assignment. UNTHSC biostatistician will be the only unblinded member of the research team to which number corresponds to the intervention or control groups when presenting data during investigator team safety reviews and data safety monitoring plan described.

The primary endpoint for this study will be the health indicators collected at the final follow-up visit comparing the corresponding intervention and control groups (e.g., intervention vs. control for men with diabetes). We computed the power and sample size based on the effect sizes estimated from our previous CDC-funded demonstration project where observations from 201 African American HIV patients at baseline whose viral loads were either detectable (>20 copies/mL) or their CD4 counts were <200 cells/mcL at baseline. Of these, 171 (85%) showed improvement (viral loads became undetectable or CD4 counts became >200 cell/mcL) at follow-up after receiving quarterly HIV-CMTM. Based on these results and even assuming a very conservative effect of 45% improvement for the control group receiving standard of care projects that a comparison between intervention and control will require 22 subjects per group. This enrollment volume enables attaining a power of at least 80% at the 0.05 level of significance for each of the comparisons. As some attrition is expected, we will recruit 25 patients per group for a total of 200 patients. We also note that the sample sizes are very likely larger as the subjects with a dual diagnosis of diabetes and hypertension will be included in the analyses, but are not included in the

sample size computations shown above. We also conducted additional power analyses based on this sample size to verify that the analyses will be sufficiently powered when the outcome measures are treated as continuous (testing means) rather than dichotomous.

Control Group Medical Record Viewing by Study Pharmacist

Pharmacists are not prohibited from requesting the complete medical record from a medical provider pursuant to normal counseling and care provided, this is just rarely (if ever) done. Pharmacists routinely contact medical providers to recommend changes to medications. If the study pharmacist, in the course of providing MTM to participants in the control group, contacts a medical provider, this will not change the status of the control group participants. If, however, the study pharmacist feels compelled to obtain the entire medical record for a participant in the control group, s/he will notify the participant and PI/ SC. Should the study pharmacist inadvertently gain access to a control participant's medical records (participant brings medical records themselves to the MTM session and the study pharmacist uses the complete medical record for the purposes of MTM), the participant will not be discontinued. In either case, the participant will not be discontinued. The time point at which the study pharmacist gained access to the medical record for participants in the control group will be noted and this will become a controlled variable in the analyses.

2) Describe both *Inclusion AND Exclusion Criteria*.

Inclusion criteria:

- >/= 18 years old or older at time of screening
- Male or female
- Self identifies as African-American or black
- Able to read and speak English sufficiently well enough to be interviewed by study pharmacist (as determined at screening visit by PI/SC)
- Confirmed diagnosis of HIV (medical record)
- Confirmed diagnosis of diabetes, hypertension, or both (medical record)
- Stated agreement to comply with study requirements during screening visit
- Able and willing to provide written informed consent
- Willing to notify study pharmacist if becomes pregnant during study
- Expresses a willingness to participate in all study-related assessments and adhere to study requirements
- Willing to notify research team if planning to relocate
- Willing to notify research team if incarcerated at any point during study

Exclusion criteria: (whether discovered at time of consent or after review of medical records)

- Inability to self-administer medications (either due to mental or physical state)
- Hospice services currently being used or anticipated within the next year
- Systemic chemotherapy (topical chemotherapy allowed)
- Currently a prisoner or have received all healthcare to date as a prisoner

Early / Administrative withdrawal criteria:

Participants may be withdrawn from the study. Participants will be withdrawn from the study if they (i) voluntarily withdraw, (ii) demand to be switched to the other group after becoming aware of assignment, (iii) are lost-to-follow-up (moved), (iv) incarcerated, or (v) participant's care provider requests withdrawal. The PI will notify any participant terminated for any reason of the reason for termination from the study via phone call (voice mail left if no answer) using the following statement, "You are no longer able to participate in the study. The Walgreens study pharmacist has been notified. You may continue to use Walgreens for your pharmacy services if you choose to do so. Please contact Dr. Howell with questions about the study."

3) Describe intended *gender*, *age range*, *intended racial and ethnic distribution*.

   The intended purpose of this study is to limit enrollment only to black/African-American adults (≥ 18) with a goal to enroll 50% women.

4) Identify the *source(s) from which you will obtain your study population*.

   Study participants will be obtained from multiple sources. There is no requirement to be a Walgreens patient to participate in this study. Walgreens pharmacists are able to provide MTM to individuals who are not their patients.

5) Describe plans for *recruitment of subjects*. All materials (e.g., flyers, ads, emails, letters, postings, handouts, etc.) to be used for recruiting subjects must be submitted to the NTRIRB for review.

   As of October 31, 2022, recruitment and enrollment of subjects are completed for the study. There are no current plans for further recruitment. Previous recruitment measures are provided below.
   John Peter Smith (JPS) Clinics: Within the JPS clinics, a site coordinator would review patient profiles with the SCREENING CHECKLIST to identify potential study participants. If the patient met inclusion criteria according to the checklist, the coordinator would either call or meet with the patient, depending on availability, for consent. The coordinator would review the consent form, including the risks and benefits, with the potential participant. If the participant agreed, they would sign the consent form. Conversations conducted over the phone would require follow up with the site coordinator for the potential participant to sign the consent form physically. The site coordinator would contact the PI/SC when patients had consented so that

the participant could be enrolled in the study.

Walgreens recruitment: There is no requirement to be a Walgreens patient prior to or during the study.Walgreens pharmacy will be used to recruit participants. Only Walgreens pharmacists will contact Walgreens' patients to make their patients aware of the study. This is being done to reduce 'cold call' aspect. Walgreens' pharmacists will review their patient profile system and attempt to identify potential study participants. Walgreens data systems does not contain racial information. Thus, only the patients the pharmacist personally believes to be African-American or black will be contacted.

A general report description is provided. The specific query mechanism used by Walgreens is proprietary. Pharmacists will perform review of prescription records to identify potential study participants by seeking current (within past 12 months) patients who have received HIV treatment (not PrEP) medications and either medicines likely to be used for diabetes or hypertension. Once this list is created, the pharmacist will review for appropriateness to consider initiating contact and making patient aware of study opportunity.

Walgreens study pharmacist will inform current patients of study opportunity either using NTRIRB approved materials or a Walgreens pharmacist may verbally engage during regular encounters (potential participant picking up routine medications from the pharmacy). The specific level of engagement will be left to the discretion of the pharmacist who knows the potential participant best. Individuals who are identified as potential research participants will be notified how to contact the PI or study coordinator. It is being left to the discretion of the study pharmacist how to provide the information regarding the study to their patient. No patient information will be shared with the UNTHSC research team for the purposes of recruitment. Walgreens personnel not approved to work on the study who are working in the study's pharmacy will direct questions and inquiries regarding the study to the Walgreens personnel approved to work on the study. NTRIRB approved materials will be provided to regional Walgreens pharmacies for distribution. The approved materials may be shared during regional Walgreens pharmacy meetings.

Community-wide (non-Walgreens based) recruitment:

There is no requirement to be a Walgreens patient to participate in this study. Recruitment will occur at other healthcare sites around the region. UNTHSC team personnel will conduct study awareness sessions with healthcare professionals in the region. This will include non-Walgreens pharmacies. PI & SC will set up meetings to inform regional healthcare providers of the study opportunity. NTRIRB approved materials will be provided for distribution per the policies of these individual institutions / entities. PI/SC may coordinate and provide meals as part of these meetings, paid for by the funding source.

NorTex Registry – Personnel who are approved to work on this protocol and with the NorTex registery will contact potential participants as per the NorTex approved procedures. If individuals are interested and qualify to participate (initial telephone screen script approved for 2018-094 will be used), a formal screening visit will be coordinated.

PI/SC will also meet with leaders of local AIDS service organizations and support groups. If invited to do so, PI/SC will return to speak to members of these organizations/groups. During these meetings, only the materials approved by the NTRIRB will be presented, shared or left for distribution. It will be left to the individual/organization to determine what, if any, additional levels of approval are needed for participants to be recruited from these potential sites. For instance, if these sites require modification to the study flyer, revised study flyers will first undergo NTRIRB review and approval before distribution.

For groups where meetings with leaders are not achieved, copies of the consent form and other NTRIRB approved materials will be sent to publicly listed addresses for these groups. It will be left to the discretion these leaders how to proceed with distribution of the materials.

Media outlets (i.e., buses, billboards, online newsletters, websites) may be used to distribute marketing materials. Health fairs and community events may also serve as a recruitment site. Only NTRIRB approved materials (regardless if static – like flyers and ads – or dynamic – such as website materials, audio or video recordings to include first approval or the script then a secondary approval of the actual media) will be distributed at these events or submitted to media outlets for distribution.

Study flyers will have a QR code that will redirect possible participants to the study website (www.unthsc.edu/addup).

No referral fees will be paid to any entity facilitating participants to contact UNTHSC research team to arrange screening visits. This applies to both healthcare and non-healthcare personnel.

G. Risk/Benefit Assessment

1) Describe the *level of risk*, and if more than minimal, describe how this research holds the prospect of a *direct benefit for the subjects*. If there is NO direct benefit to subjects, state such in protocol and in the consent documents.

Based on nature of the intervention and UNTHSC experience with both the nationwide CDC and local Tarrant County Health Department-funded demonstration projects, adverse events are not anticipated. The research team assesses this to be a 'low risk' study from any

medical perspective. We anticipate that most, if not all, adverse events will be due to the participants' medical conditions, lifestyle, or accidents. Given the nature of the study (longitudinal study, data analyses of medical record and questionnaires, and subject population), hospitalization and death caused by natural consequences of age and disease (i.e. HIV patients), and unrelated to this study, are anticipated. Such death and hospitalization will not be immediately reported, but reported at annual review. With respect to benefits, other than potentially improving the overall health of participants, there is no anticipated benefit.

2) Describe how the anticipated benefit justifies the risk.

   As there is minimal physical risk, the benefit to the participant appears acceptable. The RISKS AND DISCOMFORTS section of the consent form provide the usual and customary potential risks.

3) Describe how the anticipated benefit of this research is at least as favorable to the subjects as that to be received by available alternative approaches for the subjects.

   The anticipated benefit of improvement of control of diabetes or hypertension is potentially equivalent to if the participant sought this care from their current pharmacist. It is possible to obtain this service from another pharmacist. Obtaining MTM outside the study may require payment from the participant. Some health insurance or third-party payers do not cover MTM visits (except an annual MTM visit by Medicare).

4) Describe any potential RISKS OR DISCOMFORTS in detail.

   The potential risks that is of greatest concern is the accidental disclosure of HIV status. As such, great efforts are being taken to ensure medical records arriving at UNTHSC are delivered to PI/SC office upon arrival. Further, all documents that are being hand carried to the pharmacy will only contain limited identifiers (UID, Initials and gender). The documents will have diagnoses and other PHI. Documents will be transported in locked, secure containers to substantially reduce the likelihood that accidental spillage would occur should the UNTHSC research team personnel be involved in a motor vehicle accident on route between the pharmacy, physical assessment sites (if different) and UNTHSC. As PI/SC will be on site at Walgreens for each MTM visit, no original documents will be left in the pharmacy for storage. Only copies of CRFs (updated manually by PI/SC) [recall that no medical records are transported to the pharmacy] will remain in the pharmacy in a locked storage cabinet/file accessible only to study authorized personnel. This same cabinet/file will also house a copy of the master participant list.

Discomfort can occur by having to answer questions about health in front of the study

pharmacist and the PI/SC. This is being reduced by providing several points of contact/communication. Because there are multiple visits, participants have ample opportunity for concerns and questions to be addressed by the research team.

H. Payment/Compensation - Describe any financial payments for participant participation (e.g., compensation for time and travel). Indicate any partial payment schedule for less than complete study participation. Recall that payments cannot be perceived as coercive (overpayment for time and effort). Remember: payments are NOT benefits.

During the period of time of the COVID-19 pandemic, enrolled participants who have difficulty with any aspect of the compensation process described below will have the situation addressed by approved study personnel in accordance with approved processes (provide participant a new Greenphire card or gift card) but in keeping with minimizing physical contact with enrolled participants.

Participant compensation: The participant will receive compensation ($50) at the conclusion of the assessment collection at visit 2-9 (TOTAL $400).

Primary plan:

The initial payment will be provided via a preloaded debit card (Greenphire™ system). An image of the card is provided. The cards do not contain the participant's name. It will actually display, "Valued Cardholder".

The first debit card is provided to the participant at no cost. At all visits, including the enrollment visit, the participant who declines to have any assessments performed or agree to sign any additional medical release forms will still be compensated for completing the MTM visit ($50). As the compensation is provided remotely (via Greenphire™ debit cards), there is no incentive to physically meet with the UNTHSC team at any point during the study after Visit 2 just to be paid. If the participant has lost their Greenphire™ debit card (after Visit 2), a new one can be mailed to them (minus the cost of card replacement plus postage or roughly $3) at the address provided on the most recently updated version of the PARTICIPANT CONTACT INFORMATION FORM.

Backup plan: If there is an issue with the debit card system and an alternate means of payment is needed, participants will be provided a $50 gift card instead at the conclusion of each study visit that is applicable. This is included in the main consent form.

I. Subject Costs - Describe any anticipated costs to research participant. If none, state such.

After enrollment, participants will be asked if travel or child care represent barriers to making MTM visit appointments (at the pharmacy). If participants express a concern regarding the cost to travel to visits to the study pharmacy, UNTHSC research team will discuss the possibility to reimburse the participants for travel costs with both Office of Sponsored Programs and NIMHD. If participants express a concern with retention due to obtaining child care to free them up to come to their research visits, UNTHSC research team will work with the Office of Sponsored Programs and NIMHD to ensure this reimbursement is allowable. If either reimbursements are allowed, UNTHSC research team will develop a reimbursement procedure, estimated average amount, then work with and then submit a revised consent to the NTRIRB for approval prior to initiating reimbursement for participants, if NTRIRB deems this necessary.

Language has been inserted into the consent form (COSTS) to address if participants inadvertently receive bills for medical records. PI/SC will, upon notice from participant, immediately initiate actions to resolve the incorrect bill so as to avoid any collection notices or even late payment notices. The PI/SC will follow up with the participant weekly until such time as the issue is resolved. In the event a participant inadvertently pays for medical records that were part of the study and the PI/S learns of this, a reimbursement process will be developed and obtain approvals as necessary (NTRIRB, NIMHD, UNTHSC OSP, etc.) to ensure the participant is repaid.

J. List of KEY PERSONNEL. See Key Personnel Delegation Log

K. Literature Cited

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