VA Video Connect to Improve Access to Multi-disciplinary Specialty Care

NCT04055207

May 1, 2025

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Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Protocol Number: **H-45072**
Status: Approved
Initial Submit Date: 2/26/2019
Approval Period: 8/27/2021 - 8/27/2026

Section Aa: Title & PI

A1. Main Title

VA VIDEO CONNECT TO IMPROVE ACCESS TO MULTI-DISCIPLINARY SPECIALTY CARE

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A3a. Financial Conflict of Interest

Does any member of study personnel (Investigator (including investigator's spouse and/or dependent children)) that are involved in the design, conduct, or reporting of the research have a Significant Financial Interest (SFI) that would reasonably appear to be affected by the research for which funding is sought and/or associated with an entity/business that would reasonably appear to be affected by the research?

No

Section Ab: General Information

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A5. Funding Source:

Organization: VA HSR&D

A6a. Institution(s) where work will be performed:

BCM: Baylor College of Medicine
Michael E. DeBakey Veterans Affairs Medical Center

A6b. Research conducted outside of the United States:

Country:
Facility/Institution:
Contact/Investigator:
Phone Number:

If documentation of assurances has not been sent to the Office of Research, please explain:

A7. Research Category:

A8. Therapeutic Intent

Does this trial have therapeutic intent?
No

A9. ClinicalTrials.gov Registration

Does this protocol/trial require registration on ClinicalTrials.gov due to it: meeting the definition of an Applicable Clinical Trial, being required under the terms and conditions of an award, or being proposed to be published in ICMJE journals?
No, this clinical is not a clinical trial, or does not meet the definition of an Applicable Clinical Trial, or does not need to be registered under the terms and conditions of an award, or is not a clinical trial with results intended to be reported in an journal belonging to the ICMJE. Registration is not required.

Section B: Exempt Request

B. Exempt From IRB Review

Not Applicable

Section C: Background Information

Chronic Human Immunodeficiency Virus (HIV) is a condition in which integrated, multi-disciplinary care is standard to improve engagement in and adherence to care and to improve clinical outcomes. However, as many as 50% of people diagnosed with HIV infection are not in regular HIV primary care in the US. Antiretroviral therapy (ART) has transformed HIV infection into a treatable, chronic condition. Poor retention in HIV primary care affects access to ART and survival. It also results in lower rates of HIV suppression and, because so many persons with detectable viremia are out of care, those poorly retained in care are thought responsible for more HIV transmissions than both those in care and those undiagnosed combined. Poor retention also exacerbates racial and ethnic disparities in health outcomes: racial- and ethnic-minority patients are more likely to have poor retention in care, which is in turn associated with increased mortality.

"Retention in care" is measured by VHA as completing at least 1 visit with a primary care provider or HIV clinician in both halves of the year, at least 60 days apart. In 2016, 19% of Veterans with HIV in VHA care nationwide (27% of 948 Veterans in Houston) did not meet this standard. Of those who met the standard of retention in care and were on ART, 18% (17% of 640 in Houston) did not achieve HIV suppression, the marker of clinical effectiveness of ART. Note that more than a third (308 of 948) of Veterans in the Houston data were not included in the HIV suppression measure either because no VL data were available, they were not on ART, or they were not retained in care. Most of these 308 Veterans would also not have HIV suppression due to not being retained in care or not being on ART. The Houston data are not atypical across the VA. Despite being better than the US national average, about 1 in 5 Veterans has not achieved retention or suppression, and some facilities have populations that are doing worse than the national average. Further, out-of-care Veterans who might have suppression miss important health screenings, management of other chronic medical conditions, and healthy lifestyle interventions. How to better retain people with HIV infection in HIV care and increase the proportion with persistent HIV suppression remains one of the most important goals in HIV/AIDS care. The VHA HIV, Hepatitis and Related Conditions Program, in the Office of Patient Care Services, listed four national priorities for VA HIV care in its 2016 Annual Report, including "increasing engagement to treatment and adherence for all HIV positive Veterans."

Multi-disciplinary care has been shown to improve retention in care and adherence to ART by addressing comorbidities, providing treatment support, and addressing other barriers to care. Patients who receive care at clinics providing case-management services, including assistance with meals, housing and transportation have been shown to achieve high rates of HIV suppression, especially for patients living at or below the poverty line. Multi-disciplinary care is recommended by the US Department of Health and Human Services HIV Treatment Guidelines which VHA uses as its treatment guidelines per VA Directive 1235(1), May 2017.

Patient-reported barriers to retention in care include inability to afford transportation, unreliable public transportation, distance to clinic, difficulties with scheduling appointments, demands of family and job, depression, stigma and fear of disclosure of their status that discouraged some from regular clinic visits. We found that, as travel time to an Infectious Diseases (ID) specialty clinic increases, Veterans with HIV are less likely to use the ID clinic and more likely to use primary care. We found this difference with travel times to the specialty clinic as little as >15 minutes. CBOC-based care can reduce travel time, though often not to less than 15 minutes, but has little impact on other barriers to regular outpatient care for HIV infection.

Interventions to improve retention in HIV care have generally focused on changing the patient¿s behavior and have had limited effect, if any. A randomized, multisite trial found that reminders and enhanced contact with persons at high risk for poor retention had a modest (<10%) impact. Many intervention features in that study are already standard care in VHA, including pre-visit reminders and early outreach for missed visits. Other efforts to improve retention include mentoring, patient navigation and contingency management. These interventions have had little or no sustained impact; all rely on bringing the patient to the healthcare setting.

VA Video Connect (VVC), a VA-supported mobile health video technology that allows Veterans and providers to complete clinical visits from any remote location including the home, has the potential to transform delivery of multidisciplinary care for HIV and other chronic conditions by increasing access to care. Although VVC has the potential to address barriers such as distance and travel to the VA as well as the unique anxiety, confidentiality concerns, vulnerability, and stigma that people living with HIV may experience, very few studies of telemedicine for HIV care have been conducted. Four VHA-approved and supported options for engagement in telehealth are available to reach the largest number of Veterans possible. These modalities include webcam, iPad, cellular-enabled tablet and peripheral tablet. Veterans connect to their providers using these devices through their own internet or Wi-Fi connection at home or another private location (e.g., office, private room at a library), a hot-spot connection through their mobile data plan, or via a cellular-enabled tablet. VHA-issued cellular-enabled tablets have 4G service built in, which allows Veterans to connect to their providers regardless of the Veteran's location or access to an internet connection. In addition to the main device used for video connection, peripheral devices are available. These include blood pressure monitors, heart rate monitors, weight scales, stethoscopes, glucometers, and pulse oximeters. Some of these peripheral devices connect by a cable to the hub unit, are integrated within the hub device itself (such as a blood pressure monitor) or may connect wirelessly via Bluetooth for uploading vital signs or other biometric data. Home Telehealth staff, as part of the comprehensive assessment of each patient, determine the appropriate type of peripheral device, based on specific patient need. For example, patients with limited manual dexterity may require a tethered or integrated device. All VHA telehealth equipment has VHA-enabled encryption and is VHA-approved and supplied by the Denver Acquisition and Logistics Center and compliant with HIPAA guidelines and standards. VVC has been available as standard practice in VA since 2013, though it has not been used widely for specialty medical care. Despite the goal set by VA leadership for 5% of Veterans to receive care via VVC in FY2018, less than 0.1% of Veterans with HIV have used VVC. VVC could help fill these gaps in care.

Section D: Purpose and Objectives

To promote use of VVC-delivered, multi-disciplinary HIV treatment and care among VHA providers and Veterans, a robust facilitation strategy and effectiveness data are necessary. Implementation Facilitation (IF) is a theoretically driven and evidence-based implementation strategy developed by the Behavioral Health Quality Enhancement Research Initiative (QUERI) and collaborators. IF has been used to successfully implement a variety of health innovations. IF is a collaborative process that identifies barriers and facilitators to adoption and use strategies, such as training, support and trouble-shooting, to tailor implementation efforts to meet the needs of local contexts and to promote intervention uptake.

We will conduct a Hybrid Type II effectiveness-implementation study with the following aims:

Aim 1-Clinical Effectiveness: To determine the effectiveness of VVC-delivered, multi-disciplinary HIV care compared to routine care on retention in care.

Aim 2-Implementation: To conduct a mixed-methods formative evaluation to refine and evaluate our IF strategy to improve the reach of VVC-delivered, multi-disciplinary HIV care, to increase provider and Veteran adoption, and to determine potential for sustainability.

The clinical work will be conducted at the Michael E. DeBakey VA Medical Center (MEDVAMC) Infectious Diseases clinic, which cares for almost 1000 Veterans with HIV. Research will be housed at MEDVAMC¿s HSR&D-funded Center for Innovations in Quality, Effectiveness and Safety (IQuESt). VVC technology will increase access to HIV care for underserved Veterans and will allow VHA to better meet the needs of vulnerable Veterans and clinicians. The formative evaluation will be conducted simultaneous to Aim 1, and will inform strategies to disseminate VVC for HIV treatment and care across VHA. This proposal is particularly timely following VA's recent ruling allowing VA clinicians to provide telehealth care across state lines. This research will provide a model to increase access to comprehensive multi-disciplinary specialty care for HIV and other chronic conditions using VVC technology.

Section E: Protocol Risks/Subjects

E1. Risk Category

Category 1: Research not involving greater than minimum risk.

E2. Subjects

Gender:
Both

Age:
Adult (18-64 yrs), Geriatric (65+ yrs)

Ethnicity:
All Ethnicities

Primary Language:
English

Groups to be recruited will include:
Patients

Which if any of the following vulnerable populations will be recruited as subjects?
Employees or lab personnel

Vulnerable populations require special protections. How will you obtain informed consent, protect subject confidentiality, and prevent undue coercion?

Some employees of VA or Baylor College of Medicine may be invited to provide feedback on their experiences with VVC, exposing them to the risk of coercion to participate in the research project. Employees who are invited to participate will be informed that participation is voluntary and will not affect their current or future employment status. They will have the opportunity to decline participation in the qualitative interviews and will be informed that they may withdraw at any time. No information other than name and job title will be collected from employees who choose to complete the interviews. Employee participants will be informed that their supervisors will not know their participation status for the study. While there is a risk of loss of confidentiality, all measures described in Section J1 will be taken, such that this risk is minimized as much as possible.

E3. Pregnant woman/fetus

Will pregnant women and/or fetuses (as described in 45 CFR 46 Subpart B) be enrolled in the research?
No

E4. Neonates

Will neonates of uncertain viability or nonviable neonates (as described in 45 CFR 46 Subpart B) be enrolled in the research?

No

E5. Children

Will children be enrolled in the research?

No

Section F: Design/Procedure

F1. Design

Select one category that most adequately describes your research:

a) Chart/scan/record review

Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.

For Aim 1, the clinical effectiveness study, we will randomly assign Veterans to be offered VVC. All treatment as usual options for HIV care at MEDVAMC will be available to all patients in both randomized conditions, however the Veterans in the VVC arm will be actively offered this VA-approved technology. Each day's scheduled patients will be listed and will be randomly assigned to either have VVC offered to them or not. Randomization will be 1:1 to the two groups in random blocks of 4 or 6. Veterans who attend clinic and were assigned to be offered VVC will be informed in private that we are offering sign-ups for the service today. Veterans randomly assigned to not be offered VVC will experience usual care. Veterans attending this "initial visit" in both arms will be entered into the trial dataset. To include persons representative of the "out-of-care" population, we will mail letters to Veterans who had contact with the VA in the first 6 months of the preceding 12 months but have no completed laboratory or clinic visits for the last 6 months and have no upcoming scheduled appointments, as determined by on-going queries of the local HIV clinic "immunology case registry" database. These Veterans meet VA's definition of "out of care." The letters will encourage the Veterans to schedule an in-person appointment, and half (by random allocation) will also receive information on VVC delivery of healthcare. Veterans approached via letter outreach will be randomized as above and entered into the trial database when the letter is mailed. This mailing date will constitute the Veteran's "initial visit." These "outreach" Veterans will provide critical data on the reach, effectiveness, and acceptability of VVC. Patients who "no show" for the scheduled appointment will not be entered into the trial and will be re-randomized when they appear on the schedule for subsequent visits. Standard clinic outreach activities will occur in parallel with these study procedures.

For Aim 2, evaluation of the implementation, up to 40 Veterans will be invited to complete qualitative telephone interviews regarding their experiences receiving care via VVC. Key informants including clinic leadership and providers will also be invited to complete interviews regarding the VVC implementation.

Inclusion Criteria:

Patients: 1) Patient in the Infectious Diseases clinic at MEDVAMC with HIV infection; 2) at least 18 years of age; 3) able to speak English; 4) able to consent to the use of VVC.

Providers: 1)MEDVAMC Infectious Disease Clinic leadership and providers who provide VVC care

Exclusion Criteria:

Patients: 1) Unable to use or consent to use VVC, due to either significant physical or mental disability; 2) incarcerated (though the MEDVAMC does not generally provide care for prisoners.

Providers: 1)Does not provide VVC care. 2)Declines participation

F2. Procedure

Aim 1 Clinical Effectiveness: MEDVAMC ID Clinic providers will offer the option to receive care via VVC at the time of the in-person clinic visit for those patients who are randomly assigned to that condition. Patients who accept this VVC offer will meet with a study staff member in the specialty clinic to receive information on preparing for their first VVC visit along with a demonstration on how to use VVC on a mobile device. Study staff will follow all clinic safety protocols for COVID-19 precautions, including wearing masks, gloves, and face shields. Staff will also clean all touched surfaces including demonstration devices (e.g., iPad) after each interaction. All variables (other than randomized arm, "in-person" versus "outreach" approach, and "accept" or "decline" VVC among those offered) will be measured from the electronic medical record, so that clinical care is not impacted by research assessments. Data from the medical records will be extracted between 06/01/2020 and 12/31/2024. These variables include age, sex, rurality, OEF/OIF status, race/ethnicity, distance to MEDVAMC clinic/rurality, CD4 cell count, and HIV viral load. Validated measures consistent with routine care and available for administration within Mental Health Assistance will be collected at baseline and again at 12 months, unless clinically indicated to be administered more frequently. The Patient Health Questionnaire (PHQ-9) is a 10-item measure incorporating depression diagnostic criteria from DSM-5; it will be used for screening/monitoring symptoms and severity of

depression. The Posttraumatic Stress Disorder Checklist (PCL-5) is a 20-item measure that assesses the DSM-5 symptoms of PTSD; it will be used for screening/monitoring symptoms of PTSD. The Alcohol Use Disorders Identification Test (AUDIT) is a 10-item screening tool to assess alcohol consumption, drinking behaviors and alcohol-related problems. The Montreal Cognitive Assessment (MoCA) is a brief screening tool that assesses cognitive functioning across 8 domains: attention and concentration, executive functions, memory, language, conceptual thinking, calculations and orientation.

Aim 2: Implementation Mixed-Methods formative evaluation will be ongoing, iterative, and guided by the innovative RE-AIM QuEST framework that integrates both quantitative and qualitative data, allowing simultaneous data collection on reach, effectiveness, adoption, implementation and maintenance outcomes. The RE-AIM QuEST framework guides formative evaluations to understand contextual factors and tailor interventions and implementation strategies to address those factors (pre-implementation), adapt the intervention and/or strategy to promote uptake (implementation), and understand effectiveness outcomes and potential for sustainment (sustainability). Quantitative and qualitative data are complementary, addressing similar questions in each RE-AIM domain. For example, if we reach lower numbers of Veterans with VVC, qualitative data may indicate possible barriers such as the Veteran's comfort level with technology.

Quantitative Data Collection. Data from the medical records will be extracted between 06/01/2020 and 12/31/2024 to determine and describe percent of visits completed by VVC, by provider type; provider age; provider status (licensed independent provider or trainee); and Veteran characteristics. To efficiently track problems with VVC, we will add data tracking items to providers' CPRS notes, as we have done in other projects. Data collected will include connection quality (audio, video, blue-tooth peripheral reading) and whether calls were dropped or unable to be completed, which can be collected from the provider in a few seconds. The data will inform the National Telehealth Helpdesk, who have been our partners in previous studies and strengthened their response to technical issues with our real-time feedback.

Qualitative Data Collection. During the pre-implementation phase (months 0-6), qualitative data will be collected during interviews via telephone or VA-secured teleconferencing platform with key informants who provide consent, including clinic leadership, internal facilitators/champions and providers (n=8-10) in the participating MEDVAMC Infectious Disease clinics (including multi-disciplinary providers). These interviews will focus on potential factors that may affect Veteran enrollment in multi-disciplinary HIV care via VVC (reach), barriers and facilitators that may impact provider uptake of the intervention (adoption), provider viewpoints on the effectiveness of multi-disciplinary HIV care via VVC (effectiveness), and possible adaptations to deliver effective care via VVC (implementation). Interviews will take place by phone or VA-secured teleconferencing platform, last ~ 30-40 minutes and be conducted by Dr. Chen and a research assistant. Detailed notes of the interviews will be taken; interviews will also be audio recorded with consent to supplement written notes. We will create an interview summary document consistent with rapid qualitative methods. To inform our implementation efforts and augment our key informant interviews, we will conduct debriefing interviews with external facilitators (n=3) to document their experiences conducting IF activities such as site visits, implementation planning calls and engaging leadership. External facilitators are study team members and we expect debriefing interviews to last 30-45 minutes. The interviews will be conducted by Dr. Chen and qualitative study staff remotely, over VA-secured teleconferencing platform. The project team will engage Veteran stakeholder groups (IQuESt Veteran Community Engagement Committee) to learn Veterans' perceptions about VVC-delivered multi-disciplinary HIV care and how to improve Veteran engagement.

During the implementation phase (months 7-24), we will conduct key informant interviews interviews via telephone or VA-secured teleconferencing platform with 6 providers (e.g., mental health, primary care, infectious disease, social services) delivering multi-disciplinary HIV care via VVC who provide consent. Provider interviews will focus on motivations for adoption, barriers/facilitators to enrolling Veterans in VVC (reach), how providers delivered the intervention including adaptations (implementation) and barriers/ facilitators to maintaining VVC HIV care. Interview procedures will follow the same steps and methods outlined in the pre-implementation phase. In-depth interviews with Veterans (n=25) using VVC, and recruited for the study in-person, will be conducted. Given the diversity of the HIV patient population (e.g. demographic, military service, type of multi-disciplinary care received via VVC), maximum variation sampling will capture a wide range of experiences, but allow us to identify overarching themes crosscutting this diversity. We feel this sample will have enough "information power" given its theoretical grounding in RE-AIM outcomes, use of rich and focused interviews on reach and effectiveness of the intervention, and case-oriented analysis given our focus on 1 setting - the MEDVAMC. However, we proposed a larger sample of 25 in-depth interviews due to the variation among our participants (i.e., demographics and type of HIV care received) that may require a somewhat greater number of interviews to identify crosscutting themes. We will reassess "information power" throughout data-collection. A smaller subset of "outreach" Veterans (n=15) using VVC (i.e. those recruited for the study who were "out-of-care") will also be interviewed. We believe this group of participants will bring different perspectives on treatment engagement due to their time outside the VA system, and warrant slightly different interview questions. Veteran interviews will be conducted via telephone or VA-secured teleconferencing platform with by Dr. Chen or a research assistant, will last approximately 60 minutes, and will be audio recorded and transcribed for analysis.

In the post-implementation (sustainability phase, months 25-48), we will conduct key informant interviews via telephone or VA-secured teleconferencing platform with with internal facilitators/clinical champions, clinic leadership and providers (n=8-10). Interviews will follow the same logistical and rapid analysis procedures as in our pre-implementation phase. We will also re-engage with Veteran stakeholder groups by presenting study findings for feedback. Discussion with Veteran stakeholders will focus on developing Veteran-centric strategies to increase the reach of VVC-delivered multi-disciplinary HIV care. Interview data and stakeholder feedback will inform our plans to more widely implement and promote the dissemination of VVC for the delivery of multi-disciplinary HIV care across the VHA.

All data collected from providers regarding VVC will be collected from consented phone interviews as described above and

referenced in the attachment in Section S., "Verbal Consent Script for Qualitative Employee Interviews 2.28.23."

Audio recordings for Veteran interviews only will be transcribed by the VA's national HSR&D Centralized Transcription Service program (CTSP), as described in Section K.

Veterans who are not randomized to receive information about VVC still have the opportunity to learn about VVC outside the research context. Veterans randomized to usual care will be informed about VVC delivery of care should it be found to be beneficial in the results produced by this research. Veterans randomized to usual care will be informed about VVC delivery of care should it be found to be beneficial in the results produced by this research.

Section G: Sample Size/Data Analysis

G1. Sample Size

How many subjects (or specimens, or charts) will be used in this study?

Local: 390 Worldwide: 390

Please indicate why you chose the sample size proposed:

For Aim 1, a priori power calculations were conducted in G*Power and assumed a 2-tailed alpha of .05. With an expected 73% retention in care in usual care (the most recent rate available for the MEDVAMC HIV clinic), 360 Veterans (180 randomized to the option of VVC and 180 to usual care) would allow 80% power to detect 85% retention in care among those offered VVC. This 12% absolute difference is clinically meaningful: the "REPC" intervention produced a 10% absolute improvement in retention in care. That intervention is being packaged for dissemination by CDC.

Aim 2 studies are qualitative and sample size is chosen to achieve sufficient information power, as described in section F2:Procedure. A subset of 40 of the 360 randomized participants will be selected to complete qualitative interviews regarding their experiences receiving care via VVC. In addition, we expect to complete 30 interviews with staff and stakeholders. These 360 participants are the same participants whose medical records will be reviewed.

The total number of participants is therefore 360 plus 30.

G2. Data Analysis

Provide a description of your plan for data analysis. State the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance). Which is the PRIMARY comparison/analysis? How will the analyses proposed relate to the primary purposes of your study?

The primary outcome is the constancy measure of retention in care, a binary variable. We will conduct a multiple logistic regression model to evaluate differences in outcome between treatment groups. Constancy (1=yes, 0=no) will be the outcome, treatment group (VVC offered or usual care) will be the independent variable, and any variables that differed between treatment groups will serve as covariates.

We will conduct similar analyses for the secondary outcome, HIV suppression, which is also binary, using the last viral load in the follow-up year. We will conduct a series of analysis of covariance (ANCOVA) models to evaluate differences between treatment groups in continuous secondary outcome variables, including the "adherence" measure of retention in care; completed visits for adherence, mental health, and social services counseling; and the number of known breaches in confidentiality and other safety outcomes. Again, treatment group (VVC or usual care) will be the independent variable and variables that differed between treatment groups will serve as covariates.

While we expect random allocation to produce an even distribution of measured and unmeasured potential mediators, moderators, and confounders to measuring the impact of multi-disciplinary care delivered by VVC, we will examine the impact of known cofactors. Important cofactors known to predict clinical and adherence outcomes are age, sex, race/ethnicity, distance to clinic, substance use, trauma, depression, past engagement in care (i.e., in-person versus mail outreach contact), CD4 cell count, and HIV viral load. We will first use independent samples t-tests and chi-square analyses to determine if these variables differ between those in the VVC and usual care arms. If they do, we will include these variables as covariates in subsequent models that examine differences between treatment groups in predicting outcomes. Additionally, all analyses will consider in-person versus outreach enrollment as a cofactor.

The dataset will be analyzed as "intent to treat," with all Veterans with an "initial visit" included in the trial dataset. We will also conduct "as treated" analysis comparing Veterans who accepted, declined and were not offered (usual care) VVC to inform future research. These analyses will be identical to the ones described above, except that treatment group will include 3 levels and, if treatment group emerges as a significant predictor of outcomes, we will conduct post hoc comparisons to evaluate specific differences between treatment groups.

Qualitative analysis will include rapid analysis methods to be utilized for key informant interviews. Rapid analysis involves: a) creation of a template containing key interview domains (e.g., implementation barriers); b) testing and revision of the template through summarizing one interview; c) comparison/reconciliation of analysts' `test' summaries; d) independent summarizing of remaining interview notes once consistency is reached; and e) comparison/contrasting of domains across participants via matrix analysis. Rapid analysis will identify early barriers and solutions to inform tailoring the VVC-

delivered HIV package. We will use content analysis, and a blended inductive (a posteriori) and deductive (a priori) coding scheme based on the effectiveness and reach RE-AIM domains in the analysis of transcribed interview data.

Section H: Potential Risks/Discomforts

H1. Potential Risks/Discomforts

Describe and assess any potential risks/discomforts; (physical, psychological, social, legal, or other) and assess the likelihood and seriousness of such risks:

There is a potential risk of psychological distress to patient participants as a result of reflecting on their HIV disease during qualitative interviews. This risk is unlikely to occur as a direct result of the study, and if it does occur, it is unlikely to be serious. There is a potential risk of loss of confidentiality. Stringent methods described in sections J and K will be employed to protect against this risk, making it unlikely. Some key informants invited to provide feedback on VVC delivery of care will be employees of the VA or Baylor College of Medicine, exposing them to risk of coercion to participate in the research project. Employees who are invited to participate will be informed that participation is voluntary and will not affect their current or future employment status. They will have the opportunity to decline participation in the qualitative interviews and will be informed that they may withdraw at any time. Employee participants will be informed that their supervisors will not know their participation status for the study. There is a potential risk of loss of confidentiality, but stringent methods described in sections J and K will be employed to protect against this risk, making it unlikely.

H2. Data and safety monitoring plan

Do the study activities impart greater than minimal risk to subjects?

No

H3. Coordination of information among sites for multi-site research

Is the BCM Principal Investigator acting as the SPONSOR-INVESTIGATOR for this multi-site research?

No or Not Applicable

Is BCM the COORDINATING CENTER for this multi-site research?

No or Not Applicable

Section I: Potential Benefits

Describe potential benefit(s) to be gained by the individual subject as a result of participating in the planned work.

Some participants may, by virtue of participation in the study, be more likely to adhere to care as a result of the attention they will receive from participating in the study. Participants may also experience satisfaction from participating in research that may improve the care and outcomes of Veterans in care for HIV. Some participants may receive no direct benefit from participating in the study.

Describe potential benefit(s) to society of the planned work.

This study has the potential to test an efficient and effective way to deliver multi-disciplinary care to a chronically ill patient population. VVC may also have an effect on narrowing race/ethnicity-based disparities in outcomes and disparities for rural Veterans.

Do anticipated benefits outweigh potential risks? Discuss the risk-to-benefit ratio.

The risks to study participants are minimal. The potential benefits to improved access to and retention in HIV care outweigh the possible risks.

Section J: Consent Procedures

J1. Waiver of Consent

Will any portion of this research require a waiver of consent and authorization?

Yes

Please describe the portion of the research for which a waiver is required. (Example: chart review to determine subject eligibility)

We are requesting a waiver of consent and authorization for Aim 1 (clinical effectiveness trial) of the study in order to randomly assign scheduled patients to be offered VVC or not and to collect quantitative medical record data from the medical record for those who are randomized and entered into the study data set. We are requesting a waiver of HIPAA authorization for the entire study, as we are also requesting a waiver of written documentation of informed consent for qualitative interviews to be conducted for Aim 2.

Explain why the research and the use or disclosure of protected health information involves no more than minimal risk (including privacy risks) to the individuals.

Patients assigned to receive the offer of VVC delivery of care will have the option to receive some, all, or none of their care via this modality. The study does not change or limit the treatment options available to Veterans with HIV. All treatment as usual options for HIV care at MEDVAMC will be available to all patients in both randomized conditions. VVC has been available as standard practice in VA since 2013, though it has not been used widely for specialty medical care. Clinical data gathered for the study are data gathered in routine care, hence those procedures do not add risk. Research to date suggests that treatment delivered via video telehealth is equivalent to in person care. Standard safety protocols for use of VVC are developed and will be in place, so risks are not expected to be greater than from those associated with receiving care in person. There is a risk of loss of confidentiality. Stringent methods will be employed to protect against this risk. All electronic data will be stored behind the VA firewall on a VA server, and access will be restricted to study personnel. Paper data will be kept in a locked cabinet in a locked storage room at IQuESt, and access will be restricted to study personnel.

Explain why the waiver will not adversely affect the privacy rights and the welfare of the research subjects.

No one involved in the study will identify, directly or indirectly, any Veteran subject in any report of such research or otherwise disclose identities of participants in any manner. All subjects will continue to receive all forms of medical and mental health care available to them at MEDVAMC. Clinical data gathered for the study are data gathered in routine care, hence those procedures do not add risk.

Explain why the research could not practicably be conducted without the waiver and could not practicably be conducted without access to and use of the protected health information.

Limited identifying information is required for 1) lists of patients with HIV who are scheduled daily in the Infections Diseases Clinic at MEDVAMC and 2) lists of patients with HIV who are considered "out of care" according to VA standards in order to randomly assign patients to receive the offer of VVC care delivery or not. In order to fully evaluate the impact of care delivered via VVC, quantitative medical record data are needed for all Veterans in care in the Infectious Diseases Clinic at VA. Aside from the randomization to be offered VVC or not and whether the Veteran accepts or declines that offer, all data collection will occur from the medical record. All data (other than randomized arm, in-person or out of care status, and whether VVC is accepted or declined) will be collected directly from the electronic medical record in order to 1) reduce participant burden; and 2) prevent research assessments from impacting clinical care. Without the waiver, we would need to obtain consent from every person in the clinic for the study, including Veterans who do not attend appointments. Excluding these Veterans who miss appointments would invalidate the scientific merit of the study. There is no practical way to conduct the research without a waiver.

Describe how the research could not practicably be carried out without using the collected identifiable biospecimens in an identifiable format.

N/A

Describe how an adequate plan exists in order to protect identifiers from improper use and disclosure.

Identifying information will be stored separately from chart data, which will be coded via a study ID number. Significant protections are in place to minimize the risk of a breach of privacy. All PHI will be kept secure and not shared outside of the study team. All information will be stored in a locked file cabinet in a locked storage room at IQuESt. We will store information collected on a secure computer server behind the MEDVAMC firewall. This means that the information will be in a computer that no one outside the VA can access. A number will be assigned to each patient, which will be kept separate from all identifying information, except for a password-protected master list stored on a secure server behind the MEDVAMC firewall. The purpose of collecting information covered under 38 U.S.C. 7332 is to conduct scientific research and no personnel involved in this study will identify, directly or indirectly, any individual patient or subject in any report of such research.

Describe how an adequate plan exists in order to destroy identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

Research records, including identifiers, will be destroyed 6 years after cutoff (at the end of the fiscal year) after completion of the research project, but may be retained longer if required by other federal regulations or sponsor archive requirement.

Describe how adequate written assurances exist in order to ensure that the PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

The research team has been adequately trained and is prepared to adhere to standards of operations for handling the PHI of subjects per federal guidelines. Combined with secure storage of paper and electronic files, VA and IQuESt have established written policies concerning storage and transmission of data including PHI which will be strictly followed by the research team.

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.

Yes

Specific information concerning alcohol abuse:

Yes

Specific information concerning drug abuse:

No

Specific information concerning sickle cell anemia:
No

Specific information concerning HIV:
Yes

Specific information concerning psychiatry notes:
Yes

Demographic information (name, D.O.B., age, gender, race, etc.):
Yes

Full Social Security #:
No

Partial Social Security # (Last four digits):
Yes

Billing or financial records:
No

Photographs, videotapes, and/or audiotapes of you:
No

Other:
No

Will additional pertinent information be provided to subjects after participation?
No

If No, explain why providing subjects additional pertinent information after participation is not appropriate.
Participants will only be provided additional information in the instance that significant information, either positive or negative, is discovered about VVC during the study that could have immediate and substantial benefit or harm to participants. If this occurs, the IRB and patients will be so informed.

The purpose of collecting information regarding HIV diagnosis and treatment, alcohol use, and mental health treatment (38USC7332) is to conduct scientific research. No personnel involved in this study will identify, directly or indirectly, any individual patient or subject in any report of such research or otherwise disclose patient or subject identities in any manner.

J1a. Waiver of requirement for written documentation of Consent

Will this research require a waiver of the requirement for written documentation of informed consent?
Yes

Explain how the research involves no more than minimal risk to the participants, and the specifics demonstrating that the research does not involve procedures for which written consent is normally required outside of the research context.
We are requesting a waiver of written documentation of consent for Aim 2 (implementation) of the study, which involves qualitative interviews with both Veterans and care providers about their experiences with VVC-delivered care in the study. These interviews will be recorded and, and Veteran interviews will be transcribed as detailed in Section K. Invited Veterans and employees will be informed that participation is voluntary, and they will have the opportunity to decline participation in the qualitative interviews. Verbal consent will be obtained for participation in the interviews and audio recording. Written consent is not normally required to audio record outside the research context.

For patients who participate in these qualitative interviews, there is a potential risk of psychological distress as a result of reflecting on their HIV disease during the interviews. This risk is unlikely to occur as a direct result of the study and is unlikely to be serious if it does occur.

Some employees of VA or Baylor College of Medicine may be invited to provide feedback on their experiences with VVC, exposing them to the risk of coercion to participate in the research project. No information other than name and job title will be collected from employees who choose to complete the interviews. Employee participants will be informed that their supervisors will not know their participation status for the study and that participation or lack thereof will not be used in their performance appraisals or affect their present or future employment. While there is a risk of loss of confidentiality, all measures described in Sections J and K will be taken, such that this risk is minimized as much as possible.

J2. Consent Procedures

Who will recruit subjects for this study?

PI's staff

Describe how research population will be identified, recruitment procedures, any waiting period between informing the prospective participant and obtaining consent, steps taken to minimize the possibility of coercion or undue influence and consent procedures in detail.

Because we are requesting a waiver of consent for Aim 1, the consent procedures pertain only to Aim 2, which involves qualitative interviews. A sample of 40 patients who received care via VVC during Aim 1 of the study will be invited to take part in interviews regarding their experiences with that care. Study staff will mail an opt-out letter inviting the patient to participate in the interview. The letter will include study staff contact information and request that the patient call if they do not wish to take part in the interview. The letter will also indicate that if we do not hear from them within 10 days of mailing the letter, a member of the study team will call them to discuss participation. During that phone call, patients will be informed that we are seeking their opinions on VVC-delivered care, that participation is entirely voluntary and will not affect their benefits or healthcare available at VA, and that should they decide to participate, the interview will be audio-recorded and transcribed.

VA and BCM employees such as clinic directors, clinical providers and facilitators will also be invited by study staff to participate in interviews seeking their opinions on VVC-delivered care. We will provide an overview of the project for all clinic staff and providers to inform them of the project during a regularly scheduled clinic meeting. All potential staff participants will be informed that we are seeking their opinions on VVC-delivered care, that participation is entirely voluntary and participation status will not be reported to their supervisors or used in their employee evaluations or affect their current or future employment, and that should they decide to participate, the interview will be audio-recorded. We will then invite selected staff and providers based on their job and clinic responsibilities so that input from various clinic stakeholders is achieved. These invitations will be one-on-one and made in person and in private. Invitees will be reminded that their participation is entirely voluntary and participation status will not be reported to their supervisors or used in their employee evaluations or affect their current or future employment, and that should they decide to participate, the interview will be audio-recorded. We will also inform them that we are seeking their input on VVC-delivered care because their clinic responsibilities suggest they could provide valuable insight into implementing VVC in the clinic.

We are seeking approval of verbal consent for this process in order to minimize participant burden in terms of time required for mailing consent forms, reducing number of study contacts required, and decreasing the time lag between the decision to participate and completion of the interview.

Are foreign language consent forms required for this protocol?

No

J3. Privacy and Intrusiveness

Will the research involve observation or intrusion in situations where the subjects would normally have an expectation of privacy?

No

J4. Children

Will children be enrolled in the research?

No

J5. Neonates

Will non-viable neonates or neonates of uncertain viability be involved in research?

No

J6. Consent Capacity - Adults who lack capacity

Will Adult subjects who lack the capacity to give informed consent be enrolled in the research?

No

J7. Prisoners

Will Prisoners be enrolled in the research?

No

Section K: Research Related Health Information and Confidentiality

Will research data include identifiable subject information?

Yes

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.

Yes

Specific information concerning alcohol abuse:
Yes

Specific information concerning drug abuse:
No

Specific information concerning sickle cell anemia:
No

Specific information concerning HIV:
Yes

Specific information concerning psychiatry notes:
Yes

Demographic information (name, D.O.B., age, gender, race, etc.):
Yes

Full Social Security #:
No

Partial Social Security # (Last four digits):
Yes

Billing or financial records:
No

Photographs, videotapes, and/or audiotapes of you:
Yes

Identifiable biospecimens
No

Other:
No

At what institution will the physical research data be kept?
Michael E. DeBakey VA Medical Center Health Services Research & Development Center for Innovations in Quality, Effectiveness and Safety (HSR&D IQuESt) Nabisco Building 2450 Holcombe Blvd., Suite 01Y Houston, TX 77021

How will such physical research data be secured?
This information will be secured in a locked cabinet behind a locked door in a storage room at IQuESt and will only accessed by the study investigators and research staff.

At what institution will the electronic research data be kept?
Electronic data will be secured via M Drive: Research\Giordano_Lindsay_H-45072. The IQuESt M drive is on the VA virtual server which is located at the MEDVAMC main hospital, 2002 Holcombe Blvd, Houston, TX 77030. Research records, including identifiers will be destroyed 6 years after cutoff (at the end of the fiscal year) after completion of the research project, but may be retained longer if required by other federal regulations or sponsor archive requirement.

Such electronic research data will be secured via BCM IT Services- provided secured network storage of electronic research data (Non-Portable devices only):
No

Such electronic research data will be secured via Other:
Yes, (describe below):
Electronic data will be secured via M Drive: Research\Giordano_Lindsay_H-45072. The IQuESt M drive is on the VA virtual server which is located at the MEDVAMC main hospital, 2002 Holcombe Blvd, Houston, TX 77030. Research records, including identifiers will be destroyed 6 years after cutoff (at the end of the fiscal year) after completion of the research project, but may be retained longer if required by other federal regulations or sponsor archive requirement.

Will there be anyone besides the PI, the study staff, the IRB and the sponsor, who will have access to identifiable research data?
Yes, identify the classes of the persons:
People who ensure quality from the institutions where the research is being done, federal and other regulatory agencies will have access to all of the research data.

Please describe the methods of transmission of any research data (including PHI, sensitive, and non-sensitive data) to sponsors and/or collaborators.

Data will not leave the VA.

Will you obtain a Certificate of Confidentiality for this study?

No

Please further discuss any potential confidentiality issues related to this study.

Approved staff from the VA Salt Lake City (VASLC) will transcribe the audio files. The VASLC has a Professional Transcription Service available to VA sites and monitored by their own IRB. The audio recordings to be transcribed by VASLC staff will be labeled by the subject's unique alphanumeric code and saved behind the VA Firewall in a secure shared project folder on the M drive on the VA virtual server which is located at the MEDVAMC main hospital, 2002 Holcombe Blvd, Houston, TX 77030. The VASLC transcription staff will be given access to a sub-folder within the study's secure project folder. Approved study staff will place a copy of the audio files in this folder for an approved VASLC transcriptionist to access for the purposes of transcription. The VASLC transcriptionist will transcribe each interview verbatim and save the completed transcript in the sub-folder using the same alphanumeric code. No data (audio files, in process transcripts, or completed transcripts) will leave the MEDVAMC secure research server. As completed transcripts become available, approved study staff will move these files from the transcription sub-folder into another sub-folder that is only accessible to study staff, where they will be stored and accessed for qualitative analyses.

An Accounting of Disclosure (AOD) will be created and maintained for any disclosure of individually identifiable information (III) outside the VA. The manual spreadsheet will include the date of the disclosure, nature or description of the III disclosed, purpose of each disclosure and the name and address of person or agency to which the disclosure was made.

It is understood by the PIs that data will not be used or shared with others outside the scope of the research study as documented in the protocol approved by the IRB and MEDVAMC R&D Committee.

Removal of access to research study data will be accomplished for all study personnel when they are no longer part of the research team.

Research records, including identifiers will be destroyed 6 years after cutoff (at the end of the fiscal year) after completion of the research project, but may be retained longer if required by other federal regulations or sponsor archive requirement.

The purpose of collecting information covered under 38 U.S.C. 7332 is to conduct scientific research and no personnel involved in this study will identify, directly or indirectly, any individual patient or subject in any report of such research.

Section L: Cost/Payment

Delineate clinical procedures from research procedures. Will subject's insurance (or subject) be responsible for research related costs? If so state for which items subject's insurance (or subject) will be responsible (surgery, device, drugs, etc). If appropriate, discuss the availability of financial counseling.

There will be no costs to participants associated with research participation, as data will be collected from medical records and via telephone interviews.

If subjects will be paid (money, gift certificates, coupons, etc.) to participate in this research project, please note the total dollar amount (or dollar value amount) and distribution plan (one payment, pro-rated payment, paid upon completion, etc) of the payment.

Dollar Amount:

40

Distribution Plan:

Veterans who complete qualitative interviews regarding their experiences receiving care via VVC will receive a one-time payment of $40.

Section M: Genetics

How would you classify your genetic study?

Discuss the potential for psychological, social, and/or physical harm subsequent to participation in this research. Please discuss, considering the following areas: risks to privacy, confidentiality, insurability, employability, immigration status, paternity status, educational opportunities, or social stigma.

Will subjects be offered any type of genetic education or counseling, and if so, who will provide the education or counseling and under what conditions will it be provided? If there is the possibility that a family's pedigree will be presented or published,

please describe how you will protect family member's confidentiality?

Section N: Sample Collection

None

Section O: Drug Studies

Does the research involve the use of ANY drug* or biologic? (*A drug is defined as any substance that is used to elicit a pharmacologic or physiologic response whether it is for treatment or diagnostic purposes)

No

Does the research involve the use of ANY gene transfer agent for human gene transfer research?

No

O1. Current Drugs

Is this study placebo-controlled?

No

Will the research involve a radioactive drug?

No

Section P: Device Studies

Does this research study involve the use of ANY device?

No

Section Q. Consent Form(s)

None

Section R: Advertisements

None