A. TITLE

RESEARCH PROTOCOL

Title: Encouraging Patient-Centered Communication in Clinical Video Telehealth Visits

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B. CONTENTS

C. ABSTRACT

Background: Clinical video telehealth (CVT) offers the opportunity for more efficient access to high quality primary and specialist care for Veterans. Enthusiasm for CVT is especially high in the VA given geographical separation between many Veterans and their providers at VA Medical Centers. However, because CVT encounters are by nature less personal than in-person visits, communication during CVT visits may be more challenging for both patients and providers resulting in less patient-centered communication. Less personal visits may have less exchange of information, lower satisfaction, less trust, and poorer outcomes. Indeed, research comparing CVT with in-person consultations found that patients in CVT visits were more passive and that CVT interactions were dominated by providers when compared with in-person visits.

This project will leverage our prior work from two HSR&D-funded pilot projects to improve provider – patient communication for Veterans with type 2 diabetes mellitus. In a short-term project, SHP-08-182, we conducted focus groups to elicit and understand patients' barriers to communicating with their providers. This qualitative work was used in a subsequent pilot project, PPO-08-402 to develop an educational video to encourage Veterans to use active participatory communication in their visits to providers. This work was successfully completed and the product is a 10-minute video that, in testing, was found to be acceptable and feasible to show to VA patients immediately preceding their medical encounters.

Objectives: Our goal in this project is develop and test a video intervention and to also develop pamphlets for patients and providers to encourage active and positive communication in CVT medical interactions. Our goal was developed with and is supported by our operational partner the Office of Telehealth Services. Patient-centered communication in medical interactions is critical and plays an important, but often overlooked, role in the delivery of health services.

There are two aims. First we will develop educational interventions to encourage patients and providers to use active communication behaviors during CVT visits. Second, we will conduct a randomized trial of the video and pamphlet (intervention) vs. pamphlet alone (comparison) in a two-arm randomized effectiveness trial. We would then evaluate for improvement in visit outcomes including patient and provider measures of patient-centered care and communication, reduction in several common barriers to clinical improvement, and improved medication adherence measures and hemoglobin A1c. In addition, we will assess the mediators and moderators of the relationship of the intervention condition to outcomes.

Methods: The project will have two phases. In the initial phase (15 months) of the planned project we will develop the video intervention. We have experience developing this type of intervention and will build on that experience. Video development will include qualitative interviews with stakeholders and patients regarding CVT barriers and perceived benefits. We will use several existing resources and our expert panel of co-investigators and consultants to bring these elements together and produce the intervention. In phase 2 we will conduct a randomized trial of the intervention, evaluating for improvement in a number of outcomes.

Impacts: Our educational tools will be deliverables that could be used prior to CVT visits to improve communication and could serve as a paradigm for developing communication aids for other medical conditions and other clinical settings. We believe that use of our educational intervention will help improve communication and will be associated with better visit and intermediate outcomes. In addition, educational tools that encourage more patient-centered communication during CVT encounters may allow more rapid acceptance of CVT, thereby improving access to healthcare and enhancing the operational mission of our partner.

D. RESEARCH AIMS

Clinical video telehealth (CVT) is a communication technology that provides a real-time video and audio assessment of patients when patient and provider are geographically separated. CVT offers the opportunity for more efficient access to high quality primary and specialist care for Veterans. Enthusiasm for CVT is especially high in the VA given geographical separation between many Veterans and their providers at VA Medical Centers. However, because CVT encounters are by nature less personal than in-person visits, communication during CVT visits may be less patient-centered than communication in face-to-face encounters.[1] Patient-centered communication in medical interactions is critical and plays an important, but often overlooked, role in the delivery of health services. Patient-centered communication may improve care through its association with better patient behaviors, such as adherence.[2, 3] In fact, studies that have focused on improving patients' communication behaviors have had more success at enhancing the provider-patient encounter and improving diabetes outcomes[4, 5] than those focused on changing providers' communication behaviors.[6, 7]

This project will leverage our prior work from two HSR&D-funded pilot projects to improve doctor-patient communication for Veterans with type 2 diabetes mellitus. In a short-term project, SHP-08-182, we conducted focus groups with Veterans with type 2 diabetes mellitus to elicit and understand, from their perspective, barriers to communicating with their primary care providers. This qualitative work was used in a subsequent pilot project, PPO-08-402, to develop and conduct feasibility testing of an educational video to encourage Veterans to use active participatory communication in their visits to primary care providers (PCP). This work was successfully completed and the product is a 10-minute video that, in testing, was found to be acceptable and feasible to show to VA patients immediately preceding their medical encounters. Our goal in this project is to develop interventional materials to encourage active and positive communication targeted to patients and providers scheduled for CVT encounters. In pursuit of this goal, we will apply our prior provider-patient communication research and our previous experience producing video to encourage active communication during in-person encounters to CVT visits. The planned project represents the next phase in a trajectory of research designed to improve communication and outcomes in patients with type 1 and type 2 diabetes mellitus.

Patients can overcome barriers to using active communication behaviors in medical encounters with pre-visit preparation. A pre-visit video provides an opportunity to give patients a role model and to demonstrate acceptable, positive, and powerful active communication behaviors. Providing examples of how to talk to a provider can reduce or prevent passivity in patients' communication. Video provides an opportunity to offer pre-visit preparation that otherwise would require staff time. Staff–led communication interventions are rarely used in part owing to the expense or personnel required to provide pre-visit communication coaching. Video offers inexpensive pre-visit preparation. We plan to develop and test an educational intervention for patients designed to encourage patients' active participatory communication behaviors in CVT visits. Our goal is integral to goals of this CREATE to ensure patient-centered care in new models of care.

D.1. Specific Aims.

Specific Aim 1: Develop an educational intervention to encourage patients to use active communication behaviors during CVT visits. Educational intervention materials will include a video for patients, a pamphlet for patients and a pamphlet for providers.

Specific Aim 2a: To conduct a randomized trial of the video and pamphlet (intervention) and pamphlet alone (comparison) in a two-arm randomized effectiveness trial to evaluate visit outcomes including patient and provider measures of patient-centered care and communication, reductions in several common barriers to clinical improvement, and improved medication adherence measures and hemoglobin A1c (HgbA1c).

Hypothesis. Compared to patients getting only the pamphlet, intervention group patients (video + pamphlet) will use more active participatory communication behaviors, have higher post-visit ratings of several measures of patient-centered care, better medication adherence and improved HgbA1c.

Specific Aim 2b: To test whether the relationship between the intervention condition and outcomes is moderated by (interacts with) patient characteristics (age, gender, race, literacy, locus of control) and provider characteristics (gender, years in practice,).

Specific Aim 2c: To test whether the relationship between the intervention condition and outcomes is mediated by covariates affecting the provider-patient encounter (*e.g.*, self-efficacy).

E. BACKGROUND

E.1. Why study patients with Diabetes?

Diabetes mellitus is estimated to affect almost one in five VA patients overall.[8] Poorly controlled diabetes leads to a number of complications including cardiovascular disease, blindness, amputation, and end stage renal disease. Adherence to medication regimens (and diet and exercise) is important to achieve diabetes care goals. Adherence to recommended care is related at least in part to effective communication in medical encounters. Several studies indicate that activating patients to use more effective communication behaviors with their providers leads to better adherence to treatment and better biomedical outcomes.[2, 3] In fact, studies that have focused on improving patients' communication behaviors have had more success at enhancing the provider-patient encounter and improving diabetes outcomes[4, 5] than those focused on changing providers' communication behaviors.[6, 7] Although interventions have been developed to coach patients to use active communication in medical interactions, these interventions have not been adopted in practice largely owing to the cost of trained personnel to deliver the training. An alternative to in-person training is video-based training. This project will evaluate a video intervention in the CVT setting.

E.2. Communication is critically important in the delivery of health services

The Institute of Medicine report, "*Crossing the Quality Chasm*" identified patient-centered care as one of six aims for high quality health care.[9] Provider-patient communication is a main ingredient in delivering patient-centered care. Patient-centered communication achieves several functions including: fostering healing relationships, exchanging information, responding to emotions, making decisions, managing uncertainty, and enabling patient self-management.[10] To facilitate patient-centered communication a number of features of patient-centeredness are needed. The VA transformation to an interprofessional team-based model of care with patient aligned care teams (PACT) provides a well-organized health care system that is one leg of patient-centered care. Patient-centered care depends on clinicians' to use patient-centered communication and patients (and their companions) to be prepared to use active participatory communication.[10] Patients who have difficulty communicating are less involved in consultations with their providers, receive less information and support, and are less satisfied with their care. In turn, these patients may not understand their treatment options, may have less knowledge, less positive beliefs about treatment and less trust in providers, and may consequently have poorer adherence to treatment and self-care recommendations, and thus may experience poorer health outcomes. Our plan to test an intervention to improve patients' active participatory communication behaviors (Table 1) is intended to improve understanding of these pathways.

E.2.1. Communication in Clinical Video Telehealth (CVT) medical encounters

Clinical Video Telehealth (CVT) is a communication technology that provides a real-time video and audio assessment of patients when patient and provider are geographically separated. Often providers are located at a medical center and patients at a community-based clinic. The provision of CVT as an alternative to face-to-face (FTF) visits may improve patient access to clinical care. CVT use can increase access to specialty care and is increasingly used to provide primary care. Patients may be more satisfied with CVT largely because of convenience (*i.e.*, travel distance is reduced), but providers may be less satisified.[11, 12] Yet, communication during CVT visits is less well studied. Studies that have evaluated CVT encounters generally focused on

consultations with specialists, were small, or were methodologically weak.[13, 14] Just as in FTF visits, communication in CVT visits is important and we hypothesize it is linked to several outcomes.

There is a fundamental difference in communication in CVT compared to FTF medical encounters. Our model of provider-patient communication (see below) suggests that the clinical context for the medical encounter is one of several factors that influence communication. There are technical and interpersonal aspects of CVT visits that could influence communication. For example, the fact that CVT technology provides a unique and depersonalized environment may decrease the ability of providers to establish rapport with patients (*e.g.*, establish empathy; project warmth and caring). The diminished humanistic features of a CVT visit could impair provider-patient communication, which may in turn reduce satisfaction, trust or other outcomes shown to improve the care of diabetes patients. These depersonalization effects may be beneficial for psychiatric patients who felt less inhibitions in CVT compared FTF visits.[15] However, visits to primary care for patients with diabetes have different goals and it remains unclear how the technical and interpersonal characteristics of CVT affect communication. Additional differences to consider are related to technical problems (*e.g.*, can you hear me now?) in transmission of the video signal that are distracting at best. Also with CVT there is decreased bandwidth leading to loss of some features of non-verbal communication. Though most communication of clinical information is verbal, loss of eye contact, body language, touch, and other non-verbals with CVT may reduce the effectiveness of the medical interaction. Another technical issue is how the limited camera view and the presence of third parties may uniquely affect communication in CVT visits. Third parties could be medical staff (other providers, medical assistants) or patients' companions and they may impede communication if their participation reduces patient involvement or lessens emotional and psychosocial support, while on the other hand they could improve communication if they provide support or interpretation of medical jargon. Finally, though many providers have experience with video communication (*e.g.*, Skype™), the behavioral norms and standards for CVT are poorly developed. It is likely that there are opportunities to learn about training needs for providers and produce materials that could assist providers increase their clinical effectiveness with CVT. In addition to developing materials for patients we plan to develop materials to assist providers to increase their clinical effectiveness. As a whole our efforts will aim to evaluate whether we can increase the patient centeredness of CVT medical encounters

E.2.2. Why are patients' communication behaviors important?

Patients' active participatory communication behaviors are important because these types of active behaviors are particularly powerful and influential in medical encounters. Active behaviors are influential because communication is a two-way street. When patients are active (*e.g.*, ask a question) they can expect to get a reciprocal response from the provider (*e.g.*, an answer to their question) because of social norms of communication. A key distinction in patients' communicative behavior is between **passive** communication behaviors where patients' communication behavior consists primarily of answering providers' questions, and **active** *participatory* communication behaviors where patients take a form of conversational control. Patients' active participatory communication behaviors include four patient communication behaviors: (1) telling the medical history; (2) asking questions; (3) being assertive or making requests; and (4) communicating concerns or expressing opinions (**Table 1**).[16-18] Patients' active participatory communication is powerful because patients who ask questions, make assertions, and communicate concerns can influence providers' communication, behavior, and recommendations. Active participatory communication behaviors are associated with positive post-consultation outcomes, including adherence to and recall of providers' recommendations, patient satisfaction, improved functional status, and even improved biomedical or physiological outcomes.[4, 19-29] Nonetheless, pathways that link communication to outcomes may be indirect. Effective communication by both patients and providers can improve patient understanding, trust and clinician-patient agreement. In turn these improvements may lead to improved adherence to treatment recommendations, follow-up, and self-management, thereby minimizing the impact of disease on functional status and other health outcomes.[30]

Table 1. Active Participatory Communication

1. Telling the Medical History
2. Asking Questions
3. Being Assertive / Making Requests
4. Communicating Concerns or Opinions

E.2.3. Can an intervention of any type increase patients' active communication behaviors?

Several studies have shown that interventions to teach patients to communicate improve process and outcomes of care, including active communication, treatment adherence, functional status, and biomedical outcomes. [4, 19, 20, 23] For example, Greenfield, et. al., [20] evaluated a brief pre-visit intervention to coach patients to ask questions and negotiate medical decisions with their providers. They found that patients in the intervention condition had fewer limitations in physical and role-related activities, preferred a more active role in medical decision-making and were twice as effective in obtaining information from providers when compared to controls. In a similar trial in patients with diabetes, those in the intervention group had better functioning, were more effective eliciting information from the provider and had significantly better blood sugar control (HgbA1c).[4] Using a coaching intervention to encourage patient question-asking, Roter found that patients asked more direct questions and demonstrated improved appointment-keeping in four-months of follow-up.[19] Although these studies were done many years ago and improved outcomes, these interventions have not yet been translated into practice. Many of these interventions used trained personnel to deliver the intervention and as a result were expensive. Several reviews of the communication intervention literature have commented that more research is needed to design effective interventions to improve communication that can be integrated into practice.[2, 3, 6] Alternative interventions that are "paper-based" (*e.g.*, brochure or self-directed workbook-based interventions), often have modest or no effect on patients' communication behaviors.[2, 29, 31-33] Pamphlet or workbook methods may be less effective in part because of low levels of literacy and health literacy. Other intervention options that bridge the gap between expensive coaching interventions and paper-based interventions need to be investigated. A video intervention may overcome prior barriers to implementation because video-based approaches offer several advantages over other approaches. Patient education and treatment decision aids via video are superior to oral or written material for patients with limited literacy.[34] In addition, video-based education is acceptable to patients from a broad range of cultural backgrounds.[35] A few studies have examined video-based interventions to improve communication in medical interactions and indicate that a video can increase patients' active communication in the encounter.[21, 36] Video-based pre-consultation interventions have potential to enhance communication in medical encounters and need to be further developed and tested. Video-based direct-to-consumer programs are used effectively by the pharmaceutical industry on television. These advertisements influence patient behavior and activate patients to make specific requests. In summary, few studies have explored video as a medium for delivery of interventions to encourage patients' active communication behavior. More research is needed to understand the full potential of video, which has the advantage of being significantly less expensive than interventions requiring coaching personnel, and may be more easily disseminated than coaching interventions.

E.3. Preliminary studies and conceptual framework

This project builds on our prior work evaluating clinician-patient communication.[37-41] The project also builds on our recent prior work from two HSRD-funded pilot projects to improve doctor patient communication in Veterans with type 2 diabetes. In a short-term project, SHP-08-182, we conducted focus groups with Veterans with type 2 diabetes mellitus to elicit and understand, from their perspective, barriers to communicating with their provider. We used the findings from this qualitative work in a subsequent pilot project, PPO-08-402 to design and develop an educational video to encourage patients to use active participatory communication in their visits to providers. This work was successfully completed and the product is a 10 minute video that was found to be acceptable to patients (from 15 in-depth interviews) and feasible to show to patients immediately preceding their medical encounter (24 visits). Our video intervention used feedback from patients to ensure the program was relevant to Veterans, was clear and comprehensible, and was culturally sensitive to patients' beliefs and prior experiences. Not all video messages are effective. Based on our focus groups we chose to avoid the negative approach. Our design is different and novel and we believe our approach is better suited to Veterans. We designed a video intervention with a positive message that shows patients they can overcome communication barriers and it shows that active behaviors can be rewarded with desired responses from a provider. A script/screenplay used for the video can be found in the **Appendix**. We expect the video for this project will be similar in presentation but will be customized for the CVT setting.

What constitutes being a competent communicator? Patients are competent communicators when they: (1) have self-efficacy to communicate, (2) have some knowledge, and (3) are prepared to use active participatory communication behaviors in consultations with providers. The interventions for this project (video, pamphlets) will be developed with consideration of the conceptual framework of communication competence.[10, 42] Patients who have **self-efficacy** to actively participate – speak about their needs, opinions, concerns and preferences. Active participation is built on beliefs that it is acceptable to ask questions, to be assertive, and to communicate concerns to providers. Motivation alone is not enough for competent communication. Some **knowledge** about diabetes and about personal preferences for care are key attributes of effective communication. **Knowledge** about the medical condition includes understanding of terminology and concepts relevant to care. A patient is then more likely to understand and even negotiate their care with their provider when they engage in these behaviors. However, without **preparation** to actively participate, patients' communication may be limited to passively answering the providers' questions. Our video will also be developed with perspectives derived from social learning theory. **Social learning theory**, also referred to as **social cognitive theory**,[43] is part of the framework that will guide the development of the patient activation intervention in this project. The concepts of self-efficacy (an individual's perceptions about ability to perform an action) and outcome efficacy (expectation that performing the behavior will have a desirable result) are instrumental in producing behavior change. Bandura's social learning theory emphasizes the importance of observing and modeling the behaviors, attitudes, and reactions of others when learning new behaviors.[43] This theory is a widely used theoretical framework for training programs and behavior modification programs.

Positive role modeling is important. The role modeling method of education that we are planning is an effective method of preparing patients for visits and for encouraging appropriate behaviors[43] and is a standard in medical education. We will develop a video program that demonstrates (role models) use of active participatory communication behaviors to patients. By showing a patient-actor using active participatory communication and positive provider responses (feedback), the video will reinforce this communicative behavior. The planned intervention addresses self-efficacy and preparation, needed for competent communication and role models effective communication behaviors in a culturally competent context. Thus, a **timely intervention that specifically addresses patients' self-efficacy in a culturally sensitive manner and prepares patients for the medical visit may increase patients' active participatory communication in medical consultations.[44] Our video intervention will be designed to encourage active participatory communication behavior; will be based on feedback from a needs assessment of the target population, and will be delivered prior to the visit. The video will promote the legitimacy of active participatory communication behavior; provide medical information about diabetes and adherence (knowledge); and provide specific communication strategies and behaviors for patients to model (preparation).**

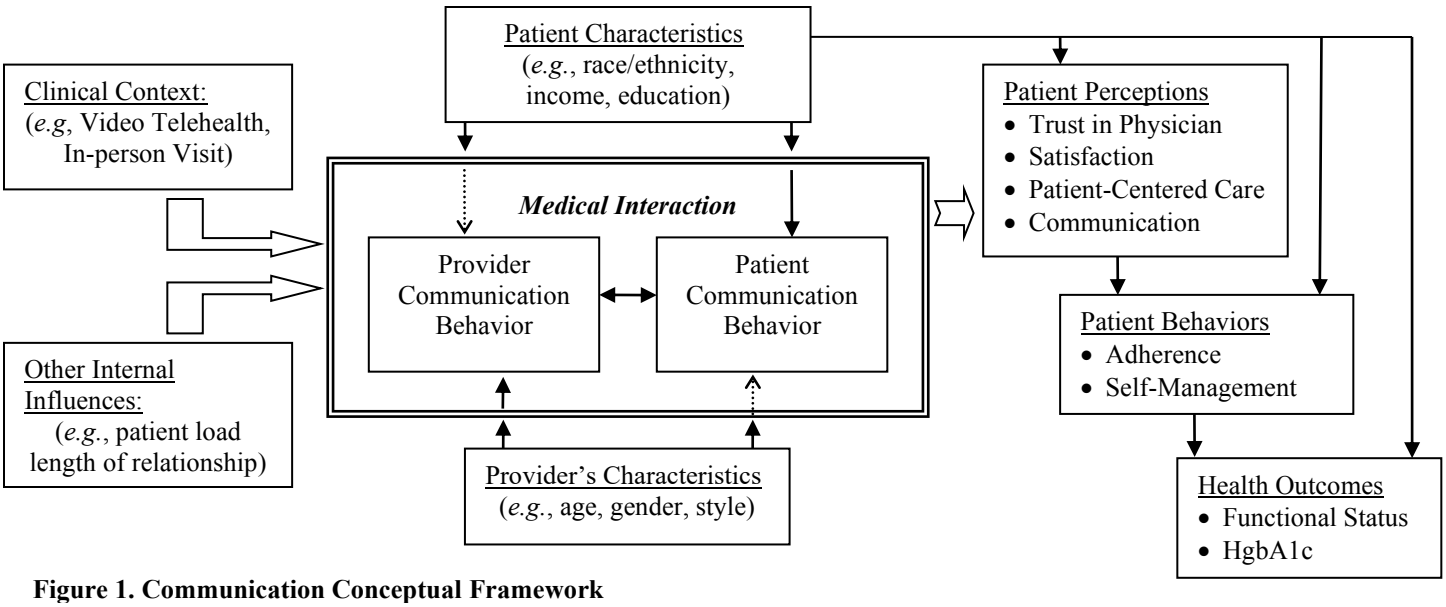


Figure 1. Communication Conceptual Framework

Our framework for this project combines models of patient-centered care[10, 45] and doctor-patient communication.[46] Our framework (**Figure 1**) provides guidance for measuring communication behaviors. Because "talk" is central to the delivery of medical care, "talk" is at the center of the framework – represented by the "Medical Interaction" in Figure 1. Communication in the medical interaction is influenced by (1) predisposing factors, such as patients' or providers' communication style (*e.g.*, an individual with an expressive style is expected to be more talkative and assertive); (2) cognitive-affective factors, such as goals, beliefs, perceptions, emotions (*e.g.*, more discussion of needs and concerns in sicker patients); and (3) the combined effect of norms of communication and the partners' communicative acts (*e.g.*, answers follow questions). Interventions to improve communication can influence each of these factors. Our framework illustrates how several factors influence improvements in communication and how improved communication could act to improve outcomes. In Figure 1, communication in the medical interaction is shown to influence patients' perceptions (*e.g.*, ratings of communication, patient-centered care, trust, satisfaction), which in turn influences patients' behaviors (*e.g.*, adherence) and subsequent health outcomes. Not shown in the Figure but still part of our model are self-efficacy to communicate which could be either predisposing factors or outcomes of communication. Our analysis will evaluate whether communication leads to improved outcomes and which factors are moderators and mediators of improved outcomes.

F. Significance

Diabetes is common, it is expensive, and it is a chronic condition. Estimates put the prevalence of diabetes at almost 20 percent in VA patients.[8] The objectives and study design are consistent with the goal of making patient care more patient-centered, which is a goal of the VA transformation and is one of the six aims for improvement in the IOM Report, *Crossing the Quality Chasm*.[9] An activated patient is important to improve quality of care. When patients are active participants in care, patient care is more patient centered and more responsive to patient preferences, needs, and values. Active patients can use proven communication behaviors (ask questions, etc.) and as a result may be more involved in their care and may be better able to assist providers to develop personalized treatment plans.

With the VA transformation efforts including new models of care, especially in using technology to communicate with patients where they are, attention is increasingly focused on patient-centered care. Improved communication is a central feature of patient-centered care. Teaching patients and providers to communicate more effectively is patient-centered because it inherently supports a patient-driven approach to delivering healthcare. Our intervention is designed to encourage patients' active communication and should be considered a potential tool to improve communication in medical encounters. When patients communicate with

their health care team more effectively, communication as a whole is improved because communication is a two-way street.

Table 2. Inclusion and Exclusion criteria

If a video based intervention was successful at increasing patients' participatory communication behaviors, similar interventions could have a wide impact in other medical conditions. Communication components related to encouraging patients' active participatory behaviors are universal. Other disease-specific components of the intervention relating to diabetes and medications would have to be changed to reflect the specific medical condition. And some factors related to patients' self-efficacy to be active participants would require condition specific research. Compared to a chronic condition like diabetes, differences in patients' self-efficacy could be expected for acute conditions, for diagnoses associated with procedures or surgery, and for cancers. Thus, our approach may be a paradigm that is transferable in part to other conditions. Our intervention design could serve as a model for the development of other communication interventions.

G. Methods

G.1. Overview.

The project will have two phases. In the initial phase (Aim 1, 18 months) of the planned project we will develop the video intervention. We have experience developing this type of intervention and will build on that experience. Pamphlet and video development will include qualitative interviews with stakeholders, providers, and patients regarding CVT barriers and perceived benefits. We will use several existing resources and our expert panel of co-investigators and consultants to bring these elements together and produce the interventions. Phase two of the project (Aims 2a, 2b, and 2c; 24 months) will be a two-arm randomized test of the intervention (video modeling + pamphlet vs. pamphlet alone) in a sample of CVT visits. In addition, a pamphlet will be given to providers that suggests tips on how to make CVT visits patient-centered.

G.2. Setting and Participants.

Patients with type 1 and type 2 diabetes mellitus getting care with CVT from primary care providers and endocrinology providers will be identified in the Eastern Colorado Health Care System (**ECHCS**) in VISN 19 and in the Jesse Brown VA Medical Center in VISN 12. VISN 19 is a national leader in the provision of clinical video telehealth services to Veterans in the VA and CVT care is expanding rapidly. Teleprimary care is used to deliver primary care services to existing CBOCs and outreach clinics to supplement the existing staffed models. Given the frontier nature of a significant portion of VISN 19, leadership in VISN 19 have established goals to implement telehealth technologies to enhance linkages between Veterans and services and to improve access to care. The number of CVT encounters is rapidly increasing and reached 28,000 in FY11, with a goal of 36,000 in FY12. Currently, VISN 19 has 804 clinic-based telehealth systems deployed with 197 at Denver VAMC and community based outpatient clinics (CBOCs). Access to telehealth providers conducting CVT visits and facilitation of the project will be coordinated by staff in Denver, Colorado. Ravi Gopal is a co-investigator, site-PI, and staff physician at the Denver VAMC, VISN 19 telehealth lead, and the network CVT manager are supportive of this project (see letters of support). VISN 12 has established a primary care telehealth hub at Jesse Brown VAMC in Chicago, Illinois. Howard S. Gordon, MD is PI of the overall study and will also serve as LSI at Jesse Brown VAMC. Dr. Gordon has support from the Chief of Staff at JBVAMC to add JBVAMC as a local site. Local JBVAMC research staff will conduct the project at JBVAMC.

G.3. Recruitment.

Eligible patients for this research will be identified and recruited from Clinical Video Telehealth clinics in ECHCS in VISN 19 and in Jesse Brown VAMC in VISN 12. The databases from which the information will be obtained are: Computerized Patient Record System, VA Corporate Data Warehouse, and national access to medical records through CAPRI application.

No subjects will be excluded from the study on the basis of gender, race, or ethnicity. We will make a concerted effort to oversample and recruit representative samples of minorities and women Veterans. Eligible patients (**Table 2**) must have an active diagnosis of type 1 or type 2 diabetes mellitus, and must have a hemoglobin A1c ≥ 7. We chose a HgbA1c ≥ 7 to capture patients whose diabetes is not controlled and who are likely to need intensification of treatment or better adherence. Patients with terminal medical conditions with life expectancy less than 6 months (*e.g.,* metastatic cancer, end-stage chronic lung or heart disease) and patients with drug induced diabetes (*e.g.,* steroids) will be excluded. Patients who are blind or have severely impaired vision not correctable with eyeglasses or who are deaf or have hearing problems uncorrectable with hearing aid(s) will not be eligible. We will obtain a partial waiver of authorization from the IRB and R&D committees and then will obtain a list of patients with diabetes and HgbA1c ≥ 7. In Phase 1 of the study, after names of potentially eligible patients are obtained, we will mail patients the study Information Sheet and a letter to inform them of their potential eligibility for the study. These documents will remind patients of their right of refusal to participate in the research. The recruitment letter will provide a phone number that they can call to indicate their wish to opt out. In 7-10 days the research assistant will call patients who did not decline participation and discuss the study in detail. A brief eligibility screen will be done to verify the age, race, and mental status (*i.e.*, to rule out dementia[47-49]) of the potential participants. We will obtain verbal consent for the Telephone Interview from interested potential study participants.

Inclusion Criteria:
- Diagnosis of type 1 or type 2 diabetes mellitus
- Hemoglobin A1c (HgbA1c) ≥ 7
- Adults, age 18 or older

Exclusion Criteria:
- Lives in skilled nursing facility
- Dementia (abnormal score on ALFI MMSE[47])
- Terminal medical condition
- Drug- (*e.g.*, steroid) induced diabetes.
- Blind or deaf (*e.g.*, unable to view/hear video)

We will recruit primary care providers and endocrinology providers involved in care by CVT with eligible patients. Providers' verbal consent will be required to conduct surveys and allow audio recording of phone interviews. Telehealth leads for VISN 19 and VISN 12 are supportive of the project. They will facilitate our efforts at staff, provider, and patient recruitment, will assist to ensure we are identifying all eligible patients, and will encourage provider participation in the project. Drs. Gordon and Gopal have successfully recruited providers and patients for research in several prior studies. Recruitment procedures will be similar for Aim 1 and for Aim 2.

Pamphlets for patients and providers will be produced in the developmental phase of the study with our expert panel of co-investigators, using our qualitative data and adapting materials from the medical literature and other resources (e.g. AHRQ). Providers will be given the pamphlets in the context of recruitment to the study. We will request feedback on the quality of the pamphlet to allow for future improvements.

G.4. Research Study Design – Aim 1 – Developing the intervention video and pamphlets

Qualitative Interviews – We will conduct qualitative interviews to evaluate technical, social, and personal barriers and benefits to communicating with CVT technology. We will conduct approximately thirty in-depth interviews with diabetes patients who had prior CVT visits at locations within ECHCS. Additional individual interviews will be conducted with key staff including CVT providers, CVT telepresenters (personnel who assist patients with the CVT technology), and CVT leadership. Guiding questions for interviews will be developed to explore specific communication issues encountered in CVT visits. Transcripts of interviews will be analyzed for statements and stories relevant to communicating with CVT technology useful for the intervention. We are choosing this methodology because it provides a rich source of information by tapping into subjects' perspectives. We will use the qualitative interviews to inform the design of our intervention materials. Factors important to patients may include diabetes specific issues (*e.g.,* treatment choices) and general issues related to active participatory communication behavior (*e.g.*, don't know what to ask). The purpose of the interviews is to obtain the patient's perspective on (1) communicating and collaborating with the provider in general; (2) communicating about diabetes; (3) communicating about medication and lifestyle adherence; and (4) communicating using CVT technology. Our recruitment of thirty patients for interviews is sufficient to ensure we have variation of patients' characteristics (*e.g.*, age, gender, race) and to gain the patients' perspective in our design of a communication intervention that is acceptable, comprehensible, and culturally sensitive. These

results will add to and build upon results from our preliminary studies in which we have conducted focus groups and interviews of patients to design and develop an intervention for in-person visits. We will then take what we learn from the new interviews and integrate the findings into the intervention for this project.

The total number of in-depth interviews to be conducted with leadership, telepresenters, and providers is in the range of 20-25. This will include at least 10 interviews with providers. In addition, we will make efforts to sample providers from diverse backgrounds according to age (e.g., younger and more experienced providers), gender (e.g., men and women), and training level (e.g., nurse practitioner, physician). Interviews will be up to 60 minutes in length and will focus on issues related to communicating with CVT. We expect that interview content will be rich and will provide substantial value in the development of the provider and patient pamphlets and production of the script/screenplay for the video.

Example questions and prompts for the interview for this project are shown in Table 3. These guiding questions are based on our conceptual model of competent communication in medical encounters. An interview guide is important as it serves as an outline for the interview and contains the list of questions developed from the theoretical framework. The interview guide for the patient interviews is focused on communication with the provider (1) in general; (2) about diabetes; (3) about medication adherence and (4) using CVT. Additional questions in the form of prompts and follow-up questions will be used to encourage discussion. Questions and prompts provide a flexible structure to keep the interview on track. A list of example questions and prompts for the interviews provided (**Table 3**). Questions are designed to get patients' perspective on the motivation to use active participatory communication behavior, the behaviors they have used, beliefs about behaviors they have used/not used and how knowledge and preparation impacted their use of active communication.

Patients participating in the interviews will be reimbursed $40 for their time. Interviews will also be conducted with several key personnel and providers who have used CVT for clinical care. The key staff include CVT providers, telepresenters, and CVT leadership. Approximately 10 of these interviews will be conducted. Interviews with providers will focus on how providers can communicate effectively with CVT technology.

Qualitative interview data will be collected in the form of audio-recordings and will be supplemented by notes recorded by an assistant to the interviewer (primarily responsible for observing the interaction). Dr. Gordon or a member of his research team, or Dr. Gopal or a member of his research team will conduct the interviews. Interviews will be conducted by phone and will last for up to 60 minutes. The analysis of the interviews will begin after the first interview is transcribed. Using the constant comparison method fundamental to grounded theory analysis, Dr. Gordon and the project manager will identify thematic categories throughout a particular transcript, especially in relation to the main research question to identify patient perspectives on the salience of factors associated with patients' active participatory communication behaviors. A similar process will be followed for the interviews with key personnel. Dr. Bokhour will assist in the review and discussion of the thematic categories and will provide expert guidance on iterative revisions of the guiding questions as needed during the data collection process. Atlas.ti computer software will be used to organize the qualitative transcript data and to assist in coding. The coding process will involve two coders meeting to discuss each transcript on a line-by-line basis. Each theme generated will be provisionally agreed upon and defined each coder. Coherence, credibility, and strength of those interpretations will be achieved with multidisciplinary triangulation among the coders. Ideas and suggestions for video development will be recorded in detail. All the investigators will meet to discuss the findings and to develop a summary document. This document will outline and guide the design of the future development of video segments used to motivate, provide knowledge and prepare patients for visits.

Table 3a. Preliminary Interview Guide (Patients)

1. We are doing the interview with you today because your primary care provider (PCP) believes that you have diabetes. Are there other things that you call diabetes? such as high sugar? (If so, try to use those terms when you refer to diabetes) How did you

find out that you might have diabetes? Who told you and what did they say?
2. Many people find it hard to talk to PCPs. Why do you think that is the case? Let's make a list of all of the things that you can think of that make it (easy or hard to talk to PCPs / easy or hard to request things / easy or hard to ask questions / give opinions)
3. Are there times that you want to ask a question but you do not? Try to remember why you didn't ask it? Are there some PCPs that are easier to talk to and ask questions to than others? What PCPs are easier to talk to?
4. How do you feel about talking to your PCP? Asking questions? Telling them your opinion? (about medication, treatments, things you read about, or heard from friends)
5. Are there times when you do not understand what the PCP is saying? What do you do? How do you decide if you will or won't ask your PCP to explain things? What do you think would make it easier to talk to your PCP?
6. Tell me about your first clinical video telehealth visit with your PCP. Tell me three good things about the CVT visit. Tell me three things that were harder in the CVT visit. What was different between the CVT visit and in-person visits?

Table 3b. Preliminary Interview Guide (Staff, Providers, Leadership)

1. Many people find it hard to talk to PCPs. Why do you think that is the case? Let's make a list of all of the things that you can think of that make it (easy or hard to talk to PCPs / easy or hard to request things / easy or hard to ask questions / give opinions)
2. Are there times that you think that patients want to ask a question but do not? Why do you think that patients may not ask questions? Are some PCPs easier to talk to and ask questions to than others? What PCPs are easier to talk to?
3. How do you think patients feel about talking to their PCP? Asking questions? Telling them opinions? (about medication, treatments, things they read about, or heard from friends)
4. Are there times when you do not understand what the PCP is saying? What do you do? How do you decide if you will or won't ask your PCP to explain things? What do you think would make it easier to talk to your PCP?
5. Tell me about your first clinical video telehealth visit with a patient (or one you observed). Tell me three good things about the CVT visit. Tell me three things that were harder in the CVT visit. What was different between the CVT visit and in-person visits?

Producing Pamphlets and Video – We will integrate content from the qualitative interviews with existing resources to develop our interventions. Existing resources include (1) data from our previous focus groups on barriers to doctor–patient communication during in-person visits (HSRD study SHP-08-182), (2) our review of medical literature on preparation for visits, barriers to communication, and communication models; (3) our team's extensive experience in communication training and research, in developing paper workbooks, running workshops, and producing video-based educational materials to improve patients' communication; and (4) input from our expert panel of co-investigators with expertise in communication, CVT encounters, and patient care. The video will be similar in structure to the "Speak Up" video Dr. Gordon directed and previously produced (grant #PPO-08-402). We expect the video will be 10-15 minutes in length. Pre-visit pamphlets for patients and providers will be developed with our expert co-investigators along with adapting materials from the medical literature, and other resources (*e.g.*, AHRQ, Ask Me 3). The expert panel of co-investigators will meet weekly to write the script/screenplay for the video and to write the materials for the pamphlets. The script for the previously developed video is included in the Appendix. We will contract with the Graham Clinical Performance Center (GCPC) at the University of Illinois to hire actors, to rent space for video production, and to edit the final video. The GCPC has experience training providers in the clinical video telehealth and has equipment that can be used to realistically depict a CVT clinical setting. Dr. Yudkowsky, Director of the GCPC, is a consultant for the project and is expert in training and simulation of clinical scenarios[50]. Dr. Gordon will direct and oversee all aspects of video production. The video will be produced on a DVD and as an appropriately formatted movie file for internet streaming video.

Efforts to Ensure a Powerful Intervention – The intervention will be strengthened by a linkage of the video and pamphlet, by the creation of video segments that can be matched to patient characteristics, and by efforts of the research team to increase delivery of intervention. For example, the video and the pamphlet will be used together to encourage subjects' involvement in their visits. The video will familiarize subjects with the clinical video telehealth equipment. The video will include activities to engage subjects to plan and prepare for active

communication behaviors in their visit. We will choose actors to vary gender and ethnicity in the video to allow patients to identify and visualize themselves in the scenarios depicted in the video. Research staff will contact patients to ensure that they have watched the video prior to visits. The research design involves a run-in period with a pre-visit survey that will be used to monitor adherence to viewing the video.

G.5. Research Study Design – Aim 2 – Randomized Trial of Intervention

We will conduct a randomized two-arm trial of the intervention in a sample of primary care CVT visits. The goal is to conduct a randomized-controlled trial of a pre-visit intervention video + pamphlet in comparison with pamphlet alone and to compare changes in patients' post-visit ratings of patient-centered care, self-efficacy to communicate, patients' actual communication behaviors, medication adherence, and diabetic control between the intervention and comparison groups using a two-sample design. In these CVT visits the patient is located at a remote site and communicates through a video and audio connection with the provider located at another VA facility. Patients will be selected to provide a clinically homogeneous sample for outcome assessment (*e.g.*, type 1 and type 2 Diabetes Mellitus). For recruitment, we have partnered with VISN 19 because of a high and growing volume of teleprimary care CVT visits. Participating patients will be randomized to receive the intervention (Video + Pamphlet) or comparison (Pamphlet) prior to their CVT visit. Primary outcomes are diabetic control (HgbA1c) several measures of adherence: medication possession ratio 6-months before and after the visit and patient-reported adherence to providers' recommendations, patients' and providers' ratings of patient-centered care and communication, and an assessment of changes in several common barriers to clinical improvement.

Rationale for two arm vs. three arm study design - We have several reasons why we chose a two-arm design over a three arm design. First, the two-arm (pamphlet vs pamphlet + video) design provides a natural means for subject recruitment and data collection. A third (usual care) arm would add the burden of study procedures without a pretext for recruitment and data collection. Patients recruited to third arm who get nothing may be frustrated with requests to complete research procedures. Second, as we discuss, the poor health literacy of many Veterans is a limiting factor in the effectiveness of a brochure. Thus, a brochure may not be different or effective compared with usual care. Third, brochures and pamphlets are now commonplace in healthcare settings and once we create one for the study, we hope it would become a standard of care in the clinical video telehealth setting. Our operations partner in this research project (Office of Telehealth) will have the opportunity to facilitate the use and dissemination of such a product across telehealth settings. Nonetheless, because there are so many pamphlets and brochures (available in clinic settings) it is not clear that a pamphlet alone leads to behavior change. Finally, a third arm introduces additional cost and complexity and would make the project less feasible.

G.5.1. Sample Size and Power Calculations.

The calculation of sample size employed the method of Rochon[51, 52] for target power = 0.80, one-sided alpha = 0.05, and expected retention of 85%. The one-sided test is appropriate for an intervention designed to improve HgbA1c (there is no possibility of claiming significance of the opposite result) and substantially economizes subject costs while giving a powerful test of the hypothesis of interest. Based on an expected reduction of HgbA1c of 0.60 percent and a standard deviation of 1.8, the effect size estimated is 0.33 (one-third SD). We will focus our power calculation (see Table 3.5) to calculate power based on a HgbA1c reduction of 0.5. Powering to detect a change in HgbA1c of this size is reasonable and is much less than HgbA1c reductions of 1.0 or more that are clinically desired in patients with poorly controlled diabetes. Assuming patient-level covariates offer $R^2 = 0.15$, a typical cross-time correlation among residuals of $\rho_T = 0.70$ (high stability of patient HgbA1c level), the test of the Group (Video + Pamphlet, Pamphlet only) × Time (Pre-intervention, Post-intervention) interaction, namely, that intervention group members reduce HgbA1c levels more than control group members, requires 82 subjects per group, or 164 total. Allowing for 85% retention, the total sample size required is 164/0.85 = 193. However, since patients will be recruited from (minimum) 14 providers who must be regarded as clusters, we assume an intraclass correlation of $\rho_I = 0.03$ and plan to recruit m=25 patients from each provider, yielding a design effect $Deff = 1 + \rho_I (m-1) = 1.72$, which means the minimum cluster-adjusted total sample size required is 193 x 1.72 = 332. Our recruitment target will be 25 patients from each of 14 providers, or 350 patients in total, which provides ample power. This number of

subjects is available in VISN 19 and can be recruited and the sample size can be accumulated within the planned time line and budget.

Table 3.5. Range of sample size for existing and revised sample size calculations

Expected Reduction in HgbA1c	Effect Size	N per group	N total	N, Allowing for retention	N, Adjusting for clustering within providers
0.60	0.33	58	116	137	236
0.50	0.28	82	164	193	332

Our other assumptions are further explained as follows. We chose ρT = 0.7, which assumes that HgbA1c within subjects is highly correlated over time. This assumption is clinically reasonable. We chose R-squared of 0.15 because the inclusion criteria are quite broad so to eliminate the effect of variation among people. This anticipates an appropriate modest correlation for between subject differences, such as demographic variation. We chose intra-class correlation (ICC) = 0.03. The ICC is the percent of variance due to clustering and was chosen because the typical values in large open population range from 0.01 to 0.05. Correlation of outcomes among subjects in the cluster is most likely due to similarities of clinicians' practice style. Correlation of other characteristics among subjects is less likely because subjects (generally) do not choose their providers but are administratively assigned to providers. Clustering has a large effect on sample size calculation due to *Deff*, the design effect, which tends to be larger when the number of clusters is smaller (or the size of the cluster is larger) holding the total sample constant. We can work to minimize cluster size by recruiting more providers, so our estimates of power are conservative. The cluster size estimates are conservative because they are based on a sample of only 14 providers. We hope to recruit a larger number of providers, which can be supported with recruitment in the VISN 19 setting. The resulting smaller cluster size reduces the design effect used to adjust sample size. Recruitment of more providers (clusters) with the same sample size gives smaller clusters and an increased statistical power.

G.5.2. Data Collection Procedures (Measures are described in Sections D.5.3 - D.5.5 and Table 5).

Patient Demographics and **Health Self-Assessment** are collected by telephone at patient recruitment / enrollment in the study.

Pre-Visit / Telephone Questionnaire 1 – Verbally consenting patients will complete a telephone pre-visit questionnaire. Patients completing this questionnaire will be given the $30 incentive, and will be eligible to continue in the study.

Provider Survey and Pamphlet – Verbally consenting providers will get a one-time questionnaire and a pamphlet

Randomization – Patient participants who complete the Pre-Visit questionnaire will be randomized using a sealed pre-selected sequence independent of patient characteristics and equal probability for two conditions.

Intervention – Patients randomized to the intervention will receive the intervention video and pamphlet by mail. Patients randomized to the comparison group will receive the pamphlet alone. Several types of control groups were considered. The reason for using a pamphlet is that it is possible that the video will add additional value over paper based informational material. The 10-15-minute video program will be mailed to patients for viewing on a DVD. An inexpensive portable DVD player will be mailed because penetration of broadband internet services in rural areas of VISN 19 may be inadequate for video streaming. Nonetheless, we will provide an option to watch the video on an internet website using a code to get feedback about if it was watched that way. Also, a post-intervention questionnaire will be used to monitor whether participants watched the video (intensity and duration[53]) and whether the video is delivered as planned (fidelity[53]).

Post-Visit / Telephone Questionnaire 2 – Patients will complete a post-visit telephone questionnaire by telephone within 7 days of the CVT visit. This data collection process will assess post-visit outcomes including self-efficacy to communicate and post-visit ratings of patient centeredness. Patient who complete the Post-Visit Questionnaire will be given $40 incentive for participation.

Post-Visit Follow-Up Interview – Adherence, resistance to treatment and patient satisfaction will be assessed 4 weeks after the CVT visit by questionnaires administered by an RA over the telephone. After

completion of the Telephone Follow-Up Interview, patients will be provided with a $30 incentive for participation.

Chart review – Data abstracted from medical records (*e.g.*, HgbA1c) will be blinded to group assignment.

Additional Interviews – After the telephone interview, we will conduct several in-depth interviews with patients who agree for another contact, to assess perceptions of the intervention. These interviews will be done to further evaluate the effectiveness of the objective contained within Aim 2 and will serve as member checks for the analyses conducted for Aim 1. Also, providers will be interviewed to determine their perceptions of the pamphlets and whether it facilitated clinical flow. An interview guide with a full list of guiding questions will be developed prior to scheduling interviews. Questions will evaluate whether specific details of the video are recalled, whether the demeanor or manner of the patient, nurse, and doctor characters are recalled, and specifically regarding the patient characters how active or passive they were toward the provider character. Questions will also evaluate patients' perceptions of their actual encounter with their provider; did they ask more questions, exhibit other active behaviors, did the provider answer their questions or respond to their active communication, and did they like the encounter better. Another set of questions will evaluate patients' sense of self-efficacy to be an active participant in future encounters – how will your visits change, how do you think the provider will react when you are more active. Up to 20 patient participants will participate in these interviews. Patient participants will be provided a $40 incentive for participation. A qualitative content analysis of the interview transcripts will be conducted using an iterative, consensus-based coding process to identify and characterize whether and how the video intervention helped patients communicate during clinic visits. Dr. Gordon has experience conducting content analyses.[54-56]

Table 4a. Preliminary In-Depth Interview Guide (Patients)

1. We are doing the interview with you today because you participated in the previous step of this study. You watched an educational video about doctor-patient communication and had a recent CVT visit with your doctor. We would like to ask you what you liked and disliked about the video and whether the video influenced your communication with your doctor during your last CVT visit.
2. What do you remember about watching the video? What do you think about the people in the video? How did they communicate? How would you communicate differently?
3. How did you remember to discuss what you need with your doctor in the limited time of your visit?
4. What did you do in your visit after watching the video? Did you ask questions or do anything like the people in the video? If you asked questions, did your doctor answered all of them?
5. How did telehealth technology affect your communication with your doctor? Did you have trouble understanding your doctor during last visit? How did what your doctor said affect what you say in the visit?
6. What would you change about the video? What didn't you understand in the video? What was missing? What didn't you like?
7. How do you prepare now for your future doctor visit? Do you do anything differently now after watching the video?

Table 4b. Preliminary In-Depth Interview Guide (Providers)

1. We are doing the interview with you today because you read our pamphlet that offered several tips for a successful Telehealth visit. We would like to ask you what you liked and disliked about the pamphlet and whether it influenced your communication with your patients during CVT visits.
2. What would you change about the pamphlet? What was missing? What didn't you like? What was useful?
3. Are there times that you think that patients want to ask a question but do not? Why do you think that patients may not ask questions? What do you think would make it easier to talk to your patient during CVT visit?
4. How do you think patients feel about talking during CVT visits? Asking questions? Telling doctors their opinions about medication, treatments, things they read about, or heard from friends?
5. Do you do anything differently after reading the pamphlet?

G.5.3. Data Collection – Primary dependent variables (Aims 2a, 2b, and 2c).

We will assess the variables (**Table 5**) that our intervention is intended to modify and that are described in our conceptual model of communication. These are (1) (2) self-efficacy to communicate as measured by questionnaire before and after the visit; (3) patient adherence measured with questionnaires by telephone 4 weeks after the visit and by review of pharmacy records; and (4) HgbA1c.

Communication Self-Efficacy (pre- and post-visit) is the degree to which a patient feels able to interact with his/her provider in order to provide information about problems, obtain desired information about diagnosis, treatment and prognosis, and participate in formulating a plan. The Perceived Efficacy in Physician-Patient Interactions[60] scale (PEPPI) is a valid and reliable measure of patients' perceived self-efficacy in interacting with physicians (alpha 0.83). The short form of the PEPPI (PEPPI-5) has 5-items. Score on the PEPPI-5 ranges from 5-25.

Patient-Centered Care (PCC) and Patient Centered Communication (collected post-visit) are measured with the Consultation Care Measure (CCM)[61, 62] which measures four domains of PCC[63] and the Patient Reactions Assessment (PRA).[64] We use the PRA (because we focus on patient-centered communication) to assess patients' ratings of their own participatory communication behavior and patients' ratings of their providers' communication.- it is a 15-item scale with 3 sub-scales that we have used in previous research.[38] Patients' ratings of their (1) providers' informativeness and the extent to which the patient understands that information (information sub-scale) are measured with 5-items; (2) patients' ratings that the provider values and respects them is measured with 5-items; and (3) patients' ratings of their own communication is measured with 5-items.[64] This questionnaire has high internal consistency (alpha = 0.91 for the 15-item PRA and alphas of 0.87, 0.91 and 0.90 for the subscales, respectively). The CCM and PRA are in the Appendix.

Patient Adherence measures are imperfect. We will address this issue by measuring adherence in more than one way. Self-reported adherence can be measured using a brief questionnaire from the medical outcomes study.[65] This measure is a general measure of adherence to providers' recommendations and includes 5 items and is scored on a 6-level Likert-type scale ranging from "none of the time" to "all of the time". Scores range from 0-100 (after normalizing the standard 6-30 range) with higher numbers reflecting better adherence. We have experience assessing adherence using this measure with a brief telephone survey 3-4 weeks following the visit (alpha = 0.70 to 0.72 in our data).[66] The self-report measures of adherence will be administered with instructions to answer based on the medications and recommendations from the study related visit. Medication adherence will also be assessed with a medication possession ratio (MPR) for diabetes medications. MPR will be based on VA pharmacy data obtained locally from the Pharmacy Service. MPR is a ratio of the number of days the patient has drug in their possession divided by the number of days in the follow-up period (*MPR = days with drug / total days*). We will use a mean MPR for patients on multiple oral hypoglycemic or insulin medications. Patient with MPR of 1 or greater have enough medication to follow the prescribed regimen. Patients with MPR less than 1 would not have received adequate medication supply to be fully adherent to the prescribed regimen. Non-adherence will be defined by MPR<0.8. Although non-VA prescriptions can be entered into CPRS, there is difficulty in knowing whether and when these non-VA prescriptions were filled, so we may not have data to calculate MPR unless patients receive their medication from VA. We expect this number will be less than 20% of participants. Nonetheless, we will evaluate if we can collect data from patients about non-VA prescriptions. In summary, because of potential variation in the assessment of patient adherence we will assess this outcome using three different measures.

Human Connection Scale - measures the extent to which patient feel a sense of mutual understanding, caring, and trust with their physicians. The scale is a valid and reliable measure of therapeutic alliance between patients and their physicians[106].

Consultation and Relational Empathy (CARE) Measure - consultation process measure based on a broad definition of empathy, which is meaningful to patients irrespective of their socio-economic background.[105] Research studies support the validity and reliability of the CARE measure as a tool for measuring patients' perceptions of relational empathy in the consultation.[105, 107]

Hemoglobin A1c (collected at Chart review) commonly abbreviated "HgbA1c" is regarded as the standard laboratory measurement ("blood test) for assessing the control of diabetes over approximately three months preceding the test. HgbA1c is often checked several times a year in patients with poorly controlled diabetes.

Table 5. Measures

	Measure	***Source***	***When measured***
PRIMARY DV			
1.	Communication Self-Efficacy (PEPPI[60])	Patient	Pre- and Post-Visit
2.	Human Connection Scale[106]	Patient	Pre- and Post-Visit
3.	Patient Centered Care (CCM[61, 62])	Patient	Post-visit
4.	Patient Centered Communication[64]	Patient	Post-visit
5.	Resistance to Treatment[68]	Patient	Post-visit
6.	Consultation and Relational Empathy (CARE)[105,107]	Patient	Post-visit
6.	Patient Adherence[67, 69]	Patient, Chart	Telephone Interview, R_x Data
7.	HgbA1c	Chart	Chart Reviews
SECONDARY DV			
9.	Trust in physician[38]	Patient	Pre- and Post-visit
10.	Patient Satisfaction[71]	Patient	Post-visit
11.	Altarum Consumer Engagement (ACE)[104]	Patient	Pre- and Post-Visit
12.	Participatory Decision-Making Style	Patient	Pre- and Post-Visit
13.	Diabetes Self-Efficacy	Patient	Pre- and Post-Visit
COVARIATES			
14.	Comorbid Diagnoses[76]	Chart	Chart Reviews
15.	Patient Demographics	Patient	Patient enrollment
16.	Health related QoL (SF12 and Neuropathy Questionnaires)	Patient	Pre-visit
17.	Health Literacy[77, 78]	Patient	Pre-visit
18.	Depression Screener (PHQ-2)[79]	Patient	Pre-visit
19.	Social Support	Patient	Pre-visit
20.	Provider Demographics	Provider	Provider enrollment
21.	Provider Burnout[99,100]	Provider	Provider enrollment

G.5.4. Data Collection – Secondary dependent variables (Aims 2a, 2b, and 2c).

Trust in Provider is an important characteristic of provider-patient relationships. Trust will be measured pre- and post-visit using a brief 5-item measure that Dr. Gordon validated in Veterans[38] using items from previously developed and longer trust scales. The scale had high internal reliability (alpha .92) and is scored on a 10-point Likert scale using the anchors strongly disagree and strongly agree.

Patient Satisfaction (collected post-visit) is assessed as the extent to which the patient is content with the relationship with her/his provider, in terms of the quality of information exchanged during medical encounters, and in terms of the demeanor of the provider toward the patient (courtesy, respectfulness, sensitivity, taking time and not being rushed).

Altarum Consumer Engagement (ACE) - the ACE Measure™ offers a tool for assessing patient engagement and consumerism behaviors in healthcare. ACE contains four subscales, each of which measures a unique aspect of engagement. in predicting a range of health outcomes and behaviors. Duke et al.[104] confirmed the validity of ACE Measure™ and its utility in screening for and finding group differences in activities related to

patient engagement and health consumerism. In exchange for a right to use the survey, we will agree to share de-identified survey results with Altarum Institute that will provide us with the survey. The following de-identified information will be shared with Antarum: 1) responses to survey questions; 2) participant's gender; 3) participant's age; 4) first two digits of participant's home zip code.

Participatory Decision-Making Style - Participatory decision-making style represents the degree to which providers involve patients in decision making. We will measure patients' ratings of PCPs' participatory decision- making style using a 4-item scale evaluated by Heisler et al. in a study of veterans with diabetes. The authors found it to be associated with better patient understanding of diabetes and self-management practices.[108]

Diabetes Self-Efficacy - We will use a 4-item scale to measure patients' confidence in their ability to manage their diabetes, validated as a predictor of better glycemic control.[68]

G.5.5. Data Collection – Covariates (Aims 2a, 2b, and 2c).

Comorbidity (collected at Chart review) is the burden of disease and may be an important predictor of a number of our measures. The items in the Charlson comorbidity index[76] will be used classify comorbid illnesses. This index includes indicators for diabetes with and without complications and we will also collect an additional indicator for whether or not a patient is prescribed insulin. Analyses will be done to determine whether to use the Charlson weights or a simpler comorbidity count.

Patient Demographics (pre-visit self-report) include: patient name, address, age, race, ethnicity, marital status, social support, education, occupation, current employment, number in household, domicile (own, rent).

Health-Related Quality of Life (pre-visit) We will use a general quality of life (QoL) measure and a diabetes specific QoL measure.[83] Patients' physical and mental health status will be assessed using the Medical Outcome Study Short Form-12 (SF-12). To account for severity of diabetes, we will use the 4-item Neuropathy Questionnaire based on patient's self-reported symptoms.

Health Literacy (pre-visit) is measured with a single item, "*How confident are you filling out medical forms by yourself*?" This item was demonstrated to have good discrimination in detecting patients with limited and limited/marginal literacy with 0.82 and 0.79 area under the receiver operating characteristic curve (ROC), respectively, when compared to the REALM as a reference standard for health literacy.[79]

Depression may be associated with worse communication.[84] We will screen all participants with the PHQ-2, a brief, validated two-item depression screener.[85] The PHQ-2 assesses depressed mood and anhedonia over the past 2-weeks and each item is scored from 0 ("not at all") to 3 ("nearly every day") with possible total scores ranging from 0-6. A score of 3 is considered the optimal cut-point for screening purposes.

Social Support - We will measure patients' level of social support using the 4-item modified Medical Outcomes Study Social Support survey[70].

Provider Demographics (collected at provider recruitment) include provider age, sex, race/ethnicity, medical training, years in practice, number of hours/week seeing patients and hours/week in CVT settings.

Provider Burnout - We will assess provider wellbeing using the modified two-question Maslach Burnout Inventory, career fit, work stress, and career satisfaction questionnaire.

Intervention Intensity and Fidelity is an assessment of participant attention while watching the video (intensity) and whether the video is delivered as planned (fidelity).[53] Patients will respond to a survey about the patients in the video to monitor whether patients watched the video (duration).

G.5.6. Additional Data Collection for Safety and Compliance

Because this research is a minimal-risk trial of an educational intervention, we do not expect serious adverse events (SAE's) or adverse events (AE's). Nonetheless, at the post-visit follow-up phone calls, we will plan to collect and report any SAE's defined as death of participant or hospitalization.

What Safety Information is Collected – If applicable, we will request dates of hospitalization, length of stay, and reason for admission from participants. If death of a participant is reported, we will request date of death, and if death occurred outside the VA, we will notify the primary care provider (PCP).

How will Safety Information be collected – Safety information will be collected from participants by telephone at a follow-up telephone interview.

Frequency of Safety Data Collection – Safety information is collected at follow-up telephone interviews. There are two planned follow-up telephone interviews for each subject.
Safety Conditions that Trigger Immediate Suspension of Research – Because this research is minimal risk, we do not anticipate any safety conditions serious enough to trigger immediate suspension of research.
Procedures to notify participants or PCP of findings affecting participants' health or welfare – There are no plans to notify participants of the findings of the research. If we learn of participant death, the local site investigator will notify the participant's PCP.
Procedures to minimize risk – One of the risks of the study is loss of confidentiality. We have taken several steps to protect the data from unauthorized disclosure. Paper forms will be stored in locked files cabinets in locked offices. Electronic data will be stored on VA servers in folders with access restricted to study personnel. All audio recordings are digitized and stored as electronic data.

G.6. Data Preparation and Management Plan.

The research assistant will maintain quality control of data collection, making every effort to prevent missing data by administering questionnaire forms and completing form data prior to processing participation incentives. Nevertheless, we expect some data will be missing and will employ methods arising from the modern perspective on missing data in our analyses.[86, 87] Should multiple imputation be warranted, a range of software is now available (e.g., MI and MIANALYZE procedures in SAS and others).[88, 89] Simpler methods such as stratified analysis, partial subscales, and indicators for missing scales may also be considered.

We strive to minimize loss to follow-up and missing data. We will use a screening procedure with the recruitment process to ensure that patients will follow the procedures in the study. This procedure will be conducted by mail and phone. Once patients have been recruited we will take several steps to keep patients in the study through completion. Subject screening will include the completion of initial surveys. Subjects who do completed the surveys will not be randomized. We will call patients and conduct the verbal informed consent process, but will not randomize subjects until after the initial survey procedures are complete. This run-in phase will help ensure that subjects are willing to participate in study procedures. We will follow-up with a phone call to ensure the pamphlet/video was viewed and to remind patients of the scheduled visits. Patients must complete these procedures to remain in the study. After visit completion patients will complete a post-visit survey. In addition to these procedures we will take additional steps to ensure that we can obtain hemoglobin A1c outcome data. Patients will be encouraged to complete f/u visit to obtain repeated hemoglobin A1c. Patient data will be accessible via medical record review. Patients will be requested to provide release of information permissions so that study personnel may obtain copies of HgbA1c reports done in non-VA facilities. Patient incentives will be structured to encourage completion of follow-up

G.7. Data Analysis.

Initially we will compute descriptive statistics by group for all variables collected. We will compute means and standard deviations for continuous variables, medians and interquartile ranges for ordinal variables, and percentages by category for categorical variables. Participants in the two groups will be compared for baseline equivalence using between-group t-tests for continuous variables and chi-square tests for dichotomous or polytomous variables. Variables for which differences are found will be examined as covariates in secondary analyses. We will also examine the distributions of variables in each group and transform variables to improve normality or employ rank-based tests as appropriate. In this section, we focus on quantitative analysis for the Specific Aim 2 (The analysis plan for qualitative data in Aim 1 was described above.)

G.7.1. Analysis of Outcome Variables (Specific Aim 2a).

Most primary and secondary dependent variables (Table 5, measures in D.5.3 and D.5.4) are measured once only, and hence experimental conditions may be compared with a one-way between-subjects analysis of variance (equivalent to a *t*-test), or with analysis of covariance when covariates are considered. Note that covariates (measures listed in D.5.5) are also collected once only prior to medical visits and are time-constant (except time-varying comorbid diagnoses from chart reviews). The remaining four primary and secondary dependent variables – HbgA1c, communication self-efficacy, and trust in physician – are measured twice, and corresponding to Specific Aim 2a, will be examined for differential pre-post change between the intervention

and control conditions. In design terms this is a Group x Time interaction on repeated measures of outcomes. The general hypothesis is directional: The Video + Pamphlet intervention with patients is expected to yield improvements in the primary outcomes above those found in the Pamphlet only control condition; for example, improved HbgA1c, improved self-efficacy, and higher trust in physician. After examining the scales for normality and applying variance stabilizing transformations as needed, repeated measures analysis will be employed, implemented via SAS PROC MIXED procedure, which can also incorporate covariates and has good missing data properties (no listwise deletion, unbiased under missing at random).[90, 91] Should normality be strongly violated, we can instead employ either a rank-based test (Friedman test) or ordinal analysis (GEE in PROC GENMOD or random effects ordinal regression with PROC NLMIXED) to test the interactions of interest. Appropriate diagnostic model-checking for influential data points (outliers) and statistical assumptions will be carried out. Since the various primary outcomes are presumably somewhat correlated, we will consider more complex analyses to take this non-independence into account (e.g., corrected alpha-levels for individual tests or MANOVA and multiple-response random effects models). As ancillary analyses we will explore the sensitivity of our results to the available patient and provider covariates (listed in D.5.5). We will also explore differences in outcomes with respect to individual PCPs treating a cluster of patients, as this may be important for planning future research. Technically, this is accomplished by including a random effect for providers in the model in order to reflect the presumed correlation among patients treated by the same provider. Exploring Mediators and Moderators (Specific Aims 2b and 2c).

As further secondary analyses we will consider whether certain covariates fulfill the role of a moderating variable in single-equation analyses, or the role of mediating variable in simultaneous equations analyses.[92] A **moderator variable** affects the strength of the relationship between an independent and a dependent variable. Moderators are between-subjects factors that interact with treatment factors or covariates, thereby showing that the effect of these is conditional on the moderator's level. In other words, the treatment or covariate has a stronger effect on certain subgroups of participants than it does on others, but equivalently so across conditions. The patient moderators to be tested are age, race, gender, health literacy, and health locus of control; the provider moderators to be tested are gender, years in practice. For example, we will examine whether patient race alters the effect of the experimental conditions on patient communication and other dependent variables. We will also examine whether communication self-efficacy plays mediating roles. A **mediator variable** is interposed between the independent variable and dependent variable to offer an alternative account for their apparent relationship. For example, one equation will test whether the experimental conditions affect self-efficacy. Another equation will test whether self-efficacy outweighs experimental conditions as a predictor of active participation. If these two conditions hold, then self-efficacy may mediate the effect of experimental condition on active participation; that is, the treatment has its effect chiefly by altering self-efficacy, which in turn alters active participation. Michael L. Berbaum and the study statistician Oksana Pugach are experts in conducting such analyses. The foregoing informal account of moderator / mediator analyses is explicated in standard references.[92-95] Mediation analyses will be conducted using the Mplus structural equations program in order to employ recommended bootstrap estimates of certain standard errors.[96]

G.7.2. Analysis of communication data

H. Dissemination and Implementation Plan

We expect that the project will advance understanding of patient-provider communication in CVT visits and in patients with diabetes. We also expect the project will provide a number of opportunities for dissemination and possibly for implementation into clinical practice. In addition, education tools that encourage more patient-centered communication during CVT encounters may allow more rapid acceptance of CVT, thereby improving access to healthcare and enhancing the operational mission of our partners.

We will take advantage of several potential avenues for dissemination of our findings and results. We will submit findings and results of the research for scholarly publication. We expect that this research project will result in submission of articles to the peer-reviewed literature in health services, diabetes, and health communication research (*e.g.*, *Medical Care, Journal of General Internal Medicine,* Diabetes *Care, and Patient*

Education and Counseling). These papers, we believe, will make important contributions to the literature on patient-provider communication in CVT visits and in patients with diabetes. Moreover, the educational intervention we develop will be a potential resource for patient education. Possible opportunities to disseminate our video program within the VA include the VA website or the veterans' health benefit web portal, "*My Health**e**Vet*". Additional opportunities for dissemination through organizations outside the VA (*e.g.*, American Diabetes Association, Center for Disease Control, Indian Health Service) will also be explored. Additionally, our intervention design may be a paradigm for encouraging active participatory communication behaviors and could be evaluated for other medical conditions, not just diabetes.

The research also may provide opportunities for implementation and implementation research. Our findings related to which factors act as mediators and moderators of patients' active participatory communication in provider visits may provide direction to future research examining the impact of interventions tailored to those factors. And, if the intervention improves the primary or secondary dependent variables, Dr. Gordon will meet with local and VISN leaders (Director, Chief of Staff) to discuss the findings and the implications for improving communication in CVT visits. In addition, if appropriate, we will consult with the Diabetes QUERI and the CIPRS QUERI resource center, VISN directors, VA Office of Performance and Quality, VA Office Patient Care Services, and other organizations to stimulate national interest in the findings.

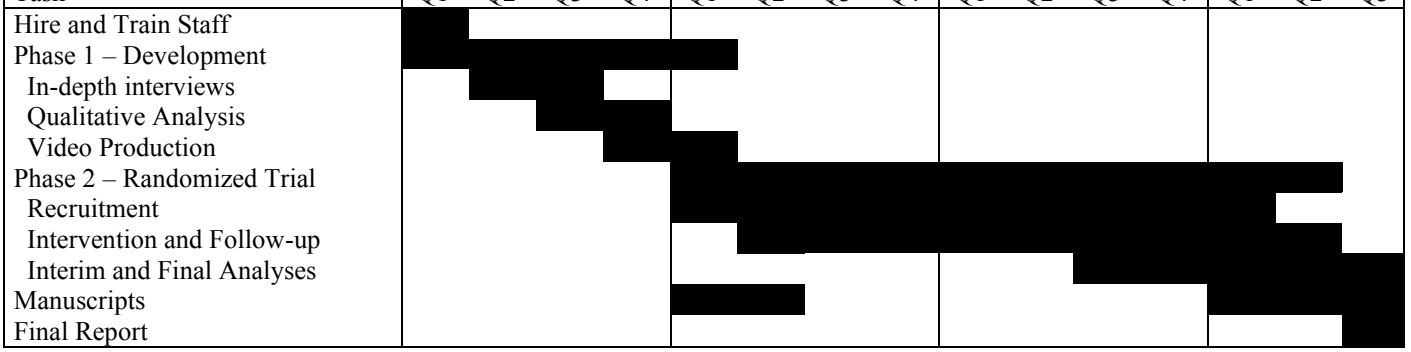
I. Project management plan

This is a 3 year 9 month study, as outlined in the Gantt chart (**Figure 2**). This project involves a qualitative phase 1 and a mixed-methods phase 2 with a randomized trial of the intervention. This project will be a multi-site study. Data will be collected from sites in VISN 19. Project management will be centered at the Denver VAMC (DVAMC) and Jesse Brown VAMC (JBVAMC) in Chicago. Office space for research staff, data storage and analysis and patient recruitment for the research will be at JBVAMC and DVAMC.

Howard S. Gordon, MD, is the principal investigator for this project. He is a staff physician at the JBVAMC, a senior investigator at the VA HSR&D Center for Management of Complex Chronic Care (CMC^3), a prior VA career development awardee, and is Associate Professor at University of Illinois at Chicago (UIC). Dr. Gordon will oversee the conduct and execution of all the phases of this project. He will supervise the hiring of research staff, the training of the staff, the preparation of the patient recruitment and survey procedures, patient, provider, and staff interviews, and data entry and quality monitoring. He will be responsible for data and safety monitoring and will monitor the process of data collection weekly and will be responsible for reporting any adverse events to the Institutional Review Boards, other Research monitors (*e.g.*, VA research and development committee), or appropriate personnel and he will oversee data analysis, interpretation, and dissemination of study findings. **Barbara Bokhour, PhD,** is expert in qualitative analysis and will assist Dr. Gordon in the analysis of qualitative data. She is a leader in the fields of patient-physician communication, patient narratives of illness, and qualitative research and is uniquely qualified to assist as co-investigator on this project.[97, 98] Her extensive experience conducting qualitative interviews with patients and staff and substantial experience analyzing qualitative data will be extremely helpful in completing this project. She will assist in the analysis of the interview transcripts by providing an independent professional viewpoint to triangulate the coding produced by Dr. Gordon and staff and she will participate in the design and development of the interventional materials for this project and in plans to assess the validity of those materials. **Ravi Gopal, MD** is the staff physician site-PI at Denver VAMC. He has conducted research using quantitative survey methods to evaluate provider well-being and is currently conducting a qualitative study of internal medicine physician well-being and its effect on behavior while working on inpatient services.[99, 100] He will supervise the research assistant at the Denver VAMC and will facilitate patient recruitment and data collection. **Richard L. Street, Jr. PhD** is expert in evaluation of patient-centered medical interactions and the use of interactive multimedia in communication training. He is Professor of Communication at Texas A&M University and is also Associate Director & Chief of Health Decision-Making and Communication at the Houston Center for Quality of Care and Utilization Studies (VA HSRD Center of Excellence). He has developed an extensive program of research over 20 years examining issues related to provider-patient communication, medical outcomes, and strategies for increasing patient involvement in care.[16-18, 37-39, 41, 44, 58, 59, 101-103] He will participate in regular team

meetings and will help with manuscript preparation. **Michael L. Berbaum, PhD** will provide expertise in biostatistics. Dr. Berbaum will oversee the statistical design of the trial and will assist Dr. Gordon in the analysis and interpretation of data. He has significant expertise in health services and chronic disease prevention research. He will oversee the data analysis and interpretation with Dr. Gordon and he will help with manuscript preparation. **Saul Weiner, MD** will assist with communication analysis and interpretation[72, 73] in phase 2 of the project. **Rachel Yudkowsky, MD, MHPE,** is Associate Professor and Director of the Graham Clinical Performance Center at UIC. She will assist in development of educational materials for patients and providers when preparing for medical encounters in a CVT setting. She will serve as a consultant and will share her expertise training physicians in the use of CVT equipment.[50] Telehealth Manager for VISN 19. VISN 19 CVT manager serve as consultants and provide operations assistance to the study.

Figure 2. GANTT Chart



Project Staff will include (1) a full-time **project coordinator** to assist Dr. Gordon and to be responsible for the day-to-day management of the project., (2) **research assistants** responsible for data collection, patient recruitment, tracking of participants, administration of questionnaires, medical record review, and data entry; and (3) a quantitative **data analyst** who is proficient in SAS, and other data management and analysis software who will be responsible for designing data entry screens, maintaining databases, coordinating database management overseeing data entry, and performing the analyses of the data for this project under the supervision of Drs. Gordon and Berbaum.

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