[IRBNET Number – 1573648-1]

An Assessment of Open Access Audio of the Clinical Encounter on Veterans and their Care

Funding Agency: Health Services Research & Development

Principal Investigator: Saul J. Weiner, MD

August 30 2022

Abstract

Background: The medical encounter can be overwhelming in term of the amount of information discussed, its technical nature, and the anxiety it can generate. Easy access to a secure audio recording from any internet enabled device is an available low cost technology that allows patients to “revisit the visit” either alone or sharing with caretakers and family. It has been introduced and tested outside the VA with evidence that it increases patient recall and understanding and may even improve physician performance. Little is known, however, about whether and to what extent these effects lead to better outcomes, such as improved treatment plan adherence and chronic disease self-management.

Objectives: The study aims to assess (1) the impact of an open access audio (OAA) program on two behaviors (patient activation, treatment plan adherence), and two chronic condition measures (glycosylated hemoglobin, blood pressure); (2) the impact of open access audio on provider communication and on their attention to patient contextual factors (i.e. individual veteran’s needs and circumstances relevant to planning effective care); and (3) patient, provider, and leadership perceptions of the extent to which the program is safe, not burdensome, and worthwhile at both the start and at two years into the program. A secondary analysis will descriptively measure the effect size of OAA on ED visits and hospital admissions.

Design: The setting will be primary care and diabetes clinics, at two facilities for generalizability. To achieve aims 1 and 2, we plan a randomized controlled three arm design: (1) the encounter is recorded, with provider and patient aware, and uploaded to a server the Veteran, provider, and research team can access post visit; (2) the encounter is recorded, with both parties aware, and uploaded to a server only the research team can access; and (3) the encounter is recorded, with only the patient aware, and uploaded to a server only the research team can access. Resource utilization and disease measures indicated in aims 1 and 2 will be collected in all arms.

Analysis: Comparisons of Arms “1” and “2” enable assessing the impact of the availability of audio on patients (for aim 1). Comparisons of Arm “2” with “3” enables isolating the effect of providers knowing they are being recorded (for aim 2). Data for aim 3 will come from survey tools, focus groups and semi-structured leadership interviews to elicit perceptions of project safety, burden, and value.

Impact: This study will assess a new resource for enhancing Veterans capacity to understand their care plan and share information from their visit with caregivers. The study design is intended to yield information to guide decision makers about the value of bringing “open access audio” (OAA) to VHA.

List of Abbreviations

Provide a list of all abbreviations used in the protocol and their associated meanings.

4C:	Content Coding for Contextualization of Care
CDW:	Corporate Data Warehouse
CIRB:	Central Institutional Review Board
COIN:	Center of Innovation
Co-I:	Co-Investigator
ED:	Emergency Department
HSR&D:	Health Services Research and Development
HgB:	Hemoglobin
HIPAA:	Health Insurance Portability & Accountability Act
OAA:	Open Access Audio
PDC:	Proportion of days covered (refill rate)
PHI:	Protected Health Information
PI:	Principal Investigator
RVA:	Return Visit Adherence
VHA:	Veterans Health Administration

Contents

1.0 Study Personnel

- Provide name, contact information, facility/organization, and affiliations/employee status for the following:
    - Principal Investigators/Study Chairs
    - Co-Investigators:
    - Collaborators:

Principal Investigator:

Saul J. Weiner, MD; Jesse Brown VA Medical Center; Staff Physician and Deputy Director, Deputy Director, VA Center of Innovation for Complex Chronic Healthcare; Professor of Medicine, Pediatrics and Medical Education, University of Illinois at Chicago. Saul.weiner@va.gov

Co-Investigators:

Frances Weaver, PhD, Site PI: Edward Hines, Jr. VA Hospital, VA Center of Innovation for Complex Chronic Healthcare; HSR&D Senior Research Career Scientist. Frances.Weaver@va.gov

Alan Schwartz, PhD; University of Illinois at Chicago; Professor, Department of Medical Education; alansz@uic.edu

Corinna D Falck-Ytter, MD, Site PI; Louis Stokes Cleveland VA Medical Center; Medical Director of Primary Care; Corinna.Falck-Ytter@va.gov

Sherry Ball, PhD; Louis Stokes Cleveland VA Medical Center; Implementation Specialist Sherry.Ball@va.gov

Paul Barr, PhD, Site PI; Dartmouth Institute, Geisel School of Medicine at Dartmouth; Paul.J.Barr@dartmouth.edu

William Haslett, PhD; Biomedical Data Science Department, Geisel School of Medicine at Dartmouth College; will.haslett@gmail.com

- Indicate the number of potential participating sites (both VA and non-VA) and if there is any graduated start-up plan for the sites

Two sites are to participate in data collection:

Jesse Brown VA Medical Center

Louis Stokes Cleveland VA Medical Center

Two sites include staff who will facilitate analysis of the data and have access to it

Edward Hines Jr. VA Hospital

Biomedical Data Science department at the Geisel School of Medicine at Dartmouth College

2.0 Introduction

- Provide scientific background and rationale for study.

Technically complex information is often shared with patients during a medical encounter. During these visits patients may be emotionally distraught, in physical pain, confused or with a level of low health literacy. A range of studies indicate patients forget as much as 80% of the information immediately following the visit.[1-4] Recent innovations to address recall problems include after-visit summaries (AVS) and providing direct access to their medical record. These strategies are less helpful when patients lack high levels of medical literacy.[5-7] They also don't capture many nuances of the visit, such as what reassurances the provider may have provided, and any questions the patient asked that were, in turn, addressed.

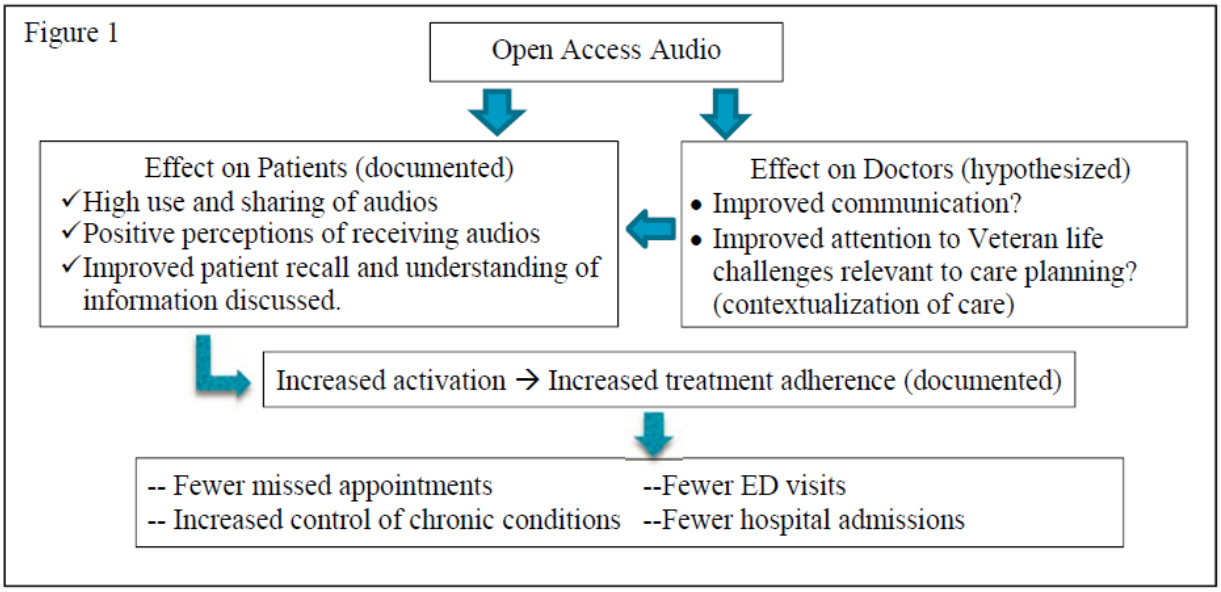
Enabling patients to access audio recordings of clinical encounters ("Open Access Audio," or OAA) offers an additional resource with the potential to improve recall and understanding of clinical instructions and, as a result, potentially improve health outcomes. Audio recordings, in contrast to AVS, provide a verbatim record of all that was discussed. Early evidence is that they are valued: Patients listen to and share them with family and/or caretakers. In a scoping review of 33 studies, on average 72% of patients listened to the audio and 60% shared it with others, e.g. a family member or caregiver.[8] Several studies show that audios provided by practices result in higher levels of engagement and recall, and that recall is associated with increased adherence.[8-10] Patients have also reported that they are less likely to second guess decisions made during the visit if they can listen to them later, which may account for fewer follow-up calls to practices after visits.[11] Finally, many believe their providers communicate more effectively and are more attentive when they know they are being audio recorded.[11,12] We saw evidence of this advantageous "Hawthorne-like" effect in research we conducted comparing how attentive providers are to patient life context in care planning, comparing when they are being openly assessed by a standardized patient in a lab (audio out in the open), to an assessment with exactly the same script portrayed by the same actor as an *incognito* unannounced standardized patient embedded in their practice (audio concealed). In the former situation they were significantly more likely to identify and address contextual factors essential to care planning (e.g. that a patient needs a less costly medication, or needs transportation) than in the latter.[13] We also found that such attentiveness predicts improved health care outcomes when measured using a blinded scoring system based on audio recordings of real patient encounters (e.g. HgB A1c more likely to come down when providers identifies cost issues and switches patient to more affordable insulin).[14] Hence, open audio recording may be beneficial to patients both directly, i.e. as a resource they can access to better

understand their care, and indirectly, by motivating their provider's behavior in ways that are beneficial to them.

- Include summary of gaps in current knowledge, relevant data, and how the study will add to existing knowledge.

Although the evidence on OAA is promising, it's measurable effects have not been substantially examined. Specifically, how might it impact service utilization and even disease specific measures? We propose the following model, in Figure 1 for how it might drive these effects, and postulate a set of desired outcomes.

Figure 1



The model postulates that audio recording visits for patients both directly improves patient recall and understanding (documented outside the VA), and that it motivates providers to do a better job communicating with their patients and getting to know their individual needs and circumstances (hypothesized) since the patient may listen to and share the audio with caregivers. In turn, patients with better understanding and recall are more likely to be activated, which leads to greater treatment adherence (documented). Finally, activated patients who adhere to their treatment plan should miss fewer appointments, and have better control of their chronic conditions. It is also possible that they become less likely to end up in the ED or hospitalized. The evidence for these linkages come from other studies: Patient activation, defined as having the knowledge, skills, and confidence for self-management, can, in fact, predict increased treatment adherence, and both have been associated with the desired reductions in resource utilization and improved self-management of chronic conditions.[15-17]

Of note: Setting up an audio recording program in the patient care setting requires considerable expertise. The research team that will conducting this study has over a decade of experience carrying out HSR&D funded studies in which encounters are audio recorded by patients, recording over 1000 visits a year in the prior three years.[12,14,18]

3.0 Objectives

- Describe the study's purpose, specific aims, or objectives.
- State the hypotheses to be tested.

In this study, we will test our model for the purpose of delineating the extent to which OAA can bring value to patient care in VHA. We plan to control for demographic factors, namely: age, sex, race, health literacy, and internet access. The project will be conducted in primary care and one specialty clinic: diabetes. We select diabetes because of its high prevalence in Veterans, the presence of a specific marker of disease control (Hgb A1C), and that disease management now relies on a growing number of medications and dietary interventions that can be complex and overwhelming for patients. OAA, hence, may offer substantial benefits to patients and their caregivers and, if it does, the effect should be captured by falling Hgb A1c levels among those with baseline poor disease control. As noted, we also plan to study the impact of OAA on uncontrolled BP, but that data can be collected entirely in primary care given the very high prevalence rate.

This study has three aims, with the first two designed to test measurable hypotheses. The third is qualitative:

Aim 1: Assess the impact of an open access audio program on two behaviors (patient activation, treatment plan adherence), and two chronic condition measures (glycosylated hemoglobin, blood pressure). Secondary analysis will descriptively measure effect size on ED visits and hospital admissions.

> Hypotheses:
> *1A:* OAA increases patient activation.
> *1B:* OAA increases care plan adherence, including fewer no-shows and more on-time refills.
> *1C:* OAA reduces Hgb A1c and BP

Aim 2: Assess the impact of open access audio on provider communication behavior and on their attention to patient contextual factors (i.e. individual Veterans needs and circumstances relevant to planning effective care).

> Hypotheses:
> *2A:* Providers obtain higher scores on measures of communication behavior when they know they are being recorded.
> *2B:* Providers obtain higher scores on measures of attention to patient contextual factors essential to care planning when they know they are being recorded.

Aim 3: Assess patient, provider, and leadership perceptions of the extent to which the program is safe, not burdensome, and worthwhile at both the start and at two years into the program.

- Indicate the relevance to Veterans and the VA

The VA has worked to empower Veterans, who disproportionately live with complex chronic health problems, with access to information related to their care through the patient portal (MyHealtheVet).[19,20] Giving them access to audio recordings of their visits is a next natural step. In contrast to the medical record which is written by providers for providers, the audio captures what the provider (or other provider) most wants their patient to understand. At a practical level it is a concrete solution to the ephemeral nature of the interaction, where much of importance is discussed, then forgotten and never shared accurately with loved ones and caretakers who need to understand the patient's care. It may also be an incentive to the provider to be more attentive and communicative.

The VHA Office of Connected Health has indicated a high level of interest in the study (and provided a letter of support), as the findings may provide a foundation of evidence for whether and how to include open access audio in their next generation patient portal.

4.0 Resources and Personnel

- Include a list of personnel, their location, role in the study and their VA affiliation status
- Provide a brief description of each individual's role in the study. Be sure to indicate who will have access to protected health information and who will be involved in recruiting subjects; obtaining informed consent; administering survey/interview procedures; and performing data analysis.
- If applicable provide information on any services that will be performed by contractors including what is being contracted out and with whom.
- If applicable provide information on any Memoranda of Understandings (MOUs), Data Use Agreements (DUAs), and/or CRADAs that are being entered into including with whom and for what reason.

Data collection will occur at two sites: The Jesse Brown VA Medical Center in Chicago, and the Louis Stokes Cleveland VA Medical Center. Data analysis will be conducted by staff at the Center for Innovation for Complex Chronic Health Care (CINCCH) based at Edward Hines Jr. VA Hospital.

In addition, we will be collaborating with colleagues in the Dartmouth Department of Biomedical Data Science who have developed and employed HealthPAL ("Personal Audio Library"), previously called Open Recording Automated Logging System (ORALS) technology, developed specifically for OAA.[21] HealthPAL, designed for sharing audios with patients, enables patients to selectively share their audio with others, such as family or caretakers, by sending them a link to establish a password. This feature additionally enables the research team to track how patients are using audios including whether they are listening to them, how often, whether they share them and whether those individuals access the audios as well. A Data Use Agreement (DUA) is currently being established with Dartmouth audio recording will not start until a DUA is in place.

Details are as follows:

Saul J. Weiner, MD will oversee the project as principal investigator, and serve as site-investigator for JBVA. He is 5/8th VA. He will have access to PHI and will participate in data analysis

Corinna D. Falck-Ytter, MD - Dr. Falk-Ytter will assist with setting up the project at the Cleveland, facilitate submission of the site IRB, and supervise the site RA. She is 8/8th VA. She will have access to PHI.

Frances Weaver, PhD will provide consultation strategies to optimize audio collection and on dissemination and implementation strategies for future work. She is based at Hines VA and is 8/8ths VA.

Gunjan Sharma, PhD Dr. Sharma has served as project manager of all previous VA studies utilizing audio collected data. She manages budget and HR, assists with any IRB activities, and participates in 4C coding. She will work 100% Jesse Brown VA via an IPA. She will have access to PHI, will be involved in recruiting subjects and obtaining informed consent.

Sherry Ball, PhD Based at the VHA Collaborative Evaluation Center at the Cleveland VA. She will lead qualitative work including implementation and assessment of adoption measures to achieve aim 3. She is 8/8th's VA. She will have access to PHI.

Alan Schwartz, PhD Dr. Schwartz, professor in the Dept of Medical Education has served as methodologist and analyst on previous studies utilizing audio collected data. He will oversee quantitative data management and conduct all quantitative analyses. He is 1 FTE at UIC, and funded via an IPA with a WOC at Jesse Brown VA. He will work with de-identified data.

Amy Binns-Calvey Amy has played a central role in the development of the 4C coding system with over 8 years of experience coding nearly 3000 encounters using the 4C method. She will lead 4C coding of the audios for Aim 2. She will be 60% UIC and 40% Hines VA on an IPA. She will have access to PHI, will be involved in recruiting subjects and obtaining informed consent.

Ben Kass He will assist with coordinating Jesse Brown VA site activities (100% on an IPA with UIC), including consenting subject, and responding to any technical issues related to accessing the audio. He will also assist Dr. Sharma with 4C coding--for which he is trained--for Aim 2. He will have access to PHI, will be involved in recruiting subjects and obtaining informed consent.

Valencia Burton will provide operational assistance to project staff, e.g., purchasing, regulatory compliance. She is 100% VA based out of Jesse Brown VAMC.

RA Cleveland (1.0 FTE on IPA, Yrs 1-3). RA will assist with coordinating Louis Stokes VA site activities, including consenting subjects, and responding to any technical issues related to accessing the audio.

Paul Barr, PhD, MSc (Co-I, 0.1 FTE IPA, Yrs 1-3). Dr. Barr is assistant professor at the Dartmouth Institute, Geisel School of Medicine at Dartmouth, where he leads the HealthPAL. He will provide continuous consultation on the design and findings given his extensive expertise studying and writing about open audio outside VHA. Although Dr. Haslett will have primary responsibility for PHI (see below), Dr. Barr will have access as well as a back-up if/when needed..

William Haslett, PhD (Co-I, 0.1 FTE IPA, Yrs 1-3). Dr Haslett, is research scientist in the Biomedical Data Science department at the Geisel School of Medicine at Dartmouth College. He will provide all technical support and guidance regarding HealthPAL. He will have access to PHI, in the form of email addresses of all subject participants.

Brian Bartle (.05 FTE in Yrs 1 and 3). Brian is a data analyst at CINCCH, 100% VA and based at Hines VA. He will extract the patient outcomes and demographic data from the Central Data Warehouse. He will have access to PHI briefly as he runs search in the Corporate Data Warehouse.

5.0 Study Procedures

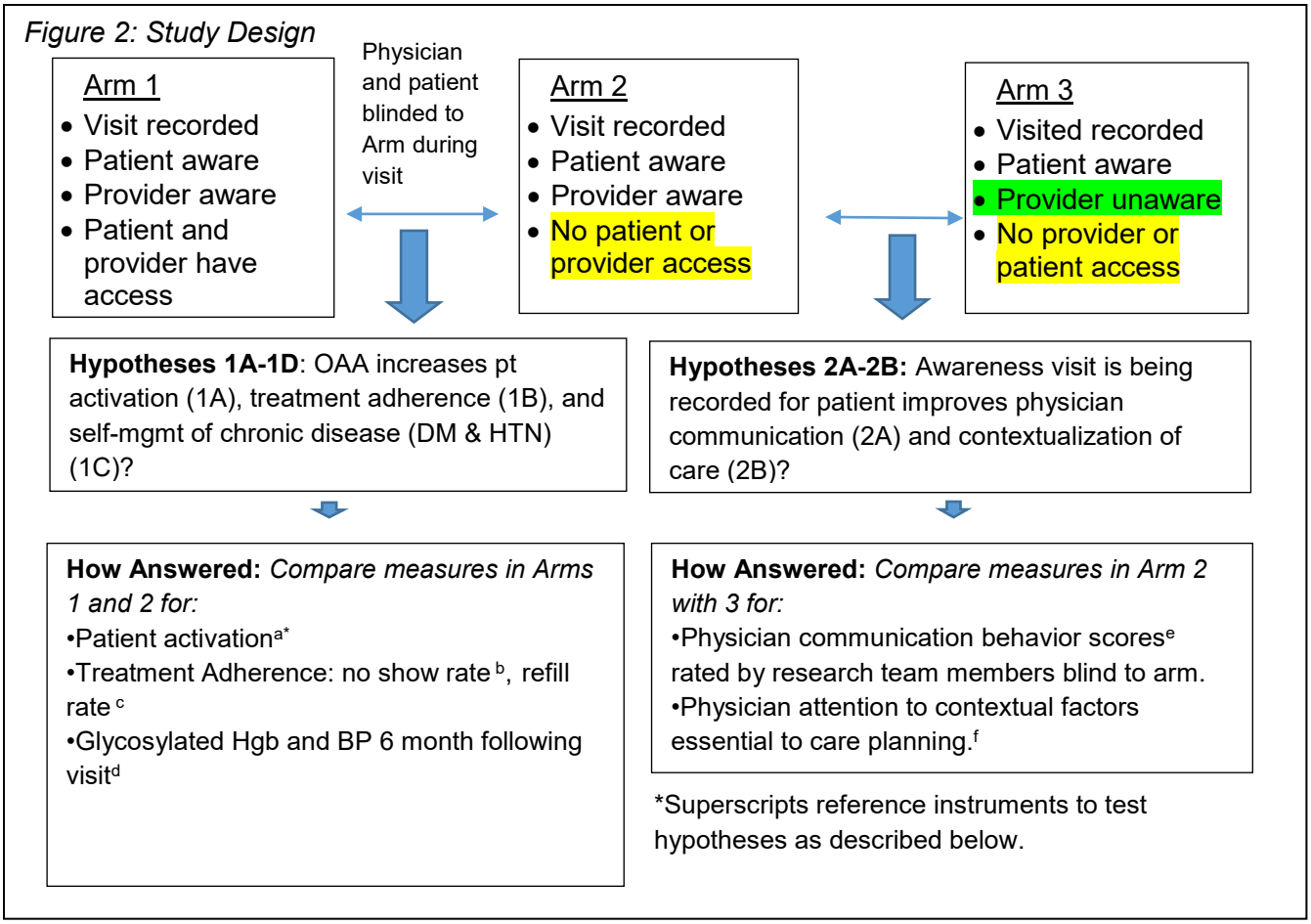
5.1 Study Design

- Describe experimental design of the study. Include sequential and/or parallel phases of the study, including durations, and delineate which interventions are standard of care and which are research.
- Include a description of how anticipated risk will be minimized and include an analysis of risk vs. potential benefit.
- Provide description of the study population (delineate all categories of subjects – patients, providers, family members, employees, etc.). Include anticipated enrollment numbers
- Include rationale for including or excluding certain populations – in particular vulnerable populations.
- As applicable, provide information on any added protections for vulnerable populations.

The setting will be primary care and diabetes specialty clinics at the two facilities. This will be a naturalistic intention-to-treat study in which all patients in these clinics are eligible to consent to participate and data from all arms will be included in the analysis regardless of whether the patient listens to the audio. Also, there will be no exclusion criteria. We have no preconceptions about who could benefit: for instance, counter-intuitively, a severely hearing impaired patient who has difficulty following face-to-face encounters might benefit if they choose to share the audio with a caregiver.

We have designed a three arm RCT (figure 2, below), with each arm varying as to who gets access to the audio after the visit and who is aware of the fact that audio recording is occurring during the visit. The design establishes the conditions for achieving the first two aims of the study, with each aim framed as testable hypotheses. Arm 1 is the intervention, with both provider and patient aware of the recording. It is designed to represent how OAA would be utilized in actual practice. In Arm 2 all parties are also aware of the audio recording, but this time neither gets access to the audio after the visit (although the research team does). Arm 2 is a control for isolating the effect of patient access after the visit to the audio in Arm 1. Both patient and physician are blind to whether they are in Arm 1 or 2 until after the visit. Comparing these two arms will achieve the first aim of the study. Arm 3 is a second kind of control, as the audio is again not shared with the patient. In this arm, however, the patient conceals the audio recorder, typically in an accessory such as an eye glass case (a method we have employed extensively[14]), so that the provider is unaware they are being audio recorded until after the visit, enabling the research team to achieve the second aim of the study by comparing Arm 3 to Arm 2, isolating the effect of being aware they are being audio recorded on the provider's interactions with the patient. Whereas in Arm 3 the physician is unaware they are being recorded, in Arms 1+2, they are aware and also know there is a 50% chance the patient will have access to the audio. This design enables Arm 2 to serve both as a control for Arm 1 to achieve Aim 1 (since patient only gains access to the audio in Arm 1) and as comparator with Arm 3 – to achieve Aim 2 -- since the physician believes the patient may gain access to the audio.

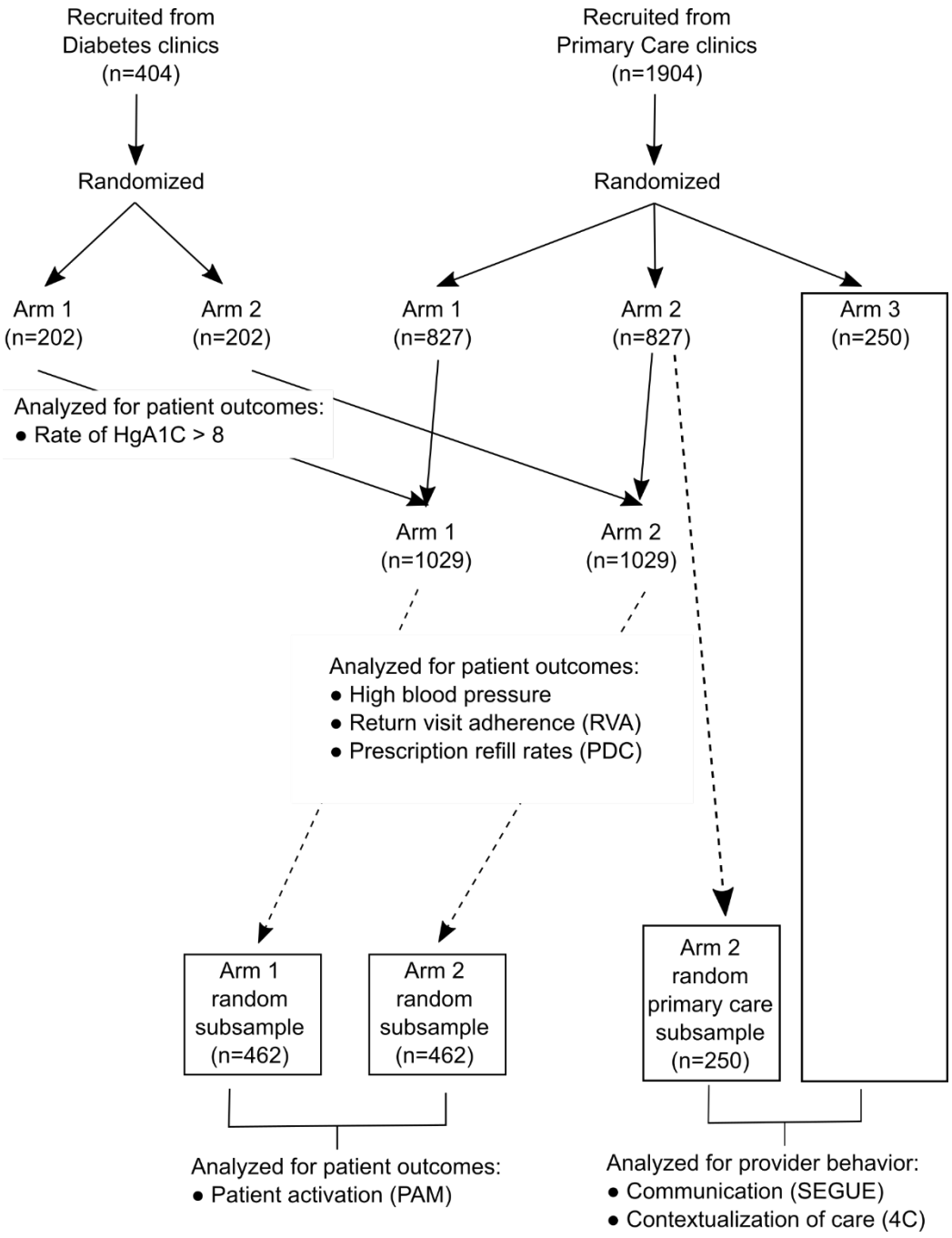
Figure 2: Study Design



The superscripts associated with each outcome in the "How Answered" boxes in figure 2 refer to the following strategies for testing the hypotheses in Aims 1 and 2: (a) A survey called the Patient Activation Measure (PAM), (Appendix A-1) is completed by patient 1-2 weeks after their visit[22]; (b) The "no show rate" is the inverse of Return Visit Adherence (RVA) rate;[23] (c) the Refill rate is "proportion of days covered" (PDC), a metric CMS utilizes in its plan ratings;[24] and (d) BP and HgB A1c are checked if they are repeated within 6 months; (e) The SEGUE Framework for evaluating and scoring communication behavior, as rated off of the audio recording by a research assistant utilizing a checklist (Appendix A-2)[25] and (f) Content Coding for Contextualization of Care, also called "4C"[26]. Note: (b-d) are extracted from the CDW and SEGUE and 4C completed while accessing the medical record and listening to the audios. Finally, for all three arms, the members of the research team collecting the data and coding the audio are blinded as to study arm. There is no arm in which the patient is unaware a visit is audio recorded. Blinding the patient is not pertinent to achieving the aims of the study.

Figure 3, the flow diagram below, allocates patients in a parallel three arm randomized controlled trial (RCT) to most efficiently achieve the aims of the study (the calculations for the specific sample sizes are justified later in the protocol – and shown in Tables 4.1 and 4.2. on pp 24+25).

Figure 3: Flow diagram for parallel RCT



Random assignment to arms will be made using computer-generated sequences within the diabetes clinics (1:1 randomization to Arms 1 and 2 in blocks of 4) and primary care clinics (5:5:2 randomization to Arms 1, 2, and 3, in blocks of 24, with one partial block of 8 patients). Solid lines represent unconditional allocation of participants to Arms; dashed lines represent random sampling of participants to create efficient unbiased subsamples for key hypothesis tests. The rationale for the design, starting at the top of the figure and working down, is as follows:

- We start with two separate pools, diabetes and primary care clinics, because measurement of the effect of OAA vs control (Arm 1 vs Arm 2) on Hgb A1c is most efficiently accomplished

just in the diabetes clinics where every patient has diabetes, many have an A1c>8, and A1c is re-checked at frequent intervals. Hence, analysis of an effect of OAA on diabetes control will occur only in the diabetes clinic population.

- All other measures to achieve Aim 1 will occur in analysis of data collected in <u>both</u> the diabetes and primary care clinics. Hence data on the effect of OAA on show-rates (visit adherence), medication refill rates, blood pressure control etc…will be pooled for patients randomized to Arms 1 and 2 in both the diabetes and primary care clinics.
- The PAM will be applied to the smallest possible subsample of Arms 1 and 2 to test hypothesis 1A (figure 2) with 80% power (Table 4.1, p 24) because it requires a phone call and takes about three minutes of RA and patient time. Subsamples will be drawn at random without replacement by computer. As shown in the Gantt chart (Table 2, p. 18), these calls will be spread out and administered 1-2 weeks post visit (Table 4.0, p 23). This is in contrast to measures of blood pressure, Hgb A1c, and visit and medication adherence, which are extracted from the data warehouse.
- Arm 3, essential to achieve Aim 2, will only occur exclusively in the primary care clinic because it requires blinding physicians to being audio recorded which is not relevant to measuring the effect of OAA on diabetes control, and would confound that measurement.
- Similar to PAM, the SEGUE and 4C analysis require RA time and effort, so will be applied to the smallest possible samples. Whereas PAM is intended to measure the effect of OAA (Arm 1) compared to control (Arm 2) on patient activation, SEGUE and 4C are intended to measure the effect of the physician knowing they are being recorded (Arm 2) versus not knowing (Arm 3) on the process (SEGUE) and content (4C) of the physician's decision making. The SEGUE checklist and the 4C coding occur while the RA is listening to the audio of a visit, randomly sampling 250 audios from the 827 primary care visit audios in Arm 2 for comparison with the 250 audios from Arm 3. Random sampling from Arm 2 primary care visits will be performed by computer without replacement and without regard to whether they are also part of the hypothesis 1A subsample.

<u>Research activities for testing each aim: Anticipating and mitigating risks</u>

Aim 1: *Assess the impact of an open access audio program on two behaviors (patient activation, treatment plan adherence), two services (ED utilization, inpatient admissions), and two chronic condition measures (glycosylated hemoglobin, blood pressure).*

Aim 1 hypotheses will be tested by comparing patients randomized to arms 1 (intervention) and 2 (control) on the outcomes specified in figure 2. Following an informed consent process (see "Informed Consent Procedures" p 20, below), the Veteran will carry an audio into the encounter, regardless of the arm to which they are assigned. They'll return the recorder when they leave. In Arm 1, the Veteran and provider will each be given access to a passcode to a website that will stream the audio from any internet enabled device. Audio is streamed rather than downloaded, to prevent inadvertent sharing. Also, with streaming, the platform can track for the research team whether, when, the number of times, and how long the audio is listened to by either party. In Arm 2 neither the Veteran nor provider will have access to the audio, but the research team can listen to it.

The decision to give the provider access to the audio whenever the patient has access is based on conversations with providers during the proposal planning process who have said they would not feel comfortable having a patient listen to a visit that they couldn't also listen to if they wished to do so. In Open Access Notes, both providers and patients have access to documentation of the visits, and so it seems logical that Open Access Audio should work in parallel, particularly given that current technology makes this feasible. The research team will be able to track whether and when either party access the audio. This will not contaminate isolating the impact of the audio on the patient (e.g. were the provider to call the patient after

listening to the audio to correct an error or elaborate), since we'll know when providers log in, enabling us to control for it as a co-variate or exclude if it's a rare event.

Aim 2: *Assess the impact of open access audio on provider communication behavior and on their attention to patient contextual factors (i.e. individual Veterans' needs and circumstances relevant to planning effective care).*

Isolating the effect of the OAA on providers requires including an arm in which the provider is unaware of the recording, but which the research team can analyze, to serve as a control. This will occur in Arm 3 (figure 2), in which the audio will be carried and concealed by the Veteran so that the provider is not aware of it. As in Arm 2, neither Veteran nor provider will have access to the audio after the visit, but the research team will be able to listen to it. This will enable comparisons of provider behavior (communication and contextualization of care) in Arm 3 (control) with Arm 2. Although the patient will not actually obtain the audio in Arm 2 after the visit, the physician does not know that, as at the time of the encounter they are blinded as to whether they are in Arm 1 (in which the patient will gain access to the audio) or Arm 2 (in which they will not).

For assessing provider behavior change based on awareness that the patient may get the audio recording and listen to it to better understand their care, we are focusing on both the process and content of the interaction. We selected SEGUE both because of its high evidence for concurrent and construct validity, and inter-rater reliability, and because it can be scored by an independent third party off of audio using a checklist.[27] Whereas SEGUE is a process measure (how effectively a provider communicates without regard to the content of the discussion), 4C is a content measure, i.e. whether they follow up on what the patient needs regardless of how they go about it. 4C is coded by a trained RA with access to the medical record and audio recording; the RA documents clues that a patient is struggling with life issues complicating their care ("contextual red flags"), whether the provider asks about them ("contextual probes"), whether the patient reveals the underlying life challenges ("contextual factors") and, if so, whether the physician addresses them ("contextualized care").[28] Contextual red flags are specific pre-determined variable extracted both from the medical record (including specific thresholds for missed appointments, emergency department visits, and medications that have not been refilled). 4C has strong published evidence for both construct validity and inter-rater reliability (90%),[26] and contextualized care significantly predicts a range of favorable patient health care outcomes.[14] Notably, we have observed that physicians are more likely to contextualize care when they know they are being recorded.[13] We have previously documented that communication performance and contextualization of care are separate constructs that do not correlate -- so must both be measured to fully assess patient centered provider behaviors.[29] Note that at the time of the coding, including completion of the SEGUE instrument, the audio coder will only have access to the designated codes for provider and patient, which will be utilized for tracking purposes. This is because the first step when audio recordings are uploaded following each encounter is to assign them codes with provider and patient names stored separately to a cross walk file.

Audio recording technology

For the audio recording device, we plan to use VHA approved audio recorders with accompanying software, the DS-9000 and DS 9600 Olympus encrypting recorders with a pin code for security. The audios will be uploaded by the RA to a workstation desktop on to our secure VHA research server, hosted in our Center of Innovation (COIN), using the VHA approved Olympus/ODMS Dictation Module 7. Each audio file name will include the Veterans last name and date of the visit., for Arm 1), The project manager will then trim the audio to remove all the identifiers using the audacity software and upload the deidentified audio directly to the HealthPAL website(https://va.audiohealthpal.com) managed by the research team at the

Department of Biomedical Data Science at the Geisel School of Medicine at Dartmouth. At that point an automated script sends an email to the patient and provider (in Arm 1) providing them a link to login to access the audio from any internet enabled device. The Dartmouth system, HealthPAL, [21] which is specifically designed for sharing audios with patients, also enables patients to selectively share their audio with others, such as family or caregivers, using a highly secure process that enables them to send an invite email and text message with a six digit code, that enables the user to set up their own unique password. This feature additionally enables the research team to track how patients are using audios including whether they are listening to them, how often, whether they share them and whether those individuals access the audios as well. Because many of the patients at participating sites are older and have low levels of technology literacy, we will make an attempt to reach by phone any subject who has not accessed HealthPAL within 7 days following their visit. These data will be variables in our analysis for the outcomes in Aim 1, e.g. for patient activation, medication adherence etc…

The data encryption and storage methods utilized in HealthPAL are highly secure. Health PAL is a web application that runs on Amazon's cloud infrastructure, Amazon Web Services (AWS). The root account under which the application is hosted is managed by Dartmouth College Central IT, which has a Business Associates Agreement in place with Amazon for the use of Amazon's HIPAA-eligible cloud services with Protected Health Information. All HealthPAL data are encrypted in-transit using HTTP over SSL, and all HealthPAL data are encrypted at rest using AES-256 encryption. and are monitored for safety using standard software storage review processes, including log analysis.

In addition, as detailed in the proposal, participating patients will complete a survey indicating any concerns they have following participation. In addition, they will be provided with a number to call if they have either technical questions or concerns, that goes directly to voicemail that the site research assistant accesses daily. Appropriate and adequate subject recruitment will be monitored by the research team which will convene across sites by conference call monthly. There is little reason to anticipate the need to change sites, given the multitude of patients at clinics at each site. Were a new site required, the principal investigator would likely contact one of several sites that are currently or have recently participated in a separate audio recording project and hence could efficiently adopt this study if needed.

Because HealthPAL is managed by Dartmouth, not the VA, we will include in the consent document that VA will not have control of the data at all times. A recent precedent is an ongoing study conducted by this project's implementation specialist (Sherry Ball) titled Home Monitoring for Early Detection of Chronic Disease Exacerbation, and approved by the Cleveland facility IRB, which will also review this study if funded. That study requires placement of hardware and software developed by an outside vendor in Veterans' homes with internet connectivity for exchanging data on health and function daily with the VA research team. The IRB/R&D decision to approve utilizing non-VA infrastructure was based on the premises that (a) the risk of data breaches is low, (b) the research question is important, (c) the patient who chooses to participate is fully informed that the VA has not approved and cannot monitor the security of all of the data, and (d) the VA does not have the required infrastructure to do the study. All are applicable for this proposed study as well.

Aim 3: *Assess patient, provider, and leadership perceptions of the extent to which the program is safe, not burdensome, and worthwhile at both the start and at two years into the program.*

In our prior research on the implementation of patient-collected audio in the clinical encounter, which utilized a RE-AIM framework to study these constructs with respect to the implementation of audio technology in the clinical setting, we identified three key determinants of implementation success encompassing reach (or adoption), acceptability and appropriateness (or "fit"): the extent to which stakeholders, including patients, providers and

organizational leaders perceive the audio recording and data use process as (a) *safe* to do so, (b) *not burdensome* and of (c) *value*[30,31]. We also found that provider perceptions often evolve, starting with some initial concern that the program may interfere with their practice routine, and/or that the audio may be used for purposes other than intended. Once the project is established and has been active for some time, these concerns typically resolve.

Although we have seen this pattern consistently in our prior work, we believe it is necessary to reassess during this study because the purpose of the data collected and its use differs. In the past, the audio has been collected solely for the purpose of assessing provider decision making during the encounter. In this study the purpose of the audio data is to assess the value of a new technological resource for patients. On the one hand, this should generate less provider anxiety, as providers are not the primary focus. On the other hand, in this project the audio is shared with the patient, which may raise concerns for some providers.

Finally, we believe that it is important to collect attitudinal data about OAA from facility leaders with decision-making authority, to gauge its potential for widespread dissemination. This will be carried out both early on and near the end of the study, when they are most uncertain and most informed about the pros and cons of the program, respectively.

Table 1 details each of the three principles as they apply to the proposed study, the planned practices for advancing the principles, and the evaluative methods.

Table 1: Principles and practices for adoption of OAA and methods of evaluation (Aim 3)

Principle	Practice	Evaluation
Project must feel safe for providers/staff and Veterans: • *Providers and staff* will feel comfortable that patients will use the audio exclusively to enhance their care. • *Leadership* will feel comfortable having staff in their service line or facility participate • *Veterans* will feel confident the audio is secure, with a clear understanding of who can access it and how. They will also feel confident that the information they disclose when completing the PAM and 4C data will be securely stored, and shared after identifiers have been removed.	Providers will have access to audio whenever their patients do and will always be informed when a visit was recorded -- in arm 3 that will occur after the visit. The encryption methods and access security features employed will be shared with patients during the informed consent process. PAM and 4C coding results are stored using a crosswalk file so as to be separated from provider identifiers.	Email link to an anonymous optional survey of providers and staff near start and end of project, regarding their experience with program: Do they feel safe? (Appendix A-3, Provider survey) Also, conduct more in-depth provider focus groups near start (Appendix A-4, Pre Provider focus groups) and end of project (Appendix A-5, Post Provider focus groups). Examine on the organizational level from the standpoint of leaders (Leadership Interviews, A-6). Patient exit survey, completed during a 3 month block each year

		(Appendix A-7) includes perceived safety assessment items.
Project should be embedded in ongoing activities for providers/staff and Veterans. • *Providers/staff:* Because of competing responsibilities for patient care, providers and staff should guide decisions about when to participate. • *Leadership* will be aware of any potentially emerging issues. • *Veterans*: Accessing audio should be easy and convenient so that it fits into daily pattern of using portable device (cell phone, ipad) or home computer.	Veterans are prepped and given the audio recorder prior to encounter. Process is aborted if patient is called for visit so as not to delay care process. Other than the presence of the recorder, nothing is added to the encounter. Patients are provided with a number to call and an email address if they are having technical problems accessing their audio. These will be accessed daily by the RA using a VA voicemail account.	Include items regarding perceived burden in provider surveys and focus groups. (Appendices A-3 through A-5) See above. Examine on the organizational level from the standpoint of leaders (Leadership Interviews, A-6). Patient exit survey includes effort assessment (Appendix A-7).
Value of project should be evident for providers/staff and Veterans: • *Providers/Staff:* To appreciate the value of audio recorded data, clinicians and staff should receive updates on the adoption of the program. • *Leadership* will advise on the sustainability of the program based on value. • *Veterans*: Participating veterans should perceive sufficient value that they will be motivated to utilize the resource when they have questions about their care by logging into to listen to the audio.	At each site, project team will provide quarterly updates on the adoption of the program, including how often their patients are accessing the audio. This can be done via email to participating providers and staff.	Include items regarding perceived value in provider surveys and focus groups. (Appendices A-3 through A-5). See above. Examine on the organizational level from the standpoint of leaders (Leadership Interviews, A-6). Patient survey includes value assessment (Appendix A-7).

Table 2: The following Gantt chart outlines each phase of the study (and initials of responsible personnel):

	Year 1				Year 2				Year 3			
Hire site RA for Cleveland Facility (CF-Y)												
Open Audio team (Dartmouth) to customize and pilot test with assistance of teams in Cleveland and Chicago (WH,PB,SW,CF-Y)												

Open Audio Data Collection (GS, BK, Cleveland RA)												
Outcomes and demographics extracted from CDW for A1c, BP, Adherence measures (BB)												
Survey providers/staff (GS, BK, Cleveland RA)												
exit patient surveys (GS, BK, Cleveland RA)												
PAM survey phone calls post visit (GS, BK, Cleveland RA)												
Focus groups staff (SB)												
SEGUE + 4C Coding of sample of recorded visits (ABC, GS, BK)												
Site leadership interviews (SB)												
Data analysis of outcomes, contextual error rates for each arm of study (AS)												
Dissemination (SW, CF-Y)												

How anticipated risk will be minimized and an analysis of risk vs. potential benefit

- Patients: The benefits of audio recording with analysis of specified outcomes, which are essential to the study, is that it will enable an assessment of whether this technology enhances patient health care outcomes as well as understanding of their care. Anticipated risks for patients included that: (a) carrying an audio recorder into a visits could be an inconvenience, could make them feel uncomfortable about disclosing private information. We minimize these risks by assuring you that if you are always welcome to turn of the audio recorder during the visit if you decide you don't want to participate for any reason. We also minimize these risks by informing you that your audio recording is managed and stored with a comparable level of data protection and security as your medical record; (b) There is the possibility that there could be a breach in confidentiality due to a data security failure related to the storage or transmission of an audio file, including during collaboration with the Dartmouth team. The reason we are working with this group is that they have developed the technology, which is currently not available within the VA. They have minimized the risk to loss of confidentiality by using the best available software systems and data security protocols which are the same or comparable to VA systems. While we cannot say how likely a data breach is, we estimate the risk to be small; (c) Some of the audio recordings will be listened to by one or more research assistants. This will occur to a random sample of 10% of audio recorded visits. The research team will minimize risk of breach of confidentiality by directly uploading the audio file to the secure HealthPAL server. (d) A VA data analyst will look up patient specific information in the CDW about blood pressure, blood sugar, emergency department and hospitalization usage, prescription refill rates and appointment attendance, but will not have access to the medical record. The privacy will be minimized by keeping patient names separate using a crosswalk file. (e) The audio recording process could possibly undermine a patients relationship with their doctor. We have minimized this possibility by only including physicians and other health care providers who want to participate and have consented to participate; (f) As explained above there are three brief questionnaires patients will or may be asked to complete. The first is the brief assessment of their knowledge and comfort with medical terminology. All participating patients do that one. The second is a brief survey just as they exit their visit and return the audio recorder. That questionnaire will ask them about whether they found the experience valuable, how much effort it took, and whether they were comfortable participating. There is about a 25% chance they will be asked to do this questionnaire. The third questionnaire is conducted by phone 1-2 weeks from their

visit and is intended to find out how confident and comfortable they are managing their health needs and care plan. There is a 45% chance they will be called to complete this questionnaire. On all three questionnaires the research team will substitute a study identification code in place of their name, so that if anyone were to find the data they would not know that it is about a particular patient. We'll keep the study ID code sheet that contains the names of all study participants with their study IDs, in a separate secure location on a server that also belongs to the VA (i.e. a crosswalk file). That sheet will be deleted at the end of the study. There may be some risk in sharing slightly personal data, including how knowledgeable you are about medical terms, and how comfortable you are managing their own care. They may find sharing this information personally uncomfortable. We minimize this risk by assuring you that if, for any reason, you wish not to answer specific questions you need not do so.

- Providers: The benefits of audio recording with analysis of provider experience, is that it will enable an assessment of whether this technology enhances patient health care outcomes as well as understanding of the providers perspective, which is essential to long term implementation planning. Risk and mitigation of risk include that providers: (a) may feel some unease that their interaction with their patient is being recorded and that they may listen to it and share it with others, such as caregivers and family. Any audio shared with patients will be streamed so patients will not have access to an audio file that can be uploaded to a third-party site; (b) There is the possibility that there could be a breach in confidentiality due to a data security failure related to the storage or transmission of an audio file. We will be using a crosswalk file as detailed directly above, with assignment of a discrete code for physician and patient, assigned to each audio and related instruments used for audio coding, such as the SEGUE. Audio data in arm 1 – the arm that shares audio with the patient and provider -- will be uploaded directly to the HealthPAL website(https://va.audiohealthpal.com) managed by *Geisel School of Medicine at Dartmouth* where a research team specializes in managing patient audio recorded data. The VA cannot vouch for the security of the system nor take responsibility for any breaches. The reason we are working with this group is that they have developed the technology, which is currently not available within the VA. They have minimized the risk to loss of confidentiality by using the best available software systems and data security protocols which are the same or comparable to VA systems. While we cannot say how likely a data breach is, we estimate the risk to be small; (c) Providers will be invited to participate in twobrief survey's over the course of the three year study. Additionally, the providers will be invited to participate in two focus groups where their names will be replaced by a code and linked to a crosswalk file. Because the information we are obtaining is not sensitive – it is solely about the experience of the providers participating in this study, , risks of participation are small but there could be some inconvenience. They are welcome to abort them at any time.

  Leadership interviews: The benefits of leadership interviews is that the data collected on their perspective will inform efforts to disseminate and implement patient collected audio more broadly if the findings demonstrate it is effective. These interviews, which will be recorded, will be voluntary, coded and linked to a cross walk document. The recording will be heard by members of the research team. There is a minimal risk of breach of confidentiality, and the data collected is not sensitive as it does not include discussions of any specific patient's care or of any particular provider.

5.2 Recruitment Methods

- State how many subjects will be needed.

The numbers and distribution of patient subjects is presented in Figure 3, above. As noted, a total of 1904 will be recruited from the primary care clinics and 404 from the diabetes clinics, totaling 2308, all above 18 years of age.

The primary subjects are Veterans. However, since providers will be audio recorded as well, and since we will be studying the effect of being audio recorded on the behavior and outcomes of their patients, providers will be considered as human research subjects as well. Since they are not a unit of study, there is no specific sample size.

We also plan to interview hospital leaders about the program. They are also subjects, but given the low risk to them, will likely be exempted from a formal consent process. We anticipate interviewing five leaders at each of the two facilities, for a total of 10.

- Describe when, where, how and by whom potential subjects will be identified and recruited.
- Describe materials that will be used to recruit subjects, e.g., advertisements. Include materials as an appendix or separate attachment.
- Describe any payments to subjects, including the amount, timing (at the end of the study or pro-rated for partial study participation), method (e.g., cash, check, gift card), and whether subjects will experience a delay in receiving the payment.

Recruitment will proceed as follows:

(A) Providers (physicians or nurse practitioners) will be notified of the project by the site investigator by attending their section meetings (at the invitation of the section chiefs — who have already indicated support of the project) and providing a brief description and study brochure (same as the one shared with patients). Those who wish to participate will sign a sheet providing their name and contact information. In addition, the PI will send out an email to providers who were not able to attend the meeting. The site investigator and/or RA will meet with all who indicate interest to complete the informed consent process.

NOTE: When clinical section meetings are held virtually because of the COVID-19 pandemic, these activities will also be conducted virtually. Handouts and sign-up sheets will be emailed.

Recruitment of providers for focus group participation will occur via email invitation, and is optional for all participating providers. Providers are first informed of the focus groups in during the informed consent process for the study, as detailed in the consent document. They are informed that they will contacted about participation, that participation will be voluntary, that the focus groups will be audio recorded, and that to minimize risk, they will be asked not to use their names or the names of any patients during the focus groups. They are also informed that lunch

will be served. The email text is provided with this protocol and informs providers that "if you are interested, please reply to this message."

(B) Recruitment of patients will occur in primary care and diabetes clinics in Chicago (Jesse Brown) and Cleveland (Louis Stokes). Since the former is nearly three times larger than the latter, it is anticipated that recruitment will be proportional. However, it will continue at both site until target numbers are achieved. The method of recruitment is as follows:

In primary care, the research team will obtain the panel lists of all participating providers. These are accessed through CPRS under each providers schedule. They will then randomly select the subset of patients necessary to contact via mail 2-4 weeks prior to their scheduled appointments informing them of the study and explaining how to opt out. Based on a 2014-16 study we conducted involving audio recording visits (SDR 12-280) we plan to mail 2767 prospective subjects, taking into account that 20% opt out, decline during the outreach call, are not reachable, don't show up in clinic, or opt out on site. About a week prior to the visit the RA will then phone those who do not opt out, to achieve recruitment of 1904 patients to be distributed across 2 sites (Chicago and Cleveland) and divided by randomization, utilizing the computer-generated sequences detailed in the research to allocate 827, 827, and 250 subjects to Arms 1, 2, and 3 respectively. Those who are reached and affirm will agree to arrive approximately 20 minutes early for their appointment.

For the diabetes clinic patients, an additional 404 patients will be randomly assigned to Arms 1 and 2. The same opt out strategy described above for primary care will be employed to recruit patients to these clinics as well.

(C) Upon arrival, they will complete the informed consent process and the brief literacy screen (REALM-SF), receive the audio recording device, and instructions based on the arm of the study to which they are randomized, as to whether to keep the audio recording out in the open (Arms 1 and 2), or to conceal it (Arm 3). A code, assigned to the encounter, will be utilized as the ID on the literacy screen, and linked to the patient name and medical record number stored in the cross walk file on a separate VHA approved server. After the encounter, patient and provider participants will receive a link to access the audio if they were in Arm 1. If they are called prior to completing the process, their appointment takes precedence and they will not participate.

(D) In addition to pre-visit outreach, the RA will recruit patients at an information desk on site when they arrive in the waiting area with a poster and a brochure inviting Veterans to learn more if they are interested.***** This will occur until recruitment targets are met. Those who are seeing a participating provider and want to participate will complete the informed consent process and the brief literacy screen (REALM-SF). They will receive a $20 gift card to remunerate them for the additional work of completing the survey after the visit and for randomly participating in a follow up call for the PAM survey. If the Veteran is called prior to completing the process, their appointment takes precedence and they will not participate.

***COVID-19 MODIFICATION: As long as infection transmission remains a risk the following protocol modification will be in place:**

- **Only phone based recruitment will occur.**
- **The informed consent process will be completed over the phone prior to the visit, except for the final signing process.**
- **The RA will still meet the patient in the waiting area, both masked. However, it will be a very brief meeting and they will remain 6 feet apart. There will be a small fold**

up table in the waiting area. The patient will sign the consent form, collecting the audio recorder, and complete the 7 item REALM-SF which consists of reading out loud 7 words, and takes less than 1 minute.

- **Post visit, the patient will return the audio recorder to the table and collect $20 gift card from the research assistant. Again, the RA will maintain a physical distance of at least 6 feet and will remain masked.**

5.3 Informed Consent Procedures

- Indicate if informed consent will be obtained and/or if you are requesting a waiver of informed consent or waiver of documentation of informed consent. If the research involves multiple phases, specify for which phases of the research the waiver(s) is being requested and/or the informed consent will be sought.

- Describe who will be obtaining informed consent, if applicable, and any circumstances that may need to be addressed (e.g. subjects with impaired decision making ability and the use of a legally authorized representative, etc.)

- If applicable, indicate how local site study personnel will be trained regarding human subjects protections requirements and how to obtain and document informed consent.

Providers: As described in recruitment section above, participating physicians and nurse practitioners will complete an informed consent process. As noted, those who wish to participate will sign a sheet providing their name and contact information. The site investigator and/or RA will meet with them to complete the informed consent process.

Patients: As described in recruitment section above, prior to participation but upon arrival for their appointment, patients will complete the informed consent process. As noted, the RA will meet patients (who have already assented by phone) prior to their appointment to complete the consent process.

All personnel will complete all mandatory VA training for human subject research and have current certificates.

Hospital Leaders: As explained above, we plan to interview hospital leaders about the program. They are also subjects, but given the low risk to them, we have requested for a waiver of documentation of consent. We will be contacting them via email asking them to participate in the research study by attaching the Informed consent explaining the research study and their participation..

5.4 Inclusion/Exclusion Criteria

- Describe the criteria that determine who will be included in or excluded from the study.

There is no plan to exclude any category of patients in participating clinics who wish to participate and complete the informed consent process. Women and minorities will be included. There is no plan to include children in this study.

Hence we plan to include individuals who consent from the following groups:

Patients who seek medical services at either the primary care clinics or the diabetes clinic; Providers who are either physicians or independent practitioners such as Advance Practices Nurses in these clinics; and hospital leaders whose portfolio of responsibilities includes management or oversight of clinical care.

5.5 Study Evaluations

- Describe all evaluations to be conducted (including screening; tests/questionnaires that will be administered; any procedures that subjects will be required to complete) and data collection methods. Include materials as an appendix or separate attachment.

There will be several sources of research material. Instruments are included in appendices A-1 through A-8 as indicated below and as attached:

A) Audio recordings of encounters made with written consent by both patients and providers. The audios are collected for research purposes.

B) The patient's medical record: Following a 10% (n=250) random sample of audio recorded visits (arm 3), again with written patient subject consent, a trained coder will extract discrete pre-determined variables for "4C" coding from the medical record after the visit, based on the referenced 4C manual.

C) Phone calls to a random (40%) sample of patients to complete the Patient Activation Measure.

C) Surveys of all patients (a brief literacy screen), and of both patients (25% of encounters) and all providers about their experience participating in an OAA program. (for patients: A-1, A-7, A-8; for providers: A-2, A-3).

D) Provider focus groups about their experience participating in an OAA program. (A-4, A-5)

E) Structured interviews with facility leaders about their experiences with the OAA program. (A-6)

5.6 Data Analysis

- Provide sample size determination and analysis (include anticipated rate of screen failures, study discontinuations, lost to follow-up etc.).
- Describe how, where and by whom the data will be analyzed.

Sample size calculations:
The samples sizes shown in each arm and sub-arm in Figure 3, above, were determined by the proportions of patients in participating clinics with the conditions or behaviors of interest. Table 3, below, provides that information, starting with the sizes of the clinic populations, drawn from the CDW. Note that for blood pressure and Hgb A1c we include the baseline rates of patients who meet BOTH the criteria of a specific threshold of poor control AND repeat measurement within a 6-month window, since six months is the window we plan to use for follow up assessment of the efficacy of the intervention compared with control.

Table 3: Clinical characteristics of participating clinical sites in 2018

	Chicago	Cleveland
Primary care clinic population (2 visits in past 2 years)	32,791	11,796
Diabetes clinic population	1,245	1073
Total	34,036	12,833
Primary care + Diabetes		
Most Recent SBP>140 or DBP>90* with repeat in < 6 Mo	10,959 (32%)	1513 (12%)
Proportion of Days Covered*	88%	84%
Return Visit Adherence**	93%	94%
Diabetes Clinic only		
Hgb A1c>8 with repeat in< 6Mo	821 (66%)	751 (70%)

*A measure of medication adherence from the CDW: proportion of days patients had pills to cover medication needs based on refill rate over a 120 day interval.
**A measure of appointment adherence from CDW: The percentage of all visits scheduled to any clinics by patients seen in these clinics in 2018.

Determining the specific sample sizes show in the flow diagram from the data in table 3 required determining the power needed to test each hypothesis with at least 80% power to detect the expected effect.

We describe next the planned analysis for testing each hypothesis to achieve each aim:

Aims 1 and 2:

As summarized in Table 4, we will apply several measures to assess the effectiveness of the intervention, testing hypotheses to achieve Aims 1 and 2. For each hypothesis, comparisons between arms will be made using mixed-effect linear or logistic regression as appropriate for the outcome, with a fixed effect of study arm, VA site, and primary vs. secondary care setting, and a random effect of provider to accommodate clustering of visits within providers. Of primary interest is the direction, magnitude, and significance of the regression coefficient associated with study arm. Primary analysis will compare arms on an intention-to-treat basis, without regard to whether audio made available in Arm 1 is actually accessed by anyone; secondary analyses will include covariates representing whether, how often, and by whom (patient or provider) audio is actually accessed in Arm 1 to assess the impact of audio use (vs. availability). As patients will be randomized to arms, we do not expect demographic or other patient differences among arms, but will conduct tests for differences, and if any variables differ significantly among arms, we will include them as covariates in the regression models.

Table 4. Hypotheses and evaluation strategy for *effectiveness* of intervention (Aims 1 and 2)

Hypothesis	**Evaluation Strategy**
1A: OAA increases patient activation.	Administer PAM (Appendix A-1) 1-2 weeks post visit via phone call and compare scores in Arm 1 vs. Arm 2
1B: OAA increases care plan adherence, including fewer no-shows and more on-time refills.	Utilizing the data warehouse measure Return Visit Adherence (RVA) and refill rates (PDC) [24,32,33] in Arms 1 vs. 2.
1C: OAA reduces Hgb A1c and BP	Same as above: Utilizing data warehouse measure A1c and BP.
2A*:* Providers obtain higher scores on measures of communication behavior when they know they are being recorded.	Completed by trained RA off of Audio: SEGUE checklist for communication completed by research team (Appendix A-2)[25], comparing randomly sampled visits in Arm 2 vs Arm 3.
2B: Providers obtain higher scores on measures of attention to patient contextual factors essential to care planning when they know they are being recorded.	4C for contextualization of care[34], comparing randomly sampled visits in Arm 2 vs Arm 3.

As noted earlier, the PAM will be completed over the phone by the RA initially at one week after the visit (this will be extended to 10-14 days if it turns out a substantial number of patients listen to the audio more than one week after the visit).

Table 4.1 lists the calculated power for the intention-to-treat analyses for Hypotheses 1A-1C by outcome. These analyses are based on data from 1029 combined primary care and diabetes clinic visits each in Arms 1 and 2 (i.e. sample size 2058), except for measuring the effect of OAA on Hgb A1c (in 1C) which is based only on 202 diabetes clinic visits each in Arms 1 and 2 (total 404). For patient activation (1A), we assume veterans with no audio access will have a mean PAM score of 56 and standard deviation of 19.5, based on a 2016 national study of VA health care users;[35] clinically meaningful differences in activation have been described as 4-6 points.[36] Since testing hypothesis 1A requires a phone call to administer the PAM, we will randomly contact 924 participating subjects, an average of 9 calls/week across sites, which will achieve 80% power, instead of calling all 2058 subjects. Baseline rates of each undesirable outcome for 1B are derived from our previously published study in the VA using recordings without provider awareness or patient access (as in Arm 3), and we expect to find an odds ratio of 0.5 for each outcome when patients have access to audios.[14] Baseline rates of each undesirable outcome for 1C are derived from the data warehouse (Chicago and Cleveland facilities – see table 3, above).

Table 4.1: Expected differences and power for planned intention-to-treat analyses for hypothesis 1A-1C

Hypothesis	Outcome	Baseline without audio available	Expected with audio available	Sample size	Power

		(Arm 2)	(Arm 1)	(total)	
1A	Patient activation (PAM 0-100 score)	56.0	60.0	924	80%
1B	Visit no-show rate	7%	4%	2058	95%
	Medication Proportion of days not covered	13%	7%	2058	80%
1C	Hgb A1c > 8 with repeat in < 6 Mo	66-70%	33-35%	404	80%
	Most Recent SBP>140 or DBP>90* with repeat in < 6 Mo	39%	24%	2058	99%

Also, while not included in Table 4.1, because it is not a primary objective of Aim 1, we will explore whether OAA is associated with fewer ED visits and hospitalizations. With the current sample size, we will in fact have 80% power to detect a decrease in inpatient admissions from 14%, the 2018 rate in our study population, to 9%.

Table 4.2 lists the calculated power for the analyses for Hypothesis 2A and 2B (comparisons of Arm 2 vs. Arm 3) based on actual Veteran visits by outcome. Baseline SEGUE scores are based on SEGUE's validation study among general internists (mean 17.5, sd 1.77); that study found that medical students in a skills lab achieved mean SEGUE scores of 21.1 (sd 2.1), and we take that as our minimal expected level of improvement from knowledge that one is being observed. Baseline rates of contextual probing and planning are based on our prior study in the VA using recordings without provider awareness or patient access (as in Arm 3), and incorporate the expectation that contextual red flags suitable for probing will be present in 2/3 of encounters and contextual factors that should be incorporated in planning will be present in ¼ of encounters overall.[14] Expected increases in probing and planning are based on odds ratios from our prior study comparing these measures in undercover visits to providers with the same cases presented to medical students in a testing setting (and are thus conservative measures of how much better providers would likely perform if they were aware vs. unaware they were being tested).[13] To obtain at least 80% power for each of these comparisons, we will randomly sample 250 primary care clinic visits (from 827 Arm 2 primary care visits), and enroll all 250 primary care visits in Arm 3 for the SEGUE and 4C coding processes. For 4C, we expect 168 visits/arm with red flags suitable for probing and 63 visits/arm with contextual factors suitable for planning.

Table 4.2: Expected differences and power for planned analyses for hypotheses 2A and 2B

Outcome	Baseline (doctor unaware, n=250)	Expected (doctor aware, n=250)	Sample size (total)	Power
SEGUE provider score	17.5	21	500	99%
Contextual probing rate[13,26]	32%	47%	500	80%
Contextual	59%	82%	500	82%

planning rate[13,26]				

All effects measured in Aim 1 and 2 will be adjusted for patient sociodemographic characteristics which will be obtained from the CDW (including age, gender, and race) or from administering the REALM-SF to assess literacy. Internet access, for those in the intervention arm, will be ascertained by census track using geocoding of patient addresses, based on FCC data, a method developed by Perzynski et al.[37,38]

Aim 3:

Qualitative work will address safety, burden and value (as operationally defined in table 1, pp 17-18 above) in regard to adoption and implementation of OAA. This analysis will be based on the data collected utilizing the instruments referenced in table 1 and contained in the appendices: the surveys of both patients and providers about their experience participating in an OAA program. (for patients: A-1, A-7, A-8; for providers: A-2, A-3); the provider focus groups about their experience participating in an OAA program. (A-4, A-5); and structured interviews with facility leaders about their experiences with the OAA program. (A-6)

Data will be analyzed using thematic synthesis of leadership interviews, focus groups and patient surveys by 2 qualitative analysts (SB and ABC) with experience in qualitative methodology and ready access to qualitative data analysis computer software. We will create an a priori framework that includes safety, burden and value on three levels: provider participant, Veteran, and leadership. Further creation of codes and themes will be iterative. To ensure rigor and validity of findings each analyst will independently code and develop emerging themes. Each theme will be discussed between the two analysts until consensus is reached.

5.7 Withdrawal of Subjects

- Describe any anticipated circumstances under which subjects will be withdrawn from the research without their consent.

  None

- Describe the consequences of a subject's decision to withdraw from the research and the procedures for orderly termination of participation by the subject (e.g., the subject contacting the investigator for an end-of-study visit).

  No consequences. No consequences. For instance, if a patient decides that they don't want to record their visit, the just default to usual care.

- Describe procedures if a subject is withdrawn or withdraws from the intervention portion of the study but agrees to continue in the follow-up phases or for safety outcome purposes.

  Not applicable. For instance, if a patient decides not to record their visit, there will be nothing to follow up.

6.0 Reporting

- Include procedures for reporting unanticipated problems, serious adverse events, and protocol deviations.

Any loss of research data (unsigned surveys submitted by physicians or patients), or notes related to focus group interviews will be reported to the IRB.

Any incident that could indicate the protocol adversely effects patient care or compromises patient privacy will prompt immediate suspension of the research.

If an SAE/UAP occurs during the course of the project, a Form 119 Report of Serious Adverse Events and Unanticipated Problems Involving Risks to Participants or Others will be filed with the CIRB. Information will be collected at the time of the incident or as soon as possible after the occurrence of the incident is made known to the study team **within the required 5 days.** Any incident impact the health or health care of a patient subject will be reported to their PCP in same time frame.

- All non-compliance with the study protocol or applicable requirements will be reported in accordance with VHA Handbook 1058.01. This will be achieved as follows:
  - The study team will discuss the importance of reporting non-compliance with the study protocol with all site investigators and will emphasize the importance of reporting non-compliance to the study team.
  - The PI/Study Coordinator will report instances of non-compliance in accordance with the VHA Handbook 1058.01.
  - If appropriate, the instance of non-compliance will be discussed between the study team and all site investigators to avoid duplication of non-compliance as well as to emphasize the importance of reporting non-compliance.
- Include information about whether the study has a Data Monitoring Committee and if so, how often it will meet.
  - Per requirement of HSR&D this project has been assigned to a VA Data Safety Monitoring Board (DSMB) since it is considered to be an interventional clinical trials. We have submitted and received approval for a Data Analysis Plan (DAP) to the DSMB via the ART website. The DSBM determined its own schedule for reviewing protocols based on VA ORS practices and policies.

7.0 Privacy and Confidentiality

- Describe whether the study will use or disclose subjects' Protected Health Information (PHI).

Patient PHI: The study will be collecting PHI, consisting of audio recordings of encounters and patient email addresses, to send them links to their audio files. As noted above, the data analyst will extract the patient outcomes and demographic data from the Central Data Warehouse. He will have access to PHI briefly as he runs search in the Corporate Data Warehouse.

For data tracking purposes, we will create a master spreadsheet with a row for each patient encounter. A code will be assigned to each encounter linked to a cross-walk file (see below).

The three patient surveys (literacy survey, exit survey, and patient activation measure) will be handled similarly: they will be assigned an encounter specific code, with a link to the cross-walk file.

Provider Subject PHI: Survey and focus group data is not PHI. However it is possible that during an employee focus group discussion about the OAA project, that a clinician could mention a patient's name or other identifier. This is not likely as the topic of the focus groups is the OAA project not the care of any specific individual.

- Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, Certificates of Confidentiality, and separation of identifiers and data)

The data encryption and storage methods are highly secure,but are monitored for safety using standard software storage review processes, including log analysis.

All study team members will be required to maintain necessary research training, and the PI of the study team will oversee completion and maintenance of any required training.

The cross-walk file will be kept in a separate file from the master file, accessible only with permission from the PI with access enabled by the IT data manager. Access is based exclusively on need, as follows: The data analyst who access the CDW to look up A1c and BP, RVA and PDC; The RA who completes the PAM 1-2 weeks post visit; and the RA who completes the SEGUE and completes the 4C coding, both off the audio.

The research records and data will be stored and destroyed in compliance with record Control Schedule (RCS) 10-1.

8.0 Communication Plan

- Include plan for ensuring all required local site approvals are obtained and notifying the Director of any facility where the research in being conducted but the facility is not engaged.

Local R&D paperwork will be submitted well in advance of implementation at each site. Implementation at each site will not occur until R&D approvals are in hand from all sites.

The PI will ensure all required local site approvals are obtained prior to the start of the study.

- Include plan for keeping all engaged sites informed of changes to the protocol, informed consent, and HIPAA authorization

All amendments and modifications to the protocol will be communicated to the engaged participating sites. This will be achieved as follows:

- Distributing any revised and approved documents to site investigator at all engaged participating sites via email and a telephone call alerting the site investigator to the change.
- Routine phone calls between the project manager, PI/study chair, and site investigator will also serve as a venue to communicate changes.

- Include plan for informing local sites of any Serious Adverse Events, Unanticipated Problems, or interim results that may impact conduct of the study.

Any adverse event related to the research will be reported to the site specific IRB.

- The study PI will report any SAEs to the site specific IRB via a memo within 48 hours.
- The study PI will also share any memos developed related to SAEs within 48 hours as well as calling a meeting between the study team and local site investigator to discuss the issue as well as any resulting actions that might need to take place.

- Include plan for ensuring the study is conducted according to the IRB-approved protocol.

The principle investigator will be checking in monthly with each site to review the protocol.

- Include plan for notifying all local facility directors and LSIs when a multi-site study reaches the point that it no longer requires engagement of the local facility (e.g., all subsequent follow-up of subjects will be performed by the PI from another facility).

The engagement of each facility will be essential to the protocol through nearly the duration of the study.

- When a study site has completed the study or engagement with study team is no longer necessary, the study team will work with the site investigator to work through the proper channels at their facility to close out the work at their site.
- The study team will notify the site specific IRB when local sites have completed the study or are no longer engaged with the study team.

9.0 References

1. Ley P. Memory for medical information. Br J Soc Clin Psychol 1979;18:245-55.
2. Jansen J, van Weert J, van der Meulen N, van Dulmen S, Heeren T, Bensing J. Recall in older cancer patients: measuring memory for medical information. Gerontologist 2008;48:149-57.
3. McGuire LC. Remembering what the doctor said: organization and adults' memory for medical information. Exp Aging Res 1996;22:403-28.
4. Rice GE, Okun MA. Older adults' memory for important medical information. Exp Aging Res 1991;17:90.

5. Belyeu BM, Klein JW, Reisch LM, et al. Patients' perceptions of their doctors' notes and after-visit summaries: A mixed methods study of patients at safety-net clinics. Health Expect 2018;21:485-93.
6. Lyles CR, Gupta R, Tieu L, Fernandez A. After-visit summaries in primary care: mixed methods results from a literature review and stakeholder interviews. Fam Pract 2018.
7. Neeman N, Sehgal NL. Meaningful utilization of after-visit summaries in the ambulatory setting. Am J Med 2015;128:828-30.
8. Tsulukidze M, Durand MA, Barr PJ, Mead T, Elwyn G. Providing recording of clinical consultation to patients - a highly valued but underutilized intervention: a scoping review. Patient Educ Couns 2014;95:297-304.
9. Ford S, Fallowfield L, Hall A, Lewis S. The influence of audiotapes on patient participation in the cancer consultation. Eur J Cancer 1995;31A:2264-9.
10. Elwyn G, Buckman L. Should doctors encourage patients to record consultations? BMJ 2015;350:g7645.
11. Elwyn G, Barr PJ, Grande SW. Patients recording clinical encounters: a path to empowerment? Assessment by mixed methods. BMJ open 2015;5:e008566.
12. Weiner SJ, Schwartz A. Contextual Errors in Medical Decision Making: Overlooked and Understudied. Acad Med 2016;91:657-62.
13. Schwartz A, Weiner SJ, Binns-Calvey A. Comparing announced with unannounced standardized patients in performance assessment. Jt Comm J Qual Patient Saf 2013;39:83-8.
14. Weiner SJ, Schwartz A, Sharma G, et al. Patient-centered decision making and health care outcomes: an observational study. Ann Intern Med 2013;158:573-9.
15. Hamilton AJ, Caskey FJ, Casula A, Inward CD, Ben-Shlomo Y. Associations with Wellbeing and Medication Adherence in Young Adults Receiving Kidney Replacement Therapy. Clin J Am Soc Nephrol 2018;13:1669-79.
16. Kinney RL, Lemon SC, Person SD, Pagoto SL, Saczynski JS. The association between patient activation and medication adherence, hospitalization, and emergency room utilization in patients with chronic illnesses: a systematic review. Patient Educ Couns 2015;98:545-52.
17. Wolever RQ, Dreusicke MH. Integrative health coaching: a behavior skills approach that improves HbA1c and pharmacy claims-derived medication adherence. BMJ Open Diabetes Res Care 2016;4:e000201.
18. Weiner SJ, Schwartz A, Weaver F, et al. Contextual errors and failures in individualizing patient care: a multicenter study. Ann Intern Med 2010;153:69-75.
19. Agha Z, Lofgren RP, VanRuiswyk JV, Layde PM. Are patients at Veterans Affairs medical centers sicker? A comparative analysis of health status and medical resource use. Arch Intern Med 2000;160:3252-7.
20. Rodriguez V, Andrade AD, Garcia-Retamero R, et al. Health literacy, numeracy, and graphical literacy among veterans in primary care and their effect on shared decision making and trust in physicians. Journal of health communication 2013;18 Suppl 1:273-89.
21. Barr PJ, Dannenberg MD, Ganoe CH, et al. Sharing Annotated Audio Recordings of Clinic Visits With Patients-Development of the Open Recording Automated Logging System (ORALS): Study Protocol. JMIR Res Protoc 2017;6:e121.
22. Hibbard JH, Stockard J, Mahoney ER, Tusler M. Development of the Patient Activation Measure (PAM): conceptualizing and measuring activation in patients and consumers. Health Serv Res 2004;39:1005-26.
23. Weiner S, Ashley N, Binns-Calvey A, Kelly B, Sharma G, Schwartz A. . Content Coding for Contextualization of Care. Version 6.0. Harvard Dataverse Network Project [on line]. December 2014.

24. Crowe, M. Do You Know the Difference Between These Adherence Measures? Pharmacy Times, July 05, 2015. Last accessed Nov 4, 2018 https://www.pharmacytimes.com/contributor/michael-crowe-pharmd-mba-csp-fmpa/2015/07/do-you-know-the-difference-between-these-adherence-measures.
25. Makoul G. The SEGUE Framework for teaching and assessing communication skills. Patient Educ Couns 2001;45:23-34.
26. Weiner SJ, Kelly B, Ashley N, et al. Content Coding for Contextualization of Care: Evaluating Physician Performance at Patient-Centered Decision Making. Med Decis Making 2013.
27. Zill JM, Christalle E, Muller E, Harter M, Dirmaier J, Scholl I. Measurement of physician-patient communication--a systematic review. PLoS One 2014;9:e112637.
28. Weiner SJ, Ashley N, Binns-Calvey A, Kelly B, Sharma G, Schwartz A. Content Coding for Contextualization of Care: Training & Coding Manual. Harvard Dataverse Network. http://dvn.iq.harvard.edu/dvn/dv/4C (last accessed 11.11.2019).
29. Weiner SJ SA, Cyrus K, Binns-Calvey A, Weaver FM, Sharma G, Yudkowsky R Unannounced Standardize Patient Assessment of the Roter Interaction Analysis System: The Challenge of Measuring Patient-Centered Communication. Journal of General Internal Medicine 2012:In Press.
30. Glasgow RE, Dickinson P, Fisher L, et al. Use of RE-AIM to develop a multi-media facilitation tool for the patient-centered medical home. Implement Sci 2011;6:118.
31. Weiner SJ SA, Sharma G, Binns-Calvey A, Ashley N, Kelly B, Weaver FM. Patient collected audio for performance assessment of the clinical encounter. Jt Comm J Qual Patient Saf 2015;42:273-8.
32. Hibbard JH, Greene J. What the evidence shows about patient activation: better health outcomes and care experiences; fewer data on costs. Health Aff (Millwood) 2013;32:207-14.
33. Content Coding for Contextualization of Care. Dataverse Network Project. at http://dvn.iq.harvard.edu/dvn/dv/4C (accessed December 24, 2012).)
34. Ross PT, Fitzgerald JT, Ravindranath D, et al. Assessing Residents' Veteran-Centered Care Skills in the Clinical Setting. Journal of graduate medical education 2018;10:279-84.
35. Etingen B, Miskevics S, LaVela SL. Assessing the Associations of Patient-Reported Perceptions of Patient-Centered Care as Supplemental Measures of Health Care Quality in VA. J Gen Intern Med 2016;31 Suppl 1:10-20.
36. Alexander JA, Hearld LR, Mittler JN, Harvey J. Patient-physician role relationships and patient activation among individuals with chronic illness. Health Serv Res 2012;47:1201-23.
37. Perzynski AT, Roach MJ, Shick S, et al. Patient portals and broadband internet inequality. Journal of the American Medical Informatics Association : JAMIA 2017;24:927-32.
38. Fixed Broadband Deployment Data from FCC Form 477. https://www.fcc.gov/general/broadband-deployment-data-fcc-form-477. Last Accessed: October 30, 2019.