Video Images about Decisions for Ethical Outcomes in Kidney Disease (VIDEO-KD): the study protocol for a multi-centre randomised controlled trial

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ABSTRACT

Introduction Older patients with advanced chronic kidney disease (CKD) often are inadequately prepared to make informed decisions about treatments including dialysis and cardiopulmonary resuscitation. Further, evidence shows that patients with advanced CKD do not commonly engage in advance care planning (ACP), may suffer from poor quality of life, and may be exposed to end-of-life care that is not congruent with their goals. We aim to study the effectiveness of a video intervention on ACP, treatment preferences and other patient-reported outcomes.

Methods and analysis The Video Images about Decisions for Ethical Outcomes in Kidney Disease trial is a multi-centre randomised controlled trial that will test the effectiveness of an intervention that includes a CKD-related video decision aid followed by recording personal video declarations about goals of care and treatment preferences in older adults with advancing CKD. We aim to enrol 600 patients over 5 years at 10 sites.

Ethics and dissemination Regulatory and ethical aspects of this trial include a single Institutional Review Board mechanism for approval, data use agreements among sites, and a Data Safety and Monitoring Board. We intend to disseminate findings at national meetings and publish our results.

Trial registration number NCT04347629.

INTRODUCTION

Advance care planning (ACP) is an iterative process that involves conversations about patients’ goals and preferences for future medical care.1 The core value of ACP lies in conversations exploring what matters most to patients and in preparation of patients and families for future ‘in-the-moment’ shared decision making.2 Conversations between clinicians and their patients about their goals and values in serious illness are associated with outcomes such as improved patient and family satisfaction about the quality of death, end-of-life care, as well as less anxiety and depression.3-7 In addition, failing to address patients’ goals and values through ACP conversations is associated with more hospital use at the end of life, more burdensome interventions, less use of hospice and more difficult bereavement for families and caregivers.8-13

ACP conversations frequently do not happen for patients with chronic kidney disease (CKD).14-16 Advanced CKD carries notable morbidity and mortality for patients and is marked by frequent interaction with the healthcare system.17-20 Older adults bear a significant burden of CKD and have high
rates of mortality from comorbid illnesses and after starting dialysis.21-25 A growing body of literature suggests that some older adults with CKD and other comorbidities who progress to kidney failure may receive few benefits from dialysis and may experience a degradation in quality of life and functional status.26-28 In addition, cardiopulmonary resuscitation (CPR) appears to be particularly ineffective in older adults with advanced CKD and overall knowledge about CPR remains low in this population.14 29 As such, experts and guidelines have called for increased efforts to improve on shared advance care planning and decision-making for older adults around initiation of dialysis and CPR preferences.30-32 Further, medical treatments, such as dialysis, are often presented as necessary rather than a matter of personal preference while the option of medical management of kidney disease without dialysis is poorly described to patients, if at all.33-38 As a result, there is a call for research to develop and test tools to improve ACP and treatment decision-making among older adults with advanced CKD.33

Traditional ACP and decision-making for patients rely on clinicians’ ad hoc verbal or paper-based descriptions of treatment options as patients consider what preferences meet their unique goals.34 39-41 This approach is limited because treatment decisions, such as those for dialysis, and medical management without dialysis options, and CPR are challenging to describe or may not be accessible to patients with limited literacy. Additionally, information provided to patients is variable and both verbal and paper explanations are hindered by literacy and language barriers. Patients often look to video media for information on CPR,42 however, fictional video representations in popular media can sensationalise and misrepresent outcomes.14 43-46 To address these shortcomings, we developed and tested a video decision aid to improve knowledge of kidney failure treatment options (including medical management without dialysis) among older patients with advanced CKD.38 The tool, which is available in both English and Spanish, significantly improved knowledge of medical management without dialysis and participants also reported high satisfaction and acceptability ratings.38 Video-based tools can improve decision making by providing visual information to capture complex medical and emotional scenarios and lead to increased ACP documentation.47 48 Additionally, a growing body of evidence supports the effectiveness and feasibility of decision aids on decision-making outcomes among patients with various serious illnesses, including in kidney disease.38 43 44 47-59 In this paper, we present the rationale, methodology and design of the Video Images about Decisions for Ethical Outcomes in Kidney Disease (VIDEO-KD) trial.

METHODS
Overview
The VIDEO-KD trial is a planned 5 years (1 April 2020–31 March 2025), multi-centre randomised controlled trial that will test the effectiveness of a two-part video intervention on the primary outcome of ACP documentation in the electronic health record (EHR) among patients aged 65 and older with advanced CKD. The first part of the intervention consists of a video aid to facilitate informed decision-making for patients with kidney disease.38 In the second stage of this intervention, patients can record their ACP preferences (called ‘video declarations’ or ‘ViDecs’) to share with their clinicians and caregivers.60 The specific aims for this study are as follows:

Aim 1: To compare ACP documentation after 1 year (or at the time of death) among English and Spanish speaking patients aged 65 or over with advanced CKD and poor prognosis randomly assigned to either: (1) an ACP video visually depicting CKD treatment options with a patient’s personalised video declaration (intervention); or (2) usual care (control).

Aim 2: To compare knowledge, decisional conflict, ACP engagement, CKD treatment preferences for CPR and dialysis, self-reported ACP conversations with clinicians and caregivers, and concordance of preferences with medical care delivery after 1 year (or at time of death) between intervention and control subjects.

Aim 3: To explore the quality of life, longevity and cost per quality-adjusted life year (QALY) associated with patients’ CKD treatment decisions in the intervention versus control groups.

Aim 4 (Exploratory): To conduct qualitative assessment of personal video declarations from 300 patients.

We will use Natural Language Processing (NLP) of the EHR to abstract our primary outcome for 600 patients. We will also assess the effect of the video intervention on secondary outcomes including decision-making experiences, treatment practices, and quality of life compared with participants who undergo usual care. Demonstrating the effectiveness of a video intervention in persons who are facing decisions regarding treatment for kidney failure represents an essential step to implementing these tools into standard clinical practice. We used the Standard Protocol Items: Recommendations for Interventional Trials reporting guidelines in preparing this manuscript.45

Patient and public involvement
Patients were involved in the design and validation of the video aids being studied in this research.

Study timeline
The first year will involve design of data collection processes, study-site staff training and standardisation activities around video delivery and patient enrolment processes. This will be followed by 42 months of recruitment and survey administration. Enrolled patients will be followed from initiation of trial procedures until death or the end of study, whichever comes first. Participants will be contacted every 2 months up until 1 year via follow-up phone calls to complete study surveys.
Sites and randomisation

We will draw participants from ten healthcare systems across several regions in the USA. These include organisations that represent the Mid-Atlantic (Hospital of the University of Pennsylvania), Northeast (Boston Medical Center, Massachusetts General Hospital, Brigham and Women’s Hospital, Renal Transplant Associates of New England), Southwest (University of New Mexico), West (Stanford University, Veterans Affairs Palo Alto Health Care System), Northwest (University of Washington) and Midwest (University of Pittsburgh Medical Center) regions. These systems represent a geographically diverse sample of patients and feature researchers and clinicians with expertise in the care of older patients with advanced CKD. Combined, these centres have over 80,000 outpatient nephrology visits annually.

VIDEO-KD will employ central, computer-generated block randomisation at each site with varying block sizes of 4 and 6, starting at a random point within the first block to blind staff from randomisation patterns and to protect against the influence of secular trends over the trial period by ensuring balance between study arms. Randomisation will be stratified by site and language, English versus Spanish, to ensure even distribution across study arms.

Population

We aim to recruit a total of 600 patients over the study period. Study participants will be selected from ambulatory nephrology practices at each site. The inclusion criteria are: (1) 65 years or older in age; and (2a) advanced CKD and/or (2b) poor prognosis. Advanced CKD will be defined by at least two measurements for eGFR <20 mL/min/1.73 m² separated by at least 90 days. Poor prognosis will be defined as less than a 1-year prognosis as determined by the treating nephrologists answering ‘No’ to the Surprise Question (‘Would you be surprised if this patient died in the next 12 months?’). A ‘No’ answer to the Surprise Question has been demonstrated to be an accurate predictor of 1-year mortality in older patients with advanced CKD not on dialysis and patients with multiple comorbidities.

Subjects aged 65–69 will require both advanced CKD and a poor prognosis while those aged 70 and older will require either advanced CKD or a poor prognosis. The exclusion criteria for the VIDEO-KD study include: (1) patients who are listed for kidney transplantation or those who have received a kidney transplant prior to study enrolment; (2) patients who have previously received or are receiving dialysis; (3) patients who are new to the clinic (ie, on their initial visit); (4) people who are visually impaired beyond 20/200 corrected; (5) patients who have been deemed by their nephrologists to have a psychological state that is not appropriate for study participation; and (6) cognitive impairment evaluated by administering the validated Short Portable Mental Status Questionnaire, where patients with two or more errors will be excluded from the study.

The inclusion and exclusion criteria aim to capture a broad population of older adults with advanced CKD for whom ACP and decisions about kidney failure therapy are relevant. We used similar enrolment criteria in a pilot study to assess the efficacy of the video decision aid. We aim to evaluate only patients returning to clinic with an established relationship with the nephrology clinic due to the sensitive nature of ACP conversations. We anticipate patients will be racially/ethnically, socioeconomically and culturally diverse.

Recruitment

Potential participants with advanced CKD will be identified by their EHR. The research assistant (RA) will review a list of scheduled patients 2 weeks prior to their clinic visit. Only established patients known to the nephrologist will be considered. Using the EHR, the RA will identify potential participants who meet our eligibility criteria. To conduct this screening procedure, a Health Insurance Portability and Accountability Act (HIPAA) waiver of individual authorisation for disclosure of personal health information will be obtained. For those patients meeting the criteria, their nephrologist will then be notified by email to solicit their opinion as to whether the patient is otherwise appropriate to approach for participation based on the nephrologist’s knowledge of the patient’s clinical status, psychological disposition and decision-making capacity. They will also be asked to review their panel of patients for any patients meeting the Surprise Question criterion but not selected by the RA. When an appropriate patient is identified, they will either be mailed an opt-out recruitment letter and then called by phone for recruitment, or, if they are seen in the clinic in person, they will be asked by a member of their care team if they would like to speak with an RA to hear about the study. If the patient is amenable, the RA will administer the cognitive screening and schedule a time to administer the informed consent. The RA will then obtain informed consent (online supplemental file 1), which will be documented in accordance with each site’s requirements for each mode (phone, video or in-person). The RA will verify the ability of the patient to provide consent by explaining the nature of the study and having the patient repeat (teach-back) the aims and risks of the study. Only those patients who can understand the aims of the project, what their involvement entails and the risks and benefits of participation will be eligible. Family members and friends who might be present with the patient will be invited to remain during the survey if that is agreeable to the patient; however, all answers will be provided by the patient. After completing informed consent, the randomisation assignment is automated within the REDCap system, telling the RA in real time if the patient has been randomised to the intervention or control arm. An analyst with the central research team created the randomisation scheme and uploaded it into REDCap so study staff can access it directly as part of patient enrolment.
have successfully used similar procedures to the above in our prior National Institutes of Health-funded trials.  

**Intervention design, implementation and adherence monitoring**

The first element of the video intervention is the video decision aid, which reviews kidney failure therapies (10 min) and CPR (2 min). The 12 min video decision aid is designed for older patients with kidney failure making decisions about medical treatments. The development of the video followed a systematic approach, using an iterative process of design, content and structure reviews by geriatricians, nephrologists, palliative care clinicians, patients with kidney disease and their caregivers. The decision aid was designed using the internationally recognised decision aid criteria (International Patient Decision Aid Standards, http://ipdas.ohri.ca/). The proposed video decision aid for this study was certified by the Washington Health Care Authority and is the only decision aid currently certified in kidney disease (https://www.hca.wa.gov/about-hca/healthier-washington/patient-decision-aids-pdas). Additionally, the video was developed with content intended to be objective and balanced. It is scripted at a sixth-grade level of health literacy in both English and Spanish and has closed captioning. The Spanish script was also back-translated into English and reviewed by multiple stakeholders to ensure cultural appropriateness and accuracy. All investigational team members have reviewed and approved the video for use at their specific site.

The video decision aid is designed for older people with advanced CKD and their family members who are making decisions regarding three kidney failure treatment options: haemodialysis, peritoneal dialysis or medical management without dialysis. The aid also reviews CPR. The goal of this tool is to use decision science to support the person’s ability to make patient-centred informed decisions by considering: (1) accurate information about each option; (2) the risks and benefits of each alternative; (3) each choice within the context of their values and lifestyles; (4) a decision based on trade-offs among options; and (5) means for engaging with clinicians to discuss and document values, lifestyle and prognoses.

The video begins with a physician introducing the viewer to the concept of ACP as well as a review of advanced CKD and kidney failure. The narrator explores each of the options for kidney failure, reviewing the risks and benefits of each, and then discussing the trade-offs among the three options. For each option, visual images illustrate the therapy while discussing risks and benefits. The visual images illustrating the first option, haemodialysis, include a patient receiving in-centre haemodialysis, nurses attending to the person on haemodialysis, and images of caregivers. The second option, peritoneal dialysis, includes visual images of a person at home on peritoneal dialysis with the assistance of caregivers, and the daily activities around peritoneal dialysis equipment care. The third option, medical management without dialysis, is introduced by the narrator as a potential option for those persons who wish to not pursue dialysis or any of its associated burdens and who would prefer to focus on their quality of life. The narrator explains that medical management without dialysis focuses on clinicians, patients and caregivers working together to treat symptoms through medical management, and other core principles of palliative care.

The narrator then begins to describe CPR and the option of whether to receive CPR or not. The images include CPR on a mannequin and the likelihood of success for older patients with CKD. Visual images include physicians, nurses, patients and caregivers in clinic, at home, and in the hospital. The video was created using filming criteria formulated by this research team. The video was filmed without the use of prompts or stage directions (ie, no actors) to convey a candid realism in the style known as cinema verité.

In order to watch the video beyond the initial exposure during the survey (for the intervention arm), participants will be given a code without expiration for home use as well as to share with their caregivers; the code can be used as many times as they wish. The research team will track use of the video (ie, number of times the patient accessed the video decision aid from home using their code).

After viewing the video decision aid, the RA will assist the participant in recording a ViDec of their ACP preferences. First, the RA invites the patient to introduce herself; afterwards, the RA will ask a series of open-ended questions intended to draw responses to a range of topics both important for a full discussion of ACP preferences and raised in our previous qualitative research. The questions and this process was developed by a core group of study team members (NE, MP-O, AV, LMQ) with expertise in health literacy, nephrology, health equity, qualitative methods, video documentary and ACP for language appropriateness and breadth of content. These topics include: awareness of the kidney disease, goals and values, kidney failure treatment preferences (ie, medical management without dialysis, peritoneal dialysis, haemodialysis), emergent medical treatments (ie, CPR, intubation), faith/spirituality and any other topics the patient would like to discuss. After recording, the RA asks the patient questions about the helpfulness and ease of making the ViDec and will share the ViDec with the patient and the patient’s nephrologist, primary care physician and any other provider that the patient requests. Clinicians will be encouraged at this time to document preferences and goals in the medical record. The video will be shared through HIPAA compliant methods (such as secure online platforms or encrypted flashdrive) approved by the IRB and privacy officer at the site where the patient was enrolled. The patient will be encouraged to share their video with family and loved ones.

To assist participants in creating a ViDec, the RA will provide a brief introduction to patients by explaining that the video is to help doctors and family understand their wishes (online supplemental file 2). The RA will
use conferencing software (eg, if visit is remote) or an iPad (if visit is in person) to ask the patient questions and record the patient's answers. If the patient declines to be video-recorded, the RA will offer an audio-only option. When the recording is complete, the RA will offer to play the video for the patient to see if they feel it accurately represents their choices and if not, if they would like to re-record their video. Patients will be able to re-record their ViDecs with each study check-in (every 2 months) or at an earlier time if they wish. We expect patients will wish to discuss their preferences with family and that their preferences may change over time. As new ViDecs replace prior videos they will again be shared with the patient and with the patient's clinicians, with the patient's permission.

To ensure appropriate delivery of the intervention, the co-principal investigators and site coinvestigators will lead weekly supervision meetings with RAs to discuss any issues regarding implementation of the video decision aid and ViDecs. Also, all video decision aid showings will be tracked with a date, time stamp and playthrough rate to ensure complete showing of the video decision aid to patients randomised to the intervention. Due to the COVID-19 pandemic, study activities will be available both in-person and remotely.

Control condition
Patients assigned to the control arm will receive the typical current ACP practices that already exist in each of their local respective sites. These will vary by site and can include activities such as distribution of educational materials reviewing dialysis, medical management of kidney failure, CPR, educational classes or instructional sessions regarding dialysis options, and ongoing site activities around engagement with ACP. Notably, especially considering the COVID-19 pandemic, ACP-improvement initiatives may be active and different across sites over the course of the trial, this heterogeneity reflects the current dynamic state of ‘usual’ care.

Outcomes
The primary outcome of the VIDEO-KD trial is the presence of ACP documentation in the EHR within 1 year of follow-up after study enrolment or death, whichever comes sooner. Secondary outcomes include: engagement with ACP, preferences stated in ACP conversations, self-reported ACP conversations, both kidney disease specific and health related quality of life, decisional conflict, acceptability of video intervention, CKD care preferences outlined in discussions (haemodialysis, peritoneal dialysis or medical management without dialysis) and healthcare costs, assessed per QALY associated with patients’ kidney failure and CPR treatment decisions.

Additional exploratory outcomes will include: (1) thematic analysis of the ViDec content; (2) analysis of ViDec change over time (for participants who record multiple ViDec recordings over the course of their participation); (3) assessment of ACP preferences as communicated in the ViDec recordings; (4) comparison of ACP preferences as communicated in the ViDec recordings to the contemporaneously reported ACP preferences documented in the medical record and in research surveys; and (5) description of the usefulness, understandability and relevance of the video intervention package.

Data sources, data elements and linkage
Table 1 shows study data elements and sources and time points of data collection.

Sociodemographics
Data on sociodemographics including age, gender, race, ethnicity, primary language, health insurance, education, and (5) description of the usefulness, understandability and relevance of the video intervention package.

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Table 1 Data elements and sources for key trial outcomes by study procedure

<table>
<thead>
<tr>
<th>Data collected</th>
<th>Purpose</th>
<th>Tool/source</th>
<th>By whom</th>
<th>When</th>
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<tr>
<td>Prognosis</td>
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<td>eGFR, SQ/EHR, RA, PN</td>
<td>2 weeks prior to visit</td>
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<td>SPMSQ</td>
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<td>ACP documentation</td>
<td>1° outcome</td>
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<td>ACP engagement</td>
<td>2° outcome</td>
<td>ACPE</td>
<td>RA</td>
<td>Baseline</td>
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<tr>
<td>ACP preferences</td>
<td>2° outcome</td>
<td>Study survey</td>
<td>RA</td>
<td>Baseline, every 2 months</td>
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<tr>
<td>ACP conversations</td>
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<td>KD-QoL</td>
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<td>2° outcome</td>
<td>Medicare claims data</td>
<td>RA</td>
<td>Expected year 4 and 5</td>
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ACP, Advance Care Planning Engagement Questionnaire; CMS, Centers for Medicare and Medicaid Services; DCS, Decisional Conflict Scale; eGFR, estimated glomerular filtration rate; EHR, Electronic Health Record; EuroQol, 5-level EuroQol-5D version (EQ-5D-5Dimension-5Level); KD-QoL-36, Kidney Disease Quality of Life; PN, primary nephrologist; RA, research assistant; SPMSQ, Short Portable Mental Status Questionnaire; SQ, Surprise Question; YDDAU, Yorkshire Dialysis Decision Aid Usefulness Scale.
marital status, religion and religious attendance will be assessed via surveys.

**ACP documentation**
Will include any documentation in the EHR reflecting an ACP conversation (completion of advance directive or Physician’s Orders for Life Sustaining Treatment (POLST); code status documentation; provider note reflecting ACP discussion) (primary outcome). The primary analysis will be based on the EHR notes of the nephrology clinic team. In the secondary analysis, we will also add notes from other providers.

**ACP engagement**
We will ask, via RA administered survey, four validated questions regarding ACP engagement.75 (How ready are you to talk to your caregiver? To your doctor? To appoint a surrogate? To sign an ACP document?)

**ACP preferences**
Resuscitation preferences regarding CPR (yes, no or unsure) and dialytic versus non-dialytic treatment (haemodialysis, peritoneal dialysis, medical management without dialysis or unsure) will be assessed after randomisation, and every 2 months until the end of study follow-up at 12 months or death.

**ACP conversations**
We will survey patients regarding whether they have had prior ACP discussions.

**Kidney disease specific quality of life**
We will also measure disease-specific quality of life using data obtained from the Kidney Disease Quality of Life (KDQOL-36)76 administered at baseline and every 60 days thereafter. Responses to each of the 36 items will be scored (0–100) and the overall mean used as the quality of life measure for each survey round.

**Health related quality of life**
To capture differences in quality of life, besides longevity, associated with the choice of kidney care approach, we will use EuroQol’s EQ-5D-5L instrument as the quality measure.77 This instrument takes responses to five questions on mobility, self-care, ability to perform usual activities, pain and anxiety/depression to produce a validated quality score (0–1). This instrument will be administered at baseline and every 60 days thereafter. The cumulative quality scores from consecutive rounds of survey will be used to obtain the QALYs for the exposure time.

**Decisional conflict**
We will measure decisional conflict using the Decisional Conflict Scale (DCS), which attempts to measure decisional uncertainty.78

**Acceptability of video intervention**
For those patients randomised to the video intervention, we will measure, via survey, acceptability of the decision aid using a modified version of the validated Yorkshire Dialysis Decision Aid Usefulness Scale.79 We will also ask questions regarding comfort viewing the video, which we have validated in our prior work.39 47 48 50 52 54–56 80

**CKD care preferences**
All patients will be asked their preferences for kidney failure care at baseline. We will then assess their follow-up preferences by chart review in the electronic medical record.

**Healthcare costs**
The main source of differences in costs between the video and control arms will be from the stream of healthcare services used, including that for kidney failure care, over the exposure time. Based on prior evidence of healthcare spending of CKD patients, we will identify the major components of services used, including inpatient, pharmacy, outpatient, emergency department and dialysis.21 81 We will also examine utilisation by subgroups with comorbidity of diabetes, heart failure and cardiovascular disease. We will use Medicare claims data to obtain the associated costs, including payments by Medicare and secondary payers (eg, out-of-pocket payments).82 Medicare claims data are available for a majority of Medicare enrollees (about 75% choose the Fee for Service plan). As these data are unavailable for the others who choose managed care plans or are enrolled from the Veterans Affairs, we will impute the costs (per year) based on the average costs for the Fee for Service participants separately by the type of kidney care chosen.81

**Natural Language Processing**
We will conduct NLP-assisted EHR review for documentation of ACP (primary outcome). This EHR review will include keyword-based searches for documentation of limitations to life-sustaining treatment, goals of care, healthcare proxy designation or communication on the patients’ behalf, palliative care involvement, hospice preference or utilisation, discussions surrounding dialytic versus non-dialytic therapies (including time-limited trials of dialysis), as well as completion of any advance directive and/or POLST. For patients who die prior to 12 months, we will conduct an NLP-assisted EHR review to assess ACP documentation (primary outcome), type of kidney failure treatment received prior to death, receipt of palliative care, hospice, or CPR/intubation in the last month of life, and place of death (eg, intensive care unit, home, etc). NLP-assisted EHR review will rely on the ClinicalRegex software, which allows for rapid semi-automated clinical note review. ClinicalRegex presents operators with clinical notes highlighted in particular areas located by keywords associated with the concepts in question. Site operators will then ensure that keywords found within the notes appear in the correct clinical context (as in the documentation of ACP conversations). This method will be used at each site to search all collected outpatient
clinical documentation data from the EHR for ACP documentation, similar to prior studies using NLP.83–85 For each NLP domain (ie, goals-of-care discussion, limitations to life-sustaining treatment), we have built a keyword library with the goal of identifying relevant documentation within clinical notes. Each keyword library will be refined and validated by the review of retrospective clinical notes in each site’s local EHRs to generate formal metrics (accuracy, sensitivity, specificity, etc) across all sites.86

All site operators who will be engaged in this NLP must participate in training on note annotation practices and must demonstrate proficiency in annotating notes containing clinical concepts expected to be found during this trial. Proficiency will be determined by the use of a calibration test consisting of 20 mock clinical narratives which will be used to cross-validate annotation practices across all sites.

The EHR data will be reviewed by Dana-Farber Cancer Institute (DFCI) data staff and unblinded investigators. The NLP results and metadata (keyword frequencies, rates of agreement between annotator and keyword library) for each domain will be used across all sites to identify out of range or unexpected results, and a summary will be sent to each site. Conference calls will be conducted with relevant investigators and programmers to adjudicate any issues. We will then finalise NLP analysis results and submit to the study statistician for further analysis.

We have data use agreements from all sites to ensure adherence to the process and procedures for the protection of human subjects and protected health information (PHI). We will collect the minimum PHI needed from study participants and store all study information on HIPAA-compliant, password secured servers. We will separate participant identifying information from password-secured files while maintaining a linkage file at study sites. The linkage file will be restricted per local rules for PHI. We will transfer study data through HIPAA-secure methods specific to each site. Data will be sent to DFCI for data management and to Boston Medical Center and Massachusetts General Hospital for analysis. The final data set will be available to trial investigators on completion of the study and others can be provided access on reasonable request.

Masking

Due to the nature of the intervention, participants and study staff will not be blinded to the intervention. The NLP outcomes adjudication used in this study is a human-assisted NLP in which a staff member validates the text presented in the software as a possible outcome. For analysis, the following steps will be taken to ensure blinding to study arm assignment by the staff member doing the NLP outcome attribution:

► Prior to adjudication activities, names will be anonymised.
► Annotation will be performed in large batches with all enrolled patients who have clinical notes to that point.

► NLP notes for adjudication will not be grouped by study ID when presented to annotators. Each note will be annotated individually, without reference to concepts contained in other notes.
► When possible, a staff member who did not enrol the participants will perform the annotation.

Statistical analysis

Our primary analyses will use an intention-to-treat approach including all randomised patients in the analysis regardless of whether patients receive the intended intervention. Secondary analysis will be used to address any non-compliance issues (eg, patients in the control group review publicly accessible videos or patients in the intervention group choose not to watch study videos). For all outcomes, we will include known predictors of outcomes in the regression models to increase the precision of the effect estimates. We will also evaluate the possibility of secular trends through including information such as year of study enrolment in the models. We will examine the heterogeneity of treatment effect by testing the interaction between intervention and prespecified subgroups (LatinX and non-LatinX, whites and non-whites, English speaking vs non-English speaking) to determine whether the intervention effect differs among subgroups. We will conduct subgroup analysis if there is evidence of an interaction between subgroup and study arm. For outcomes assessed every 2 months (eg, treatment preferences, ACP conversations), we will use a repeated measures analysis to include data from all available time points (2, 4, 6, 8, 10, 12 months) to (1) compare the trend over time and (2) compare outcomes at each time point using the Generalised Estimating Equations (GEE) approach.

ACP documentation

Our primary outcome is clinician ACP documentation within 1 year. We will use a Poisson model to compare the rate of patients with ACP documentation with the length of follow-up treated as an offset. Patients lost to follow-up or patients who died within 1 year will be considered as ‘censored’ in this approach.

ACP engagement

ACP engagement will be summarised using the 4-item survey tool.75 We will use a repeated measures analysis with GEE to compare the level of engagement at each time point and the trend over time.

ACP preferences

We will use $\chi^2$ tests to compare the proportion of participants choosing ‘No CPR’ and ‘medical management without dialysis’ at any point during the study between the two arms. For the analysis of CPR, patients who choose ‘Unsure’ will be considered ‘Yes CPR’ since in clinical practice patients who are unsure receive the clinical default of ‘Yes CPR’.47–49 The repeated measures analysis will be used to summarise the stability of treatment preferences over time. Treatment preference concordance will be treated as a dichotomised variable aligning
what patients say or (after the intervention for patients randomised to this arm) with CKD care received after 1 year (or at time of death) and compared using a \( \chi^2 \) test. For people who are deceased, we will use NLP to extract data from the EHR for the last 3 months of life for all deceased patients regarding CKD care received.

### ACP conversations

The number of patient self-reported ACP conversations will be compared using a Poisson regression model with repeated measures analysis.

### Quality of life and costs

Due to differential preference for medical management without dialysis, we expect patients randomised to the video arm to have different health outcomes (longevity and quality of life) and healthcare utilisation relative to the control group. We will first estimate the impact of the video on longevity, quality of life and healthcare utilisation separately. Depending on these results, we will use cost-effectiveness analysis to compare the value of the services used between the two groups.\(^9^7\) For our primary analysis we will use the perspective of the healthcare payer (Medicare). Using generalised Poisson regression models, we will separately estimate the average difference in quality of life and costs associated with the video arm relative to the control arm, expressed per 1 year of exposure time. Using generalised linear and survival models we will also examine longevity both as a dichotomous survival indicator (0/1) and as a continuous measure. We will adjust for systematic differences across hospitals using either a random or fixed effects specification.\(^8^9\) We will use incremental net benefit (INB) as the cost-effectiveness measure.\(^8^9\)

INB is defined as the difference between change in quality of life evaluated at monetary valuation of 1 QALY (currently $100,000) and change in costs. Positive INB indicates net gains from both the improvement in quality of life and lower healthcare utilisation from the video intervention, while a negative INB denotes a worsening of quality of life. In the case of improvement in quality of life and lower healthcare utilisation from the video intervention, INB captures gains from both the improvements. We will obtain 95% CI of the INB estimates based on bootstrapping estimation.\(^8^9\)

### Decisional conflict

Decisional conflict scale\(^7^8\) is a continuous variable ranging from 3 to 15 and will be compared using a two-sample t-test.

### Statistical power and sample size requirements

#### ACP outcomes

Our prior studies showed that 81% of video participants had ACP documentation compared with 46% in controls.\(^4^7\) With 300 patients per group, the study will have >90% power to detect such a difference with a two-sided 0.05 significance level. For CKD preferences, the study will have 90% power to detect a difference of 46% of video participants choose medical management without dialysis vs 33% in the control arm estimated from our pilot study. Assuming 60% of video participants achieve preference concordance, the study will have 96% power to detect a 15% difference (60% vs 45%) and 84% power to detect a 12% difference (60% vs 48%). For continuous outcomes such as ACP engagement, the study will have 90% power to detect an effect size of 0.265 and 80% power to detect an effect size of 0.229. Both are considered as small to medium effect sizes.

#### Quality of life

Figure 1 gives the sample sizes needed to distinguish utility differences for quality of life.

![Figure 1](http://bmjopen.bmj.com/). If a 20% combined loss to follow-up and study withdrawal is included, the sample enrolled would be 588 participants.

### Qualitative analyses

Qualitative analyses will begin by transcribing ViDecs verbatim, adding non-verbal cues such as emotional expressions. We will create a preliminary codebook based on a prior ViDec project\(^6^0\) and the ViDec questionnaire guide to identify ACP preferences, goals and values, among others. One team member will lead the coding process and meet with team members to conduct peer debriefing sessions\(^9^2\) to discuss and resolve coding differences, refining, adding and deleting codes as needed.\(^9^3\) We will group similar codes to conduct a thematic analysis of the ViDec content and compare these themes over time.
for participants who record multiple ViDec recordings. After identifying the ACP preferences from the ViDecs (including expressions of preferences that are unclear), will indicate how often ACP preferences match or do not match the preferences stated in the medical record and in research surveys. Finally, we will use information from patients about the helpfulness and ease of making a ViDec and use a case study approach to identify subsets of patients, caregivers (who may or may not have seen the ViDec) and clinicians to describe the video intervention package along several dimensions including usefulness, understandability and relevance. NVivo V.12 will serve as the data management platform.

### Regulatory considerations
The use of Institutional Review Board (IRB) review and approval, data use agreements among partners, and an independent Data Safety and Monitoring Board (online supplemental file 3) provide the foundation of regulatory efforts for VIDEO-KD. This study was approved via a single IRB (protocol version 3.0, Western IRB (WIRB) #20193921) as a multi-centre trial. Each study location established official agreements to use the WIRB as their primary regulatory agent. Any protocol changes will be communicated in written form by all relevant parties. This is a minimal risk study for study subjects and principal and site investigators will report unforeseen adverse events to the IRB. We have created committees of study personnel to manage oversight of project direction and administration, implementation, quality and monitoring of data, and regulatory/ethical considerations. A HIPAA authorisation was approved for the EHR review to identify potentially eligible study participants. Waivers of documentation of consent were approved for cognitive screening assessment and for caregiver surveys.

### Ethics and dissemination
The VIDEO-KD trial will be the first large, multi-site trial to evaluate the impact of a video intervention on ACP and patient experience. The strengths of the study include the innovative video intervention and the diversity of the population of study participants. This study has the potential to add to a growing literature around the use of video decision aids and declarations in supporting people with advanced kidney disease as they learn about their illness and make decisions with clinical teams about what types of care help them to best achieve their goals. We aim to distribute results of this study through invited presentations and manuscripts.

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### Acknowledgements
We would like to thank the participating site teams at each of our sites for their involvement in this study.

### Competing interests
NE is a scientific advisor for Somatus and Davita. MKT has received honoraria from the American Federation of Aging Research and serves as Associate Editor at CJASN. Views expressed are those of the authors and not necessarily those of the Department of Veterans Affairs. AV has a financial interest in ACP decisions, a non-profit organisation developing advance care planning video decision support tools. AV’s interests were reviewed and are managed by MGH and Mass General Brigham in accordance with their conflict-of-interest policies. No other disclosures to report.

### Patient consent for publication
Not applicable.

### Provenance and peer review
Not commissioned; externally peer reviewed.

### Supplemental material
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REFERENCES


RESEARCH CONSENT FORM

Basic Information

TITLE: Improving Medical Decision Making for Older Patients with End Stage Renal Disease

PROTOCOL NO.: H-39981
WIRB® Protocol #20193321

SPONSOR: National Institutes of Health, National Institute on Aging (NIH/NIA)

INVESTIGATOR: Name
Address
City, State Zip Code
Country

STUDY-RELATED PHONE NUMBER(S): Phone Number
Phone Number

Concise Summary

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled. Your alternative is not to participate in the research.

How long will I be in this research?

We expect that your taking part in this research will last 12 months.

Why is this research being done?

The purpose of this research is to understand and help older adults with chronic kidney disease make decisions about the care they receive.
Project Title: Improving Medical Decision Making for Older Patients with End Stage Renal Disease
Principal Investigator: [Name]

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What happens to me if I agree to take part in this research?

If you decide to take part in this research study, the general procedures include answering a series of survey questions every two months over the course of one year. At your first study visit you will be randomly assigned to one of two groups.

If you are assigned to the intervention group, we will show you two short videos about advance care planning decisions. We will then help you record a short personal video of your own. In this video, you will describe in your own words what you would want for yourself regarding your future. We will then ask you some questions about the experience of making this short personal video. We will audiotape this part of the visit. Afterwards, we will discuss how to get a copy of your personal video for yourself and how you can share it with your family member or caregiver. After this visit, we are going to send this to your nephrologist.

We will call you every 2 months for one year to ask you some questions about your health and ask if you would like to re-record your personal video also known as a “video-declaration”. If you would like to re-record your declaration, we will audio-record you over the phone.

If you are assigned to the usual care group, you will not be shown the advance care planning video and you will not be asked to record a personal video about your preferences. You will be asked to complete a survey by phone every two months one year after the first survey is completed.

Could being in this research hurt me?

The most important risks or discomforts that you may expect from taking part in this research include being uncomfortable or upset with questions that we may ask. If this happens, you do not have to answer those questions. In addition, you may feel uncomfortable or upset by the video decision aid or the video declaration process, if that happens, you do not have to complete either activity. Another small risk is a loss of confidentiality, that your private health information will be seen by people who would not normally be able to see it.

Will being in this research benefit me?

The most important benefit that you may expect from taking part in this research include helping the investigators learn about the video decision aid and/or the video declaration process. It is not expected that you will personally benefit from this research.

Overview

We are asking you to be in a research study. A research study is an organized way of collecting information about scientific questions. This form will tell you what you should expect if you agree to be
in the study. There are programs in place to make sure that investigators fulfill their obligations listed in this form.

It is your decision whether or not to join the study. We are doing the research to help older adults with chronic kidney disease make decisions about the care they receive. If you agree, you will answer a series of survey questions every two months over the course of one year. You will be in the study for up to one year if you decide to stay for the whole study. You will find more information about what will happen in this study later in this form.

The main risks of being in the study are that you might feel uncomfortable with the survey questions or with the information given to you in a decision making video, but if you feel uncomfortable with any part of the study, you can request to skip any question or activity. You will find more information about risks later in this form.

Your doctor may also be an investigator in this research study. Being an investigator means your doctor is interested in both you and the study. You may want to get another opinion about being in the study. You can do so now or at any time during the study. A doctor who is not part of this study could give you their opinion about being in the study. You do not have to agree to be in this study even though it is offered by your doctor.

Purpose
We are trying to understand what participants with Chronic Kidney Disease think of a video decision aid and video declaration process compared to usual care.

What Will Happen in This Research Study
In order to complete this research, we are doing the same process at several locations. We will be asking adults over the age of 75 who have a diagnosis of chronic kidney disease (CKD) to participate in this randomized controlled trial. If you are eligible and agree to participate, we will ask you a series of questions about your healthcare knowledge and preferences. You will be actively enrolled in the study for one year. From the time you are enrolled until the study is complete, we will periodically review your medical chart and extract information relating to care that you receive.

At your first study visit you will be randomly (like the flip of a coin) assigned to one of two groups.

If you are assigned to the intervention group, we will show you two short videos about advance care planning decisions. We will then help you record a short personal video of your own. In this video, you will describe in your own words what you would want for yourself regarding your future. We will then ask you some questions about the experience of making this short personal video. We will audiotape this part of the visit. Afterwards, we will discuss how to get a copy of your personal video for yourself and how you can share it with your family member or caregiver. After this visit, we are going to send this to your nephrologist. Are there any other providers you would like us to send it to?
Please note that the personal video you record as part of this study is not legally binding like a formal written advance directive would be. It is merely informational and will not be included in your medical record. The declaration is considered strictly a research activity and it will not guarantee that your medical team will follow your wishes expressed in the declaration. If you want to make sure your wishes are followed it is best to consult with your doctor and your caregiver and family members, and update or put in place a formal written advance directive.

After you are enrolled, we will call you every 2 months for one year to ask you some questions about your health, and ask if you would like to re-record your personal video also known as a “video-declaration”. If you would like to re-record your declaration, we will audio-record you over the phone.

If you are assigned to the usual care group, you will not be shown the advance care planning video and you will not be asked to record a personal video about your preferences. You will be asked to complete a survey by phone every two months one year after the first survey is completed.

We are asking a small sample (around 20) of people from this study to be in an additional interview about barriers to care. This interview would last about 30 minutes and take place at your last study visit. The interview would be audiotaped. This interview is voluntary, you can still participate in the study even if you don’t do the interview. People who complete the interview will receive an additional $30. Please initial your choice below:

I am interested in being contacted for the extra interview.  ______Yes   ______No

You will be one of approximately 600 subjects who will be asked to be in the study.

**Risks and Discomforts**
This study does not have many risks involved. You might feel uncomfortable or upset with questions that we may ask. If this happens, you do not have to answer those questions. In addition, you may feel uncomfortable or upset by the video decision aid or the video declaration process, if that happens, you do not have to complete either activity.

Another small risk is a loss of confidentiality, that your private health information will be seen by people who would not normally be able to see it. The way we will keep your information private is described in the “Confidentiality” section below.

**Potential Benefits**
You will receive no direct benefit from being in this study. Your being in this study may help the investigators learn about the video decision aid and/or the video declaration process.

It is possible that some of the research conducted using your information eventually will lead to the development of new commercial products. Should this occur, you will not receive any financial compensation generated from such profits.
Costs
There are no costs to you for being in this research study.

Payment
You will receive $50 for completing the initial visit today. You will also receive $20 for each of the 6 telephone follow-ups that you complete (1 every 2 months for a year). You will receive an additional $30 if you are contacted to complete the extra interview. If you complete all study activities, you will receive $200. All payments will come on a pre-loaded debit card.

Confidentiality
We must use information that shows your identity to do this research. Information already collected about you will remain in the study record even if you later withdraw.

We will store your information in ways we think are secure. We will store paper files in locked filing cabinets. We will store electronic files in computer systems with password protection and encryption. However, we cannot guarantee complete confidentiality.

We have three options to share your video declaration with you. (1) We can post the declaration video on a website called Box, which is Boston Medical Center’s secure file sharing site. We would then provide you with a web link to view the video online. (2) We can put the video on a password protected flashdrive and mail it to you; (3) We can post your declaration video on a YouTube unlisted video setting and provide the web link to you. An unlisted video can be seen and shared by a web link and is not secure. The unlisted video is not supposed to be available on YouTube’s search results or for people who do not have access to the web link. Since we do not control the YouTube website, it’s possible that they can change their settings without our knowledge and your video could be viewed by others.

Please note, we cannot guarantee the confidentiality of your information. For example:
   a. If you lose the flashdrive it may be recovered and accessible by someone else; or
   b. A link to Box or YouTube could be sent to the wrong person;
   c. If the video is shared with another person, they may be able to reshare to anyone.

If you agree to be in the study and sign this form, we will share information that may show your identity with the following groups of people:
   • People who do the research or help oversee the research, including safety monitoring.
   • People from Federal and state agencies who audit or review the research, as required by law. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health.
   • Any people who you give us separate permission to share your information, such as YouTube.
We will share research data where we have removed anything that we think would show your identity. There still may be a small chance that someone could figure out that the information is about you. Such sharing includes:

- Publishing results in a medical book or journal.
- Adding results to a Federal government database.
- Using research data in future studies, done by us or by other scientists.

A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

### Use and Sharing of Your Health Information

The research team has to use and share your health information to do this study, including information that may identify you. By agreeing to be in this study and signing this form, you are giving us your permission where needed to use and share your health information as described in this form.

Health information that might be used or shared during this research includes:

- Information that is in your hospital or office health records. The records we will use or share are those related to the aims, conduct, and monitoring of the research study.
- Health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.

The reasons that your health information might be used or shared with others are:

- To do the research described here.
- To make sure we do the research according to certain standards set by ethics, law, and quality groups.
- To comply with laws and regulations. This includes safety-related information.

The people and groups that may use or share your health information are:

- Researchers involved in this research study from [Site], and/or other organizations
- Other people within [Site] who may need to access your health information to do their jobs such as for treatment, research administration, payment, billing, or health care operations
- People or groups that the researchers use to help conduct the study or to provide oversight for the study
- The Institutional Review Board that oversees the research and other people or groups that are part of the Human Research Protection Program that oversees the research
- Research monitors, reviewers, or accreditation agencies and other people or groups that oversee research information and the safety of the study
Project Title: Improving Medical Decision Making for Older Patients with End Stage Renal Disease
Principal Investigator: [Name]

We ask anyone who gets your health information from us to protect the privacy of your information. However, we cannot control how they may use or share your health information. We cannot promise that they will keep it completely private.

The time period for using or sharing your health information:

- Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

Your privacy rights are:

- You have the right not to sign this form that allows us to use and share your health information for research. If you do not sign this form, you cannot be in the research. This is because we need to use the health information to do the research. Your decision not to sign the form will not affect any treatment, health care, enrollment in health plans, or eligibility for benefits.

- You have the right to withdraw your permission to use or share your health information in this research study. If you want to withdraw your permission, you must write a letter to the Principal Investigator at the address listed on the first page of this form. If you withdraw your permission, you will not be able to take back information that has already been used or shared with others. This includes information used or shared to do the research study or to be sure the research is safe and of high quality. If you withdraw your permission, you cannot continue to be in the study.

When the study has been completed for everyone, you have the right to request access to the health information that we used or shared to make your treatment or payment decisions. If you ask for research information that is not in your medical record, we might not give it to you, but we will explain why not. You may use the contact information on the first page of this form to find out how to get your health information. You may also contact the HIPAA Privacy Officer at [Site] at [Contact information]. We would like to ask your permission to contact you again in the future. This contact would be after the study has ended. Please initial your choice below:

- Yes   No   You may contact me again to ask for additional information related to this study
- Yes   No   You may contact me again to let me know about a different research study

Subject’s Rights

By consenting to be in this study you do not waive any of your legal rights. Consenting means that you have been given information about this study and that you agree to participate in the study. You will be given a copy of this form to keep.

If you do not agree to be in this study or if at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled. Your participation is completely up to you.
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Principal Investigator: [Name]

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Your decision will not affect your ability to get health care or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get.

We may decide to have you stop being in the study even if you want to stay. Some reasons this could happen are if staying in the study may be bad for you, or if the study is stopped.

Questions

The investigator or a member of the research team will try to answer all of your questions. If you have questions, complaints or concerns at any time, contact [Name] at [Number]. Also call if you need to report an injury while being in this research.

You may also call (800) 562-4789 or email help@wirb.com. You will be talking to someone at the IRB. The IRB is a group that helps monitor research. You should call or email the IRB if you want to find out about your rights as a research subject. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, complaints, or problems.

By agreeing to be in this research, you are indicating that you have read this form (or it has been read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study.

Subject: ____________________________________________
Printed name of subject

By signing this consent form, you are indicating that
• you have read this form (or it has been read to you)
• your questions have been answered to your satisfaction
• you voluntarily agree to participate in this research study
• you permit the use and sharing of information that may identify you as described

_________________________________________  ___________
Signature of subject            Date

Researcher: ____________________________________________
Printed name of person conducting consent discussion

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I have personally explained the research to the above-named subject and answered all questions. I believe that the subject understands what is involved in the study and freely agrees to participate.

Signature of person conducting consent discussion        Date
**For Sites in California**

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:
- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits.

Who may use and give out information about you?
The study doctor and the study staff. [They may also share the research information with [enter SMO company name], an agent for the study doctor. delete if the site does not have an SMO]

Who might get this information?
The sponsor of this research. “Sponsor” means any persons or companies that are:
- working for or with the sponsor, or
- owned by the sponsor.

Your information may be given to:
- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- The institution where the research is being done,
- Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
- Institutional Review Board (IRB).
Why will this information be used and/or given to others?
• to do the research,
• to study the results, and
• to make sure that the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?
This permission will be good until December 31, 2070.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.
Authorization:
I have been given the information about the use and disclosure of my health information for this research study. My questions have been answered.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

**AUTHORIZATION SIGNATURE:**

Signature of Subject  Date
Supplementary Material: Video Declaration Script for Research Assistant

As you make the video, please use the following instructions and questions as a guide:

1. If you wish, introduce yourself. You may use your full name, first name, or any other manner in which you refer to yourself.
   a. If Yes, let the subject introduce themselves.
   b. If No, move to next question.

2. What has your kidney doctor said to you about your kidney health? Did they seem worried about your kidneys?

3. Given what you understand about your illness, what’s most important to you right now?
   By the way, please re-state the question as you give your answer, for example, you could start with: ‘what’s most important to me is…’
   a. After subject responds, state “What other things are most important to you?” and then let subject respond and move to next question.
   b. For one word or very limited responses, like ‘family’, ask a probing question, e.g., How is <family> important to you?

4. As you think about the future, what worries you?

5. Some people find it helpful to understand their choices for medical care in terms of balancing quality of life (living as well as you can) vs. quantity of life (living as long as possible even if it means being in the hospital). What is important to you as you make medical decisions?
6. At this point, what do you think are the best next steps in treating your kidney disease? What do you think about these choices: medical management without dialysis, peritoneal dialysis, hemodialysis.

a. If patient does not understand the options or asks for an explanation, ask “Would you like to watch the video again? We can stop the video along the way so you can ask questions. Or would you like me to describe the options for you?”

7. What kinds of information would you like to know in order to make the best decision for you?

8. If you became very sick, are there any specific medical treatments that you would or would not wish to receive, and why? Please think about whether you would choose to receive CPR if your heart stopped beating or have a breathing tube placed if you stopped breathing.

9. Please talk about how your faith or spirituality affects how you think about medical decisions toward the end of life, or whatever else affects how you think about medical decisions. Some examples in addition to faith and spirituality may include family, upbringing or personal experiences with end of life.

a. For very limited responses, like ‘my faith is important’, ask a probing question, e.g., How is your faith important to you? Can you give me some examples?

10. Anything else you would like to say?
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DRAFT DSMB Charter

Title: Improving medical decision making for older patients with End Stage Renal Disease

Shortened Title: Video Images about Decisions for Ethical Outcomes in Kidney Disease (VIDEO-KD)

Grant #: 1 R01 AG066892

Principal Investigators: Michael Paasche-Orlow and Angelo Volandes

Institution: Boston Medical Center

1. Introduction

This DRAFT Charter is for the Data and Safety Monitoring Board (DSMB) for the Video Images about Decisions for Ethical Outcomes in Kidney Disease (VIDEO-KD) study. One of the first acts of the DSMB would be to edit, finalize, and the Charter. In addition, the DSMB may wish to review and further edit the Charter at regular intervals to determine whether any changes are needed.

2. Responsibilities of the DSMB

The DSMB will act in an advisory capacity to the National Institute on Aging (NIA) Director to monitor participant safety, data quality and progress of the study by the Principal Investigators Michael Paasche-Orlow, MD, MA, MPH and Angelo Volandes, MD, MPH for the VIDEO-KD grant 1 R01 AG066892 and any successor grants, funded by the National Institute on Aging.

In addition, the DSMB may be asked to make recommendations, as appropriate, about:

- Efficacy versus futility of the study intervention in relation to enrollment and power to discern effects
- Benefit/risk ratio of procedures and participant burden
- Selection, recruitment, and retention of participants
- Adherence to protocol requirements
- Completeness, quality, and analysis of measurements
- Data and statistical analysis plan
- Amendments to the study protocol and consent forms, including whether any new data from other sources affect the equipoise of the study being monitored
- Participant safety, including review of consent form
- Notification of and referral for abnormal findings
- Participant burden
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3. Communications, Organization, and Interactions

The DSMB will meet yearly throughout the study to receive an update and discuss ongoing study procedures. The project coordinator and data manager will share information with the DSMB as requested.

To avoid appearance of conflict of interests, neither the investigators nor the DSMB members should directly communicate on any study-related issues. This includes any protocols, manual of procedures, reports, recommendations and other study-related correspondence.

All such communications should be conducted exclusively through the NIA Program Official as described elsewhere in this document.

4. DSMB Members

DSMB members and their expertise are listed in Appendix A.

5. Conflict of Interest Reporting

All DSMB members will complete conflict of interest reports. Prior to the beginning of each DSMB meeting, all members will be asked to report any new conflicts of interest.

6. Scheduling, Timing, and Organization of Meetings

DSMB meetings will usually be held by video conference call. The initial DSMB meeting will be held prior to initiation of participant enrollment. If applicable, IRB approval of any protocol revisions that emerge from response to this meeting would need to be obtained prior to initiation of the protocol.

Subsequent meetings will be held via video teleconference at least every six months with additional meetings or conference calls scheduled as needed. The study coordinator in collaboration with the PIs will schedule meetings and conference calls.

The agenda for DSMB meetings and calls may be drafted by the study coordinator and the PIs. The study coordinator will send a draft of the agenda to the Program Officer and the chair of the DSMB for their review. Based on feedback on the draft agenda, the study coordinator will finalize the agenda and distribute the agenda two weeks before each meeting. All meeting and follow-up materials (agendas, reports, minutes, responses) will be distributed electronically.

The purpose of the first meeting will be to:

- Convey expectations for DSMB operations
- Provide an overview of study activities
- Review and accept the protocol or make recommendations for changes related to human subjects safety and ethics
- Review this Charter, confirm any edits to the Charter, and ratify the Charter

In subsequent annual meetings, the DSMB will review study-related adverse events, data quality and completeness, adherence to the protocol, and enrollment data to ensure proper trial conduct. Study personnel should provide any new literature particularly pertinent to the trial, along with their recommendation as to whether it affects the trial conduct or design. The DSMB will review the informed consent form when it reviews the protocol. The DSMB will review the consent periodically and/or as needed and consider whether the consent form requires revision in light of any new findings or amendments.
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No interim analyses or early stopping rules are planned. In addition to regular meetings, it may be necessary to convene the DSMB urgently or on an ad hoc basis to discuss any information that raises questions about equipoise, safety, or anything else that would compromise the trial.

It is expected that all DSMB members will attend every meeting. The Board may wish to decide if particular expertise is needed within the quorum for a particular meeting or if additional members are needed to add to augment the expertise represented in the DSMB in an ad hoc fashion. All standing Monitoring Board members are voting members. The Board may decide in advance whether ad hoc members can vote.

7. Discussion of Confidential Material

DSMB meetings and calls will be organized into open, closed, and executive sessions.

During the open sessions, information will be presented to the DSMB by the study investigators, with time for discussion.

During the closed sessions (as needed), the DSMB will discuss confidential data from the study, including information on efficacy and safety by treatment arm. If the closed session occurs on a conference call, steps will be taken to ensure that only the appropriate participants are on the call, and to invite others to re-join the call only at the conclusion of the closed session. The NIA Program Official, who is considered to be Executive Secretary, can participate in the closed session. The Project Scientists do not participate in the closed session.

The DSMB may hold an executive session in which only the DSMB members are present (i.e., without NIH representatives or Investigators). The DSMB Chair will be responsible for summarizing the DSMB’s discussion and recommendations for executive sessions.

Each meeting must include a recommendation to continue or to terminate the study made by a DSMB majority or unanimous vote. Should the DSMB decide to issue a termination recommendation, the full vote of the DSMB is required. In the event of a split vote, majority vote will rule and a minority report should be appended. The DSMB Chair provides the tiebreaking vote in the event of a 50-50 split vote.

A recommendation to terminate the study may be made by the DSMB at any time by majority vote. The Chair should provide such a recommendation to the NIA immediately by telephone and email. After the NIA Director makes a decision about whether to accept or decline the DSMB recommendation to terminate the study, the PIs will be immediately informed about the decision.

At the conclusion of the closed and executive sessions, the DSMB chair may provide a summary of the preliminary recommendations to the lead investigators to provide an opportunity for study investigators to ask questions to clarify the recommendations.

8. Reports of DSMB Deliberations

Following review by the Principal Investigators, the study manager will send the minutes to the DSMB members for review. After receiving the DSMB members’ input, the study manager will finalize the minutes and transmit them to the DSMB Chair for final review and approval. The DSMB Chair may sign the minutes or indicate approval electronically via email. The final, approved minutes will be sent electronically to the Principal Investigators and will be stored in electronic versions at BMC. A response to action items contained in the minutes will be included in the report for the subsequent DSMB meeting. The Principal Investigators will distribute the meeting minutes to study investigators. It is the responsibility of each clinical center to forward this information to their local IRB.

When a closed session of the DSMB is held, the procedure for reporting the minutes will be similar. However, the minutes from the closed session will be created and stored separately from the session minutes. The minutes from the closed session (drafts of final versions) will not be sent to the Principal Investigators.
The study manager is responsible for preparation and transmission of the formal DSMB minutes 14 calendar days after each meeting or call. Minutes will document whether there is conflict of interest on the part of Board members and will summarize the key points of the discussion and debate, requests for additional information, response of the investigators to previous recommendations, and the recommendations from the current meeting. The minutes are sent to the DSMB Chair, who will approve them on behalf of the DSMB. The minutes from the closed session (drafts of final version) will not be sent to the Principal Investigators.

9. Reports to the DSMB

The DSMB should discuss at the first or subsequent meetings what data they wish to review and how the data should be presented. The study team will be responsible for sharing data with the study team.

10. Statistical Monitoring Guidelines

The DSMB will review the adequacy of the statistical monitoring plan. Because potential adverse effects associated with the planned intervention are likely to be minor, uncommon, and anticipated, no interim analysis of the data is planned. If the DSMB request interim analyses, guidelines should be provided in advance for early termination for benefit, futility, or safety reasons.

11. Confidentiality

All materials, discussions and proceedings of the DSMB are completely confidential. Members and other participants in DSMB meetings are expected to maintain confidentiality.
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Appendix A: DSMB Members

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