



UH2 Project: Pragmatic Trial of Video Education in Nursing Homes

PROVEN

Susan Mitchell, MD, MPH

Vincent Mor, PhD

Angelo Volandes, MD, MPH

April 22, 2015
2:00pm – 3:00pm EST

Attendees:

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| <input checked="" type="checkbox"/> Josie Briggs, MD <i>NIH / NCCIH</i> | <input checked="" type="checkbox"/> Jonathan McCall, MS <i>Duke Clinical Research Institute</i> | <input checked="" type="checkbox"/> Tammy Reece, MS, PMP, CCRA <i>Duke Clinical Research Institute</i> |
| <input type="checkbox"/> Elaine Collier, MD <i>NIH / NCATS</i> | <input checked="" type="checkbox"/> Jerry Menikoff, MD, JD <i>OHRP</i> | <input type="checkbox"/> Marcel Salive, MD, MPH <i>NIH / NIA</i> |
| <input type="checkbox"/> Brett Hagman, PhD <i>NIH / NIAAA</i> | <input checked="" type="checkbox"/> Cathy Meyers, MD <i>NIH / NCCIH</i> | <input checked="" type="checkbox"/> Irene Stith-Coleman, PhD <i>OHRP</i> |
| <input checked="" type="checkbox"/> Catherine Hammack, JD, MA <i>Duke Clinical Research Institute</i> | <input checked="" type="checkbox"/> Jeri Miller, PhD <i>NIH / NINR</i> | <input checked="" type="checkbox"/> Jeremy Sugarman, MD, MPH, MA <i>Johns Hopkins University</i> |
| <input checked="" type="checkbox"/> Lauren Johnson Hartsmith, JD <i>OHRP</i> | <input checked="" type="checkbox"/> Susan Mitchell, MD, MPH <i>Hebrew Senior Life</i> | <input type="checkbox"/> Angelo Volandes, MD, MPH <i>Massachusetts General Hospital</i> |
| <input checked="" type="checkbox"/> Adrian Hernandez, MD, MHS <i>Duke Clinical Research Institute</i> | <input checked="" type="checkbox"/> Vincent Mor, PhD <i>Brown University</i> | <input checked="" type="checkbox"/> Wendy Weber, MD, PhD, MPH <i>NIH / NCCIH</i> |
| <input type="checkbox"/> Cheri Janning, BSN, RN, MS <i>Duke Translational Medicine Institute</i> | <input type="checkbox"/> Andrew Narva, MD <i>NIH / NIDDK</i> | <input checked="" type="checkbox"/> Kevin Weinfurt, PhD <i>Duke Clinical Research Institute</i> |
| <input checked="" type="checkbox"/> Julie Kaneshiro, MA <i>OHRP</i> | <input type="checkbox"/> Jane Pearson, PhD <i>NIH / NIMH</i> | <input type="checkbox"/> Barbara Wells, PhD <i>NIH / NHLBI</i> |
| <input checked="" type="checkbox"/> Julie Lima, MPH, PhD <i>Brown University</i> | <input checked="" type="checkbox"/> Ivor Pritchard, PhD <i>OHRP</i> | |

These minutes were circulated to all attendees for two rounds of review and they reflect all corrections that were received.

| Agenda Item | Discussion | Action Item |
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| Brief review of Pragmatic Trial of Video Education in Nursing Homes (<i>PROVEN</i>) | <ul style="list-style-type: none">• Dr. Mitchell gave an overview of the <i>PROVEN</i> project.<ul style="list-style-type: none">○ <i>PROVEN</i> is a pragmatic cluster randomized controlled trial.○ The study will involve two (2) nursing home systems with a combined total of approximately four hundred and twenty-five (425) nursing homes. The <i>PROVEN</i> team estimates that approximately four hundred and five (405) will meet the eligibility criteria. Of those nursing homes, 230 will be randomly selected and then randomly assigned to the control and intervention arms (115/arm), stratified based on healthcare system and hospitalization rate of patients with advance disease in the prior year. Rate of hospitalization in long-stay patients with advanced dementia, COPD, CHF over 12 months is the primary outcome.○ The intervention is a set of five (5) videos meant to enrich advance care planning by nursing home patients.<ul style="list-style-type: none">▪ Nursing homes in the intervention arm will be rolling out the video program using the existing processes for rolling out new clinical programs, such that the nursing homes will be using the videos as a standard operating procedure in their facilities.▪ Each video is four to six minutes long, uses visual images and verbal descriptions of three levels of care: comfort, intermediate/basic, and aggressive.▪ These videos have been previously tested in traditional efficacy studies. They have been generally well-received and no adverse events have been reported; in fact, all four pilot sites have requested permission to use the videos after the pilots ended, and the videos are currently going through state-wide implementation in Hawaii. | |

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| | <ul style="list-style-type: none">▪ The videos will be shown within seven days of admission; they will be re-shown to long-stay patients approximately every six months.▪ Patients and family can refuse to watch the videos with no undue effect.▪ For intervention nursing homes, the team will be providing the videos and training, which will include a “toolkit” instructing staff on how to implement the video program in the existing work flow of the nursing home <i>and</i> how to use the videos with individual patients. This toolkit is meant to guide nursing home staff while allowing each facility some leeway in determining which patients see which video, who shows the videos to them (for example, social workers or registered nurses), and other logistical matters.○ The study population is all nursing home patients in the control and intervention sites during the 18-month implementation period.<ul style="list-style-type: none">▪ The target population for analyses is long-stay patients who have very advanced diseases (specifically, congestive heart failure, lung disease, and dementia).▪ Secondary analyses include hospitalization rates in short-stay patients with advanced disease and patients without advanced disease.▪ Other secondary outcomes include hospice enrollment and rates of completion of advance directives.○ The team will use existing databases; thus, all data used in PROVEN will have already been collected for clinical or administrative purposes. It was noted that the video status report will become part of the patient’s medical record.○ Dr. Mitchell explained that advance care planning is required in every nursing home by federal law. Thus, advance care planning is already being done in every nursing home involved. The video program is meant to facilitate these ongoing activities, <i>not</i> replace them. In other words, advance care planning is already standard practice in every nursing home regardless of PROVEN.● In response to questions regarding the relationship between the showing of the videos and hospitalization, Dr. Mitchell explained that the intent of the videos is to enhance advance care planning. In all the prior efficacy studies, generally patients with the | |
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| <i>IRB status and approval</i> | <p>aforementioned advanced diseases prefer <i>less aggressive</i> care. Therefore, the PROVEN team expects that once patients in the target population see the videos, as a group they will tend to opt for less aggressive care, which will be translated into advance directives that reflect their preferences, which should translate into fewer avoidable hospitalizations.</p> <ul style="list-style-type: none">• There was some concern raised regarding the videos' potential effects on the care of patients with advanced dementia; those on the call questioned the possibility of the videos' influencing the views of proxy or surrogate decision-makers (or others who may be included in a decision about whether to hospitalize a patient or not).<ul style="list-style-type: none">○ Dr. Mitchell explained that there is a specific video that is <i>about</i> patients with advanced dementia that is intended for proxy or surrogate decision makers. All other videos are all meant to be seen by patients themselves as well as proxy or surrogate decision makers.• In response to questions regarding whether or not the study could include a survey of patients (or proxy or surrogate decision makers) to analyze how (if at all) the intervention influenced their decision making, Dr. Mitchell explained that this is currently being done in more traditional R01s, and that they know from prior studies that patients and families like these videos and would recommend them to others. However, in this instance they opted to <i>not</i> include such a survey because it would not be in the rubric of pragmatic trials, citing the number of nursing home patients and the undue burden on nursing home staff. <ul style="list-style-type: none">• Dr. Mitchell explained that the main trial protocol was submitted to the Brown University IRB in March; approval will likely come through soon. <u>[Post call note:</u> Protocol approval from the Brown IRB was received on April 22, 2015.]• There was a brief discussion regarding attendees' request to view PROVEN's complete and final protocol, insofar as some details of the study were not included in the Summary Document [<i>attached</i>], as it is an extraction of a much larger version.<ul style="list-style-type: none">○ Dr. Sugarman explained that the UH2 Demonstration Projects, including PROVEN, are in varying stages of "protocol" development. Prior to approval | |
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| | <p>from each project's Institutional Review and Data and Safety Monitoring Boards (IRBs and DSMBs), there does not exist a complete and final protocol insofar as each is continuously evolving through these review processes. In an attempt to maintain version control and to avoid burdening meeting attendees with additional information which may change pursuant to the pending IRB and DSMB reviews, draft protocols were not circulated. The Core and NIH is assessing potential processes for the dissemination of final protocols upon IRB and DSMB approval.</p> <ul style="list-style-type: none">• Additional information is included in the Summary Document <i>attached</i> hereto. | |
| <p>Risk <i>Does the project meet regulatory criteria for being considered minimal risk?</i></p> | <ul style="list-style-type: none">• Dr. Mitchell explained her team's justification for proposing that the PROVEN study constitutes minimal risk.<ul style="list-style-type: none">○ As explained earlier, advance care planning is currently part of routine clinical practice as required by federal law. The PROVEN intervention is merely an adjunct to the current standard practice. Thus, the intervention is not expected to pose any additional risk.○ In addition, all data to be used in PROVEN has already been (or will be) collected as part of routine clinical care except that the video status report will be embedded as part of the nursing home's usual workflow. Thus, data collection will not pose any additional risk.• While the video(s) may cause some viewers to become upset, this is not likely to be meaningfully different from existing advance care planning processes. Accordingly, attendees agreed that watching the video(s) likely constitutes minimal risk. However, discussion returned to the issue of the videos' purpose or effect on patients' (or proxy or surrogate decision makers') decisions. So, the question is the possibility of changing a person's decisions in a way that is "<i>incorrect</i>"—or, in other words, in a way that poses <i>more</i> risk to them (than what they would have otherwise decided).<ul style="list-style-type: none">○ Drs. Mitchell and Mor explained that the study's goal is <i>not</i> to change patients' (or proxy or surrogate decision makers') minds or otherwise affect their | |

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| | <p>decisions. Rather, the goal is to provide people with <i>informed</i> decision making such that patients will get care that is aligned with their actual preferences and choices. So, if someone happens to watch a video and thinks that <i>more aggressive</i> care is what they actually want, then this goal is nonetheless met because that decision was <i>informed</i> by the video.</p> <ul style="list-style-type: none">▪ Dr. Mitchell noted that it is difficult to measure the outcome of alignment with goals of care, particularly in a pragmatic trial of this scale.▪ Drs. Mor and Mitchell explained that they are not requiring anyone to complete an advance directive after viewing the video (or ever)—instead, they are merely trying to augment these important advance care planning conversations. <ul style="list-style-type: none">• There was some confusion regarding why PROVEN's primary outcome is <i>hospitalization</i>, which may suggest greater risk, rather than the completion of advance directives regardless of whether they result in hospitalizations or not; attendees believed that the latter would be most informative.<ul style="list-style-type: none">○ Dr. Mitchell reminded the group that they will, indeed, be assessing the rate of advance directive completion as one secondary outcome, or one factor, of many—they believe that it is a link in the causal chain. However, the team is analyzing how the intervention impacts actual <i>care</i>, rather than mere decisions or perceptions about care.○ Dr. Mitchell explained that the primary hypothesis of PROVEN is reduced hospitalization in people with advanced diseases when it is not concordant with their goals of care; the relationship between having an advance directive (specifically, a “do not hospitalize order” (DNH)) translates into a reduced rate of hospitalization. The existing literature supports this hypothesis.• Similarly there was some concern that there will be many instances in which patients' families will be watching a video which may be perceived to be suggesting that they should not hospitalize a family member. In other words, well-intentioned attempts to improve advance care planning and facilitate these conversations may be perceived differently by observers of this study. | |
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| | <ul style="list-style-type: none">Attendees agreed that some concern regarding a minimal risk determination remains. Some indicated that the complete, final protocol may be critical to helping make this determination. <u>[Post-call note:</u> Additional information regarding the selection of hospitalizations for the primary outcome was prepared by the investigators and is appended to the minutes.] | |
| Consent Planned processes for relevant subjects | <ul style="list-style-type: none">Dr. Mitchell explained her team's justification for proposing that individual informed consent should be waived.<ul style="list-style-type: none">Dr. Mitchell explained that because all patients are already engaged in advance care planning per routine practice and the videos are enriching this process, they are not adversely affecting the rights or welfare of patients; if anything, they are <i>enhancing</i> their rights and welfare.<ul style="list-style-type: none">She noted that all patients are free to refuse to view the videos and otherwise decline to participate in the existing advance care planning process; in other words, patients will be offered the intervention, but they can refuse it just the same as they can refuse any part of their clinical care.Furthermore, consent is not otherwise required or part of standard practice in the course of everyday advance care planning.Dr. Mitchell cited practicability also as an issue related to a waiver of consent. Requiring individual informed consent would not be feasible given the large number of nursing homes that are geographically dispersed for an intervention that is delivered in the context of clinical care (and not by research personnel). Dr. Mitchell clarified that the team is not planning to use any public postings or other notifications, nor will there be any opt-out provisions (in addition to waiver); rather, what the team proposes is a simple waiver. | |

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| Privacy Including HIPAA | <ul style="list-style-type: none">• Dr. Mitchell explained her team's justification for proposing a HIPAA waiver for the use of protected health information.<ul style="list-style-type: none">◦ With respect to data management and its effect on privacy and confidentiality, the PROVEN team explained that they will be receiving data directly from the two partners described above, and that these data will be comparable to what they otherwise receive from the Centers for Medicare and Medicaid services (CMS) on a regular basis.<ul style="list-style-type: none">▪ They described their existing procedures as a "well-oiled machine" for bringing information together from various sources, integrating it, protecting it by keeping it in restricted area, and they added that they have passed each of their previous inspections "with flying colors." | |
| Monitoring and Oversight | <ul style="list-style-type: none">• The PROVEN team explained that their Data and Safety Monitoring Board (DSMB), assembled by the National Institute of Aging (NIA) with help from Marcel Salive, MD, MPH, will be providing oversight to this study. The DSMB charter has been outlined, and its initial meeting was held last week and a follow-up meeting will occur on Monday (April 27, 2015).<ul style="list-style-type: none">◦ In response to questions regarding any plans for periodic looks at data, Dr. Mitchell explained that the DSMB will receive data on an ongoing basis.<ul style="list-style-type: none">▪ Each of the three (3) principal investigators (PIs)—Drs. Mor, Mitchell, and Volandes—will be blinded, but the statisticians will be able to review data as it comes in to the extent necessary.▪ The DSMB has not yet decided or communicated to the team what will be required in terms of monitoring, but the team is in position to do whatever is necessary; in other words, they are prepared to adhere to whatever reporting structure the DSMB may require. | |

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| Issues beyond this project <i>Regulatory and ethics concerns raised by the project, if any</i> | <ul style="list-style-type: none">• <i>No questions or concerns raised.</i> | |
| Other | <ul style="list-style-type: none">• There was some discussion regarding whether or not the nursing homes themselves and/or the staff thereof will be engaged in human subjects research.<ul style="list-style-type: none">○ Control sites will not know that they are part of the research study due to pre-randomization; intervention nursing homes will know that a new program is being integrating into the existing advance care planning procedures.○ The Brown University IRB likely would not consider NH staff in the control and intervention sites to be engaged in research.○ The nursing homes and/or staff are not <i>direct</i> subjects because the team will not be collecting any data about them. | |

PARTICIPATING STUDY SITES:

The study is being conducted at 230 NHs owned by Genesis HealthCare and Pruitt Health Care Corporations. Barbara Yody (Genesis) and Sherry Johnson (Pruitt) lead the project at these health care networks.

A. PROJECT SUMMARY

Objective: To conduct a pragmatic cluster randomized control trial (RCT) of an advance care planning (ACP) video support intervention for nursing home (NH) patients cared for in two NH health care systems; Genesis and UHS-Pruitt Health Systems.

Design and Outcomes: Aim 1 of this study is to conduct a pragmatic cluster RCT that will evaluate an ACP video support intervention for patients ≥ 65 with advanced disease cared for in 230 NHs (115/arm) within two NH health care systems, Genesis and PruittHealth Systems. The intervention consists of a suite of 5 videos designed to assist NH patients with ACP decisions. The ACP video intervention will be implemented in NHs assigned to the intervention arm for 18 months. Data needed to assess outcomes will be derived from the NH electronic medical record (EMR) systems merged with Minimum DataSet and Medicare files. NHs randomized to the control arm will use the usual ACP procedures practiced in their facilities.

In this stratified cluster RCT, the unit of random assignment is the facility but the unit of analysis is the patient, clustered within the facility. The intervention will be implemented facility-wide, thus all patients cared for in the NHs during the 18-month implementation period are subjects in this study ($N \sim 97,213$). However, outcomes will be analyzed in targeted sub-populations with advanced comorbid conditions for whom the opportunity and need to improve ACP and goal-directed care are greatest. These subgroups include very disabled older patients with advanced dementia and advanced congestive heart failure (CHF) or chronic obstructive pulmonary disease (COPD) (i.e., cardiopulmonary disease).

Outcomes to be compared between the intervention and control include: advance directives orders (e.g., do-not resuscitate, (DNR), do-not-hospitalize (DNH)), hospitalizations, use of other burdensome interventions (e.g., feeding tubes), and Medicare hospice enrollment. The effectiveness of the intervention to improve these outcomes will be assessed among long-stay (> 90 days) NH residents (Aim 2) and new admissions to post-acute care (short-stay < 90 days) (Aim 3) with advanced illness. Finally, we will evaluate the effects of the intervention by examining the aforementioned outcomes among long-stay NH patients and new admissions who do NOT have either of the pre-specified advanced illnesses (Aim 4). The primary outcome for this pragmatic trial is hospitalizations (quantified as number of hospitalizations/person-day) over a 12-month follow-up period among long-stay residents with advanced dementia and/or advanced CHF/COPD. Secondary outcomes include advance directive orders, other burdensome treatments, and hospice use.

Interventions and Duration: The intervention consists of a suite of 5 videos designed to address common ACP decisions confronting NH patients and their families, including: 1. Basic Goals of Care, 2. Goals of Care for Advanced Dementia, 3. Hospice, 4. Hospitalization, and 5. ACP for the Healthy Patient. NHs randomized to the control arm of the study will use the usual ACP procedures already practiced in their facilities. The ACP video program will be implemented for 18 months in the intervention facilities. Individual patients in both arms who are in the NHs during

the 18-month implementation period are eligible and their outcomes will be assessed for up to 12 months for the long-stay cohort and 100 days in short-stay cohort.

Sample Size and Population: The ACP video intervention will be implemented facility-wide in the NHs randomized to the intervention arm. Thus, ALL patients who are cared for during the 18-month implementation phase are potential participants in the trial and comprise the study population ($N \approx 97,213$). However, the analyses described in Aims 2 and 3 will focus on target populations with advanced comorbid conditions that are cared for in the NHs during the 18-month implementation period. For Aim 2, the target sample are long-stay patients with advanced dementia or CHF/COPD ($N \approx 8652$). As the primary study trial outcome is hospital transfers in the long-stay patients, sample size estimates and power calculations are based on this target group. For Aim 3, the target sample are short-stay patients with advanced dementia or CHF/COPD. For Aim 4 the target sample is long-stay and short-stay NH patients who do NOT have either of the pre-specified advanced illnesses.

In this stratified cluster RCT, the unit of random assignment is the facility. Facilities will be randomized in the following strata in the following order: 1. Health care system (Genesis and Pruitt), and 2. Hospitalization rates in the 12 months prior to recruitment in target sub-populations (grouped as terciles). Outcomes analyses will not differ by strata.

STATUS OF INSTITUTIONAL REVIEW BOARD REVIEW (IRB): Brown University is central site for approvals. Approval received for pilot study. Application for full trial was submitted in March and approval is pending.

B. RISK: We are seeking a minimal risk determination for the PROVEN trial as per HHS 45 CFR 46.102: “*Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*”

Justification for a minimal risk determination is based on several considerations. First, all NHs must engage patients and families in ACP as part of routine clinical practice. There is currently no standardized method by which NHs conduct ACP. PROVEN will compare a practice intervention (rolled out in intervention sites as standard operating procedures as directed by corporate leadership) that uses videos to enrich ongoing ACP practices. Prior studies evaluating the ACP videos by our group included several hundred subjects, including healthy older adults, NH patients, family members of patients with life-limiting illnesses and patients with advanced cancer and congestive heart failure. The videos were also tested in our UH2 pilot study. Finally the videos have been seen by thousands of patients in Hawaii as part of an on-going state-wide implementation program. In prior research, our pilot testing, and Hawaii initiative, there were no instances of untoward viewer distress and the videos never had to be stopped because of adverse viewer reactions. Thus, we believe the intervention does not incur any greater distress than usual ACP practices.

Second, data collection also conforms with the definition of minimal risk. No direct input from the resident or family member is needed to complete any data for this study. All the data are already being collected as part of routine medical care (EMR, MDS, Medicare data). The only additional data being collected in the intervention NHs is the Video Status Report, which is being embedded into the EMR. The Video Status Report is needed to monitor intervention fidelity and will be incorporated into the intervention facility’s ACP protocol.

Adverse Events and Serious Adverse Events: The potential *adverse event (AE)* that could occur during this trial is serious distress by patients or family members in the intervention NHs while viewing an ACP video. As described above, we anticipate that such AEs will be exceedingly rare. Nonetheless, serious distress may be manifested as a very negative emotional reaction while watching, or after watching, a video, asking for the video to be stopped, or leaving the room while a video is being shown. Due to the sensitive nature of the material, tearing up by the proxy can be expected and is not deemed to be a reflection of distress.

We do not believe that there are any potential consequences of this trial that meet the definition of *serious adverse events (SAEs)*.

(We do not believe death should be considered a SAE for the PROVEN trial for the following reasons. First, the study is being conducted in a frail NH population with advanced illnesses. Thus, death is often not an unexpected event in their clinical course. Second, all NHs must engage patients and families in ACP as part of routine clinical practice. The videos are meant as an adjunct to facilitate ACP counseling. The underlying intent of all ACP, regardless of how it is done, is to help patients make informed treatment decisions so they receive care that is concordant with their preferences. For patients who prefer comfort or palliation as a main goal of care (vs. life prolongation), death is not an adverse outcome. Finally, it is not known whether more aggressive care (i.e., hospitalization) would result in greater mortality compared to less aggressive care (i.e., conservative or palliative treatment on-site in the NH). Therefore, while we hypothesize that there will be fewer hospitalizations among NH patients with advanced disease randomized to the intervention arm (vs. control), it is impossible to predict how this may impact mortality rates.)

C. INFORMED CONSENT: There are special informed consent considerations for individual patients in this pragmatic, cluster RCT. The NH is the unit of randomization, the intervention is of relatively low risk, and will be implemented facility-wide as part of the intervention facilities' standard operating procedures for ACP. In the control arm, usual care for ACP will be in place. In both study arms, all data will be ascertained from existing sources. NH administrators, who either agree or disagree to facility participation in the intervention arm are serving as gatekeepers for the study. Thus, we will seek a waiver of individual informed consent so as set forth by the four criteria found in HHS 45 CFR 46:116.¹³⁷

(1) *The research involves no more than minimal risk:* See Section B for rationale for Minimal Risk Determination

(2) *The waiver will not adversely affect the rights and welfare of the subjects:* All NHs must engage patients and families in ACP as part of routine clinical practice. There is currently no standardized method by which NHs conduct ACP. The ACP video program is intended to enrich ongoing ACP practices in the intervention NHs. Study randomization is at the level of the NH, not the patient. While the patients in the intervention arm are not informed of the study itself they are asked whether or not they want to be shown the video. They are free to decline as they are free to decline any type of ACP discussion. Patients in control NHs will be exposed to usual care. For NH residents in both study arms, we will be using data previously collected for non-research purposes (EMR and CMS data). These data will be obtained and managed in a confidential manner for study purposes (see Section 10.2).

(3) The research could not practicably be carried out without the waiver: It would be impossible to conduct this *pragmatic trial* if it required ascertainment of individual informed consent for several reasons. Doing so would undermine the very intent of the pragmatic trial design; to test whether the videos are effective in a “real-world” application under usual conditions. ACP is part of usual NH care and is simply being augmented in the intervention facilities with the videos. Getting written informed consent is not ‘usual’ for everyday NH care. In that vein, members of the NH staff are offering the videos to the patients in the intervention facilities, not the research team. The ACP videos are being integrated into the NHs’ standard operating procedures and offered to ALL NHs residents as part of the facility’s daily work-flow. It would not be feasible for the NH staff to obtain informed consent from all residents being offered the videos, especially since the videos are being integrated into the standard of care in that NH. With regards to data acquisition, all the data used in the study are already being collected for non-research purposes in both the intervention and control NHs. If permission to use these data were required by way of informed consent, this would have to be done for ALL residents in all facilities by staff in BOTH the control and intervention NHs. It would be impossible and put undue burden on the NH staff and the residents themselves to collect individual consent for the use of their records. Such an approach would once again undermine the pragmatic intent of the study and also dramatically reduce both NH and patient participation to the extent the study would not be possible.

(4) If appropriate, the subjects will be provided with additional pertinent information after participation: We will provide the NH corporations, Pruitt and Genesis, with copies of the reports and manuscripts that result from this project. They are free to share the information with their NHs and the NHs will be free to share the information with interested families and patients.

D. PRIVACY: We request a HIPAA Waiver of Requirement for Authorization for Release of Protected Health Information for Research Purposes from the Brown IRB to conduct this study. Brown University’s Center for Gerontology and Health Care Research will receive EMR patient-level data from Pruitt and Genesis. Both NH systems have integrated sophisticated EMR systems in their facilities. Genesis uses PointClickCare™, and UHS-Pruitt uses American Health Tech. The NH networks already have experience extracting MDS from their EMR systems for purposes of submitting mandatory, regular MDS reports to CMS. To protect patient confidentiality, the two corporations will place their data in a SSH secure server; and will provide login information to Brown. Data transfer to Brown secure servers will be via SFTP protocol with password protection. Once the files have been uploaded to Brown's servers they will be stored, unmodified, in a secure file location specific to these uploads. They will then be read into SAS datasets, one per file type. Brown will then notify the facilities that the data was successfully downloaded and extracted, at which point the facilities will remove the data from their servers. All data files will be accompanied by a manifest detailing the number of distinct persons and records expected in them. Brown will connect to the corporation servers on a weekly basis. Identifiers such as HICs and SSNs, will be included in order to be able to merge these person-level data to the data received from CMS. Brown’s information systems manager will be in charge of the data transfer, and he will replace the HICs and SSNs fields with a Brown-generated identification number (throughout our different data sources) to allow linkage of data for analytic purposes.

E. MONITORING AND OVERSIGHT: A Data and Safety Monitoring Board (DSMB) for PROVEN 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. External DSMB members include: Christine S Ritchie, MD, MSPH (University of California San Francisco) (Chair), Cynthia J. Brown, MD, MSPH (University of Alabama at Birmingham), and Arthur V. Peterson, Jr., Ph.D (Department of Biostatistics, University of Washington). Members of the PROVEN team who will participate in the open sessions of the DSMB include the 3 co-PIs (Mitchell, Mor, Volandes), the lead biostatistician (Gatsonis), and project director (Elaine Bergman). The NIA project officer for PROVEN, Dr. Marcel Salive, will attend DSMB meetings and serve as the liaison between the DSMB and NIA. A PROVEN DSMB Charter outlines its roles and responsibilities.

F. OTHER ISSUES:

We have submitted our IRB application for full trial from the perspective that the NH staff are NOT engaged in human subjects research.

PROVEN: SUPPLEMENTARY MATERIAL
BACKGROUND AND RATIONALE FOR THE PROVEN TRIAL

2.1. Epidemiology: Nursing homes (NHs) care for approximately 3 million individuals annually, including 1.5 million frail older persons with advanced chronic disease requiring long-term care, and a growing proportion of seriously ill patients admitted for post-acute care.^{1, 2} Approximately 11% of Americans over 85 years reside in NHs. In the past 3 decades, NHs have evolved into complex health care systems serving an increasingly sick and heterogeneous population. While NHs serve a growing number of patients recuperating from acute illnesses, they also are a common site of care for patients with very advanced disease who may be nearing the end-of-life.³ In 2009, 45% of US Medicare beneficiaries who died were in a NH during the last 90 days of life, and 28% died in that setting.⁴ Taken together, NHs are often charged with guiding patients with complex medical problems and advanced illness through challenging decisions about the direction of their treatment.

2.2. Need to improve advance care planning (ACP) in NHs: Advance care planning (ACP) is a process of communication between providers and patients/families to identify anticipated medical decisions and clarify goal-directed treatment preferences. Ideally, ACP leads to completion of *advance directives that come into effect if/when a patient becomes incapacitated*. Advance directives include living wills, appointment of a health care proxy, and formal medical orders to withhold specific treatments, such as resuscitation. In observational studies, ACP is the strongest and most consistent modifiable factor associated with better outcomes in the NH setting for patients with very advanced chronic illnesses.⁵⁻¹⁰ The lack of advance directives has been associated with greater use of feeding tubes,^{8, 11, 12} more terminal hospitalizations,^{6, 13-15} higher health care costs,¹⁰ worse family satisfaction and mental health outcomes,^{7, 11, 16, 17} and lower hospice use.^{11, 18}

The Patient Self-Determination Act (PSDA) of 1991 mandated that NHs ascertain and document patients' advance directives.¹⁹ Unfortunately, advance directive completion remains inadequate and does not always reflect the patient's goals of care.^{5, 7, 9, 19-25} The proportion of NH patients with DNR orders increased from 31% in 1990 to 52%,²⁰ but has remained relatively unchanged thereafter.²⁶ Other, perhaps more consequential directives for NH patients, were not influenced by the PSDA and continue to be low. In 2007, only 4% of US NH patients had DNH orders and 11% had orders to withhold tube-feeding.²⁶ Not surprisingly, markers of the quality of end-of-life care, such as terminal hospitalizations, have also not improved.²⁶ Other serious concerns related to advance directives in the NH persist, most notably marked racial and regional disparities,^{9, 27-30} and very low completion rates in post-acute care, where only 32% and 2% of patients have DNR and DNH orders, respectively.³⁰

There have been some, albeit limited, efforts to design and evaluate approaches other than legislation to improve advance directives in NHs.³¹ An RCT from the late 1990s of an advance directive program in 6 Ontario facilities resulted in more advance directive documentation, fewer hospitalizations, and lower expenditures, with no change in survival.³² A more recent initiative is the Physician Order for Life-Sustaining Treatment (POLST) program, which translates treatment preferences into medical orders that are documented on a form designed to be portable across care settings. POLST does not intervene on the process of counseling patients about how to make preference-based decisions. While many states have adopted POLST programs in NHs,³³ its efficacy and effectiveness are under-studied. A retrospective cohort study from 90 NHs found that POLST resulted in care consistent directives and greater advance directive documentation.^{34, 35}

There is growing recognition that improving goal-directed care in NHs will require greater focus on improving the *process* of ACP (i.e., helping to prepare patients for medical decision-making), rather than just static advance directive completion.^{19, 36-38} In one of the few rigorous RCTs designed to improve this process, social workers were trained how to have structured ACP discussions with all newly admitted NH patients.³⁹ This approach reduced unwanted care and increased advance directive documentation, but was never adopted into practice perhaps because such complex interventions are resource intensive, require on-going staff training, and are difficult to replicate across facilities. A recent meta-analysis of implementation studies underscored both the challenge and need to find ways to routinely incorporate ACPs in clinical settings where multiple and competing demands impact on practice.⁴⁰ Interventions most likely to meet with success are those that make elements of ACP workable within complex and time pressured clinical workflows. The proposed pragmatic RCT of the video ACP program addresses many of the lessons learned, research gaps, and on-going concerns about ACP in NHs by rigorously evaluating the implementation of a standardized, practical intervention that targets the ACP process in two large NH systems.

2.3. Hospitalizations of NH patients with very advanced illness: There is broad concern in the clinical and scientific communities,^{6, 41-44} US federal agencies,⁴⁵ and media³ about decisions to hospitalize NH patients with very advanced illnesses for whom hospital-level care may be non-beneficial, potentially harmful, and not aligned with the patient's treatment preferences. An estimated 15% of frail NH patients are hospitalized in the last week of life.²⁶ Between one-third and one-fifth of patients in sub-acute skilled nursing facilities (SNFs) are re-hospitalized within 30 days.⁴⁶ Prior work reports suggest that 23-60% of hospitalizations of NH patients are either unnecessary or unwanted, and if averted, could potentially save the US health care system billions of dollars annually.^{41, 42, 45, 47, 48}

A basic tenet of high-quality medical decision-making is that patients (or their proxies) are fully informed of the risks and benefits of treatment options and their choices are aligned with their goal of care (i.e., prolongation of life vs. comfort). For NH patients with advanced disease, such as those in the PROVEN trial's target population with very advanced cancer and cardiopulmonary disease, the potential disadvantages and advantages of hospitalization for a new medical problem versus treatment at the NH must be carefully understood and weighed in the context their underlying health status and preferences. The most common acute illnesses precipitating hospitalization decisions in such patients include infections, shortness of breath, and transient changes in mental status.^{6, 13, 41-44}

Care transitions places all NH patients at risk of medical errors, complications, and adverse drug events.^{49, 50} For very frail NH residents hospitalization can be particularly traumatic as it typically involves uncomfortable tests and interventions.^{22, 51-53} For some NH patients, these burdens and risks may be acceptable in order to receive potential curative or life-sustaining treatments. However, for older NH patients with very advanced chronic illnesses and a limited prognosis whose primary goal of care is comfort, the risks of hospitalization often outweigh the benefits. For example, patients with advanced dementia are at the final stage of a progressive, incurable illness, and typically are bedbound, no longer recognize family members, dependent on others for all their care, and have minimal verbal ability. Over 90% of proxies for NH residents with advanced dementia state they want comfort-focused care. Hospitalization seldom promotes comfort with rare exceptions, such as a hip fracture. Hospitals are also a key site of treatment decisions although decision-making is often suboptimal due to the discontinuity of care, unfamiliar providers, and pressures for timely discharge.⁵¹⁻⁵⁴ For example, 68% of feeding tubes are placed in NH residents with advanced dementia during a hospitalization⁵³, an intervention that has no demonstrable benefits in this population and associated risks.⁵⁵⁻⁵⁸ In fact, leading organizations American Geriatric Society, ABIM Foundation Choosing Wisely campaign, American Association of Hospice and Palliative Medicine, and Alzheimer's Association have position statements against tube-feeding in advanced dementia.⁵⁵⁻⁵⁸

For NH patients with advanced chronic illness who want potentially curative but relatively conservative care (e.g., antibiotics) that does not include aggressive intensive care (e.g., mechanical ventilation), treatment on-site at the NH may also be reasonable. Many of the conditions precipitating hospitalization (i.e., infections), can be usually treated with the same efficacy in the NH.⁵⁹⁻⁶² For those patients with advanced disease who still want to receive all potential life-prolonging treatments that can only be provided in a hospital setting (e.g., care in an intensive care unit, mechanical ventilation, surgery), even with the understanding that such treatments may be transiently uncomfortable and not successful, then hospitalization may make sense.

Taken together, informed decision-making and ACP is a key strategy to ensure NH patients are transferred to the hospital only when it is concordant with their wishes. Prior research suggests that when ACP is better integrated into NH care, fewer NH patients are hospitalized. NHs with higher rates of DNR orders, a marker of facility culture with better ACP, have lower hospitalization rates among dying patients.²⁶ A before and after study of an ACP-focused intervention in NHs reduced re-hospitalization rates by 20%.⁶³ The Interventions to Reduce Acute Care Transfers (INTERACT) program, of which ACP is a key component, has also been shown to reduce NH hospitalizations.⁴³ The underlying premise for these observations is that when NHs provide more judicious ACP that includes information about the risks and benefits of hospital-level care together with counseling about how to weigh this information with preferences, NH patients with very advanced chronic illnesses are more likely to opt for on-site care in the NH.⁴⁵ **It is this reasoning that underlies the choice of hospitalization rates among long-stay NH patients with advanced dementia and advanced cardiopulmonary disease as the primary outcome of the PROVEN trial, and our hypothesis that the ACP video program will reduce hospitalization rates in this population.**

2.4. Video decision support tools improve ACP for multiple conditions: The traditional approach to ACP primarily relies on ad hoc verbal descriptions of hypothetical clinical states and interventions. This approach is limited because complex scenarios are difficult to envision, provider information is inconsistent, and verbal

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explanations are hampered by literacy and language barriers. Decision support tools have been used to overcome some of these barriers,⁶⁴⁻⁷⁰ and are meant to supplement, not replace, provider counseling by providing standardized information about options, and a framework for weighing options with preferences.

More than 700 decision support tools exist, including 50 that utilize videos.⁶⁸⁻⁷⁰ Video addresses some of the limitations of traditional verbal ACP by providing realistic visual images of complex medical scenarios. A growing body of work, including several RCTs, supports the effectiveness and feasibility of video decision support tools for ACP for various advanced illnesses (e.g., dementia, cancer, heart failure) and among patients in different settings (out-patient, hospital, short-term rehabilitation) (see *Section 3.C.i.c. Preliminary Studies*).⁷¹⁻⁸⁰ These studies consistently find that subjects who view the video compared to those who listen to verbal information, have greater knowledge about their condition and treatment choices, and are more likely to choose less aggressive interventions as their preferred care. Findings also show that the videos reduce the racial and health literacy disparities that typically characterize traditional verbal counseling.^{74, 81}

The promise of video for ACP is reflected by the widespread attention this work has received by the scientific community,⁸²⁻⁸⁴ media,^{85, 86} the US Congress, and early adoption by major health care systems. Kaiser Permanente, Group Health Cooperative and the Palo Alto Foundation are currently using the ACP videos in their out-patient and hospital practices. The state of Hawaii is using these tools across health care settings, including NHs. However, none of these efforts involve formal research designs or evaluation. Thus, the proposed pragmatic trial is a logical next step towards understanding the real world application of a video ACP support tool for NH patients.

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