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## **Goals of Care Study Protocol**

### **Administrative Information**

**Study title:** Goals of Care: A Nursing Home Trial of Decision Support for Advanced Dementia

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## **Protocol Introduction**

### **Background**

Nursing home care is common in for persons with advanced dementia and 67% die in this setting. Dying residents have high rates of pain, dyspnea, problems with personal cleanliness, and emotional distress. Family decision-makers express more dissatisfaction with communication and care in nursing homes than any other setting. Poor communication is a major practical barrier to improved care.<sup>1,2</sup> One retrospective study found 71% of residents had resuscitation and 30% end-of-life hospitalization contrary to their preferences.<sup>3</sup> In the prospective CASCADE Study (Choices, Attitudes and Strategies for Care of Advanced Dementia), Mitchell followed 323 nursing home residents with advanced dementia and surrogates for 18 months. Only 38% of surrogates recalled involvement in medical decisions, and less discussion was associated with poor quality care.<sup>4 5</sup>

Over 20 randomized trials show decision aids improve time efficiency and quality of decision-making by improving knowledge and reducing conflict for patients.<sup>6,7,8,9,10</sup> They influence treatment choices in studies of prostate cancer screening, hysterectomy, and genetic testing.<sup>11,12,13</sup> Two recent trials found video decision aids on advance care planning increased geriatric or oncology outpatients' interest in comfort care.<sup>14,15</sup>

*Decision support research has addressed key outpatient choices, yet many clinically and ethically significant decisions are made by surrogates who speak for seriously ill patients.<sup>16</sup> In intensive care, printed information and structured family meetings improve knowledge and reduce emotional distress.<sup>17,18,19</sup> Surrogates for persons with dementia experience similar caregiver stress and anticipatory grief, yet the nature of this illness requires them to make health care decisions for years.<sup>20</sup> We completed the first randomized trial of a decision aid intervention for surrogates, addressing the choice of feeding options in advanced dementia.*

Use of the goals of care framework is endorsed in professional ethics and included in prominent national training curricula for end-of-life care.<sup>21</sup> Exploring and defining goals of care allows decision-makers to 1) frame treatment choices based on ability to achieve goals, and 2) create care plans inclusive of treatments to promote chosen goals, not just treatments to be withheld. While a few studies establish its feasibility, no clinical trial translates this framework into practice. Dementia patients in a small qualitative study were able to select goals of care.<sup>22</sup> In a larger descriptive study, patients (50% vs. 16%) and their surrogates (44% vs. 13%) favored the goals of care approach to advance care planning over a treatment-based approach, and usually prioritized goals of function and comfort.<sup>23</sup> Physicians are able to discern a logical pattern of treatments related to goals.<sup>24</sup>

One pre-post study asked nursing home residents or surrogates to prioritize the goals of longevity, function, and comfort, and accept one of 5 care plans. Of 38 participants, 71% of residents and 88% of surrogates were willing to prioritize goals.<sup>25</sup> Another pre-post study of goals of care decision-making in a Program for All-inclusive Care of the Elderly site showed a temporal shift toward prioritizing palliation.<sup>26</sup> These studies show the feasibility and promise of goals of care interventions.

## **Study Aims**

Family decision-makers in **intervention** sites will receive a decision support intervention with two components: a decision aid followed by a structured interdisciplinary care plan meeting. The **control** decision-makers will view a video about dementia care of similar length, and participate in routine nursing home care planning. An attention control condition was chosen to ensure that the content of decision support, and not simply additional interpersonal attention, is tested. The **overarching objective** is to test whether decision support for Goals of Care can improve quality of communication and decision-making, and improve the quality of palliative care for nursing home residents with advanced dementia.

**Aim 1.** To test the effect of the Goals of Care decision support intervention compared to *an attention control*, on the quality of communication and decision-making, defined at 3 months follow-up as:

- a) quality of communication
- b) surrogate – health care provider concordance on goals of care, and
- c) surrogate report of treatment consistent with *the resident's* wishes

*Hypothesis 1: Compared to controls, surrogates in the intervention group will report significantly higher quality of communication, greater concordance on goals of care, and treatment more consistent with the wishes of the resident with dementia.*

**Aim 2.** To test the effect of the Goals of Care decision support intervention on quality of palliative care for residents with advanced dementia, defined at 6 months follow-up as:

- a) number of palliative care domains addressed for the resident in the care plan
- b) symptom management
- c) surrogate satisfaction with care for advanced dementia.

*Hypothesis 2: Compared with controls, residents in the intervention group will have a significantly higher number of palliative care domains addressed in their quarterly care plans.*

*Hypothesis 3: Compared with controls, residents in the intervention group will have significantly better symptom management, and surrogates will have greater satisfaction with care for advanced dementia.*

**Aim 3.** To test the effect of the Goals of Care decision support intervention on quality of dying for residents with advanced dementia, measured after death as:

- a) surrogate – health care provider concordance on goals of care, and
- b) resident comfort in dying.

*Hypothesis 4: Compared with controls, residents' comfort in dying in the intervention group will be significantly higher.*

## **Methods**

### **Study design**

Initial research, including our own, demonstrates the acceptability and feasibility of goals of care decision support for surrogate decision-makers for persons with dementia. We propose a **cluster randomized trial** to test a decision support intervention for Goals of Care in advanced dementia. Family decision-makers in **intervention** sites will receive a decision support intervention with two components: a decision aid followed by a structured interdisciplinary care plan meeting. The **control** decision-makers will view a video about dementia care of similar length, and participate in routine nursing home care planning.

### **Study setting**

Study subjects will be recruited in 20 skilled nursing facilities in North Carolina, varied in size, profit status, and diversity of residents. We expect 23 eligible resident-surrogate dyads per site. We expect to enroll 65-69% of those eligible, or 15-16 dyads per site, to reach 300 participants.

### **Participant Eligibility**

Study subjects will be 300 residents with advanced dementia and their surrogates. Enrollment criteria are associated with 6-month mortality risk of 28%, resulting in clinical triggers to utilize Goals of Care to frame specific treatment decisions.

- **INCLUSION:** Nursing home residents with “moderate to severe dementia”
  - Age 65+
  - Diagnosis of dementia
  - Score 5, 6 or 7 on GDS (update GDS every 3 months)<sup>27</sup>
  - Surrogates who are the LAR – guardian, Health Care Power of Attorney, or the usual family surrogate decision-maker identified by the face sheet in the chart. The decision maker may live out of the local area, but must speak English.
  - Hospice enrollees are included, MOST participants are included; Hospice is invited to Care Plan meeting for study participants
- **EXCLUSION:** patients whose surrogate is a court appointed guardian who is a non-family member.
- **EXCLUSION:** participants from the NPCRC Goals of Care pilot will not be eligible.

### **Intervention and Control**

The 2-part intervention consists of the Goals of Care Decision Aid and a structured care plan meeting to discuss goals of care. During their baseline interview, intervention surrogates will view the audiovisual Goals of Care Decision Aid, covering content on dementia, goals of care, treatment approaches to expect with each choice, and personal goals. It concludes with prompts to talk with treating physicians, and “Questions to Consider in Care Planning.” During viewing of the Decision Aid, Research Assistants will be present but will not discuss or add information. Within a few weeks

intervention surrogates will be invited to the structured Goals of Care meeting with the interdisciplinary team. The meeting protocol uses the “VALUE” principles for family meetings, addresses the role of the surrogate, answers questions on health status and examines goals and a related treatment plan. Treating physicians, nurse practitioners or physician’s assistants will be encouraged but not expected to attend. They will receive a copy of the Goals of Care plan and must approve any changes in orders. The team will allow 30-60 minutes for this meeting, consistent with usual meetings for a change in health status.

We will use an attention control condition. During their baseline interview, control surrogates will view an informational video on ways to interact with dementia patients, with content on dementia, its causes and stages, and stage-specific ways a family caregiver can communicate with and engage the person with dementia.<sup>28</sup> This control is relevant to surrogates but neutral for outcomes. Research Assistants will be present but will not add information. Within 2 weeks control surrogates will be invited to usual care plan meetings with the interdisciplinary team. All other aspects of study participation will be identical.

## **Fidelity Assessment**

INTERVENTION: Completed Care Plan Guide data will be collected on all meetings

- May be completed by telephone with liaison / IDT leader
- A random 10% sample of INTERVENTION care plan meetings will be audio-recorded to add data on fidelity.
- Core: Fidelity to the intervention – sites must meet this criterion for 70+% of participants
  1. Surrogate reviews DA (Baseline interview)
  2. Surrogate participated in meeting, and asked for input on treatments within 3 months; can occur outside the usual care plan meeting schedule; at least 2 disciplines from staff must participate (Guide; use 3 month interview as back-up source)
- Descriptive: Quality of the intervention
  1. Components of the meeting – health status, goals discussed, choice of goal, treatment plan confirmed or changed (Guide; use 3 month interview as back-up source)
  2. Participation by MD / NP / PA providers (Guide)
  3. Quality of communication with care plan team – VALUE items (3 / 6 month interviews)
  4. Documentation of the meeting – discussion of goals, setting a primary goal, treatment decisions confirmed or made (3 / 6 month chart reviews)
  5. Audiotapes of 10% of meetings – confirmation of components of the meeting (tape transcript vs. Guide)

## **Outcome Measures**

### **Primary Outcome Measures Aim 1**

- Quality of Communication will be measured interviews using the Quality of Communication (QOC) instrument.<sup>29</sup> Respondents rate 13 items on a 10-point scale, to give potential scores ranging from 0 (“very worst”) to 10 (“very best”). A score of 0 is imputed for no communication; missing values are imputed to the median. Summary scores are generated as the mean score of all items; a separate item rates communication overall. The QOC has convergent validity with measures of

overall communication and understanding; it has been used in research on family meetings.<sup>30</sup> Items form two subscales measuring general (Cronbach's alpha=0.91) and end-of-life communication (Cronbach's alpha=0.79).

- Health care provider-surrogate concordance on goals of care will be defined as the percent of surrogates that report a primary goal (comfort, function, survival, other) the same as the primary goal for providers. At each Follow-up Interview, surrogates will be asked; "The most common medical goals for treatment are prolonging life, maintaining function, and improving comfort. Which goal would you say is the best goal to guide his / her care and medical treatments?" Response options include these three medical goals, "other" or "uncertain." They will also answer "Based on your discussions with the nursing home staff and physician, which of these goals is their top priority for his / her care and medical treatment?"
- Treatment consistent with wishes will be measured using the Advance Care Planning problem score from the Toolkit Family Interview.<sup>31</sup> The Toolkit is a reliable and valid instrument based on a conceptual model of patient-focused, family centered end of life care. The Toolkit includes "problem scores" for domains of care; each problem score is valid for independent use.<sup>32,33</sup> The Advance Care Planning problem score consists of 3 items assigned one desired answer; a "problem score" is calculated as percent of respondents giving a non-desired answer to one item:
  1. Did RESIDENT's doctor or the nursing home staff who care for him / her speak to you about his / her wishes about medical treatment? (YES / NO)
  2. Did his / her doctor or the nursing home staff who care for him / her speak to you about making sure his / her care was consistent with his / her wishes? (YES / NO)
  3. Since I last spoke with you, was there any medical procedure or treatment that happened to him / her that was inconsistent with his / her previous wishes? (YES / NO)
- Combined results for these three measures are identified as the primary study outcome for clinical trial registration (Clinicaltrials.gov NCT 01565642, 3/26/12)

### **Outcome Measures Aim 2**

- Number of palliative care domains addressed for resident plan of care will be measured by reviewing the relevant Care Plan at each time point for content in 10 domains of palliative care -- prognosis, goals of care, plan for physical symptoms, plan for emotional needs, plan for spiritual needs, and 5 treatment preferences: resuscitation, artificial feeding, intravenous fluids, antibiotics, and hospitalization. Since the goal of the intervention is to improve shared decision-making regardless of treatment choice, domains will be scored on whether they are addressed; not choice for or against a treatment. Each domain will be scored as present or absent for a potential score of 0-10. For example, a point will be given if resuscitation was addressed, regardless of a choice for or against. We estimate a baseline score of 2 domains.
- Symptom Management will be measured using the Symptom Management at the End of Life in Dementia (SM-EOLD) instrument, developed and validated concurrently with the SWC-EOLD and CAD-EOLD below. This instrument measures symptom control for 6 psychological and 3 physical symptoms common in advanced dementia. Items are rated on a 0-5 categorical scale and summed, for a total potential score of 0-45. This instrument has good internal consistency (Cronbach's alpha 0.68 to 0.78) and convergent validity with a quality of life measure for dementia. Originally designed for after-death interviews, it has been successfully modified for use in a prospective cohort study of advanced dementia care.<sup>34,35,36</sup>

- Satisfaction with Care will be measured using the reliable and valid Satisfaction With Care at the End of Life in Dementia (SWC-EOLD) which includes 1 month recall of family satisfaction with decision-making, information, nursing and medical care; 10 items are rated 1-4 and summed, for a total potential range of 10-40. It has good internal consistency (Cronbach's alpha 0.83-0.90) and convergent validity ( $r=0.81$  with the Decision Satisfaction Inventory). Like the SM-EOLD, this instrument has been modified to gather prospective data.<sup>34'35'36</sup>

### **Primary Outcome Measures Aim 3: After Death**

- Health care provider-surrogate concordance on goals of care (see above) We will use this measure comparing the final quarter chart review before death to surrogate's reports in After Death interview.
- Comfort in Dying will be measured using the Comfort Assessment in Dying for Dementia instrument (CAD-EOLD). This instrument asks the surrogate to rate 14 items rating comfort during the dying phase of dementia. Subscales measure physical distress, emotional distress, well-being and symptoms of active dying. All items are rated on a 3-point Likert scale and summed, for a total potential score of 14-42. The instrument demonstrates good internal consistency (Cronbach's alpha 0.82-0.85) and convergent validity ( $r=-0.50$  with a quality of life measure for dementia).<sup>34'35'36</sup> This measure will be used in After Death interviews.

### **Additional Secondary Outcome Measures**

- Quality of Life in Dementia will be measured using the Quality of Life in Late-Stage Dementia scale (QUALID) in each Surrogate Interview. The QUALID is developed for advanced dementia patients who cannot rate their own quality of life. Surrogates rate 11 items (range 12-45). Internal consistency is good (alpha = 0.77); inter-rater and test-retest reliability are very good ( $r=0.83$  and  $0.81$ ).<sup>37,38</sup>
- Quality of Dying in Long-term Care (QOD-LTC) – This instrument (Cronbach's alpha = 0.66) measures the family surrogate's perception of the quality of the dying experience; it will be measured in After Death Interviews. This 11-item instrument has 3 subscales measuring personhood, closure and preparatory tasks before dying. Items are rated on a 5-point scale for a total potential score of 5-55.<sup>39</sup>
- Frequency of communication will be defined as the number of discussions of goals of care with providers reported by surrogates after each follow-up interval. Communication with physician, nurse practitioner, physician assistant, or nursing home staff will be rated 0-1 and summed (range 0-3). Communication with physicians in hospital will be described but not counted, as it is dependent on use of hospitalization.
- Hospice referral will be measured by recording presence and date of referral from Chart Reviews.
- Hospitalizations will be measured by recording the rationale and date from Chart Reviews.

## **Randomization**

- Matching and randomization of sites in blocks of size 4, matched by profit / non-profit, percent African-American.
- Study biostatistician randomizes sites using computerized random number generation

- Randomization allocation concealed until assigned to site
- PI, Project Manager, Biostatistician and site liaisons are aware of assignment

## Blinding

- Project team members who are collecting outcomes data, and study subjects are blinded to assignment

## Sample Size

We have an adequate sample necessary to detect clinically meaningful differences between intervention and control conditions for our primary outcomes. Statistical power is shown based on 2-sided alpha of 0.05 significant tests, and using standard deviation estimates from published measures **(3.4.f.)** adjusting for correlation among respondents within nursing homes. Power calculations are corrected for anticipated dropout and potential non-independence of observations within the 20 nursing homes (clusters), using potential intra-class correlations of 0.01, and 0.05, based on observed intra-class correlation in our prior work. As an example, for the number of palliative care domains for Aim 2a, we expect 95% power to see at least a 2 point improvement in the intervention arm compared to the control group at six months, and 79% power after death, based on an intra-class correlation of 0.01. We did not calculate power for the outcome concordance on goals of care since it is not a standardized measure. Power to detect clinically meaningful differences is excellent and 3 and 6 months, and good after death.

**Table 5: Power for Comparing Intervention and Control Arms Based upon the Study Design with 20 NHs and intraclass correlations of 0.01 (1<sup>st</sup> entry) and 0.05 (2<sup>nd</sup> entry)**

Aim	Measure (range)	Baseline Mean	SD	Mean Difference Or Percent	Follow-up occasion		
					3 Mos. n=285	6 Mos. n=243	After Death n=135
1a	Overall QOC (0-10)	8.8	1.7	0.8	95,85	NA	73,64
	EOL Communication (0-10)	3.8	2.8	1.5	98,93	NA	83,75
1c	ACP Problem	--	--	20%*	94,83	NA	71,63
2a	Number of PC Domains (0-10)	2	4	2	97,90	95,87	79,71
2b	SM-EOLD (0-45)	36.4	7.8	4	98,91	96,88	81,73
2c	SWC-EOLD (10-40)	30.9	4.1	2	97,88	94,85	77,69
3	CAD-EOLD (14-42)	33.6	5.0	3	NA	NA	91,85

\*15% vs 35%

## **Study Standards and Operational Procedures**

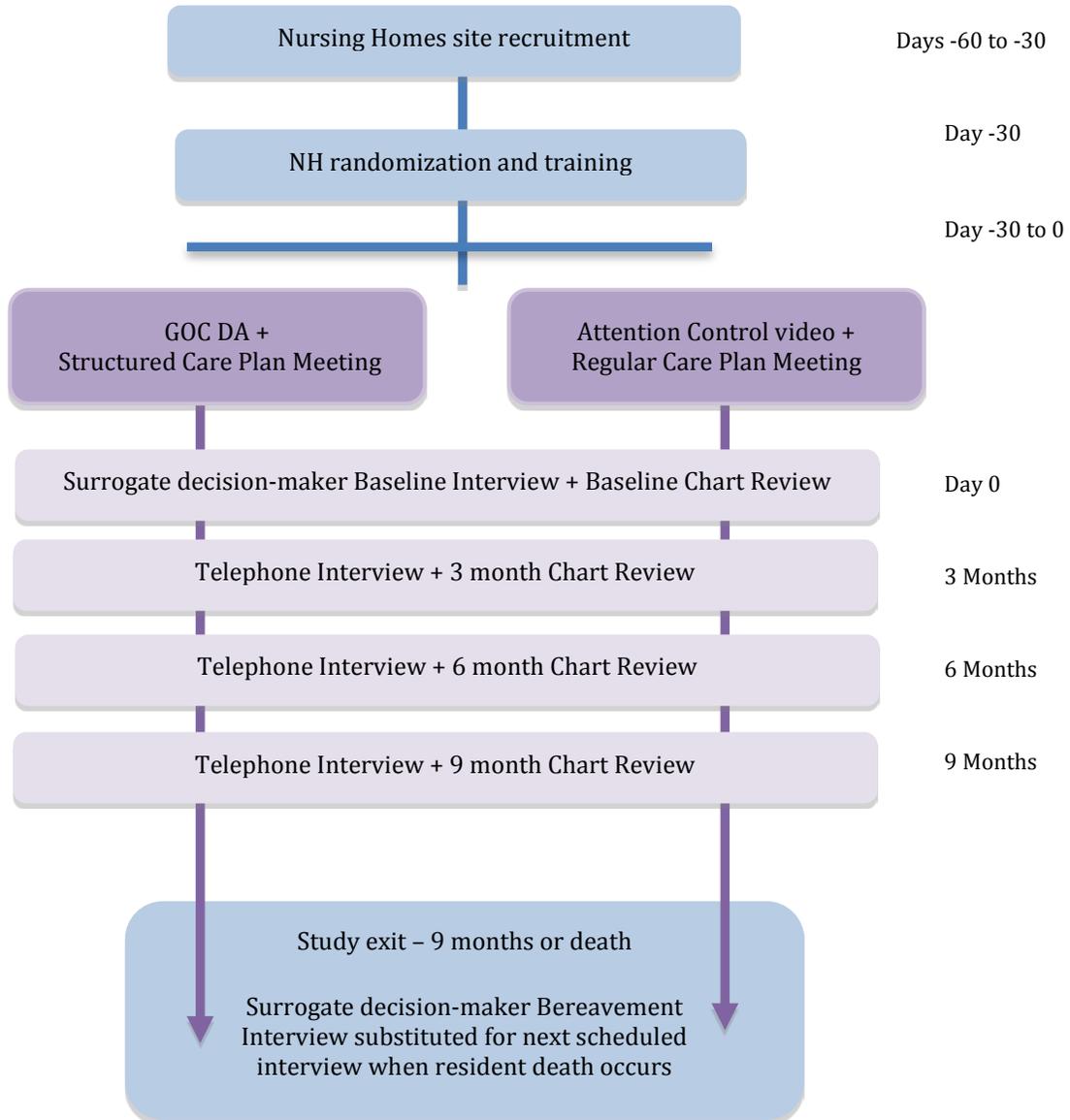
### **Recruitment of Nursing Home Sites**

- Set up introductory meetings at 20 nursing home sites to confirm participation and ensure HIPPA and Human Subject protections
  - Initial calls by PI to administrator confirm interest in hearing more about the study.
  - Introductory meeting obtains nursing home leadership agreement to participate regardless of how the site will be randomized (INTRODUCTION document).
  - Each site designates a staff liaison who will facilitate communication about study procedures between other nursing home staff and research staff.
  - The staff liaison helps facilitate referrals and determine where to file the study consents and HIPPA authorizations at the facility.
- Set up secondary meetings after randomization at 20 nursing home sites to review study procedures
  - INTERVENTION: At intervention sites only, the second meeting introduces the care plan team and other facility staff to recruitment, data collection procedures, and the nature of the intervention. Participants see the Goals of Care decision aid, learn about the “VALUE” principle approach, and are taught to use the “Care Plan Guide” to guide and record the GOC care plan meeting. They are encouraged to consider use of sample goal-directed care plans, MD communication care to promote MD role, and specialized documentation (e.g. MOST) to record decisions made in the meeting.
  - CONTROL: At control sites only, the second meeting introduces the care plan team and other facility staff to recruitment, data collection procedures, and the attention control video. Care plan meetings will continue as usual in the control sites.
- Each nursing home site will receive a \$250 incentive for each quarter they are able to successfully recruit subjects or up to a \$1000 incentive per site.

### **Provider Approval and Engagement**

- The Medical Director is contacted by the PI or other MD investigator to review the study and give approval for participation. Physician investigators introduce the study to each treating physician, NP or PA by telephone; they also offer to meet face-to-face or to share a 1-page summary by the providers’ preferred method of contact.
- All MD, NP, and PA providers with eligible residents are contacted by the PI or other MD investigator to review the study and give approval for participation by their residents and families.
  - INTERVENTION ONLY: MD, NP and PA providers receive a written notice of the GOC Care Plan meeting time and location; notice may be given before the meeting (if the provider plans to attend) or after (if the provider prefers to follow-up later); providers with enrolled residents and families are given a time-limited option to view the GOC Decision Aid.

## Participant Timeline



## Recruitment of Subjects

- Retrieve names of potential subjects from nursing home liaison, identifying residents with probable moderate to severe dementia. Initial screening may include MDS C1000=2,3 for impaired decision-making for efficiency in sites with electronic access to the MDS. Initial screening may also include talking with primary nurses about their residents using the GDS.
- Use a HIPPA waiver to conduct a screening chart review of nursing home record. Residents who are 65+, have a diagnosis of dementia, and a moderate to advanced dementia score of a 5, 6 or 7 on the Global Deterioration Scale (GDS) per the resident's primary nurse, and a valid surrogate are eligible.
  - Defined data tracking used for refusals to ensure generalizability
- Update the GDS score review every 3 months
- Recruiting letters come from the nursing home; cover letter or recruiting letter on NH letterhead (NIH requirement).
- Send recruiting letters 6 weeks or more before their scheduled care plan meeting to give time for the baseline interview to occur before the meeting.
- Allow 7-10 days to pass after recruiting letters are mailed, and then begin recruiting calls.
- Have a toll free number on recruiting letter and an opt out card for decision makers to mail in if they do not want to receive a recruiting call.
- Recruiting calls can permit decision-makers time to decide; if currently stressed or with competing time demands, they may delay the decision to participate until a later date.

## Data Collection: Nursing Home Organizational Variables

- Each participating nursing home liaison completes a short data form with variables describing the nursing home site and the resident population it serves; data includes organizational characteristics, resident descriptors, current use of MOST, Hospice contract, and any specialized on-site palliative care approaches or services; LTC Focus site and NH Compare can be used to abstract some of this data.

## Baseline Data Collection

- Complete written informed consent and baseline interview in person; subjects will be paid \$35 for the baseline interview.
  - INTERVENTION subjects will view the Goals of Care video decision aid
  - INTERVENTION subjects will receive a paper copy of the decision aid and a Care Plan Guide to further review and to share with other family members involved in the decision making process.
  - CONTROL subjects will view the dementia informational video
  - Families whose usual decision-making approach is to include more than one surrogate will be allowed to include other family members in the interviews; however, the primary decision-maker will be the unique research participant and will take final responsibility for interview responses. The total number of additional participants will be recorded as a variable.
- *If decision maker lives out of town*, complete consent process through the mail and complete baseline interview over the phone. The INTERVENTION decision aid or CONTROL video will be

reviewed either by DVD or online through [www.vimeo.com](http://www.vimeo.com) depending on ease of use and internet access. A link to the decision aid will be emailed to those opting to view the decision aid online. This link is password protected, and the password will be changed after each interview. The DVD, with explicit directives to wait for instructions from the interviewer before viewing, will be mailed to those preferring that option.

- Complete a full baseline chart review at the time of enrollment.
- Measurement of communication / treatment in 10 palliative care domains including prognosis, goals of care, plan to assess and treat physical symptoms, plan to assess and meet emotional needs, plan to assess and meet spiritual needs, and preferences for use of 5 treatments: resuscitation, artificial feeding, antibiotics, hospital transfers and hospice will be inclusive of evidence found in progress notes / orders / care plan. Training for each data collector will specifically include testing of inter-rater reliability for this variable, as it is constructed uniquely for this study.

### **Care Plan Meeting**

- In INTERVENTION sites, the next quarterly care plan meeting, or special meeting for “change in health status” outside the care plan schedule will be scheduled with invitations to the surrogate, the IDT, and the treating MD, NP or PA.
  - This meeting may be a “special” meeting or part of the routine care plan meeting schedule, but must include at least 2 disciplines
  - MD, NP or PA providers will receive written notice of the meeting beforehand, or after if they do not plan to attend (see MD LETTER)
  - The staff liaison will complete the Care Plan Meeting Guide after the meeting, to provide fidelity data
  - The staff liaison will be encouraged, but not required, to provide the treating MD, NP or PA with information regarding the surrogate’s need for further communication and discussion of treatment options (see MD / NP / PA Communication)
- In CONTROL sites, care plan meetings will be scheduled as usual.
- During and after the care plan meeting, care plans and treatment decisions will remain completely controlled by the primary MD / NP / PA, the nursing home team, and the surrogate decision maker.

### **Follow-Up Data Collection**

- The 3 month, 6 month, and 9 month (from baseline date) follow-up interviews with decision makers provide primary, and most secondary outcome measures.
  - AIM 1 – Quality of Communication, Toolkit ACP Problem Score, Surrogate / IDT concordance on primary goal of care
  - AIM 2 – SM-EOLD (symptoms), SC-EOLD (satisfaction with care), # palliative care domains addressed
  - AIM 3 – CAD-EOLD (comfort in dying), Surrogate / IDT concordance on primary goal of care

- OTHER SECONDARY OUTCOMES – quality of life (ADRQL), quality of dying (QOD-LTC), frequency of communication, hospice referral, hospitalizations, Family Perceptions of Physician-Family Caregiver Communication (FPPFC)
- Subjects will be paid \$35 for 3 and 6 month follow-up interviews and \$50 for 9 month interviews.
- All chart reviews will also examine interval changes in health status and goals of care or treatments, and surrogate and MD / NP / PA provider presence at care plan.
- 9 month chart review: The 9 month chart review’s window will extend one week outside of the due date to account for information that may be entered in the chart late.
- If the enrolled surrogate decision develops their own disabling illnesses or cognitive difficulties over the 9 month follow-up period, the facility liaison will be contacted to discuss how to proceed with the remaining follow-up interviews. If the facility is still considering the enrolled decision maker to be the legally authorized representative, the PI will determine if the follow-up interviews need to be suspended due to the decision maker’s declining health or cognitive status. If the facility liaison indicates another family member is now the legally authorized representative, the new decision maker will be sent a letter of invitation. If this decision maker agrees to participate in the study, the interviews will begin with the Baseline interview with the new family decision maker.
- BEREAVEMENT INTERVIEW – If a resident with dementia dies, the next and final follow-up interview will be modified in wording to reflect review of treatment during the final phase of illness.
  - INTERVENTION surrogates
    - Asked to complete an extended bereavement interview with the additional audiorecorded qualitative interview reflecting on their experience with Goals of Care decision-making; this expanded interview requires addendum consent.
    - Interviewers to be flexible about timing of the interview and whether it is on the phone or in person
    - Shorter telephone version may be completed if participation in extended format is refused.
  - CONTROL surrogates
    - Bereavement interviews all over phone

## **Analysis Plan**

QB- Baseline Interview, Q3- 3 month follow-up interview, Q6- 6 month follow-up interview, Q9- 9 month follow-up interview, QD- After-Death interview  
 CB-Baseline Chart Review, C3- 3 month chart review, C6- 6 month chart review, C9- 9 month chart review, CD- After-Death chart review

### **Analysis to meet Aim 1: Quality of Communication and Decision Making**

To test the effect of the Goals of Care decision support intervention on the quality of communication and decision-making, we will compare control and intervention groups on pre-specified outcomes; we will focus on 3 month data.

*Hypothesis 1: Compared to controls, surrogates in the intervention group will report significantly higher quality of communication, greater concordance on goals of care, and treatment more consistent with the wishes of the resident with dementia.*

#### 1.a. Quality of Communication:

- Quality of Communication (QOC): Baseline [QB\_M10a-m and QB\_M30a-m] and 3mo & 6mo FU Interview [Q3,6\_I10 a-m and Q,3,6\_I30 a-m]
  - 13 items on a 10-point scale, 0=very worst – 10=very best
  - 1 overall summary score and 2 subscales
    - Summary score= mean score of all items
    - Subscale 1- General Communication= mean score of items a-f
    - Subscale 2- End-of-Life Communication= mean score if items g-m
    - Missing values are imputed to the median for the individual (DK, missing)
    - OMIT items for which 30% or more of respondents have missing data
    - “Didn’t do” is scored as “0” (assumption is that communication should be present for seriously ill patient care)
  - Higher numbers indicate better communication
  - Change scores will be created comparing 3 month scores to baseline

#### 1.b. Surrogate – Health Care Provider Concordance on Goals of Care:

- Concordance on Goals: Baseline Interview [QB\_D20 & QB\_D30], 3mo FU Interview [Q3\_D20 & Q3\_D30], 6mo FU Interview [Q6\_D20 & Q6\_D30], 9 mo FU Interview [Q9\_D20 & Q9\_D30], & After Death Interview [QD\_D20 & QD\_D30]
  - 1= Concordant - Surrogate goal (from interview) and perceived nursing home goal (from interview) are the same.
  - 0= Discordant - Surrogate goal (from interview) and perceived nursing home goal (from interview) are different
  - Percent of surrogates with 1=Concordant
- Separate Analysis on Concordance: Baseline Interview [QB\_D20] & Baseline CR, [CB\_42], 3mo FU Interview [Q3\_D20] & 3mo FU Chart Review [C3\_43], 6mo FU Interview [Q6\_D20] & 6mo FU Chart Review [C6\_43], & 9mo FU Interview [Q9\_D20] and 9mo FU Chart Review [C9\_43], & After Death Interview [QD\_D20 & CD\_43]
  - 1= Concordant - Surrogate goal (from interview) and Care Plan goal (from CR) are the same.
  - 0= Discordant - Surrogate goal (from interview) and Care Plan goal (from CR) are different
  - Percent of surrogates with 1=Concordant

#### 1.c. Treatment Consistent with Resident’s Wishes:

- Advanced Care Planning (ACP) Problem Score: Baseline [QB\_L30-L50]
  - 3 items assigned to the following desired answers
    - 1= non-desired response (L-30=No, L-40=No, L-50=Yes)
    - 0= desired response (L-30=Yes, L-40=Yes, L-50=No)
  - Problem score calculated as % of subjects with at least one non-desired response
  - Separately calculate % with non-desired response to each item
  
- ❖ Decisional conflict: Baseline [QB\_I-10 a-c, QB\_I-20 a-c, QB\_I-30 a-c, I-40 a-c, I-50 a-d] and 3mo & 6mo FU Interviews [Q3,6\_F-10 a-c, F-20 a-c, F-30 a-c, F-40 a-c, F-50 a-d]
  - 5-point Likert scale, 1=strongly agree – 5=strongly disagree
  - Lower numbers indicate lower decisional conflict
  - 1 overall summary score and 5 subscales
    - Subscale 1(QB\_I-10 a-c & Q3,6\_F-10 a-c)= Decision Uncertainty
    - Subscale 2 (QB\_I-20 a-c & Q3,6\_F-20 a-c )= Informed Subscale
    - Subscale 3 (QB\_I-30 a-c & Q3,6\_F-30 a-c)= Values Clarity Subscale
    - Subscale 4 (QB\_I-40 a-c & Q3,6\_F-40 a-c)= Support Subscale
    - Subscale 5 (QB\_I-50 a-d & Q3,6\_F-50 a-d)= Effective Decision Subscale
  - All Don't Know answers should be coded to midpoint (3)
  - If the Score or Subscore is reported as a percentage or on a 0-100 scale no conversion is required. If the average Score or Subscore is reported on the 1-5 scale then to convert these scores to the equivalent 0-100 scale; a) subtract 1 from the score; b) then multiply by 25. If the Score or Subscore is reported as a sum of items that used the 1-5 scale then to convert these scores to the equivalent 0-100 scale: a) divide the score by the number of items summed; b) then subtract 1; c) then multiple by 25.

### **Analysis to meet Aim 2**

To test the effect of the GOC decision support intervention on quality of palliative care for residents with advanced dementia; we will focus on 6 month data.

*Hypothesis 2: Compared with controls, residents in the intervention group will have a significantly higher number of palliative care domains addressed in their quarterly care plans.*

*Hypothesis 3: Compared with controls, residents in the intervention group will have significantly better symptom management, and surrogates will have greater satisfaction with care for advanced dementia.*

#### **2.a. Number of Palliative Care Domains Addressed for Resident in the Care Plan**

- Palliative Care Domain Score: Baseline CR [CB\_41-50] and 6mo FU CR [C6\_42-51]
  - Each domain scored present or absent, range 0-10
    - Scored on whether they are addressed, not choice for or against a treatment
  - 10 items: prognosis, goals of care, plan for physical symptoms, plan for emotional needs, plan for spiritual needs, resuscitation, artificial feeding, IV fluids, antibiotics, and hospitalization
  - Change scores will be created comparing 6 month scores to baseline

## 2.b. Symptom Management

- Symptom Management at the End of Life in Dementia (SM-EOLD) Scale: Baseline [QB\_O-10-90] and 6mo FU Interviews [Q6\_L10-90]
  - 0-5 categorical scale, 0=never – 5=every day
  - **Responses are summed, Range 0-45**
    - ALL ITEMS EXCEPT O-40 (as well as L-40 in follow-up interviews) require reverse coding for calculation of the total score
  - 3 physical symptoms: pain, shortness of breath, and skin breakdown
  - 6 psychological items: calm, depression, fear, anxiety, agitation, and resistance to care
  - Higher scores indicate better control of symptoms
  - Missing values are imputed to the subject's mean score
    - If more than 2 items (25%) are missing the participant's responses should be excluded for them scale score

## 2.c. Satisfaction with Care

- Satisfaction with Care at the End of Life in Dementia (SWC-EOLD): Baseline [QB\_N10-100] and 6mo FU Interviews [Q6\_K10-100]
  - 4-point Likert scale, 1=strongly disagree – 4=strongly agree
  - **Responses are summed, Range 10-40**
    - N-20, 50, and 100 (as well as K-20, 50 and 100 in follow-up interviews) require reverse coding for calculation of the total score
  - Higher scores indicate greater satisfaction with care
  - Missing values are imputed to the subject's mean score
    - If more than 2 items (25%) are missing the participant's responses should be excluded for them scale score

## Analysis to meet Aim 3

To test the effect of the Goals of Care decision support intervention on quality of dying for residents with advanced dementia, measured after death.

*Hypothesis 4: Compared with controls, residents' comfort in dying in the intervention group will be significantly higher.*

## 3.a. Surrogate – Health Care Provider Concordance on Goals of Care:

- Concordance on Goals: After Death Interview [QD\_D20 and QD\_D-30]
  - 1= Concordant - Surrogate goal (from interview) and perceived nursing home goal (from interview) are the same.
  - 0= Discordant - Surrogate goal (from interview) and perceived nursing home (from interview) are different
  - Percent of surrogates with 1=Concordant
- Separate Analysis on Concordance: After Death Interview [QD\_D20] and After Death Chart Review [CD\_43]

- 1= Concordant - Surrogate goal (from interview) and Care Plan goal (from CR) are the same.
- 0= Discordant - Surrogate goal (from interview) and Care Plan goal (from CR) are different
- Percent of surrogates with 1=Concordant

### 3.b. Comfort in Dying

- **Comfort Assessment in Dying for Dementia (CAD-EOLD):** After Death Interview [QD\_M 10-140]
  - 3-point scale, 1=not at all, 2=somewhat, 3=a lot
  - **Responses are summed, Range 14-42**
    - M-120, M-130, M-140 Serenity, Peace, and Calm require reverse coding for calculation of the total score
  - Higher scores indicate better symptom control
  - 1 overall summary score and 4 subscales
    - Subscale 1= Physical Distress (discomfort, pain, shortness of breath, and restlessness)
    - Subscale 2= Emotional Distress (anxiety, fear, moaning, and crying)
    - Subscale 3= Well Being (serenity, peace, and calm)
    - Subscale 4= Active Dying (choking, gurgling, difficulty swallowing, and shortness of breath)
  - Missing values are imputed to the subject's mean score
    - Summary score- if more than 3 items (25%) are missing the participant's responses should be excluded
    - Subscale 1- if more than 1 item is missing, participant's responses excluded from subscale
    - Subscale 2- if more than 1 item is missing, participant's responses excluded from subscale
    - Subscale 3- if any items are missing, participant's responses are excluded from subscale
    - Subscale 4- if more than 1 item is missing, participant's responses excluded

### Secondary Outcome Measures

- Quality of Life in Dementia
  - **Alzheimer Disease Related Quality of Life (ADRQL):** Baseline Interview and 9 mo follow-up interview [QB,9\_10-1-12, QB,9\_20-1-8, QB,9\_30-1-15, QB,9\_40 1-5, QB,9\_B50 1-7]
    - 2 point scale, 1=Agree, 2=Disagree
    - Subscale 1= Social Interaction (B10\_1, B10\_2, B10\_3, B10\_4, B10\_5, B10\_6, B10\_7, B10\_9, B30\_1, B30\_9, B30\_15, B40\_3)
    - Subscale 2=Awareness of Self (B10\_10, B20\_1, B20\_2, B20\_3, B20\_5, B20\_6, B20\_7, B50\_1)
    - Subscale 3=Feelings and Mood (B10\_11, B10\_12, B30\_2, B30\_3, B30\_4, B30\_5, B30\_6, B30\_8, B30\_10, B30\_11, B30\_13, B50\_5)
    - Subscale 4=Enjoyment of Activities (B40\_1, B40\_2, B40\_4, B40\_5)

- Subscale 5=Response to Surroundings (B30\_7,B50\_2, B50\_3, B50\_7)
  - 0 assigned to responses which do not reflect a good quality of life
  - Higher numbers indicate higher quality of life
  - Step 1. Score each domain by summing the scale value (please refer to end of this document for scale values) assigned to the responses across items in that domain.
  - Step 2. Divide the total from Step 1 by the maximum total scale value for the domain.
  - Step 3. Multiple the result (or quotient) from Step 2 by 100 to obtain a percentage score ranging from 0 to 100.
  - To calculate an overall score for the ADRQL, sum the scale values assigned to the responses across all 40 items in the instrument and divide the sum by the maximum total scale value for the overall ADRQL, then multiple the quotient by 100 to obtain a percentage score. Table A.2 lists the maximum total scale values for the 5 ADRQL domains and for the overall ADRQL that should be used
  - To score the ADRQL when one or more items are missing, subtract the scale value for each item that is missing from the maximum total scale value (see Table A.2). The resulting *modified* maximum total scale value should be used as the denominator in Step 2 of the scoring procedures described above.
- Quality of Dying in Long-term Care (QOD-LTC): After Death Interview [QD\_N10-110]
  - 5-point scale, 1=not at all – 5=completely
  - Range 1-5
  - Higher score indicates a more positive dying experience
  - 1 overall mean summary score and 3 subscales
    - Subscale 1= Personhood (kept clean, compassionate touch, dignity, who person, and comfortable with nurse or aide)
    - Subscale 2= Closure (humor, prepared to die, and at peace)
    - Subscale 3= Preparatory tasks (treatment preferences in writing, appointed a decision maker, and planned funeral)
  - Missing values are imputed to the mean score
    - Summary score- if more than 2 items (25%) are missing the participant's responses should be excluded
    - Subscale 1- if more than 1 item is missing, participant's responses excluded from subscale
    - Subscale 2- if any items are missing, participant's responses excluded from subscale
    - Subscale 3- if any items are missing, participant's responses are excluded form subscale
- Knowledge questions about dementia: Baseline Interview [QB\_E10-80]
  - E10, E50, E80=true,
  - E20, E30, E40, E60, E70=false
  - Number correct

- Frequency of communication: Baseline [QB\_K-10 – K60] and Follow-up interviews 3 & 6 mo [Q3,6\_G10- 50]
- Treatment clarification questions [QB\_H10-H270]: Descriptive
- Hospice referral: Follow-up Chart Reviews [C3,6,9,D\_13]
- Hospitalizations: Follow-up Chart Reviews [C3,6,9,D\_15]

### **Covariates**

- Demographics
  - Surrogate age [QB\_R20], gender [QB\_R10], race and ethnicity [QB\_R40], religious affiliation [QB\_R60] and degree [QB\_R50]: Baseline Interview
  - Resident race and ethnicity [QB\_Q30], religion [QB\_Q40]: Baseline Interview
  - Resident age [CB\_4] and gender [CB\_3]: Baseline CR
- Family visit frequency: Baseline Interview [QB\_A20-40]
- Surrogate Spiritual Well-Being
  - Functional Assessment of Chronic Illness Therapy – Spiritual Well-being Scale (FACIT-Sp) : Baseline Interview [QB\_P10-120]
- Functional status: Baseline CR [CB\_9a-g]
- Dementia stage: Baseline CR [CB\_5 & 6]
- Severity of illness: Baseline & Follow-up CR's – Use Adept Score

### Adept Score

Give the points indicated for each of these (max points=32.5)

[CB\_7\_D] Nursing home stay <90 days: 3.3 points

[CB\_4] Age:

- 65 but <70: 1 point
- 70 but <75: 2 points
- 75 but <80: 3 points
- 80 but <85: 4 points
- 85 but <90: 5 points
- 90 but <95: 6 points
- 95 but <100: 7 points

Greater than or = to 100: 8 points

[CB\_3] Male: 3.3 points

[CB\_18, C3\_27, C6\_27, C9\_27, CD\_27 ]=1, 2 or 3 (Shortness of Breath): 2.7 points

[CB\_25, C3\_34, C6\_34, C9\_34, CD\_34]= 2,3, or 4 (At least one pressure ulcer, greater than or equal to stage 2): 2.2 points

[CB\_9, C3\_18, C6\_18, C9\_18, CD\_18 ]=28: (Total dependence for ADL's): 2.1 points

[CB\_31, C3\_40, C6\_40, C9\_40, CD\_40 ]=1(yes for bedfast): 2.1 points

[CB\_29, C3\_38, C6\_38, C9\_38, CD\_38]= 1 (yes, leave ≥25% at most meals): 2.0 points

[CB\_10, C3\_19, C6\_19, C9\_19, CD\_19 ]=1(yes for bowel incontinence): 1.9 points

[CB\_21 and CB\_22, C3\_30 and C3\_31, C6\_30 and C6\_31, C9\_30 and C9\_31, CD\_30 and CD\_31]: (BMI <18.5 kg): 1.8 points

[CB\_23, C3\_32, C6\_32, C9\_32, CD\_32]= 1 (yes for Weight Loss): 1.6 points

[CB\_12, C3\_21, C6\_21, C6\_21, C9\_21, CD\_21 ]=1(yes for CHF): 1.5 points

- Surrogate perception of prognosis: Baseline Interview [QB\_C10]
- Advance directives: Baseline CR [CB\_35]
- Mortality: Facility staff and North Carolina Death Index
- Nursing home characteristics: Organizational Survey
  - % feeding tubes, bed size, % Medicaid, profit status, staffing ratio, staff turnover, and presence of palliative care or special approaches to palliative care or dementia

### Care Plan questions

Interview Data- All descriptive data

- Decision maker care plan attendance: Baseline Interview [QB\_K20], 3,6,9 mo and bereavement interview [Q3,6,9,D\_E10]
  - 0=No
  - 1=yes; Date of meeting[Q3,6,9,D\_E10\_specify]
  - 2=No, but other family attended and role of family[Q3,6,9, D\_E10\_FR\_specify]
- Care plan team ask input on treatment decisions: 3,6,9 mo and bereavement interview [Q3,6,9,D\_E20]
  - 0=No
  - 1=yes
  - Open ended treatments discussed [Q3,6,9,D\_E20\_SP]
- Care plan team value input : 3,6,9 mo and bereavement interview [Q3,6,9,D\_E30]
  - 1=Never, 2=Sometimes, 3=Most of the time, 4=All of the time, 7=Don't Know, 8=Refused
  - Open ended team value input [Q3,6,9,D\_E30\_SP]
- Care plan team pay attention to emotions you may be feeling: 3,6,9 mo and bereavement interview [Q3,6,9,D\_E40]
  - 1=Never, 2=Sometimes, 3=Most of the time, 4=All of the time, 7=Don't Know, 8=Refused
  - Open ended team pay attention to emotions [Q3,6,9,D\_E40\_SP]
- Care plan team listen to what you have to say: 3,6,9 mo and bereavement interview [Q3,6,9,D\_E50]
  - 1=Never, 2=Sometimes, 3=Most of the time, 4=All of the time, 7=Don't Know, 8=Refused
  - Open ended team listen [Q3,6,9,D\_E50\_SP]
- Care plan team understand "Resident" as a person: 3,6,9 mo and bereavement interview [Q3,6,9,D\_E60]
  - 1=Never, 2=Sometimes, 3=Most of the time, 4=All of the time, 7=Don't Know, 8=Refused
  - Open ended team understand [Q3,6,9,D\_E60\_SP]
- Decision Maker encouraged to ask questions: 3,6,9 mo and bereavement interview [Q3,6,9,D\_E70]

- 1=Never, 2=Sometimes, 3=Most of the time, 4=All of the time, 7=Don't Know, 8=Refused
  - Open ended response encouraged to ask questions [Q3,6,9, D\_E70\_SP]
- Care plan meeting most helpful: 3,6,9 mo and bereavement interview [Q3,6,9,D\_ E80]
  - Open ended response
- Ways to improve care plan meeting [Q3,6,9,D\_ E90]
  - Open ended response

Chart Review Data- All descriptive data

- Decision maker care plan attendance: [C3,6,9,D\_3]
  - 0=No
  - 1=Yes, Date of Care Plan
- Primary Health provider attendance: [C3,6,9,D\_4]
  - 0=No
  - 1=Yes, Date of Care Plan
- Discussion of Goals documented in care plan: [C3,6,9,D\_5]
  - 0=No
  - 1=Yes
- Any discussion of changes to key treatment decisions: [C3,6,9,D\_6]
  - 0=No
  - 1=Yes
  - Open ended response changes to key treatment decisions [C3,6,9,D\_SP]
- Goal of Care documented in care plan: [C3,6,9,D\_7]
  - 0=No
  - 1=Yes, Goal chosen [C3,6,9,D\_7\_SP]

## **Research Ethics**

### **Data Management and Storage**

All data will be maintained in confidentiality, and confidentiality protections will be included in study staff research training. Data collection will employ standardized data forms, accessible in paper or electronic versions. Study data will be collected entered on-site into the study database using electronic data capture when possible; however, as many NHs will not have internet access some data will be entered from paper forms on secured computers at the university. All databases will be constructed for direct data entry by Research Assistants, with centralized data management and quality checks. Standardized electronic data validation checks will be developed within the database constructs using data entry discrepancy flags, programmed query rules, and, in certain cases, external rules using SAS code.

Monthly reports (in aggregate and by NH site) will be generated summarizing accrual, completeness of follow-up, and study withdrawals. Periodic reports will be generated at the request of the Project Manager or the Principal Investigator. The study Biostatistician will generate all these reports, working collaboratively with the Data Analyst and the Data Management team.

The study database complies with current data security standards, and provides real-time data entry validation, and provides audit trails documenting any changes or corrections of the study data. Data entry or review requires logging into a secure portal with a username and password. The database is hosted by the Cecil Sheps Center for Health Services Research at the University of North Carolina-Chapel Hill, and is HIPAA-compliant. Explicit identifying information will be recorded on separate forms and will NOT be sent to the database; these forms will be maintained in a secure location.

### **Human Subjects**

**Participants:** The target population is n = 300 nursing home residents (150 in control, 150 in intervention group) with advanced dementia. Residents with dementia are participants for chart review, but family surrogate consent and participation is required for all residents as the severity of their dementia will make them incapable of informed consent. Surrogate decision-makers will be defined as the legally authorized representative (LAR) for the resident with dementia, a) their guardian, b) Health Care Power of Attorney, or if no HCPOA is available, c) the usual family surrogate decision-maker identified by the primary nurse or physician. Study sites will have 20-30% minority residents, and we anticipate 25% minority participation.

**Potential Risks:** The primary risk of this study for family surrogates is emotional distress related to learning more about dementia prognosis and goals of care decisions for frail and cognitively impaired residents. Participation in the study, particularly in the intervention group, may draw family members' attention to serious illness, and may result in anxiety over the health consequences of these problems. Primary risk to nursing home residents is loss of confidentiality. Care plans and treatment decisions will remain completely controlled by the primary treating physician, the nursing home team, and the surrogate decision-maker.

**Adequacy of Protection Against Risks:** All study procedures, informed consent forms, and recruitment procedures will undergo review by the Institutional Review Board at the University of

North Carolina-Chapel Hill prior to initiating research, and will be subject to annual and other required reviews. At the introductory meeting in each nursing home site, we will ensure that procedures are in place to protect human subjects.

- Each nursing home will be included in a Federal Wide Assurance (FWA) agreement with the primary Institutional Review Board (IRB) at the University of North Carolina, or with a local IRB with which they have a previous agreement. In the latter instance, we will seek secondary IRB approval prior to enrollment.
- All surrogate decision-makers will provide written informed consent for their participation, and surrogate informed consent for the participation of the person with advanced dementia for chart review data collection. Through the informed consent process, we will address the risks of confidentiality and of emotional distress for family surrogates. We will provide information on confidentiality protections, and will inform the participants of their right to skip items, pause during participation, or withdraw from the study at any time.
- We will identify a referral resource for distressed family members within each facility, including on-site social workers for emotional distress and hospice for bereavement support. Drs Hanson and Zimmerman will discuss any surrogate concerns with RAs, and facilitate appropriate referrals in coordination with on-site social workers.
- We will address the protection of confidential medical information from nursing home residents recorded in structured chart review. All health status and health care utilization data will be recorded on coded forms without personal identifiers. Data will be entered in a password protected secure database, and all documentation will be maintained in locked files.
- During the course of data collection, the Research Assistant may identify serious but previously untreated health problems for the nursing home resident, or clinical concerns or emotional distress on the part of the decision-maker. The Principal Investigator or other senior investigator will be available at all times to provide explicit guidance for identification and reporting of such health problems, and be available on page for immediate consultation. She or he will take primary responsibility for direct communication of such health problems or care concerns to the resident's treating physician, or for referral of the distressed family member to appropriate counseling, support or advocacy.

Potential Benefits of the Proposed Research to Subjects and Society: Study subjects may benefit from the information in the decision aid, and increased opportunity to communicate with health care providers. Societal benefits include enhanced understanding of interventions to improve communication and shared decision-making. We will test a decision aid for effect on quality of the decision-making process, quality of care and outcomes, extending this area of research to surrogate decision-makers and the nursing home setting. If this trial has positive effects on decision-making, the methodology has broad potential application to improve clinical decision-making in nursing home and dementia care.

All surrogates will provide written informed consent for their participation, and for participation of the person with advanced dementia. Surrogates, acting on their own behalf and on behalf of persons with dementia, may discontinue their participation in this study at any time. If a surrogate chooses to discontinue, we will solicit reasons via a brief open-ended interview conducted either in-person or via telephone. We will assure the withdrawing surrogate that he/she may decline to participate in any further way without any repercussions whatsoever for treatment or care.

## Data Monitoring Plan

Although the primary participants in this intervention study are family decision-makers, the intervention has the potential to impact nursing home residents with dementia. Safety monitoring is the responsibility of a Data Safety Monitoring Board (DSMB) composed of the Principal Investigator (Hanson), the study biostatistician (Lin), and two experienced dementia investigators from the University of Indiana who will function as independent Safety Monitors. Dr. Malaz Boustani is an NIA-funded geriatrician investigator with expertise in clinical dementia research. Dr. Greg Sachs is an academic geriatrician with expertise in bioethics and in clinical care of advanced dementia patients, and an investigator whose research focuses on innovative models of outpatient palliative care for dementia. The DSMB will meet every 6 months during active recruitment and data collection and analysis. The DSMB will review participant accrual, inclusion / exclusion criteria, and adherence to research protocols and procedures. They will review any modification of protocols, and preliminary data trends in primary and secondary outcomes. Finally, they will review procedures for protection of human subjects, including study withdrawals or adverse event reports. The DSMB will devise stopping rules based on potential harms or adverse events.

- During active enrollment, data collection and analysis Drs. Hanson, Lin, Sachs and Boustani will meet every 6 months for data safety review.
- Drs. Sachs and Boustani will provide written statement regarding potential and actual conflicts of interest, and confidentiality agreements for study protocols and results
- Adverse event reporting is structured for mortality rates only. Other adverse events are collected using a passive approach, based on study subjects' concerns or complaints such as expression of emotional distress.
- During the January 2013 meeting, DSMs recommended future reports should include explicit proactive tracking of Hospice enrollment, hospitalizations, restraint use and presence of pressure ulcers for intervention vs. control subjects. Trial discontinuation for adverse effects will be based on the judgment of the DSMs after data review.
- During the January 2013 meeting, stopping rules were discussed; DSMs recommended no formal data stopping rules for this relatively low risk behavioral intervention. Early trial discontinuation was discussed as undesirable, since data on secondary outcomes will be lost.

## Dissemination Plan

- At the end of data collection, an in-service on the use of the Goals of Care decision aid will be provided at each facility.
- Treating MD, NP or PA will be provided with a packet inclusive of the decision aid, and a summary of results or key publications for review.

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