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| TITLE:Goals of Care: A Nursing Home Trial of Decision Support for Advanced Dementia |
| PRINCIPLE INVESTIGATOR(S): | Laura C. Hanson, MD, MPH |  | SITE(S) (if applicable): |
| 20 Nursing Homes in North Carolina |
| COORDINATING SITE: | University of North Carolina at Chapel Hill |  |
| STUDY PERIOD |  |
| START: | April 2011 |  |
| LAST SUBJECT CONTACT: | September 2014 |  |
| OBJECTIVES: |
| **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.**Aim 2**. To test the effect of the 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; and c) surrogate satisfaction with care for advanced dementia. **Aim 3.** To test the effect of the 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. This research will provide the first empiric test of the goals of care framework for dementia. It extends decision support research to surrogates, who make most decisions for patients with serious and incurable illness. To permit dissemination, the intervention design is pragmatic and well integrated with nursing home interdisciplinary care.  |
| PARTICIPANTS |
|  | ENROLLMENT | ELIGIBILITY CRITERIA |
| Patients: | 302 | The resident subjects must have a diagnosis of dementia, age 65 and older, have a Global Deterioration Scale Score (GDS=5,6, or 7), a cognitive decision making score indicating moderate or severe impairment from the Nursing home assessment instrument, the MDS (C100=2 or 3 and BIMS score less than 13).  In addition, the Bedford score indicating the level of functional impairment will be 17 or over and the resident will have a family decision maker, not a court appointed, non-family guardian. |
| Informal Caregivers: | 302 | The family decision maker must be 18 and older, able to consent, and not currently residing in a nursing home themselves.  The study follows the informed consent laws applicable to clinical care in North Carolina, identifying the person who has the highest level of legal decision making authority.  If the person identified at the highest level of decision making prefers for another family member to complete the family subject interviews due to living close by or for other reasons, the family member selected by the legally defined subject will be able to participate as long as the legally defined family subject signs the resident consent form and HIPAA form authorizing the resident’s participation in the study.  In addition, the family decision maker may live out of town and complete all study activities over the phone.  |
| Health Care Providers: | n/a | n/a |
| METHODOLOGY: |
| *Trial design*: The study was a single-blind cluster randomized trial of the Goals of Care intervention compared to an attention control. Nursing homes were randomized to minimize contamination and parallel how decision aids are implemented. Outcomes were assessed at the level of the resident-family dyad. The University of North Carolina institutional review board approved the protocol prior to initiation of research, and two Data Safety Monitors reviewed study procedures and preliminary data every six months. Family decision-makers provided written consent for themselves and the resident with advanced dementia. *Randomization of nursing home sites:* Nursing homes were eligible if located within a 60-minute driving radius of the University of North Carolina-Chapel Hill. Administrators and medical directors agreed to site participation, and treating physicians gave permission to recruit families. The study statistician randomized 22 nursing homes in blocks of 4, except for a final block of 2, matched by profit vs non-profit status and percent African-American residents.  |
| INTERVENTION (if applicable): |
|  Family decision-makers in intervention sites had the 2-part Goals of Care intervention, consisting of an 18-minute Goals of Care video decision aid and a structured discussion with the nursing home care team. The intervention was developed using International Patient Decision Aid Standards and tested for feasibility and acceptability. The decision aid provided information on advanced dementia, choosing goals of prolonging life, supporting function, or improving comfort, treatments consistent with each goal, and how to choose a primary goal. Decision-makers were shown the decision aid by research staff during their initial study visit and given a print copy of the decision aid and a discussion guide called “Questions to Consider in Care Planning.”  After viewing the video, family decision-makers were asked to participate in a Goals of Care discussion with nursing home staff. Investigators gave a 1-hour training session to nurses, social workers, therapists, and nutritionists who create care plans. They viewed the Goals of Care decision aid, learned the VALUE (“Value family comments, Address emotions, Listen, Understand the patient as a person, and Elicit family questions”) principles for family communication, and observed a short role play of a Goals of Care discussion. Research staff also provided them with a written Goals of Care discussion guide, and reminders to meet with decision-makers. Physicians and nurse practitioners were invited to attend, though this is not usual practice. Research staff monitored both components of the intervention and required re-training if 70% fidelity was not achieved.  Family decision-makers in control sites experienced an attention control consisting of an informational video on interaction with someone with dementia and a usual care planning meeting with staff. Nursing home staff received a 45-minute training on study procedures. All other procedures were identical for intervention and control participants. |
| MEASURES: |
| Primary Outcome Measure Aim 1* **Quality of Communication** will be measured interviews using the Quality of Communication (QOC) instrument.100 Respondents rate 13 items on a 10-point scale, to give potential scores ranging from 0

(“very worst”) to10 (“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.101 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 resident goal (comfort, function, survival, other) the same as the primary goal indicated by providers. As in our pilot work the quarterly care plan and primary provider progress notes will be reviewed for text on goals of a) prolonging life, b) promoting function, c) providing comfort, d) personal goals, or e) no goal specified. At each Follow-up Interview, surrogates will be asked; “Doctors and nurses sometimes describe the goals of medical care as prolonging life, maintaining function, and maximizing comfort. If [ RESIDENT ] was able to make a choice about which of these three goals was most important for his / her treatment to achieve, what do you believe he / she would most prefer?” Response options include these three medical goals, “another personal goal” or “uncertain.”* **Treatment consistent with wishes** will be measured using the Advance Care Planning problem score from the Toolkit Family Interview. 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. 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**)Primary 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 of0-45. 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.* **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 of10-40. 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.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). This measure will be used in After Death interviews.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).* 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.* 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.

Covariates* Demographics – resident and surrogate age, gender, race and ethnicity, religious affiliation from surrogate

Baseline Interview* Family visit frequency –since visit frequency is correlated with report of care quality, surrogates will be asked to

estimate visit frequency for themselves during Baseline and Follow-up Interviews.* Surrogate Spiritual Well-Being – measured at Baseline for the surrogate decision-maker using the Functional

Assessment of Chronic Illness Therapy – Spiritual Well-being scale.112 Internal consistency is very good (Cronbach’s alpha=0.8-0.88), and convergent validity is established with correlation with overall quality of life measures.113* Functional status – measured using the Minimum Data Set (MDS) Activities of Daily Living index.
* Dementia stage – measured using the validated and reliable Global Deterioration Scale.
* Severity of illness will be measured using Prognostic Risk Score from MDS variables in Baseline and Follow-up

Chart Reviews. This score is predictive of 6-month mortality among residents with advanced dementia; area under the ROC curve is 0.70-0.74. Anticipating introduction of MDS 3.0, we will collect data on a similarly validated risk score for all residents compatible with the new MDS.* Surrogate perception of prognosis will be measured using a single item in the Baseline Interview asking the

surrogate what they expect will happen to the resident during the next 6 months, with response options of “get better,” “stay about the same,” “get worse” or “likely to die.”* Advance directives – measured by recording presence or absence of a living will or Health Care Power of Attorney

in Baseline Chart Reviews.* Mortality – measured as days to death; if resident is absent from the facility at any Chart Review interval up to 9

months the Research Assistant will contact the facility’s Director of Nursing to confirm the resident’s current vital status and date of death. In cases where a resident’s vital status or date of death is unknown we will search the North Carolina Death Index.* Nursing home characteristics – baseline percent of residents with feeding tubes, bed size, percent Medicaid,

profit status, staffing ratio, staff turnover and presence of feeding aides or feeding assistance protocols will be measured at baseline in introductory discussions with administrators |

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| SUBJECT FLOW (CONSORT): |
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| STUDY CALENDAR: |

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| BASELINE CHARACTERISTICS (TABLE 1) |

**PCRC STANDARDIZED DATA ELEMENTS**

***Please see the separate information sheet*** [***“DISC Standardized Data Elements”***](file:///%5C%5Ccecil.ad.unc.edu%5Cproject_folders%5CPCRC%5CPCRC%20Data%20Repository%5CInfo%20Sheet%20-%20DISC%20Standardized%20Data%20Elements_v2018.08.docx) ***for the exact wording and format of the data elements.***

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| **DATA ELEMENT** | **Collected?** | **Var Name(s)** | **Data source (e.g. self-report, EHR) or reason not applicable** |
| 1. **Site ID (if multi-site)**
 |[x]  FACID | Study determined  |
| 1. **Who is the research participant? (e.g., patient, caregiver, etc.)**
 |[x]  QB\_S80 | Baseline Interview-Self-report  |
| 1. **Sex**
 |[x]  QB\_R10, CB\_3 | **Baseline Interview-Self-report; Medical Record Review**  |
| 1. **Ethnicity**
 |[x]  QB\_R30, QB\_Q20 | Baseline Interview-Self-report, proxy-report |
| 1. **Race**
 |[x]  QB\_R40, QB\_Q30 | Baseline Interview-Self-report, proxy-report |
| 1. **Age in years**
 |[x]  QB\_R20, CB\_4 | **Baseline Interview-Self-report; Medical Record Review**  |
| 1. **Current Marital Status**
 |[x]  QB\_Q10 | Baseline Interview-Proxy-report  |
| 1. **Primary life-limiting diagnosis/illness**
 |[ ]    |   |
| 1. **Performance status (AKPS)**
 |[x]  CB\_9 | **Medical Record Review** |
| 1. **Enrolled in Hospice**
 |[x]  CB\_39 | **Medical Record Review** |
| * 1. **If yes to hospice, where is hospice care provided?**
 |[ ]    |   |
| 1. **Receiving Palliative Care (PC)?**
 |[ ]    |   |
| * 1. **If yes to receiving PC, where is PC provided?**
 |[ ]    |   |
| 1. **Source of Death information**
 |[x]   DEATH | **Medical Record Review & Bereavement Interview**  |
| 1. **Location of Death**
 |[ ]    |   |
| 1. **Enrolled in Hospice at time of death?**
 |[x]   QD\_A3 | **Medical Record Review; Proxy-report**  |
| 1. **Receiving PC at time of death?**
 |[ ]    |   |

***Cells in blue only need to be collected for patient research participants. Cells in orange should be collected regardless of participant type.***

**PATIENT REPORTED OUTCOME INSTRUMENTS**

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| **CONTENT***(e.g., PS)* | **ABBREV***(e.g., AKPS)* | **INSTRUMENT NAME***(e.g., Australian Modified Karnofsky Performance Status)* |
| Quality of Life  | ADRQL | Alzheimer Disease Related Quality of Life |
| Communication | QOC | Quality of Communication Questionnaire |
| Quality of Care at End of Life  | SWC-EOLD | Satisfaction With Care at the End of Life inDementia |
| Quality of Care at End of Life  | SM-EOLD | Symptom Management at End of Life |
| Spiritual Aspects of Care Quality of Care at End of Life  | FACIT-Sp | Spiritual Well-being Scale |
| Quality of Care at End of Life  | CAD-EOLD | Comfort Assessment in Dying for Dementia |
| Quality of Life  | QUALID | Quality of Life in Late-Stage Dementia |
| Quality of Care at End of Life  | QOD-LTC | Quality of Dying in Long-term care |
| Advance Care Planning | ACP Problem Score | Advance Care Planning Problem Score  |
| Decision Making  | DCS | Decisional Conflict Scale  |