TITLE OF PROPOSED STUDY: Quality of care in assisted living compared to skilled nursing facilities for individuals with dementia

1. Specific Aims: State the specific aims of this study.

Specific Aim 1: Compare quality of care outcomes for individuals with dementia living in a skilled nursing facility (SNF) vs. an assisted living facility (ALF).

Specific Aim 2: Compare mood changes for individuals with dementia living in a SNF vs. an ALF.

Specific Aim 3: Compare behavior changes for individuals with dementia living in a SNF vs. an ALF.

2. Condition Burden and Impact: Briefly state the importance of the condition or problem in terms of prevalence and/or impact.

The Alzheimer’s Association reports that 14% of older people in the U.S. have dementia, with 11% having the most common form of dementia, Alzheimer’s Disease. Fully 38% of those over 85 have Alzheimer’s Disease. Between 1990 and 2010 disability-adjusted life-years for Alzheimer’s Disease rose from the 25th most burdensome disease in the United States to the 12th. No other disease or condition increased that much. Total annual payments for all dementia care is estimated to rise from $214 billion in 2014 to $1.2 trillion in 2050.

3. Gap Analysis: Add a statement describing the evidence gap; be sure to include references, such as systematic review(s), guidelines, and other evidence.

Public and private insurers are more likely to pay for SNF care than ALF care. A systematic review led to the conclusion that more research is needed regarding the best setting for long-term residential care for those with dementia. Sloane and colleagues compared health and functional outcomes in many facilities, but not psychosocial outcomes for those with dementia. Goal 2 of the National Plan to Address Alzheimer’s Disease is to “Enhance Care Quality and Efficiency.” Healthy People 2020 includes the goal “Reduce the morbidity and costs associated with, and maintain or enhance the quality of life for, persons with dementia, including Alzheimer’s disease.”

4. Study Design: Please provide a concise description of the study design including theoretical or conceptual framework and how it informs the design and variables being tested. Indicate whether the main (CER) question under study is to be addressed as a randomized trial (individual level or cluster), observational study (retrospective, prospective), quasi-experimental study, or other (please specify).

Based on the theory of person-centered care for individuals with dementia, it is hypothesized that the functional, health, behavioral, and quality outcomes will be similar or improved in ALF care compared to SNF care. ALF care is less focused on medical and health interventions and often offers more personal attention and support in a calmer environment than SNF care. The ALF care studied will be in dementia-focused units.

This study will use a prospective cohort design in four continuing care retirement communities (CCRC) in Michigan. Each CCRC offers SNF care as well as ALF care. Minimum Data Set (MDS) measures as developed by the Centers for Medicare and Medicaid Services (CMS) as SNF quality of care measures will be collected quarterly at least three times (over 6-7 months) in the SNF and ALF for residents with dementia who are expected to be long-stay residents.

In this study, each resident is repeatedly measured over time and therefore the measurements for the same resident are more likely to be correlated. Thus we will implement longitudinal data analysis, such as the generalized estimation equation and the quadratic inference function, to identify whether the response variable is influenced by care setting. These approaches can incorporate informative correlations, control for other variables such as characteristics of residents, and therefore, provide an accurate and effective comparison model.
5. **Description of Participants and Participating Study Site(s):** Describe the relevant demographic characteristics of the participants who are the target of the intervention, including how well they represent the target population, source of participants, and inclusion and exclusion criteria. Where the unit of randomization is a study site, rather than the participant, please describe representativeness of proposed participating sites.

Four continuing care retirement communities will participate in the study as volunteers. While sites were not randomly selected, there is no basis to conclude they will vary greatly from non-volunteers for the purposes of this study. There will be no change in admissions or care practices for participating organizations.

6. **Outcomes:** Describe the study outcomes, the key constructs to be measured, the validated measures to assess key constructs, and why the outcomes are important to patients, relevant to health systems and capable of changing practice.

Outcomes measures are from the CMS MDS 3.0\textsuperscript{8}, validated by CMS and highly relevant to skilled nursing facilities as their public quality reports are based on those measures. The primary outcomes in this study are:

1. Percent of residents whose need for help with activities of daily living has increased.
2. Percent of residents whose mood has declined.
3. Percent of residents whose behavior has declined.

These measures reflect key factors in decline for individuals with dementia and can significantly affect care setting costs and the personal experience or distress of a person with dementia.

7. **Power Calculations:** State the power of the proposed study to detect the hypothesized effect, including support for all assumptions, (e.g., type-1 error level, standard deviation in outcome measure, underlying event rate). Note power for important subgroups, if applicable.

<table>
<thead>
<tr>
<th>Percentage for Group A</th>
<th>Percentage for Group B</th>
<th>Odds Ratio</th>
<th>Power</th>
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<tbody>
<tr>
<td>.40</td>
<td>.25</td>
<td>2.00</td>
<td>.81</td>
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<tr>
<td>.35</td>
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<td>1.61</td>
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<tr>
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<td>.25</td>
<td>1.00</td>
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Power calculations are based on two-sample proportions tests that determine whether or not the proportions in two groups are different \textsuperscript{11}.

8. **Hypothesized Effect Size for Intervention on Main Patient-Centered Outcome:** State the hypothesized effect size and cite references to support that the effect size is both realistic and clinically meaningful.

In this non-inferiority study even similar outcomes are of interest in these two settings. However based on sample size, the hypothesized effect size comparing different settings are described above.

9. **Sample Size:** Provide the total sample size for the main CER analysis and the number per arm (\(N_1, 2, 3, 4 \ldots\)), as applicable.

\[ N = 320 \]
\[ N_1 = 160 \]
\[ N_2 = 160 \]

10. **Comparators:** List the interventions being compared.

1. Care in a skilled nursing facility setting
2. Care in an assisted living setting
11. Description of Comparators: Describe each intervention listed above under “Comparators,” including:
   a) Evidence of the efficacy or effectiveness of each or statements about its acceptance in widespread practice despite having limited evidence of efficacy or effectiveness
   b) An estimate of frequency of use in clinical practice
   c) If usual care is a comparator, justification of its inclusion and a proposal to clearly describe and document its components

SNF care has been commonly provided and publicly funded since 1965. ALFs grew rapidly in the 1990s and the majority of states do not offer public funds to pay for such care, though it is lower in cost. Similarly, long term care insurers are less likely to cover assisted living care than skilled nursing care. Both settings house a high percentage of residents with dementia. The two settings are compared to determine the impact of these common care settings on persons with dementia.

12. Engagement: Briefly state how patients and stakeholders are involved in all aspects of the research and list specific organizations involved.

The leadership of LeadingAge of Michigan approached the PI to conduct this study. LeadingAge is a trade association representing most continuing care retirement communities (CCRC). A key stakeholder is Jay Prince, a LeadingAge board member who is the executive director of a local CCRC. Mr. Prince approached the PI in fall 2015 with a request for this comparative effectiveness research because of frustration with seeing persons with dementia being moved from assisted living to skill nursing solely due to reimbursement issues by public or private insurers. The PI met with LeadingAge leaders to clarify the specific aims of the study. Participating sites are LeadingAge members and the organization leadership will be part of the research team during the entire project.

13. Duration of Study: State duration of intervention and length of follow-up as they fit in to a 3-year project or up to 5 years.

The setting has no limited duration. Researchers will collect data on the individuals in the two types of settings for at least six months, adding participants as they are admitted to participating facilities.

14. Cost of Study: State whether the study is small (up to $1.5 million in total direct costs for up to 3 years) or large (up to $5 million in total direct cost for up to 5 years).

This is a small study with $528,151 in direct costs and $797,508 in total direct and indirect costs. This includes extensive data collection, data entry, statistical analysis, reporting and dissemination of results. The research team will conduct the study over three years.

15. “Real-Life” Applicability of Strategies: State how the intervention will be delivered and received in real-life clinical settings and will provide practical information that can help patients and other stakeholders make informed decisions about their health care and health outcomes.

Study results can be used to inform reimbursement policies of insurance companies covering long-term care and state-based reimbursement decisions of the Medicaid program. In addition, results can help inform families faced with care decisions regarding persons with dementia.
References: