I. Background and Objectives for the Systematic Review

Dementia is a progressive, irreversible decline in mental function, marked by memory impairment and often deficits in reasoning, judgment, abstract thought, registration, comprehension, learning, task execution, and use of language. Types of dementia include Alzheimer’s disease, vascular dementia, mixed dementia, dementia with Lewy bodies, and frontotemporal dementia. The Diagnostic and Statistical Manual of Mental Disorders, 4th Edition, Text Revision (hereafter DSM-IV-TR) defines dementia as “the development of multiple cognitive deficits that include memory impairment and at least one of the following cognitive disturbances: aphasia, apraxia, agnosia, or a disturbance in executive functioning. The cognitive deficits must be sufficiently severe to cause impairment in occupational or social functioning and must represent a decline from a previously higher level of functioning.”

According to the Alzheimer’s Association, one in every eight people ages 65 years or older has dementia. The number of Americans with dementia is expected to increase because of the aging of the baby boomers and lengthening of the average lifespan. The number of people ages 65 years or older with Alzheimer’s disease is estimated to reach 7.7 million in 2030, a 50 percent increase over 2006. Dementia and Alzheimer’s disease cause significant morbidity and mortality and create a substantial burden on the people affected, caregivers, health systems, and society. In 2006, Alzheimer’s disease was the seventh-leading cause of death across all ages in the United States. It was the fifth-leading cause of death for Americans ages 65 years or older.

Almost 11 million Americans provide unpaid care to a person with Alzheimer’s disease or another form of dementia. In 2009, family and friends of affected individuals provided 12.5 billion hours of unpaid care, which is estimated to be valued at almost $144 billion. Caregivers of older adults with dementia often experience high levels of stress, exhaustion, anxiety, and depression and are at a higher risk for illness and death.

People with dementia, especially individuals who have comorbidities, are high users of health care, long-term care (LTC), and hospice. Most people with dementia have other

1 Apraxia is defined as the “impaired ability to execute motor activities despite intact motor abilities, sensory function, and comprehension of the required task.”
2 Agnosia is defined as the “failure to recognize or identify objects despite intact sensory function.”
serious medical conditions. The presence of other serious medical conditions compounds the need for more advanced care than family members can provide at home.\(^1\)

LTC for people with dementia represents high costs to individuals, families, and health care systems and payers. Dementia costs more than $148 billion in the United States annually.\(^4\) In 2004, total per-person payments from all sources for health care, LTC, and hospice were three times as high for Medicare beneficiaries aged 65 years or older with dementia as for other Medicare beneficiaries in the same age group ($15,145 vs. $5,272 per person). Similarly, in 2004, Medicaid payments per person for Medicare beneficiaries aged 65 years or older with dementia were more than nine times as high as Medicaid payments for other Medicare beneficiaries in the same age group ($6,605 vs. $718 per person). Medicaid is the only Federal program that pays for LTC services. A person must meet several eligibility criteria, including low income, to qualify for payment.

Although about 70 percent of people with dementia are cared for at home, many families decide to place their members affected with dementia into LTC settings as care needs increase.\(^1\) It is the norm rather than the exception that older adults who live in residential LTC settings were cared for by family members before their placement and that caregiving does not end after placement.\(^5-7\) After placement, families visit LTC residents an average of 1.9 times a week, for approximately 4.0 to 4.2 hours a week; during this time, they provide support for activities of daily living (ADLs), thereby augmenting the care provided by staff.\(^5-7\)

Families constitute an important resource to staff because they have knowledge of the resident’s history, and they are important to the resident to maintain emotional connectedness and psychosocial health. Indeed, family presence improves resident psychological and psychosocial well-being, the accuracy of diagnosis, and therefore the resultant care.\(^8\) Family members are called upon to make decisions regarding care for cognitively impaired residents and to provide continuity that may otherwise be lacking because of staff turnover.\(^9,10\)

Historically, LTC systems have generally not been welcoming of family involvement.\(^11\) LTC practices have tended to reflect a “visitor” philosophy that treated families as outsiders or a “servant” philosophy that dictated the nature of involvement, as opposed to a “client” philosophy that coordinated with family members to meet the needs of all parties.\(^12,13\) Family members were at a loss as to their proper role and continued to experience caregiver burden and emotional distress.\(^14,15\) In large part, stressful relations stemmed from the fundamental difference between LTC settings and the family: the former operated on a formal, bureaucratic, impersonal level and the latter on an informal and personal level.\(^16,17\) As the LTC setting assumed caregiving responsibilities, tension arose in family-staff relations.\(^18\) Consequently, some family members vented their frustrations and were verbally aggressive toward staff, further engendering discontent and impeding quality care.\(^19\)

Thus, it is of major significance that the LTC system has not recognized the resource that families might constitute in improving care both directly and indirectly by combating
work stress, burnout, and turnover. Efforts to smooth these tensions are likely to benefit families by helping them feel needed and effective, thereby increasing their own ability to cope and reducing their distress.\textsuperscript{20} In fact, a recent study indicates that the more a family participates in resident care in LTC, the more connected they feel to the resident.\textsuperscript{21}

Settings for residential LTC for people with dementia are numerous and differ in their organizational characteristics, structures, and processes of care. For example, settings may offer different levels of care, and there is no comprehensive evidence-based guidance on which type or characteristics of setting is best for which type of patient/resident based on age, disease severity, or other characteristics. People with dementia are found in all types of LTC settings, including the following\textsuperscript{1,22}:

- **Residential care/assisted living.** Estimates from various studies indicate that 45 to 67 percent of residents of RC/AL residences have dementia. Between 23 and 42 percent of residents in RC/AL settings have moderate or severe cognitive impairment.\textsuperscript{23} RC/AL settings provide room, board, 24-hour oversight, health monitoring, and assistance with ADLs and are licensed by the States. Residents often live in their own apartment within a building. The complex provides some care that those who live independently would perform themselves (such as taking medicine). Social and recreational activities are usually provided. (Note: These settings are subsumed under the terminology “RC/AL.”)

- **Nursing homes (NHs; skilled nursing setting).** In June 2008, 47 percent of all NH residents had a diagnosis of dementia in their NH records.\textsuperscript{1} NH settings provide room, board, 24-hour oversight, health monitoring, assistance with ADLs, health services, recreational activities, and skilled nursing services. NHs are licensed by the Federal Government.

- **Alzheimer’s special care units.** NHs had a total of 86,669 beds in Alzheimer’s special care units in June 2008, accounting for 5 percent of all NH beds at that time. The total number of NH beds in Alzheimer’s special care units increased in the 1980s but has decreased since 2004, when there were 93,763 beds in such units. Given that almost half of NH residents have dementia, and only 5 percent of NH beds are in Alzheimer’s special care units, it is clear that the great majority of NH residents with dementia are not in Alzheimer’s special care units. The same is true for RC/AL settings, where the majority of residents with dementia do not reside in special care units.\textsuperscript{24}

- **Board and care homes.** Board and care homes are group living arrangements designed to meet the needs of individuals who cannot live independently but do not need a skilled nursing setting. Most homes provide some degree of help with ADLs. (Note: These settings are also referred to as assisted living and fall under the terminology RC/AL.)

- **Continuing care retirement communities (CCRCs).** CCRCs are retirement communities with different housing and level-of-care options. The area in which a person lives depends on the level of care he or she needs. Residents
may move from one area to another depending on care needs but stay within the same CCRC.

- Hospice care. The number of people with dementia who receive hospice care has increased in recent years from 6.8 percent in 2001 to 10.1 percent in 2007.

Studies have evaluated various organizational characteristics, structures, and processes of care within and across settings. A recent study of RC/AL residences and NHs compared various components of care and resident quality of life. The organizational characteristics, structures, and processes of care of interest from that work include the following:

- Organizational characteristics. These characteristics encompass residence type, age, profit status, affiliation with another level of care, number of beds, presence of a dementia-specific unit, and resident case-mix (related to dementia diagnosis).

- Structures of care. These may include aspects of staffing, including the following: stability of care provider-resident assignment, universal worker perspective (where staff fill multiple roles), and/or a specialized worker perspective (where staff have specialized roles), the number of nurses and nursing or personal care aides, staff turnover, previous experience in dementia care, and physical structure (e.g., lighting, cleanliness).

- Processes of care. These include care planning (professional staff involvement and aide involvement), policies and practices (admission, discharge, acceptance of behavioral symptoms, policy choice), assessments and treatments conducted, and activities.

Unfortunately, quality in LTC settings, as reflected through their organizational characteristics and structures and processes of care, is variable. In 2001, the Institute of Medicine Committee on Improving the Quality of Long-Term Care specifically noted that ongoing quality concerns “...extend beyond nursing homes to home and community-based services and residential care facilities.” Nationally, 2.3 million elderly people reside in LTC settings, two-thirds (1.56 million) of whom are in one of the country’s 16,840 NHs, and the remainder of whom are in one of 37,237 RC/AL residences. RC/AL residences are licensed by the States at a non-NH level of care; provide room, board, 24-hour oversight, and assistance with ADLs; and can respond to unscheduled needs for assistance. They are known by a multiplicity of names, including sheltered housing, domiciliary care, intermediate care housing, adult foster care, assisted living, and congregate care.

Beyond the basic definition, there is wide variation in how the term assisted living is used, the specific services provided, and the appropriate target population. There are no national standards of RC/AL, and the diversity among residences is striking. For example, they range in size from 1 to more than 1,400 beds; some have private apartments, others have four residents sharing a room; and they include family homes and
multilevel campuses.\textsuperscript{30,31} Further, there is no consensus about the level of care they should provide. In fact, there are differing perspectives on the role of RC/AL: 1) that it lies along the continuum from home care to NH care and 2) that it constitutes an approach and philosophy that can apply to all people, regardless of their level-of-care needs.\textsuperscript{32} In fact, in some cases, RC/AL residences provide care for residents who meet the level-of-care criteria for NHs.\textsuperscript{33}

Several consumer/patient guides are available to help the public choose the type of LTC setting that may be best for their family member; however, it is unclear whether any of these guides are based on evidence. It appears that most guides use criteria such as level of care needed, desired location, and cost as factors to consider when choosing an LTC residence.

Further, the extent to which this field has been subjected to rigorous study, through randomized controlled trials, seems sparse. For example, we identified one Cochrane Collaboration review that focused on the settings and population of interest. This review examined specialized units for people with dementia and Alzheimer’s disease.\textsuperscript{34} The review found no randomized controlled trials that examined the effects of special care units on behavioral symptoms. From the identified evidence of nonrandomized controlled trials, there was no strong evidence of benefit from special care units. The authors recommended implementing best practice rather than providing a specialized care environment. Therefore, it is necessary to examine the evidence related to organizational characteristics, structures, and processes of care and their effect on outcomes (such as quality of life), so as to provide guidance to families as they seek LTC settings for their members with dementia.

The topic of our review—the comparison of characteristics of NHs and other residential LTC settings for people with dementia—addresses uncertainty for families that are trying to make the best decision in regard to the setting of care for individuals with dementia. It does not appear that current guidance for choosing an LTC setting is based on evidence of effectiveness. In general, choosing a setting of care is based on the level of care and assistance needed by the individual, the location, and the cost.

\section*{II. The Key Questions}

The key questions were posted for public comment (from June 27, 2011 to July 25, 2011) and finalized by the EPC after review of the comments. The public comments suggested including specific examples of processes of care and outcomes. These examples are included within the scope of the review.

\textbf{Question 1}

What is the effectiveness of organizational characteristics, structures, or processes of care in nursing homes and other residential long-term care settings for improving health outcomes for people with dementia?

- Organizational characteristics (e.g., proprietary status, resident case-mix)
• Structures of care (e.g., physical environment, staffing)
• Processes of care (e.g., specialized dementia care, nursing services)

**Question 2**

What is the effectiveness of organizational characteristics, structures, or processes of care in nursing homes and other residential long-term care settings for improving psychosocial outcomes for people with dementia?

**Question 3**

What is the effectiveness of organizational characteristics, structures, or processes of care in nursing homes and other residential long-term care settings for improving health outcomes for informal caregivers of persons with dementia?

**Question 4**

What is the effectiveness of organizational characteristics, structures, or processes of care in nursing homes and other residential long-term care settings for improving psychosocial outcomes for informal caregivers of persons with dementia?

The following question will be considered in the context of studies included for Key Questions (KQs) 1 to 4.

**Question 5**

Does the effect of organizational characteristics, structures, or processes of care on health and psychosocial outcomes vary by the characteristics of the person with dementia (e.g., severity of dementia, functional status) or of the informal caregiver (e.g., age, relationship, health status)?

An illustrated framework of the populations, interventions, and outcomes that will guide the literature search and synthesis can be found in Figure 1. The PICOTS (Populations, Interventions, Comparisons, Outcomes, Timing, and Setting) criteria for the KQs above are as follows:

• Population(s):
  The population of interest for KQs 1, 2, and 5 includes people with dementia (i.e., Alzheimer’s disease or a related disorder). People with mild cognitive impairment will not be included because these individuals do not have dementia. Because many studies will not have required a formal diagnosis of dementia for subject inclusion, our review similarly does not require that the dementia be specified as “diagnosed” dementia. Dementia will be determined either by formal diagnosis, signs or symptoms (e.g., cognitive status assessment), or report by staff or an informal caregiver. Severity of dementia (reflected in cognitive impairment and/or behavioral symptoms), functional impairment, severe or unstable comorbid disease (e.g., diabetes, congestive heart failure, chronic obstructive pulmonary
disease), gender, race, ethnicity, and socioeconomic status are all characteristics of interest. The population will also include people with various comorbidities (i.e., we will not exclude studies that evaluated populations with comorbidities) such as stroke, HIV infection, and substance abuse.

The population of interest for KQs 3, 4, and 5 will include informal caregivers of individuals with dementia, of any age or gender. Informal caregivers are unpaid individuals who provide care to relatives or friends. Characteristics of interest include the informal caregiver’s relationship to the person with dementia (e.g., type, duration, quality), race, ethnicity, and socioeconomic status.

- **Interventions:**
  Intervention elements of interest include organizational characteristics, structures, and processes of care in NHs and other residential LTC settings for individuals with dementia. In addition, combinations of certain organizational characteristics, structures, and processes of care as exhibited in particular models of care (e.g., traditional nursing homes, the Green House model, the small NH model, residential care/assisted living residences) are also of interest.

  **Organizational characteristics** include proprietary status, affiliation (e.g., chain, hospital, CCRCs), location (urban vs. rural), size of setting or unit, diversity, cultural fit, cost, and resident case-mix (e.g., dementia, Medicaid).

  **Processes of care** refers to programs and services implemented at the system/setting level in an LTC setting. Examples may include specialized dementia care (i.e., a physically separate unit or entire building that provides, or claims to provide, care that meets the special needs of individuals with dementia) services (e.g., assistance with ADLs, case management); involvement of informal caregivers in activities; delivery structure (individualized activities vs. group activities); care planning (e.g., in terms of resident’s desires, the integration of family/informal caregiver planning with formal caregiving); involvement of nurse practitioners, medical directors, and other providers in day-to-day care; palliative care; and the extent of resident control/autonomy.

  **Structures of care** refers to the capacity of the setting to provide care in relation to elements such as physical characteristics and management. These may include aspects of staffing such as hours of care per resident per day by type of worker, consistency of assignment, and/or universal worker perspective, expertise of staff, level of staffing, safety measures, diversity of workforce; and aspects of physical structure such as private rooms and/or bathrooms, design (e.g., neighborhoods), nursing desk (e.g., location), “familiar” home components (e.g., scale of environment, materials, finishes, noise, technology), and access to outdoors.

- **Comparators:**
  Comparators include various types/amounts (e.g., consistent vs. rotating staffing) of the intervention elements above or combinations of certain intervention elements above, as exhibited in particular models (e.g., the Green House model). We will compare elements of interventions with one another and combinations of interventions.
Examples of comparisons of types/amounts of individual organizational characteristics, structures, and processes of care include: not-for-profit versus for-profit, smaller size versus larger size (setting or unit), consistent staffing versus rotating staffing, larger proportion of care paid by Medicaid versus private pay, urban versus rural location, specialized dementia care versus nondementia care, more versus fewer hours of care per resident per day by type of worker, private versus nonprivate rooms and/or bathrooms, neighborhood versus non-neighborhood designs, centralized versus noncentralized nursing desk, and access to outdoors versus no access to outdoors.

Examples of comparisons of combinations of certain organizational characteristics, structures, and processes of care with other combinations include: NH versus RC/AL residences and the Green House model/small NH models versus traditional NHs. In the Green House model, small houses are homes for 6 to 12 residents in which care is given as much attention as treatment and is provided by a consistent, self-directed team of staff who are responsible for care ranging from preparation of meals in a centrally located open kitchen to ADLs, to engagement in social activities.37

- Outcomes measures for each KQ:
  Health outcomes for people with dementia include the following:
  - Pain
  - Functional decline
  - Cognitive decline
  - Symptoms of depression
  - Falls
  - Morbidities (e.g., pressure ulcers)
  - Hospitalization
  - Mortality
  - Sleep quality

  Psychosocial outcomes for people with dementia include the following:
  - Anxiety
  - Social engagement (including withdrawal, suspicion, mistrust)
  - Activity engagement
  - Positive and negative affect
  - Pleasure
  - Quality of life
  - Spiritual well-being
  - Control
  - Autonomy
  - Choice
  - Quality of dying
  - Satisfaction
  - Use of psychoactive medications
  - Use of restraints
Health outcomes for informal caregivers of people with dementia include the following:

- Symptoms of depression
- Morbidities (e.g., eating disorders, cardiovascular risk)
- Sleep quality

Psychosocial outcomes for informal caregivers of people with dementia include the following:

- Anxiety
- Guilt
- Emotional stress
- Psychosocial stress
- Financial burden (e.g., economic impact due to lost wages, impact on job performance)
- Caregiver burden
- Family conflict
- Self-efficacy
- Grief reactions
- Perception of suffering
- Quality of relationship with person who has dementia
- Satisfaction
- Quality of life

• Timing:
The time period of interest is any duration of time beginning after the admission of the person with dementia to an NH or other residential LTC setting until the end of a study, the time of permanent transfer to another setting, or death.

• Settings:
NHs and other residential LTC settings, including RC/AL residences Although LTC can be provided in many settings, including private homes, our evidence-based review will be limited to residential LTC—that is, settings that provide room and board, 24-hour oversight, health monitoring, and support for ADLs and are licensed by the Federal Government and/or the States as NHs, RC/AL residences, or other similar names that will be subsumed within this category.

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3 Caregiver burden is defined as “the strain or load borne by a person who cares for an elderly, chronically ill, or disabled family member or other person. It is a multidimensional response to physical, psychological, emotional, social, and financial stressors associated with the caregiving experience.”

Source: [www.effectivehealthcare.ahrq.gov](http://www.effectivehealthcare.ahrq.gov)
Published Online: November 3, 2011
III. Analytic Framework

Figure 1. Analytic framework for comparisons of nursing homes and other residential long-term care settings for people with dementia

IV. Methods

A. Criteria for Inclusion/Exclusion of Studies in the Review - Table 1 presents the inclusion/exclusion criteria for our review. We do not repeat all of the PICOTS information related to the inclusion/exclusion criteria.
<table>
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<th>Category</th>
<th>Inclusion</th>
<th>Exclusion</th>
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| Population             | - People with dementia residing within a long-term residential setting with or without unstable comorbid disease  
                         | - Informal caregivers of people with dementia                           | - No indication of dementia                                               |
|                        |                                                                          | - Studies in which the case-mix proportion of the population with dementia is <80%<sup>a</sup> |
| Geography              | - United States                                                          | - All other countries<sup>b</sup>                                          |
| Sample Size            | - Trials with an N ≥ 30<sup>c</sup>                                      | - Trials with an N < 30<sup>c</sup>                                        |
|                        | - Observational studies, if included, N ≥ 100<sup>f</sup>                | - Observational studies with an N < 100                                     |
| Time period            | - 1990 to present; searches to be updated after draft report is submitted for peer review | - Articles published prior to 1990                                           |
| Length of followup     | - No minimum study duration limit will be set                             |                                                                            |
|                        | - Beginning after the admission of the person with dementia to a nursing home or other residential long-term care setting until the end of a study, the time of permanent transfer to another setting, or death |                                                                            |
| Settings               | - Nursing homes                                                          | - Adult day centers                                                        |
|                        | - Residential care                                                       | - Program of All Inclusive Care for the Elderly (PACE)                      |
|                        | - Assisted living                                                        | - In-home                                                                  |
|                        | - Green House homes                                                      | - Accessory dwelling units                                                 |
|                        | - Small nursing homes                                                    | - Hospital                                                                 |
|                        | - Alzheimer’s special care units                                        |                                                                            |
|                        | - Residential long-term hospice care                                     |                                                                            |
|                        | - Board and care homes                                                   |                                                                            |
|                        | - Continuing care retirement communities                                 |                                                                            |
| Interventions          | - As defined above in the PICOTS                                         | - Interventions delivered at the person-level                              |
|                        |                                                                          | - Prescribed therapies (e.g., medication trials, nutritional supplements)  |
|                        |                                                                          | - Staff training interventions<sup>d</sup>                                |
|                        |                                                                          | - In-home                                                                  |
|                        |                                                                          | - Community services                                                       |
|                        |                                                                          | - Interventions that require the individual to leave the long-term care setting to receive the intervention |
| Outcomes               | - As defined above in the PICOTS                                         | - Biomarkers                                                               |
| Publication language   | - English                                                                 |                                                                            |
| Admissible evidence    |                                                                            | - All other languages<sup>e</sup>                                          |
| (study design and other| - Original research; eligible study designs include the following<sup>1</sup>: Randomized controlled trials  
                         | - Nonrandomized controlled trials with                                  | - Case series                                                             |
|                        |                                                                          | - Case reports                                                             |
|                        |                                                                          | - Nonsystematic/narrative reviews                                         |
|                        |                                                                          | - Editorials                                                               |


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<th>Category criteria</th>
<th>Inclusion</th>
<th>Exclusion</th>
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<tbody>
<tr>
<td></td>
<td>concurrent eligible controls</td>
<td>• Letters to the editor</td>
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<tr>
<td></td>
<td>Systematic reviews with or without meta-analyses</td>
<td>• Pre/post designs without a comparison group</td>
</tr>
<tr>
<td></td>
<td>Subgroup and/or post-hoc analyses of data from relevant controlled trials</td>
<td>• Focus groups</td>
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<td>• Qualitative Interviews</td>
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<td>• Observational studies</td>
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<td></td>
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<td>• Articles rated as poor during quality assessment</td>
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\(^a\) This will be an iterative process to determine whether this is an appropriate cutoff.

\(^b\) Our aim is to conduct a review of evidence that is applicable to care in the United States. Thus, we are examining characteristics, structures, and processes as they exist in the United States. There are substantial differences in health care systems and approaches to long-term care in other countries that make studies from other countries much less applicable to the United States.

\(^c\) If we do conduct meta-analyses, we will include studies of any size.

\(^d\) Staff training interventions will not be included in this review because they are a proxy for and a presumed indicator of care. Level of training in the context of staff role (i.e., certified nursing assistant, registered nurse, licensed practical nurse, licensed vocational nurse, medical technologist, and other direct-care workers) will be considered in this review.

\(^e\) Because of limited time and resources, we will include only studies published in English.

\(^f\) Taking a “best evidence” approach, if evidence is insufficient for the main interventions and comparisons of interest, we will consider expanding our review to include specific observational study designs according to the methodology set forth in the *Methods Guide for Effectiveness and Comparative Effectiveness Reviews* and related training module. If evidence is not available or is insufficient, we will first consider including case-control and prospective cohort designs. If additional evidence is not identified, we will then consider including cross-sectional study designs.

### B. Searching for the Evidence: Literature Search Strategies for Identification of Relevant Studies to Answer the Key Questions

To identify articles relevant to each KQ, we will begin with a focused MEDLINE® search on LTC settings, dementia, and informal caregivers by using a variety of terms, medical subject headings (MeSH®), and major headings and limiting our search to English and human-only studies. Relevant terms are listed in Table 2. We will also search the Cochrane Library, the Cumulative Index to Nursing and Allied Health Literature (CINAHL®), EMBASE®, AgeLine®, and PsycINFO® by using analogous search terms. We will conduct quality checks to ensure that the known studies (i.e., studies identified during topic nomination and refinement) are identified by the search. If they are not, we will revise and rerun our searches.

We will limit our database search to articles published from 1990 through the present to reflect the changing nature and evolution of nursing homes and other residential LTC settings, especially after the Omnibus Budget Reconciliation Act (OBRA) of 1987 (Public Law 100-203), which established new regulatory standards of NH care.

We sent our search strategy to the Technical Expert Panel (TEP) for feedback.
The TEP did not suggest any changes. In addition, to attempt to avoid retrieval bias, we will manually search the reference lists of landmark studies and background articles on this topic to look for any relevant citations that might have been missed by our electronic searches.

We will also conduct an updated literature search (of the same databases searched initially) concurrent with the peer review process. Any literature suggested by Peer Reviewers or public comment respondents will be investigated and, if found appropriate, incorporated into the final review. Appropriateness will be determined by the same methods listed above.

### Table 2. Literature search terms

<table>
<thead>
<tr>
<th>Populations</th>
<th>Settings Search Terms AND at least one of the following:</th>
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</table>


<table>
<thead>
<tr>
<th>Limits</th>
<th>Humans</th>
</tr>
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<tbody>
<tr>
<td>English language</td>
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</table>

**NOT the following:**

### C. Data Abstraction and Data Management -

All titles and abstracts identified through our searches will be independently reviewed for eligibility against our inclusion/exclusion criteria by two trained members of the research team. Studies marked for possible inclusion by either reviewer will undergo a full-text review. For studies without adequate information to determine inclusion or exclusion, we will retrieve the full text and then make the determination. All results will be tracked in an EndNote® database.

We will retrieve and review the full text of all articles included during the title/abstract review phase. Each full-text article will be independently reviewed by two trained members of the research team for inclusion or exclusion based on the eligibility criteria described above. If both reviewers agree that a study does not meet the eligibility criteria, the study will be excluded. If the reviewers disagree, conflicts will be resolved by discussion and consensus or by consulting a third member of the review team. As described above, all results will be tracked in an EndNote database. We will record the reason that each excluded full-text publication did not satisfy the
eligibility criteria so that we can later compile a comprehensive list of such studies.

For studies that meet the inclusion criteria, we will abstract important information into evidence tables, organizing it in terms of characteristics and structures and processes of care (i.e., the interventions under study). We will design data abstraction forms to gather pertinent information from each article, including characteristics of study populations, settings, interventions, comparators, study designs, methods, and results. Trained reviewers will extract the relevant data from each included article into the evidence tables. All data abstractions will be reviewed for completeness and accuracy by a second member of the team.

D. Assessment of Methodological Quality of Individual Studies - To assess the quality (internal validity) of individual studies, we will use predefined criteria based on those developed by the U.S. Preventive Services Task Force (ratings: good, fair, poor) and the University of York Centre for Reviews and Dissemination. In general terms, a “good” study has the least bias, and its results are considered to be valid. A “fair” study is susceptible to some bias but probably not sufficient enough to invalidate its results. A “poor” study has significant bias (e.g., stemming from serious errors in design or analysis) that may invalidate its results. If observational studies are included, we will perform quality assessments by using the criteria outlined by Deeks and colleagues. We will not include poor-quality studies in our results.

Two independent reviewers will assign quality ratings for each study. Disagreements between the two reviewers will be resolved by discussion and consensus or by consulting a third member of the team. We will give a good-quality rating to studies that meet all criteria. Fair-quality ratings will be given to studies that presumably fulfill all quality criteria but do not report their methods sufficiently to answer all of our questions. We will give a poor-quality rating to studies that have a fatal flaw (defined as a methodological shortcoming that leads to a very high risk of bias) in one or more categories. We will not include poor-quality studies in our analyses.

E. Data Synthesis - Prioritization and/or categorization of outcomes has been determined by the research team with input from TEP members. If we find three or more similar studies for a comparison of interest, we will consider quantitative analysis (i.e., meta-analysis) of the data from those studies.

To determine whether quantitative analyses are appropriate, we will assess the clinical heterogeneity of the studies under consideration. We will do this by qualitatively assessing the PICOTS of the included studies, looking for similarities and differences. We anticipate that we will synthesize the literature qualitatively and expect that there will likely not be a sufficient number of similar studies with common interventions and comparators to conduct a quantitative synthesis (i.e., meta-analysis).
We will organize the results by characteristics, structures, and processes of care. We plan to stratify analyses and/or perform subgroup analyses when possible and appropriate. Planned stratifications or categories for subgroup analyses include severity of dementia and functional status for people with dementia and include age, relationship, and health status for informal caregivers. These analyses will take place in the context of KQs 1 to 4.

F. Grading the Evidence for Each Key Question - We will grade the strength of evidence based on the guidance established for the Evidence-based Practice Center (EPC) Program. Developed to grade the overall strength of a body of evidence, this approach incorporates four key domains: risk of bias (including study design and aggregate quality), consistency, directness, and precision of the evidence. It also considers other optional domains that may be relevant for some scenarios, such as dose-response association, plausible confounding that would decrease the observed effect, strength of association (i.e., magnitude of effect), and publication bias.

Table 3 describes the grades of evidence that can be assigned. Grades reflect the strength of the body of evidence to answer the KQs on the comparative effectiveness, efficacy, and harms of the interventions in this review. Two reviewers will assess each domain for each key outcome, and differences will be resolved by consensus.

<table>
<thead>
<tr>
<th>Grade</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>High confidence that the evidence reflects the true effect: Further research is very unlikely to change our confidence in the estimate of effect.</td>
</tr>
<tr>
<td>Moderate</td>
<td>Moderate confidence that the evidence reflects the true effect: Further research may change our confidence in the estimate of the effect and may change the estimate.</td>
</tr>
<tr>
<td>Low</td>
<td>Low confidence that the evidence reflects the true effect: Further research is likely to change our confidence in the estimate of the effect and is likely to change the estimate.</td>
</tr>
<tr>
<td>Insufficient Evidence either is unavailable or does not permit estimation of an effect.</td>
<td></td>
</tr>
</tbody>
</table>

Table 3. Definitions of the grades of overall strength of evidence

Source: Owens et al., 2010

We will grade the strength of evidence for the outcomes deemed to be of greatest importance to decisionmakers, Key Informants, and TEP members. The TEP identified the following outcomes for people with dementia to include pain, anxiety, function, cognitive decline, falls, depression, the use of psychoactive medications, and the use of restraints. Outcomes for informal caregivers of people with dementia that were suggested by the TEP for inclusion are guilt, stress, anxiety, caregiver burden, symptoms of depression, morbidities, and family conflict.

G. Assessing Applicability – We will assess the applicability of individual studies as well as the applicability of a body of evidence following guidance from the Methods Guide for Effectiveness and Comparative Effectiveness Reviews. For individual studies, we will examine conditions that may limit
applicability based on the PICOTS structure. Such conditions may be associated with heterogeneity of treatment effect, measurement of absolute (rather than relative) benefits and harms, and the ability to generalize the effectiveness of an intervention to use in everyday practice. Examples include the following:

- **Population:**
  Differences between study resident populations and general resident populations, race, ethnicity, gender, comorbidity, extent of cognitive impairment, functional status

- **Intervention:**
  Intensity and delivery of interventions; the years in which the studies were performed

- **Comparator:**
  Use of substandard comparators

- **Outcomes:**
  Use of composite outcomes that mix outcomes of different significance to individuals

- **Timing:**
  Studies of different duration that may have various implications for applicability

- **Setting:**
  Standards of care that differ markedly from setting of interest (e.g., varying practice standards from State to State)

We will abstract and report key characteristics that may affect applicability into evidence tables. To assess the applicability of a body of evidence, we will consider the consistency of results across studies that represent an array of different populations. If the data allow, we will perform subgroup analyses to explore the influence of specific factors (e.g., age, race/ethnicity, gender). We will also describe the limitations of the aggregate evidence with regard to inclusion of relevant populations, interventions, comparisons, outcomes, and settings.

V. References


36. United States Congress Office of Technology Assessment. Special Care Units for People With Alzheimer's and Other Dementias: Consumer Education, Research,


VI. Definition of Terms

**Agnosia** is defined as the “failure to recognize or identify objects despite intact sensory function.”

**Apraxia** is defined as the “impaired ability to execute motor activities despite intact motor abilities, sensory function, and comprehension of the required task.”

**Dementia** is defined as “the development of multiple cognitive deficits that include memory impairment and at least one of the following cognitive disturbances: aphasia, apraxia, agnosia, or a disturbance in executive functioning. The cognitive deficits must be
sufficiently severe to cause impairment in occupational or social functioning and must represent a decline from a previously higher level of functioning.”

Informal caregivers are unpaid individuals who provide care to relatives or friends.

Residential care/assisted living settings provide room, board, 24-hour oversight, health monitoring, and assistance with activities of daily living and are licensed by the States. Residents often live in their own apartment within a building. The complex provides some care that those who live independently would perform themselves (such as taking medicine). Social and recreational activities are usually provided. (Note: These settings are subsumed under the terminology “RC/AL.”)

Nursing home (skilled nursing setting) settings provide room, board, 24-hour oversight, health monitoring, assistance with activities of daily living, health services, recreational activities, and skilled nursing services. Nursing homes are licensed by the Federal Government.

VII. Summary of Protocol Amendments

In the event of protocol amendments, the date of each amendment will be accompanied by a description of the change and the rationale.

(NOTE THE FOLLOWING PROTOCOL ELEMENTS ARE STANDARD SECTIONS TO BE ADDED TO ALL PROTOCOLS)

VIII. Review of Key Questions

For all EPC reviews, key questions were reviewed and refined as needed by the EPC with input from Key Informants and the Technical Expert Panel (TEP) to assure that the questions are specific and explicit about what information is being reviewed. In addition, for Comparative Effectiveness reviews, the key questions were posted for public comment and finalized by the EPC after review of the comments. Revisions suggested by members of our Technical Expert Panel (TEP) included providing rationale for why persons with mild cognitive impairment will not be included in this review.

Based on input from the TEP, we excluded environmental practices (e.g., presence of pets, use of music in groups) and activities from the interventions of interest if they are not at a system/setting level.

The TEP also suggested adding sleep quality, activity engagement, positive affect, negative affect, pleasure, use of psychoactive medications, and use of restraints as outcomes of interest for people with dementia. Additional outcomes for informal caregivers suggested by the TEP include emotional stress, psychosocial stress, family conflict, and self-efficacy.
IX. Key Informants

Key Informants are the end users of research, including patients and caregivers, practicing clinicians, relevant professional and consumer organizations, purchasers of health care, and others with experience in making health care decisions. Within the EPC program, the Key Informant role is to provide input into identifying the Key Questions for research that will inform healthcare decisions. The EPC solicits input from Key Informants when developing questions for systematic review or when identifying high priority research gaps and needed new research. Key Informants are not involved in analyzing the evidence or writing the report and have not reviewed the report, except as given the opportunity to do so through the peer or public review mechanism.

Key Informants must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their role as end-users, individuals are invited to serve as Key Informants and those who present with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

X. Technical Experts

Technical Experts comprise a multi-disciplinary group of clinical, content, and methodologic experts who provide input in defining populations, interventions, comparisons, or outcomes as well as identifying particular studies or databases to search. They are selected to provide broad expertise and perspectives specific to the topic under development. Divergent and conflicted opinions are common and perceived as health scientific discourse that results in a thoughtful, relevant systematic review. Therefore study questions, design and/or methodological approaches do not necessarily represent the views of individual technical and content experts. Technical Experts provide information to the EPC to identify literature search strategies and recommend approaches to specific issues as requested by the EPC. Technical Experts do not do analysis of any kind nor contribute to the writing of the report and have not reviewed the report, except as given the opportunity to do so through the public review mechanism.

Technical Experts must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals are invited to serve as Technical Experts and those who present with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

XI. Peer Reviewers

Peer reviewers are invited to provide written comments on the draft report based on their clinical, content, or methodologic expertise. Peer review comments on the preliminary draft of the report are considered by the EPC in preparation of the final draft of the report. Peer reviewers do not participate in writing or editing of the final report or other products. The synthesis of the scientific literature presented in the final report does not
necessarily represent the views of individual reviewers. The dispositions of the peer review comments are documented and will, for CERs and Technical briefs, be published three months after the publication of the Evidence report.

Potential Reviewers must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Invited Peer Reviewers may not have any financial conflict of interest greater than $10,000. Peer reviewers who disclose potential business or professional conflicts of interest may submit comments on draft reports through the public comment mechanism.

XII. EPC team disclosures

With the exception of the following, the team had no interests to disclosure:

Lead Investigator’s Statement of Disclosure of Business and Professional Interest:

- Board of Directors: CCAL - Advancing Person-Centered Living Social Work Hospice and Palliative Care Network
- Advisory Board: Center for Excellence in Assisted Living
- Technical Panel Expert Advisor: AHRQ-funded project on low magnitude mechanical stimulation
- Investigator: NIH, AHRQ, AOA, foundation, private, and industry-funded projects on: (a) family involvement, (b) end of life care and outcomes, (c) medication prescribing, and (d) restorative care in assisted living settings and nursing homes; (e) physician care, (f) quality, (g) mental health assessment, (h) disclosure, (i) falls, and (j) transitions in assisted living settings; (k) end-of-life care, (l) oral care, (m) psychosocial care, (n) gastroenteritis, and (o) small house models in nursing homes; (p) low magnitude mechanical stimulation in independent living; (q) stigma and (r) alcohol use across residential settings: and (s) primary care provider dementia assessment and community referral, (t) cancer survivorship, (u) end-of-life communication, and (v) blue light for adults with dementia in community populations.

Co-Investigator A’s Statement of Disclosure of Financial Interests and Business and Professional Interest:


- On the board of Charles House, a not-for-profit adult day center that serves people with dementia, and have been invited to be on the board of a continuing care retirement community that of course serves persons with dementia. Both are volunteer tasks, without compensation.

Co- Investigator B’s Statement of Disclosure of Business and Professional Interest:

- Project Director of an ASPE project evaluating apprenticeship design options for long-term care workers in various settings (nursing home, home health assisted leaving, group homes).

Co-Investigator C’s Statement of Disclosure of Financial Interests and Business and Professional Interest:

- NIH-Building Interdisciplinary Research Centers in Women’s Health; Institutional K-12 awardee; NC translational and Clinical Science Institute Grant.

- Orange County of North Carolina of NC Dept on Aging Wellness Board; National PACE Association Virtual Ethics committee.

XIII. Role of the Funder

This project was funded under Contract No. 290 2007 10056 I from the Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services. The Task Order Officer reviewed contract deliverables for adherence to contract requirements, including the objectivity and independence of the research process and the methodological quality of the report. The authors of this report are responsible for its content. Statements in the report should not be construed as endorsement by the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.