Using Culture Change to Further and Sustainably Reduce the Overutilization of Antipsychotics among Long-Stay Residents in Nursing Homes with Dementia: A Proposal for a National Demonstration

Introduction

Background
The term “culture change” refers to a voluntary movement by pioneers in the long-term care industry to transform the traditional institutional model of nursing home care into a person-centered model that is more home-like. During the last three decades, creative practitioners have developed a range of culture change practices, including re-designing interior layouts to more closely resemble homes; modifying staff training and deployment to focus on resident preferences and to encourage personal relationships; and building new facilities in the heart of communities to make them less isolated and more welcoming to non-residents.

In recognition of this, Section 6114 of the Affordable Care Act (ACA) calls on the HHS Secretary to conduct a national demonstration project on culture change “for the development of best practices in skilled nursing facilities and nursing facilities that are involved in the culture change movement (including the development of resources for facilities to find and access funding in order to undertake culture change).” The provision further directs the agency to take into account “the special needs of residents…who have cognitive impairment, including dementia” – a key factor, since nearly 60 percent of nursing home residents have Alzheimer’s or another dementia. (Alzheimer’s Association, n.d.). The statute specifies that the duration of the demonstration is to be three years, with award payments allocated among applicant facilities on a competitive basis.

In the next decade, as the U.S. health system gears up to prepare for an unprecedented number of frail older adults living with dementia, there is a window of opportunity for development and widespread dissemination of best practices derived from culture change. Growth in the cohort of Medicare beneficiaries over the age of 85, when dementia prevalence is highest, is expected to triple between 2015 and 2050. One in nine older adults today are estimated to have dementia, with an estimated 5 million Americans living with dementia; that number is projected to grow to 14 million by 2050 (Alzheimer’s Association, 2015). Older adults have the highest level of healthcare spending (Kaiser, 2007), and dementia has become the most expensive chronic
condition for public payers and individuals, costing significantly more than heart disease and cancer (Hurd et al., 2013; Kelley, McGarry, Gorges, & Skinner, 2015).

For nursing homes, these trends have important implications. Long-term care residential facilities are the primary provider of residential health care and long-term services and supports (LTSS) for people age 65 and older, and are highly likely to remain on the frontline of serving older adults with dementia.

Purpose
This conceptual proposal outlines an approach to inform CMS’ thinking about how a national demonstration on culture change in nursing homes can be structured to accelerate progress in a key quality improvement goal – further, sustainable reduction in the use of antipsychotics among long-stay residents with dementia. It is the result of consensus deliberation and contributions from individuals and organizations who called attention to the ACA provision in a May 2015 letter sent to CMS Acting Administrator Andy Slavitt.

Nursing Home Culture Change Demonstration

Principles of demonstration
A key goal of Sec. 6114 is to accelerate the shift from a traditional institutional model of facility-based LTSS into an environment that supports and promotes person-centered practices for residents living with dementia who retain the ability and desire to engage, as well as other populations of frail elders. Generally speaking, the operations of many nursing homes today are patterned on hospitals. They are characterized by:

- Top-down leadership and managerial hierarchy with limited input in decision-making by front-line staff and individuals who are being served. Decisions are primarily based on medical knowledge and the economics of service delivery, taking priority over relationships with residents and patients;
- Clinical orientation to a person’s physical condition rather than a broader biopsychosocial-spiritual orientation;
- Task-centered organization and deployment of staff, which places completion of certain activities by staff ahead of the varying preferences of individual patients/residents and their experiences of care and quality of life.

Because an institutional culture is driven strongly by achieving certain measures of clinical performance, this can make it difficult for staff to know how to respond effectively to indicators of poor well-being, including depression, apathy and agitation.
in residents with dementia, who often have difficulty articulating their needs and emotions. Additionally, there is evidence that a strict orientation to task-centered work can contribute to dissatisfaction among frontline staff (Ronch, 2004), which in turn may be a factor in high staff turnover rates.

A traditional institutional approach generally uses medications to address agitation, distress and other “behavior symptoms” (GAO, 2015) to “calm” residents with dementia. These reactions, typically classified as “behavior symptoms,” can include yelling, hitting, taking off clothes, and other actions deemed “disruptive.” Often they are not well understood by staff, and are not perceived as actions that might effectively communicate the resident’s experience. Rather they may be viewed as unwelcome interruptions in the facility’s routine that are most easily addressed with sedating medications, principally antipsychotics. However, a growing body of evidence points to significant downsides associated with widespread use of antipsychotics in frail elderly residents. (Schneider, Dagerman, & Insel, 2005; Power, 2014). Prominent among these is that antipsychotics, pose a higher risk of mortality among frail elders. Antipsychotics carry a “black box” warning from the Food and Drug Administration:

**WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS**

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of seventeen placebo-controlled trials (model duration of 10 weeks) largely in patients taking atypical antipsychotic drugs, revealed a risk of death in drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to come characteristic(s) of the patients is not clear.


Further, studies have demonstrated a correlation between antipsychotics and increased reports of falls, fractures and delirium (Power, 2014). To change an institutional approach that looks to administration of antipsychotics or other types of sedating medications as a first response to “behavior symptoms” in residents with dementia is multi-factorial (Gitlin, Kales, & Lyketsos, 2012). It requires grounding in fundamental changes in organizational culture at all levels in order to support person-centered care. Further, it requires adequate numbers of staff and quality education for all staff in best
practices for person-centered care for individuals with dementia, including guided hands-on learning experiences and mentoring, in order to enable staff to adopt new understandings and beliefs about the experience of the person with dementia. In turn, this helps staff create an environment that supports resident well-being and builds capacity to respond quickly and effectively to challenging situations.

Research shows that behavioral expressions by residents, in particular those living with dementia, can occur for multiple underlying reasons, including unaddressed pain, boredom, lack of appropriate structure, anxiety about staff approach, environmental complexity, or simply a desire for greater comfort. When the causal factors contributing to a state of “ill-being” are identified, individualized care and responses that address and resolve the underlying needs can be implemented (Kales, Gitlin, & Lyketsos, 2014). Biological, psychosocial, caregiving, and environmental factors have been found to play a role in influencing behaviors (Morgan et al., 2012; Kunik et al., 2010; Volicer & Hurley, 2003). Additionally, aspects of nursing home life can cause difficulties for some persons with dementia. In general, the care provided by aides and nurses emphasizes clinical tasks. Research shows that often, resident responses can be directly tied to the manner in which the person living with dementia is approached (Cohen-Mansfield, 2005) and that residents living with dementia exhibit significantly more expressions of distress in the context of task-centered caregiving (Gilmore-Bykovskyi et al., 2015). However, resident well-being can be proactively supported by staff trained to use person-centered practices that are grounded in a thorough understanding of an individual’s background, preferences and personhood (Gitlin et al., 2008).

Broadly speaking, differences in approach between an institutional culture as compared to a person-centered culture for individuals with dementia are described in Table 1, below:

Table 1.

<table>
<thead>
<tr>
<th>Institutional Framework</th>
<th>Person-Centered Framework</th>
</tr>
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<tbody>
<tr>
<td>Ethos that views dementia as a tragic,</td>
<td>Ethos that views dementia as a chronic</td>
</tr>
<tr>
<td>progressive and fatal illness</td>
<td>condition; people are enabled to live the fullest possible lives</td>
</tr>
<tr>
<td>Orientation to symptoms, interventions</td>
<td>Orientation to the person and his or her needs and capabilities</td>
</tr>
<tr>
<td>and treatments</td>
<td></td>
</tr>
<tr>
<td>Decisions are made by managers/leadership</td>
<td>Decisions are made by the individual or together with his/her</td>
</tr>
<tr>
<td></td>
<td>“care partner” staff</td>
</tr>
<tr>
<td>Behavior symptoms are mostly problems</td>
<td>Behaviors are mostly</td>
</tr>
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<table>
<thead>
<tr>
<th>to be managed or treated through pharmacological interventions</th>
<th>expressions/reactions to underlying needs that convey meaning for care partners</th>
</tr>
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<tbody>
<tr>
<td>Activities are structured, group-oriented, and stage-appropriate</td>
<td>Engagement in what is meaningful, including opportunities for growth, are based on each individual’s abilities, interests and preferences</td>
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<tr>
<td>Professional-only relationships are maintained with residents</td>
<td>Resident-staff personal relationships are encouraged</td>
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<tr>
<td>Task completion and efficiency is prioritized over the resident’s personal style and preferences</td>
<td>Meeting individual needs and creating pleasing situations is as important as task completion</td>
</tr>
<tr>
<td>Staffing levels and assignments based on efficiency and cost</td>
<td>Staffing levels based on the needs of the population, e.g., greater use of consistent assignment</td>
</tr>
<tr>
<td>Persons suffering from dementia fade away</td>
<td>Persons living with dementia have a higher quality of life when their individual characteristics, including treatment preferences, goals and capabilities, are clearly understood by “care partner” staff who are charged with supporting their well-being</td>
</tr>
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**Incentives for demonstration**

The authorizing language of Sec. 6114 calls for demonstrating and testing a culture change framework through “development of best practices...that are involved in the culture change movement.” Accelerating the use of known best practices is particularly important for people living with cognitive impairment who also often have co-occurring chronic conditions and functional limitations (Sabat & Harre, 1992; Kitwood, 1997; Fazio, 2008), and whose numbers in long-stay nursing homes are increasing. This population is highly vulnerable to poor care by staffers who are inadequately trained in communicating and working with residents who cannot clearly convey their needs and follow instructions and who may be considered “uncooperative” or “difficult.”

Overutilization of antipsychotics among frail elderly residents living with dementia was clearly established by a 2011 report issued by the Office of Inspector General, Dept. of Health and Human Services (HHS OIG, 2011), “Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents.”
In 2012, the Centers for Medicare and Medicaid Services (CMS) launched the National Partnership to Improve Dementia Care in an effort to address the causal issues cited in the HHS OIG report, and to respond to another ACA provision calling for improved training of frontline aides in dementia care and abuse prevention (Sec. 6121). A primary goal of the Partnership initiative is to reduce utilization of antipsychotics. The initial goal was a 20% reduction for long-stay nursing home residents with dementia, which was achieved by the end of 2014. Subsequently, CMS has set two new goals: a 25% reduction by the end of 2015 and a 30% reduction by the end of 2016. Some dementia care experts argue it may be difficult to achieve sustained reductions in utilization of antipsychotics and other sedating medications among residents with dementia without more fundamental changes in nursing home operational culture (Power, 2014). Others believe that the goal for antipsychotics use in residents with dementia and no diagnosis of psychosis will vary depending on resident characteristics, while others assert that the rate should be close to zero (Evans, testimony before Senate Special Committee on Aging, 2011).

While independent development efforts have been underway for over 30 years to promote culture change (Pioneer Network, Green House, Eden Alternative), a recent study found that fewer than 2% of nursing home operators have successfully done so (Grabowski et al, 2014). Similar findings were reported in a 2007 national survey in which only 5 percent of nursing directors said their facilities completely met the description of a nursing home transformed through culture change (Doty, Koren, & Sturla, 2008). A chief aim of a demonstration on culture change, then, would be to examine and test the ability of culture change practices to accelerate progress in a key quality improvement goal – further, sustained reduction in the use of antipsychotics.

Culture change operators have reported approaching the process or “journey” of transforming a traditional institutional framework into a person-centered one according to a set of principles spanning direct care, organizational and human resource practices, and design of the physical environment. They advocate altering departmental hierarchies and creating more flexible job descriptions, including allowing nurse aides more control over how they do their jobs and relate to residents, and augmenting staff training to focus more closely on the preferences of individual residents. In 2006, CMS demonstrated an interest in furthering culture change practices by issuing the “Artifacts of Culture Change” (CMS & Edu-Catering, 2006). The agency’s interest in the subject is also evident in a proposed Requirements of Participation regulation issued in July 2015, which encompasses a range of possible reforms (Medicare and Medicaid Programs; Reform of Requirements for Long Term Care Facilities, 2015). Among these is a provision calling for comprehensive person-centered care planning, which has the
potential to positively shift the operational culture of nursing homes toward services that better reflect individual preferences and quality of life goals. Yet various quality “report cards,” including the one used in “Nursing Home Compare,” continue to emphasize clinical data, with virtually no incorporation of person-centered quality of life metrics or measurement of care planning and implementation.

Without a more robust evidence base and appropriate incentives to catalyze widespread dissemination of culture change practices, it seems unlikely that most nursing home operators will be highly motivated to adopt culture change practices. To implement these practices on a consistent and sustainable basis will require thoughtful testing and evaluation of a series of well-organized practices that are grounded in changes in organizational leadership approaches and governance (see core elements in list below). Concomitantly, achieving lasting, successful reduction in the utilization of antipsychotic medications for long-stay nursing home residents living with progressive dementia is likely to require all staff to understand how to respond to the individual characteristics and preferences of these residents.

A culture change approach, therefore, must be embedded in the facility’s overall operational system of care. Following are core elements:

1. Leadership and governance buy-in and commitment to culture change, including training and an ongoing support structure (e.g., a collaborative of ongoing interaction and shared learning, and/or coaching and mentoring arrangements) for Administrator/Executive Director and other leaders (including corporate leaders where applicable);
2. Evaluation of existing operational culture and setting of facility goals based on initial evaluation and baseline outcomes;
3. Assignment of an internal culture change champion, leader or designee who is charged with moving the organization forward and holding it accountable to realize agreed-on goals, and having access to “culture change” experts and an implementation structure that includes on-site assessments and feedback;
4. Education, support/communication and mentoring staff programs;
5. Interdisciplinary teams working collaboratively to implement person-centered care practices;
6. Continuous tracking of data, e.g., on resident/family satisfaction, staff satisfaction, staff engagement (i.e., commitment and motivation) and retention, infections, use of antipsychotics, falls, pressure ulcers, hospitalizations and readmissions;
7. Shared learning and collaboration with other facilities implementing culture change practices.
8. Involvement of residents and family members, as possible, in a range of processes (e.g., workshops, team discussions on quality of care and quality of life, learning circles and formal councils).

The core elements discussed above can also be understood as translating into “best practices” interventions and operational protocols that enhance resident direction; staff empowerment and teamwork training benefiting leadership, frontline aides and nurses on how to better understand and address the individual and varying needs of elders, particularly those living with dementia; promotion of a homelike atmosphere that prioritizes the personal choices and preferences of residents (e.g., for privacy, autonomy, and basic routines such as sleeping and eating at varying times); fostering of close relationships between residents, and between residents and staff; ongoing quality improvement that includes measuring the quality of life reported by elders and surrogates; and collaborative decision-making processes that encourage nurse aides to participate in facility discussions and daily decisions that affect residents’ quality of care and quality of life (Koren, 2010). Formal evaluation of these processes can be conducted using existing quality measures (for further discussion, see pgs. 11-13), while allowing for development of new quality of life measures and assessment of their potential to be replicated across the country by interested facilities at an affordable cost.

Accordingly, we propose that CMS sponsor a national culture change demonstration, in collaboration with national culture change organizations (Pioneer Network, Eden Alternative, Green House) and other interested stakeholders, to model how sustainable reductions in the use of antipsychotic medications can be achieved and maintained for residents living with dementia using an approach similar to that outlined here. Rather than focusing only on training for certain types of staff, the demonstration would implement a comprehensive approach inclusive of medical directors, facility leadership and governance, and incorporation of proven management practices that support translation of learning into daily operations. The primary emphasis would be on person-centered care for those living with dementia using approaches implemented at the organizational system and process level, and with supporting content related to care strategies and best practices specific to serving persons with dementia. Some of the organizational practices/systems that support person-centered care would include: front-line staff empowerment to foster decision-making closest to the resident; consistent staff assignments (for which reducing turnover is a necessary precondition); structures and processes that support effective, timely communication among all staff and between staff, other providers (e.g., physicians, pharmacists) residents and families;
adequate staffing to allow for time to provide care in a relationship-centered way; and environmental changes to support an atmosphere that reduces stress and chaos and that fosters quality of life and resident and family engagement.

In addition to implementing Sec. 6114, this approach would complement and further the progress of other HHS initiatives, namely:

- **CMS’ National Partnership to Improve Dementia Care initiative;**

- Widespread implementation of the “Hand in Hand” dementia training program and toolkit developed by CMS. The program and toolkit were distributed to all nursing homes in 2014.

- Promulgation of revised Requirements of Participation for skilled nursing facilities and nursing homes. As proposed, the requirements focus on reducing overutilization of antipsychotic medications for residents with dementia through: 1) a directive that certified nurse aides receive 12 hours of in-service training per year on dementia management and resident abuse prevention; and 2) a requirement that residents receiving antipsychotics be placed on a gradual dose reduction regimen unless clinically contraindicated, and with behavioral interventions substituted in place of these medications in order to reduce any agitation that may occur.

- The National Alzheimer’s Project Plan (NAPA), signed into law in 2011, calls on HHS to address Alzheimer’s comprehensively. One of the principal aims is to optimize the quality of care for people living with dementia.

**Conditions of Participation**

*Type and size of facility*
We recommend a selection of nursing homes with representative samples of diversity of ownership, and with representative samples of diversity of number of residents, income status, and ethnicity. With regard to the number of nursing homes, we recommend a well-constructed sample to support a robust research design in a range of states and in facilities of different sizes with varying antipsychotic prevalence rate reductions.

*Length of participation*
Participating nursing homes would commit to the full 3-year demonstration project.
Geographic context (regional or national)
We recommend a selection of nursing homes with representative geographic samples of urban, suburban and rural locations.

Length of time facility has been in business
We recommend a minimum of five years.

Quality measures of facility (rating)
We recommend a selection of nursing homes with representative samples of quality ratings and star ratings.

Implementation

Timeframe for demonstration project
We recommend three years.

Reimbursement mechanisms
We recommend a modest financial incentive ($10,000-$20,000 per year) to nursing facilities agreeing to participate. The first year amount would be provided upfront; the second and third year amounts would be provided upon submission of all required data/reporting. Penalties would apply only for non-reporting, and would not be tied to performance.

Performance measures
In general, the measures would have several distinct and interrelated aims, or three major goal areas:

1. To decrease utilization of antipsychotic medications by long-stay nursing home residents living with dementia by 50% or more;
2. To transform, measure and sustain operational processes to reflect person-centered caring and dementia-capable practices; and
3. To further develop processes and metrics that focus on maximizing the quality of life and well-being for all residents.

In the first goal area, practices would broadly aim at:
- implementation of operational practices to support individualized, whole-person assessment and care, close staff/resident relationships and interactions, and support of resident decision-making and their exercise of rights and preferences.
Such practices would include front-line staff empowerment to foster decision-making closest to the resident; consistent staff assignments (for which reducing turnover is a necessary precondition); structures and processes that support effective medication management and timely communication among all staff and between staff, other providers (e.g., physicians, pharmacists) residents and families; adequate staffing to allow for time to provide care in a relationship-centered, non-rushed way; and environmental changes to support an atmosphere that reduces stress and chaos, fosters quality of life and resident and family engagement.

- workshops, discussions and trainings that facilitate broader cooperation among all relevant stakeholders, including residents, families, staff, physicians and pharmacists, to support the goal of reducing antipsychotic use.

In the second goal area, practices would aim at fostering:
- focused leadership development training to help leaders develop the skills needed to lead and support this initiative and then to sustain it after the 3 year project period
- education of all staff, families and other residents (who do not have dementia) to help them understand that expressions and indications of distress among individuals with dementia are often a form of communication and signal underlying needs that require effective, timely responses
- reorganization of staff, with an emphasis on teamwork, to empower different types of staff to be able to recognize, make decisions, and respond effectively to the needs of residents with dementia
- measurement/analysis/tracking of the rate of behavioral disruptions in the facility that are either prevented or addressed with appropriate non-pharmacological interventions
- collaborative decision-making (including, as possible, residents and families) with an emphasis on establishing a flattened hierarchy and participatory management systems
- close relationships between residents, family members, staff, and the community.

In the third goal area, practices would aim to:
- enhance quality improvement processes, as agreed by family and front-line staff to be adequate to monitor performance and guide improvement, by including data in domains of resident comfort and security, relationships, meaningful activities (defined as discretionary experiences of a resident’s choice) independence, enjoyment, autonomy, privacy, individuality, dignity and spiritual well-being.
**Ability to monitor progress**

A formal annual process and impact evaluations would be designed with specific fidelity measures to monitor the progress within each nursing home during the demonstration project.

These would include (but not necessarily limited to) tracking of:

- the presence and use of a process for resident, family, and/or representative communication regarding the risks and benefits of antipsychotics and similar medications, and documentation of discussions and consent
- fall rates
- pressure ulcers
- evidence of reduced use of antipsychotics
- consistent use of non-pharmacologic approaches to care, and their impact
- staff compliance with implementing individualized care plans
- hospitalizations and emergency room transfers
- clear documentation of expressions or indications of distress and staff responses
- resident/resident and resident/staff altercations
- documentation of appropriate indication for use of antipsychotics or similar medications, and documentation of specific goals of therapy
- ongoing monitoring of the resident to evaluate effectiveness in achieving therapy goals, and the development or presence of any adverse effects
- documentation of the use of antipsychotics or similar medications only for the duration specified, and at the lowest effective dose.
- identification of gradual dose reduction (GDR) opportunities
- increased use of pharmacy/consultant pharmacists in medication reconciliation
- implementation of person-centered care practices that can improve quality of life and well-being
- staffing levels

**Evaluation Criteria**

In general, evaluation criteria will employ a logic model with both process and outcome evaluation goals and measures, and will aim to maximize generalizability and effectiveness in nursing facilities of all types.

Among the likely criteria would be:

- number of residents on antipsychotics – dementia vs. other diagnosis
establishment of protocols that assure indications and diagnoses are documented for antipsychotics and similar medications – including a clear process for initiating antipsychotics and a requirement for physicians and other prescribers to document and explain the rationale for a script
resident and family participation in care planning processes, and documentation of whether the resident or his or her surrogate articulated quality of care and quality of life goals
facility GDR process and discontinuation of antipsychotics and similar medications, including the number of residents on GDR and success rate
presence of a process for residents and family members to discuss the risks and benefits of antipsychotics and similar medications, including documentation of actions taken by facility if a resident or family member insists on medication that is not recommended or if the resident or family member refuses medication that is recommended
change in fall rates
change in hospitalizations and emergency room transfers
change in use of non-pharmacologic approaches and documentation of specific approaches
change in utilization of antipsychotics and similar medications among long-stay residents with dementia
improvement in person-centered care practices using Artifacts of Culture Change tool

Resident satisfaction
The experiences and well-being of residents living with dementia could possibly be assessed using the Well-being Assessment for Elder Care Partners (Eden Alternative, 2014) and the Collaborative Elder Well-Being Assessment (ARC, 2014) making use of the proxy and self-reported measures.

Assessment tool rating
The research group would engage in testing of selected instruments (or adaptations of existing instruments) to ensure validity and reliability.

Quality of life assessment
Decreased use of antipsychotic medications (possibly using National Research Corp survey data, and person-centered measures related to how thoroughly staff explained medications to residents)
Quality of life measures for nursing home residents (possibly using measures developed by Kane et al., 2003)
Increased staff satisfaction, engagement and well-being (possibly using National Research Corp survey data)
Staff engagement (possibly using a staff engagement assessment tool developed by the Gallup organization)
Staff satisfaction and well-being (possibly using the Well-Being Assessment for Employee Care Partners (Eden Alternative, 2014); satisfaction and well-being of family care partners could possibly be assessed using the Well-Being Assessment for Family Care Partners (Eden Alternative, 2014).

*Staff turnover rate*
Reduction of unintended (by management) staff turnover (possibly using National Research Corp survey data, or data from CMS payroll-based journal)

*Avoidable Hospitalizations*
Reduction of potentially avoidable hospitalizations

*Overall cost savings*
Reduced drug utilization
Reduced expenses associated with unintended staff turnover
Reduced avoidable hospitalizations
Reduction of overall Medicare costs through reduced falls, fractures; and/or other outcomes measures.
REFERENCES


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