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A Novel Psychotropic Risk Assessment To Enhance Medical Management Of Patients With Behavioral And Psychological Symptoms Of Dementia

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Abstract

There is growing evidence and concern documenting the risks of antipsychotic use, and psychotropic medication burden in general, for older adults with behavioral and psychological symptoms of dementia (BPSD). Yet nearly 25 percent of all long term care residents take antipsychotics for behavioral disturbances associated with dementia as “off-label” use, despite their modest efficacy and FDA black box warnings (CMS, 2013). Expert consensus calls for non-pharmacological strategies as the first line treatment, yet some patients with BPSD may require a combination of non-pharmacological interventions and pharmacological treatments for symptom reduction (AGS, 2011). The relief of debilitating symptoms aims to improve quality of life, and reduce patient and caregiver distress. The purpose of this quality improvement project was to implement use of an evidence-based psychotropic risk assessment checklist, that integrates palliative medicine with the dementia disease trajectory, to guide treatment decisions for psychotropic risk reduction, and improve the documentation of outcome measures and person-centered care. The checklist was initially used in four separate skilled nursing facilities over a period of eight weeks. The adoption of the checklist to change practice patterns, and influence the prescribing culture in the nursing homes, was founded on Roger’s Diffusion of Innovation theory (Rogers, 2003). Evaluation methods included qualitative impact results from the interdisciplinary team, and chart review for increased utilization and documentation of non-pharmacological interventions, and shared-decision making on goals of care. Additional future outcomes may include, reduced psychotropic use for public reporting with national benchmarking, and improved survey results from oversight and regulatory organizations. The checklist is simple yet comprehensive, has good feasibility for long-term care, and is projected to expand to the electronic health record for clinician access and utilization in diverse settings.

A Novel Psychotropic Risk Assessment To Enhance Medical Management Of Patients With Behavioral And Psychological Symptoms Of Dementia

Introduction

Background and significance

There is a mounting body of evidence documenting the risks of antipsychotic use for the older adult with behavioral and psychological symptoms of dementia (BPSD). At the same time, the prevalence of these medications in U.S. nursing homes is still about 24 percent (CMS, 2013). Geriatric agitation is seen in about 50-60 % of patients with advanced dementia and as much as 80 % in patients with dementia in nursing homes (Castle, Hanlon, & Handler, 2009; Huybrechts, et al., 2012; Kamble, Chen, Sherer, & Aparasu, 2009; Lester, Kohen, Stefanacci, & Feuerman, 2010). The symptoms of BPSD include agitation, aggression, anxiety, hallucinations, delusions, and depression. The most common antecedents to institutionalization are wandering, agitation, incontinence, and psychosis (Ballard, Waite, & Birks, 2006; Hersch & Falzgraf, 2007; Liperoti, Pedrone, & Consonello, 2008). Expert consensus recommendations call for non-pharmacological strategies to be used as the first line treatment, yet some patients with BPSD may require a combination of non-pharmacological interventions and pharmacological treatments for symptom reduction (AGS, 2011; O'Neil, Freeman, Christensen, Addleman, & Kansagara, 2011). These symptoms pose a significant physical and emotional burden on patients and families, and often precipitate nursing home admissions due to caregiver burnout and fatigue (AGS, 2011; Kamble et al., 2009; Lester, et al., 2011).

Management of these difficult behaviors aim to reduce risk of injury, and improve quality of life (QoL), (Lyketsos, et al., 2006; Lyketsos, 2007; Mohamed et al., 2012). Some evidence suggests that psychosis and agitation in patients with dementia not only decrease QoL (Liperoti, et al., 2008; Ryu, Ha, Park, Yu, Livingston, 2011; Wetzels, Zuidema, Jonghe, Verhey, Koopmans, 2010), but may also predict a worse prognosis (Banerjee, et al., 2006; Hersch, & Falzgraf, 2007; Matsui, et al., 2006; Tun, Murman, Long, Colenda, & Von Eye, 2007). Tun, et al., (2007), found the presence of BPSD correlated negatively with survival rates over a three year period, and other studies have reported psychosis in Alzheimer's disease is associated with increased mortality and accelerated cognitive decline (Gauthier, et al., 2010; Salzman, et al., 2008).

There is a paradigm shift emerging in healthcare, gradually spreading to long-term care as well, that supports a movement away from the medical model or a clinician-disease ethos, to person-centered care (Kolanowski, & Van Haitsma, 2013). The seminal report, *Crossing the Quality Chasm* from the Institute of Medicine (IOM) in 2001, described healthcare in the United States as "impersonal and fragmented". In an effort to achieve optimal healthcare and well being, care must address the whole person, including the bio-psycho-social-spiritual aspects of being. The term person-centered has become accepted as the gold standard, and refocuses care to meeting goals and shared decision-making. Person-centered values and practices emerged from humanistic psychology and the foundational work of Carl Rogers and Abraham Maslow. Person-centered care, as taken from the "Toolkit: Promoting Positive Behavioral Health, Person-Centered Care: An Overview" (Kolanowski, & Van Haitsma, 2013)

- Focuses care on choices, goals for care, and personal preferences.
- Emphasizes and recognizes the individual person's self-determination, unique set of values, perspectives, histories and interests (Koren, 2010).
- Promotes a life affirming, satisfying humane, and meaningful experience (para. 2).

Local problem

The treatment of BPSD in advanced dementia is challenging, because these patients are often frail, and have numerous comorbid conditions that may affect the disease trajectory, (see Figure 1 for dementia disease trajectory). Yet the relief of these debilitating symptoms may improve the QoL, and reduce patient and family distress (Hersch & Falzgraft, 2007; Liperoti, et al., 2008; Wetzels, et al., 2010). As patients move along the dementia disease trajectory and across different settings of care, a palliative care approach with comfort-focused strategies may assist clinicians with treatment decisions to improve quality outcomes for older adults with late life BPSD, and decrease the burden of disease.

Person-centered palliative care can be integrated into dementia care as a new clinical pathway to restructure care services that incorporate the expertise of the IDT to work collaboratively to meet the needs of the patient. Utilizing the knowledge from pharmacists, dieticians, gero-psych practitioners, therapists, and nursing will strengthen the care delivery system. Discussions with family members or the proxy to establish realistic goals of care with comfort care as a priority, is a process of shared decision-making, that is often undocumented, or not well established.

After a complete medical evaluation, and if a substantial trial of non-pharmacological interventions have failed to ameliorate the patient's symptoms, or if the symptoms of distress persist or escalate, the decision to start antipsychotic medication at low doses may be inevitable for some patients. Other psychotropic medications with a safer risk profile may be considered first if appropriate, (e.g. antidepressants, cholinesterase inhibitors, and mood stabilizers), depending on the target symptoms of most concern (Hersch, & Falzgraft, 2007). The medical evaluation of patients with BPSD requires a thorough and systematic approach with critical thinking that is often chaotic or undocumented. The application of clinical guidelines and best practice have been lacking in long-term care. Increased knowledge of geriatric pharmacology is an ongoing need for nursing home clinicians.

The medical management of patients with BPSD is complex, and requires experienced clinicians and professionals on the interdisciplinary team (IDT), and a referral to a behavior specialist or a psychiatric nurse working collaboratively with a psychiatrist, for a gero-psychiatric evaluation may be beneficial. Nursing home clinicians are challenged by healthcare systems that have limited resources and staff with high rates of turnover. Advanced training in dementia care with an emphasis on non-pharmacological approaches is needed (Kolanowski, & Van Haitsma, 2013).

The recommended maximum doses of antipsychotics for elderly patients with dementia based on examination of therapeutic and adverse effects are: risperidone 1.5 mg/day; olanzapine 10 mg/day; quetiapine 200 mg/day; and aripiprazole 12 mg/day (Jeste et al., 2008). Potential side effects from antipsychotics include sedation, tardive dyskinesia, gait disturbances, falls, anticholinergic side effects, extrapyramidal symptoms, orthostatic hypotension, QT interval prolongation, cerebrovascular events, and increased mortality (Hersch, & Falzgraft, 2007).

Antipsychotic medications require a careful consent process, and discussion with the patient or their surrogate decision maker, and documented in the medical record (AGS, 2011). Efforts should be made to design and implement improved consent processes with shared decision-making in long-term care. Disclosure of potential benefits and risks of all psychotropic medications is required. Nursing home clinicians must consider complex risk and quality concerns with multiple sources of information, but the process of critical thinking and analysis is often obscure, undocumented, or unavailable to the IDT.

Although some states restrict advance practice nurses (APNs) from prescribing antipsychotics in nursing home settings, they are often responsible for the clinical oversight of patients with BPSD, and need to be aware of antipsychotic safety concerns. Close monitoring for side effects by APNs and direct care staff, is important to evaluate treatment response, with an effort to keep the dose low, and begin dose reduction when possible. See the case presentation attached, demonstrating the role of APNs working collaboratively with IDT members to manage patients with BPSD. The case presentation also illustrates how utility of the Psychotropic Risk Assessment Tool and a palliative care approach informs clinical decision-making for an older adult with BPSD in a nursing home setting, and improves his quality of life.

An important source of information for clinicians on prescribing guidelines for antipsychotic medications is the *American Geriatrics Society 2012 Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults* (AGS, 2012). This source gives strong evidence-based recommendations to avoid antipsychotic medications in patients with dementia and cognitive impairment, and specifies these medications should not be used for the behavioral problems of dementia, unless non-pharmacological options have failed, or it the patient is a threat to self or others. However, the AGS 2012 Updated Beers Criteria also lists medications that may be used with caution in older adults, whereby, antipsychotics in this category are associated with more risks than benefits, but may be considered appropriate in certain circumstances, or with individuals near the end of life (AGS, 2012). The full document together with accompanying resources can be accessed online at www.americangeriatrics.org.

Intended improvement

Clinicians may be prompted by the IDT or regulatory organizations, to provide a statement of benefit/risk, to justify extended therapy with psychotropic medications, but they lack tools and guidelines to provide these critical appraisals. The purpose of this quality improvement project was to compile evidence on psychotropic medications and dementia, implement use of an evidence-based psychotropic risk assessment checklist, and evaluate the benefits of this checklist at area skilled nursing facilities. The psychotropic risk assessment checklist brings previously developed instruments together into an easy to use checklist that is incorporated into the medical record. Clinicians and IDT members may use the checklist to implement and evaluate the effectiveness of non-pharmacological and pharmacological treatments, to enhance the appropriate use of psychotropic medications for nursing home residents with BPSD, and improve documentation.

Review of the evidence

Despite consensus recommendations that non-pharmacological interventions are the first-line treatment (Azermai, et al., 2011; Gauthier, et al., 2010; Salzman, et al., 2008), there are few proven, effective non-pharmacological interventions for the persistent and problematic behaviors of advanced dementia, and severe geriatric agitation (Buhr, & White, 2006; Huybrechts, et al., 2012; O'Neil, et al., 2011; Sink, Holden, & Yaffe, 2005). Livingston, Johnson, Katona, Paton, & Lyketsos (2007) found in a systematic review, that some behavior management therapies, caregiver and staff education, and possibly cognitive stimulation appear to have lasting effectiveness for the management of BPSD, however due to lack of high quality, well-designed or significantly powered research, the conclusions are limited. Kuerno, et al., (2008) reported in a systematic review of the literature, behavioral and pain management, environmental management, caregiving training, increasing pleasant events and lowering stress, are moderately efficacious in patients with mild to moderate dementia, but it remains unclear whether these strategies are effective in the later stages of the disease.

A comprehensive evidence-based synthesis of non-pharmacological approaches for BPSD was conducted by O'Neil, Freeman, Christensen, Addleman, & Kansagara (2011) at the Portland VA Medical Center, and funded by the Department of Veteran's Affairs. It was titled, *A Systematic Evidence Review of Non-pharmacological Interventions for Behavioral Symptoms of Dementia* (June, 2011). O'Neil and colleagues developed this evidence-based synthesis program in order to develop best practice guidelines on clinical topics relevant to veterans in order to fill the gaps in our current knowledge of effective interventions for the treatment of BPSD. They searched MEDLINE, Cochrane Database of Systematic Reviews and Cochrane Database of Reviews of Effects through 2009 for systematic reviews related to dementia. Based on 21 good quality systematic reviews of a single non-pharmacological interventions, and seven good quality systematic reviews of comparisons of multiple interventions, they reported a few promising results with stimulation/sensory approaches (e.g. acupuncture, aromatherapy, light therapy, massage, music, Snoezelen Multisensory Stimulation Therapy, or TENS-Transcutaneous Electrical Nerve Stimulation). These interventions may be valid, but there were no head-to-head comparisons and the evidence was inconsistent. There were a few behavior techniques that showed some promise, but need additional validation and replication of results. These included, providing a calm predictable schedule, identifying and avoiding situations that agitate the patient, and redirecting and refocusing the patient. Behavioral techniques are primarily focused on caregiver training and support. They found some positive effects of exercise on sleep, and physical health. However, potential harms of exercise in older adults, such as increased risk of falls or physical injuries, and have not been well studied in older adult populations. Lastly, this comprehensive report proposed that non-pharmacological interventions may have potentially fewer and less severe harms versus pharmacological interventions for BPSD, but they cannot recommend any, for lack of evidence.

In a recent systematic review performed by Seitz, Brisbin, & Herrmann, (2012) investigating the efficacy and feasibility of non-pharmacological interventions for BPSD in long-term care settings, they reported some evidence that, effectiveness of non-pharmacological interventions improve if they are consistently implemented over time. Seitz and colleagues concluded that research in this area, that has rigorously tested non-pharmacological interventions on older adults with BPSD, has been limited by small sample sizes, and the use of research teams to implement interventions rather than the nursing home staff.

National consensus guidelines supported by multiple professional associations, call for an increased emphasis of non-pharmacological interventions, as the first line treatment for BPSD in long-term care settings. Recently, at the Gerontological Advanced Practice Nurses Association (GAPNA) annual meeting September 18-21, 2013, there was a panel discussion entitled, Antipsychotics and CMS Behavioral Health Initiative. A Toolkit was presented by Ann Marie Kolanowski, PhD, RN, to improve behavioral health in nursing homes, and was funded by the Commonwealth Foundation (Kolanowski & Van Haitsma, 2013). The purpose of the Toolkit was to compile resources and evidence-based recommendations with regard to alternative approaches to manage the challenging behaviors of BPSD. Dr. Kolanowski acknowledged, that the Toolkit: Promoting Positive Behavioral Health, was developed to address concerns that a void in care may be evident if psychotropic drug reduction is not supplemented by alternative approaches to problematic behaviors. In addition, there were long-term care administrative concerns, that a major barrier to implementing non-pharmacological interventions in these settings is a lack of education for long-term care providers. More education and training is needed to update clinicians, nursing, and direct-care staff with skills and competencies. The toolkit and additional information is available for review and use at www.nursing.psu.edu/Hartford/toolkit. For a complete list of non-pharmacological approaches for treating BPSD recommended in the Toolkit, see Tables 1 and 2. On the Toolkit website, there are multiple 3-minute evidence-based coaching videos, to demonstrate how to engage residents who are exhibiting challenging behaviors during activities of daily living, and strategies to ameliorate agitation.

The Toolkit provides current evidenced-based information that will help long-term care staff to understand the behaviors of BPSD, and provides information on clinical decision support approaches, and practical guidance for health care providers. Addressing the challenges that long-term care staff encounter when responding to the difficult behaviors of patients with BPSD in a resource-challenged environment, experts are increasingly emphasizing the need to identify non-pharmacological approaches that are feasible and efficacious (Kolanowski & Van Haitsma, 2013). Resource challenges faced by nursing home health care providers include, limited access to staff with advanced training in dementia care, limited resources, and high rates of turnover. Kolanowski recommends the Toolkit as a guide to assist nursing homes to identify the “optimal evidence-feasibility fit” for their residents and facility. Feasibility was defined using Seitz and colleagues guidelines: high feasibility approaches require fewer resources, less cost of supplies, less complexity of the activity, minimal staff training, less need for additional personnel and less specialized personnel (Seitz, et al., 2012).

To date, there are no Federal Drug Administration (FDA) approved medications for BPSD and the off-label prescribing of antipsychotics has been a growing concern to clinicians, patients, families, policy-makers, state and federal agencies and consumer groups. In 2005 the FDA issued a black box warning when atypical antipsychotics were associated with a 60 percent increased risk of death compared with placebo in randomized controlled trials among older adult patients with dementia (Schneider, Dagerman, & Insel, 2005). Later in 2008, a black box warning was issued for the conventional antipsychotics as well (Huybrechts, et al., 2012). Since then, the prevalence of antipsychotics for the treatment of BPSD in U.S. nursing homes still ranges from 15-33 percent (Kamble, Chen, Sherer, & Aparasu, 2009; Lester, et al., 2011).

A recent five-year retrospective study conducted by Rossom and colleagues, (2010) using U. S. Veterans Administration data from more than 89,000 veterans did not find an increased risk of death in veterans with dementia who were prescribed lower doses of olanzapine (<2.5 mg/d), quetiapine (<50 mg/d), or risperidone (<1 mg/d). However, at higher doses, these atypical antipsychotics (excluding quetiapine) were associated with an increased risk of death. All doses of haloperidol, a conventional antipsychotic, were associated with increased mortality.

The mechanism(s) for increased mortality associated with antipsychotic use is still not well understood, and needs further research and analysis (AGS, 2011). One study that examined mortality risk, was a large epidemiological five-year retrospective nested case-control study of primary care patients in the United Kingdom (Parker, et al., 2010). They found that there was a 32% greater risk for venous thromboembolism (VTE) in those prescribed antipsychotics in the previous 24 months versus non-antipsychotic users. The risk was greater for new users and those who were prescribed atypical antipsychotics. The study examined risk stratification by type of antipsychotic drug, potency and dose, and adjusted for comorbidity and concomitant drug exposure. The sample was (N=25,532) with a total of 89,491 matched healthy controls. The median age for all participants was 67 years. The researchers concluded more evidence is needed to understand the mechanisms for adverse events from antipsychotic therapy leading to mortality, to allow risk profiling of patients, and eventually lead to approaches to minimize risk in those patients who otherwise may need and benefit from these medications (AGS, 2011).

Data for antipsychotic utilization in U.S. nursing homes from 1996 through 2006, demonstrates that antipsychotic use increased from 16.4% to 25.9% respectively, despite the FDA black box warnings. A study conducted by Lester, Kohen, Stefanacci, & Feuerman (2011) using a nationwide survey to assess changes in antipsychotic utilization patterns since the black box warnings were imposed, found no decrease in their use, but noted a large number of U.S. nursing home facilities had implemented policies for informed consent on the use of these medications.

Current literature and expert consensus supports gradual dose reductions and short-term use of antipsychotics for BPSD, however a recent RCT with high-grade (Level 2) evidence, conducted by Devanand, et al., (2012) has relevance to clinical practice, and may influence treatment decisions for dose reduction or discontinuance of antipsychotic medications. These researchers found in patients with Alzheimer's disease who had psychosis or agitation-aggression, and had responded to risperidone for 4 to 8 months, had an increased risk of relapse of symptoms once risperidone was discontinued, over the group that received placebo. A total of 110 patients met criteria for randomization, and were randomly assigned to one of three regimens: continued risperidone (mean dose 0.97 mg daily) for 32 weeks (group 1), risperidone therapy for 16 weeks followed by placebo for 16 weeks (group 2), or placebo for 32 weeks (group 3). In the first 16 weeks after randomization, the rate of relapse was higher in the group that received placebo than in the groups that received risperdone (60% [24 of 40 patients in group 3] vs. 33% [23 of 70 in groups 1 and 2]; P=0.004; hazard ratio with placebo, 1.94; 95% confidence interval [CI], 1.09 to 3.45; P=0.02). During the next 16 weeks, the rate of relapse was higher in the group that was switched from risperidone to placebo than in the group that continued to receive risperidone (48% [13 of 27 patients in group 2] vs. 15% [20 of 13 in group 1]; P=0.02; hazard ratio, 4.88; 95% CI, 1.08 to 21.98; P=0.02). The findings suggest patients with psychosis or agitation-aggression, who had a sustained response to antipsychotic medications for 4 to 8 months, had a significantly increased risk of relapse for at least 4 months after discontinuation, and this finding should be weighed against the risk of adverse effects with continued antipsychotic treatment (Devarnand et al., 2012).

Centers for Medicare and Medicaid Services (CMS) is concerned about the high off-label use of antipsychotics in nursing homes and sponsored an educational event in March 29, 2012 entitled, *Launch of the Initiative to Improve Behavioral Health and Reduce the Use of Antipsychotic Medications in Nursing Home Residents*. This program showcased a national movement to increase awareness about the high prevalence of off-label use of antipsychotic medications, in nursing homes as a quality improvement initiative. This initiative set a modest goal to reduce antipsychotic use by 15 percent by the end of 2012. Centers for Medicare and Medicaid Services extended partnership with federal and state agencies, nursing homes nationally, advocacy groups and health care professionals to ensure appropriate use of antipsychotics with dementia care.

Centers for Medicare and Medicaid Services has emphasized the strategies of partnership and increased education, transparency and awareness, although some believe more regulation and enforcement with penalties is needed to ensure appropriate use of antipsychotic medications (Senate Special Committee, CMS, 2012). Nursing homes are required to post their rates of antipsychotic utilization on a CMS website, Nursing Home Compare, which began in July, 2012 for increased transparency, national benchmarking and quality measures. Centers of Medicare and Medicaid Services has declared a higher goal in 2013, by reducing inappropriate prescribing of antipsychotics in nursing homes by 40 percent (CMS, 2013).

In May, 2011, the high cost of antipsychotic drugs for nursing home residents was reported by the Department of Health and Human Service, Office of Inspector General (OIG) to be $116 million for a six-month period, January 1-June 30, 2007. This report from OIG addressed the utilization of atypical antipsychotics, including 1) 14% of elderly nursing home residents had Medicare claims for atypical antipsychotic drugs; 2) 83% of Medicare claims for atypical antipsychotics were for off-label conditions and 88% of Medicare claims were associated with the condition specified in the FDA black box warnings; 3) 51% of Medicare atypical antipsychotic drug claims for elderly nursing home residents did not comply with Medicare's reimbursement criteria, amounting to $116 million in claims; and 4) 22% of the atypical antipsychotic drugs claimed through Medicare were not administered in accordance with the CMS standards regarding unnecessary drug use in nursing homes (OIG, 2011).

Centers for Medicare and Medicaid Services objects to the high cost of antipsychotic medications for Medicare beneficiaries primarily because Medicare guidelines do not allow for off-label prescription reimbursements, in addition to the significant health risks, with imposed black box warnings for older adults with BPSD (Edelman, 2012). Data from CMS from 2010, demonstrates more than 17 percent of nursing home residents had daily doses exceeding the recommended levels, and 40 percent of nursing home residents with dementia were receiving antipsychotic medications even though there was no documented diagnosis of psychosis, according to CMS Chief Medical Officer and Director of Clinical Standards and Quality, Patrick Conway MD (CMS Press Release, 2012).

The Centers of Medicare and Medicaid Services acknowledges that there are clinical indications for the use of antipsychotics and other psychotropic medications, in some older adults with BPSD (CMS.gov, 2013). They have updated the training of state surveyors, from the Medicare Learning Network, to evaluate the process of care when antipsychotic medications are used in long-term care facilities by looking for 1) person-centered care based on individualized needs, 2) documentation of the evaluation of new or worsening condition and target symptoms warranting antipsychotic drug use, 3) evidence of critical thinking related to antipsychotic drug use, 4) monitoring for potential side effects, 5) engagement of the resident/family or representative in decision making, and 6) quarterly documentation for gradual dose reduction to support continued use.

Little is known about the prevalence and treatment of BPSD near the end of life (Banerjee, et al., 2006; Kverno, Rabins, Hicks, Black, 2008). Most research has focused on the mild to moderate stages of dementia. Still, there is limited evidence on available therapeutic strategies for late stage dementia and current recommendations are mainly from expert consensus (Alexopoulos, et al., 2005). Banerjee, et al., (2009) report in a systematic review of English papers up to October 2007, we know almost nothing about the natural history of QoL in patients with dementia or what interventions improve or worsen QoL. Additionally, most evidence-based clinical guidelines are based on the management of a single condition, whereas many older adults have multiple comorbidities (Levenson, & Morley, 2007). Some symptoms such as agitation and aggression tend to worsen as the dementia becomes more advanced, (Lyketsos, et al., 2000), yet other patients may experience a decline in agitation as they approach the end of life.

Lawton (1991) provided a broad conceptual framework for QoL that laid a foundation to guide research in older adult populations. He identified four domains of importance: behavioral competence, the objective environment, psychological well-being, and perceived QoL. Each of these domains is highly relevant to evaluate QoL in older adults with cognitive impairment (Logsdon, et al., 2002).

Quality of life measures for older adults with dementia are still emerging, however over the last decade, there have been important strides in contributing new knowledge to what we know about the long debilitating illness of Alzheimer's disease (Crespo, Hornillos, & Bernaldo de Quiros, 2013). Quality of life measures for patients with dementia are utilized to evaluate the efficacy of interventions (e.g. behavioral interventions, drug treatments, or environmental modifications), (Black, Rabins, & Kasper, 2009). Additionally, QoL measures guide clinical decision-making and end-of-life (EOL) care, support decisions to initiate or discontinue treatments, and informs payors and policy-makers which treatment alternatives are most cost-effective (Black, et al., 2009).

Researchers interested in long-term care quality, have begun to shift their focus from how care is delivered or process of care, to how care affects residents, or outcomes of care (Slone, et al., 2005). Although defining and measuring QoL with persons who have dementia is complex, and a "gold standard" instrument does not exist, the current literature supports a combination of methods and sources to provide the most useful information on QoL (Slone, et al, 2005; Selai, & Trimble, 1999).

Patients with dementia have increasing difficulty articulating their symptoms as the disease progresses. When patients with dementia loose their ability to participate in evaluating their self-perceived QoL, researchers and clinicians rely on information from proxies, or a close observer (e.g., nurses, or caregivers), (Slone, et al., 2005). It is generally accepted that patients with severe cognitive impairment, and a Mini-Mental State Examination (MMSE) score below 10 are unable to give reliable answers to questions for a number of reasons, (e.g., lack of memory, inability to concentrate, loss of words or language skills, or lack of awareness of their impairments and disabilities), (Slone, et al., 2005). A MMSE score below 10 has become the cutoff for "interviewability" (Mozley, et al, 1999; Naglie, et al, 2011).

Current evidence suggests there is poor correlation with the patient's own self-report, and the reports of proxies or staff (Logsdon, Gibbons, McCurry, & Teri, 2002; Slone, et al., 2005). However, it has been interpreted that patient and proxy report may represent valid but different perspectives on QoL (Ready, Ott, & Grace, 2004). Multiple sources of information may be necessary to better understand QoL in persons with dementia.

Crespo, Hornillos and Bernaldo de Quiros (2013) found in a small cross-sectional study, (n=102 residents, 184 relatives, and 197 staff) that QoL of residents in nursing homes with dementia were correlated primarily with their emotional state (depression level), while proxies perceptions (both family and staff) were mainly associated with the resident's functional ability in activities of daily living, and therefore perspectives of residents with dementia and proxies were not congruent. An additional finding in this study that adds evidence to support the current literature, was managing depression is an important intervention for impacting QoL for persons with dementia (Crespo, et al., 2013; Naglie, et al., 2011).

Naglie, et al. (2011) conducted a Canadian cross-sectional study, (n=370) to discover whether core symptoms of Alzheimer's disease (AD) consistently predict patient self-rated QoL as assessed by a variety of QoL instruments. They interviewed patients with AD in nursing homes, rated their QoL, and tested for cognition, function, behavioral and psychological symptoms, and depression. They found self-rated symptoms of depression were a consistent independent predictor of patient-rated QoL across diverse QoL measures. These findings are clinically relevant, and support the current evidence in the importance of identifying and treating depression in patients with AD.

Cordner, Blass, Rabins, & Black (2010) found in a cross-sectional study of advanced dementia nursing home residents, that QoL can be improved in this population by appropriate assessment of pain, and effective management of behavior problems. An additional outcome was support for the Alzheimer's Disease Related QoL scale (ADRQL) administered to nursing home residents, surrogate decision-makers, and nursing home staff. They found the ADRQL is a valid indicator of QoL in nursing home populations with advanced dementia, yielding clinically relevant information with important implications for practice, primarily attention to pain and behavior problems.

Over the past decade, there have been a variety of scales developed to measure QoL for persons with dementia. They range from single component measures to some that capture multiple domains. Sloan et al., (2005) sought to compare existing instruments for interrater reliability, internal consistency, and greater understanding of how resident measures correlate with proxy and staff measures. Two of these instruments have particular applicability and utility for nursing home settings and for populations of persons with advanced dementia. The Quality of Life in Alzheimer's Disease (QOL-AD) scale; (Logsdon et al., 2000), has 13 items rated on a 4-point scale (1 = poor, and 4 = excellent) yielding a summative score ranging from 15 to 60. The QOL-AD has one version designed for a person with AD, and one version designed for administration to a caregiver. The reported coefficient alpha for the patient version is 0.87 (Logsdon et al., 2000). The other instrument of interest, and previously mentioned, is the

ADRQL (Rabins, & Steele, 1996). This instrument of 47 items is completed by a caregiver and describes behaviors that are judged by family caregivers and professionals to be important in the evaluation of health-related QoL in AD. The following 5 domains are measured: social interaction, awareness of self, feelings and mood, enjoyment of activities, and response to surroundings. Summary scores are added for each domain and for global quality of life, and range from 0 (lowest quality) to 100 (highest quality). The internal reliability of this scale is reported to range between 0.77 and 0.91 (Lyketsos et al., 2003).

Other instruments used in addition to the QOL-AD and the ADRQL, to capture measurements of cognition, depression, pain, and agitation are likely to provide a comprehensive and complete picture of QoL for advanced dementia residents in nursing homes. The Geriatric Depression Scale (GDS) is a 30-item scale to rate the patient's depressive symptoms, with scores greater than 10 suggestive of clinical depression (Yesavage, et al., 1983). The Neuropsychiatric Inventory (NPI) is a caregiver rated measure of 12 behavioral and psychological symptoms. The score rages from 0-144, with higher scores indicating more severe behavioral symptoms and agitation (Cummings, et al., 1994). Simple pain scales are commonly utilized by nurses and patients in nursing home settings, and a single number from 1-10, (with 10 signifying the greatest pain), is used as an index to monitor pain management. The Numeric Rating Scale (NRS) is a reliable and valid pain intensity scale when used for older adults (Herr, & Garand, 2001).

There are clear similarities between the behaviors and body language of agitation and physical pain. Scales for detecting and measuring pain in patients with severe dementia cannot easily distinguish between physical and emotional pain (Treloar, et al., 2010). Therefore, considering individualized pain management and addressing depression are evidence-based strategies for the ongoing evaluation of a patient with BPSD.

Although antipsychotic medications are associated with an increased risk of mortality and morbidity, and evidence-based guidelines recommend their use only when other interventions have failed, antipsychotics may be justified using a palliative care model, by reducing severe distress in patients who are nearing the end of life (Treloar, et al., 2010). When antipsychotics and other psychotropic medications are used for a target symptom causing distress, they may in fact relieve suffering. Not all potentially inappropriate medications can be avoided, particularly when used as a last resort, and when the patient or the family and the clinician agree the potential benefit outweighs the risk (Fick & Semla, 2012). Antipsychotic prescribing decisions should be based on the patient's individual needs, with medical, functional, social considerations, and quality of life with prognosis (Pretorius, Gataric, Swedlund, & Miller, 2013).

There is evidence that antipsychotics have modest efficacy, and may improve psychosis and aggressive behaviors with a number needed to treat (NNT) of between 5 and 11 (Banerjee, et al., 2009). But conversely, some international studies link psychotropic drugs to poor QoL with functional and cognitive decline, and a high rate of adverse effects (Kleijer, et al., 2009; Ruths, Straand, Nygaard, & Aarsland, 2008; Wetzels, et al., 2010). These studies collectively suggest that trial dose reductions and drug cessation attempts should be attempted at regular intervals.

Some evidence suggests that behavioral focused interventions, supportive comfort therapies and individualized meaningful structured activities can maximize QoL, dignity and comfort, but these therapies need to be standardized, consistent and documented, or it appears to surveyors and researchers that these non-pharmacological interventions are lacking in long-term care delivery systems (Kverno, et al., 2008). Interventions and goals of care that are poorly documented, inconsistent, or found in multiple areas of the chart can be misleading.

Theoretical framework

The adoption of a new Psychotropic Risk Assessment Checklist to change practice patterns, and influence the prescribing culture in the nursing homes, was based on Roger's Diffusion of Innovations theory (Rogers, 2003). The adoption of change in practice for care of patients with BPSD; specifically, an increase in non-pharmacological interventions, a decrease in psychotropic use, and a person-centered care plan, will affect each nursing home individually. The diffusion of new knowledge flows through channels, over a period of time, as communication and dissemination between members of a healthcare system. Innovation translates to change in practice patterns as ongoing sustainable improvements in care delivery, as per Roger's Diffusion of Innovations theory (Rogers, 2003). Each nursing facility is a unique living environment, and adapts to change at a pace that evolves over time. The early adoption of the assessment checklist, by the director of nursing, as an individual of influence and respect, demonstrates quality improvement leadership as a change agent. The quality of the evidence and new knowledge, the perceived relevance to the practice setting and population, and feasibility are important factors that determine rates of adoption. For a conceptual model of the theory see Figure #3.

The Diffusion of Innovations theory is based on the assumption that certain conditions increase or decrease the likelihood that a new concept, product or practice will be adopted by members of a given culture or social system. This theory predicts that media and interpersonal relationships provide information, and influence others opinions and judgment. Rogers defined four stages of innovation: invention, diffusion or communication channel through a social system, time and the social system or context. As information flows through networks, the roles of opinion leaders determine the likelihood that the innovation will be adopted by exerting their influence on audience behavior.

Rogers defined five characteristics that determine the likelihood that an innovation will be adopted. These characteristics also determine the rate of adoption:

- Relative advantage
- Compatibility
- Complexity
- Trialability
- Observability to members within the social system

Communication, or the process of diffusion, is accomplished by members of a social system sharing information and reaching a mutual understanding (Rogers, 2003). Communication channels are mass media channels or interpersonal channels, where mass media are more effective in creating new knowledge, but interpersonal channels are more effective in forming and changing attitudes toward a new idea. Rogers asserted that most individuals evaluate an innovation through subjective evaluation of peers and colleagues who have adopted an innovation rather than on scientific research or expert opinion alone.

Time intervals in the process of diffusion, can be measured in three different ways (Rogers, 2003). The first is a 5-step innovation-decision process involving, 1) an individual’s first knowledge of an innovation, to 2) forming an attitude toward the innovation, to 3) a decision to adopt or reject the innovation, to 4) implementing the innovation to 5) confirming or evaluating the innovation. An individual seeks information at various stages in this process to confirm progression through the process and increase certainty about an innovation’s perceived consequences.

The second way in which time is involved in diffusion is captured by five adoption categories and is based on a standard deviation-curve where very few innovators adopt the innovation in the beginning (2.5%), early adoptors arrive (13.5%) a short time later, followed by the early majority (34%), the late majority (34%), and finally the laggards who represent (16%) of the adoptors. Rates of adoption are influenced by the five perceived characteristics of an innovation previously mentioned.

The third way in which time is involved in the rate of adoption or the relative speed with which an innovation is adopted by members of a social system.

The social system represents the fourth main element in the diffusion of innovation, and Rogers defined it as a set of interrelated units that are engaged in joint problem solving to accomplish a common goal. The units of a social system may be individuals, informal groups, organizations or subsystems. A change agent is an individual who attempts to influence other members innovation-decisions in a direction that is perceived as beneficial to the organization.

An important concept in understanding the nature of the diffusion process is the critical mass. Critical mass occurs at the point at which enough individuals have adopted the innovation so that the innovation’s further rate of adoption becomes self-sustaining. Strategies to reach critical mass should be targeted to the early adoptors, (13.5%) in the social system. These early adoptors are often influential opinion-leaders, and serve as role models for many other members in the organization.

Rogers describes innovators, the first 2.5% of individuals in a system to adopt an innovation as unique, because they understand and apply complex technical knowledge to solve problems in new ways. The innovator must be able to cope with uncertainty about an innovation at the time of adoption. The innovator is usually not limited by financial resources, but may weigh heavily against unprofitable projects. The innovator plays an important role in the diffusion process by launching the innovation and by importing the innovation into the organization from outside the organizational boundaries. Therefore, the innovator has a gatekeeping role in the flow of ideas into a social system.

The early adoptors are the next 13.5 percent of the members of a social system to adopt an innovation. They are described as opinion leaders and speed the diffusion process. The early adoptors are generally respected by their peers and know that to continue to earn the respect of colleagues, they must make judicious innovation-decisions. The early adoptors serve to decrease uncertainty about an innovation by adopting it, and then sharing their perceived benefit to peers by interpersonal connections.

The next group of individuals to adopt an innovation in a social system, are known as the early majority (34%). The early majority group adopts innovations just before the average member of a social system. They interact frequently with their peers, but rarely have positions of opinion leadership. They represent an important adoptor category because they provide interconnectedness in the social system's network of members.

The late majority is the next 34 percent of individuals in a social system to adopt an innovation. This adoptor category, adopts new ideas just after the average member of a social system, and they are likely to be influenced by increasing peer pressure. They may be skeptical and cautious before they motivated to make a change. The late majority group is characterized by having relatively scarce resources, which means they need confidence and low risk to adopt new ideas.

Rogers classified the last group of individuals to adopt an innovation as the laggards, or 16 percent of the members of a social system. Many laggards are relatively isolated in the social network and their usual point of reference rests on process and patterns of the past. They may resist innovation and similar to the late majority, are resource limited, and may fear failure.

Methods

Ethical issues

APNs and other clinicians have important professional and ethical obligations to older adults, with advanced dementia and behavioral disturbances. Especially challenging is the medical management with psychotropic medications in the setting of long-term care. Knowledge of the dementia disease trajectory may inform treatment decisions with a goal for palliative care and symptom reduction to relieve suffering and improve QoL. The ethical virtues of nonmaleficence (do no harm), beneficence (do good), autonomy (respect for individual rights), and advocacy (speaking for the interests of those who cannot speak) are based in our professional code of ethics, and are relevant for vulnerable populations. APNs can rely on our professional organization, the American Nurse's Association's *Code of Ethics for Nurses with Interpretative Statements* for a position statement on end of life care:

> Nursing care is directed toward meeting the comprehensive needs of patients and their families across the continuum of care. This is particularly vital in the care of patients and their families at the end of life to prevent and relieve the cascade of symptoms and suffering that are commonly associated with dying. (ANA, 2001, p.12)

In an effort to provide more optimal dementia care, the tool provides a checklist to critically appraise the benefits and risks of psychotropic medications, and to establish the goals of care, including QoL measures, with shared decision-making, for person-centered care. With the knowledge that nursing homes are living-environments for residents who live there, long-term care providers should preserve and promote QoL, as important as other health outcomes (Kane, et al., 2003).

Setting

The Psychotropic Risk Assessment Checklist was implemented in four separate skilled nursing facilities (SNF) over a period of eight weeks, to document the medical management for a total of 17 long-stay residents with BPSD. The SNFs were local to the community of Napa, California, and ranged in size from 50 beds to 190 beds. Two of the SNFs were contracted with Kaiser Permanente (KP) for skilled care. As a KP employed nurse practitioner, my caseload included skilled care residents in addition to a total of 92 long-stay residents, among the four facilities. Each facility had individual interdisciplinary teams (IDT) and leadership philosophies, with individual rates of adoption of new knowledge, and willingness to change. The directors of nursing were enthusiastic about implementing the Psychotropic Risk Assessment Checklist, and became the facility champion for implementation. They perceived the new checklist as quality improvement for a process of care delivery that was poorly documented, and located in many sections of the chart. The checklist is simple but comprehensive, streamlined, and inexpensive to implement. The checklist seemed a good fit with individual organizational missions and IOM philosophies; to deliver safe, efficient, equitable, timely, high-quality, person-centered care.

Planning the intervention

Discussions with the administrators and directors of nursing at the individual SNFs, regarding their concerns with the general lack of documentation in the medical records with the medical management of residents with BPSD, revealed their readiness to participate in a revised process of care. Potential penalties related to non-compliance with regulations on inappropriate psychotropic use, was an additional concern. The checklist was simple, concise but comprehensive, and was feasible for implementation in their organizations. It included a list of the resident's medical condition and staging of dementia, target symptoms, individualized non-pharmacological interventions employed, a complete list of psychotropic medications prescribed with their indications, psychotropic risk review, QoL indicators, and engaged families or patient proxies for shared decision-making. Additional value from the checklist comes from the integration of palliative care with dementia care, addressing the goals of care, with a focus on the resident's experience. Engaging the IDT and psychotropic review committee at each facility, strengthens the care delivery process through collaboration. The checklist could be accessed and updated by clinicians and other IDT members, and utilized as a quarterly update and review of the medical management for residents with BPSD and psychotropic risk reduction. Decisions to attempt psychotropic dose reductions or discontinuations would be carefully evaluated and documented on the checklist. Engagement of the family or the patient's proxy would be documented as an important part of the process. An electronic version of the checklist, by utilizing informatics to access psychotropic risk assessment information along the continuum, would meet expectations of busy primary health care physicians as high end-users. As the checklist evolves as a simple, concise documentation aid, with a point and click format, it may simplify the process of critical thinking and risk analysis in the medical management of BPSD. Sharing an electronic version of the checklist with colleagues and eventual spread to other Kaiser Permanente service areas can be accomplished by introducing the checklist at medical conferences and the annual long-term care summit. Dissemination of the checklist can spread rapidly by submitting for publication to geriatric medical and nursing journals. A complete project implementation Gantt Chart is included as an appendix.

Implementation of the project

Project education and implementation began in January 2013. An educational update on best practice guidelines on the medical management of patients with BPSD with evidence-based risk and safety concerns, was delivered to Kaiser Permanente nurse practitioners in the San Francisco bay area who worked in long-term care facilities, in February 2013. Later, in September, a similar educational update was delivered to KP primary care physicians in the Napa Medical Offices. In October 2013, an educational update was presented to interdisciplinary health professionals at a KP SNF Summit. A checklist concept evolved as a method to aid documentation and address critical thinking toward psychotropic use for residents with BPSD. The evolution of an electronic version of the checklist, came from discussions with primary care physician colleagues who were end-users and familiar with the KP Healthconnect electronic health record.

How the checklist works

The checklist is a 2-page, front and back paper form, with multiple components including; disease severity and prognosis, target symptoms, individualized non-pharmacological interventions, psychotropic drugs prescribed with indications, risk analysis, QoL indicators, and shared decision-making with proxy or family discussions including trial dose reductions based on perceived benefit and risk, and goals of care. The dementia disease trajectory, although not included in the checklist, helps the clinician to define dementia as a progressive and terminal disease. This knowledge of the temporal pattern of the disease process leading to a person's death, suggests when to commence palliative care or hospice.

The Psychotropic Risk Assessment Checklist involves the evidence-based FAST (Functional Assessment Staging Test) a scale that helps to predict end of life parameters for dementia disease, where a score above 7 correlates with advanced disease (Reisberg, 1988). Stage 7c of the FAST scale has been suggested by the National Hospice Organization as an appropriate point to enroll patients with a primary diagnosis of dementia into hospice (National Hospice Organization, 1996). At stage 7c or greater, more than two-thirds of persons with dementia will die within 6 months (Hanrahan, Raymond, McGowen, & Luchins, 1999). Patients cannot be staged using the FAST criteria unless their disease progresses in the ordinal sequence of the scale (Luchins, Hanrahan, & Murphy, 1997). It is important to note that not all patients with dementia follow the progression of disease designated by the FAST. The Psychotropic Risk Assessment Checklist prompts the clinician to identify the type, severity or stage of dementia, and considers other co-morbid conditions that may affect the clinical course and treatment choices.

The target symptoms of most concern, or distress to the patient, are identified and defined. Expert consensus calls for non-pharmacological strategies to be first line treatment, and should be designed for each individual patient according to patient preference, or what is beneficial to ameliorate the target symptoms. Feasible and effective non-pharmacological interventions may include (e.g. time outside, exercise or movement, music or sing-a-longs, animal assisted therapy, or scheduled family visits). Many patients with mild to moderate BPSD will not need pharmacological treatments if non-pharmacological interventions are effective, and utilized consistently. However, some patients with advanced disease and severe symptoms may inevitably need psychotropic treatments, and the checklist matches the prescribed medication with a specific target symptom of concern.

The checklist provides a condensed synopsis of evidence-based psychotropic risk concerns, such as fall risk, extrapyramidal side effects, or the cumulative effect of anticholinergic burden, as well as QT interval prolongation. New evidence from Rossom, et al., (2010), suggests lower doses of antipsychotic medications are associated with lower risk for mortality and morbidity, and may guide treatment decisions for trial dose reductions. Using the lowest possible dose to achieve efficacy is an important clinical tip for prescribing for older adults.

Evidence of QoL measures for dementia patients at the end of life, suggest strong correlatations with decreased pain, depression and agitation. The Psychotropic Risk Assessment Checklist prompts clinicians to address pain management, symptom reduction, depression management, and sleep quality with interventions to improve QoL. The qualitative value of the checklist lies in the integration of palliative medicine with dementia care, with comfort-focused strategies to relieve suffering of those who are near the end of life. The checklist acts as a guide to inform discussions with patient's family or proxy regarding prognosis and goals of care. When optimizing the care of persons with dementia, and addressing the goals of comfort and shared decision-making, the use of psychotropic medications may be justified in the management of debilitating symptoms (AGS, 2012). In this framework of therapeutic analysis, the perceived benefits of psychotropic treatments may exceed the risks, in certain individuals who are near the end of life. In cases with extended psychotropic therapy, the decision to mainstay or decrease the psychotropic burden, is based on the patient's QoL benefit, or preference for risk reduction by trial dose reduction. Clear documentation of a benefit/risk statement regarding a patient's psychotropic use, is a key value of the Psychotropic Risk Assessment Checklist.

The checklist may become more widely utilized in long term care settings to provide clinicians and IDT members with an evidence-based method for risk appraisal, to inform the selection of appropriate non-pharmacological approaches, and lowest risk options for psychotropic therapy, if necessary. Researchers may find the checklist beneficial in designating performance measures and outcome statistics, risk management and QoL indicators for those with BPSD in diverse settings. This checklist is not a scale, and does not stratify risk or predict outcome measures for mortality or morbidity indices, for example. Nor has the checklist been endorsed as policy or best practice by Kaiser Permanente.

Planning the study of the intervention

The checklist represents a process improvement with a focus on person-centeredness, engaging the IDT, utilizing an evidence-based process of critical thinking and analysis, and informatics. Retrospective chart review was planned to capture measures of increased utilization and documentation of non-pharmacological interventions and shared decision-making with residents and their families or proxy. By the essence of using the checklist, where a chaotic process existed before, it was assumed that utilization and documentation of these measures would improve. There were no actual baseline measures to compare, and it was assumed that if non-pharmacological interventions were undocumented, that they were not done, or done inconsistently.

A gap analysis can be viewed as an appendix.

Methods of evaluation

A full SWOT assessment with known internal and external forces can be viewed as an appendix. The Psychotropic Risk Assessment Checklist supports the Kaiser Permanente (KP) culture of knowledge sharing and evidence-based practice, and is congruent with the KP mission to provide high-quality and cost effective care to the members and communities it serves. The checklist also supports the individual nursing home missions, and was perceived as an innovation that adds value to their current care delivery system. The checklist is easily accessed by the IDT members, and enhances collaboration and expertise of other health disciplines. Each individual nursing home has unique leadership styles and resource constraints and therefore, different rates of adoption to change. The checklist satisfies CMS and national initiatives to improve care for patients with BPSD and reduce psychotropic use. The checklist may reduce potential external pressures posed by regulatory agencies and penalties with inappropriate psychotropic use, and improve compliance with laws and regulations concerned with prescribing practices.

Retrospective chart review was conducted to collect data for increased documentation of multiple components of BPSD management. The utilization of the Psychotropic Risk Assessment Checklist facilitated concise documentation on the type and severity of dementia, the disease staging (to integrate palliative medicine into the goals of care), the target symptoms causing distress, the effective non-pharmacological interventions, the psychotropic drug prescribed, the dose and indication, adverse effect monitoring, and QoL indicators. The decision to implement a trial dose reduction of psychotropic medications was a collaborative decision with the patient, family, or members of the IDT and documented on the checklist. Finally, the checklist documents and acknowledges discussions with family or proxies on shared decision-making and goals of care (e.g. palliative, comfort, hospice). The checklist will be utilized as a quarterly clinical assessment for all patients with BPSD who use psychotropic medications. By the very essence of using the checklist as a new process, there will be enhanced documentation of the various components in the management of BPSD, that were previously undocumented, and measured as a process improvement.

The qualitative impact results were captured by a phone survey conducted to elicit feed back from the directors of nursing who were the Quality Improvement Coordinators and lead the psychotropic review process at each nursing facility. An informal phone survey was also conducted to patient's family or proxy, to capture evaluative remarks about the provision of care for patients with BPSD, and satisfaction.

Analysis

The methods used to capture data included both quantitative and qualitative strategies and are still emerging. Quantitative and qualitative metrics include, 1) increased utilization and documentation of non-pharmacological interventions, 2) improved satisfaction with care, and shared decision-making, 3) improved QoL measures, and 4) qualitative impact results from the IDT. Additional future outcomes include reduced psychotropic use with cost savings, improved public benchmarking, and improved survey results from oversight and regulatory organizations. Developing a formal quarterly patient/family or proxy survey will measure perceptions with care delivery. This kind of data provides rich content for evaluating the project impact. Clinician satisfaction with the Psychotropic Risk Assessment Checklist comes from comprehensive but concise documentation of BPSD management. The checklist simplifies the complex task of weighing benefits and risks of psychotropic use, and risk reduction. Patients and families who are satisfied with their care, is an additional value. An electronic version of the checklist will improve clinician access and end-user efficiency.

The project implementation is primarily nonlinear, with a less defined structure. There are anticipated outcomes that influence care management, with improved documentation of a care delivery process that was previously fragmented and disorganized. Other important anticipated outcomes extend to influence culture change with psychotropic prescribing, and increased emphasis on non-pharmacological interventions. Metrics collected are both simple, as with retrospective chart review, and other complex metrics emerge from organizational impact and culture change, as outcomes with care for patients with BPSD.

Results

Program evaluation

The checklist was implemented with 17 long-stay residents with BPSD on psychotropic medicines, with a mean age = 86.7 years (range = 65-97 years). There were 16 females (94%), and 1 male (6%). From a total of 92 long-stay residents on my case-load, there were 17 residents on psychotropic medications for BPSD management which represented 18.4% residents on psychotropic medicines. The Mean FAST score for dementia severity was (6.71); a score over 7 represents severe dementia.

The checklist improved documentation of non-pharmacological interventions, for the management of BPSD, on all 17 residents. Psychotropic dose reductions were documented on a total of 7 residents, which represented a 41% reduction in psychotropic medication use during the eight week project, conducted January 1, 2014 through February 28, 2014. One resident experienced a relapse of severe symptoms after dose reduction, and after a gero-psych evaluation, had a subsequent increase in psychotropic medications. All four of the directors of nurses reported, the checklist represented quality improvement by increased documentation of the non-pharmacological interventions employed for each resident, the target symptoms of distress, the dementia disease severity, the psychotropic medications prescribed and indication, adverse effect monitoring, quality of life indicators, and goals of care. Each of the directors of nursing, or facility champion, readily adopted the checklist into process improvement, because it was concise, streamlined, comprehensive, and had a good feasibility fit for their residents and facility. There was no cost associated with the tool implementation to the facilities, and three of the four directors of nursing believed there may be significant cost saving with decreased psychotropic medication use, and a potential decrease in penalties associated with inappropriate medication use.

Additional qualitative impact measures were elicited from a phone survey conducted with patient's family or proxies. Most, (72%) expressed appreciation and increased satisfaction by being informed, and included in the process of developing realistic goals of care, in the context of end stage dementia disease, with perceived QoL, and shared decision-making. Some families or proxies commented that these discussions helped them feel significantly better about the care provision, and decreased their worries and perceived burden of care.

Discussion

Summary

We know the treatment for late life BPSD is particularly challenging because of debility and frailty of older adults, existing comorbidities, and polypharmacy contributing to risk of adverse drug events. Still, clinicians have been in a quandary lacking clear guidelines and tools for clinical decision-making and few options for effective treatments for those who suffer with the debilitating symptoms of BPSD. Nursing home clinicians who consider treatment options for late life BPSD strive to ease the burden of suffering and the disease, and influence quality outcomes for end of life care. A person-centered palliative care approach offers a clinical pathway that is compatible with the dementia disease trajectory, and should be introduced as patients and families or proxies consider treatment choices and advanced directives.

This quality improvement project provided a novel approach to the management of long-term residents with BPSD. The checklist was rapidly adopted by each long-term care facility as an innovation because it supported the over-all mission of each individual organization. Early integration of palliative medicine with dementia care, promoted enhanced identification of realistic goals of care, with person-centered outcomes, and improved patient and care giving experience.

The organizational leadership team and stakeholders (Administrator, Director of Nursing, and Medical Director) at each individual implementation site played an essential role in system integration and sustainability of a new care process (Kolanowski & Van Haitsma, 2013). More in-depth strategic planning up front should have included meetings and partnership with these key stakeholders. Planning meetings with each individual director of nursing was critical, but including the other members of the leadership team would have further boosted our efforts. Another important lesson learned, is articulating the vision of person-centered care early into project planning. When the vision is clearly shared, the quality improvement project is sure to spread and succeed, and increases the likelihood of being sustained.

This quality improvement project has important implications for Advanced Nursing Practice. Developing, testing, and implementing new nursing care models for treating persons with BPSD and vulnerable populations has been identified as a major emphasis for gerontological nursing (Kolanowski & Priven, 2006). As new evidence and guidelines emerge in the care of the geriatric patient with BPSD, new knowledge will need continual translation to practice, using the strength and diversity of the interdisciplinary team.

Educational programs to update and inform clinicians and IDT members on best practice recommendations for non-pharmacological and pharmacological interventions will improve clinical competencies in the management of BPSD and support sustainability in practice changes over time.

The Psychotropic Risk Assessment Checklist changes the paradigm of care delivery, recalibrating the goals of care for comfort, instead of health maintenance, and permits less restrictive treatment modalities. The checklist provides a method to restructure care services that incorporate the entire IDT to work collaboratively to meet the needs of the patient. Utilizing the expertise of pharmacists, dieticians, gero-psych practitioners, therapists, and nurses strengthens the care delivery system. More planning is needed to develop a quality team to include pharmacist participation. Their expertise and involvement in the medical management of psychotropic medications cannot be underestimated. As clinical pharmacists complete their routine chart review, their input into the checklist and plan of care, with recommendations and modifications is highly valued.

The checklist was feasible, and streamlined as a quality improvement strategy for clinicians to critically appraise the medical management of all patients with BPSD, for risk reduction and symptom amelioration.

The dissemination plan for the Psychotropic Risk Assessment Checklist will proceed towards submission for publication and regional presentations to share with other KP service areas. Additionally, moving from a paper form to an electronic version of the checklist will enhance documentation and user accessibility. As each long-term care facility uploads the checklist to their own electronic health record systems, there will be further spread and increased generalizability.

Relation to other evidence

The current emphasis on first line approach with non-pharmacological interventions for BPSD represents an evolving culture change at each individual facility. Regardless of the current evidence base, patient and family preferences should guide clinical decision-making. Clearly, caregivers and family members are eager to discuss what interventions have helped and which ones have not helped, and the Psychotropic Risk Assessment Checklist provides a unique and concise format to incorporate these behavioral interventions into the care plan.

Other long-term care facilities will be looking for ways to increase utilization and documentation of non-pharmacological interventions and decrease inappropriate use of antipsychotic medications. So far, an emphasis on education and training for clinicians, direct care staff, and caregivers has the best efficacy and long effect. National benchmarking and public reporting of antipsychotic utilization rates on the CMS website, Nursing Home Compare is still new and data is emerging.

Qualitative feedback responses from the directors of nursing indicate, they value the opportunity to improve documentation of non-pharmacological interventions, because the lack of documentation may lead to misguided evaluations from oversight organizations. Partnership with individual nursing home stakeholders to adopt a variety of non-pharmacological strategies with sufficient allocation of resources for staff training and support is needed.

Kolanowski's Toolkit for Promoting Positive Behavioral Health: A Non-pharmacological Toolkit for Senior Living Communities gives comprehensive and practical guidance to assist long-term care facilities to identify the most optimal and feasible approaches that match their residents and individual capabilities. The challenges they face as resource-limited organizations are formidable, although low-cost and efficacious approaches are good solutions for the complex problems in the management of BPSD.

Long-term care facilities are living-environments, unlike hospitals, and need to promote comfortable environments for senior living. Many basic needs are met in long-term care facilities, because they are therapeutic living environments, where caregivers are trained to provide adequate food, clothing, hygiene, safety, and rest. However, other more complex needs may require additional services structured for behavioral and psychological problems, meaningful social activities, cultural or spiritual needs that affect QoL (Kolanowski, & Van Haitsma, 2013). The allocation of resources from basic levels of care toward more complex potentially unmet needs may have a positive impact on health-related QoL for residents with advanced dementia (Scholzel-Dorenbos, Meeuwsen, Olde Rikkert, 2009), and this has important implications for clinical practice and for health policy and planning. Ongoing evaluation and management of pain, depression, and behavioral disturbances are evidence-based approaches to improve QoL for individuals with advanced dementia, and should be emphasized.

Attention to quality of life for residents in nursing homes is still emerging but for residents with advanced dementia and BPSD, clearly an emphasis on pain, depression, and the target symptoms of BPSD has the greatest potential to make the most difference for those persons.

Please see attached synthesis of evidence of literature review as an attachment, for QoL for persons with advanced dementia in long term care settings.

Barriers to implementation/Limitations

Efforts should be made to design and implement improved informed consent processes with shared decision-making with psychotropic use. A discussion with disclosure of potential benefits and risks of psychotropic medications with thorough documentation is required in long-term care. APNs are capable of facilitating these processes, and are largely responsibile for the clinical over-sight of psychotropic medications in long-term care settings. Legislative action to remove scope of practice barriers should be examined, since California law under the Health and Safety Code prohibits APNs from obtaining informed consent or prescribing antipsychotic medications in these settings. Off-label prescribing of psychotropic medicines for BPSD is an additional concern for all clinicians and healthcare professionals.

Clearly articulating a vision for person-centered care and incorporating that vision into strategic planning (Kolanowski & Van Haitsma, 2013) is critical for the culture change movement. Moving away from the medical model of care, towards a person-centered philosophy, involves every member of the IDT, administrative and stakeholders alike. This vision should be foundational to any quality improvement project.

Identifying a champion at each facility, who is an expert on the Psychotropic Risk Assessment Checklist is essential to facilitate the ongoing implementation and sustaining the quality improvement effort. The director of nursing at each facility worked well in this leadership role, to advance the culture change and project implementation, however other disciplines will provide additional expertise.

Time limitations created a barrier to further develop a formal quarterly patient/family satisfaction survey. A survey to include medical management with antipsychotics and other psychotropic medications will be an effective strategy for a continuous quality improvement process, to measure ongoing quality outcomes and guide clinical decision-making. Other outcome measures of perceived management of pain, depression, and BPSD symptoms should be included in the survey as components of patient/family satisfaction with care. Conducting patient/family satisfaction surveys will provide important information about what patient needs may be still unmet, and provides an opportunity for patients or families, and caregivers to reflect on whether an intervention has made a meaningful difference in their life. Information from surveys can be an important link between the patient and family needs and health care services provided.

Interpretation

Continued efforts to improve care for older adults with BPSD by utilizing the Psychotropic Risk Assessment Checklist will require a longer period of time to verify and evaluate practice improvements, by measuring continuous quality outcomes and sustained change. Outcomes such as improved staff satisfaction, improved state surveillance, continued accreditation, and averting potential penalties with psychotropic use, were not yet realized. Nursing homes may capture improved antipsychotic utilization rates with national benchmarking status as they proceed with trial dose reductions and stop medications that are not needed.

The degree of agreement regarding the desirability of, or the need for change was enthusiastic among the four directors of nurses. One director of nurses has since retired, and so new relationships will evolve over time as an ongoing process of sustainability in practice improvement. The director of nurses at each facility was the key change agent, and was the leader of the IDT psychotropic review process. There are important implications for future professional and staff development by allocating resources for education, and for direct care staff and caregiver support. Care of older adults with BPSD will require new skills and competencies as knowledge of best practices emerge.

A new checklist must be quick, easy, and accessible for busy clinicians to use. Time constraints are a constant reality for clinicians who strive to deliver person-centered, comprehensive, safe, timely and equitable care. As the checklist evolves as an electronic version on the EHR, and disseminates to diverse settings along the continuum of care, it becomes easily accessible to clinicians, nurses, pharmacists, and others on the IDT. Then, it will impact care for patients with BPSD, and facilitate responsible risk management for psychotropic use. It is essential that APNs take a leadership role in the development and implementation of guidelines for improved medication management among older adults. Nurses must stay engaged in the critical appraisal of psychotropic medication use and lead the culture change in improved implementation of non-pharmacological alternatives.

Conclusion

The Psychotropic Risk Assessment Checklist is innovative, modern, evidence-based, and congruent with the CMS national initiatives to reduce unnecessary and inappropriate psychotropic and antipsychotic use. However, the checklist provides a pathway for clinicians to justify these medications for some individuals with advance dementia who may be near the end of life, where symptom reduction achieved by a combination of non-pharmacological and pharmacological treatments, may improve their QoL. As clinicians interweave palliative medicine with dementia care, the Psychotropic Risk Assessment Checklist informs decision-making, leads to improved documentation, and engages the IDT in the provision of person-centered care. Improved outcomes and QoL for older adults with advanced dementia and BPSD is a prominent concern for all long-term health professionals.

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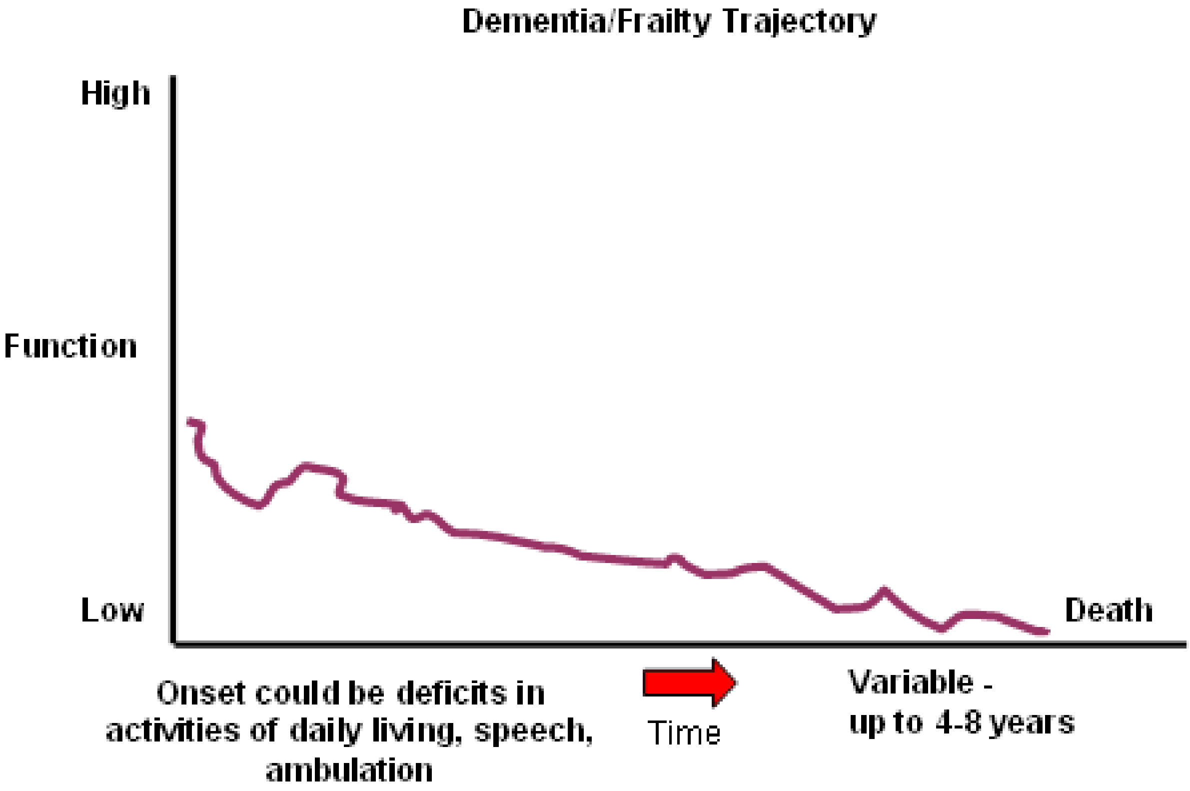


Picture 1

Dementia Disease Trajectory retrieved from online/data_dx/reg/1020/img/1020-4-iline.gif

Name:_Mr O___________________________________MR#_________________Date_____________

Psychotropic Risk Assessment Checklist for Patients with BPSD

Type and Severity of Dementia: (check which applies)
_**X**_ Alzheimer's __ Vascular __ Lewy Body Dementia _X_ Other ______________________
Other Co-morbidities: __diabetes __CHF_**X**_ CVA__Other_CAD, Anemia w/o further w/u________
_X__advanced age: 88 y/o

Staging with (FAST) Functional Assessment Staging Test:

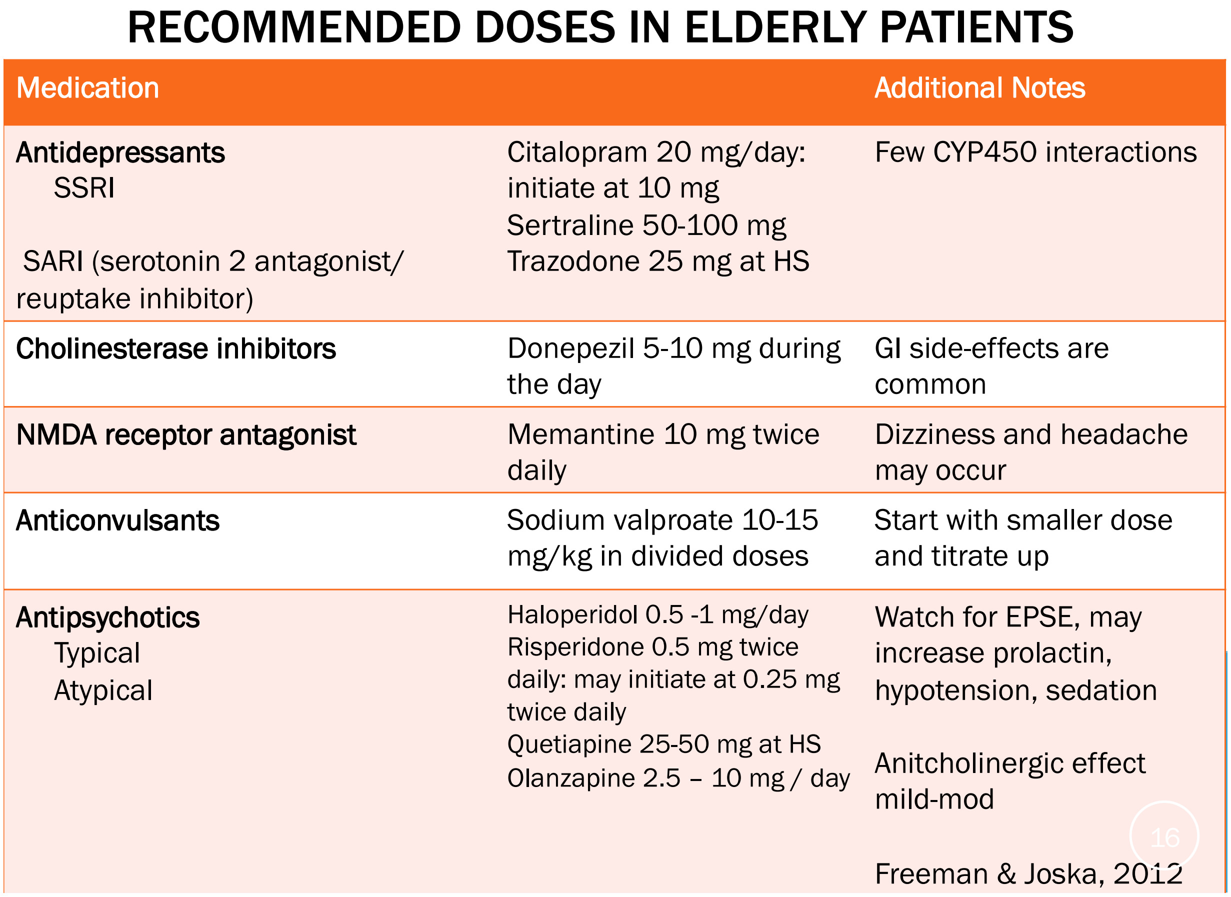
Stage	**Stage Name**	**Characteristic**	MMSE score
1	Normal Aging	No deficits	29-30
2	Poss Mild Cog Impairment	Subjective functional deficit	28-29
3	Mild Cognitive Impairment	Objective functional deficit interferes w complex tasks	24-28
4	Mild Dementia	ADLs become affected	19-20
5	Moderate Dementia	Needs help selecting proper attire	15
6a	Moderately Severe Dementia	Needs help putting on clothes	9
6b	Moderately Severe Dementia	Needs help bathing	8
6c	Moderately Severe Dementia	Needs help toileting	5
6d	Moderately Severe Dementia	Urinary incontinence	3
6e	Moderately Severe Dementia	Fecal incontinence	1
7a **X**	Severe Dementia	Speaks 5-6 words during day	0
7b	Severe Dementia	Speaks only 1 word clearly	0
7c	Severe Dementia	Can no longer walk	0
7d	Severe Dementia	Can no longer sit up	0
7e	Severe Dementia	Can no longer smile	0
7f	Severe Dementia	Can no longer hold up head	0

Target Symptom causing distress or danger to the patient: __ hallucinations _X_delusions __ severe anxiety_X_combativeness _X_persistent yelling _X other _Insomnia/Sleep Disorder_

Non-pharmacological Interventions: _X_time outside _X_ exercise or movement_W/C rides_healthy- snacks __ puzzles or activities __ family photo album __ pet or stuffed animal
_X_ scheduled family visits __ purse or wallet to hold __ hair brushing __ music__other___

List Psychotropic Drugs: dose and frequency and target sx
1. _Sertraline 100mg q day for agitated depression/grieving________________________
2. _Quetiapine 100mg q HS for delusional disorder_-DC'd________________________
3. _Donepezil 10mg q morning_for dementia_with behavioral disturbance_____________
4. _Lorazepam 0.5m_twice daily as needed for agitaton -DC'd______________________
5._Olanzapine 5mg q HS x 5 days, then 10mg, then 15mg q HS delusional disorder w distress
6._Depakote Sprinkles 250mg q AM_x 5 days then twice daily for mood stabilizer, agression

Pain Management:
1.____
2.____
3.____



RECOMMENDED DOSES IN ELDERLY PATIENTS

Medication		Additional Notes
Antidepressants SSRI SARI (serotonin 2 antagonist/ reuptake inhibitor)	Citalopram 20 mg/day: initiate at 10 mg Sertraline 50-100 mg Trazodone 25 mg at HS	Few CYP450 interactions
Cholinesterase inhibitors	Donepezil 5-10 mg during the day	GI side-effects are common
NMDA receptor antagonist	Memantine 10 mg twice daily	Dizziness and headache may occur
Anticonvulsants	Sodium valproate 10-15 mg/kg in divided doses	Start with smaller dose and titrate up
Antipsychotics Typical Atypical	Haloperidol 0.5 -1 mg/day Risperidone 0.5 mg twice daily: may initiate at 0.25 mg twice daily Quetiapine 25-50 mg at HS Olanzapine 2.5 – 10 mg / day	Watch for EPSE, may increase prolactin, hypotension, sedation Anitcholinergic effect mild-mod Freeman & Joska, 2012

Evidence suggests lower dose poses lower risk: (Rossom et al., 2010).
Olanzapine < 2.5 mg /day; Quetiapine < 50 mg/day; Risperdone < 1 mg /day.

QT interval Risk: last QTc__**420**_____________date ____________

Fall Risk: ___ Patient ambulates __ unsteady gait _X_Patient nonambulatory

Adverse effects or anticholinergic burden: __dysphagia __EPSE__hypotension _X_sedation

QoL : _**X**_ target symptom reduction __ pain managed _X_ depression managed_X_sleep quality

Discussion with DPOA and family: date __**done**_______________ **Outcome: palliative care/comfort care/ hospice:** Comfort care is priority, family wants to avoid hospitalizations, Hospice care when indicated

_**X**_consider dose reduction _in 4 week intervals_______________________________________
___dose reduction not recommended because of QoL benefit
___dose reduction may put patient at risk of symptom relapse or emotional instability
_X patient has a good response to current regimen without adverse reaction and benefit exceeds risk.

Reference:
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SWOT Analysis

A Psychotropic Risk Assessment Checklist for Clinicians and IDT

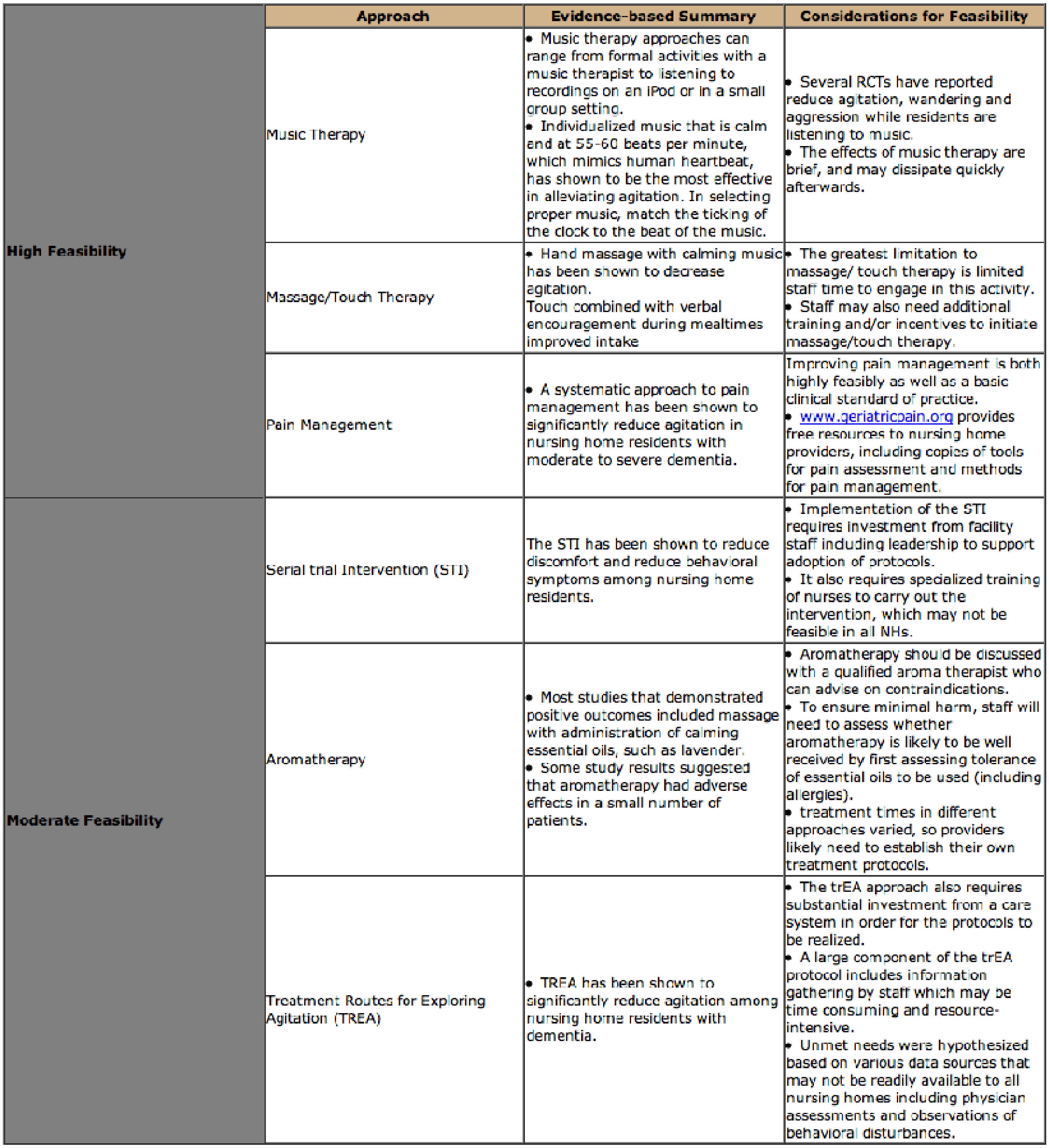
INTERNAL to the Organization	STRENGTHS: • KP culture approves knowledge sharing & EBP • Supports KP mission and individual SNFs • Provides guide for licensed healthcare workers • Involves SNF IDT regionally • Checklist promotes collaboration with pharmacists, nurses, and clinicians • Good feasibility for SNFs • Improved documentation for person-centered care and QoL indicators • Patient/family satisfaction	WEAKNESSES: • Practice change resistance • Clinicians preconceived ideas about best practice standards • Each SNF has individual culture & demands on resources • Time constraints for busy clinicians
Found in EXTERNAL Environment	OPPORTUNITIES: • Satisfies CMS initiative to increase awareness of AP utilization • Supports community nursing homes • Improves transparency ratings for nursing homes & quality measures re: AP use • Lower costs of SNF care by decreased AP utilization • Meets criteria for certification surveys	THREATS: • Potential regulatory agency penalties for AP use • Potential litigation threats for noncompliance with laws and regulations • AP use benchmarked on public websites as quality indicator • Drug costs are rising • Liability risk with off-label prescribing

Figure 2

Table 1. Review of Non-pharmacologic Approaches for Treating Behavioral and Psychological Symptoms of Dementia

Type of Non-Pharmacologic Approach	**Description/ Specific Approaches**	**Efficacy for Reducing Behavioral and Psychological Symptoms of Dementia**
Sensory Stimulation Approaches	Sensory stimulation approaches focus on stimulating the senses of the person with dementia. The aim of these approaches is to respond to the unmet needs for stimulation, to enhance the senses and to achieve therapeutic effects such as pain control, relaxation and reduction of anxiety. Some sensory stimulation approaches are informed by physiological models regarding the calming influence of sensory touch or proximity associated with some techniques such as massage. Examples include: • Aromatherapy • Light therapy • Massage and touch therapy • Music therapy • Snoezelen Multisensory Stimulation Therapy (MSS) • Transcutaneous Electrical Nerve Stimulation (TENs) • White Noise	• Music therapy has demonstrated efficacy in reducing agitation (albeit for short periods of time) among persons with dementia, although overall study findings have been inconsistent. Various types of music therapy have been rigorously tested including gentle songs and individualized music therapy. • MSS combines light, music, tactile, and aroma therapies. Findings regarding the effect of MSS on behavioral symptoms are inconsistent but some preliminary randomized trials have demonstrated improved short term BPSD outcomes when using Snoezelen as well as other positive experiences associated with the treatment, meriting further testing. • Several RCTs testing TENs have demonstrated no effect on BPSD. There is no evidence to support the use of TENs to treat behavioral symptoms. • Insufficient evidence exists to recommend the use of white noise in treating behavioral symptoms. • Insufficient evidence exists to recommend light therapy in reducing behavioral symptoms. • Massage and touch therapy has demonstrated a moderate effect on BPSD, specifically agitation. • Aromatherapy has demonstrated moderate efficacy in reducing agitation, however more rigorous research is needed.
Behavior Management Approaches	Behavior management approaches are intended to support adaptive behavior of people with dementia through reinforcing certain kinds of social behavior and reducing behavioral symptoms through, for example, ignoring the behavior. Examples include: • Habit training • Communication training • Cognitive-behavioral therapy • Individualized behavioral reinforcement therapies	• Inconsistent study results and limited methodological rigor provide insufficient evidence to support the use of behavioral management techniques at this time.[11,15]
Cognitive/Emotion-Oriented Approaches	Cognitive/Emotion-Oriented Approaches focus on eliciting positive emotional behavioral responses. Examples include: • Reminiscence therapy • Simulated Presence Therapy (SPT) • Validation Therapy • Reality Orientation	• Currently, evidence does not support the use of any of these approaches for BPSD. There is limited and inconsistent evidence regarding the use of cognitive/emotion-oriented interventions. Some of these interventions, such as simulated presence therapy (SPT)) and reality orientation may actually have an adverse effect in some persons with dementia and are not recommended for treatment of BPSD.
Structured Activity Approaches	Structured activity approaches may include recreational activities as well as certain forms of exercise on a regular basis. The goals of structured activity approaches are often to develop and/or stimulate the social, cognitive and physical abilities of persons with dementia and to reduce boredom. Examples include: • Exercise • Recreation activities	• There is insufficient evidence to conclude the effects of exercise interventions or structured activities on BPSD; this is largely due to methodological limitations of existing studies.[12,16] • There is also limited evidence regarding the effect of exercise on BPSD, however, other benefits of exercise programs such as improved sleep may merit their use depending on individual care needs.[15]
Social Contact Approaches (with real or simulated stimuli)	Real or simulated social contact approaches may include face-to-face interaction, group activities or audiotapes from family members. Social interactions are believed to produce positive mood/affect and to subsequently reduce BPSD[17]. As nursing home residents also experience boredom and social isolation, social interaction is believed to generally improve the well-being of people with dementia. Examples include: • Animal-assisted therapy • One-on-one interaction • Simulated presence therapy (i.e. simulated family presence)	• While Animal-Assisted Therapy (AAT) has demonstrated preliminary positive findings, the current evidence base is very limited and includes primarily non-randomized, very small scale studies. Additional research is needed to understand whether AAT effectively reduces BPSD.[15] • There is currently an insufficient evidence base to support the efficacy of one-on-one interaction for reducing BPSD, however further testing of this approach is merited because preliminary work suggests that people with dementia benefit by being engaged in social contact.[18-2011,15] • There is currently inadequate evidence to recommend the use of simulated-presence therapy and it may have an adverse effect in some individuals.[15]
Environmental Modification Approaches	Environmental modification approaches focus on matching the environment to the needs of the person with dementia. This can be done in different ways by providing conditions that help to maintain the person's autonomy and independence, create a home-like atmosphere and thereby reduce the level of stress. The approaches are often designed specifically to reduce wandering behaviors, or mood/sleep disturbances. Examples include: • Wandering areas • Natural/enhanced environments • Reduced stimulation units.	• Environmental modification interventions have not demonstrated efficacy in reducing BPSD.>[11,15]
Clinically-Oriented Approaches	Clinically-oriented approaches are generally (but not always) multi-faceted and aim to guide providers in relieving the underlying unmet needs or causes contributing to BPSD. The intended outcomes include reducing the use of psychotropic drugs and BPSD, along with improving other health outcomes. Examples include: • Pain management • Comprehensive assessment • Restraint removal • Decision-support approaches • Delirium recognition and management	• Most of these interventions have demonstrated positive (not necessarily significant) effects in reducing BPSD but few have been tested in rigorous trials and as a result are not included in many systematic reviews. • A systematic approach to pain management has been shown to significantly reduce agitation in nursing home residents with moderate to severe dementia. • Individualized interventions that utilize a systematic algorithm to support clinical-decision making demonstrate strong potential for treating and managing BPSD and unmet needs of persons with dementia.[21,22] Since these approaches are particularly promising, more information is provided later in this document.
Staff-training Approaches (See also Education and Leadership Development section of Toolkit)	Caregiver development as an approach is intended to increase the knowledge of staff who are called upon to respond to BPSD. The aim of this type of approach is to reduce behavioral symptoms and the stress caregivers experience themselves. Most staff training approaches are educational or psychosocial and teach: • Communication skills • Person-centered bathing or towel bathing[23] • Minimizing care-resistant behaviors during oral hygiene[24,25] • Strategies for responding to needs of persons with dementia • Understanding and responding to BPSD	Generally, findings from staff-training approaches demonstrate limited sustained improvement in BPSD and suggest that continual training or reinforcement are needed to influence behavior change. These studies have produced inconsistent findings for the strategies used and are difficult to evaluate due to methodological limitations, as such insufficient evidence exists at this time to support the efficacy of most staff-training approaches for reducing BPSD. Some specific approaches merit replication in a more rigorous manner. [11,14,15]
Person-centered Care Approaches[4,8]	The concept of person-centered care is to train care providers to focus on the person during the task rather than the task itself. This training may also emphasize abilities-focused care and maximizing comfort An example of a person-centered care approach to reduce agitation includes: • Person-centered bathing or towel bathing[23]	• Use of person-centered bathing and towel bathing has demonstrated reduced agitation and aggression during bathing experiences.[23]

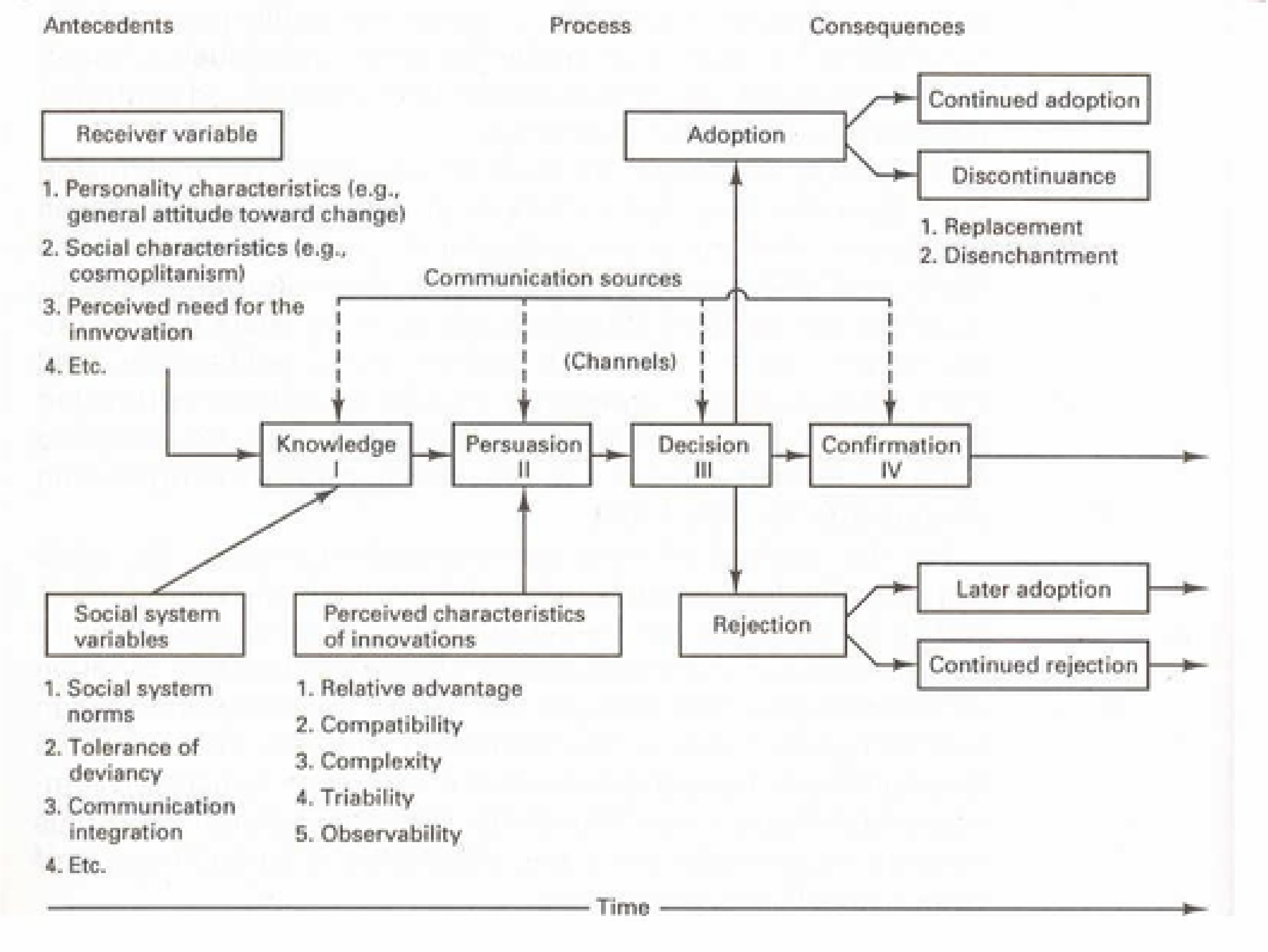
Table 2. Efficacious and Feasible Non-pharmacological Approaches for Behavioral and Psychological Symptoms of Dementia



	Approach	**Evidence-based Summary**	**Considerations for Feasibility**
High Feasibility	Music Therapy	• Music therapy approaches can range from formal activities with a music therapist to listening to recordings on an iPod or in a small group setting. • Individualized music that is calm and at 55-60 beats per minute, which mimics human heartbeat, has shown to be the most effective in alleviating agitation. In selecting proper music, match the ticking of the clock to the beat of the music.	• Several RCTs have reported reduce agitation, wandering and aggression while residents are listening to music. • The effects of music therapy are brief, and may dissipate quickly afterwards.
	Massage/Touch Therapy	• Hand massage with calming music has been shown to decrease agitation. Touch combined with verbal encouragement during mealtimes improved intake	• The greatest limitation to massage/ touch therapy is limited staff time to engage in this activity. • Staff may also need additional training and/or incentives to initiate massage/touch therapy.
	Pain Management	• A systematic approach to pain management has been shown to significantly reduce agitation in nursing home residents with moderate to severe dementia.	Improving pain management is both highly feasibly as well as a basic clinical standard of practice. • www.geriatricpain.org provides free resources to nursing home providers, including copies of tools for pain assessment and methods for pain management.
Moderate Feasibility	Serial trial Intervention (STI)	The STI has been shown to reduce discomfort and reduce behavioral symptoms among nursing home residents.	• Implementation of the STI requires investment from facility staff including leadership to support adoption of protocols. • It also requires specialized training of nurses to carry out the intervention, which may not be feasible in all NHs.
	Aromatherapy	• Most studies that demonstrated positive outcomes included massage with administration of calming essential oils, such as lavender. • Some study results suggested that aromatherapy had adverse effects in a small number of patients.	• Aromatherapy should be discussed with a qualified aroma therapist who can advise on contraindications. • To ensure minimal harm, staff will need to assess whether aromatherapy is likely to be well received by first assessing tolerance of essential oils to be used (including allergies). • treatment times in different approaches varied, so providers likely need to establish their own treatment protocols.
	Treatment Routes for Exploring Agitation (TREA)	• TREA has been shown to significantly reduce agitation among nursing home residents with dementia.	• The trEA approach also requires substantial investment from a care system in order for the protocols to be realized. • A large component of the trEA protocol includes information gathering by staff which may be time consuming and resource-intensive. • Unmet needs were hypothesized based on various data sources that may not be readily available to all nursing homes including physician assessments and observations of behavioral disturbances.

References for Table 1 and 2 can be found on the Toolkit website: http://www.nursinghometoolkit.com/

Conceptual Model



Diffusion of innovation model.
Source: Rogers (1995)

http://www.tcw.utwente.nl/theorieenoverzicht/Theory%20clusters/Communication%20and%20Information%20Technology/Diffusion_of_Innovations_Theory.doc/

Figure 3

Case Presentation

The following case presentation demonstrates how the Psychotropic Risk Assessment Checklist informs clinical decision-making, substantiates a clear benefit/risk analysis, and enhances documentation of non-pharmacological, pharmacological interventions, and QoL outcomes. It also illustrates the role of APNs working in collaboration with IDT members, to manage residents with BPSD in a long-term care setting.

Mr. O is an 88 year-old African American retired Baptist minister with Alzheimer's disease (AD) for seven years, and recently admitted to a nursing home for custodial care because his wife who cared for him at home has died. His medical history is remarkable for stroke, Coronary Artery Disease with stent placement, and a several year history of anemia with intermittent rectal bleeding that was not fully worked up because of his inability to tolerate the gastrointestinal prep for a colonoscopy. A gastrointestinal evaluation was postponed because a hospital-based palliative care and family conference determined Mr. O's debility and dementia progression was significant and the goals of care were re-established for comfort and symptom management.

Mr. O is unable to make healthcare decisions and his daughter is his DPOA. He has a POLST form for No CPR with Comfort Care and no artificial feeding tubes. Mr. O has moderately severe dementia on the Functional Assessment Staging of Alzheimer's Disease (FAST stage 7) criteria. The nursing home interdisciplinary team (IDT) requested a medication review after Mr. O had several falls with night-time wandering and elopement attempts. Mr. O's psychotropic medications included sertraline 100 mg orally daily, quetiapine 100 mg orally every night, donepezil 10 mg orally every night, and lorazepam 0.5 mg orally twice a day as needed for agitation. The staff nurses reported Mr. O has an unsteady gait, frequent delusions, physical and verbal aggressive behavior, and frequent attempts to leave the building because he is looking for his wife or his car. These behaviors occurred mostly on the evening and night shifts. Mr. O enjoys brief time outside but is unable to calm down or participate in activities due to his short attention span and inability to focus. He wants to be pushed around in his wheelchair to be in constant motion, and requires 1:1 staffing, except when his family is visiting, which poses a significant challenge.

The NP reviews his medical history and recent labs, completes a physical exam and considers possible comorbidities such as an acute illness, pain or depression with grieving the loss of spouse and adjustment to a new environment. The NP reviews the social history completed by the LSW and noted Mr. O has two grown children and nine grandchildren who visit daily and participate in his care. He has a chronic sleep disorder and for many years his wife had trouble with his nighttime wandering, irritability and restlessness. Mr. O is unaware that his wife has died and often calls for her and demands to see her. He is able to remember that he was a minister and is able to recall his children's names. The NP finds Mr. O irritable on exam, using sarcastic and hostile language. She does not detect or elicit pain on palpation or movement of any extremity. The NP orders a UA with culture and sensitivity, discontinues the lorazepam because of fall risk, changes the donepezil dose to the morning for maximum efficacy for behavior, and calls the gero-psyche team for a referral. The NP reviews the care plan with the family and DPOA, and the staff nurses, answers questions and listens to concerns.

Two days later, the psychiatric nurse specialist (PNS) assesses that Mr. O continued to eat and drink well, his UA was negative, and his behaviors continued to escalate. She notes, his significant sleep disorder is affecting his quality of life. When staff nurses come to assist him, he strikes out at them, and yells at them to "get out of here", and when the staff explain to him that they must help him with his self-releasing belt alarm, he strikes out at them in rage. The PNS finds Mr. O is oriented to him self only, and observes his inability to join activities because of his severe irritability and short attention span. She notes he is distrustful of staff, easily distracted, with impaired judgment, insight, memory, and impulse control. Mr. O is hyper-vigilant and combative to direct care staff, putting him and others at risk for injury. The PNS interviews the family and administers a proxy informant Quality of Life-AD scale that revealed a low score based on Mr. O's energy level, mood, memory, recent loss of spouse, change in residence, and death of several close friends in the past year. The family believes Mr. O's QoL is poor because of his inability to read his Bible, watch TV, or listen to gospel music that he used to enjoy. They are sad by his cursing and shouting because they remember him as a calm and proper man before he developed AD. Per consultation with a gero-psychiatrist and in collaboration with the physician, NP and family, a recommendation to taper off quetiapine and start olanzapine 5 mg orally every night for 5 nights then increase olanzapine to 10 mg orally every night with depakote sprinkles 250 mg orally daily.

A complete discussion of possible benefits and risks including increased risk of stroke or death was conducted, and consent forms were signed by the DPOA. The diagnosis for antipsychotic use is AD with delusional disorder with behaviors that risk harm to self or others. The target symptoms are hours of sleep, mood and verbal and physical aggression. A monitoring system was created on the nurse's medication administration record to document frequency of symptoms per shift and hours of sleep. The sertraline was continued for depression, and donepezil was continued, with a possible dose increase later for maximum effect on behavior. Advise was given to nursing to continue fall risk precautions and continue 1:1 care giving which the family provides 4 hours per day.

The goals of care were defined within a palliative care model to improve quality of life and reduce distress from debilitating symptoms. The family agreed to hospice care once Mr. O became more bedbound, less verbal, developed eating or swallowing problems, or developed an acute illness or infection. The family wanted to avoid future hospitalizations that did not address the underlying disease trajectory and the terminal nature of advanced dementia. Several days later the PNS assessed Mr. O and documented that he continued to eat and drink well and take his medicines but remained hyper-vigilant and combative to direct care staff. She implemented a Cohen-Mansfield Agitation Inventory (CMAI) short form, and Mr. O’s score was 45, which is a measure of symptom frequency. In collaboration with the gero-psychiatrist, a recommendation to increase the olanzapine to 15 mg at night and increase the depakote sprinkles to 250 mg twice daily with a CBC, ALT, and drug level in one week to monitor for a possible adverse drug reaction. The family agreed to the plan, and the DPOA signed another consent to increase the dose of the medications as recommended. The physician and NP were consulted and implemented the medication changes, and lab orders.

A week and a half later, the NP noticed Mr. O was enjoying more time outside, occasional chaplain visits, and was able to listen to his grandson read the Bible to him. The NP checked the follow-up labs and completed another CAMI short form and Mr. O’s score was 18, showing a significant improvement. This was reported to the gero-psych team and the nursing home IDT who projected in 4 weeks, a re-evaluation of the medical regimen would be possible, and a dose reduction may be considered if symptom management remained stable. The family returned a quarterly satisfaction survey as a quality outcome measure of their approval of the care delivery. The physician and NP continue to monitor for efficacy and tolerability of medications on routine medical rounds and update the documentation on the Psychotropic Risk

Assessment Checklist quarterly. Discussions with the patient’s family or proxy at that time review the benefits versus the risks of psychotropic medications, and consider trial dose reductions to lower the risk burden if the patient’s perceived QoL benefit can be maintained or improved.

Gap Analysis

A gap analysis is based on the knowledge that current clinical care for patients with advanced dementia, complicated by the behavioral disturbances of BPSD, is often fragmented and disease oriented, rather than person-centered in long term care. There were no known pre-existing tools to assist clinicians to formulate risk/benefit analysis with psychotropic use. Incorporating palliative care components such as end of life care, quality of life (QoL) concepts, and shared decision-making for BPSD management, is not new, but has not been readily applied to the critical thinking with psychotropic use. Many care delivery strategies and non-pharmacological interventions are inconsistently applied or undocumented. There has been a void between palliative care and QoL measures for individuals with advanced dementia who are near the end of life. This project implementation was an early attempt to weigh the benefits against the risks of psychotropic medications for those with BPSD, and blend palliative care with advanced dementia care, with a focus on QoL outcomes.