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A Toolkit for Administration of Antipsychotic Medications in Nursing Homes

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Abstract

Psychotropic medications should be used with extreme caution in older adults residing in long-term care facilities. Delirium and altered mental status are associated with multiple complex underlying medical conditions and can be difficult to recognize, particularly among the elderly residing in long-term care facilities. The use of the California Department of Public Health (CDPH) Skilled Nursing Facility (SNF) Antipsychotic Toolkit allows for ethical and evidence-based care of the elderly within the regulations and best practice for use of antipsychotics. This Doctor of Nursing Practice quality improvement project is designed to provide a toolkit for practitioners of behavioral modification measures and an introduction to the CDPH SNF Antipsychotic Toolkit for use among local nursing homes in the San Francisco Bay Area of California. The clinical relevance is for geriatric nurses and health care providers to recognize value of utilizing the CDPH SNF Antipsychotic Toolkit before prescribing and administering antipsychotic medications to the older adult population in nursing homes. The toolkit emphasizes the importance of recognizing possible adverse effects and the importance of identifying delirium and interventions.

Section II: Introduction

Problem Description

According to the National Center for Health Statistics, 47.8% of patients residing in long-term care (LTC) facilities have been diagnosed with Alzheimer's disease or other dementia (Centers for Disease Control and Prevention [CDC], 2016). Individuals with dementia are at great risk of developing delirium secondary to age-related changes. As a result, the pain process is altered, they are less able to ask for help with basic needs, and they are less able to communicate that they are in pain or feeling unwell (Featherstone, Hopton, & Siddigi, 2010). It is important that health care workers, nursing, and support staff understand how to prevent, recognize, and manage delirium, because delirium can be mistaken as dementia.

Delirium and altered mental status are associated with multiple complex underlying medical conditions that can be difficult to recognize, particularly among elderly residing in LTC facilities. The American Psychiatric Association's Diagnostic and Statistical Manual, 5th edition (DSM-V) lists five key features that manifest delirium: (a) disturbance in attention and awareness; (b) the disturbance develops over a short period of time, represents a change from baseline; (c) disturbance in cognition (memory deficit, disorientation, or perception); (d) the disturbances are not better explained by preexisting disorder or established as neurocognitive disorder; and (e) there is evidence from the history, physical examination, or laboratory findings that the disturbance is caused by a medical condition, substance intoxication or withdrawal, or medication side effect (in Francis & Young, 2014). Although a number of criteria exist for dementia, the DSM-V criteria for dementia include the following: (a) significant cognitive impairment in at least one of the cognitive domains (learning and memory, language, executive function, complex attention, perceptual-motor function, and social cognition); (b) impairment

represents a significant decline from previous level of functioning; and (c) cognitive deficits interfere with independence in everyday activities (Larson, 2016).

Failure to assume responsibility of nursing home management, licensed nurses, and most especially, nurse practitioners and medical doctors who are prescribing the antipsychotic medications, can lead to very serious consequences and even death in elderly patients. Progress has been shown with the Centers for Medicare and Medicaid Services' (CMS) strategies to reduce antipsychotic drug use in nursing home residents with dementia. Continuous monitoring and consistent enforcement are needed to ensure decline in unnecessary use of antipsychotics and psychoactive medications in nursing homes (Lucas & Bowblish, 2017).

Ferguson, Montgomery, Mossey and Duncan (2018), in a summarized evidence of non-pharmacological nursing interventions for delirium prevention in LTC facilities, concluded that there is limited evidence on nursing interventions to prevent delirium in LTC facilities. Ferguson et al. reported (a) an increased need for education of delirium risk factors, (b) the importance of knowledge of the resident as an individual, and (c) potentially modifiable risk factors associated with increased delirium severity, such as dehydration, disorientation, absence of assisted device, absence of family member, environmental management, constipation prevention, physician/staff communication, catheter care, pain management, and use of physical restraints. The physiological symptoms and behavior of delirium may include challenging behaviors, such as altered mental status, agitation, restlessness, yelling, crying, and refusal of care (Mayo Clinic, 2018). Though these behaviors are common, they may be socially unacceptable in nursing homes. These behaviors can interfere with residents' activities of daily living, such bathing, feeding, walking, toileting, and bed transfer.

Daly, Bay, Levy, and Carnahan (2015) reported, "More than 80% of nursing home residents with dementia exhibit one or more challenging behaviors … (including) agitation, anger, depression, disrobing, eating abnormalities, hoarding, inappropriate sexual behavior, irritability, paranoia, physical and verbal aggression, repetition, swearing, and withdrawal" (p. 182). Nurses can use behavioral modification techniques to ameliorate these behaviors; however, these interventions can be time consuming (Weinberg, 2016). Staff may seek pharmacologic methods to manage behaviors, but using antipsychotic medications inappropriately as a chemical restraint is unethical and may cause adverse effects for elderly individuals (Department of Health & Human Services [DHSS], 2014).

Current Nursing Home Practice

Nursing homes are often short staffed, and the staff work long hours with a high volume of residents. Certified nursing assistants (CNAs) provide much of the care in nursing homes. Routine CNA duties in nursing homes include providing activities of daily living, such as feeding, bathing, toileting, transferring, and walking or exercising the residents (California Department of Human Resources, 2017). When staffing is short, CNAs are assigned additional residents, which increases their normal workload (Weinberg, 2016). These factors contribute to the lack of time needed to implement behavioral management of residents with disruptive behaviors. For these reasons, staff often pressure prescribers to order psychotropic medications to control nursing home resident behaviors rather than using behavior modification to manage these challenging behaviors (Tjia, Gurwitz, & Briesacher, 2012). Unfortunately, many residents are given antipsychotic medications as an initial intervention to manage their challenging behaviors without a proper interdisciplinary evaluation. Because of lack of training in behavioral management and lack of knowledge in the use of psychotropic drug therapy, nursing staff may

not be aware of the dangers of these medications in the older adult population and may not be prepared to adequately care for residents with challenging behaviors (Daly et al., 2015). Staff may seek pharmacological methods using psychotropic drugs to manage behaviors.

Available Knowledge

Despite the black box warning issued by the Food and Drug Administration (FDA), nursing home residents continue to receive antipsychotic medication as initial intervention for behavioral modification. Levin (2012) noted, the "FDA issued the black box warnings for antipsychotics in response to approximately 15,000 elderly nursing home residents dying each year from the off-label use of antipsychotic drugs" (p. 12). Prescribing these medications when they are not medically indicated or in the patient's best interest is the same as using a chemical restraint and/or unnecessary drug.

In a literature review, Pakpoor and Agius (2014) found that neuroleptic malignant syndrome, which includes fever, diaphoresis, rigidity, confusion, fluctuating consciousness, fluctuating blood pressure, tachycardia, leukocytosis, and altered liver function tests, was a fatal side effect for all antipsychotic medications. These side effects can lead to fatality, most especially in an older adult because of age-related changes that affect kidney, liver, and gastrointestinal function. The aging process can affect how the body metabolizes a drug from ingestion to secretion through the kidneys, as well as specific action of the medications in fragile older individuals (Braun & Frolik, 2000). Free radicals that are by-products of metabolism cause oxidative damage to biomolecules as they damage the cellular membranes and impair physiological functioning (Miller, 2018). Antipsychotic medication when used in the older adult population needs frequent monitoring of side effects, vital signs, lab work, and possible dose regulation due to the differences in body chemistry and drug metabolism in this population.

A cohort study conducted by Huybrechts et al. (2012) included 83,959 Medicaid recipients, age 65 or older, in 45 nursing homes in the United States, who initiated atypical antipsychotic medication treatment after nursing home admission from 2001 to 2005. Huybrechts et al. concluded that bacterial infections, myocardial infarctions, and hip fracture rates were higher, and there was a risk of cerebrovascular events in those who initiated with antipsychotic medications in nursing homes. Demonstrative conclusions were reached regarding the adverse impact of antipsychotic medication, which can be fatal in the older adult population (Huybrechts et al., 2012).

Alzheimer's disease is a cognitive disorder that can manifest behavioral symptoms of agitation or aggression (Lyketsos et al., 2011). These types of behaviors can be overwhelming to residents, as well as to caregivers. According to the Alzheimer's Association (2007), more than 50% of nursing home residents have some form of dementia or cognitive impairment, and many residents with cognitive impairment manifest challenging behaviors, such as kicking, restlessness, agitation, yelling, or refusing to receive care. Frequently, antipsychotic medications are used as initial interventions, which may be why the use of antipsychotics has increased. It is clear that many of these symptoms are physiological, are to be expected, and should not be treated with antipsychotic medications.

Bonner et al. (2015) conducted a qualitative study of residents diagnosed with dementia who received an antipsychotic medication. Bonner et al. conducted the research at 26 medium and large facilities in five CMS regions. The researchers concluded that many of the prescribed psychotropic drugs lacked evidence of supporting documentation for medication necessity or proper diagnosis in the resident's medical record (Bonner et al., 2015).

It is critical for clinicians to recognize and uncover the underlying medical conditions of behavioral disturbance or altered mental status for elderly residing in LTC facilities. Kiely et al. (2013) studied delirium in 2,158 patients newly admitted to a post-acute facility and, using the diagnostic algorithm of the Confusion Assessment Method, found approximately 16% of these patients had delirium. In a 2009 study, High et al. concluded noted urinary tract infection at an incidence of 0.12% cases per 1,000 resident-days. High et al. also found that pneumonia develops among elderly nursing home residents at a rate of one episode per 1,000 days of care. The elderly residing in LTC facilities are at greater risk for infection because of multiple comorbidities that complicate in identifying such infections.

Basso, Siminioato, Dimonte, Scaglione, and Campagna (2018) conducted a retrospective descriptive study using nursing home clinical records data from 2013 to 2016. Basso et al. found that during that time period, 143 emergency department accesses occurred, with 55 (38.6%) for medical problems in 48 residents. The most frequent reason for hospitalization was infection (22): 18 respiratory infections, two urinary infections, and two with both respiratory and urinary infection. On emergency department admission, prevalent signs and symptoms were desaturation (13), dyspnea (10), and fever (nine). Basso et al. stressed the importance of explicit criteria to promptly monitor changes in clinical conditions and the importance of educating professionals to suspect an infection even with non-specific symptoms.

Ferguson et al. (2018) conducted a systemic review of 23 international studies to examine the status of older adults living in LTC facilities and found variation in fluid intake intervention and associated measurement of hydration outcomes. Across all of the reviewed evidence, dehydration was identified as a leading threat to the health status of residents in LTC facilities (Ferguson et al., 2018).

Rationale

Dr. Jean Watson's nursing theory of philosophy and science of caring promotes the health of the nurse and the wellbeing of the patient (McEwen & Wills, 2014). Dr. Watson believes that nurses are caring. She defines the nursing care profession as it combines with human and scientific values to provide patient care. The theory assumption is that health professionals make social, moral, and scientific contributions to humankind and that nurses' caring ideal can affect human development (McEwen & Wills, 2014). Dr. Watson believes that nursing care is a transforming process for both the patient and the nurse. Philosophy and science of caring defines the interpersonal process in the fulfillment of a patient's need as the result of caring (McEwen & Wills, 2014). For example, the facility or providers should find behavior modification alternatives or examine the cause of the behaviors before prescribing antipsychotic medication. Non-pharmacological interventions include redirection, encouraging residents to verbalize feelings, music, art, massage, or providing other activities that residents enjoy.

Dr. Watson defined three of the four metaparadigm concepts (human being, health, and nursing), and these concepts support the California Department of Public Health (CDPH) Skilled Nursing Facility (SNF) Antipsychotic Toolkit (see Appendix A; McEwen & Wills, 2014). The toolkit upholds the philosophy and science of caring. Examples of use of the toolkit include, health care providers should examine the pathological causes of behavioral disturbance, and residents presenting with behavioral and psychological symptoms of dementia should undergo routine blood analysis and urinalysis. This can lead to both recognition of delirium and reduced usage of antipsychotic medication (Wilson, Power, Owens, & Lawlor, 2019).

Project Purpose

Specific Aims

Introduction of the CDPH SNF Antipsychotic Toolkit may reduce the rate of prescribing antipsychotic medications compared to usual practice of antipsychotic use. Delirium and altered mental status are associated with multiple complex underlying medical conditions and can be difficult to recognize, particularly among elderly residing in LTC facilities. This DNP quality improvement project involved the introduction of the use of the CDPH SNF Antipsychotic Toolkit in the context of an educational training workshop designed to minimize negative effects of age-related changes and modifiable risk factors of delirium. Three SNFs in Northern California were invited to participate in the educational workshop training.

Goals

The quality improvement goals of this DNP project are:

1. Provide a mini course in behavioral modification interventions appropriate for the older adult.
2. Introduce the CDPH SNF Antipsychotic Toolkit.
3. Encourage participating SNF staff to utilize the CDPH SNF Antipsychotic Toolkit.
4. Introduce the CDPH SNF Antipsychotic Toolkit into the facility policy for care.

Objectives

The objectives of this DNP project include:

1. Identify at least five SNFs in Northern California willing to coordinate educational workshop training in reducing antipsychotics use, including criteria for delirium and dementia by December 2018.

2. Design a lesson plan and learning objectives workshop educational training presentation by March 2019.
3. Design a tool to analyze effectiveness of educational workshop training (e.g., pre- and post-survey workshop evaluation).
4. Present findings to interdisciplinary team (nursing home administrator [NHA], director of nursing [DON] services, social worker, nursing staff, and rehabilitation therapist) by July 2019.

Section III. Methods

Context

The key members and stakeholders on this DNP project included the NHA, the DON, social worker, nursing staff, health care provider, and rehabilitation therapist. Licensed nurses should receive continuing education in taking care of the geriatric population, especially the side effects of psychotropic medications and the guidelines in administration of psychotropic medications. Educational training included identifying and preventing delirium, which can have a positive effect on quality of care in nursing homes. The educational lecture included the biologic theories of aging. Strengths, weaknesses, opportunities, and threat analysis (SWOT, see Appendix B) and gap analysis (see Appendix C) of DNP project were identified.

Local Problem

A random review of public records in the Health Facilities Consumer Information System under the CDPH noted a nursing home was cited for a FTAG 154 Informed of Health, Care, & Treatments in March 2017 during the annual CDPH audit (see Appendix D). Based on the survey audit, interviews, and record reviews, the facility failed to follow its policy and procedure to ensure a physician-obtained informed consent for psychotherapeutic medication in a timely manner prior to administering. This failure had a potential for a random sample resident receiving psychotherapeutic medications without information needed to weigh benefits against risk associated with psychotherapeutic medications, putting at risk for medication-associated injury and harm (CDPH, 2017, p. 2). Using the CDPH SNF Antipsychotic Tool, along with behavior modification techniques, is an ethical process that provides guidance in the appropriate use of antipsychotics in older adults in nursing homes.

The first step was contacting the NHA and the DON to collaborate for educational workshop training through emails and phone calls. The NHA and the DON help to approve and set up the workshop training in their facilities. Seven SNFs in Northern California were contacted and three SNFs (Oakland, Hayward, and San Jose) agreed to the training. The training was completed in December 2018.

In the second step, the DNP student integrated a literature review related to use of antipsychotic medications in nursing homes. A comprehensive literature review to support these recommendations was completed through Scopus, CINAHL, Joanna Briggs Institute EBP Database, PubMed databases, and UpToDate. Search terms used were *antipsychotic, adverse effects, nursing home, dementia, Alzheimer, prevalence, assisted living facility, psychotropic, side effects, chemical restraints, geriatric,* and *morale nursing home staffing*. Publication dates for the literature search were limited to 2000 to 2019. Limited information was found with initial date limitation of five years, so the literature search was expanded to 20 years, then to less than 10 years, resulting in 166 articles. The critical appraisal of evidence (see Appendix E) noted research from 2012 to 2018 relevant to the DNP project. The search was refined by limiting acceptance of articles published in less than 10 years, English, reviews of the literature, qualitative and quantitative research involving the geriatric population, LTC facilities, delirium, and dementia. Eleven articles were selected applicable to the DNP project based on clinical practice guidelines. These articles and systemic review significantly emphasized the effect of antipsychotics medication in older adults, highlighted inappropriate use of psychoactive medications in nursing homes, and emphasized the importance of identifying delirium. This process of the DNP program was conducted from Fall 2016 to Spring 2019.

In the third step, the DNP student created learning objectives for an educational training workshop. The DNP student sought advice from two professors on the student's committee at the University of San Francisco. These two professors are family nurse practitioners with degrees of Doctorate of Nursing Practice and Doctor of Philosophy in Nursing. It was identified that criteria for dementia and delirium should be included in the workshop educational training.

Timeline

The Gantt chart presents the timeframe of DNP project (see Appendix F). The DNP student interviewed SNF administrators in December 2018. In January 2019, the SNFs in Bay Area, California were contacted to participate in the educational training program in managing use of antipsychotics and in recognizing symptoms of delirium. The lesson plan for in-service training was developed in February 2019. Itemized materials and tools for workshop training were finalized in March 2019. Workshop training was completed June 3, 2019. Synthesis of data, summarized recommendations, and outcome findings were concluded June 5, 2019.

Cost Summary and Benefits Analysis

LTC facilities are required to provide in-service training in managing dementia residents, managing residents with behavioral disturbance, and the use of psychotropic medications. There was no additional cost to the facilities for this DNP project, as this project can be used for the mandatory in-service trainings.

Projected staffing and labor costs are presented as an estimated budget. Rates of employees are presented as fair market value in Bay Area, California. In a 50-bed licensed skilled nursing home, projected total staffing of three shifts includes 22 CNAs, 12 licensed vocational nurses, six registered nurses (RNs), and one social worker. The projected annual cost for a 1.5 hour training class is $1,591.50 (see Appendix G).

Inappropriate use of antipsychotic medications in nursing homes can result in substantial care deficiency or a resurvey during annual audit from the Department of Health. A declaration from State Operations Manual, Survey and Enforcement Process for Skilled Nursing Facilities, notes penalties can range from $1,000 to $10,000 per instance (CMS, 2018). Utilizing the CDPH SNF Antipsychotic Toolkit is cost effective in avoiding citations and penalties. The check off list of the toolkit is a guidance for ethical and evidence-based practice use of antipsychotics in nursing homes.

Return on Investment

The return on investment in utilizing the CDPH SNF Antipsychotic Toolkit is improving the quality of care of nursing home residents. The toolkit will help nursing home staff effectively manage the clinical risk factors attributable to antipsychotic medication use in the elderly. Nursing home staff will have the knowledge and resources to follow the guidelines step-by-step in the use of antipsychotics medication in SNFs. The residents in LTC facilities will benefit from using the off-label use of antipsychotics, which will improve the appropriate use of antipsychotics in nursing home residents diagnosed with dementia, Alzheimer's, and/or cognitively impaired.

The return on investment of utilizing the CDPH SNF Antipsychotic Toolkit is avoidance of imposition of civil money penalties from the CMS. A declaration from the State Operations Manual, Survey and Enforcement Process for SNF, State Medicaid Agency may impose a civil money penalty between $3,050 and $10,000 per day of immediate jeopardy (CMS, p. 7301.1, 2018).

Intervention

Antipsychotic Use Survey Toolkit

The use of the CDPH SNF Antipsychotic Toolkit may reduce the use of antipsychotic medications compared to the usual practice of prescribing antipsychotic medication (California Association of Long-Term Care Medicine, 2012). The CDPH has created a process to monitor inappropriate use of psychotropic medication in nursing homes. The CDPH SNF Antipsychotic Toolkit checklists for administering antipsychotic medications includes:

1. Check to be sure behavioral symptoms are not due to:
    a. An underlying medical condition (e.g., delirium, infection, pain, fluid or electrolytes imbalance, polypharmacy side effects) that can be resolved or improved.
    b. Failure to recognize delirium. Clinicians often fail to recognize delirium, in some reports, in more than 70% of cases (Francis & Young, 2014).
    c. Environmental stress and psychological stressors (e.g., abuse, inadequate or inappropriate staff response, unfamiliar care provider, change in daily routine).
    d. Psychosis (e.g., auditory, visual, or other hallucinations; delusions) or the behavioral symptoms present a danger to the resident or others.
2. Eliminate those non-evidence-based reasons:
    a. Pertinent non-pharmacological interventions must be attempted, unless contraindicated.
    b. The prescribed medication represents the primary indication for use of the antipsychotics.

c. Monitor for effectiveness of prescribed antipsychotic, as well as the presence of adverse consequences.
d. If the antipsychotic was initiated within the last year, the facility must attempt a gradual dose reduction in two separate quarters.
e. Documentation present in the resident's clinical record was reviewed monthly by a consultant pharmacist.
f. Determine the prescribing physician provided material information necessary to obtain informed consent and received consent from the resident.

Alternatives to Antipsychotics

Behavior modification as an alternative to the use of medications may include any of the following (California Association of Long Term Care Medicine, 2012):

- Review medications regimen. Older adults are at a higher risk of adverse drug events due to physiological changes with advanced aged. Each medication should be evaluated to identify side effects that can possibly cause alterations in mental status that can manifest through behavioral disturbance (e.g., restlessness, irritability, psychomotor agitation, and confusion).
- Assess for pathological causes. Assess for underlying medical cause of altered mental status. Order laboratory tests, such as comprehensive panel to examine for electrolyte imbalance, dehydration, and infection.
- Assess for depression. Depression can manifest through agitation and irritability; physical and verbal aggression may be the primary manifestation of depression.
- Review pain management. Pain is another example of physiological causes of undesired behavior. Many nursing home residents cannot speak out for themselves

when they experience pain, which can manifest through change of mood, such as agitation, irritability, and restlessness.

Additional behavior modification recommendations from the Alzheimer's Association (2009) include:

- Facilitate therapeutic communication. For example, use appropriate communication aids or interpreter to meet resident's communication needs. Use a comforting tone of voice.
- Assess and know the resident well. Learn to read his or her body language and get to know the resident's preference with care. Provide choices to resident to promote dignity and independency.
- Provide a routine and therapeutic environment. Allow sufficient time for the resident to complete self-care.
- Build a good rapport with the resident. Demonstrate a caring attitude, active listening, and acknowledgement of resident's feelings.
- Avoid interrupting resident with cognitive impairment. They may lose their train of thought. Speak slowly and calmly, and use short, simple words.

The projected implementation of the project was June 2019 (see Appendix F). The development of the manuscript, prospectus development, and DNP project was completed in August 2019. The project included educational workshop training, with in-services funded from the educational training budget. The training was planned for approximately 45 minutes of lecture and 15 minutes for open discussion. Nursing home facilities are mandated to provide training in-services for all staff annually on care of dementia residents and managing behavioral disturbance. The DNP project did not affect the training budget of the facility.

The plan was to communicate to the NHA. The DON and the director of social services work strictly on psychotropic medications. The DON coordinates the education for licensed nurses and the interdisciplinary team members. A flyer was posted prior to the educational training on site (see Appendix H). The work breakdown structure was used in communicating with key personnel in the nursing skilled facilities (see Appendix I). Flyers provided to nursing skilled facilities that participated in educational training.

Study of Intervention

The Department of Public Health (DPH) has created a process to monitor inappropriate use of psychoactive medications to determine if clinical notes and care planning support the prescription of these drugs. The CDPH SNF Antipsychotic Toolkit is an evidenced-based assessment toolkit that allows for ethical care of the elderly within the regulations and evidenced-based practice for use of antipsychotics. It is best practice to use the CDPH SNF Antipsychotic Toolkit before prescribing and administering antipsychotic medications. The toolkit emphasizes the importance of identifying signs and symptoms of delirium with care for elderly in nursing homes. It is more ethical if nursing home facilities find behavior modification alternatives or examine physiological changes that can alter mental cognition (urinary tract infection, dehydration, and pulmonary tract infection) before prescribing and administering antipsychotic medication (Alzheimer Association, 2009). The goal of behavioral management is to provide health care providers with an understanding of factors that can contribute to cognitive impairment in the older adult population, to identify and treat factors that are reversible, and to suggest appropriate interventions to promote behavior management (Institute for Caregiver Education, n.d). The purpose of this alternative to psychotropic medication is for each resident to

attain and maintain his/her highest practicable wellbeing in an environment that prohibits the use of restraints for discipline or convenience (DHSS, 2014).

Measures

Upon completion of the educational training of the DNP project, the health care provider will be able to:

1. Identify at least three behavioral clinical presentations of delirium in elderly.
2. Identify behavioral side effects of common medications that could be misdiagnosed as dementia or delirium.
3. Identify at least three possible outcomes from using antipsychotic medications in elderly.
4. Identify possible non-pharmacological interventions in managing delirium or dementia with behavioral disturbance.
5. Identify at least five criteria for psychotropic medication use in a nursing skilled facility based on the CDPH SNF Antipsychotic Toolkit.

Analysis

The intended outcome of the project was to educate the nursing home staff, including providers and nursing home management, that the CDPH SNF Antipsychotic Toolkit may reduce the use of antipsychotic medications compared to usual practice on the use of antipsychotic medication(s). The actual performance and potential gap analysis of the DNP project, including SWOT analysis, were identified. Gannt chart and resources and materials (see Appendix J) are itemized.

Evaluation and testing in education can be challenging for nursing home staff and in developing a strong structured of learning and evaluation. A pre- and post-questionnaire should

involve planning based on the staff's knowledge of the purpose of the learning evaluation and must correlate to test taker background knowledge. Pre- and post-questionnaires and workshop evaluation were generated to evaluate effectiveness of workshop training and the DNP project (see Appendix K).

Ethical Considerations

The University of San Francisco's (USF, n.d.) core values are belief and commitment to advancing social responsibility in achieving the university's mission to create, communicate, and apply knowledge to a world shared by all people. The DNP project was a quality improvement project approved by the USF School of Nursing and Health Professions DNP committee. The DNP project did not involve human subjects, and it did not require Institutional Review Board (IRB) for the Protection of Human Subjects approval (see Appendix L). In 1987, to protect elders and dependent residents from abuse and neglect in LTC facilities, federal legislation mandated minimum health care requirements for nursing homes, including limitations on the use of psychotropic medications. Any mandated reporter, within the scope of his or her employment, has knowledge of an incident that reasonably appears or suspects to be physical abuse, abandonment, abduction, isolation, financial abuse, chemical restraints, or neglect, shall report immediately or as soon a practicably possible (California Department of Aging, (n.d).

The USF is committed to Jesuit values. The USF promotes a global perspective that educates leaders who will fashion more humane care (USF, n.d). Jesuits draw on the rich tradition of Ignatian spirituality and reflection and seek for the good of all humanity (Jesuits, n.d). This DNP project promotes Jesuits values and clinical relevance of the CDPH SNF

Antipsychotic Toolkit in geriatric populations. Jesuits values are well-suited with the ethical practice of health care using evidence-based practice.

Results

Qualitative Findings

The plan was to implement the workshop training in three SNFs. Only one nursing home succeeded in receiving the workshop training. The three NHAs were the direct contacts for the DNP project.

The first SNF is licensed with less than a 100-bed capacity in Oakland, California. The NHA cancelled the workshop training a week before the scheduled date. It was cancelled because the facility was currently experiencing widespread concern related to care that could potentially harm residents. The NHA stated it may take some time to correct the current problem, but the NHA remarked as to the importance of utilizing the SNF Antipsychotic Toolkit, since the use of psychotropic medications is highly regulated in the SNF. The NHA stated SNFs are experiencing deficiency ratings due to inappropriate use of antipsychotics and lack of educational training in managing residents with diagnosis of dementia.

The second SNF is one of the largest sub-acute centers in Northern California. The training at this facility was cancelled on the week of the scheduled date because the Department of Health was there for the annual audit. The NHA corresponded that it was important to use the SNF Antipsychotic Toolkit to decrease the use of psychotropic medications in elderly populations. The NHA emphasized the importance of educating the nursing home staff with non-pharmacological interventions and periodic workshop training in managing residents diagnosed with dementia.

The third SNF has a less than 50-bed licensed capacity. The workshop educational training was held as planned. The NHA has more than five years of experience in SNFs. The NHA specified that staff would be able to do better in understanding psychotropic regulations if staff utilized the CPDH SNF Antipsychotic Toolkit. The social worker at this facility has a Master's in Social Work, with more than five years of experience. The social worker would like to learn more about the side effects of psychotropic medications. The director of utilization rehabilitation (DUR) therapy corresponded utilizing the CDPH SNF Antipsychotic Toolkit is imperative.

The training attendees (NHA, social worker, DUR, and RN) are interested in attending a follow-up, more advanced workshop on this same subject. The attendees recommended that the workshop be offered to other colleagues. They also stated that the training was applicable to their job and that the educational training will more likely change their practice in relation to psychotropic medications.

Quantitative Findings

One of the three SNFs invited to participate in the training succeeded in presenting the educational workshop training. There were seven participants in the educational workshop training. Two participants were excluded in the quantitative analysis because they did not provide direct patient care and one nursing participant did not complete the surveys. Five participants were included in the analysis. See Appendix M for the full results.

Pre-training survey. Although the staff have experience working in nursing homes, the findings suggest that staff need training in the use of antipsychotic medications in LTC facilities. Most participants felt neutral or somewhat comfortable in the use of antipsychotic medications. Pre training, the staff were not comfortable with answering the CMS guidelines with step-by-step

instructions in an effort to reduce use of unnecessary antipsychotic use. The staff were not at all comfortable in identifying signs and symptoms of delirium that can be mistaken as dementia in nursing homes. These finding suggest that the staff need training in providing non-pharmacological interventions prior to use of psychotropic medications. Table 1 displays the full results from the pre-training questionnaire

Table 1

Pre-Training Survey

Question	Mean	*SD*
How comfortable are you with Department of Health Surveyors during annual survey in answering questions in relation of using antipsychotic medication with residents?	3.60	1.14
How comfortable are you in identifying signs and symptoms of delirium?	3.80	0.84
How comfortable are you in providing non-pharmacological interventions with residents manifesting behavioral disturbance	3.80	0.84
How comfortable are you in identifying possible adverse effects of antipsychotic with in older adults?	3.60	0.55

Post-survey. Post-training, the participants felt more comfortable, on average, with the use of antipsychotic medications and in identifying the signs and symptoms of delirium.

Table 2

Post-Training Survey

Question	Mean	*SD*
How comfortable are you with Department of Health Surveyors during annual survey in answering questions in relation of using antipsychotic medication with residents?	4.60	0.55
How comfortable are you in identifying signs and symptoms of delirium?	4.60	0.55
How comfortable are you in providing non-pharmacological interventions with residents manifesting behavioral disturbance	4.60	0.55
How comfortable are you in identifying possible adverse effects of antipsychotic with in older adults?	5.00	0.00

Workshop evaluation. Post-training, the participants feedback on workshop training that it is relevant and applicable to their practice.

Table 3

Workshop Evaluation

Question	Mean	*SD*
The workshop was applicable to my job.	5.00	0.00
I will recommend this workshop to my colleagues.	5.00	0.00
The educational training will more likely to change my practice.	4.80	0.45
I would be interested in attending a follow-up, more advanced workshop on this same subject.	5.00	0.00

Post-implementation. The DNP student promoted the utilization of the CDPH Antipsychotic Toolkit into practice. NHAs are considering enforcement in utilization of the CDPH Antipsychotic Toolkit into practice. The NHA and the DNP student (a former DON) are former colleagues in a 140-bed SNF in Northern California. The NHA and the DNP student utilized the CDPH Antipsychotic Toolkit in that facility, with a remarkable decrease in use of psychotropic medications. The NHA expressed that nursing staff, including the interdisciplinary team at the current facility, need to attend periodic workshop training to understand dementia, delirium, and the purpose of CDPH Antipsychotic Toolkit.

Section IV: Discussion

Summary

Goal 1

Goal 1 was to implement the workshop training into at least three SNFs. The goal was successful with one SNF. The DNP student contacted at least five SNFs in Bay Area, California. Three SNFs agreed to participate in the educational workshop training. Due to facility circumstances, two SNF trainings did not materialize as planned. The DNP student was able to implement the training at one SNF. The DNP project educational workshop training was implemented at a local SNF in Northern, California. The SNF is a less than 50-bed licensed facility located in Eastbay, California. This SNF was closed down by the DPH due to substandard care and negligence. It is now under new ownership and management. The SNF received the license to operate again in the first quarter of 2019.

Goal 2

Goal 2 was for the DNP student to provide educational training on delirium and dementia. The DNP student was able to provide introduction of clinical presentation of delirium in the elderly. The staff was able to identify behavioral side effects of common medications that could be misdiagnosed as dementia or delirium. The DNP student was able to discuss possible outcomes from using antipsychotic medications in elderly.

Goal 3

Goal 3 was to provide a behavioral modification intervention workshop training. The DNP student discussed possible non-pharmacological interventions in managing delirium or dementia with behavioral disturbance. The DNP student remarked that nursing home staff need

periodic training of non-pharmacological interventions in managing delirium, dementia, and residents with behavioral disturbance.

Goal 4

Goal 4 was to introduce the CDPH SNF Antipsychotic Toolkit. The DNP student was able to discuss the criteria and step-by-step utilization of the CDPH SNF Antipsychotic Toolkit. The DNP student emphasized the importance of utilization of the CDPH SNF Antipsychotic Toolkit to reduce the inappropriate use of psychotropic medication in current practice.

Final Goal

The final goal of the DNP project was to have the participating SNF utilize the CDPH SNF Antipsychotic Toolkit into practice. The DNP student discussed this with the NHA post-implementation in utilizing the CDPH SNF Antipsychotic Toolkit. The NHA recommended that periodic workshop training is important to enforce the use of the toolkit.

Interpretation

Despite studies that support the danger of psychotropic drug use in older adult populations and an FDA black box warning about the serious side effects, psychotropic drugs are still commonly used in nursing homes instead of finding alternatives to managing residents' behavioral and emotional states. Elder abuse and neglect is one of the complex and serious consequences that affects this vulnerable population (Miller, 2018). Inappropriate use of antipsychotic drugs is a form of elder abuse, with chemical restraints imposed for purposes of convenience, and is not required to treat the resident's medical symptoms. Implementing the CDPH SNF Antipsychotic Toolkit will increase awareness of guidelines on the use of antipsychotics and in recognizing signs and symptoms of delirium with the elderly population residing in LTC facilities. It is critical for nursing home staff to identify signs and symptoms of

delirium and to communicate identified symptoms and behavior change(s) to the medical provider to correct modifiable risk factors of delirium (dehydration, infection, environmental risk factors, and medications).

Limitations

There were limitations identified in implementing the quality improvement project. Due to the educational budget, the maximum time allotted for the DNP project workshop training was 45 minutes at the nursing home site. The learning objectives of the educational workshop training was for at least two hours that would include discussions. The goal of the DNP improvement project was to increase awareness of guidelines using antipsychotics (goal is to decrease use of antipsychotics) in the elderly in LTC facilities. Evaluating the effectiveness of DNP project in actual performance (use of antipsychotic medications) needs at least three quarters of the year for data collection. Use of antipsychotic medications may also depend on risk factors and comorbidity of residents.

Conclusions

Nursing home staff should have increased awareness in clinical manifestations of delirium (psychomotor agitation, sleep-wake reversals, irritability, anxiety, emotional lability, and hypersensitivity to lights and sounds), because elderly residents with delirium often do not look sick separately from their behavioral changes (Francis & Young, 2014). Nursing care should focus on minimizing negative effects of age-related changes (e.g., sensory and cognition impairment and chronic health conditions) and modifiable risk factors of delirium (dehydration, infection, environmental risk factors, medications, and restraints). The CDPH SNF Antipsychotic Toolkit promotes older adult wellness in physical and psychosocial function. Nursing home residents have the right to be free from involuntary seclusion and free from any physical or

chemical restraints imposed for purposes of convenience, which are not required to treat the resident's medical symptoms (Braun & Frolik, 2000). Antipsychotic medications must be used with caution because of the serious side effects (e.g., cardiac arrest, abnormal involuntary muscle movement, altered liver function, and neuroleptic syndrome) that can lead to serious health issues. The CDPH SNF Antipsychotic Toolkit emphasizes the importance of identifying signs and symptoms of delirium with care for elderly in nursing homes. The CDPH SNF Antipsychotic Toolkit is an evidenced-based assessment toolkit that allows for ethical care of the elderly within the regulations and evidence-based practice for use of antipsychotics.

Disclosure

The DNP project was a quality improvement development approved by the DNP committee chair in School of Nursing and Health Professions at USF. The DNP project did not involve human participant subjects and did not require IRB approval. The DNP project protected the privacy of participants and the facility involved.

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VI. Appendices

Appendix A

CDPH L&C Antipsychotic Use Survey Toolkit

CDPH L&C SNF Antipsychotic Use Survey Tool

(Mandatory use for any resident receiving antipsychotic medication)

Facility: _____ **Date of Record Review:** ___/___/___

Resident Name: _____ **Unit/Room/Bed:** _____

Resident Identifier: _____ **DOB:** ___/___/___ **Age:** ___ **DOA:** ___/___/___ **Readmit**

Event ID: _____

Surveyor Name/Discipline/Federal ID No.: _____

Antipsychotic Name:	Daily Dosage:	Order Date:	Behavioral Manifestation:

1. Which of the following represents the primary indication for use of the antipsychotic? (complete for each antipsychotic)	**Yes**	**No**
1. Schizophrenia		
2. Schizo-affective disorder		
3. Schizophreniform disorder		
4. Delusional disorder		
5. Mood disorders (e.g., bipolar disorder, severe depression refractory to other therapies and/or with psychotic features)		
6. Psychosis in the absence of dementia		
7. Medical illnesses with psychotic symptoms (e.g., neoplastic disease or delirium) and/or treatment related psychosis or mania (e.g., high-dose steroids)		
8. Behavioral or psychological symptoms of dementia (BPSD)		
9. Tourette's Disorder or Huntington disease		
10. Hiccups (not induced by other medications) or nausea and vomiting associated with cancer or chemotherapy		
11. None of the above (indication not in accordance with standards of practice)		

If "Yes" to any indications 1 – 9 complete all remaining sections of the tool;

If "Yes" to indication 10 skip Sections 2-4 and continue with Section 5;

If "Yes" to indication 11 cite at F329 (inadequate indication for use) or F222 (chemical restraints) and continue with Section 2.

2. Determine if resident's documented behavioral symptoms meet the following criteria:	**Met**	**Not Met**	**N/A**
☐ The behavioral symptoms present a danger (documented) to the resident or to others; **AND** one or both of the following:			
☐ The symptoms are identified as being due to mania or psychosis (such as auditory, visual, or other hallucinations, delusions, paranoia or grandiosity); **OR** ☐ Behavioral interventions have been attempted and included in the plan of care, except in an emergency			

If criteria "Not Met," cite at F329 (inadequate indication for use) or F222 (chemical restraints).

If behavioral interventions have not been attempted and included in the plan of care (except in an emergency) cite at F309 (note additional guidance in "Checklist: Review of Care and Services for a Resident with Dementia").

3. If the antipsychotic is being used for long term behavioral management complete section 3A; if used to manage an acute situation complete section 3B; if resident admitted to SNF on an antipsychotic medication complete section 3C to evaluate appropriateness.

3A. Chronic or Prolonged Conditions The target behavior must be specifically identified and monitored objectively and quantitatively prior to its use to ensure the behavioral symptoms are:	**Met**	**Not Met**	**N/A**
☐ Not due to a medical condition or problem (e.g., pain, fluid or electrolyte imbalance, infection, obstipation, medication side effect or polypharmacy) that can be expected to improve or resolve as the underlying condition is treated or the offending medication(s) discontinued; **AND**			
☐ Not due to environmental stressors alone (e.g., alteration in the resident's customary location or daily routine, unfamiliar care provider, hunger or thirst, excessive noise for that individual, inadequate or inappropriate staff response, physical barriers) that can be addressed to improve the symptoms or maintain safety; **AND**			
☐ Not due to psychological stressors alone (e.g., loneliness, taunting, abuse), anxiety or fear stemming from misunderstanding related to his or her cognitive impairment (e.g., the mistaken belief that this is not where he/she lives or inability to find his/her clothes or glasses, unaddressed sensory deficits) that can be expected to improve or resolve as the situation is addressed; **AND** ☐ Persistent (the situation/condition recurs over time and the resident's quality of life is negatively impacted by the behaviors/symptoms); **AND**			
☐ Documented non-pharmacological interventions (e.g., psychological counseling, massage therapy, comfort-focused care) have been attempted but failed to adequately address the behavioral/psychological symptoms.			

3B. Acute Psychiatric Situation/Emergency (must meet all of the following and be related to one or more clinical conditions in Section 1):	**Met**	**Not Met**	**N/A**
☐ The acute treatment period is limited to 7 days or less; **AND** ☐ A clinician in conjunction with the interdisciplinary team must evaluate and document the situation within 7 days, to identify and address any contributing and underlying causes of the acute psychiatric condition and verify the continuing need for antipsychotic medication; **AND** ☐ If the behaviors persist beyond the emergency situation, pertinent non-pharmacological interventions must be attempted, unless contraindicated, and documented following the resolution of the emergency situation.			

3C. New Admissions (pertains to residents admitted to the SNF already on an antipsychotic medication who do not require PASSR screening – see F285):	**Met**	**Not Met**	**N/A**
☐ Facility has re-evaluated antipsychotic at the time of admission and/or within two weeks of admission (at the time of the initial MDS assessment) and has evaluated whether the medication can be tapered or discontinued.			

If any of the above criteria "Not Met," cite at F329 (inadequate indication for use) and/or F222 (chemical restraints). Additionally, if the facility failed to monitor the behaviors in an objective and quantitative manner, cite at F329 (for inadequate monitoring).

If non-pharmacological behavior interventions have not been attempted cite at F309.

4. Dosage	Met	Not Met	N/A
☐ If the antipsychotic is used to treat behavioral symptoms associated with a dementing illness, the daily dosage does not exceed that listed in F329 ("Table 1: Daily Dose Thresholds for Antipsychotic Medications Used to Treat Residents with BPSD" and also in attached supplemental guidance).			
☐ Resident is receiving one antipsychotic medication.			

If any of the above criteria "Not Met," cite at F329 (in excessive dosage or duplicate therapy) unless the prescriber has documented resident specific clinical rationale/justification demonstrating the benefit exceeds the associated risk.

5. Monitoring for Effectiveness	Met	Not Met
Target behavior(s) are:		
☐ Identified in the resident's care plan.		
☐ Monitored objectively (behaviors are specifically identified and not generalized such as; "agitation, restlessness") and quantitatively (number of behavioral episodes exhibited over a specified course of time)		
☐ Consistent with the primary indication for use (e.g., schizophrenia as manifested by auditory hallucinations or dementia as manifested by hitting other residents during activities).		
☐ Evaluated **at least** quarterly (during care plan review) after initiating antipsychotic or dosage increase.		
Behavioral data are:	Met	Not Met
☐ Made available to the prescriber in a consolidated manner at least monthly.		
☐ Sufficient to provide the prescriber with the necessary information to determine antipsychotic medication effectiveness/ineffectiveness as well as the presence of adverse consequences.		

If any of the above criteria "Not Met," consider deficiencies at F329 (inadequate monitoring) and/or F279 (care planning); or Title 22 72319(j)(2) and 72311(a)(1) for nursing care plan data that does not specify data to be collected for use in evaluating the effectiveness of the drugs and occurrence of adverse reactions; or Title 22 72319(j)(3) if consolidated monthly behavioral data not available to prescriber.

6. Monitoring for Adverse Consequences	Met	Not Met	N/A
Adverse consequences to be monitored shall include at least the following:			
☐ Significant or severe consequences, such as those listed in FDA boxed warnings (manufacturer's package insert) and those that may be significant based on the resident's clinical condition.			
☐ Those listed in Table 1 of F329 and also in attached supplemental guidance.			
☐ The associated adverse consequences are identified in the resident's care plan.			
If the resident has experienced possible or actual antipsychotic related adverse consequences the facility has documented such and taken action.			

If any of the above criteria "Not Met," cite at F329 (inadequate monitoring; or presence of adverse consequences which indicate the dose should be reduced or discontinued; or if antipsychotic continued despite adverse consequences and facility/prescriber risk/benefit documentation is not present in clinical record).

7. Gradual Dose Reduction (GDR)	Met	Not Met	N/A
If the antipsychotic was initiated within the last year the facility has attempted a GDR in two separate quarters (with at least one month between attempts).			
If the resident has been receiving the antipsychotic for more than one year the GDR has been attempted annually. If no antipsychotic GDR has been attempted the prescriber has documented a taper is clinically contraindicated (as defined in supplemental guidance).			

If any of the above criteria "Not Met," cite at F329 (for excessive duration/GDR).

8. Provision of Consultant Pharmacist Services	Met	Not Met	N/A
Documentation is present the resident's clinical record was reviewed monthly by a consultant pharmacist.			
If non-compliances related to antipsychotic use were noted in Sections 1 – 7 the consultant pharmacist identified irregularities in writing to the attending physician and director of nursing.			
If the consultant pharmacist **did** identify (in the monthly Medication Regimen Review report) irregularities related to antipsychotic inappropriateness the facility acted on the report.			

If any of the above criteria "Not Met," cite at F428 (Drug Regimen Review).

9. Informed Consent (Note: RP = Responsible Party)	Met	Not Met	N/A
If the antipsychotic was initiated **prior to** admission to the facility the clinical record contains documentation of previous informed consent; or verification of resident consent after admission. ***If "Not Met" cite T22 Section 72528(c).***			
If the antipsychotic was initiated **after** admission to the facility the clinical record contains verification of resident informed consent. Exception is use for an emergency basis as defined in T22 Section 72528(e). ***If "Not Met" cite T22 Section 72528(c).*** If the antipsychotic dosage was increased the clinical record contains verification of resident informed consent. ***If "Not Met" cite H&SC 1418.9.***			
Interview the resident (or RP if the resident does not have capacity) to determine if the following material information was provided prior to the use of the antipsychotic:	**Met**	**Not Met**	**N/A**
(1) The reason for the treatment and the nature and seriousness of the resident's illness; and (2) The nature of the proposed treatment including frequency and duration; and			
(3) The probable degree and duration (temporary or permanent) of improvement or remission, expected with or without such treatment; and			
(4) The nature, degree, duration, and probability of the side effects and significant risks (e.g., FDA boxed warning), commonly known by the health professions; and [1] (5) The reasonable alternative treatments and risks, and why the health professional is recommending this particular treatment; and			
(6) That the resident has the right to accept or refuse the proposed treatment, and if he or she consents, has the right to revoke his or her consent for any reason at any time.			

Except as noted immediately below, if identified as "Not Met," cite the facility at T22 Section 72528(b)(1-6) as applicable.

[1] Per 72528(f): Notwithstanding Sections 72527(a)(5) and 72528(b)(4), disclosure of the risks of a proposed treatment or procedure may be withheld if there is documentation of one of the following in the resident's health record:

(1) That the resident or resident's representative specifically requested that he or she not be informed of the risk or material information concerning the treatment or procedure. This request does not waive the requirement for

providing the other material information concerning the treatment or procedure.

(2) That the licensed healthcare practitioner acting within the scope of his or her professional licensure relied upon objective facts, as documented in the health record, that would demonstrate to a reasonable person that the disclosure would have so seriously upset the resident that the resident would not have been able to rationally weigh the risks of refusing to undergo the recommended treatment and that, unless inappropriate, a resident's representative gave informed consent as set forth herein.

	Met	Not Met	N/A
Determine if the prescribing physician provided material information necessary (listed above) to obtain informed consent and received consent from the resident. ***If "Not Met," cite the facility at T22 Section 72528(a) and/or H&SC 1418.9.*** Prior to giving informed consent, the information provided was understood and questions were satisfactorily answered. ***If "Not Met," cite at F156.*** The resident/RP has been invited to participate in care planning as it relates to the use of the antipsychotic medication. ***If "Not Met," cite F280 or T22 Section 72527(a)(3).***			

If the resident does **not** have capacity to give informed consent and has **no** designated RP/person with legal authority to make those decisions on behalf of the resident:	Met	Not Met	N/A
☐ The attending physician has identified efforts (resident interview/family members consulted, etc.) no person with legal authority exists. ☐ The facility IDT has documented review, assessment and care planning (unless in an emergency) of the proposed antipsychotic order in accordance with H&SC 1418.8 (e)(1) through (e)(6) prior to receipt of the medication. ☐ In the case of an emergency antipsychotic medication intervention, the IDT has met within one week for an evaluation of the intervention. ☐ The IDT has (at least quarterly or upon a significant change of condition) evaluated the antipsychotic therapy.			

If any of the above "Not Met," cite at H&SC Section 1418.8.

Determine the following regarding informed consent policies and procedures:	Met	Not Met	N/A
☐ The facility has written patients' rights policies and procedures related to psychotherapeutic informed consent.			
☐ Licensed nursing staff is familiar with written informed consent facility policies and procedures and are able to explain the process of verifying psychotherapeutic informed consent.			
☐ The resident's attending physician has verified (on interview) that antipsychotic informed consent was obtained in accordance with facility policies and procedures and regulatory requirements.			

If any of the above "Not Met," cite at T22 Section 72527(a).

Consider issuance of a civil money citation* for one or more of the following non-compliance(s):

- ☐ ***Resident/RP indicates (on interview) required material information (as defined in T22 Section 72528 (1-6)) was not received in order to make an informed decision prior to receipt of the antipsychotic medication.***
- ☐ ***Physician did not obtain informed consent from the resident (the process of informed consent was delegated to licensed nursing staff, ward clerk, etc.).***
- ☐ ***Facility failed to develop and implement patients' rights policies and procedures, in accordance with state laws and regulations, related to psychotherapeutic informed consent.***

(*See H&SC Section 1424 in Supplemental Guidance)

10. Medical Director/Quality Assessment & Assurance (QAA)	Met	Not Met	N/A
Medical Director has ensured resident care policies and procedures were developed and implemented regarding antipsychotic informed consent and behavioral health/psychopharmacological medication use.			
Medical Director has addressed facility-identified clinically inappropriate use of antipsychotic medications in the context of regulatory requirements and current standards of practice. QAA has developed and implemented an action plan related to non-compliances with policy and procedure implementation regarding antipsychotic informed consent; appropriate antipsychotic use; care of residents with dementia; or acting on consultant pharmacist MRR recommendations related to inappropriate antipsychotic use (note: facility not required to disclose QAA minutes).			

If either of the first two items "Not Met," cite at F501 (Medical Director is responsible for implementation of resident care policies and/or the coordination of medical care in the facility); if the last item "Not Met," cite at F520 (QAA committee develops and implements appropriate plans of action to correct identified quality deficiencies).

Please note: If professional licensing board referral (MBC, BOP or BRN) appears appropriate discuss with DO Supervisor.

Appendix B

SWOT Analysis

Strengths

- It provides an educational training for health care providers and nursing home management to learn and utilize the CDPH SNF Antipsychotic Toolkit.
- Many nursing home staff lack training in following guidelines of antipsychotics in SNF.
- Increase knowledge on residents' rights in nursing homes.
- Increase knowledge in physiological effect on antipsychotic medication in older adults.
- Increase awareness in signs and symptoms of delirium.

Weaknesses

- NPs, MDs, Psychologist, and Psychiatrist may not attend the educational training and utilize CDPH SNF Antipsychotic Toolkit.
- Nurses can use behavioral modification techniques to modify these behaviors; however, these interventions can be time consuming.

Opportunities

- Receive training on behavioral modifications of residents with a diagnosis of dementia or cognitive problems including behavioral symptoms.
- The CDPH SNF Antipsychotic Toolkit can be included in the policy and procedure of the facility in using antipsychotics medications.
- The nursing staff will have increased knowledge in clinical presentations of delirium in elderly.
- The facility must try non-pharmacological interventions in managing behavioral symptom(s).

Threats

- It will cost money/budget to pay the nursing staff for the educational training.
- Nursing homes are often short staffed and offer low pay, with long work hours and high work volume.
- Because of the short staffing and longer work hours, caregivers do not have enough time to complete the policy and procedures required to document or provide safe and quality care, most especially maintaining dignity of residents (Weinberg, 2016).

Appendix C

Gap Analysis

Actual performance

- Despite studies that support the danger of psychotropic drug use in elderly populations and an FDA black box warning about the serious side effects, psychotropic drugs are commonly used in nursing homes instead of finding alternatives to managing residents' behavioral and emotional states.
- Due to lack of training in behavioral management and knowledge in use of psychotropic drug therapy, nursing staff may not be aware of the dangers of these medications in elderly populations and may not be prepared to adequately care for residents with challenging behaviors (Daly et al., 2015).

Potential

- The utility of CDPH SNF Antipsychotic Toolkit may reduce the use of antipsychotics compared to usual practice in the use of antipsychotic medications.
- Nursing staff in nursing homes, including nursing assistants, will have increased awareness in signs and symptoms of delirium.
- Before prescribing a drug regimen to a resident, most especially antipsychotics, a comprehensive assessment and referrals to other disciplines (psychiatrist, psychologist, or social services) should be considered and to be aware of the possible adverse effects.
- To assess and discuss possible adverse effects of the drug regimen, such as monitoring of lab works, abnormal involuntary body movements, and electrocardiogram to monitor heart rhythm.

Appendix D

Health Facilities Consumer Information System

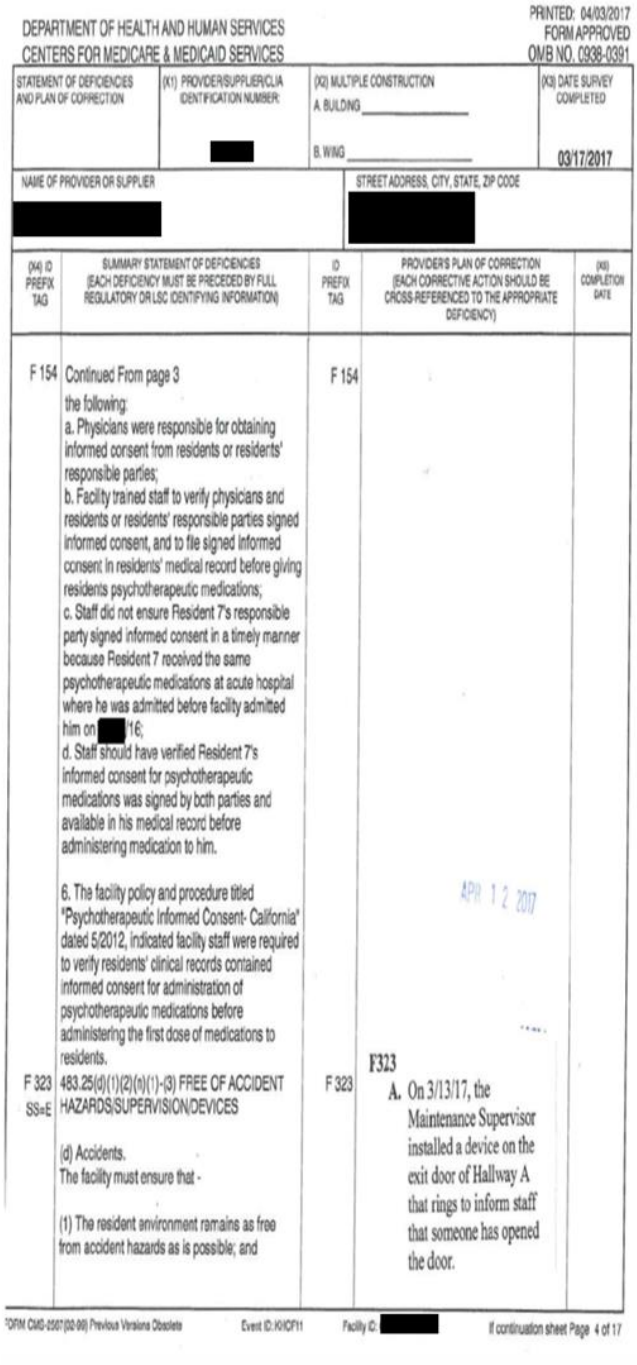
DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 04/03/2017
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	[redacted]	A. BUILDING _____ B. WING _____	03/17/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
[redacted]	[redacted]

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
F 154	Continued From page 2 2. Review of Order Summary Report dated 12/30/16, indicated physician ordered the following psychotherapeutic medications for Resident 7 on 12/19/16, to be initiated on 12/20/16: a. Ativan Tablets 1 milligram (mg) one tablet by mouth in the morning, at 6:00 a.m., for anxiety (nervousness); b. Risperidone Tablets 2 mg one tablet by mouth in the morning, at 6:00 a.m., as an antipsychotic medication (medication used to treat thinking distortions); c. Risperidone Tablets 3 mg one tablet by mouth at bedtime, at 9:00 p.m., as an antipsychotic medication. 3. Record review of INFORMED CONSENT - Psychoactive Medication dated [redacted]/16, indicated physician signed informed consent form for administration of medications on [redacted]/16, the same date he ordered medications, and facility admitted Resident 7. Resident 7's responsible party (the person making decisions for him) signed informed consent form on 12/27/16, eight days after the date physician ordered psychotherapeutic medications and signed informed consent form. 4. During a review of clinical record for Resident 7, the Medication Administration Record dated 12/1/16-12/31/16 indicated facility administered psychotherapeutic medications to Resident 7 on 12/21/16 to 12/27/16, six days before Resident 7's responsible party signed consent form for administration of medication to him. 5. During interview with Director of Nursing (DON), on 3/16/17, at 11:00 a.m., the DON stated	F 154		



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 04/03/2017
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	[redacted]	A. BUILDING _____ B. WING _____	03/17/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
[redacted]	[redacted]

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
F 154	Continued From page 3 the following: a. Physicians were responsible for obtaining informed consent from residents or residents' responsible parties; b. Facility trained staff to verify physicians and residents or residents' responsible parties signed informed consent, and to file signed informed consent in residents' medical record before giving residents psychotherapeutic medications; c. Staff did not ensure Resident 7's responsible party signed informed consent in a timely manner because Resident 7 received the same psychotherapeutic medications at acute hospital where he was admitted before facility admitted him on [redacted]16; d. Staff should have verified Resident 7's informed consent for psychotherapeutic medications was signed by both parties and available in his medical record before administering medication to him. 6. The facility policy and procedure titled "Psychotherapeutic Informed Consent- California" dated 5/2012, indicated facility staff were required to verify residents' clinical records contained informed consent for administration of psychotherapeutic medications before administering the first dose of medications to residents.	F 154		
F 323 SS=E	483.25(d)(1)(2)(ii)(1)-(3) FREE OF ACCIDENT HAZARDS/SUPERVISION/DEVICES (d) Accidents. The facility must ensure that - (1) The resident environment remains as free from accident hazards as is possible; and	F 323	F323 A. On 3/13/17, the Maintenance Supervisor installed a device on the exit door of Hallway A that rings to inform staff that someone has opened the door.	

Appendix E

Critical Appraisal of Evidence

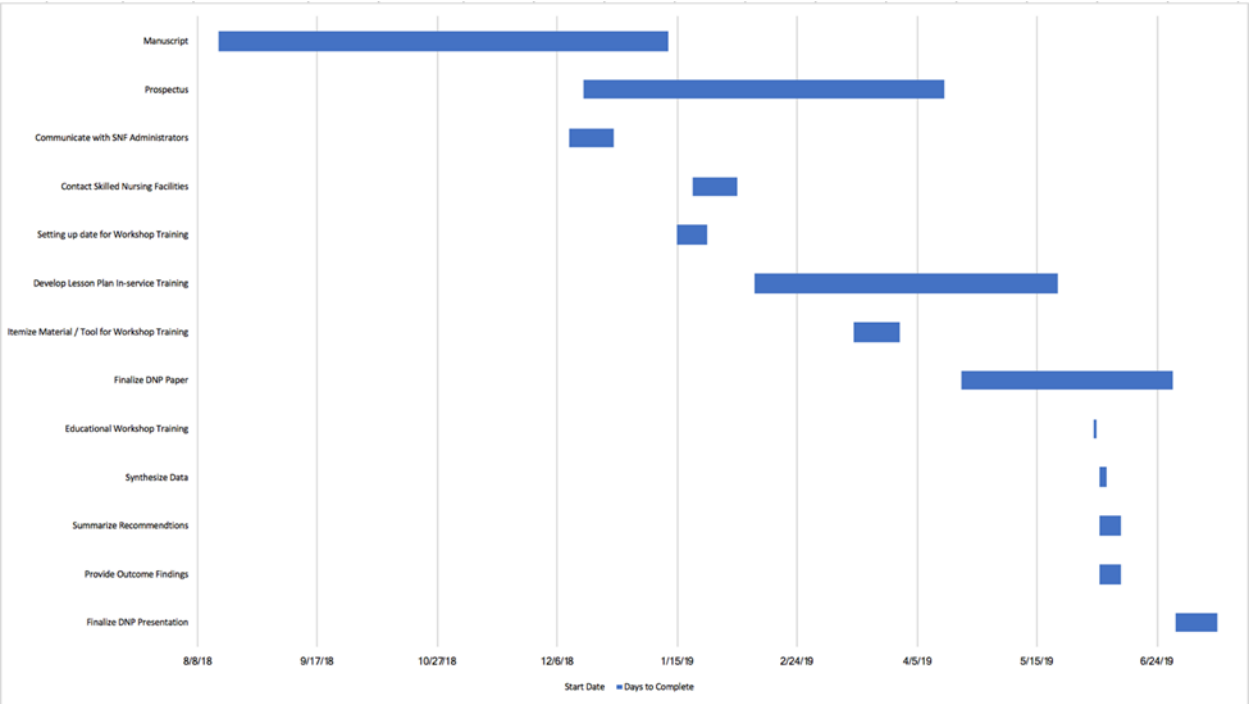
Citation	Conceptual Framework	Design/ Method	Sample Setting	Variables Studied and Their Definitions	Measurement	Data Analysis	Findings
Huybrechts et al., 2012	None	Quantitative study, comparative safety of antipsychotic medications in nursing home residents.	Nursing homes in 45 U.S. states. 83,959 Medicaid eligible residents ≥ 65 who initiated antipsychotic treatment following nursing home admission in 2001-2005.	Reviewed data for an association between typical and atypical antipsychotics and the main side effects.	Hospitalization for MI, CVA, bacterial infections & hip fracture within 180 days of treatment initiation.	Propensity score-adjusted proportional hazards models were used.	Bacterial infections, myocardial infarction, and hip fracture rates and risks of cerebrovascular events demonstrated significant risk.
Bonner et al., 2015	None	Qualitative and descriptive, rationales of providers and family members for use of antipsychotics in nursing home.	26 medium and large facilities in five CMS regions.	Individuals diagnosed with dementia who received an antipsychotic medication.	Medical record abstraction, interviews with prescribers, staff, family.	Coding scheme and coded reasons for antipsychotic use.	Many of the prescribed psychotropic drugs lacked evidence of supporting documentation for medication necessity or proper diagnosis in the resident medical record.

Pakpoor & Agius, 2014	None	Literature review, adverse side effects associated with antipsychotics as related to their efficacy.	Review the data for an association between typical and atypical antipsychotics.	EPS, metabolic effects, tardive dyskinesia – typical, weight gain, QTc.	Not applicable.	Reported subcategories side effect of typical, atypical antipsychotics.	The study concluded neuroleptic malignant syndrome is a fatal side effect for all antipsychotic medications.
Levin, 2012	None	Literature review, lifting the fog: The problem of antipsychotic drug use in nursing facilities.	Address complex medical issues of treating elderly in nursing homes with antipsychotics and summarize federal legislation in nursing homes.	Reviewed data on excessive dependence on antipsychotic treatment for dementia-related behavioral problems.	Not applicable.	Review of legislative, judicial, and policy consideration.	Food and Drug Administration issued the black box warnings for antipsychotics in response to 15,000 nursing home residents dying each year from the off-label use of antipsychotic drugs.
Azermai et al., 2014	None	Mixed-method study involving an expert meeting, a survey using structured questionnaires distributed to responsible nurses and treating general practitioners.	On selected nursing home residents in Belgian nursing homes to generate case-specific information.	Antipsychotic users (*n* = 113) had a mean age of 81 years (range 57–97); 62% were female and 81% had moderate to severe cognitive impairment.	Not stated.	Not stated.	Nurses and general practitioners share a very low willingness and high barriers to antipsychotic discontinuation.

Basso et al., 2018	None	Retrospective study using nursing home clinical records from 2013-2016.	Nursing home residents transferred to ED for respiratory, cardiovascular, and neurological problem and symptoms of infections.	Not available	Not stated.	In 4 years (2013-2016), 143 ED access occurred, 55 (38%) for medical problems in 48 residents.	Most frequent reason for ED: infection (22) respiratory (18), urinary (2) or both (2). The week before ED 1/3 of residents were asymptomatic. ED admission prevalent signs: desaturation, dyspnea, fever.
Kiely et al., 2013	None	Delirium status was categorized into four groups: full, two or more symptoms, one symptom, and no delirium.	2,158 subjects were recruited from seven Boston-area SNFs specialized in post-acute care.	CAM – defined delirium at admission to the post-acute facility.	Assessment instrument included Mini-Mental Status Exam, Delirium Interview, Memorial Delirium Assessment Scale, and CAM.	Descriptive statistics were calculated and chi-square analyses and an analysis-of-variance were used to examine delirium characteristics by group.	Among 2,158 subjects, 16% CAM-defined delirium at admission to post-acute, 13% had two or more symptoms of delirium, 40% had one delirium symptom, 32% had no delirium symptoms.

Appendix F

Gantt Chart



	Finalize DNP Presentation	Provide Outcome Findings	Summarize Recommendtions	Synthesize Data	Educational Workshop Training	Finalize DNP Paper	Itemize Material / Tool for Workshop Training	Develop Lesson Plan In-service Training	Setting up date for Workshop Training	Contact Skilled Nursing Facilities	Communicate with SNF Administrators	Prospectus	Manuscript
Start Date	6/21/19	6/5/19	6/5/19	6/5/19	6/3/19	4/20/19	3/15/19	2/10/19	1/15/19	1/20/19	12/10/18	12/15/18	8/15/18
Days to Complete	5	7	7	2	1	70	15	101	10	15	15	120	150

Appendix G

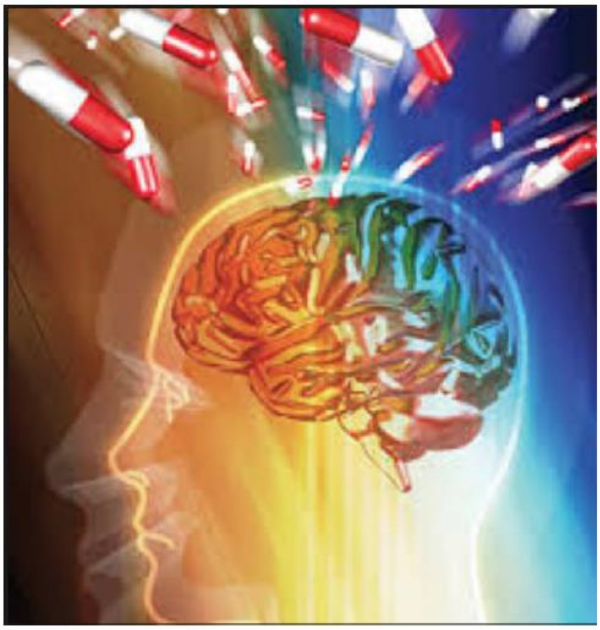
Cost Benefit and Analysis

Project Cost of In-Service in 50-Bed Facility

Trainees	Fair Market Rate Nursing Homes In Bay Area, California Per Hour	Projected Staffing	Total Cost Annually
Certified Nursing Assistant (CNA)	$18.00 x 1.5 hours	22 CNAs	$594.00
Licensed Vocational Nurse (LVN)	$30.00 x 1.5 hours	12 LVNs	$540.00
Registered Nurse (RN)	$45.00 x 1.5 hours	6 RNs	$405.00
Social Worker (SW)	$35.00 x 1.5 hours	1 SW	$52.50
PROJECTED TOTAL COST			$1,591.50

Appendix H

Flyer



HAZARDS OF ANTIPSYCHOTICS IN NURSING HOME TRAINING WORKSHOP

JUNE 03, 2019

JUNE 07, 2019

Contact: Nino Dantes Flores
E: ndflores5@usfca.dons.edu

UNIVERSITY OF SAN FRANCISCO
School of Nursing and Health Professions

People with dementia are at great risk of developing delirium secondary to age-related changes.

It is emphasized importance of the healthcare workers, nursing and to support staff to understand how to prevent, recognize, and manage delirium because delirium can be mistaken as dementia.

Antipsychotic medications must be used with caution because of the serious side effects (e.g., cardiac arrest, abnormal involuntary muscle movement, altered liver function, and neuroleptic syndrome) that can lead to serious health issues.

It is critical for geriatric nurses and providers to know the guidelines for administering and prescribing antipsychotic medications to the older adult population in nursing homes and to be aware of the possible adverse effects.

CDPH SNF Antipsychotic Toolkit emphasized importance of identifying signs and symptoms of delirium with care for elderly in nursing homes. Therefore, the CDPH SNF Antipsychotic Toolkit is an evidenced-based assessment toolkit that allows for ethical care of the elderly within the regulations and evidenced-based practice for use of antipsychotics.

Appendix I

Work Breakdown System / Communication Plan

	Color Coding	Hazards of Antipsychotic in Nursing Homes Project	Due Date	Assigned To	Status	Comments
1		**High Priority (6)**				
2		~~Manuscript~~	~~04/04/19~~	~~DNP-S~~	~~Completed~~	~~waiting for second advisor feedback~~
3		~~Formative Research Review: Conduct Nursing Home Review Audit from CDPH~~	~~02/13/19~~	~~DNP-S~~	~~Completed~~	~~access public records results of surveys in Bay Area Nursing Homes~~
4		~~Prospectus~~	~~06/03/19~~	~~DNP-S~~	~~Completed~~	~~waiting for advisor for approval~~
5		~~Conduct Literature Reviews Criteria of Delirium and Dementia~~	~~05/01/19~~	~~DNP-S~~	~~Completed~~	~~recommendation from second advisor reader~~
6		~~DNP Residency~~	~~06/03/19~~	~~DNP-S~~	~~Completed~~	~~need follow up post implementation~~
7		DNP Project	07/13/19	DNP-S	In Progress	present DNP Project to board
8		**Medium Priority (6)**				
9		~~Coodinate with Nursing Home 1~~	~~12/10/18~~	~~DNP-S~~	~~Completed~~	
10		~~Nursing Home Administrator 1 (coordinate with staff)~~	~~04/10/19~~	~~NHA-1~~	~~Completed~~	~~pending annual audit CPDH~~
11		~~Coordinate with Nursing Home 2~~	~~03/05/19~~	~~DNP-S~~	~~Completed~~	
12		~~Nursing Home Administrator 2 (coordinate with staff)~~	~~12/10/18~~	~~NHA-2~~	~~Completed~~	~~pending clear direct care concerns with residents~~
13		~~Coordinate with Nursing Home 3~~	~~12/10/18~~	~~DNS-2~~	~~Completed~~	
14		~~Nursing Home Administrator 3 (coordinate with staff)~~	~~06/03/19~~	~~NHA-3~~	~~Completed~~	
15		**Low Priority (4)**				
16		~~Contact at at least 5 nursing homes in Bay Area, California~~	~~01/20/18~~	~~DNS-S~~	~~Completed~~	~~3 nursing homes agreed for workshop training~~
17		~~Create Workshop Lesson Plan~~	~~05/15/19~~	~~DNP-S~~	~~Completed~~	
18		~~Create Pre and Post Survey Tool~~	~~05/22/19~~	~~DNP-S~~	~~Completed~~	
19		~~Create Workshop Evaluation~~	~~05/22/19~~	~~DNP-S~~	~~Completed~~	
20		**Completed (4)**				
21		~~Synthesis Data~~	~~06/05/19~~	~~DNP-S~~	~~Completed~~	~~call a colleague for help with data analysis~~
22		~~Summarize Recommendations~~	~~06/05/19~~	~~DNP-S~~	~~Completed~~	
23		~~Provide Outcome Findings~~	~~06/05/19~~	~~DNP-S~~	~~Completed~~	
24		Finalize DNP Presentation	07/05/19	DNP-S	In Progress	

Appendix J

Resources and Materials

Print Materials

- California Department of Health L&C SNF Antipsychotic Use Survey Toolkit
- Power Point presentation on Hazards of Antipsychotics in Nursing Homes
- Pre- and post-questionnaires
- Workshop Evaluation
- Agenda
- Flyers

Online Access Resources

- California Department of Health L&C SNF Antipsychotic Use Survey Toolkit: https://www.caltcm.org/assets/documents/forms/cdph_lc_antipsychotic_survey_tool_07_11_12.pdf
- Department of Health & Human Services. Centers for Medicare & Medicaid Services. CMS Manual System: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R22SOMA.pdf
- Long-Term Care Community Coalition: http://www.ltccc.org/publications/documents/ltccc-antipsychotic-drugs-oversight-ftags-mar2013.pdf

Appendix K

Pre- and Post-Questionnaire and Workshop Evaluation

Pre-Questionnaire

Your response will provide the best possible outcome of the educational training.

What is your job title?
□ MD □ NP □ RN □ LVN □ Others_____

How many years of experience in your profession?
□ <1 year □ 2-3 years □ 4-5 years □ > 5 years

Did you ever use or know about the SNF Antipsychotic Toolkit prior to this training?
□ YES □ NO

1. How comfortable are you in identifying or recognizing signs and symptoms of delirium?

	O	O	O	O	O	
Least Comfortable	**1**	**2**	**3**	**4**	**5**	**Very Comfortable**

2. How comfortable are you what to examine to a resident before administering or prescribing antipsychotic medication in nursing skilled facility within the regulation?

	O	O	O	O	O	
Highly Comfortable	**1**	**2**	**3**	**4**	**5**	**Very Comfortable**

3. How comfortable are you in providing non-pharmacological interventions with resident manifesting behavioral disturbance?

	O	O	O	O	O	
Highly Comfortable	**1**	**2**	**3**	**4**	**5**	**Very Comfortable**

4. How comfortable are you with Department of Health Surveyors during annual survey in answering questions in relation of using antipsychotic medication with residents?

	O	O	O	O	O	
Highly Comfortable	**1**	**2**	**3**	**4**	**5**	**Very Comfortable**

5. How comfortable are you in identifying possible adverse effects of antipsychotic medication with in older adults?

	O	O	O	O	O	
Highly Comfortable	**1**	**2**	**3**	**4**	**5**	**Very Comfortable**

6. How comfortable are you when verifying or prescribing antipsychotic medication in nursing skilled facility within the regulation?

	O	O	O	O	O	
Least Comfortable	**1**	**2**	**3**	**4**	**5**	**Very Comfortable**

Post-Questionnaire

Your response will provide the best possible outcome of the educational training.

1. How comfortable are you in identifying signs and symptoms of delirium?

	O	O	O	O	O	
Least Comfortable	**1**	**2**	**3**	**4**	**5**	**Very Comfortable**

2. How comfortable are you what to rule out before administering or prescribing antipsychotic medication in nursing skilled facility within the regulation?

	O	O	O	O	O	
Least Comfortable	**1**	**2**	**3**	**4**	**5**	**Very Comfortable**

3. How comfortable are you in providing non-pharmacological interventions with resident manifesting behavioral disturbance?

	O	O	O	O	O	
Least Comfortable	**1**	**2**	**3**	**4**	**5**	**Very Comfortable**

4. How comfortable are you with Department of Health Surveyors during annual survey in answering questions in relation of using antipsychotic medication with residents?

	O	O	O	O	O	
Least Comfortable	**1**	**2**	**3**	**4**	**5**	**Very Comfortable**

5. How comfortable are you in identifying possible adverse effects of antipsychotic medication with in older adults?

	O	O	O	O	O	
Least Comfortable	**1**	**2**	**3**	**4**	**5**	**Very Comfortable**

6. How comfortable are you when verifying or prescribing antipsychotic medication in nursing skilled facility within the regulation?

	O	O	O	O	O	
Least Comfortable	**1**	**2**	**3**	**4**	**5**	**Very Comfortable**

Workshop Evaluation Form

Training Location: _____

Date: _____

Job Title: _____

Years in present position? <1 1-3 3-5 +5

INSTRUCTIONS:
Please

	Strongly agree				**Strongly disagree**
1. I was well informed about the objectives of this workshop	1	2	3	4	5
2. The workshop was applicable to my job	1	2	3	4	5
3. I will recommend this workshop to my colleagues	1	2	3	4	5
4. The program was well paced within the allotted time	1	2	3	4	5
5. The educational training will more likely change my practice	1	2	3	4	5
6. The material was presented in an organized manner	1	2	3	4	5
7. The instructor was knowledgeable on the topic	1	2	3	4	5
8. I would be interested in attending a follow-up, more advanced workshop on this same subject	1	2	3	4	5
9. I would be interested in attending a follow-up, more advanced workshop on this same subject	1	2	3	4	5

10. Given the topic, was this workshop: ❑ a. Too short ❑ b. Right length ❑ c. Too long

11. In your opinion, was this workshop: ❑ a. Introductory ❑ b. Intermediate ❑ c. Advanced

12. What did you most appreciate/enjoy/think was best about the course? Any suggestions for improvement?

---

14. What is the least valuable about this workshop?

---

15. What is the most valuable about this workshop?

16. I would be able to do my work better if I knew more about>

---

17. Please describe the top two topics you would like to learn more about in the next 12 months:

Topic

1:_____

Topic

2:_____

Please return this form to the instructor or organizer at the end of the workshop. Thank you.

Appendix L

DNP Statement of Non-Research Determination Form

Student Name: Nino D. Flores, RN MSN

Title of Project: Hazards of Antipsychotic in Nursing Homes

Brief Description of Project: Introduction of the California Department of Public Health's Skilled Nursing Facility (CDPH SNF) Antipsychotic Toolkit may reduce the use and or prescribing of antipsychotic medications compared to usual practice of antipsychotic use. Delirium and altered in mental status are associated with multiple complex underlying medical conditions and they can be difficult to recognize, particularly among elderly residing in long term care facilities.

A) Aim Statement: The use of the CDPH SNF Antipsychotic Toolkit allows for ethical and evidence-based care of the elderly within the regulations and best practice for use of antipsychotics.

B) Description of Intervention: Quality improvement project is to provide: a) an educational training on delirium and dementia, b) behavioral modifications, and c) introducing CDPH SNF Antipsychotic Toolkit to local nursing homes in Northern, California.

C) How will this intervention change practice? Increase awareness and knowledge in regulations use of CDPH SNF Antipsychotic Toolkit may decrease use of antipsychotics in residents of nursing homes and to increase awareness signs and symptoms of delirium.

D) Outcome measurements: Pre and Post survey questionnaires, and workshop evaluation will be administered to healthcare participants.

To qualify as an Evidence-based Change in Practice Project, rather than a Research Project, the criteria outlined in federal guidelines will be used:
(http://answers.hhs.gov/ohrp/categories/1569)

☐ **X** This project meets the guidelines for an Evidence-based Change in Practice Project as outlined in the Project Checklist (attached). Student may proceed with implementation.

☐ This project involves research with human subjects and must be submitted for IRB approval before project activity can commence

Comments:

EVIDENCE-BASED CHANGE OF PRACTICE PROJECT CHECKLIST *

Instructions: Answer YES or NO to each of the following statements:

Project Title: Hazards of Antipsychotics in Nursing Home	**YES**	**NO**
The aim of the project is to improve the process or delivery of care with established/ accepted standards, or to implement evidence-based change. There is no intention of using the data for research purposes.	Yes	
The specific aim is to improve performance on a specific service or program and **is a part of usual care**. ALL participants will receive standard of care.	Yes	
The project is **NOT** designed to follow a research design, e.g., hypothesis testing or group comparison, randomization, control groups, prospective comparison groups, cross-sectional, case control). The project does **NOT** follow a protocol that overrides clinical decision-making.	Yes	
The project involves implementation of established and tested quality standards and/or systematic monitoring, assessment or evaluation of the organization to ensure that existing quality standards are being met. The project does **NOT** develop paradigms or untested methods or new untested standards.	Yes	
The project involves implementation of care practices and interventions that are consensus-based or evidence-based. The project does **NOT** seek to test an intervention that is beyond current science and experience.	Yes	
The project is conducted by staff where the project will take place and involves staff who are working at an agency that has an agreement with USF SONHP.	Yes	
The project has **NO** funding from federal agencies or research-focused organizations and is not receiving funding for implementation research.	Yes	
The agency or clinical practice unit agrees that this is a project that will be implemented to improve the process or delivery of care, i.e., **not** a personal research project that is dependent upon the voluntary participation of colleagues, students and/ or patients.	Yes	
If there is an intent to, or possibility of publishing your work, you and supervising faculty and the agency oversight committee are comfortable with the following statement in your methods section: *"This project was undertaken as an Evidence-based change of practice project at X hospital or agency and as such was not formally supervised by the Institutional Review Board."*	Yes	

ANSWER KEY: If the answer to **ALL** of these items is yes, the project can be considered an Evidence-based activity that does NOT meet the definition of research. **IRB review is not required. Keep a copy of this checklist in your files.** If the answer to ANY of these questions is **NO**, you must submit for IRB approval.

*Adapted with permission of Elizabeth L. Hohmann, MD, Director and Chair, Partners Human Research Committee, Partners Health System, Boston, MA.

STUDENT NAME (Please print):

Nino Dantes Flores, RN MSN

Signature of Student:

DATE

SUPERVISING FACULTY MEMBER (CHAIR) NAME (Please print):

Dr. Jo Loomis, DNP, FNP-C, CHSE, CLC, ANLC, NCMP, CNL

Signature of Supervising Faculty Member (Chair):

DATE

Appendix M

Results