Strategies to Reduce Antipsychotic Medication Use in Nursing Home Residents with Dementia

By

Sydney Malimpenet

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Approved: Deborah Erickson PhD, RN May 20, 2019
(DNP Project Team Chairperson name, credentials & date)

Approved: Oliver Punogbayan MSN, MDS, RN May 20, 2019
(DNP Project Team Member name, credentials & date)

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Abstract

Background: Antipsychotics are not a standard pharmacologic regimen for the management of dementia-related behavioral symptoms. However, its off-label use continues to be practiced in nursing homes according to the Centers for Medicare and Medicaid Services (CMS, 2014). The CMS discourages such practice, labelling it as equivalent to using chemical restraints, and emphasizing that antipsychotics should not be used for the convenience of caregivers. Studies suggest that staff education can reduce this problem. **Aim:** The purpose of this Doctor of Nursing Practice (DNP) project was to develop and implement an in-house educational program to the staff of a dementia care unit, focusing on the nonpharmacologic management of behavioral symptoms to enhance resident outcomes. **Design*:*** Eighteen staff members attended the program. Fifteen residents were involved in the project. The residents were assessed prior to intervention using the Appropriate Psychotropic Drugs Use in Dementia (APID) index scores. The staff members were encouraged to apply the knowledge gained from the in-house educational program to residents in the dementia care unit. After two months, the residents were re-assessed using the same tool. **Results:** All of the 15 residents (100%) had improved APID Index scores from a summated mean of 4.01 to 1.47, which was a 66.54% improvement, with the corresponding P-value of 0.00. The results suggest that an in-house educational program may be an effective intervention in reducing the inappropriate use of antipsychotics in residents with dementia. A dialogue with the clinical leaders of the setting may be necessary to sustain the changed practice behavior and continue the benefits of the program.

Keywords: dementia, antipsychotics, caregiver training, BPSD

Table of Contents

Chapter I

Antipsychotic medications are commonly used to manage behavioral and psychological symptoms of dementia. Inappropriate use of this medication prescription is a common problem in residents living in nursing homes, both on admission and later. Gurwitz, Bonner, and Berwick (2017) cited that the excessive use of antipsychotic medications in nursing home residents with dementia has been among the most challenging issues in the care of this vulnerable population.

Introduction to the Problem

The probable overuse of antipsychotic medications has been criticized because of evidence of limited efficacy and significant adverse effects (Carnahan et al., 2017). According to Coon et al. (2014), several large studies have demonstrated a clear association between treatment with antipsychotic medications and increased morbidity and mortality in people with dementia. Psychotropic medications were found to increase the risk for falls (Bloch et al., 2011), increase the risk for fractures (Lee et al., 2017) and is associated with stroke (Carnahan et al., 2017). Despite warnings about their harmful effects, these drugs continued to be prescribed. The national initiative of the Centers for Medicare & Medicaid Services (CMS) launched a campaign to reduce antipsychotic use in nursing homes.

According to data from 2013-2014, dementia affects 50.4% of the 1.4 million persons residing in the 15,600 nursing homes in the United States (Gurwitz et al., 2017). Approximately one-third of these elderly residents with dementia are prescribed an antipsychotic medication to manage psychosis-related symptoms such as delusions, hallucination, aggression, and agitation. Azermai, Stichele, Bortel, and Elseviers (2013) used data taken from Medicaid-eligible long stay residents in seven states and found that about 52% of residents were administered an antipsychotic without an approved CMS/FDA indication. The Food and Drug Administration

(FDA) requires drug manufacturers to include warning labels to alert prescribers about the increased risk of death when antipsychotics are used in residents with dementia (CMS, 2014). In 2011, the Office of the Inspector General of the Department of Health and Human Services emphasized the need to reduce the use of antipsychotic medications for off – label use among nursing home residents (CMS, 2016). According to Lucas and Bowblis (2017), many prescribers confront the challenge of how to manage nursing home residents with behavioral symptoms of dementia. Given the frequency of the symptoms and the lack of a drug to treat them that has been approved by the FDA, often the solution is to use antipsychotic medications. These medications have sedating effects and, when provided to nursing home residents with behavioral symptoms of dementia, are viewed as a form of "chemical restraint" (Lucas & Bowblis, 2017).

Dementia is a term used to describe a syndrome that may be caused by a number of illnesses in which there is progressive decline in multiple areas of function, including decline in memory, reasoning, communication skills, and the ability to carry out daily activities (Lucas et al., 2014).

Watson-Wolfe, Galik, Klinedinst, and Brandt (2014) found that approximately 25% of all nursing home residents take antipsychotics for behavioral disturbances, despite limited efficacy and warnings against their use. Clinically significant behavioral and psychiatric symptoms of dementia (BPSD) are found in approximately 80% of residents with dementia residing in long term care facilities. BPSD includes a broad range of behavioral symptoms which include depression, anxiety, delusions, hallucinations, aberrant motors behaviors, verbal aggression, physical aggression, and disinhibition (Watson-Wolfe et al., 2014).

Trifiro and Spina (2011) mentioned as individuals age, certain physiological and psychological changes increase the effects of medication in the body. Advancing age is also

associated with loss of functional units in some individuals, which could lead to increased susceptibility to environmental or internal stress and increasing risk of morbidity and mortality. Interventions to improve the quality of drug prescription and reduce inappropriate use of antipsychotic medications in nursing home residents would be expected to reduce the number of adverse drug reactions (ADRs) and to improve other outcomes that are closely related to inappropriate use of drugs. The fact that ADRs lead to hospitalization, it is therefore worth examining if gradual dose reduction (GDR) of psychotropic medications will reduce ADRs and hospitalization, both of which have clinical and financial implications. The CMS (2014) is maintaining a focus on reducing unnecessary antipsychotic medication use. The CMS surveyors have been directed to speak with physicians, nurse practitioners, and other prescribers in order to understand how decisions are made regarding the use of antipsychotic medications, especially with dementia residents.

Background and Significance

Geriatric research has focused on strategies and interventions to reduce inappropriate use of antipsychotic medications in nursing home residents. In an effort to address these alarming statistics, a large number of randomized controlled trials have investigated the efficacy of a number of different intervention strategies. Growing evidence indicates that inappropriate use of antipsychotic medications can be reduced with proper compliance on the treatment guidelines recommended by the Omnibus Budget Reconciliation Act (OBRA) of 1987 (Gurvich, Pharm, & Cunningham, 2000; Watson-Wolfe et al., 2014). This legislation is directed at protecting residents of nursing home facilities from medically unnecessary “physical or chemical restraints” imposed for purposes of discipline or convenience. To improve dementia care and reduce inappropriate use of antipsychotic medications in nursing homes, CMS used the

multidimensional approach that included research, state-based coalitions, and new strategies for monitoring compliance (Watson-Wolfe et al., 2014).

Problem Statement

The CMS (2014) has determined that the use of inappropriate antipsychotic medication is increasing, which exposes patients to medication side effects and can lead to deterioration of medical and cognitive status. The CMS regulation requires health care facilities to show evidence of attempted gradual decrease of antipsychotic medication use. Those facilities who have not met the requirements will not only be affected by delays in the reimbursement of healthcare costs, but will also possibly face the consequences of a citation during annual surveys. According to the CMS (2014) Interim Report on National Partnership to Improve Dementia Care in Nursing Homes, the GDR citations have increased since 2009 as compared to all other citations. The CMS (2014) is tracking the progress of the National Partnership to Improve Dementia Care in Nursing Homes by reviewing publicly reported measures. The official measure of the Partnership is the percentage of long-stay nursing home residents who are receiving an antipsychotic medication, excluding those residents diagnosed with schizophrenia, Huntington's Disease, or Tourette’s Syndrome. In the fourth quarter of 2011, 23.9% of long-stay nursing home residents were receiving an antipsychotic medication; since then there has been a decrease of 28.8%, to a national prevalence of 17.0% in the fourth quarter of 2015. Success has varied by state and CMS region; some states and regions had a reduction greater than 25% (CMS, 2014).

This scholarly project will be conducted at Alpha Center for Rehabilitation and Nursing, a provider of quality sub-acute rehabilitation and skilled nursing care in the East Coast. Alpha Center for Rehabilitation and Nursing proclaims a long history of commitment to the community, and features seven floors with 380 beds dedicated to progressive rehabilitation and

specialized clinical excellence in orthopedic aftercare, amputee rehabilitation, ventilator care, stroke recovery, and dementia care. The facility was almost cited in 2015 and 2017 during a re-certification survey for noncompliance with the CMS F-329 regulation (O. Punongbayan, personal communication, January 23, 2017). In 2006, CMS established regulation F-329, which focuses on the prescription of unnecessary medications and GDR of psychotropic medications (Lindsey, 2009). As a result, the facility instituted and emphasized the importance of following the GDR policy of antipsychotic medications. This evidence-based project evaluated the effectiveness of an educational in-service to facilitate the appropriate use of antipsychotic medications in nursing home residents with dementia.

Project Aim

Antipsychotic medications, when used appropriately, can help promote elderly residents' highest practicable mental, physical and psychosocial well-being. Ensuring that elderly residents receive medications that are needed and appropriate for their medical condition is a critical component of safe and effective care. The aim of this project was to provide evidence-based tools on non-pharmacologic interventions for residents with dementia and to assess the effectiveness of an intervention used to reduce inappropriate use of antipsychotic medications to the elderly residents with dementia in nursing homes.

Clinical Question

In nursing home residents, to what extent can an educational intervention reduce the incidence rate of inappropriate use of antipsychotic medication for patients with dementia?

Congruence with Organizational Strategic Plan

Nursing home leaders are charged with making sure that their residents receive appropriate care to prevent or minimize the symptoms or behaviors associated with mental

illness or dementia. Evidence-based tools, resources, and guidance in prescribing medications related to the use of antipsychotic drugs assist the nursing home to provide a high standard of care to its residents. Person-centered care may lead to increased resident and family satisfaction and thus improve nursing home marketability. Alpha Center for Rehabilitation and Nursing cultivates certain shared values within the organization. The organization's approach on providing excellent service is centered on placing the residents' physical and emotional well-being as of paramount priority. This project aligned with the shared values of the organization in terms of protecting the physical welfare of the residents by reducing the use of antipsychotic drugs to the elderly as this has been associated with increased incidence of falls (Bloch et al., 2011), stroke (Carnahan et al., 2017), increased risk for fractures (Lee et al., 2017) and mortality (Coon et al., 2014). Consequently, the emotional welfare of the residents was also addressed by the program through teaching physicians, nurse practitioners, nurses, nursing assistants, and pharmacists in the organization about nonpharmacologic means to manage residents' care.

Synthesis of Evidence

A comprehensive literature search was conducted using Cochrane Library, Cumulative of Nursing and Allied Health Literature, MEDLINE, PubMed, and EBSCOhost databases using the following key terms: inappropriate medications, antipsychotic medications, antipsychotic reduction, inappropriate drug prescription, polypharmacy, educational intervention, dementia, nursing homes, systematic review, and elderly population. In addition, references from relevant articles and archives of select nursing research and gerontology journals were searched. Ten articles were reviewed. Most of the articles were intervention research studies related to reduce antipsychotic medication use in nursing home residents with dementia. Articles that were fully relevant to the project were used as evidence. Appendix A (Evidence Evaluation Table) provides

a list of studies, with their respective details, which were cited in this DNP project. This list is a testament that the best possible evidence from previous studies and clinical data were used to support this project.

The CMS launched the National Partnership to Improve Dementia Care in Nursing Homes to promote comprehensive dementia care and therapeutic interventions for nursing home residents with dementia-related behaviors. The goals of this initiative include a focus on person-centered care and the reduction of unnecessary antipsychotic medication use in nursing homes and eventually other care settings as well. The CMS is using several approaches to successfully implement this initiative; CMS is developing and conducting trainings for nursing home providers, surveyors, and consumers. The CMS is conducting research, raising public awareness, using regulatory oversight, and public reporting to increase transparency (CMS, 2014).

According to the FDA, elderly patients with dementia-related psychosis treated with antipsychotic medications are at an increased risk of death. Furthermore, antipsychotic medications are not approved for the treatment of dementia-related psychosis. The CMS prohibits physically or chemically restraining residents for staff convenience, but the government alleged that major pharmaceutical companies and the largest long-term care pharmacy illegally marketed antipsychotics to treat symptoms of dementia. The FDA has required the manufacturers of conventional antipsychotic medications to add a warning label to the prescribing information about the risk of mortality in elderly patients treated for dementia-related psychosis (CMS, 2014).

A review of literature shows that reducing inappropriate use of antipsychotic medication in nursing home residents with dementia is an important concept that has been studied frequently, as evidenced by the research articles available on the topic. Amin (2014) specifically

synthesized evidence of the effectiveness of interventions to reduce inappropriate prescribing of antipsychotic medication to dementia residents in nursing homes. Interventions such as the use of nonpharmacologic means in dementia care and staff education can improve medication safety. In a cross-sectional dementia population study, the prevalence rate of antipsychotic use decreased from 38% in January, 2011 to 13% in June, 2013. According to Amin (2014), the retrospective review of antipsychotic use among 418 residents in June, 2013 revealed: 170/418 (40.6%) received antipsychotic anytime; discontinuation of medication was attempted for 161/170 (94.7%) residents; discontinuation for 138/161 (85.7%) was successful. There have been substantial reductions in antipsychotic medication use in nursing homes by addressing facility factors such as staff support, communication and perceptions, and practice regarding use of medications. These interventions/strategies may be effective in the short term, but longer-term, more robust studies are needed.

In a prospective, randomized, multicenter study done by Gollarte, Julvez, Lopez, Diaz, and Jentoft (2014) in nursing homes in Spain, the effect of an educational intervention directed to nursing home physicians in reducing inappropriate prescription and improving health outcomes and resource utilization was assessed. The study involved 60 nursing home physicians caring for approximately 3,900 nursing home residents in 37 centers. The physicians were randomized to receive an educational intervention or no educational intervention. The antipsychotic prescription rates fell as a result of this intervention (9.1% for the control group vs 3.2% for the intervention group). Other, less complex studies and smaller studies have shown similar results. An educational intervention reduced the risk of delirium and falls, and reduced the use of health care resources, including emergency room visits and days spent in hospital. For instance, in the study by Gollarte et al. (2014), the number of fall incidents increased in the control group (19.3% to

28%) while it decreased in the intervention group (from 25.3% to 23.9%). Patients with delirium increased in the control group (3.8% to 9.1%) while it decreased in the intervention group (from 6.1% to 3.2%). Significant reductions were observed in the intervention groups' number of visits to physicians (-0.76, P=0.01) and number of visits to a nurse (-1.43, $P < 0.001$). There were no significant changes in the emergency room visits and hospitals days spent for the intervention group, but these variables have increased for the control group by +0.12 and +0.38, respectively.

Ellis, Molinar, Dobbs, Smith, and Hyer (2015) used a qualitative design to explore how nursing homes responded to the 2012 Centers for Medicare and Medicaid initiative to reduce inappropriate antipsychotic medication use among residents. The aim was to examine strategies that have been implemented and determine what still needed to reach the prescribed goal. The sample included 276 nursing home professional staff members, nursing home administrators, and directors of nursing who are primarily involved in the execution of patient care, operating procedure, facilities policies, and management and education of all staff members. Results confirm the majority of nursing homes are actively working to reduce unnecessary antipsychotic medications, with over 75% of the respondents reporting the goal was 'very likely' or 'somewhat likely' to be achieved. The overall findings of the study suggest that majority of facilities are participating actively to the initiative. However, there are difficulties in some areas such as in education, finding mental health support, and reimbursements (Ellis et al., 2015).

Lucas et al. (2014) described a proposed measure of quality of antipsychotic medication use that is based on CMS Interpretive Guidelines, Food and Drug Administration (FDA) Indications for Antipsychotic Medications, and severity of behavioral symptoms. The proposed measure identifies nursing home residents who receive an antipsychotic medication, but do not

have an approved indication for antipsychotic medication use. The data from Medicaid-eligible, long-stay residents aged 65 years and older in seven states were used. In this study, multivariable logistic regressions were used to compare it to the current CMS Nursing Home Compare quality measure. They found that 52% of these residents are elderly people with dementia and receiving an antipsychotic medication lacking indications approved by CMS/FDA guidelines compared with 85% for the current CMS quality measure.

According to van der Putten, Wetzels, Bor, Zuidema, and Koopmans (2014), the majority of nursing home residents with dementia experience behavioral and psychological symptoms like apathy, agitation, and anxiety. In this study, the differences in antipsychotic medication prescription rates in residents with dementia living in dementia special care units (SCUs) in Dutch nursing homes were assessed. A multilevel regression model was used to assess the difference in antipsychotic medication prescription rates between SCUs adjusted for age, gender, global deterioration scale stage, type of dementia, and Cohen-Mansfield agitation inventory factor score. The results included 290 residents who met the inclusion criteria. Among this lot, 32% were prescribed antipsychotic medication. It was found that antipsychotic medications are prescribed not only in physically aggressive patients, but also for those who are non-aggressive. Patients with mixed dementia are more often prescribed antipsychotic medications than those with other types of dementia. The use of antipsychotic drugs differed significantly among the SCUs. It was noted that SCUs with a high prevalence of drug use have an increased likelihood of prescribing antipsychotics to patients (2.76 times as high, 95% confidence interval (CI) 1.14-6.69) as compared to the SCU with the lowest prevalence of drug use. This study showed that antipsychotic medications are not only prescribed for their clinical indications such as agitation and aggression but are associated with environmental factors such as the prescribing culture of a

specific SCU. It must be taken into account that antipsychotics should be used judiciously (Braun & Frolik, 2000). The use of antipsychotics for dementia is not approved by the FDA to treat dementia symptoms (Jones, 2006). Prescribing antipsychotic medications to nursing home residents for the convenience of the staff can be classified as a chemical restraint and is prohibited by federal law (Braun & Frolik, 2000).

A study conducted by Helvik, Benth, Wu, Engedal, and Selbaek (2017) in Norwegian nursing homes revealed that the prevalence and persistent use of antipsychotic drugs at two consecutive time points were high in residents with and without dementia. The study included 1163 nursing home residents in a 72-month longitudinal study with five assessments: use of psychotropic drugs, neuropsychiatric symptoms, severity of dementia, and physical health were assessed each time. Use of conventional antipsychotics did not differ between residents with or without dementia at any time point. In this study, psychotropic drugs were frequently used as a long-term treatment among nursing home residents and were associated with severity of neuropsychiatric symptoms, but not with severity of dementia. Hervik et al. (2017) identified the importance of closely monitoring the side effects of psychotropic drug treatment and stopping treatment when the risk is not balanced with the benefit from the treatment, i.e. patients receiving palliative or end-of-life care.

All of the research regarding the inappropriate use of antipsychotic medications by nursing facilities, when cited, is nearly always described as causing residents harm (CMS, 2014). However, CMS rarely imposes sanctions against facilities that violate standards of care. Improving enforcement of federal standards would reduce the inappropriate use of antipsychotic medications in nursing facilities. As more studies are needed to establish safer criteria for antipsychotic medication use in nursing home residents, non-pharmacological interventions

should still be considered the first-line treatment option for nursing home residents with dementia related behavioral disturbances (Chiu, Bero, Hessol, Lexchin, & Harrington, 2015).

Conceptual or Theoretical Framework

Since the aim of this project was to effect changes in the use of antipsychotic medications and increase the implementation of nonpharmacologic means to manage residents with dementia through an educational intervention, the project was based upon of the Diffusion of Innovations Theory by Rogers.

According to Rogers (2003), diffusion is "the process by which an innovation is communicated through certain channels over time among the members of a social system" (p. 5). There is profound evidence that this theory can produce successful results when adopted in studies wherein change or innovation is to be applied (Barker, 2004).

Dearing (2009) defined innovations as either new policies, practices, or programs that are being introduced into various forms and levels in organizations. The science of diffusion in application to healthcare, however, should not be confused with making something new, it is rather about effectively diffusing, adopting, or acculturating existing tried and tested innovations (evidence-based policies, programs, and practices) into current practices to effect significant changes (Dearing, 2009).

Roger's Theory of Innovation Diffusion is applicable to this project intervention because it supports the use of staff education as the innovation to effect clinical changes in the care of dementia patients. Dementia education to staff members may decrease the inappropriate use of antipsychotic drugs (Ervin, Cross, & Koschel, 2012; Alden, 2012).

The theory of diffusion posits that the spread of a new idea, concept, practice or innovation follows an S-shaped pattern (Dearing, 2009). The rate of adoption starts out as slow

with the early adopters embracing the change and then it gradually accelerates by 5-7% (through positive word of mouth and communication) and eventually produces a high increase in adopters.

The concept of diffusion can be operationalized in projects wherein the rate of adoption can be controlled – either by slowing it down or accelerating it through strategies that affect change in its components. There are five key components in this theory and in each component, the implementer can do certain actions that will increase the rate of adoption. These components include the innovation, the adopter, the social system, the individual adoption process, and the diffusion system.

The attributes of an innovation can greatly influence the decisions of individuals on whether or not to adopt the innovation. These attributes can be summarized in the following way. Relative advantage refers to the perception of how advantageous in terms of cost and effectiveness the change will be as compared to its alternatives and the current practice. Compatibility refers to how suitable or fit the change is to the individuals who will adopt the change and to the organization that will undergo the change. Complexity refers to the degree to which the innovation is perceived to be difficult to use or understand. Trialability pertains to the availability of opportunities to test the innovation before wide-scale adoption. Lastly, observability refers to the extent that the results are observable or visible to others.

The chosen innovation of the project is an in-house educational program to the staff members of the selected facility -- the physicians, nurse practitioners, nurses, nursing assistants, and pharmacists. The educational program was constructed in a way wherein its attributes encourage fast absorption; that is, the program was cost-effective, suitable to the target audience, simple to understand, relevant to the project setting, and produced quantifiable and visible

clinical outcomes when applied. According to Strom (2001), face-to-face education is an effective method for changing clinical practices.

Rogers (2003) identified different kinds of adopters based on their degree of innovativeness or readiness to accept change as compared to others. Adopters are identified as the innovators, the early adopters, early majority, late majority, and laggards. This project applied the said concepts in terms of choosing the participants of the in-house educational program. Attendance to the program was open to all nursing home staff including the physicians, nurse practitioners, nurses, nursing assistants, and pharmacists; but attendance was compulsory for permanent staff members only. Permanent employees are those working for the company under a permanent contract, thus they have an established employee-employer relationship with the company. Permanent staff members may be more committed with their time than casual ones, therefore it was easier for the nurse project coordinator to arrange for their schedules. A nurse project coordinator is a facility staff member chosen by the DNP student to be the primary point of contact with regard to all issues, research-related activities, and important correspondence from the DNP student to the staff members of Alpha Center for Rehabilitation and Nursing and vice-versa.

In addition, the facility is in a better position to demand that attendance to the educational program is compulsory if the relationship between the manager and employee is more fixed and official (position of power). In relation to the theory, the DNP student would like to know if non-permanent employees would emulate the permanent ones (early adopters) by also attending the educational program as a result of the diffusion process.

Consequently, innovators in the chosen facility were identified and together with the DNP student, they developed the educational program to meet the desired clinical outcomes of

the project. The innovators were composed of a specialist in aged care, a clinical pharmacist, and a nurse with a Master of Science in Nursing degree. Then, this group served as the persuaders of early adopters to join the training so that they, in return, may also influence the early majority to take part in the innovation project. Once this training program has been acculturated to even a few members of the staff, as according to the theory, the early majority and late majority may be swayed to adopt the said innovation.

The social system refers to the structure of the system. In molding the social system to increase the adoption rate, there are certain roles that may be given to suitable individuals. The use of local informal opinion leaders proves to be a significant tool in influencing the diffusion rate of an innovation. The opinion leader should be knowledgeable regarding the innovations of the program so that he/she can therefore provide useful information and advice to the organization's members. Local opinion leaders can create a form of social pressure to potential adopters, prompting them that they need to accept the innovation. The identification of a local informal opinion leader shall be part of the project's intervention. This opinion leader is one of the professionals who will help formulate educational program module.

The Individual Adoption-Process component describes the five key stages in the process of innovation diffusion: knowledge, persuasion, decision, implementation, and confirmation. In the knowledge stage, the individual wants to know more about the innovation and how it works. In the persuasion stage, individuals are concerned about the advantages versus disadvantages of using the innovation. In the decision stage, the individual chooses whether to adopt or implement the said change. Once the stakeholders have decided to accept the innovation, then the implementation stage begins.

To expedite the adoption process through this component, the project intervention shall employ approaches that are tailored to each potential adopter's stage in this individual-decision making process. Such approaches may be one of the following: advocacy by organizational champions, employment of change agents, and cooperation of informal opinion leaders.

To spread the use of an innovation, a diffusion system, one wherein knowledge originates from a central point and is spread into the periphery, must be established. In the said component, the use of an external change agency or agent/s who will be able to influence and intervene with the client opinion leaders and staff members shall play a pivotal role in the process of diffusion. The change agent in the said project is the DNP student.

Rogers (2003) also introduced the change agent as a facilitator of the flow of innovations from the change agency to the clients or potential adopters. Rogers (2003) introduced the sequence of change agent roles from which this study will pattern its actions. Figure 1 summarizes the said concept and its corresponding application to the project. This framework is influenced by a similar study by Watson-Wolfe et al. (2013).

In general, this project is guided by Roger's Diffusion of Innovations Theory using several of its concepts. First, it will use diffusion to replicate the effects of an already established innovation (staff education) to produce statistically significant clinical changes in patients with dementia. In addition, it will use several concepts in the theory to accelerate the process of adopting the said innovation into practice in the given setting. It is significant to note that the role of an opinion leader shall be of emphasis in the project as according to the theory, the opinion leader will establish and reinforce the continuity of the changes the project is trying to take into effect. This theory is applicable to the clinical question since it may guide the development and delivery of the innovation or intervention (educational program) and eventually provide support

of whether such innovation or intervention can indeed lead to decreasing the inappropriate use of antipsychotics in patients with dementia.

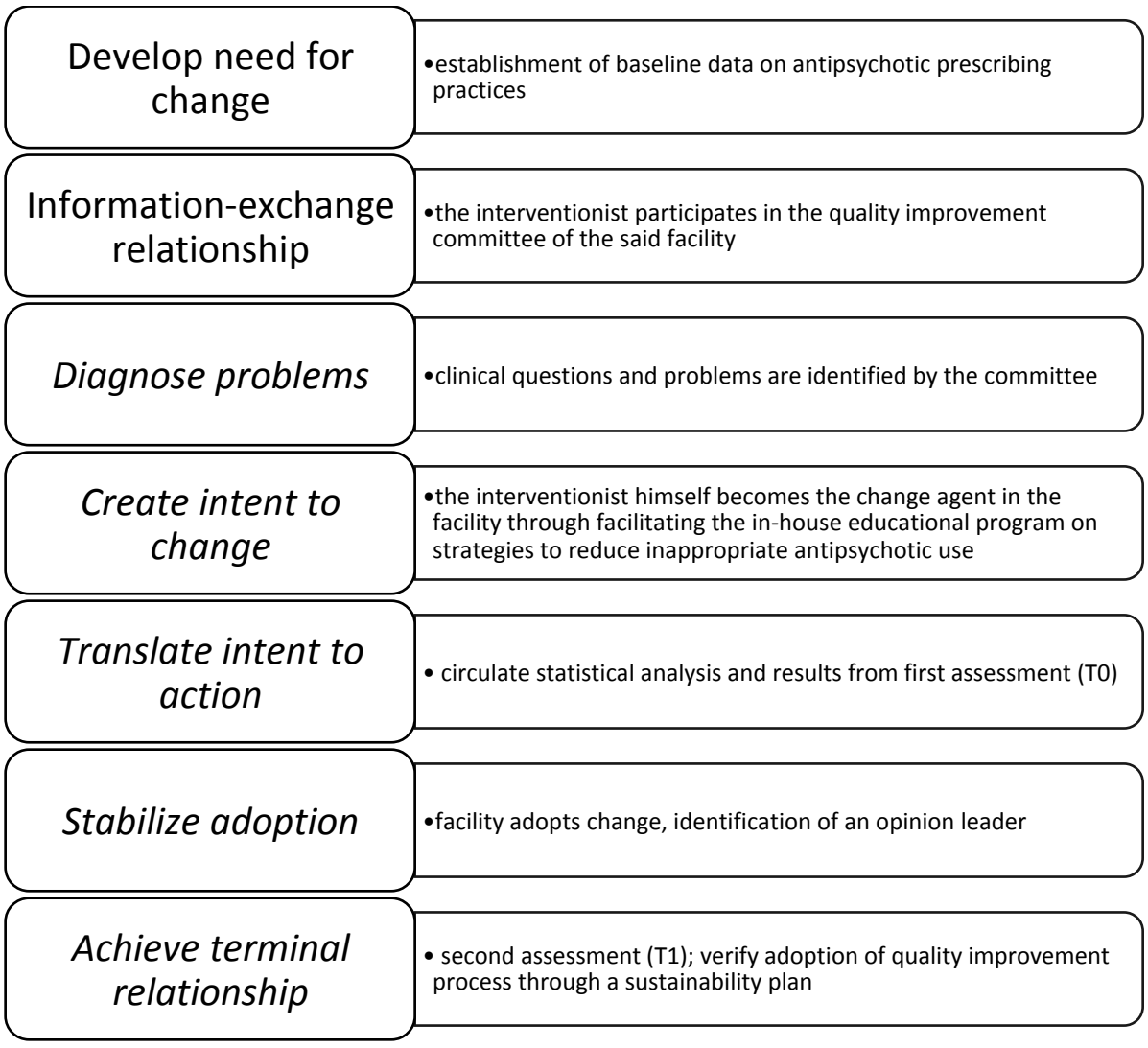

Figure 1. Application of the diffusion of innovations theory to the project.

Chapter II:

Methodology

Needs Assessment

Medications are said to be inappropriate if their disadvantages outweigh the perceived benefits. Drugs that quell the behavioral problems associated with dementia may also place the residents at risk for deteriorated health and death. This is a serious problem in the U.S. according to multiple researchers. The JAMA Psychiatry Researchers Report found out that there are more than 91,000 retired American soldiers suffering from dementia (Arbor, 2015). The risk of death was found to be higher in residents with dementia who used antipsychotic medications when compared to those who did not use the drugs (Arbor, 2015). This study gives sufficient evidence that the use of psychotropic drugs to treat residents with dementia has more negative effects than benefits and thus the need to educate residents, their families, and health care providers on the best ways to help residents with dementia is necessary.

The use of antipsychotic drugs to treat residents with dementia has been a problem in the United States (U.S.) for a long time. Consequently, the U.S. government has implemented several measures to ensure that the use of these drugs is reduced for residents in nursing homes. The first measure was a legislation to reduce off-label antipsychotic use in nursing homes (Desai, Heaton, & Kelton, 2012). Nonetheless, this solution has not been fruitful as the use of antipsychotic drugs is still considerable in these care environments. The FDA has also tried to control the issue of the misuse of antipsychotic drugs among nursing home residents with dementia. Markedly, the FDA required that a warning regarding the adverse effects of the use of label psychotropic drugs be included in all such products (Desai et al., 2012). The CMS, through the Antipsychotic Appropriateness in Dementia Patients educational program (IA-ADAPT) also

created awareness programs in nursing homes to educate healthcare professionals of the disadvantages of using off-label psychotropic drugs in residents with dementia (Carnahan et al., 2017).

Social support and education for staff remain the two viable means of reducing the use of antipsychotic drugs among residents with dementia in nursing homes. The improvement of staff education, as well as good communication between professional and personal caregivers, are effective means of reducing the abuse of antipsychotic drugs (Carnahan et al., 2017). Education passes the message that antipsychotics should not be the first treatment option for people with psychological symptoms of dementia. Education also ensures that physicians and nurses are made aware of the risks involved with the use of antipsychotic drugs among this population. Richter et al. (2015) mentioned that education and support for nursing home staff can reduce the number of prescriptions for antipsychotic drugs to residents with dementia.

A community assessment of the number of residents with dementia is supportive of the need for educational awareness to take place in nursing homes. According to a report provided by the U.S. Government Accountability Office in 2012, more than one-third of elderly residents receiving care in nursing homes for a duration of more than 100 days received an antipsychotic medication (U.S. Government Accountability Office, 2015). These statistics elevate the importance of conducting educational sessions for staff working in nursing homes to reduce the abuse of these drugs because dementia is mostly associated with older people.

Based from these assessments, the proposed project includes educational programs for nursing home staff members regarding additional information to reduce unnecessary antipsychotic use in residents with dementia.

A SWOT (strengths, weaknesses, opportunity, threats) analysis of Alpha Center for Rehabilitation and Nursing shows that its leaders are agreeable to quality improvement interventions within the facility. Support from the facility's leaders is a crucial factor to this project because its preliminaries heavily rely on formal approvals and endorsement of the project through proper channels. However, the bureaucratic structure of the organization may become a threat to the smooth implementation of the project intervention in a sense that to formally institutionalize some nonpharmacologic means of managing residents with dementia, a review and approval by the leaders must first be secured, and it can prove to be a long process in a hierarchical environment. Thus, although the facility's leaders have expressed their openness to change, the process of change itself can be difficult to manage especially since Alpha Center for Rehabilitation and Nursing is a large organization (Watters & McGrath, 2013). The weakness of Alpha Center for Rehabilitation and Nursing can be its lack of internal quality assurance activity in terms of following the standards in using antipsychotics in residents with dementia. It has been previously mentioned that Alpha Center for Rehabilitation and Nursing was almost cited twice by CMS as having practices that deviate from GDR policy and guidelines. These deficiencies were discovered only through an audit from an external agency (i.e. CMS). However, an internal audit specific for antipsychotic use in residents with dementia would have shown these lapses earlier and the necessary reparations could have been done before the external audit took place. The opportunities that Alpha Center for Rehabilitation and Nursing has is that it has a multidisciplinary staff composed of physicians, nurse practitioners, nurses, nursing assistants, and pharmacists who can contribute to the improvement of their policies regarding the use of antipsychotic drugs in residents with dementia through providing suggestions and participating in the project's educational program.

Pertaining to the project proposed by the DNP student, since there is evidence that staff-related educational offerings are helpful in reducing antipsychotic use on patients with dementia, the U.S. government provides support and informational resources regarding the conduct of educational programs in nursing homes. A possible weakness of this project would be poor attendance, however the program is compulsory for permanent staff members. These employees are those who are working under a permanent contract for the company. Since the educational program is compulsory, a stronger, more official employer-worker relationship should be present so that the unit manager is in a better position to mandate an employee should attend the educational offerings.

Nevertheless, this project still provides an opportunity for healthcare workers in the chosen facility to increase their knowledge regarding new modalities for the proper management of residents with dementia. Aside from bureaucracy issues mentioned earlier, perceived threats to this program are financial constraints and possible inadequate commitment from the staff members. Financial constraints include the costs associated with the training itself: payment to facilitators, travel costs, catering, venue, and materials.

Project Design

This project implemented a quality improvement intervention. Interventions seek to enhance the implementation of innovations in clinical practice or research findings or to effect change in professions or teams (van Bokhoven, Kok, & van der Weijden, 2003). Improvement in appropriately prescribing antipsychotic medications in a selected nursing home through an in-house educational program is the intervention of this project. The said educational intervention provided information regarding concepts about the management of residents with dementia, including the proper use of antipsychotic drugs and the use of nonpharmacologic interventions

like behavioral therapy and communication, to physicians, nurse practitioners, nurses, nursing assistants, and pharmacists.

Setting. The project was implemented in Alpha Center for Rehabilitation and Nursing in the East Coast. Operating under its parent company, XYZ, Alpha Center's services span from orthopedic rehabilitation, wound care, cardiac care, respiratory therapy, pain management, diabetes care, etc. The facility has seven floors with 380-bed capacity. This setting was chosen because the facility also offers a dementia program for elderly residents.

Recruitment, study population, sample size. The participants of this project included all residents in the dementia care unit who met the inclusion criteria. Fifteen (15) out of 20 residents were eligible and consented to join the study. Three of these residents who needed a legal representative to provide consent. The remaining five patients were excluded as they have not reached the minimum age of inclusion. There were no demographic data collected from the residents and therefore there is no information regarding their profile.

Permanent staff members working in the unit which included physicians, nurse practitioners, nurses, nursing assistants, and pharmacists were required to attend the educational program as discussed prior with the unit manager. Casual staff members were also invited to join the educational offerings, but their attendance was not made compulsory. The reasons as to why only permanent staff members were required to join were explained in the theoretical framework. The reasons were related to the time commitment of staff members, the position of power of the manager, and the application of the assumptions of Roger's (2003) Diffusion of Innovations Theory.

Inclusion criteria

Residents: 65 years old and above diagnosed with dementia. The age preference was to facilitate fast patient recruitment as according to data, the most common form of dementia is prevalent in patients aged 65 and above (Vardarajan et al. 2014).

Exclusion Criteria

Residents: Diagnosis of Schizophrenia, Tourette Syndrome, Huntington's Disease

There were 12 staff members who joined the in-house educational program. This project did not focus on the profile of the staff members and therefore there is limited information regarding their age, sex, and diversity. Permanent nurses and nursing assistants worked full-time in the facility (37.5 hours/week) while casual ones worked in unspecified hours. According to the facility manager, the nurse to resident ratio in this unit is 1 to 15 while the nursing assistant to patient ratio is 1 to 6. While the nurses are highly involved in the administration of resident medications, the nursing assistants are helping residents in their activities of daily living. According to the unit manager, if nursing assistants are preoccupied in providing for the needs of one resident, the behavioral problems of other residents may not be attended to as soon as possible. If residents with dementia have a challenging behavior episode, nursing assistants usually respond by escalating the problem to the nurse. Upon employment, nurses and nursing assistants receive training on dementia care and facility policy. The dementia care training for nursing assistants is focused more on the delivery of activities of daily living (ADL) such as skin care, oral care, and hygiene. There was no nurse practitioner who joined the program. Physicians and pharmacists are not always present in the dementia unit. The physician reports during scheduled resident rounds, is on call while the pharmacist visits the dementia unit to check the controlled drugs, and responds if called by the nurse in special circumstances.

Through verbal conversations, the DNP student learned that caregivers usually manage challenging behaviors by distracting the resident such as relocating him/her to another location or by offering tea or food. If the resident refuses, the caregivers leave the resident to be alone in a safe distance where the resident may still be observed. If the resident becomes anxious, aggressive or was disturbing other residents, the nurse calms down the resident through the use of prescribed antipsychotics.

Tools or Instruments

To measure the clinical outcomes of this study, the Appropriate Psychotropic Drugs Use in Dementia (APID) index was used to measure the primary outcome. The APID index is an instrument developed by van der Spek et al. (2015), which was derived from a pre-existing Medication Appropriateness Index (MAI). This new APID index is suitable for studies that assess the appropriateness of psychotropic drug use in patients with dementia exhibiting neuropsychiatric symptoms (NPS).

In developing the APID index, an expert panel reviewed items in MAI to form the items for the APID index (van der Spek et al., 2015). To verify the content validity of the items, another group of experts reviewed the selection. A study to assess the interrater reliability was also conducted (N=54). A summated index score was developed which was based on weighted item scores. The results showed that all items including the summated index score possess moderate to almost perfect interrater reliability. The intraclass correlation coefficient for agreement is 0.577 -1. There were no multicollinearity issues found with the summated index score.

The APID index includes five MAI items; there were adjustments made to the "indication" item. A new item, which is "evaluation," was added. The APID index comprises

seven domains of appropriateness, namely: dosage, drug-drug interactions, indication, evaluation, drug-disease interactions, therapy duration, and duplications.

The APID index is a valid and reliable tool for measuring the appropriateness of psychotropic drug use for patients suffering from dementia who are exhibiting neuropsychotic symptoms; it can be used in clinical studies (van der Spek et al, 2015). The advantage of this tool is that for patients who are using multiple psychotropic drugs, the scores for each drug can be added to formulate an overall score. Although there is no specific interpretation given for each particular score, a higher overall score denotes that the antipsychotic medication may not be appropriate for the resident. This tool is useful in longitudinal research studies (van der Spek et al., 2015). The APID index is found in Appendix B.

An APID index results form was created by the DNP student to record the APID scores of the residents. The clinical pharmacist reviewed the residents' charts and assigned scores to residents per domain using the guidelines in the APID index. The scores per domain were written by the clinical pharmacist on the APID index results form. This APID index results form was considered as a source document for this project and could be accessed by the clinical pharmacist, the nurse project coordinator, and the DNP student. This form is found in Appendix C.

A fall frequency documentation form was created by the DNP student to record the incidence of falls in residents enrolled in the study. A literature review by Rimland et al. (2016) cited that nonpharmacologic interventions can decrease the incidence of falls in older people; exercise was identified as the most effective intervention. Thus, falls incidence reduction can be an indicator that nonpharmacologic interventions are effective, are applied by the staff members, and are well-received by the residents.

The fall frequency documentation form is for recording purposes and was used in making a frequency table in the data analysis section. The fall documentation form is found in Appendix D.

Project Plan

Before implementing the project, an approval from the ethics committee identified as the Committee on the Use of Human Subjects in Research (CUHSR) of Bradley University was secured by the DNP student. Afterwards, a formal written permission was taken from the top-level management of Alpha Center for Rehabilitation and Nursing through the unit manager. The Institutional Review Board/Ethical Issue section further explains this process.

After the necessary permissions were granted, the DNP student started the recruitment of residents in the dementia care unit of Alpha Center for Rehabilitation and Nursing who met the inclusion criteria. A strict consenting process was followed in subject recruitment as the elderly are part of the vulnerable population. Prior to any project-related activity done to the resident, an informed consent form was completed by each resident, signed by the residents' legal representatives if the resident is not able to provide a consent (such as if the resident failed in the monthly mental health assessment). The informed consent process strictly followed the guidelines set in the International Conference on Harmonization's Good Clinical Practice Guidelines.

In terms of securing consent from the elderly, who are part of the vulnerable population, determining the resident's competence and capacity to consent was done by the primary care provider of the resident – the physician, who performs an assessment of the cognitive function of the residents on a regular basis. The facility is currently undergoing regular cognitive assessment of residents as part of their standard care measures. Tools like the Mini-Mental State Exam are

used to measure the cognitive function of these residents. Residents who were evaluated by the facility's physician as cognitively impaired during the last review were considered as not capable of providing consent. In such cases, the legal representative was contacted. The DNP student asked for details of the resident's legal representative from the facility. The DNP student then called the legal representative and requested a viable time to personally meet and discuss the project. The whole consenting process was performed by the DNP student with the legal representative as if it were the resident him/herself. The appropriate ethical requirements were secured for this recruitment process to commence. The informed consent form is in Appendix H.

After the recruitment process, the project was implemented in three stages. The first phase involved the completion of a baseline assessment of the residents (T0). Two assessments were made at this time. The first assessment was the appropriate use of antipsychotic medications for each patient using the APID index; this assessment was completed by a clinical pharmacist not taking part in the project intervention. This clinical pharmacist was different from the pharmacist who assisted in designing the educational program. The following antipsychotic medications were prescribed to the patients and whose appropriateness were scored using the APID index: Aripiprazole (Abilify), Chlorpromazine (Thorazine), Clozapine (Clozaril), Haloperidol (Haldol), Olanzapine (Zyprexa), Quetiapine (Seroquel), and Risperidone (Risperdal). Patients who were taking more than one antipsychotic were scored by getting the summated APID index score for each drug and computing for the mean (APID index mean score).

The second assessment involved counting the frequency of falls for all residents in the dementia unit who are part of the study. The nurse project coordinator reviewed the fall incident

reports and documented the frequency into the fall frequency documentation form for this project (Appendix D).

The second phase of the project was the implementation of the in-house educational program to physicians, nurse practitioners, nurses, nursing assistants, and pharmacists working in the dementia unit of Alpha Center for Rehabilitation and Nursing. The second phase spanned for two months. The first month was allotted for the implementation of educational program and the remaining month was used to give the staff members time to apply the concepts they had learned from the educational program.

In the project proposal, the educational program was to be developed by the DNP student along with qualified professionals working in the said facility who fulfilled the following qualifications: a specialist in aged care, a clinical pharmacist, and nurse with a Master of Science in Nursing degree. However, due to lack of time to look for an available nurse with a Master of Science in Nursing degree who should have been the fourth person to help in developing the module for the educational program, the DNP student decided that the module would be completed by the three available professionals – one aged care specialist, one pharmacist, and the DNP student. Since the DNP student also holds a Master of Science in Nursing degree, the need for another nurse with the same qualification was satisfied. Out of these professionals, one was identified as the program's local opinion leader. The educational program module was developed and completed two weeks after the approval of the project.

The DNP student and the nurse project coordinator worked together to facilitate the educational program. An aged care specialist conducted the educational sessions. The training was done in a traditional instructor-led method; Strom (2001) identified that face-to-face education is an effective quality improvement intervention. However, there were four staff

members who opted to receive the training digitally as they were unable to physically attend the offerings.

The educational program design consisted of three sessions. The first session was attended by physicians, nurse practitioners, nurses, nursing assistants, and pharmacists. The second session was specific to physicians, nurse practitioners, and pharmacists. However, since there was only one physician and one pharmacist who joined the in-house educational program, one session was delivered via one-on-one discussion instead of a group activity. The third session was attended by nurses and nursing assistants.

Suggested topics in the first session included the following: various ways to prevent inappropriate use of antipsychotic drugs for residents with dementia; CMS initiatives to decrease the use of antipsychotics; documentation requirements; using communication; current state of antipsychotic use in nursing homes in the U.S., in the state of New York, and in the facility; and factors associated with the use of antipsychotics to patients with dementia such as behavior-related ones.

The second session, attended by a physician and pharmacist, included the following topics: a review of CMS guidelines on gradual dose reduction; documentation requirements; efficacy of antipsychotic use in patients with dementia; risks associated with antipsychotic use; target symptoms and behaviors; and rationale for antipsychotic initiation. The third session, attended by nurses and nursing assistants, included topics such as causes of behavioral symptoms, associated nonpharmacological interventions for patients with dementia, and how to implement these interventions into practice.

Nonpharmacological interventions to address behavioral symptoms in patients with dementia, specifically with the use of Cognitive Intervention (CI) were included in the

educational program; there is evidence that these interventions provide small, but consistent positive effects in managing dementia (Alves et al., 2013). In addition, the use of communication with dementia patients to identify their unmet needs, was also introduced. A study by Tjia et al. (2017) revealed that dementia patients have trouble with communication, thereby prompting healthcare providers to be more adept at identifying these needs even with limited verbal signals. Teri, Logsdon, Uomoto, and McCurry (1997) found that behavioral therapy can significantly reduce depressive symptoms in patients with dementia. Engaging patients in certain activities, such as social support and contact, also prove to be beneficial. A study by Rovner, Steele, Shmuely, and Folstein (1996) found a 71% decrease in agitation when residents where engaged in mentally and physically stimulating activities. Rachal and Kunik (2006) stated that age-appropriate exercise, as well as socially engaging activities, may help decrease agitation.

The final objectives and content for the educational program were determined by the developers, which were previously defined as a team composed of one specialist in aged care, a clinical pharmacist, and a nurse with a Master of Science in Nursing degree. The concepts in the educational program also included input from the staff members as they can provide practical information regarding the actual challenges that they face in the said unit. The educational program fostered interdisciplinary collaboration. Interdisciplinary approaches to care plans were also incorporated into the topics discussed. The DNP student provided additional input regarding the topics to cover in the educational program. The additional topics included how to handle challenging behaviors and how to communicate to families of dementia residents.

The educational program was conducted in a span of two months. It was offered in two separate occasions. The first offering was initiated a week after T0; this was to allow enough preparation time for the coordinators. There was a gap of two weeks between the first and second

offering as the staff roster changes every two weeks. Although all staff members, comprised of physicians, nurse practitioners, nurses, nursing assistants, and pharmacists, were invited to attend the education program, attendance was compulsory for the permanent staff members only for reasons stated earlier. The physicians and nurse practitioners who were involved in the direct care of residents in the dementia unit were invited. Then, all nurses and nursing assistants were asked to join. To communicate this educational program to staff, the unit manager sent an email regarding the project to all staff members. This email was drafted by the unit manager and informed all staff in the dementia unit that the educational program was made compulsory to permanent staff members. In addition, the manager informed the staff that their emails will be shared to the DNP student for future correspondence. Staff members who wished not to have their emails shared could opt out of the list and they shall then be informed regarding the project via posters, through the monthly meeting, and during the DNP student's visit. There were no staff members who opted out of the email list, but the DNP student still posted posters of the project. The said educational program was also presented by the unit manager to the staff during their monthly meeting.

After all necessary components of the program were completed (e.g. training module, formal communication to top-level management, logistics, recruitment, materials, etc.), a formal written invitation was sent to the potential participants via electronic mail by the DNP student (see Appendix G). Additionally, a face-to-face recruitment was done by the DNP student to further reinforce the project details and to answer queries. The DNP student visited the facility on two occasions, the first visit was on October 22, 2018 and the second visit was on November 5, 2018. The visit dates were based on the availability of the DNP student. Preferably, the first visit shall be on T0 and the second visit is after two weeks as the staff roster changes fortnightly.

Two posters (Appendix M) were placed in staff bulletin boards to disseminate information using print media channel. The in-house educational program was offered in two occasions to cover staff members who were unable to attend the first schedule and also to give time for the late majority to make decisions and emulate the action of the early ones. There were eight participants during the first offering, four during the second offering. The time of the sessions was during work hours. Hence, the nurse project coordinator made a participant list which contained the names of staff members and the corresponding date that they were scheduled to attend an educational session. The DNP student arranged with the unit manager, that if possible, staff members who were scheduled on a particular training date shall be off duty.

Primary outcome. At the end of the third phase of the project, at least 15% of the residents involved in the study shall have an improved APID index score.

Secondary outcome. At the end of the third phase of the project, the incidence of falls shall decrease by at least 50%.

The third phase of the project (T1) was the re-assessment of the outcome measures in phase one (T0) namely: appropriate use of antipsychotic medications and incidence of falls. This phase was initiated two months after phase one (T0). These measures were completed by the same individuals identified in phase one (T0). The same assessment procedures in T0 were followed by the clinical pharmacist and nurse project coordinator in T1, accordingly. An evaluation of the data collected in T0 and T1 for accuracy was conducted and are explained in the subsequent sections. The following summarizes the phases of the project:

T0: assessment of appropriate use of antipsychotic medications and incidence of falls

Intervention Phase: In-house educational program provided

T1: re-assessment of appropriate use of antipsychotic medications and incidence of falls

Data collection. Primary data collection was done at baseline (T0) and then after the educational program intervention was completed (T1), approximately two months after T0. The clinical pharmacist who collected the data using the APID index was trained in data extraction. This clinical pharmacist is an employee in the facility and has access to the residents' charts. The clinical pharmacist completed the APID index form for each resident in the project at T0. To ensure the accuracy and confidence of the scores calculated by the clinical pharmacist, the clinical pharmacist reviewed the scores in the APID index form for each resident after one week. The APID index form only bears the subject ID of the resident (Appendix C). Following the review of the APID scores of the residents, the pharmacist verbalized that there were residents taking more than one antipsychotic drug. The pharmacist asked if a mean APID index score for each resident be taken. The DNP student consulted the statistician, who also researched other studies and emailed the author of the instrument, Dr. van der Spek. Dr. van der Spek confirmed through an email correspondence that the APID score may be calculated on a patient level (Appendix N).

Falls incidence was reviewed before the intervention (T0) and after the intervention (T1) for all residents in the dementia unit to determine if there was a reduction in frequency. During the data collection process, the nurse project coordinator reviewed fall incident reports in the dementia unit, taking note of the frequency. Then, the nurse project coordinator completed the fall frequency documentation form of this project (Appendix D). Thus, the DNP student did not directly look at the fall incident reports but instead gathered data based from the fall frequency documentation form completed by the nurse project coordinator. To ensure accuracy, the clinical pharmacist reviewed the fall frequency documentation form completed by the nurse project coordinator against data from the fall incident reports of the facility to make sure that the written

figures were correct. This review by the clinical pharmacist was done a week after the fall frequency documentation form had completed by the nurse project coordinator. There were no identifiers in the fall frequency documentation form to protect the confidentiality of the residents and the names of the staff members who were involved in each fall incident report.

The results of the assessment in both T0 and T1 were shared with the DNP student and encoded to the statistical tool. To test for accuracy of transcribing the data from the source document (APID index form and fall documentation form) to the statistical tool, a double encoding method was used. In this method, the data from the source documents were transcribed to the statistical tool twice and then the results were analyzed. If there was a difference between the results, it meant that an error in transcription has occurred. The error should be identified and be corrected promptly by the DNP student. The were no errors in the data encoding. The tools used in the data collection were discussed in the earlier section.

In the interest of confidentiality, the residents were assigned a subject ID using an assigned number i.e. 001, 002. The subject ID assignment was made in chronological sequence; which means, subject 001 should have enrolled in the project earlier than subject 002. As mentioned, information gathered from the participants was recorded in a paper source document which included the resident's Subject ID, the results of the APID index and the researcher-made fall frequency documentation form. No demographic data was collected from the residents. Each participant had an individual folder where the informed consent and the APID index results form were stored. The fall frequency documentation form was kept in a separate folder. All folders were locked in a cabinet inside the facility with the key only accessible to the DNP student, his mentor, the clinical pharmacist, and the nurse project coordinator.

Evaluation and sustainability plan. The results of the data collected were analyzed and presented to the facility's administrators. To address the sustainability of the project, a planned initiative includes meeting with some stakeholders including the facility's top management on a proposed integration of the intervention to the quality management system of the organization so that it will be eventually adopted as part of the quality improvement (QI) process.

An evaluation of the data collected in terms of accuracy was conducted. As explained earlier, the APID index results were reviewed twice by the clinical pharmacist to ensure accuracy and confidence in the given scores both for T0 and T1. This review happened a week after the first assessment had been done. Changes in the scoring were documented and defended by the clinical pharmacist on the remarks section of the APID index results form. The final data that was used for analysis were the scores given by the clinical pharmacist after the review. For the falls documentation, the data transcribed by the nurse project coordinator were reviewed by the clinical pharmacist for accuracy both for T0 and T1. After the nurse project coordinator reviewed the falls incidence report of the facility at T0 and T1, the clinical pharmacist counter checked the data transcribed into the fall frequency documentation form. This method ensured that data from the falls incident report forms of the facility where accurately transcribed to the fall documentation form of the project. Data from the reviewed fall frequency documentation form was the final data used in the data analysis.

To ensure accuracy in transferring data from the APID index results form and the fall documentation form to the statistical tool, the DNP student encoded the data twice. The statistician then checked if there were discrepancies between the two sets of data encoded. The reviewed and corrected data set was used for statistical analysis.

An evaluation of the overall project itself was also done. The project was evaluated using a results-based model. This model assesses the outcomes of the project in terms of whether the goals were achieved and if there are foreseen and unforeseen effects of the project to all stakeholders involved (Calidoni-Lundberg, 2006) For this project, the methodology used in performing the results-based evaluation was a goal-bound evaluation. In a goal-bound evaluation, the effectiveness of a project is measured based on whether the earlier stated goals and objectives were met (Calidoni-Lundberg, 2006). This evaluation was done by the DNP student and his mentor.

Timeline. The planned implementation of the project was a span of five months. However, due to some delay with securing an approval from the ethics committee and some delay in analyzing the results, it extended up to seven months in total including the final presentation. The detailed description of the research activities is outlined in Appendix E.

Data Analysis

Data preparation was done by the principal investigator. The collected scores from the results of the APID index and number of falls were entered into the statistical tool's database. The database was stored in a personal computer with a passcode.

The statistician used descriptive analysis as the statistical treatment for the data gathered including the use of mean and number of valid cases. A frequency distribution table was made for the falls incidence.

In the primary outcome, the change in APID index at T1 was tested using a t-test for dependent samples. In the secondary outcome, a tabulation was done to document the number of falls. Data was checked for any inaccuracies or lack thereof. All statistical analyses were done

using the Statistical Package for Social Sciences (SPSS) version 25. A statistician was hired to assist the DNP student in the statistical treatment and analysis of data.

Treatment fidelity. Treatment fidelity was evaluated with regard to training, delivery, and receipt of the educational part of the intervention. A training module for the educational program was developed and written to ensure that the coverage of the topics and the delivery were the same for each offering. In addition, there was one trainer or facilitator who conducted the educational sessions to ensure consistency, identified earlier as the aged care specialist. The aged care specialist is one of the professionals who formulated the educational program together with the DNP student, the clinical pharmacist, and the nurse with a Master of Science in Nursing Degree (which was also the DNP student).

Institutional Review Board/Ethical Issues

Since the study involved geriatric residents with dementia who are part of a vulnerable population, approval of the project protocol was sought from an ethics review committee. The chosen ethics review committee for this project was Bradley University's Institutional Review Board known as the Committee on the Use of Human Subjects in Research (CUHSR). The DNP student submitted an application to CUHSR together with the informed consent for the project. In the initial review, it was found that the project would need to secure a partial waiver of HIPAA authorization for some protected health information such as the resident's name (not disclosed to the DNP student but was shown to the staff); age (staff indicated to the DNP student whether the subject was 65 years old and above or not); existing diagnosis (necessary for the exclusion criteria), and name and contact details of the patient's legal representative (used in case the patient was not assessed to be cognitively able to give a consent at the time of subject recruitment). Each resident's source document was assigned a subject ID, which is a number in

sequential order. Aside from clinical staff members who were directly involved in the care of the residents, only the clinical pharmacist and the nurse project coordinator were allowed to access the charts of the residents for data collection related to this project. The clinical pharmacist reviewed the electronic charts of the residents as it is necessary to complete the APID index. The nurse project coordinator reviewed the falls incident report of the facility and transferred data to the fall frequency documentation form made by the DNP student. The APID index results form and the fall frequency documentation form were made available to the DNP student and his mentor. The APID index results form only contained the subject ID of the resident. The de-identification of the charts was not necessary as the DNP student did not access the charts but used the forms stated above to collate the data for analysis. No demographic data was documented in either the APID index results form or the fall documentation form. The APID index results form and the fall documentation form were the source documents for this project. All source documents were treated as confidential. Each resident had an individual folder wherein the source documents were filed. These folders were kept in a locked, safe place by the DNP student. All residents' charts were to be kept as per the facility's regulation.

All forms related to ethical considerations can be found in the Appendices section: Informed Consent Form (Appendix H), Application for Partial Waiver of Authorization (Appendix I), Approval of the Partial Waiver for HIPAA Authorization (Appendix J) and the Ethics Committee Approval (Appendix K). A copy of the letter of request to conduct a research is found in Appendix L, this was originally signed by the facility head of Alpha Center for Rehabilitation and Nursing to show approval of the research project.

Chapter III:

Organizational Assessment and Cost Effectiveness Analysis

Organizational Assessment

An educational program to teach physicians, nurse practitioners, nurses, nursing assistants, and pharmacists about the dangerous effects of using antipsychotic drugs in residents with dementia is a viable intervention method that can be utilized to minimize the off-label use of these drugs in nursing homes. With Alpha Center for Rehabilitation and Nursing being the focus of this project, it is imperative to assess the readiness for change in the organization. If the organization agrees to hold an in-house educational program for its staff, it shows the willingness of the organization to change from a hierarchical level i.e. from the management to the employees.

However, there might be several barriers and facilitators of implementation associated with the in-house educational program. The first barrier is associated with financial restraints. The lack of sufficient funds to support the entire program is the first major challenge associated with this initiative. The second barrier involves resistance from care givers. Markedly, some of the staff may not be cooperative enough during the training or may not implement what they have learned in practice; this may result in unbalanced training among all the caregivers in the health institution in the sense that one group of health professionals may become more adept at managing patients with dementia than the others (Boise, 2006). Issues with inconsistent implementation may also arise from this. For the program to be effective, all participants should make it a lifelong commitment to reduce the misuse of antipsychotic drugs. On the other hand, a significant facilitator of change is theoretical training. When staff members are engaged in

theoretical lessons regarding the abuse of antipsychotic drugs, they are likely to implement the information they have learned in a practical setting.

There are several risks associated with the educational program proposed for this project. The first major problem is the presence of gaps in the content of the educational program. It is essential to ensure that this educational program is comprehensive to ensure that caregivers have all the relevant information needed. The project employed three qualified professionals to make sure that the educational program was comprehensive. The lack of a regular refresher educational program is another problem that can be expected (Hirst, 2017). If the center fails to conduct regular refresher courses, physicians, nurse practitioners, nurses, nursing assistants, and pharmacists might not be aware of the up-to-date trends in the management of residents with dementia. There should also be reinforcement from the management that the interventions taught in the educational program are expected to be implemented.

Interprofessional collaboration has significant benefits not only in the treatment of dementia but also in the entire health industry. First, through this collaboration in formulating care plans, caregivers learn to respect one another and, therefore, improve resident care from a team-based perspective. Interprofessional collaboration happens when healthcare workers from different professional backgrounds work together to achieve a common objective. Resident outcomes, the care and cost of care delivery, and the quality of care are optimized through this form of unity. In addition, the rate of noncompliance is significantly reduced when interprofessional collaboration is utilized. Therefore, the role of interprofessional collaboration is appreciated due to the increased quality and magnanimity of the outcomes achieved as compared to that of just having a single profession tackle the work at hand (Green & Johnson, 2015).

Interprofessional collaboration in providing care was one of the topics covered in the educational program. For instance, the various healthcare professionals were asked to make a care plan for a specific resident wherein each professional was able to make his/her own assessment and contribution to the plan. As a result, the formulated care plan was highly comprehensive and was tailor-made to the specific needs of the resident. The staff were encouraged to apply the care plan to the resident in the real clinical setting.

Another prime example of interprofessional collaboration is collaborative effort. Each healthcare professional has a role to play in minimizing antipsychotic use in the clinical setting. Physicians and nurse practitioners should make themselves aware of existing laws governing the use of antipsychotics in residents in nursing homes. They should also be highly cognizant of the adverse effects that antipsychotics may cause to residents with dementia. Thus, physicians and nurse practitioners have a crucial role in the control of antipsychotic use as they have the discretion to withhold such medication if it is not necessary and beneficial to the resident. Similarly, pharmacists have an equal responsibility of making sure that each antipsychotic prescription is appropriate, and they may even serve as consultants to physicians and nurse practitioners to prompt dose reduction if needed. Finally, the nurses and nursing assistants can contribute to the reduction of the use of antipsychotics through arming themselves with extensive knowledge and skills in managing challenging behaviors of dementia residents and not resort to antipsychotics at the slightest difficulty encountered.

Cost Factors

The proposed budget for this study is available in Appendix F. To minimize the costs associated with the project intervention, which is an in-house educational program, the investigator approached the leadership of the facility and proposed the project as part of their

quality enhancement process. Support from the management encouraged the staff members to join the educational program. Endorsement from the top-level management also facilitated the emergence of potential volunteers who were willing to develop the educational program. Resources which are available to the investigator beforehand were used such as computer hardware and software requirements.

In terms of reducing the cost of the educational program itself, the investigator asked if the organization can provide the venue under the premise that their organization is going to benefit from this project, specifically their staff members and eventually, their residents. During the intervention phase, the facility was able to provide a venue for the training. A large portion of the appropriation is for personnel-related costs, the investigator perceived that a long-term solution to this financial issue is for the management to adopt the said intervention in their quality system and include it in the yearly budget of the facility.

Chapter IV:

Results

This chapter presents the data gathered and synthesized to answer the research objectives.

Analysis of Implementation Process

Prior to implementation of the project, the DNP student secured formal approval to implement the DNP project. There was a month delay in the initial project timeline due to adjustments made in the project proposal; changes were needed to obtain approval from the ethics committee, which is CUHSR. After approval, the DNP student, aged care specialist, and a pharmacist formulated the training module for the in-house educational program covering the topics stated in the proposal as well as additional inputs from staff members such as: how to handle challenging behaviors and communicating with the family of dementia residents. The staff members verbally expressed their satisfaction with the training module.

While the training module was being developed, the DNP student enrolled participants into the project. Initially, it was believed that the total number of residents in the dementia unit was 33-35 (O. Punongbayan, personal communication, July 8, 2018). However, upon visiting the facility, this number was corrected by O. Punongbayan; it was confirmed that there were 20 residents in the unit. The said number included interim care patients; these residents were in the facility for only a period of time and therefore were not to be considered as permanent residents. Thus, there was a total of 20 residents in the dementia care unit and 15 residents met the inclusion criteria. The remaining five did not make it to the minimum age required to join the DNP project.

There were 15 residents who consented to participate in the project as they were deemed fit and whose participation were solicited as per the method stated in Chapter 3, Methodology

section. Three out of the 15 residents had their consents given by a legal representative. The pre-assessment phase was conducted by the pharmacist and the nurse project coordinator. During this phase, the pharmacist raised a concern about how to use the instrument if there are residents who are prescribed more than two antipsychotics. The DNP student consulted with the statistician about this question, to which, as according to previous studies, the APID index mean score may be taken at the patient level. This information was also confirmed by Dr. van der Spek in an email correspondence (Appendix L). Thus, the pharmacist collected the mean APID index score for residents who were taking more than two antipsychotics.

It was discovered by the DNP student that the facility has a well-planned and implemented fall prevention system in the unit. Thus, the fall incidence level is too low to be considered statistically significant. However, the DNP student, after consulting with the statistician, still proceeded with presenting the fall incidence rate. The nurse project coordinator collected the falls incidence data.

In total, there were 12 staff members who participated in the in-house educational program. The first offering was done on November 5, 2018 (eight participants) and the second offering was done on November 26, 2018 (four participants). The breakdown of the participants are as follows: one physician, one pharmacist, three nurses, and six nursing assistants. There were four staff members, one nurse and three nursing assistants, who wished to join the training but were not physically able to do so. They have asked for a digital copy of the training material to which the DNP student agreed to provide. An online training module was raised as a possible alternative to the face-to-face training as it is more cost-effective and staff members may review the materials in their own availability. However, this may not be as effective as a face-to-face training as staff participation is an essential component to increasing learning (Blume, Ford,

Baldwin, & Huang, 2009). In addition, an online training would not give the participants the opportunity to develop an individualized care plan, which is one of the activities in the face-to-fact instruction. There were also two non-permanent staff members who joined the in-house educational program during the second offering, which exemplified the Diffusion Theory of Roger (2003). After the training, the staff members were encouraged to apply what they had learned in the day-to-day care of residents in the dementia unit.

It was, however, not part of the project to survey the nonpharmacologic methods of managing dementia the staff members applied in the care of the residents; thus, it is difficult to identify which nonpharmacologic method may be attributed to the results of the project.

After the in-house educational program had been completed, which was two months after the initial assessment, the residents were re-assessed using the APID index and fall documentation forms. The collected data were gathered and stored as per the data handling and confidentiality protocols stated in the project proposal. There was no breach in data privacy and confidentiality while implementing the project and data was stored securely. The in-house educational program attendees were advised to use initials of residents when referring to them during question and answer portions or group discussions.

Part of evaluating the accuracy of the data collected was to review it. The pharmacist who reviewed the APID index scores admitted to making changes to the scoring in the first review but re-iterated that it was only for the first three residents. As the APID index scoring for each resident progressed, the pharmacist became more familiar with the tool and became more confident with the scores that were given to each parameter in the APID index. There were no errors found in the transcription of the APID index scores to the APID Index Results Form (Appendix C) and as well as the Fall Documentation Form (Appendix D). There were no errors

in the encoding of data to the statistical tool using the double encoding method. The DNP student posits that the error-less encoding was due to the small number of subject population and thus the data encoding was done accurately and not with haste.

Analysis of Project Outcome Data

This DNP project identified two outcomes. The primary outcome was to improve the APID index scores of at least 15% of residents involved in the study and the secondary outcome was to reduce the incidence of falls by 50%. Tables 1 and 1a show the data analysis results for the primary outcome while Table 2 shows the results for the secondary outcome. Significant statements are provided to further illustrate the substance of the statistical data, to justify the use of such statistical test, and to provide weight for evaluation.

Table 1 shows the comparison result of the APID index mean scores of residents during baseline assessment (T0) and post-intervention re-assessment (T1).

Table 1

Comparison result of the APID index mean scores of patients during baseline (T0) and after intervention (T1)

Respondent N=15	(T0) Baseline assessment	(T1) Post-intervention assessment	Difference	% Improvement
	TOTAL APID INDEX	TOTAL APID INDEX		
1	3.25	0.75	-2.50	76.92
2	4.06	0.94	-3.13	76.92
3	3.77	1.48	-2.28	60.58
4	3.69	0.87	-2.82	76.40
5	3.42	0.97	-2.46	71.73
6	4.00	1.00	-3.00	75.00
7	7.00	3.00	-4.00	57.14
8	2.00	1.00	-1.00	50.00

9	2.00	0.00	-2.00	100.00
10	5.00	2.00	-3.00	60.00
11	5.00	2.00	-3.00	60.00
12	3.00	0.00	-3.00	100.00
13	6.00	4.00	-2.00	33.33
14	2.00	1.00	-1.00	50.00
15	6.00	3.00	-3.00	50.00
Mean	**4.01**	**1.47**	**-2.55**	**66.54**

Legend:

0.00 - 4.66 = Highly Observed
4.67 - 9.33 = Moderately Observed
9.34 - 14.00 = Almost Not Observed

During baseline assessment (T0), respondent numbers 7, 10, 11, 13 and 15 received the highest APID index ratings of at least 5.00, which fall under moderately observed level, whereas all the rest got APID indexes that fall on a highly observed level. Findings can be inferred that prior to the intervention, 5 out of 15 respondents or 33.33% have relatively high APID index scores. Such high scores can be attributed to the inappropriateness of antipsychotic drugs used for these dementia patients.

After the intervention, a re-assessment (T1) was done. The result of the re-assessment shows remarkable improvement on the APID index mean scores of all the respondents (N=15, 100%), gaining a total APID index below 4.00, all categorized as highly observed. Furthermore, the highest improvement (100%) can be observed from respondents 9 and 12, gaining a perfect APID index score of 0.00. All the rest of the respondents show an improvement in APID index scores of greater than or equal to 50%.

Table 1a shows the t-test for the significant difference in the total APID index results between assessment (T0) and re-assessment (T1). The Dependent t-test or Paired Sample t-test was used because the data treatment was to compare two means which came from the same

individual subjects, of which, the two means represent two different times, the Baseline Assessment (T0) and the Post-intervention Assessment (T1). Furthermore, t-test is the most appropriate data analysis or data treatment tool for this type of data because of its type (interval data) and because the data is normally distributed (Kim, 2015).

Table 1a

T-test for the significant difference in the total APID index results between assessment (T0) and re-assessment(T1)

	Variable	Mean	Standard Deviation	Mean Difference	T-Value	P-Value
T0	Assessment of appropriate use of antipsychotic medication	4.01	1.13	-2.54	-12.293**	0.000
T1	Re-assessment of appropriate use of antipsychotic medication	1.47	1.54			

Legend: **highly significant (P≤0.01)

The computed T-value -12.293 with the corresponding P-value of 0.00 shows a highly significant result (P-value <0.01). Significant improvement after the intervention was observed in the re-assessment with a mean APID index of 1.47, from 4.01 during the prior assessment. Findings further imply that a decline of 2.54 points (66.54%) on the APID index scores of respondents was observed during the re-assessment. The highly significant improvement in the total APID index score during re-assessment can be attributed to the effect of the intervention.

Table 2 shows the fall incidence rates in the facility at two different timeframes. There is a marked decrease in the frequency of falls from 11 in T0 to just four in T1. The percent decrease has been computed as 63.6%. However, although the rate of patient falls has decreased, its direct correlation to the intervention could not be solely attributed. There were other measures that the facility has adopted in managing falls such as increased frequency of patient rounds while the

project was implemented. The frequency table also does not reveal whether the change was per individual. The rate is the summated frequency per month. Thus, one patient may have had several falls. In addition, the data collector who is the nurse project coordinator stated that there were some patients who did not have a fall in T0 but had one in T1. To specify, the data was collected at the end of each month for the baseline assessment and the re-assessment. Baseline assessment (T0) was done in October 2018 and the re-assessment was done in December 2018.

Table 2

Fall frequency rates, Dementia Care Unit of Alpha Center for Rehabilitation and Nursing at two separate timeframes

Timeframe	Frequency	Difference	Percentage Decrease
T0 (October 2018)	11	7	63.6
T1 (December 2018)	4		

Chapter V:

Discussion

Findings

This evidence-based, quality improvement project aimed to reduce the inappropriate use of antipsychotics in nursing home residents with dementia. Through implementation of an in-house educational program to staff members (physicians, nurse practitioners, nurses, nursing assistants, and pharmacists), staff members were encouraged to employ nonpharmacologic measures to manage dementia and broaden their knowledge regarding the use of antipsychotics for residents in nursing homes. This project evaluated the reduction of antipsychotic medication use and reduction of falls following the educational program.

The findings show that the primary outcome measure of the project was achieved. Of the 15 residents who participated in the project and have been the direct recipient of the new knowledge and skills gained by caregivers from the in-house educational program, 15 or 100% have an improved APID index mean score in T1.

The secondary outcome measure was also achieved. Data showed that fall incidence rates were reduced by 63.6%. However, it was later realized by the DNP student and the statistician that this result may not conclude that nonpharmacologic interventions solely resulted in the reduction of fall incidence rates since there were other factors that could have influenced the results. In addition, the fall incidence rate can be attributed to only a few residents involved in the study. The majority of participants themselves were not high risk for falls during baseline. In addition, the project was done in a short span of time, for two months. For one to be able to declare that the in-house educational program influenced the fall incidence rate, a retrospective

accounting of the fall incidence rate pattern of the dementia unit must be done for a longer period of time.

This project evaluated the potential of an in-house educational program as a feasible and effective intervention in reducing the inappropriate use of antipsychotics in nursing home residents with dementia. The project incorporated various strategies to learning such as lecture-discussion, demonstrations, and actual resident-based scenarios. The training module and contents were concise and brief. The trained health professionals were encouraged to apply the knowledge they had learned to the day-to-day cares and management of residents with dementia.

Limitations or Deviations from Project Plan

There were certain limitations identified in this project, and as it progressed, there were additional questions revealed which would warrant further research and exploration. For instance, a survey on which nonpharmacologic methods were employed by the staff members would provide information on which specific measures may have led to the improvement in the APID index mean scores of the residents.

The project also did not include an evaluation or interview of the physicians pertaining to their practices after the in-house educational program was delivered. It was not ascertained whether they have decreased or stopped some prescriptions for residents after assessing that such antipsychotic medications were not really necessary.

In addition, the project only focused on determining whether an in-house educational program can improve the appropriate use of antipsychotics to manage patients with dementia. The project did not go into the specifics of which particular intervention e.g. change in prescribing culture, use of nonpharmacologic means, communication or improved interdisciplinary collaboration, have most likely influenced the findings. However, this topic is

an interesting subject for future research. The DNP student also observed that the use of nonpharmacologic strategies were much easier to apply rather than changing the prescribing culture of the unit. According to Tjia, Gurwitz and Briesacher (2012), the culture of a nursing home is one of the most difficult to change in favor of improving patient outcomes primarily because an institution is a complex system. A more in-depth discussion of this challenge is narrated in the implications section.

There were certain challenges encountered by the DNP student in the implementation of this project. One of the difficulties encountered by the DNP student was the delay in the initial timeline of the project due to the formalities involved in securing an approval from the ethics committee. It has been established that the facility currently does not have a privacy board in place and the protection of its residents when research is involved lies entirely in the basic tenets of patient rights and safety in conducting clinical research. Although legal protection such as the HIPAA Privacy Act and the provisions in the Good Clinical Practice guidelines of the International Council on Harmonization in conducting clinical studies were sufficient, a privacy board may provide extra protection for vulnerable participants such as residents with dementia if they are the target population of a quality improvement or research project. In lieu of a privacy board, the DNP student asked approval from the head of the facility, but suggested that a privacy board or council be established for future researches.

While the project progressed, the DNP student encountered difficulties in arranging for the schedule of the trainings and in disseminating the information to staff members regarding the training because of the bureaucracy involved. The bureaucratic arrangement of the facility was both beneficial and limiting to the implementation of the project. It took time for the DNP student to be able to acquire the approval from the facility head to require the permanent staff

members in the Alpha Rehabilitation and Nursing Dementia Care Unit to participate in the project. However, it was also of assistance as a significant number of participants was achieved, although not all permanent staff members were able to attend the program. Due to time constraints and budget issues, the in-house educational program was shortened. The original module stated that there would be one session dedicated solely for physicians and nurse practitioners. However, as there was only one physician and one pharmacist who were available to do the training, it was made into a one-on-one session for each professional. The face-to-face delivery was also not fully applied; there were three participants who opted for an online delivery of the training material due to their inability to attend the face-to-face training. Another deviation from the proposal was the cost associated with the project. There were adjustments made to the budget appropriation and it has exceeded the initial projected cost by 500 USD.

Overall, using a results-based approach to evaluate the project, it has been established that its objectives were achieved. The results of this quality improvement project were promising, implicating that staff education can improve the appropriate use of antipsychotics in nursing home residents with dementia. In terms of evaluating the data accuracy, the proposed evaluation plan in the proposal was followed and confidence in the data collected was high. However, there is much work to do when it comes to translating knowledge into practice. This project was rather small and limited in duration; it has only served as a springboard to a greater, more complex task to eliminating the inappropriate use of antipsychotics for residents in nursing homes.

Implications

Based on the findings of this project, it has been ascertained that an in-house educational program proves to be beneficial to both staff and residents. However, the sustainability of this

project is another issue to be tackled. The cost associated with conducting the in-house educational program may undermine one of the aims of the organizations, which is to maintain financial gain. Thus, supporting the idea of absorbing this project into the quality system of the dementia unit may prove to be a long process if there is lack of support from the clinical leaders and as well as if there is no concrete plan of where the funding would be taken.

Since the project's end-product is the improvement of the quality of care, which could not be measured using monetary value, the exact return on investment of this project may not be calculated. Although, it is significant to emphasize to the clinical leadership of the organization that quality of care may influence residents to maintain occupancy (Cioltan et al., 2017). In addition, following the requirements of CMS to reduce the use of antipsychotics in nursing homes, avoids a CMS citation. A corresponding consequence of a CMS citation may be difficulties in claiming reimbursements for healthcare services provided by the facility.

There are also indirect monetary benefits that the in-house educational program may contribute to the organization, such as a decrease in the use of antipsychotics to residents with dementia, thus minimizing drug expense as well as decreasing fall incident rates, which can help save money for the organization as falls may result in fractures and hospitalizations.

Taking into consideration the cost to conduct the in-house educational program, including it in the quality improvement plan of the organization may mean increasing the budget. Thus, it is in this aspect where the values and principles of the organization will be tested—whether it will adopt this project and fund its associated costs. The findings of this project will be shared with the stakeholders of the facility so that they are able to make evidence-based decisions in the dementia care unit. Furthermore, the DNP student offered more cost-effective means of delivering the training such as using an online alternative.

It has been established that organizational culture can influence a facility's approach to quality improvement (Tjia, Gurwitz, & Briesacher, 2012). An assessment of Alpha Center for Rehabilitation and Nursing has revealed that it resembles a strong medical director and bureaucratic culture and therefore interventions and proposed changes are better introduced through centralized coordination. As of this writing, the clinical leaders of Alpha Center for Rehabilitation and Nursing have expressed their willingness to incorporate the in-house educational program to the quality improvement system of the facility. However, at this point the clinical leaders are determining the associated costs of such an intervention. The availability of the training facilitators and staff will also need to be considered.

In relation to the project's implications for practice change, it is noteworthy to include that due to the improvement of the APID index mean scores in T1, it suggests that the staff members in the facility are applying what they learned during the training. However, these positive results also do not guarantee that the change in the staff's practice behaviors will be continued over time. According to Burgio, Stevens, Burgio, Roth, Paul, and Gestle (2002), the outcomes of the project may have been influenced by its short duration.

A systematic review or supervisory system must be in place to ensure that changes in practice are monitored over time. According to Spector, Orrell, and Goyder (2013), caregivers tend to return to their pre-training behavior and practices if there is no ongoing supervisory system in place. Thus, this implies that should the organization seek to include the in-house educational program in its quality system, a formal supervisory system must also be established.

As the project implementation progressed, the DNP student came to realize that reduction in antipsychotic use in residents with dementia may require more than an educational program. To sustain the reduction in antipsychotic use, a trifecta of education, resident-centered activities,

and standard prescribing guidelines, as suggested by Tjia, Gurwitz & Briesacher (2012), will create a more significant and noticeable improvement in the use of antipsychotics for residents with dementia with sustained benefits over a long period of time.

In terms of the project's contribution to nursing practice, the project has further concretized that staff education on the pharmacologic and nonpharmacologic means to manage dementia is effective in reducing antipsychotic abuse. It is important to emphasize how debilitating improper use of antipsychotics can be to residents with dementia. There are associated adverse effects of antipsychotic overuse (Carnahan et al., 2017); it increases morbidity and mortality in patients with dementia (Coon et al. 2014), increases the risk for falls (Bloch et al., 2017) and fractures (Lee et al., 2017), and may even be associated with stroke (Carnahan et al., 2017).

Several studies have established the effectiveness of nonpharmacologic means of managing patients with dementia and its role in reducing antipsychotic use (Coon et al., 2014) and nonpharmacologic interventions are highly suggested as first-line treatment for nursing home residents with dementia-related behavioral disturbances (Chiu et al., 2015). Thus, nurses, as forefront workers in healthcare are in the best position to apply these nonpharmacologic methods in the day to day cares of nursing home residents with dementia and produce significant improvement in residents' outcomes.

Nursing practice in the facility should be focused on making appropriate, individualized nursing care plans for residents with dementia, with a clear application of nonpharmacologic interventions. Furthermore, family education regarding dementia management should also be carefully included in the care plan. A study by Simmons et al. (2018) cited family resistance as one of the barriers to reducing the use of antipsychotic medications. The DNP student suggests

that exercise, art therapy, cognitive interventions, mind games, and activities that socially engage the residents be included in the daily or weekly schedule of activities in the nursing home.

Future research. Moving forward from the completion of this project, the next question is how to translate evidence into clinical practice. It has been a challenge for the DNP student to ascertain the sustainability of the project and therefore barriers to its implementation should be carefully studied. For instance, research that would focus on change management and how to implement organizational change will provide an informative and distinctive step by step blueprint on how an organization may be able to implement an in-house educational program seamlessly into its operations.

Another topic that can spark further exploration in reducing the use of antipsychotics in residents with dementia is by looking at the problem at an organizational level. Clearly, a multi-pronged approach of culture change, education, staff involvement, clinical leadership, and interdisciplinary communication is needed to create a significant decrease in the use of antipsychotic medications for residents with dementia within the facility. An educated inquiry into the soft and hard elements and the daily clinical operations and practices of Alpha Center for Rehabilitation and Nursing may reveal key issues that should be addressed in order to solve the problem at hand.

Implications to health policies. Since this project is relatively small and short in duration, its implication may influence only the health policy of the microcosm to which it was applied, which is the Alpha Center for Rehabilitation and Nursing. It has previously been identified that sustaining an in-house educational program comes with its own challenges. The CMS has a national program that aims to reduce unnecessary antipsychotic use in nursing homes. Alpha Center for Rehabilitation and Nursing may utilize this government agency for

support on how to implement the in-house educational program on a long-term basis and use the findings of this project as a foundation. This project also implies that a regular monitoring of antipsychotic use in its dementia care unit is warranted due to the high APID index mean scores of patients during baseline assessment (T0). Finally, as mentioned, a privacy board or a policy that will protect residents with dementia should be established by the facility concerning the involvement of their residents in quality improvements projects or ion research studies.

Chapter VI:

Conclusion

Value of the Project

The use of off-label antipsychotic medications to treat behavioral symptoms of residents with dementia is a pressing concern in the U.S. (CMS, 2016). Amidst the growing evidence of the effectiveness of staff education and nonpharmacologic interventions, current data shows that the inappropriate use of antipsychotics in nursing home residents with dementia could not be fully eradicated and efforts of the CMS and national programs are only to the extent of minimizing the problem.

This project has not only provided empirical evidence that staff education decreases the inappropriate use of antipsychotics and decreased falls incidence in dementia residents of Alpha Center for Rehabilitation and Nursing, it has also uncovered a number of issues that need to be addressed in order to continuously maintain the desired results. Decisions and resulting new policies must be made by the facility in order to foster the formal incorporation of the in-house educational program to the quality system of the organization. A robust support from the clinical leaders of the organization is needed for this project to be concretized and thus declare that such evidence was put into practice. Strong, internal audit measures regarding the use of antipsychotics in the dementia unit should also be prioritized to avoid a citation from the CMS during re-certification. The creation of a privacy board for the protection of the facility's residents during implementation of quality improvement projects and clinical research is indicated. This project has therefore provided Alpha Center for Rehabilitation and Nursing a foundation from which quality healthcare practices may be further improved in relation to antipsychotic use in residents with dementia.

In a wider scale of things, this project has added to the bank of knowledge present regarding the link between staff education and antipsychotic use in nursing home residents with dementia. Although this project is not without limitations, its findings were consistent with current data.

DNP Essentials

Through this project, the DNP student was able to meet all the eight DNP Essentials, but was able to specifically identify more with the organizational and systems leadership for quality improvement and systems thinking DNP essential. The challenges endured by the DNP student during the implementation of this project has brought forth a new perspective, thinking, and skills to the DNP student, especially on greater issues that circumvent bureaucratic organizations in order to bring forth improved patient and health outcomes.

One of the recommendations from the DNP project was the incorporation of the designed in-house educational program to the quality system of the facility. The DNP student also proposed the introduction of an internal audit system within the facility, which would serve as a monitoring system for the use of antipsychotics within the dementia unit. However, the realization of these two suggestions were both met with challenges. The DNP student was able to understand that innovations may not just be assimilated into a well-structured group without first assessing its feasibility into the current political, cultural, economic, and organizational milieu of the facility to which it will be integrated.

Furthermore, the DNP student was able to develop his political skills in terms of lobbying for the in-house educational program to be included in the quality system of the facility by having a dialogue with the clinical leadership of the organization. The DNP student was also able

to assess the needs of the target population (dementia residents) and analyze what system-level approaches should be institutionalized so that the needs of this population will be met.

In addition, the DNP student was able to build his business and financial acumen, although not to a great extent (because this is not the focal area of the project), but to a certain level by introducing cost-effective means of delivering the in-house educational program such as through an online medium. The project was able to provide an avenue for the DNP student to assess the organization, identify existing issues within the domain, and then ultimately devise ways on how to implement organization-wide changes in the delivery and practice of care to residents.

Plan for Dissemination

The findings of this project imply that an in-house educational program (which teaches staff about the proper use of antipsychotics and how to use nonpharmacologic means to manage residents with dementia) can reduce antipsychotic use in the target population and reduce falls. The objective of this dissemination plan is to ultimately use these findings as a basis to incorporate the in-house educational program to the quality system of Alpha Center for Rehabilitation and Nursing. The primary end users of this information are the clinical leaders of the said facility, its nursing service provider staff, and the residents or the public. The secondary end users are external statutory organizations especially CMS and the academia.

The DNP student plans to disseminate the project findings to the end users by using multiple vehicles for dissemination such as face-to-face interactions, use of electronic media, and publications. In line with face-to-face interactions, the DNP student would like to involve the primary end users to the dissemination effort by identifying a local opinion leader which is already part of the DNP project itself. The designated local opinion leader is the nurse project

coordinator. The local opinion leader will help the DNP student in disseminating the results of the project by word of mouth and as well as by being a representative during staff meetings. The DNP student will furnish a summarized written report of the project's findings and the local opinion leader may distribute these to the end users. In addition, the DNP student will initiate a dialogue with the management or clinical leaders of the facility to discuss the results of the study and lobby for the incorporation of the in-house educational program to the quality system of the facility.

Publishing the results in print is another medium that the DNP student would like to use. Internally, Alpha Center for Rehabilitation and Nursing has an official newsletter wherein the nurses, nursing assistants, patients and their families would be able to read about the project. The DNP student also plans to print an infographic of the findings and post it on the bulletin board of the facility for a span of two to three months. The DNP student also plans to present the research findings in a professional meeting or conference if a platform arises. Professional nursing conferences are often held in different area across the U.S. and the DNP student will look for an opportunity to share this DNP scholarly project.

The main indicator that the dissemination plan was successful would be the acknowledgement of the clinical leaders of Alpha Center for Rehabilitation and Nursing of the significance of the project through either a written confirmation or through the adoption of the in-house educational program to its quality system. However, the said pursuit also comes with its own challenges. Thus, the DNP student would like to keep in contact with the facility manager until the in-house educational program is accepted into the quality system of the facility. Other end users of the findings may provide feedback via email. The email address of the DNP student will be provided in each copy (either print or digital format) of the project findings.

Attainment of Personal and Professional Goals

The completion of this DNP project has opened doors for the DNP student in the attainment of personal and professional goals. Personally, the project served as the DNP student's motivation to continue learning as there is so much more to explore, study, and research on the said topic. The DNP student feels that the quest for knowledge is a never-ending process and even more so is the translation of knowledge into practice. Professionally, the DNP student has lofty dreams and aspirations such as becoming a manager someday. Thus, this doctorate learning has provided the DNP student a key to unlocking more doors and possibilities in the future. Currently, the DNP student is focused on finding ways on how to make tangible changes in its chosen organization especially in improving healthcare delivery and patient outcomes. For the DNP student, to be able to concretize this project and eventually advocate for its sustainability, is already a great professional achievement.

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Appendix A

Evidence Evaluation Table

Sydney Malimpenet - Evidence Evaluation Table

Clinical Research Question: **In nursing home residents, to what extent can an educational intervention reduce the incidence rate of inappropriate use of antipsychotic medication for residents with dementia.**

Headings	Study, Source, and Search Terms	Purpose of Study	Design/Method	Sample/Setting Ethics	Major Variables	Measurement Tools	Data Analysis	Findings	Concepts/Themes	Applicability to Own Research
Explanation of Headings	*(APA Citation, Database, Key Words)*	*(Why study was done as stated by authors)*	*(How was study carried out?)*	*(Number & characteristics of participants; attrition rate & why) (How are subjects' rights protected; risks vs benefits; informed consent, etc.)*	*(List & define independent & dependent variables)*	*(Name & author of scale(s) used to measure outcome variables; include reliability & validity data)*	*(Statistics used to answer clinical question)*	*(Statistical or qualitative findings)*	*(Identify main concepts/themes & provide a descriptor or definition. These will help organize the literature review)*	*(Describe how/why it relates to your research)*
Reducing unnecessary antipsychotic medications in the management of dementia related behavior	Armin, R. PubMed. JAMDA. 2013. 15(3).	To improve safet by reducing unnecessary antipsychotic medications, and fostering a culture change	SR (PubMed), searched 6 databases 2009-2013	Retrospective review, 418 participants; Attrition: not reported. IRB approval obtained; Informed consent obtained	IV: people living with dementia. DV: mixed-method retrospective review	Quality improvement methonds. Standardized the formulation and implementation of behavior management	Odds Ratio	Qualitative findings	Reduction in cross sectional prevalence of antipsychotic use in nursing facilities	Addressing facility factors such as staff support, communication and perceptions
An educational intervention on drug use in nursing homes improves health outcomes resource utilization and reduces inappropriate drug prescription	Gollarte, F.C et al. PubMed. JAMDA. 2014.	To assessed the effect of an educational intervention directed to nuring home physicians in reducing inappropriate prescription.	SR (PubMed), searched 6 databases 2010-2014	N-2 studies; 37 nursing homes; informed consent described, data saftey plan described	IV: Inappropriate drug prescription. DV: Nursing homes	Randomized controlled trials	Mean	1018 residents were randomly selected; 516 intervention group, 502 in control group; mean age 84.4 +/- 12.7 year old; 73% woman. Intervention group (1.29+/-1.56 vs 0.81+/-1.13)	An educational intervention on drug use is feasible in nursing home	Importance of appropriate use of antipsychotic drugs which include the general aspects of prescription and drug use in geriatric patients
Assessing approaches and barriers to reduce antipsychotic drug use in Florida nursing homes	Ellis, M.L et al. EBSCohost database. 19(6), 507-516 (10p)	To examine qualitative data, explore strategies that have been implemented	SR (Ebscohost) searched 10 databases -2015	Convenience sampple 276 nursing home professional staff members; survey; open-ended questions	IV: Assessing approacahes. DV: Florida nursing homes	Descriptive and open-ended qualitative	Odds Ratio	Qualitative findings	Produce comprehensive assessment of antipsychotic mediation use	This study explores how nursing homes responded to the 2012 CMS initiative to reduce inappropriate antipsychotic medication use among residents
Antipsychotic medication use in nursing homes: a proposed measure of quality	Lucas, J.A. et al. Wiley Online library. 2014. 29(10); 1049-1061	To propose a measured based on CMS Interpretive Guideline, FDA indications for antipsychotic medication use	SR (Cochrane) database 6searched 6 databases 2010-2014	Medicaid-eligible long stay residents aged 65 years and older	IV: antipsychotic medication use. DV: quality measure	Minimum Data Sets (MDS), Merged with medicaid analytic extract (Max) data	Review authors	Qualitative findings	Demonstrated an antipsychotic medication use quality measure that is based on CMS Guidelines	Provides an important foundation on how to reduced inappropriate use of antipsychotic medications in NH

Persistent use of psychotropic drugs in nursing home residents in Norway	Helvik, A.S. et al. CINAHL database. 2017	To describe the prevalence and persistence in use of a psychotropic drug	SR.(CINAHL) searched 8 databases from 2005-2013.	1163 NH Residents; Informed consent described; Data safety plan described	IV: Psychotropic durg. DV: Nursing homes in Norway	Longitudinal Study with five assessments	Odds Ratio	OR (95% CI) lag I, N=1406; Antipsychotics 30.7 (21.8; 43-1)	The prevalence and persistent use of PTD at 2 consecutive tie points was high, both for the	Psychotropic drug were frequently used as a long-term treatment among NH residents
Inappropriate drug prescription at nursing home admission	Garcia-Golarte, F. et al. EBSCohost. 2012	To determine the value of the screening tool of older persons potentially inappropriate prescriptions/screening tool to alert doctors to the right appropriate indicated treatment	SR(EBSCOhost) searched databases 2012	cross-sectional study of 100 consecutive patients	IV: drug prescription. DV: nursing home admission	STOPP-START criteria and Australian criteria	Odds Ratio	79%-inappropriate prescription (STOPP). 95% - potential problem (Australian criteria)	High numbers of inappropriate drug prescription detected at the time of admission	Both STOPP-START and Australia criteria were effective
Improving nursing home compliance vs. Revised antipsychotic use survey tool	Bach, L.et al. EBSCOhost. 2017	To analyze the effect of using a pharmacist-initiated antipsychotic use survey tool on improving nursing home compliance for appropriate use in patients with dementia	SR(EBSCOhost) searched databases 2017	GDR survey tool for 20 study population residents	IV: Antipsychotic. DV: survey tool	antipsychotic gradual dose reduction tool	review authors	qualitative findings	Overall performance-compliance improved and antipsychotic use declined	Pharmacy initiative improved compliance
Impact od programs to reduce antipsychotic and anticholinergic use in nursing homes	Carnahan, R., et al. CINAHL. 2017	To evaluate the impact of these programs on medication use and BPSD among nursing home residents	SR(CINAHL)	Medicare and assessment data ; 427 eligible Iowa nursing homes, 114 exposure to IA-ADAPT	IV: antipsychotic/ anticholinergic . DV: nursing homes	Quasi-experimental longitudinal study	Odds ratios	OR, 0.96; 95 anticholinergic use. OR, 0.83 antipsychotic doses per CMS gudiance; CI, 1.02-1.11	IA-ADAPT and the CMS partnership improved medication use	Evaluate the effectiveness of the BPSD interventions
A literature review of clinical outcomes associated with antipsychotic medication use in North American nursing home residents	Chiu, Y., et al. CINAHL. 2018	To provide a realist literature review, summarizing original research studies on the clinical effects of conventional and atypical antipsychotic medication use in nursing home	SR(CINAHL)	searches multiple databases identified 424 relevant research articles, of which 25 met the inkusion criteria	IV: antipsychotic. DV: literature review	systematic review	review authors	qualitative findings	Certain antipsychotic medications dosing regimen and shorter duration of use might have adverse events	highlightened the clinical consequences of the antipsychotic medication use in nursing home populations
Application of the antipsychotic use in dementia assessment audit tool to facilitate appropriate antipsychotic use in long term care residents with dementia	Wolfe, K.W., et al. CINAHL. 2018	To test the utility of an educational-inservice to facilitate the appropriate use of antipsychotics for nursing home residents with dementia	SR(CINAHL)	the sample included de-identified medical record on a sixty bed dementia special care unit	IV: antipsychotic. DV: dementia assessment tool	descriptive analyses	odds ratio	At prescribing rate of antipsychotic medications was 20.3% (n=2)	educational intervention and assessment can serve as a model for use in the long term care facilities	evaluate the effectiveness of the educational - in service

Appendix B

Appropriate Psychotropic Drugs Use in Dementia (APID) Index

Table 1. General psychotropic drug scoring rules and medical record inspection period per item

	Score 0	Score 1	Score 2
Indication	-Recommended by the VGPB and found in the medical record within 2 months after the start of PD. -Recommended by the VGPB and found within 6 months after DSCU admission.	The typical PD not recommended by the VGPB but another PD of similar ATC3 level.	Other or no indication found within the medical record inspection period.
Evaluation	-Within 2 weeks after starting medication? (for antidepressants within 8 weeks)	Within 6 months after the start of PD	No evaluation found in the medical record inspection period.
Dosage	Recommend by VGPB or the SmPC.	Too low	Too high
Drug-drug interaction	No interaction indicated at the SmPC	Indicated as interaction at the SmPC. Although not recommended, when adequately monitored administration is possible	Do not administrate, indicated at the SmPC.
Drug-disease interaction	No interaction indicated at the SmPC	Indicated as interaction at the SmPC. Although, not recommended, when adequately monitored administration is possible.	Do not administrate, indicated at the SmPC.
Duplication	No duplication in the same grouped PD.	Duplication, without exceeding the total maximum combined dosage.	Duplication, exceeding the total maximum combined dosage.
Duration of therapy	-Recommended by the VGPB or SmPC.	Antipsychotics 3 to 6 months.	Exceeding recommendations

Abbreviations: VGPB (Verenso Guideline for Problem Behavior), Dutch association of elderly care physicians and community geriatricians (Verenso); PD, psychotropic drug; DSCU, dementia special care unit; ATC3 level, Anatomical Therapeutic Chemical classification three level/same grouped psychotropic drug; SmPC, summary of product characteristic.

[a]The total maximum combined dosage was calculated based on each of the PDs percentage of their individual maximum dosage. The percentage was then summed up; if this exceeded a total of 100% a score 2 was given.

Appendix C

APID Index Results Form

SUBJECT ID: _____

Timepoint	Score				Remarks
	(T0)		(T1)		
	First Assessment	Review	First Assessment	Review	
DATE					
Indication					
Evaluation					
Dosage					
Drug-drug interaction					
Drug-disease interaction					
Duplication					
Duration of Therapy					
TOTAL SCORE					

Form completed by: _____ Date completed: _____

Appendix D

Fall Frequency Documentation Form

Strategies to Reduce Antipsychotic Medication Use in Nursing Home Residents with Dementia
By: Sydney Malimpenet, RN

Fall Frequency Documentation Form
Dementia Care Unit
Alpha Center for Rehabilitation and Nursing

Timepoint	T0	T0 (Review)	T1	T1 (Review)	Final Total (After review)
Date					
Incidence of falls (all residents)					

Form completed by: Date:

_____ _____

Form reviewed by: Date:

_____ _____

Appendix E

Project Timeline

Strategies to Reduce Antipsychotic Medication Use for Nursing Home Residents with Dementia

ACTIVITIES	SEP 2018				OCT 2018				NOV 2018				DEC 2018				JAN 2019				FEB 2019				MAR 2019				APR 2019	
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2
Submission of Research Proposal to Ethics Committee and Approval		/	/	/																										
Recruitment of subjects/residents				/	/																									
T0 Assessment Data Collection						/																								
Review of T0 Assessment							/																							
Facility visit by the student (first visit)						/																								
Facility visit by the student (second visit)								/																						
Intervention (First Offering)									/																					
Intervention (Second Offering)												/																		
T1 Re-assessment Data Collection														/	/															
Review of T1 Assessment																/														
Data Analysis																	/	/	/											
Formulation of Chapters 4 and 5																				/	/	/								
Presentation of Final Paper and Editing																							/	/	/	/	/	/	/	/

Planned Milestones:

1. Submission of Research Proposal to Ethics Committee
2. Subject Recruitment
3. Data Collection T0
4. Intervention
5. Data Collection T1
6. Data Analysis
7. Drafting Results and Discussion
8. Presentation of Final Paper and Editing

Appendix F

Budget Table

Project Period: 5 months

Particulars	**Amount (USD)**	**Rationale**
Personnel		
Academic personnel (Aged care specialist, clinical pharmacist, Nurse with Master of Science in Nursing degree)	300	Honorarium for the developers of the training module, gift certificate worth 100 each
Statistician	100	To perform data analysis (outsourced via an online freelance platform)
Study Coordinator	200	Allowance of staff who shall coordinate the training and be the point person between the investigator and the site
Clinical Pharmacist	200	Honorarium (assessment using APID Index)
Editorial assistant	100	To proofread final manuscript (outsourced via an online freelance platform)

Equipment		
Computer/Laptop	Provided by student	Will use investigator's own
Printer	Provided by student	Will use investigator's own
IT (SPSS)	Accessible	Free to download online
Materials and Supplies		
Stationery and markers, pens	20	To be used for communication letters, APID index forms, fall documentation forms and other documentation purposes
Test materials	20	For reproduction of instrument
Folders	20	To keep source document files
Intervention Costs (Training)		
Training venue & equipment	Provided by facility	Tentative, to check with facility if they can provide free
Trainer (aged care specialist)	200	Honorarium for the educational program (75 per offering, total of 2 offerings)

Handouts	10	Participants may bring their own writing materials, handouts will be distributed
Food/snacks/catering	100	Approximate for 25 persons per offering (total of 50 persons)
Posters/communication	30	Approximate for 2 posters; advertising purposes
Transportation		
Travel costs of investigator	200	Based on an estimate of nine months consumption
Total	1500	Total

Appendix G

E-mail Invitation (For All Staff)

Email Subject: Invitation to participate in an educational program

Graduate School of Bradley University
Department of Nursing
Illinois, USA

(Date)

Dear Sir/Madame:

Good day!

As introduced prior by your unit manager during your previous monthly meeting and in her separate e-mail, I am Sydney Malimpenet, a doctorate student in Nursing currently pursuing a project entitled "*Strategies to Reduce Antipsychotic Medication Use in Nursing Home Residents with Dementia.*" As part of this project, I would like to conduct an educational program in this institution wherein you are invited to attend.

The aim of my project is to reduce the use of off-label antipsychotic medications to residents with dementia through staff education. This educational program shall cover various topics on how to manage dementia and aggressive behavior in the elderly; the module was developed by healthcare professionals.

There will be two offerings for the educational program, each offering consists of three sessions. The dates are the following:

November 5, 2018; 9:00 am – 5:00 pm

November 26, 2018; 9:00 am – 5:00 pm

You can arrange a schedule with your unit manager. To know more regarding this educational program, you may reach me through (smal20@yahoo.com) or (347-465-2890).

I am going to personally visit your institution on October 22-23, 2018 to answer questions and or clarifications. Meanwhile, attached herewith is the schedule of activities of the educational training and the topics to be covered for your perusal.

Very truly yours,

Sydney Malimpenet, MSN, RN

Appendix H

Informed Consent Form

Strategies to Reduce Antipsychotic Medication Use in Nursing Home Residents with Dementia

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the research with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

My name is Sydney Malimpenet, I am a nurse enrolled in a Doctor of Nursing Practice program at Bradley University. I am doing research on strategies to reduce inappropriate use of antipsychotic medications in people with dementia. I am going to give you information and invite you to be part of this research.

There may be words which you do not understand. In such instances, please ask me to stop as we go through the information and I will take time to explain. If you have questions later, I will provide you with my contact information.

Purpose of the research

The use of off-label antipsychotic medications for dementia is currently being reduced as it can lead to adverse effects. The Centers for Medicare and Medicaid Services launched an initiative to reduce the use of these medications. This project aims to assess the effectiveness of an educational intervention in decreasing the inappropriate use of antipsychotic medications in patients with dementia.

Type of Research Intervention

The research intervention does not directly involve you. There will be an educational offering to the nursing home staff regarding the nonpharmacological ways to manage dementia. The interventions learned by the staff members will be applied to your care through changes in your care plan and management. The effectiveness of this nonpharmacological interventions will then be assessed.

This research will involve two assessments. In the first assessment, your patient chart will be evaluated by a professional. In the second assessment, the frequency of falls in the unit will be monitored; you do not actively take part in this assessment.

Participant selection
I am inviting all residents aged 65 years old and above, specifically those who are diagnosed with dementia, and who are currently taking prescription antipsychotics.

Voluntary Participation
Your participation in this research is entirely voluntary. It is your choice whether you participate or not. Whether you choose to participate or not, all the services you receive at this facility will continue and nothing will change. If you choose not to participate in this research project, you will receive the same standard of care that is provided by this facility. Your cares and the staff members in this facility will provide you with the same quality of care as other residents who participated in this research as based on Centers for Medicare and Medicaid Services guidelines. You may change your mind later and stop participating even if you agreed earlier.

Duration
The research takes place within five months.

Side Effects
There are no anticipated side effects in participating in this research.

Risks
Since you are not going to receive any drug intervention in this study, the risks associated with this study are very minimal. You will be the recipient of the knowledge gained by staff members regarding the use of non-pharmacologic interventions to manage dementia. You may, however, find it inconvenient that there are some changes to your care plan that affects your daily routine (e.g. introduction of exercise activities, new ways of communicating to you, having art therapy sessions, etc.).

Benefits
If you participate in this research, there is no monetary benefit. However, a benefit may be your healthcare providers' additional knowledge regarding the appropriateness of the medicines prescribed to you. Another benefit would be that staff members would be more knowledgeable in applying non-pharmacologic interventions in addressing your needs. Your participation, however, is likely to help find the answer to the research question. The results of this research may provide additional knowledge about the use of staff education in reducing inappropriate antipsychotic use in residents with dementia.

Reimbursements
You will not be given any money or gifts to take part in this research.

Confidentiality
The information I collect from this study will be deemed confidential. Information about you that will be collected during the research will be put away on my computer with a passcode. Information will only be shared with my research advisor and statistician. All documents collected pertaining to you in this study will be filed in an individual folder and stored in a locked, secured place.

Sharing the Results

The knowledge that I gain from doing this research shall be shared with you through community meetings before it is made widely available to the public. Confidential information will not be shared. There will be small meetings in the community and these will be announced. After these meetings, we will publish results in order that other interested people may learn from our research.

Right to Refuse or Withdraw

You do not have to participate in this research study if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected.

Who to Contact

Questions about this project may be directed to the DNP project student, Sydney Malimpenet at (347-465-2890), or the DNP project advisor, Dr. Erickson (309-677-4974), during normal business hours. You may also contact the Committee on the Use of Human Subjects in Research (CUHSR) office (309-677-3877) with any questions or concerns related to this project.

Sincerely,

Sydney Malimpenet, MSN, RN

PART II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant or Legal Representative_____

Signature of Participant or Legal Representative_____

Date _____
Day/month/year

If illiterate
A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ AND Thumb print of participant

Signature of witness _____

Date _____
Day/month/year

Statement by the researcher/person taking consent

I have accurately read the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done during the study: 1) review chart for use of antipsychotic medications, 2) non-pharmacologic interventions to manage dementia will be applied to participants, 3) review of falls incident reports.

I confirm that the participant or legal representative was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____
Day/month/year

INFORMED CONSENT PROCESS

SUBJECT ID _____

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Form completed by: Date:

_____ _____

Appendix I

Application for Partial Waiver of Authorization

September 7, 2018

Committee on the Use of Human Subjects in Research
Bradley University
Peoria, IL

RE: APPLICATION FOR PARTIAL WAIVER OF HIPAA AUTHORIZATION

Dear Committee Members:

My name is Sydney Malimpenet, a DNP student currently pursuing a project entitled ***"Strategies to Reduce Antipsychotic Medication Use in Nursing Home Residents with Dementia"***which is under this committee's review as of the moment. Upon initial review, it was determined that I would need to request for a partial waiver of HIPAA authorization with regard to the enrollment of subjects/ residents into my project.

In line with this, I would like to request for a partial waiver of authorization for the following PHI (protected health information):

a) Name
b) Age
c) Existing diagnosis of the resident
d) Name and contact details of the resident's legal representative

To the best of my knowledge, the project cannot be done without access to the above PHI for the following reasons:

RATIONALE
The project involves elders who are part of a vulnerable population. The inclusion criteria include residents 65 years old and above who were diagnosed with dementia and are prescribed with antipsychotics; and the exclusion criteria include diagnosis of Schizophrenia, Tourette Syndrome and Huntington's Disease. Thus, it is crucial that the diagnosis of the resident be made available to the investigator so that the resident's eligibility for the study may be determined.

It was stated in the informed consent process of this proposal that residents may provide consent given that the primary care provider (physician) has established that the resident is competent and capable of providing one. The facility is conducting regular cognitive assessment of residents using tools such as the Mini-Mental State Exam. Those residents who were evaluated as cognitively impaired during the last review will be considered as incapable of providing consent, in which, the legal representative will be contacted. Hence, the investigator would need the details of the resident's legal representative which shall include his/her name, mobile/phone number and email address for the purpose of discussing the project and obtaining proper consent.

To reduce the risk to the privacy of the resident in the use or disclosure of the resident's PHI. I am identifying the following: my plan to protect the identifiers from improper use and disclosure, my plan in destroying the identifiers at the earliest opportunity consistent with the conduct of the research unless there is a health or research justification for retaining the identifiers or as otherwise required by law, and assurance that the PHI will not be reused or disclosed to another person or entity, except as required by law, for authorized oversight of the research study, or other research for which the use or disclosure of PHI would be permitted.

PLAN TO PROTECT THE IDENTIFIERS

Name: The name of the resident will not be disclosed to the investigator. Instead, a staff member in the facility will only identify the resident.

Age: The exact age of the resident will not be disclosed to the investigator. Instead, a staff member in the facility will only identify the resident as either aged 65 and above or not.

Name and contact details of the resident's legal representative: The name and contact details of the legal representative will be obtained by the investigator from the staff member of the facility. This shall also be written on the informed consent form of the resident and shall be filed in the individual folder of the resident and locked in a secure place (file cabinet) in the facility with the key accessible only to the investigator.

PLAN TO DESTROY THE IDENTIFIERS/JUSTIFICATION FOR RETAINING

The identifiers will be part of the informed consent process and documentation of the DNP project. As according to the HIPAA policy, it will be retained for up to 6 years after the completion of the project. The informed consent forms will be destroyed by shredding and will be done by the investigator.

Upon careful analysis of the privacy risks to individuals whose PHI will be used or disclosed, I conclude that the anticipated benefits outweigh the risks. This project's aim is to help reduce the use of antipsychotic medication in nursing home residents with dementia through educating the staff on how to employ non-pharmacologic interventions in managing symptoms of dementia. To reach this aim, it is important that the inclusion and exclusion criteria of this project be followed to include only the target population. With the above plans in place, there is minimal risk to the privacy of the residents.

Declaration:

I hereby declare that the waiver will NOT adversely affect the privacy rights of the individual.

I hereby declare that the Principal Investigator whose name is stated above will be the only member of the research team (who is not a staff member in the facility) who will access the PHI.

I hereby declare that by affixing my signature below, the requested PHI will not be reused or disclosed to another person or entity, except as required by law, for authorized oversight of the research study, or other research for which the use or disclosure of PHI would be permitted.

I certify that all information in this letter is true and correct to the best of my knowledge. I have enclosed a copy of the informed consent form. Should you want to contact me regarding this request, you may find my information below.

Sincerely,

Sydney Malimpenet
347-465-2890
smalimpenet@mail.bradley.edu

Appendix J

Approved Partial Waiver for HIPAA Authorization

Bradley University
Committee on the Use of Human Subject in Research (CUHSR)
(Bradley University's Institutional Review Board [IRB])

Protocol # **52-18:** Strategies to reduce antipsychotic medication use in nursing home residents with dementia.
Principle Investigator: **Sydney Malimpenet**

Statement of Approval/Denial of Waiver/Alteration of Authorization

To Custodian of Patient Information: Federal privacy standards issued by the Department of Health and Human Services pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") permit you to use or disclose to an investigator, patient information pursuant to documentation of the waiver/alteration of patient Authorization by the investigator's Institutional Review Board (IRB) (45 C.F.R. § 164.512(i)). This Statement satisfies the JIPAA requirement for documentation that the IRB has reviewed the waiver/alteration request in accord with the requirements of the Federal Human subject protection regulations and, having determined that the criteria set forth at 45 C.F.R. § 164.512(i)(2)(ii) have been met and have been approved as follows:

Purpose of the Waiver. This statement certifies the IRB named above approved a request to waive the HIPAA Authorization requirement to permit the use or disclosure of patient protected health information (PHI) to the investigator named above the purposed of:

Partial Waiver. For screening or identifying prospective research participants.
Partial Waiver. For contacting or recruiting prospective research participants.

PHI Permitted to be Released. In approving the waiver/alteration the Board has determined that access/use by the investigator named above to/of the following information is necessary for the research activity and that the investigator is permitted to use/disclose the following:

All information described in the Investigator's Request for Waiver or Alteration of HIPAA Authorization for Research.

The scope of the Board's Waiver/Alteration to Authorization is limited solely to this information. Please contact the Committee for the Use of Human Subject in Research at 309-677-3877 should you have any questions regarding this statement.

Institutional Review Board Action (For IRB Use Only)

Approved
X **Via Expedited Review by IRB Chair (or Designee) On:** 9-25-2018
____ **Via Full IRB Committee On:**_____

Not Approved
____ **Via Expedited Review by IRB Chair (or Designee) On:** _____
____ **Via Full IRB Committee On:**_____

____ **Approval Deferred Pending the Following Actions:**_____

Andrew J Shuttleworth 9-25-2018
Signature of the IRB Chair (or Designee) **Dated**

Appendix K

CUHSR Approval (E-mail)

From: **Andrew Strubhar** <ajs@fsmail.bradley.edu>
Date: Tue, Sep 25, 2018 at 2:41 PM
Subject: CUHSR #52-18 Approval
To: Sydney I Malimpenet <smalimpenet@mail.bradley.edu>, Deborah Erickson <erickson@fsmail.bradley.edu>, Ross Fink <rf@fsmail.bradley.edu>, Sharon Rast <srast@fsmail.bradley.edu>

Dear Investigators:

Your study (CUHSR 52-18) *Strategies to reduce antipsychotic medication use in nursing home residents with dementia* has been reviewed and was found to be expeditable under Category 7, Research on group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs, or practices, and social behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies).

All vita and ethics certificate are on file.

Be aware that future changes to the protocol must first be approved by the Committee on the Use of Human Subjects in Research (CUHSR) prior to implementation and that substantial changes may result in the need for further review.

While no untoward effects are anticipated, should they arise, please report any untoward effects to CUHSR promptly (within 3 days).
As this study was reviewed and approved for one year, the maximum allowed under regulations. Please complete a final status report when the study is completed. If the study is not completed within one year, please submit a Continuing Review form before the one year date with adequate time for CUHSR to review to prevent a lapse in approval. These forms can be found on our website, http://cushr.bradley.edu/# Forms.
This email will serve as your written notice that the study is approved unless a more formal letter is needed. Just let me know. Also attached in the Statement of Approval of Waiver/Alteration of HIPAA Authorization.
Andrew J Strubhar, PT, PhD
Associate Chairperson, CUHSR
Bradley University

--
Andrew J Strubhar, PhD, PT
Associate Professor
Associate Department Chair
DPT Graduate Program Coordinator
Associate Chair CUHSR
Bradley University
Department of Physical Therapy and Health Science

1501 W. Bradley Ave
Peoria, IL 61625
(309)-677-3489
ajs@bradley.edu

Appendix L

Request for Permission to Conduct Research and Approval

Mr. Rosario Cortez, PhD, RN

Director of Nursing

*Alpha Center for Rehabilitation and Nursing

Brooklyn, New York

Dear Mr. Cortez,

Greetings!

I am Mr. Sydney Malimpenet, MSN, RN, a nurse who is currently undertaking a Doctor of Nursing Practice degree at Bradley University, Illinois. As part of this course, I am spearheading a research entitled *"Strategies to Reduce Antipsychotic Medication Use in Nursing Home Residents with Dementia,"* this scholarly project aims to minimize the abuse of antipsychotic medications in nursing homes through staff education.

In line with this, I have chosen to conduct this research project in Alpha Center for Rehabilitation and Nursing because I believe that my project can contribute significantly to further enhancing its services and improving its patient outcomes. As the head of this organization, I would like to formally ask for your approval to allow me to recruit residents and staff members from your facility as participants of my research project.

Enclosed herewith is a copy of the research proposal where you may find all ethical considerations, the informed consent forms for the residents and the approval from the Committee on the Use of Human Subjects in Research of Bradley University (ethics committee).

After completion of the project, the results will be shared to the school and to your facility. Should you have further questions please do not hesitate to contact me at smal20@yahoo.com or 347-465-2890.

Sincerely,

Sydney Malimpenet, MSN, RN

*Changed for confidentiality purposes

Appendix M

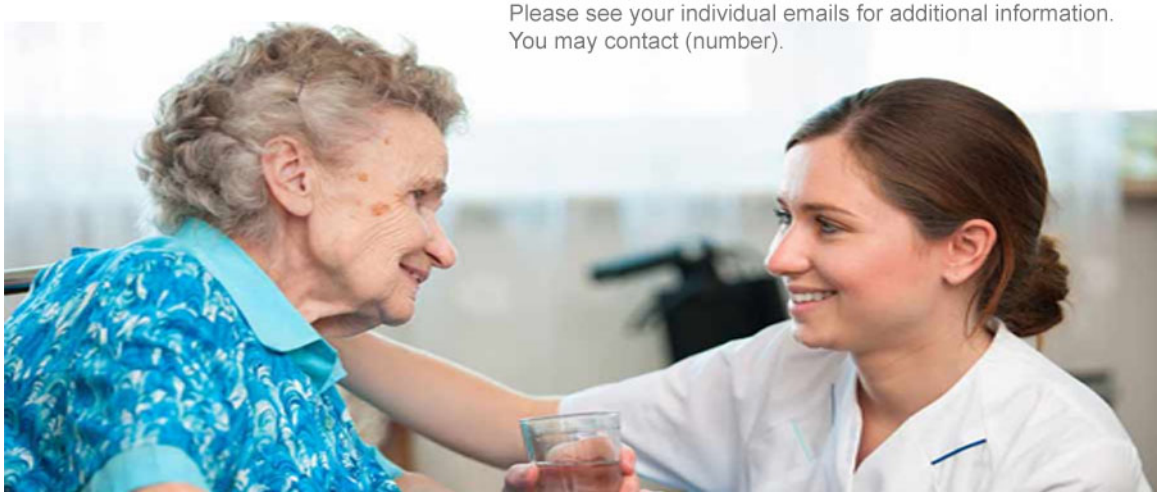
Poster Advertisement

Enhance your skills. Learn something new.

To: All Dementia Unit Staff

You are invited to take part in an educational program about non-pharmacological strategies in dementia care.
When: (Date of First Offering) & (Date of Second Offering)

This is compulsory to all permanent staff members.
Please see your individual emails for additional information.
You may contact (number).



Appendix N

Letter from the Author of the APID Index

Dear (DNP student),

In reply to your question. During the analyses for the studies we have executed with the APID index we used the average APID index sumscores and the average itemscores (i.e. indication, evaluation and therapy duration) per nursing ward (dementia special care unit). Thus averaged on cluster level, considering the potential contamination bias; patients have the same prescriber and nurses on a ward. However, depending on your sample, you could also average on patient level.

Additionally, leading up to the development of the APID index, adding up APID scores crossed our mind, considering that this way we could have a appropriateness measure that also consists of the amount of psychotropics that are prescribed. However, we decided to leave that idea; do the analyses separately on the amount of psychotropic prescriptions and described these in a separate study. This way we would have a measure that solely describes the appropriateness of the psychotropic drug prescriptions for neuropsychiatric symptoms in people with dementia.

Hopefully this will answer your question. If you have any more questions, please feel free to contact me.

Kind regards,

Klaas van der Spek I PhD
Academisch Psychiatric Centre from the Academic Medical Centre (AMC) Amsterdam, the Netherlands