

ANTICHOLINERGIC BURDEN SCREENING AND REDUCTION FOR OLDER ADULTS  
IN LONG-TERM CARE

A Doctor of Nursing Practice Project Report

by

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BSN, Texas A&M-Corpus Christi, 2014

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This Doctor of Nursing Practice Project Report meets the standards for scope and quality of  
Texas A&M University-Corpus Christi and is hereby approved.

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August 2019

## DEDICATION

I would like to dedicate this work to my grandfather, Francisco Arredondo, who was greatly afflicted by dementia in his final years. May this work serve to illuminate the potential for improvement in the care of our beloved elders, amidst their most vulnerable times, and remind us that sometimes less is more.

## ACKNOWLEDGEMENTS

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## ABSTRACT

Anticholinergic (ACH) medication use amongst older adults has been associated with cognitive decline, development of dementia, counteraction of cholinergic dementia treatments, numerous adverse effects and subsequent prescribing cascades. Older adults in long-term care facilities (LTCF) are exceptionally vulnerable to these adverse effects. This quality improvement project implemented an evidence-based ACH cognitive burden screening and reduction program for adults aged 60 and older ( $N=31$ ) in a south Texas LTCF to maximize cognitive function. Based on ACH medication screenings, reduction recommendations were made to prescribers for 19 residents. A three-group comparative design was used. The 3 groups included: those without recommended ACH reductions ( $n=12$ ), those with recommendations for reduction which were approved by their prescribers ( $n=11$ ) and those with recommendations which were not approved ( $n=8$ ). Cognitive function was measured with the Short-Blessed Test (SBT) and ACH use with the Anticholinergic Cognitive Burden (ACB) scale. The group with approved reduction recommendations had a decreased mean ( $M$ ) ACB score (0.73 points lower,  $p=0.233$ ) and a lower  $M$  SBT score (1.82 points lower,  $p=0.051$ ) at 60-days post-intervention when compared to pre-intervention. Overall, the 31 participants had a significant decrease in  $M$  SBT (by 1.06,  $p=0.026$ ) and a decrease in  $M$  ACB (by 0.23,  $p=0.422$ ) in the same period. Those without any ACH reduction recommendations ( $n=12$ ), were found to have a significantly increased  $M$  ACB, from 0.42 to 1.08 at the conclusion ( $p=0.013$ ). The application of an evidence-based ACB screening and reduction program decreased ACB and was associated with clinically improved cognitive function in the residents of this facility. These findings were clinically significant and may also provide useful clinical outcome data to support research into, and improvement of, prescribing practices in LTCFs.

# ANTICHOLINERGIC BURDEN SCREENING AND REDUCTION FOR OLDER ADULTS IN LONG-TERM CARE

## Introduction

The size of the United States (U.S.) elderly population is growing rapidly and is outpaced only by the number of medications they are taking. As the number of medications increases, so does the risk of adverse drug effects. Of concern, are the often-unnoticed number of anticholinergics (ACHs) given to the elderly in long-term care facilities (LTCFs). A prescribing cascade begins when new medications are erroneously given to treat adverse effects of current medications (Kalisch, Caughey, Roughead & Gilbert, 2011). Medications with ACH effects can lead to a significant decline in cognitive function, increased dementia, and potentially trigger prescribing cascades (Gill et al., 2005). There is no formal system in place to regularly evaluate and reduce anticholinergic cognitive burden (ACB) in long-term care residents. This project aims to improve quality of care in a south Texas LTCF and maximize cognitive function through the application of an ACB screening and reduction program.

The U.S. elderly population (65 years and older) is expected to more than double and account for nearly 24% of the population by the year 2060 (Population Reference Bureau, 2016). According to the National Health & Nutrition Examination Survey (NHANES) survey estimates, the number of older adults taking more than five prescribed medications has more than tripled from 12.8% in 1988, to 39.0% in 2010 (NHANES, 2012; Charlesworth, Smit, Lee, Alramadhan, & Odden, 2015). As determined by the most widely used prescribing criteria, the *Beers Criteria for Potentially Inappropriate Medication Use in Older Adults*, one of every three older adults admitted to the hospital was taking at least one inappropriate medication (Scott, Gray, Martin, & Mitchell, 2012). Inappropriate medications are drugs with risks that may possibly outweigh the benefits in this population or are no longer indicated (Scott, Gray, Martin, & Mitchell, 2012).



Another study found that 40% of U.S. nursing home patients had received at least one potentially inappropriate medication and on average, took seven different medications daily which placed them at up to an 82% increased risk of having adverse drug effects (Liu, 2014). In nursing homes specifically, one study found that 50% of residents were found to be taking more than five ACHs and 33% were taking at least two (García-Gollarte, Baleriola-Júlvez, Ferrero-López & Cruz-Jentoft, 2013; Kolanowski, Fick, Campbell, Litaker & Boustani, 2009). Medications with ACH properties have been found to be associated with a 16% increase in the development of delirium and a 14% increase in the risk for hip fracture in this elderly population (Chatterjee et al., 2016; Landi et al., 2014,).

As people age, their cholinergic neurons deteriorate, contributing to a cognitive decline (Mate et al., 2015). This deterioration of neurons is believed to be the basis for conditions such as dementia and ACH medications can further exacerbate such cognitive declines (Mate et al., 2015). These declines in cognitive function are often erroneously attributed to the progression of disease and not to the possibility of being caused by adverse drug effects due to usage of drugs such as ACHs (Mate et al., 2015). Dementia patients who take cholinergic medications, such as Aricept (donepezil) and are also taking ACHs, are at risk for reduced effectiveness of their dementia medications (Mate et al., 2015).

Anticholinergic use can result in the development of Parkinson's-like tremors, muscle rigidity, pupil dilation and decreased visual acuity, tachycardia, increased bronchial secretions, decreased gastric secretions and motility, decreased urinary output and urinary retention, confusion, hallucinations, agitation, decreased renal and hepatic clearance, and increased risk of developing dementia and Alzheimer's Disease (Hall, 2009). Therefore, the cumulative results of

these common side effects may include an increased risk for falls, increased risk of hospitalizations, initiation of antipsychotics, and increased number of medications.

Older people have altered pharmacokinetics due to their body mass composition and reduced abilities to metabolize and excrete drugs resulting in increased plasma concentrations of medications (Hall, 2009). ACH drugs can result in a further decrease in renal and hepatic clearances, resulting in a vicious cycle (Fortin et al., 2011). Recent research has focused on the effects of medications with low-level-ACH side effects and the cumulative burden thereof. Yet, there are still an estimated 600 medications with unrecognized levels of ACH properties (Fortin et al., 2011).

There is currently not a regularly scheduled, or formal evaluation process specifically focused on encouraging the reduction of ACHs in the LTCF. Instead, there are only checks in place to attempt gradual dose reductions (GDRs) of pain medications, anti-psychotics and anxiolytics. These types of medications often have some anticholinergic effects themselves, but the cumulative ACH load is not addressed. Lists of medications to avoid, such as the *Beers List*, *McLeod Criteria*, and the *Improved Prescribing in the Elderly Tool* are widely promulgated yet not widely used in a formal or very consistent manner (Scott et al., 2012). Lists such as these have a very low sensitivity and specificity and have not been shown to reduce inappropriate prescribing (Scott et al., 2012). These lists instead, are frequently used by pharmacist consultants to make recommendations to prescribers, after-the-fact, that inappropriate medications use has been identified, but again, these are not specifically focused on ACH medications (Scott et al., 2012). Current best practice involves regular medication reviews with subsequent indicated medication adjustment, but this practice is usually the least carried out (Scott et al., 2012).

The current practice in nursing homes to prevent the over-utilization of ACH drugs are lacking despite current recommendations (Scott et al., 2012). There is a clear need for improved prescribing and discontinuation, or deprescribing, practices for older adults residing in LTCFs. Anticholinergic cognitive burden is a problem that is often overlooked and can compound over time with the addition of seemingly innocuous medications. The elderly are among the frailest, and most vulnerable populations, with compromised ability to metabolize medications (Vetrano et al., 2016). A quality improvement (QI) project was undertaken to fill this clinical gap in practice by addressing unchecked ACH cognitive burden. The following PICOT (Patient population, Intervention, Comparison Intervention, Outcome, Time) question guided this QI project: Amongst those aged 60 and older, living in a South Texas LTCF, does an ACB screening and medication reduction program reduce ACB and subsequently improve cognitive function in patients whose ACH medications were reduced, as compared to residents who receive no medication reduction, from the same facility over a 60-day period? The purpose of this project was to trial an evidence-based ACB screening and reduction program in a south Texas nursing home, over a 60-day period, to maximize resident cognitive function through an ACH medication reduction protocol. If successful, the screening and reduction program would be proposed as a new clinical protocol and ideally be expanded to other facilities within the company.

This QI project implemented an evidence-based intervention to regularly and effectively evaluate ACB in long-term care residents and to maximize the reduction of described burden. In doing so, the project was primarily associated with DNP Essentials II and VI. Essential II involves organizational and systems leadership for quality improvement. Correspondingly, this project entailed the development of new programs and clinical protocols using evidence-based

interventions and evaluating practice outcomes. Essential VI involves the inter-professional collaboration for improving patient & population health outcomes. Accordingly, the project director (PD) led an inter-professional team, including nursing staff, nursing assistants, advanced practice registered nurses, physicians, and facility administrative personnel to conduct this QI project.

### **Review of the Literature**

The use of ACH drugs have been consistently associated with decreased cognitive and functional impairment. Boccardi et al. (2017) concluded that use of ACH drugs are associated with functional impairment, particularly in the elderly (>65 years) who already have some degree of cognitive impairment and minimizing ACB should result in maintaining daily functioning. Another retrospective, cross-sectional, study included 134 elderly individuals who attended memory-daycare in France and assessed the effect of drugs with ACH properties on verbal episodic memory function (Fortin et al., 2011). They concluded ACH use was associated with reduced performance on tasks which assessed verbal memory ( $p<0.05$ ). Fox et al. (2014) conducted a systematic review of literature examining 43 studies focused on cognitive function, and 60,944 participants to determine the effect of ACH use on cognitive function, delirium, physical function and mortality. In this review, 77 % of those 43 studies ( $n=33$ ) reported a statistically significant correlation between increased ACB and cognitive decline ( $p<0.05$ ). Furthermore, 65% of studies also found a decline in physical function as ACB increased (Fox et al., 2014). In a cross-sectional prospective study, Pasina et al. (2013) sought to evaluate the association between ACB and both cognitive and functional status in 1380 older adults. Cognitive status was analyzed with the Short-Blessed Test (SBT) and physical function with the Barthel Index. Anticholinergic cognitive burden was evaluated using the *ACB Scale*. They were

able to identify a dose-dependent association between ACB Scale score, cognitive impairment and the ability to perform activities of daily living (Pasina et al., 2013).

In general, all the studies found that ACH medications were associated with cognitive impairment in older adults. Minimizing ACB would increase the likelihood of maintaining daily functioning and ADLs. There is a paucity of randomly controlled trials (RCT) and a general lack of evidence related to the reduction of ACHs in this population. The study findings reviewed support that a reduction in ACB maximizes cognitive function in the elderly treated with ACHs. The purpose of this QI project was to institute a program to reduce ACHs prescribed to a group of south Texas LTCF residents, to maximize cognitive function as evidenced by decreased SBT scores.

### **Conceptual Framework**

The Iowa Model of Evidence-Based Practice to Promote Quality Care (Iowa Model) was found to be a relevant model to guide the development of this QI project. The Iowa model was based upon the earlier Everett Roger's Diffusion of Innovations theory from 1983 and was developed by a team of nurses from the University of Iowa Hospitals and Clinics (UIHC) and their College of Nursing (Buckwalter et al., 2017). It is a heuristic model which allows for exploration, and self-learning, and progress towards immediate goals in the preliminary translation of evidence into practice (Buckwalter et al., 2017). The Iowa model is a widely used, well-validated model for the development and evaluation of evidence-based practice changes to small subsets prior to the translation to larger units or other facilities (Buckwalter et al., 2017). The first step in the model identifies a trigger, or problem, in current practice and for us, this trigger was the identification of prescribing cascades, and impaired cognitive function, in long-term care residents, possibly due to the overuse of anticholinergic medications (Brown,

2014). The next step was to verify the problem as a priority and to determine if the intervention was the best use of current resources (Brown, 2014). The Project Director (PD) met with the medical director and director of nurses of the LTCF and it was determined that this project was a valuable use of resources to implement in this facility as it would place minimal strain on the staff's current workload and offer great potential benefits to residents, if successful. Management agreed to the high priority of the problem, recognizing the potential for unnecessary adverse effects upon their residents. Management also agreed to afford the resources needed to implement the QI project and if indicated, to sustain the needed program/protocol in the future.

Team development was the next step in the Iowa model. The team consisted of the PD, the director of nursing, the assistant director of nursing, the medical director, staff nurses, and attending providers. The next Iowa Model step, was to form a PICOT question, perform a literature review, and determine if the intervention was worthwhile upon critical appraisal of the existing literature (Brown, 2014). Next the project was launched as a small pilot-type program initially, before being considered for further expansion (Brown, 2014). The QI project was the pilot-tested program with intention to expand within the LTCF corporation in the form of a new clinical protocol. See the Iowa Model Conceptual Diagram, Appendix 1.

## **Methods**

### **Project Design and Specific Aims**

This QI project was conducted using a three-group comparative design. The PD evaluated the ACH medications prescribed for these residents and, based on those numbers, advocated for reduction. The PD then monitored residents for any change in cognitive function over time and compared changes in residents whose providers approved the reductions, to

residents in the same facility whose ACB score did not warrant reduction recommendations, to a third group of residents in the same facility who received an ACB score warranting recommendations but whose providers denied ACH reduction requests. The specific aims of the project were to reduce ACB and maximize cognitive function in LTCF residents in a south Texas nursing facility by: 1) observing a decrease in ACB as evidenced by a statistically significant ( $p<0.05$ ) improvement in post-intervention *M* ACB Scale score when compared to pre-intervention or a post-intervention mean score at least one point lower than pre-intervention; and 2) observing an improvement in cognitive function as evidenced by a statistically significant ( $p<0.05$ ) decreased post-intervention *M* SBT scale score when compared to pre-intervention or a post-intervention mean score at least one point lower than pre-intervention.

### **Setting**

The location for the project was a 112-bed long-term care nursing facility located in south Texas. The facility was comprised of four residential hallways, with approximately 18-28 residents per hall. Two halls were dedicated to long-term care, one to short-term post-acute rehab patients, and a fourth secure hall for residents with severe dementia. Both long-term halls were included in the project, initially totaling 41 residents (31 one at conclusion) over 60 years of age with multiple comorbidities. The two long-term halls were staffed by one licensed vocational nurse (LVN) for each hall as well as a team of three certified nursing assistants (CNA's). The facility was overseen by a physician Medical Director, the Director of Nursing (DON) and the Assistant Director of Nursing (ADON), the latter, both registered nurses. Please see Facility Letter of Support, Appendix 2.

### **Sample**

The Texas A&M University-Corpus Christi Office of Research Compliance, reviewed this quality improvement project and approved the project to proceed based on a “Not Human Subjects Research Determination.” Please see Office of Research Compliance Letter, Appendix 3. The project did not involve the collection of any identifiable information and confidentiality of the residents was maintained. All data were de-identified, reported in aggregate and stored on a secured, password protected device. All residents were included in the project if they resided in the long-term care unit, were 60 years of age or older, and were able to complete the SBT. They were excluded : if they died or were transferred during the data collection period. A total of 41 residents were initially identified for the project. Two were nonverbal or not capable of completing the SBT, one was younger than 60 years, six died during the project, and one transferred to another LTCF which left a total of 31 participants. The demographic ranged from 60 to 99 years of age, the *M* age was 84.19, 77% were female and 23% male. A table of the participants’ demographics can be found as Appendix 4. Please see a table of the breakdown of participants by group as Appendix 5.

The facility consisted of two long-term care designated hallways and initially, participants were divided into two groups by their geographic location, with one hall randomly designated as the control group (not receiving ACB reduction recommendations) and the other hall designated as the treatment group (receiving reduction recommendations). The initial response rate from the attending prescribers in the treatment group regarding the medication reduction recommendations (RRs) was poor, i.e. four residents’ ACH medications were authorized for reduction. The project was then expanded to include ACB screenings and reduction recommendations for all long-term care residents from both hallways and recommendations were then proposed for 19. The change provided for a more ethical approach,



as all those discerned as having excessive ACB would also have received RRs instead of just being observed in a control group. This change allowed for the expansion of the reduction recommendations to 19 residents, resulting in a greater number (n=11) of residents with approved ACH medication reductions.

### **Intervention**

The treatment group in this project received an ACB screen delivered by the PD. Residents were assessed using the ACB Scale to identify ACH medications which may no longer be indicated or were contributing to elevated ACB (Aging Brain Care, 2012). Prescribers were informed of the results of the screening and given recommendations for medication reductions via written correspondence in their nursing facility Inbox. Both groups were assessed for cognitive function using the SBT, every 30 days. The baseline SBT was obtained at the time the ACH discontinuation orders were placed. The second SBT evaluation was conducted 30 days later and the final SBT screening was done 60 days post intervention.

### **Data Collection**

The PD conducted the ACB screen, SBT, and collected the data to minimize threat to validity due to interrater reliability; however, having the same interviewer could have introduced a threat to internal validity. ACB scores were first collected on March 1, 2019 (*day -30*) and monthly three more times through June 1, 2019. Medication reductions were implemented on April 1, 2019 (*day 0*). The first SBT was conducted at this time (*day 0*) for all residents, the second on May 1, 2019 (*day 30*), the third was conducted 60 days post-intervention (*day 60*) on June 1, 2019. Data analysis, synthesis and conclusion development were completed in June 2019. Please see attached timeline attached as Appendix 6.

**Measurement tools.** The Short-Blessed Test (SBT), was developed by Katzman et. al., (1983), in an abbreviated form from the original 1968 version, to assess for deficits in cognitive function and dementia development. The SBT is available in the public domain without any fees or permission required by the authors and has been shown to have very good psychometric properties when used in older adults. The SBT was found to have 78.6% and 100% sensitivity and specificity, respectively, and was found to be more sensitive than the Mini-Mental State Examination (MMSE) in distinguishing mild dementia (O'Sullivan, O'Regan & Timmons, 2016). An SBT requires less than 5-minutes to conduct by a trained person. An example of the SBT can be found as Appendix 7.

To quantify the ACB, the project used the *ACB Scale* developed by the Aging Brain Program of the Indiana University Center for Aging Research (Rudolph, Salow, Angelini & McGlinchey, 2008). The scale is found in the public domain. Pasina et al. (2013) were able to identify a dose-dependent association between ACB score and cognitive impairment, with a similar population, as measured by SBT [9.2 (95 % CI 8.6-9.9) vs. 8.5 (95 % CI 7.8-9.2);  $p = 0.05$ ]. The scale lists 44 medications as level one anticholinergics, 12 as level two stronger ACH effects, and 43 as the strongest level three ACHs. Each medication adds to the cumulative ACB scale score with points added according to their level on the ACB scale. For example, a patient taking hydroxyzine (level three) and prednisone (level one) would have an ACB scale score of four.

## **Data Analysis**

Deidentified data was initially compiled into an Excel spreadsheet and results retained on a password protected secure computer. The data was then imported into Statistical Package for the Social Sciences (SPSS), version 23 for statistical analysis. Descriptive statistics were

analyzed to describe the demographics. Paired t-tests, or Students t-tests, were then conducted monthly, to determine if there were any statistically significant changes in the *M* ACB and SBT scores.

The SBT scores were analyzed for changes by groups: those without recommended ACH reductions ( $n=12$ ), those with recommendations for reduction which were approved ( $n=11$ ), those with recommendations which were denied ( $n=8$ ), and again for the entire group of residents ( $n=31$ ). Again, a paired t-test was conducted to detect any significant difference between the means of the cognitive function scores, as measured by the SBT, pre-intervention, again at 30-days and 60-days post intervention. Paired t-tests were also conducted to evaluate for any significant changes in the means of the ACB scores for these same three groups. The ACB scores were tracked at day -30, day 0 (ACH reduction day), day +30, and day +60. The data was found to be normally distributed. Effect size was calculated using *Cohen's d*. There was no missing data throughout the project, as the PD had full access to all medical records.

### **Context and Risk Assessment**

The major risks for this project were that residents would not want their medications reduced and/or that prescribers would not agree with reducing the anticholinergic medications. To mitigate the risk that patients would not want their medications reduced, participating residents were educated by the PD about the forthcoming potential medication reductions and the risks of unchecked ACB. The residents were also advised that their providers would be reviewing their medications for a possible decrease in the dose (ACB) as the medication could have unwanted side effects with a standard dose in the elderly due to slowed metabolism. All participants agreed to proposed medication reductions.

The providers/prescriber risk could have occurred if providers viewed recommendations as being critical of their prescribing practice, or over-stepping boundaries. Therefore, the providers were presented with an example of the ACB scale for reference and a written rationale for the medication reduction recommendations which were provided with recommendations. Prescribers were also provided with an educational letter describing the aims and procedures of the project prior to its inception.

Medication discontinuation introduced a level of risk for adverse events. To mitigate this risk, the nursing staff was asked to monitor patients with medication changes and report any concerns of change in resident status to the DON during morning report. If there were noted changes in status related to the medication discontinuation, the nursing staff would communicate concerns to the prescribing provider and likely the medication would revert to as originally prescribed. The risk assessment and mitigation table can be found as Appendix 8.

### **Feasibility and Preliminary Budget**

The initial costs for the project involved \$150 in travel expenses for the PD. The education of the staff was conducted on site during regularly scheduled work hours. The assessments and medication reviews were conducted by the PD, but will need to be conducted by the nursing staff and DON in the future. The budget anticipates 60 hours of labor for the DON and 60 hours for the LVNs to continue to carry out the project in the future, quarterly (\$3900/quarter). The budget can be found as Appendix 9.

### **Evaluation Model**

The Institute for Healthcare Improvement Model for Improvement (IHIM) provided a foundation for the evaluation of this DNP QI project. More specifically, the Plan-Do-Study-Act (PDSA) cycle of the IHIM was used as an evaluation model for this QI project. The first step of

the PDSA cycle was to *Plan* the test or observation including a plan for collecting data, developing an objective, and making predictions. The second step (*Do*) involved testing the QI project on a small scale, identifying problems, and beginning analysis of the data. Step 3 (*Study*) of the PDSA involved analysis of the data and interpreting results, comparing the data to predictions, summarization and reflection. The last step (*Act*), included modifying or refining the intervention based on what was learned and planning for the next test – starting the cycle again. The *Plan* and *Do* stages have been described above. The Results and Conclusions sections next in this paper continue the PDSA Evaluation process and complete the last step in the Iowa model. A flowchart of the PDSA cycle can be found as Appendix 10.

## **Results**

Twelve residents were not recommended for medication changes due to their low baseline ACB scores. For these 12, the DON had also voiced concerns that these residents had minimal ACBs and advised against any reductions due to strong perceived need for those medications, in their current conditions. Anticholinergic reductions were suggested to the prescribers for 21 residents. Of the 21 total recommendations, 11 were approved by prescribers for medication reductions and the other 10 were not approved by the prescribers. Of these 10 that were not approved, two passed away prior to project completion, leaving 8 in this *not approved* group and a final number of 19 recommendations for the project. A total of 18 different medications were approved for discontinuation amongst the 11 residents. The *M* pre-intervention ACB score was 3.63 for those 19 who received RRs and 0.43 for those 12 who did not receive RRs for their medications.

Expectedly, the *M* ACB scores decreased in those with approved ACH reduction recommendations ( $n=11$ ) after the initial 30 days. However, the magnitude of the decrease was

unexpected, as their *M* ACB fell 70% from a 3.64 ACB score to 1.09 with the initial reductions. Those with recommendations which were denied by prescribers ( $n=8$ ), revealed a *M* ACB score rise of 10.19% from a 3.63 ACB score, to 4.00 in the same period, indicating a slight elevation of ACHs since initially assessed ( $p=0.08$ ). Those without any RRs ( $n=12$ ) had no change in their *M* ACB scores, of 0.42, during this initial 30-day period. It should be noted that the group with approved ACH RRs began with the highest ACB scores. The higher number of ACH medications likely influenced the providers' approval of these reductions and although it may be seemingly limiting, reducing elevated levels of ACB was the intent of the program.

Overall, there was a lasting decrease in the *M* ACB observed from the initial observation amongst the intervention group, those with approved ACH RRs ( $n=11$ ), from 3.64 (30 days pre-intervention) to 2.91 sixty days post-intervention ( $p=0.233$ ). Those with denied ACH RRs ( $n=8$ ) saw their *M* ACB decrease from 3.63 initially, to 2.75 at conclusion ( $p=0.111$ ). Those without any ACH RRs made ( $n=12$ ), were found to have increased *M* ACB from 0.42 to 1.08 at the conclusion ( $p=0.013$ ). The group, as a whole ( $n=31$ ), also saw the *M* ACB score remain lower at the conclusion, decreasing from 2.39 to 2.16 ( $p=0.422$ ) for this same 90-day period. Please see a chart of *M* ACB scores over time as Appendix 11.

The SBT scores in those with approved ACH RRs ( $n=11$ ), had a *M* SBT decrease (lower is better), of 1.82 from 17.09 (at day 0), down to 15.27 sixty days post-intervention ( $p=0.051$ ). Surprisingly, those with denied RRs ( $n=8$ ) also saw a 1.87 decrease in *M* SBT, from 18.00 to 16.13, during this time ( $p=0.04$ ). The group without any RRs ( $n=12$ ), exhibited a slight increase from 24.00 to 24.17 ( $p=0.806$ ) during this time. The entire group (of  $n=31$ ) saw statistically significant decrease (1.06 points) in *M* SBT from 20.00 to 18.94 during the program ( $p=0.026$ ). Please see the chart of *M* SBT scores changes as Appendix 12.

The changes amongst all groups, for both *M* ACB and *M* SBT, were analyzed using Cohen's *d* for effect size. The effect size of the *M* SBT decrease, in the group with approved RRs from day zero to 60 days post-intervention, was medium ( $d=0.67$ ). The group without RRs reflected a large effect size ( $d=0.86$ ), regarding the increase of the *M* ACB by conclusion.

The first specific aim of this project was to identify a post-intervention *M* ACB Scale score for the intervention (approved RRs) group of at least one point lower ( $p<0.05$ ) than pre-intervention. The aim was not met as the decrease of 0.73 points (ACB score) fell short of the one-point goal. However, this improvement was clinically significant as every one-point increase in ACB scale score, has been associated with both a 0.33 decline in MMSE score in just 2 years and also a 26% increased risk of death (Fox et al., 2011).

The second aim was not met as the 1.82 points decrease in *M* SBT scores for the intervention group (approved RRs) was not statistically significant ( $p=0.051$ ). Overall, the 31 participants collectively saw a significant 1.06-point decrease in the *M* SBT ( $p=0.026$ ). A table of the results, depicting the changes in *M* ACB and changes in *M* SBT can be found as Appendix 13 and Appendix 14, respectively.

**Unintended findings.** From March 1<sup>st</sup>, 2019 through May 31<sup>st</sup>, 2019, there were 15 fall incidents in the LTCF. The group without RRs experienced 6 falls, those with denied RRs had 8, and those with approved recommendations had one fall. There were 3 urinary tract infections recorded during the 90-day project with one infection in each group. Please see Appendix 15 for a chart illustrating the number of resident falls during the project timeframe.

## Discussion

In accordance with step 3 (*Study*) of the PDSA, the following sections relate to the analysis of the data, interpreting results, comparing the data to predictions, summarization and

reflection. The project did not identify a statistically significant decrease in the *M* ACB scores of those who received RRs but did identify a statistically significant increase in ACB scores in those who were not identified as having elevated ACB initially and did not receive any RRs. The overall ACB scores for the facility did decrease over the course of the project. While the overall ACB decrease for the facility was not statistically significant, it was clinically significant as there was an increased awareness of the potential for increased ACB amongst the interdisciplinary team, including the providers. This increased awareness was likely a factor in the other ACB reductions that were seemingly unprovoked, not suggested, or made after initial requests were denied to begin with, as the group with denied recommendations ( $n=8$ ) *M* ACB fell 24% by the conclusion of the project. According to the literature reviewed for this project, the reduction of the number of medications being given to these residents potentially reduced their risk for adverse drug effects, risk of drug-to-drug interactions, drug-disease interactions, cost of care, medication pill burden, and burden of the medication administration staff (Lui, 2014; Mate et. al., 2015).

The results from this project provide potential for overall improved cognitive function, prescribing practices and quality of life of the residents in this south Texas facility; while also reducing the cost of care, the number of unnecessary hospitalizations, and the incidence of prescribing cascades. In accordance with the final step in the Iowa model, the results have been presented to local facility administration and are being considered for integration into the LTCF policies and promulgated for utilization in a larger number of LTCFs within the same corporation. Continued improvements in resident cognitive function using this protocol may provide critical data to convince key stakeholders to advocate for future state and federal legislation to make this type of screening mandatory for Medicare recipients in LTCFs.



There was some difficulty in retrieving completed medication *reduction recommendations* (RRs) from the treating providers. Some of the forms were returned and signed but many were left blank. These initial responses did not specify any agreement or disagreement with recommendations. The forms were then rewritten to include a simpler, faster, dichotomous check-box style response in which the provider could quickly sign the form and check a single box to carry out their orders – instead of having to hand-write directions. This change brought a better response rate of 90% with just 4 recommendations being returned unfilled and unsigned from a new physician who declined to participate in medication reviews.

In accordance with the *Act* phase of the PDSA evaluation model, the PD plans to revisit the facility 120 days post-intervention (August 2019) to re-evaluate the population again using the same SBT and ACB scale for monitoring and refinement. At this point, in August 2019, the facility is considering permanently incorporating the program, beginning the PDSA cycle once again.

### **Limitations**

The threat to internal validity of testing exists, as the same SBT was utilized every 30 days and may have sensitized the participants. The threat of statistical regression remains, as the providers agreed to a reduction in ACHs for those with higher initial ACBs -although this was the intent of the project. The small sample size (n=31) and single location limits the statistical power of findings; however, this project helped to identify methods that could be tested and adopted across several sister facilities of this corporation, with a larger sample size. The possible threat to internal validity due to interrater reliability of instrumentation was mitigated by having a single rater conduct all assessments. However, the PD served as this single rater which may have increased potential for biased observation. The PD reviewed medications and made

reduction recommendations in conference with the DON as a courtesy, as she was a key stakeholder in the success of this project, but the attending providers made the ultimate decision to adjust the patient medications, as they were the prescribers. The staff nurses were independently tasked with observation of the patient response to the medication changes and often relayed patient requests to re-start many medications.

Another limitation identified was that the ACB scale did not take into consideration the daily dose of medications (total daily dose based on frequency). “As needed” or “PRN” medications were only included in initial ACB score if they were administered to the resident in the previous 30 days. The facility changed ownership during the project and also changed from paper charts to electronic medical records (EMRs). The change to EMRs made data collection easier but did disrupt the initial data collection procedures. In the future, it would be very useful to have an ACB screening program built into the EMR. For instance, the providers would benefit from a *live* ACB score at the top of each patient’s medication list, constantly updated as medications are added or removed. Such a feature could also be programmed to regularly prompt the provider to perform ACH reductions.

The definition of elderly is traditionally defined as those 65 years and older. However, this project included all residents 60 and older to maximize the sample size. Forty of the initial 41 long-term care residents identified for the study were 60 or older. There were 3 persons under 65 included; one age 60 with denied RRs, one age 62 with approved RRs, and one age 64 without any recommendations. This age group, 60 years and older, represents 97.5% of the long-term care population in this facility. This QI project included a wide range of ages, from 60 to 99 year of age, but the *M* was skewed towards the upper range at 84.19, possibly affecting

results -as younger residents could have skewed data as they may have been more resilient to the adverse effects of medications (Fox et al., 2014).

### **Conclusion**

This project was successful in increasing the screening of ACHs in one institution and raised awareness amongst the nursing home staff, including the physicians and nurse practitioners, of the risks associated of ACH use in older adults. The project was clinically successful in reducing the *M* ACB score of all participants by 9.62% overall, and by 20% in the group where prescribers agreed to decrease ACH medications (ACB day -30 to ACB day +60). Despite the small sample size of this quality improvement project, an association between anticholinergic use and cognitive function was noted, as was supported by the literature reviewed prior to the initiation of this project. There was also an overall improvement in cognitive function as evidenced by the decrease in *M* SBT scores by 5.3% overall, and by 10.65% in those who received the ACB reductions at conclusion.

The results are very promising for this LTCF in south Texas and indicate potential room for improvement in the care of this corporation's residents. Given the promising results of this QI project, a greater QI project is warranted in a larger number of the corporation's facilities, to determine if cognitive improvement results can be duplicated and if it would be sustainable. The decreases in these vulnerable resident's SBT scores and decreases in ACB scores should compound into greater and more significant changes in a larger population or over a longer period.

After completion of this project, on June 25<sup>th</sup>, 2019, the Journal of the American Medical Association published an article detailing anticholinergic drug exposure and the risk of dementia in 3,638,582 individual records of adults aged 55 to 100 years. The study found that these older

adults taking a minimal daily dose of a single strong anticholinergic, for just 3 years, had nearly 50% increased odds (1.06 to 1.49) of developing dementia, as compared to those without similar recent use (Coupland, Hill, Denning, Morriss, Moore & Hippisley-Cox, 2019).

In summary, the decrease in ACB that was accomplished by this quality improvement project, while lacking statistical power is clinically significant, very promising and highlights the room for improvement in prescribing practices and the need for increased screening in this south Texas LTCF. The preservation, or improvement, of cognitive function in these residents after a medication change could be life changing for them and their loved ones. This quality improvement project underscores the importance of monitoring prescribing practices in the future to ensure they are based on the most recent literature available. The application of available evidence regarding the use of ACB screening and resulting recommendations for reduction in ACH medications have proven useful in improving cognitive burden and function in the residents of this facility. These findings may also provide useful clinical outcome data to support further research into, and improvements, of prescribing practices in long-term care.

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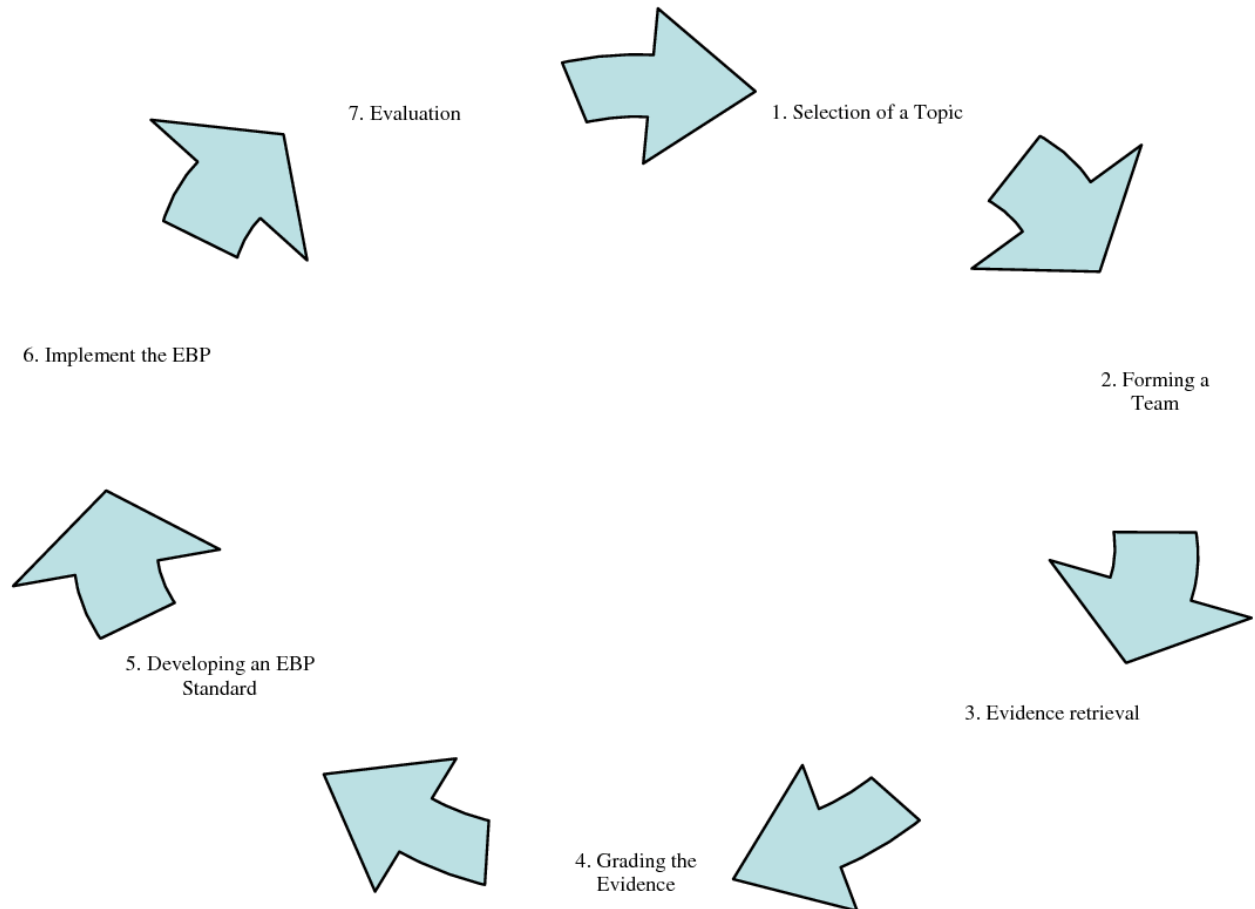
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## APPENDIX 1: The Iowa Model Conceptual Framework



The Iowa Model served as the conceptual framework for the QI project, guiding the development and implementation of the processes.

## APPENDIX 2: Letter of Support

12/3/18

Dr. Yolanda Keys  
Associate Dean for Academic Programs  
College of Nursing and Health Sciences  
Texas A&M University – Corpus Christi  
6300 Ocean Drive  
Corpus Christi, TX 78412

Dear Dr. Keys,

The purpose of this letter is to provide Derek Arredondo, a Doctor of Nursing Practice student at Texas A&M University College of Nursing and Health Sciences, support in conducting a quality improvement project at River Ridge. The Quality Improvement Project aims to increase screening for anticholinergic burden in south Texas long-term care Residents in order to preserve and improve cognitive function.

The purpose of this project is to implement and evaluate an anticholinergic screening and reduction program over a period of 90 days. River Ridge was selected for this project because of Mr. Arredondo's previous experience with the high standards and the leadership's desire for constant quality improvement. Derek Arredondo is not employed at this institution but does have an interest in improving care at this facility.

I, Jennifer Quinn, Director of Nursing at River Ridge do hereby fully support Derek Arredondo in the conduction of this quality improvement project for the spring of 2019.

Sincerely,



Jennifer Quinn, RN, DON

## APPENDIX 3: Office of Research Compliance Letter



TEXAS A&M UNIVERSITY  
CORPUS CHRISTI

OFFICE OF RESEARCH COMPLIANCE  
Division of Research, Commercialization and Outreach  
6300 OCEAN DRIVE, UNIT 5844  
CORPUS CHRISTI, TEXAS 78412  
O 361.825.2497

Human Subjects Protection Program

Institutional Review Board

DATE: January 2, 2019  
TO: Theresa Garcia, Nursing and Health Sciences  
CC: Derek Arredondo, Student  
FROM: Office of Research Compliance  
SUBJECT: Not Human Subjects Determination

Activities meeting the DHHS definition of research or the FDA definition of clinical investigation and involves one or more human subjects are subject to IRB review and approval.

On January 2, 2019, the Texas A&M University-Corpus Christi Institutional Review Board reviewed the following submission:

Type of Review:	Not Human Subjects Determination
Title:	Screening for Anticholinergic Burden in South Texas Long-Term Care Residents to Improve Cognitive Function
Project Lead:	Theresa Garcia
IRB ID:	NHS 51-18
Funding Source:	None
Documents Reviewed:	Arredondo - 600.02 Form, Not Human SRR v2 Arredondo - 600.02 Template, QIP, v3 121618 Arredondo LOS DNP

Texas A&M University-Corpus Christi Office of Research Compliance determined that the proposed activity does not meet the DHHS definition of research or the FDA definition of a clinical investigation.

Therefore, **this project does not require IRB approval.** You may proceed with this project.

This determination applies only to the activities described in the documents reviewed. **Any planned changes require submission to the IRB to ensure that the research continues to meet criteria for a non-human subject research determination.**

Please do not hesitate to contact me with any questions at [irb@tamucc.edu](mailto:irb@tamucc.edu) or 361-825-2497.

Respectfully,

Rebecca Ballard,  
JD, MA, CIP

Digitally signed by Rebecca  
Ballard, JD, MA, CIP  
Date: 2019.01.02 10:08:46  
-06'00'

Rebecca Ballard, JD, MA, CIP  
Director, Research Compliance  
Division of Research, Commercialization and Outreach

## APPENDIX 4: Demographics

Table 1

*Participant Demographics*

Demographic	Value	Units
Participants	31	Residents
Male	22.58	%
Female	77.42	%
Minimum Age	60	Years
Maximum Age	99	Years
Mean Age	84.19	Years

## APPENDIX 5: Groups: By Anticholinergic Reduction Recommendation

Table 2

*Number of residents with anticholinergic reduction recommendations (RRs) made to the treating prescribers*

Reduction Recommendations Made	Number	Percent
No	12	38.7 %
Yes	19	61.3 %
Total	31	100%

Table 3

*Three groups for comparison: By outcomes of anticholinergic reduction recommendations (RRs) made to prescribers*

Outcome	Number	Percent
Not Approved	8	25.8%
Approved	11	35.5%
<i>None made</i>	<i>12</i>	<i>38.7%</i>
Total	31	100%

## APPENDIX 6: Time Line

Table 4

*Timeline for Quality Improvement Project completion*

<b>Task</b>	<b>Date</b>
Project proposal development	September 2018
Preliminary discussion with facility stakeholders	October 2018
Proposal meeting with facility stakeholders	December 2018
Population assessment and group assignment	December 2019
Training of staff	December 2019
Meet Medical Director to discuss reduction	January 2019
Data collection begins	February 2019
ACB pre-assessment (ACB -30)	March 1, 2019
Recommendation sheets to treating providers	March 1, 2019
Revised recommendation sheets to providers	March 15, 2019
Orders received from treating providers	April 1, 2019
ACB assessment #2 (ACB 0) & SBT #1	April 1, 2019
ACB assessment #3 (ACB +30) & SBT #2	May 1, 2019
ACB assessment #4 (ACB +60) & SBT #3	June 1, 2019
Data collection ends, analysis begins	June 2019
Data synthesis and conclusion development	June 2019
Completion of capstone project analysis paper	June 28, 2019
Publication	August 2019

## APPENDIX 7: The Short-Blessed Test

Patient: \_\_\_\_\_  
Age: \_\_\_\_\_

DATE: \_\_\_\_\_

### Short Blessed Test (SBT)<sup>1</sup>

"Now I would like to ask you some questions to check your memory and concentration. Some of them may be easy and some of them may be hard."

- |                                |                |                  |
|--------------------------------|----------------|------------------|
| 1. What year is it now? _____  | Correct<br>(0) | Incorrect<br>(1) |
| 2. What month is it now? _____ | Correct<br>(0) | Incorrect<br>(1) |

Please repeat this name and address after me:

John Brown, 42 Market Street, Chicago  
John Brown, 42 Market Street, Chicago  
John Brown, 42 Market Street, Chicago

(underline words repeated correctly in each trial)  
Trials to learning \_\_\_\_\_ (can't do in 3 trials = C)

Good, now remember that name and address for a few minutes.

- |                                                                                                                                                                                  |                |                  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|------------------|
| 3. Without looking at your watch or clock, tell me about what time it is.<br>(If response is vague, prompt for specific response)<br>(within 1 hour) _____<br>Actual time: _____ | Correct<br>(0) | Incorrect<br>(1) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|------------------|

- |                                                                                                                                                                                 |              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
| 4. Count aloud backwards from 20 to 1<br>(Mark correctly sequenced numerals)<br>If subject starts counting forward or forgets the task, repeat instructions and score one error | 0 1 2 Errors |
| 20 19 18 17 16 15 14 13 12 11<br>10 9 8 7 6 5 4 3 2 1                                                                                                                           |              |

- |                                                                                                                                                                                                                                   |              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
| 5. Say the months of the year in reverse order.<br>If the tester needs to prompt with the last name of the month of the year, one error should be scored<br>(Mark correctly sequenced months)<br><br>D N O S A JL JN MY AP MR F J | 0 1 2 Errors |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|

- |                                                                                                                                                                                          |                    |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| 6. Repeat the name and address I asked you to remember.<br>(The thoroughfare term (Street) is not required)<br>(John Brown, 42 Market Street, Chicago)<br><br>_____, _____, _____, _____ | 0 1 2 3 4 5 Errors |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|

Check correct items

USE ATTACHED SCORING GRID & NORMS

<sup>1</sup> Katzman R, Brown T, Fuld P, Peck A, Schechter R, Schimmel, H. Validation of a short orientation-memory concentration test of cognitive impairment. Am J Psychiatry 140:734-739, 1983.

(Katzman, Brown & Fuld, 1983).



## APPENDIX 8: Risk Assessment and Mitigation Table

Table 5

*Risk Assessment and Mitigation Table*

	Risk 1	Risk 2	Risk 3	Risk 4
Risks	Resident reluctance for discontinuation	Provider reluctance for discontinuation	Interrater Bias	Adverse effects of discontinuation
Intervention	Education was effective	Education was effective	Single rater	Nursing staff monitoring and reporting processes.

## APPENDIX 9: Budget

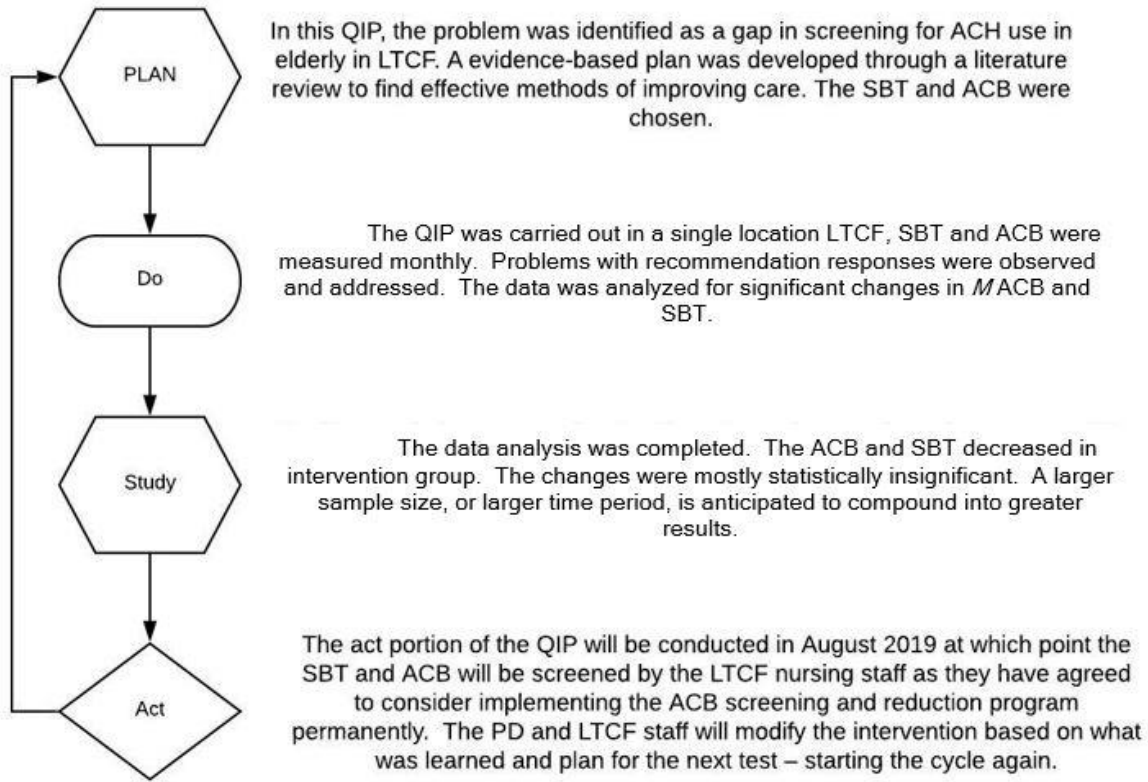
Table 6

*Budget for Scholarly Project and Anticipated Ongoing Quality Improvement Program*

<b>One-Time Costs</b>	<b>Dollars</b>
PD Travel to and from facility (Gas and mileage)	150
Assessments and med reviews (PD time: 60 hrs x \$0)	0
Other – use of questionnaire tool	0
<i>Total Initial Costs</i>	150
<b>Capital Cost</b>	
Equipment- conference room, utilities and video (no cost - facility)	0
<i>Total Capital Costs</i>	0
<b>Quarterly Ongoing Costs</b>	
Medication Review Specialist – (DON time: 60 hrs x \$40/hr)	2400
Assessments and med reviews - (LVN time: 60 hrs x \$25/hr)	1500
Other: Copying questionnaire	10
<i>Total Initial Costs</i>	<b>150</b>
<i>Total Quarterly Ongoing Costs</i>	<b>3910</b>

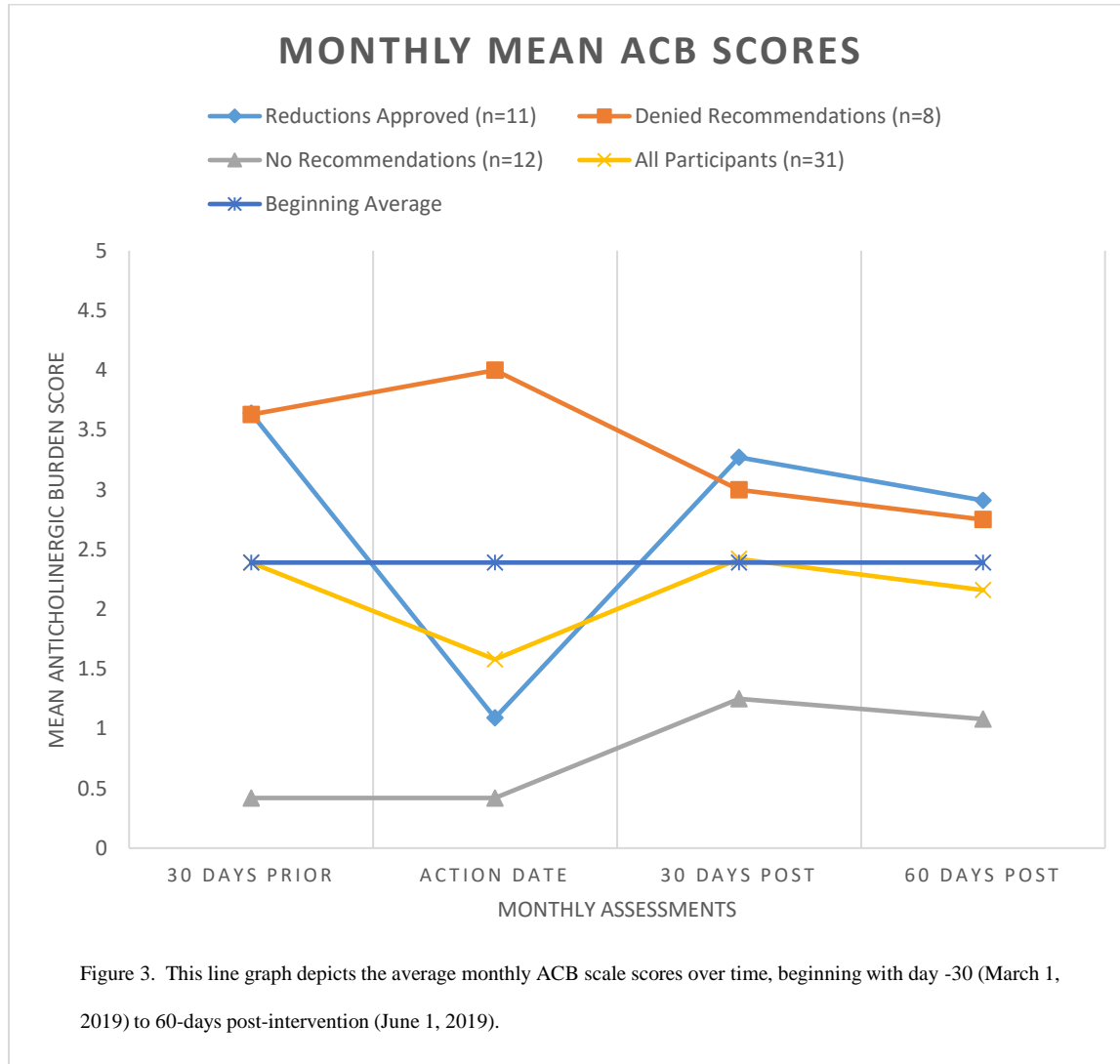
## APPENDIX 10: The Plan Do Study Act Cycle

Figure 2: The Plan Do Study Act Cycle



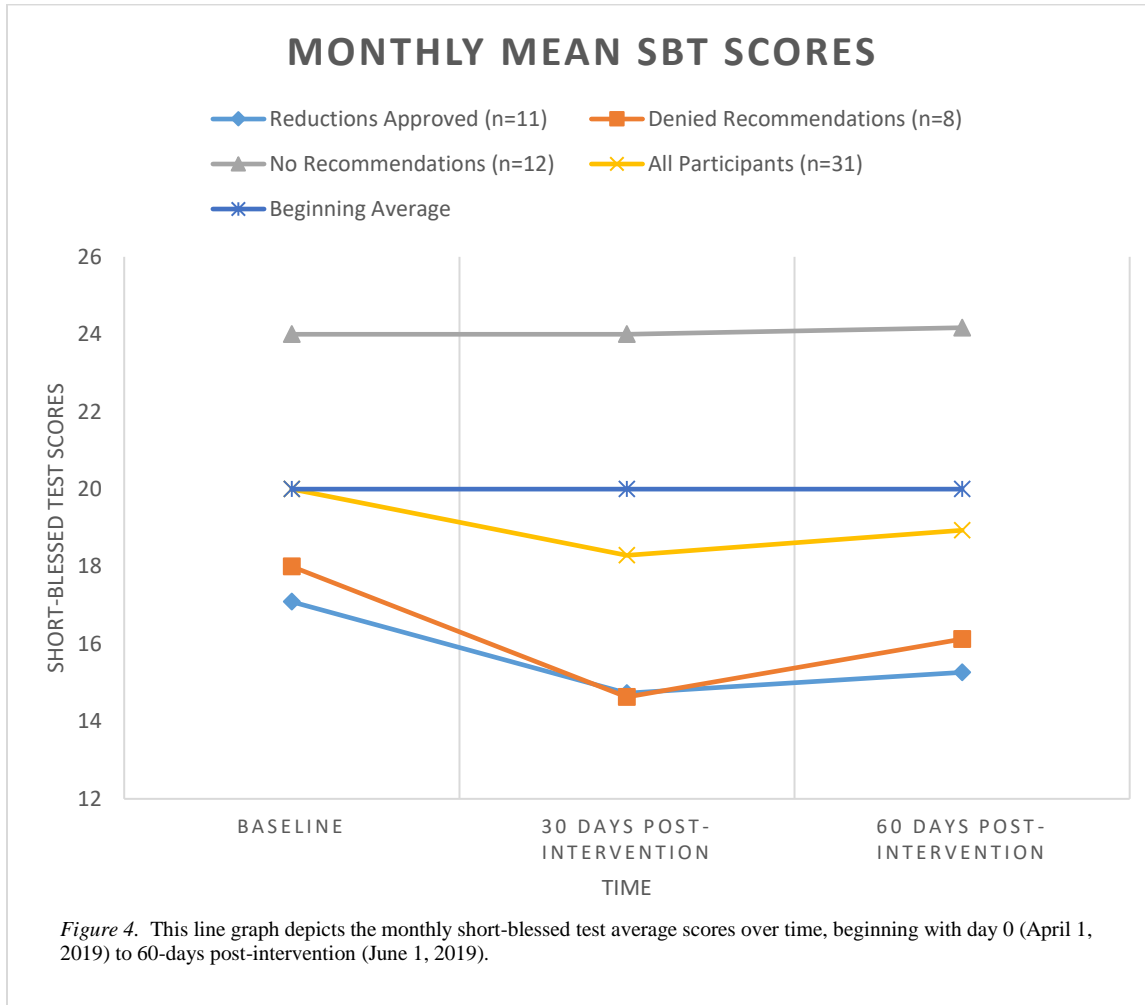
## APPENDIX 11: Anticholinergic Cognitive Burden Scale Scores

Figure 3: Anticholinergic Cognitive Burden Scale Scores



## APPENDIX 12: Short-Blessed Test Scores

*Figure 4: Short-Blessed Test Scores*



# APPENDIX 13: ACB Results Table

Changes in Mean Anticholinergic Cognitive Burden (ACB) Scale Scores, Over Time, By Group

Table 7

## *Without any Anticholinergic Medication Reduction Recommendations (n=12)*

	Beginning Mean ACB	Ending Mean ACB	Mean ACB Change	SD	Sig (2- tailed)	Cohen's d
Day -30 to Day 0	0.42	0.42	0	*	1.00	0.00
Day 0 to Day 30	0.42	1.25	0.83	0.84	0.005	0.99
Day 30 to Day 60	1.25	1.08	-0.17	0.84	0.504	0.20
Day -30 to Day 60	0.42	1.08	0.67	0.78	0.013	0.86

\*Could not be calculated because the standard error of the difference is zero.

## *Approved Anticholinergic Medication Reduction Recommendations (n=11)*

	Beginning Mean ACB	Ending Mean ACB	Mean ACB Difference	SD	Sig (2- tailed)	Cohen's d
Day -30 to Day 0	3.64	1.09	-2.55	1.44	0.00	1.77
Day 0 to Day 30	1.09	3.27	2.18	1.60	0.001	1.36
Day 30 to Day 60	3.27	2.91	-0.36	1.03	0.267	0.62
Day -30 to Day 60	3.64	2.91	-0.73	1.90	0.233	0.38

## *Disapproved Anticholinergic Medication Reduction Recommendations (n=8)*

	Beginning Mean ACB	Ending Mean ACB	Mean ACB Difference	SD	Sig (2- tailed)	Cohen's d
Day -30 to Day 0	3.63	4.00	0.38	0.52	0.080	0.72
Day 0 to Day 30	4.00	3.00	-1.00	1.77	0.155	0.56
Day 30 to Day 60	3.00	2.75	-0.25	0.71	0.351	0.35
Day -30 to Day 60	3.63	2.75	-0.88	1.36	0.111	0.65

## *All Participants (n=31)*

	Beginning Mean ACB	Ending Mean ACB	Mean ACB Difference	SD	Sig (2- tailed)	Cohen's d
Day -30 to Day 0	2.39	1.58	-0.81	1.58	0.008	0.51
Day 0 to Day 30	1.58	2.42	0.84	1.85	0.017	0.45
Day 30 to Day 60	2.42	2.16	-0.26	0.86	0.103	0.30
Day -30 to Day 60	2.39	2.16	-0.23	1.54	0.422	0.15

# APPENDIX 14: SBT Results Table

Changes in Mean Cognitive Function as Measured by the Short-Blessed Test (SBT), Over Time,  
By Group

Table 8

## *Without any Anticholinergic Medication Reduction Recommendations (n=12)*

	Beginning Mean SBT	Ending Mean SBT	Mean SBT Change	SD	Sig (2- tailed)	Cohen's d
Day 0 to Day 30	24	24	0.00	4.05	1.00	0.00
Day 30 to Day 60	24	24.17	0.17	2.66	0.832	0.06
Day 0 to Day 60	24	24.17	0.17	2.29	0.806	0.07

## *Approved Anticholinergic Medication Reduction Recommendations (n=11)*

	Beginning Mean SBT	Ending Mean SBT	Mean SBT Change	SD	Sig (2- tailed)	Cohen's d
Day 0 to Day 30	17.09	14.73	-2.36	3.3	0.039	0.72
Day 30 to Day 60	14.73	15.27	0.55	2.91	0.548	0.20
Day 0 to Day 60	17.09	15.27	-1.82	2.71	0.051	0.67

## *Disapproved Anticholinergic Medication Reduction Recommendations (n=8)*

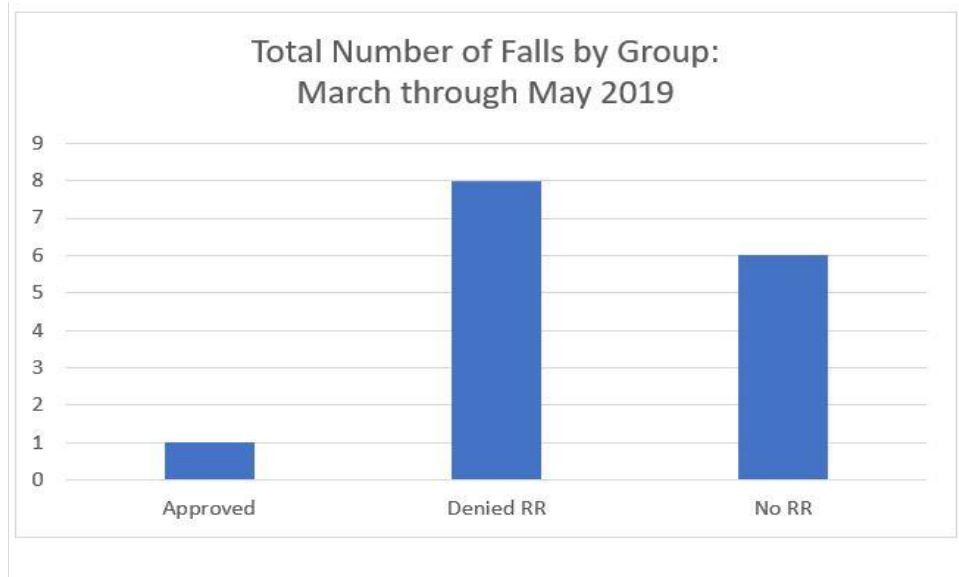
	Beginning Mean SBT	Ending Mean SBT	Mean SBT Change	SD	Sig (2- tailed)	Cohen's d
Day 0 to Day 30	18	14.63	-3.38	2.56	0.007	1.32
Day 30 to Day 60	14.63	16.13	1.5	1.69	0.04	0.89
Day 0 to Day 60	18	16.13	-1.88	2.1	0.04	0.89

## *All Participants (n=31)*

	Beginning Mean SBT	Ending Mean SBT	Mean SBT Change	SD	Sig (2- tailed)	Cohen's d
Day 0 to Day 30	20	18.29	-1.71	3.64	0.014	0.47
Day 30 to Day 60	18.29	18.94	0.65	2.52	0.165	0.26
Day 0 to Day 60	20	18.94	-1.07	2.53	0.026	0.42

## APPENDIX 15: Number of Falls by Group Chart

*Figure 5: Number of Participant Falls*



*Figure 5:* This chart depicts the total number of falls, amongst participants, from the month of March 1, 2019 through May 31, 2019, by groups. *Approved* = participants with approved medication reduction recommendations. *Denied RR*= participants with recommendations which were not approved. *No RR* = participants without any medication reduction recommendations made.