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TRENDS IN HEALTH OUTCOMES BEFORE AND AFTER LONG TERM CARE
FEDERAL REGULATIONS LIMITED ANTIPSYCHOTIC MEDICATION USE: A
SECONDARY DATA ANALYSIS

A Dissertation

Submitted to the School of Nursing

Duquesne University

In partial fulfillment of the requirements for
the degree of Doctor of Philosophy

By

Karen Robson

August 2022

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Karen Robson

2022

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FEDERAL REGULATIONS LIMITED ANTIPSYCHOTIC MEDICATION USE: A
SECONDARY DATA ANALYSIS

By

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ABSTRACT

TRENDS IN HEALTH OUTCOMES BEFORE AND AFTER LONG TERM CARE FEDERAL REGULATIONS LIMITED ANTIPSYCHOTIC MEDICATION USE: A SECONDARY DATA ANALYSIS

By

Karen Robson

August 2022

Dissertation supervised by Linda Garand PhD, RN, GCNS-BC

Despite a boxed warning and subsequent regulations restricting its use, antipsychotic medications (APMs) are administered in long-term care facilities (LTCFs) to address neuropsychiatric symptoms (NPS) associated with dementia. The first manuscript (Chapter One) is the study proposal outlining the importance of investigating health outcomes in LTCFs associated with APM use. The second manuscript (Chapter Two) details the results of the quantitative, descriptive, retrospective study exploring trends in falls, falls with major injury (fractures), mobility (independent transfers), and urinary continence after LTCF regulations restricted APM use. The approved final manuscript will be submitted to the *Journal of Nursing Informatics* for publication consideration.

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Chapter One: Study Proposal

Specific Aims

Antipsychotic medications (APMs) are contraindicated for the health of older adults. When administered to older adults, APMs are associated with adverse health outcomes including, but not limited to falls, fractures, and increased mortality (French et al., 2007; Huybrechts et al. 2011; Oliveria et al., 2006; Van Doorn et al., 2003). Yet, healthcare providers often administer APMs to long-term care facility (LTCF) residents demonstrating neuropsychiatric symptoms associated with dementia (Gustafsson et al., 2013). Due to the negative effects on older adults, federal regulations were enacted in 2011 to reduce the inappropriate use of APMs in LTCF residents with dementia [Department of Health and Human Services (HHS), Office of Inspector General (OIG), 2011].

The proposed study contributes to the literature by examining adverse health outcomes associated with APM use among United States (U.S.) LTCF residents before and after federal regulations restricted the use of APMs for residents with dementia. Specifically, the proposed study was designed to extend the literature by comparing rates of falls, falls with major injury (fractures), functional decline (change in transfer status) and urinary continence among LTCF residents in 2011 (when the regulations were initially enacted) and ten years after the LTCF regulations prohibited the APM use for residents with dementia (in 2021). Secondary analysis of aggregate, quarterly LTCF assessment data (Minimum Data Set or MDS 3.0) was used to conduct the study.

Study Primary Aims:

1. Determine if there is a significant reduction in the number of falls among LTCF residents after the 2011 federal regulations were enacted.

H1: There will be a significant reduction in the number of falls among residents after the 2011 federal regulations were enacted.

2. Determine if there is a significant reduction in the number of falls with major injury (fractures) among LTCF residents after the 2011 federal regulations were enacted.

H2: There will be a significant reduction in the number of fractures among residents after the 2011 federal regulations were enacted.

3. Determine if there is a significant reduction in functional decline (increase in independent transfer status) among LTCF residents after the 2011 federal regulations were enacted.

H3: There will be a significant reduction in functional decline (increase in independent transfer status) among LTCF residents after the 2011 federal regulations were enacted.

4. Determine if there is a significant reduction in incontinence (increase in continence) among LTCF residents after the 2011 federal regulations.

H4: There will be a significant reduction in incontinence (increase in continence) among LTCF residents after the 2011 federal regulations were enacted.

Over the past two decades, studies show that APM use in US federally-funded LTCFs has diminished, yet no studies have located describing if the 2011 federal regulations

resulted in improved health outcomes. With the aging population, and the projected high rates of dementia (Shih et. al., 2014), it was important to determine if the 2011 federal regulations related to inappropriate APM use in LTCFs have had a positive impact on the health of LTCF residents. Quality standards, such as the elimination of inappropriate resident medications, must be evaluated as LTCFs strive to become high reliability organizations.

Significance

The risk of dementia increases with age. This is significant as the United States population age 65 years and older is anticipated to increase from 58 million in 2021 to 88 million in 2050 (Alzheimer's Association, 2022). Approximately 75% of older adults age 80 years and older with dementia reside in a long-term care facility (LTCF) (Alzheimer's Association, 2022). More than 80% of residents with dementia in LTCFs exhibit neuropsychiatric symptoms (NPS) including agitation, aggression, apathy, and irritability (Zuidema et al. 2007). APMs are inappropriately prescribed to manage NPS in older adults with dementia in U.S. LTCFs [Centers for Medicare and Medicaid Services (CMS), 2022].

The Omnibus Budget Reconciliation Act (OBRA)

The Omnibus Budget Reconciliation Act of 1987 is known as the Federal Nursing Home Reform Act or OBRA. OBRA created a set of minimum standards of care and rights for people living in CMS-certified nursing facilities in the US. The changes OBRA brought to nursing home care are enormous. One of the quality standards OBRA addressed is the freedom from unnecessary medications and chemical restraints (Long Term Care Community Coalition, 2012). APMs are included in OBRA regulations since

APMs are often inappropriately used for the treatment of NPS among residents with dementia and the serious adverse effects associated with APM use with older adults (Gurvich & Cunningham, 2000).

U.S. Food and Drug Administration (FDA)

The U.S. Food and Drug Administration (FDA) (2005) identified an association between mortality and atypical APM use among older adults suffering from dementia. According to placebo-controlled trials, administration of APMs to older adults with dementia was associated with higher mortality rates secondary to cardiac events (heart failure or sudden death) or infections (predominantly pneumonia). When the FDA has determined an approved drug may produce severe or life-threatening risks, the drug manufacturer is required to include a boxed warning (previously referred to as a black-box warning) on the drug label. The purpose of the boxed warning is to alert prescribers and consumers of the risk associated with the drug. In April 2005, the FDA (2005) required manufacturers of atypical antipsychotics to include the boxed warning regarding the known risk of mortality when APMs are used to address behavioral disorders in older adults with dementia.

Office of the Inspector General (OIG) Regulations

Six years after the FDA boxed warning, the Office of the Inspector General (OIG) (2011) conducted a study that showed an increased risk of death associated with both typical and atypical APM use among older adults in LTCFs. The FDA (Boxed Warning) and OIG studies led the OIG Department of Health and Human Services (2011) to enact regulations to specifically prevent the inappropriate use or misuse of APMs in older adults with dementia residing in federally-funded LTCFs. Four-years after the 2011 OIG

regulations were enacted, the U.S. Government Accountability Office (2015) reported that approximately one-third of residents with dementia and residing in a LTCF for greater than 100 days were inappropriately prescribed an APM. In 2022, CMS reported that the use of APMs in LTCF residents with dementia decreased from approximately 24% of the residents in 2011 to 14.4% of the residents in 2021 and some regions demonstrated greater than a 45% reduction in APM use (CMS, 2022). Despite the decline in APM prescriptions since 2011, the use of the inappropriate agents continues.

APMs and Falls among LTCF Residents with Dementia

The American Geriatrics Society (AGS) Beers Criteria® (2019) identifies APMs as potentially inappropriate medications (PIM) for use with older adults due to a strong relationship between APM use and falls and fracture (AGS, 2019). The increased risk for falls is supported by a large literature demonstrating that both conventional and atypical APMs increase the risk of falls among older adult (Frenchman, 2005; Galik et al., 2018; Van Doorn et al., 2003; Wei et al., 2017) and veterans residing in U.S. LTCFs (French et al. 2007).

A comparison of two different atypical APMs (risperdal or olanzapine) showed an equally increased risk for falls among residents receiving either of these medications (Fontaine et al., 2003). However, Frenchman (2005) noted a significant increase in injury due to falls among residents receiving olanzapine, compared to those receiving risperidone. When the dose APM was considered, one study showed that LTCF residents with dementia are at increased risk for falls the first 24-hours after initiating a low dose of conventional or atypical APM, but not by increasing the dosage (Berry et. al., 2016).

When residents are prescribed psychotropic medications (APMs, anti-anxiety, mood stabilizing, or antidepressants), they fall more than residents not prescribed these medications (Thapa et al. 1995; kat et al., 2017). There is no difference in resident fall rates when different types of psychotropic medications were compared in some studies (Galik et al., 2018; Thapa et al. 1995). Although, a comparison of fall rates among residents starting treatment with APM or benzodiazepine showed that residents are at greatest risk for falls during the first 24-hours after starting benzodiazepines (for anxiety), and that risk for falls is lowered when the benzodiazepines are discontinued (Berry et. al., 2016).

APMs and Fractures among LTCF Residents with Dementia

Studies show a positive association between hip fracture and APM use in residents with dementia (Berry et al. 2018, Jalbert et. al., 2010; Huybrechts et al. 2012, Katz et al. 2004) and residents experienced more hip fractures when given conventional (older) APMs, compared to (newer) atypical APMs (Jalbert et al. 2010; Huybrechts et al. 2012). Regarding atypical APMs, residents prescribed risperdal had fewer hip fractures than residents prescribed quetiapine (Huybrechts et al., 2012) or olanzapine (Frenchman, 2005; Jalbert et al., 2010). The rates of hip fracture increased steadily during the first six months of olanzapine therapy, then remained high and stable after six months (Jalbert et al., 2010).

APMs and Resident Functional Status Among LTCF Residents with Dementia

Older adults experiencing NPS associated with dementia are more likely to be ambulatory and verbal (Miller et al. 2011) and APM use with this population contributes to functional decline (Dutcher et al., 2014). Yet, an overview of medical treatments for

older adults with dementia recommends Risperdal (an atypical APM) for the treatment of dementia-related NPS; emphasizing the point that the residents' ability to ambulate (rather than APM use) increases the resident's risk for falls (Tariot, 2003). Such conclusions are not supported by the literature.

A large study of nearly 19,000 LTCF residents found that female residents prescribed APMs demonstrated more functional decline than male residents prescribed APMs, or residents of both sexes not prescribed APMs (Dutcher et al., 2014). Also, a case study described functional decline (restricted range of motion in one's neck) in an 87-year-old female LTCF resident when her dose of an atypical APM (risperidone) was increased from 0.5 milligram (mg) to 1mg (Abel Boenerjous et al., 2015). Another case study described the use of a conventional APM (haloperidol) to treat wandering behaviors and aggression in an 81-year-old female resident with dementia (King & Mallet, 1991). After approximately two months of haloperidol use, the resident suffered a brachial plexus injury (due to positioning) that resulted in loss of right arm function. Once the dose of haloperidol was reduced, the resident regained use of her right arm (King & Mallet, 1991). Conversely, an observational study of 19 residents with dementia suggests that residents participate in more in activities of daily living and social functioning after they were prescribed atypical APMs (olanzapine or risperidone) (Ellingrod et al., 2002).

A study examining if fall risk is APM dose-dependent suggests that resident wandering (ambulation) plays a role in resident falls. One mg of risperdal reduced fall risk by 70% in residents with the highest level of wandering (Katz, 2004). However, 2mg of risperdal increased the risk of falls, especially, among ambulatory individuals with low

levels of wandering (Katz, 2004). Results of the study suggest that ambulation status may influence the risk of falls when LTCF residents with dementia are treated with risperdal (Katz et al., 2004).

APMs and Urinary Incontinence Among Older Adults with Dementia

When compared to LTCF residents not taking APMs, residents taking APMs demonstrate a higher incidence of urinary incontinence due to an overactive bladder (Brandeis et al., 1997; Zarowitz et al., 2015). The pharmacological action of APMs on the 5HT2-receptor may explain the influence of APMs on urinary incontinence (Lauterbach & Bralatei, 2009). No literature in this review described an association between bowel function and LTCF resident APM use.

High Reliability Theory

When designing the Federal Nursing Home Reform Act, the Institute of Medicine (IOM) (2001) emphasized the importance of high reliability among the interprofessional healthcare team to achieve safe, desired resident outcomes. Principles of high reliability include evaluating and improving systems to achieve intended outcomes (Nolan et al. 2004). In healthcare organizations, high reliability means consistent excellence in quality and safety across all services, maintained over long periods of time. This high level of performance, which includes the elimination of major quality failures in U.S. LTCFs, needs to be addressed. The study was guided by the high reliability theory (HRT) since it was designed to evaluate results of one component of the 2011 OIG regulations on LTCF resident health outcomes. A reliable clinical environment is intended to protect consumers and nurses play a key role in establishing and promoting a highly reliable healthcare environment (Riley, 2009).

Importance of Research to Nursing

If an older adult with dementia resides in U.S. LTCFs and receives APM(s), there exists a risk of harm and unintended outcomes (falls, falls with major injury, functional decline and incontinence). The interprofessional team and healthcare industry has placed the older adult at risk by its actions and decisions when APMs are administered to residents with dementia. Knowledge generated from the study contributes to an understanding of the impact of the 2011 OIG LTCF regulations on resident (consumer) health. Results of the study provide evidence for policy makers, organizational leaders, and healthcare providers to develop educational programs, health care practices and policies so residents living in LTCFs are free from the known risk of harm associated with the inappropriate use of APMs.

Using CMS data (MDS 3.0), the study was designed to determine the impact of the OIG regulations on the rates of falls, falls with major injury, functional decline, and incontinence among LTCF residents with dementia (before and after the regulations were enacted). Outcomes of the study contribute to an understanding of the health effects of the OIG 2011 regulations, while adding to the literature on the adverse effects of APM use among older adults with dementia. Such work has the potential to stimulate the design and evaluation of interventions to appropriately address NPS associated with dementia (rather than inappropriate use of APMs). The study results also have the potential to stimulate stronger regulations to ensure that U.S. LTCF residents with dementia are not harmed (nonmaleficence). Since the 1987 OBRA and OIG 2011 regulations were designed to improve the health and quality of life for U.S. LTCF

residents, results of this study provide empirical evidence regarding the outcomes of the regulations.

Innovation

The proposed study is innovative since there is a paucity of information regarding health outcomes of the 2011 OIG LTCF regulations. Knowledge generated from the proposed study extend the literature by demonstrating the impact of the governmental LTCF OIG 2011 regulations (related to APM use) on falls, falls with major injury (fractures), functional decline (change in transfer status) and urinary incontinence among older adults with dementia.

If the study results suggested that there was a reduction in APM use, and health outcomes of LTCF residents with dementia improved after the 2011 regulations, results of the study may provide preliminary support for the regulation. However, if the results suggested that APM use decreased and health outcomes did not improve after the 2011 OIG regulations, the study should be replicated using individual, resident data which allow to control for confounding variables. If consensus is reached, that the 2011 OIG regulations did not improve resident health outcomes, further research will be needed to determine why residents (and not prescribed APMs) are at increased risk for falls, falls with major injury (fractures), functional decline (change in transfer status) and urinary continence. While it is widely accepted that APM use contributes to negative health outcomes for older adults with dementia (Fick et al., 2019), it is possible that a moderating (i.e., age, gender) or mediating (i.e., hypotension or cardiovascular disease) variable has a stronger impact on health outcomes than APM use. The proposed study provided a foundation for such investigations.

Approach

Preliminary Work

Six years after the OIG 2011 regulations were enacted, the principal investigator conducted a qualitative (unpublished) study investigating the lived experience of Registered Nurses (RN) working in U.S. LTCFs. A hermeneutic phenomenological method was used to explore the perception of RNs caring for older adults with dementia since the OIG 2011 regulations. This particular methodology aligned with the study purpose as it promoted reflection to uncover the experiences of RNs through one's own view and perception of the lived experience (Cohen et al. 2000). Data was collected through semi-structured interviews with RNs (n=2) asking participants to describe the lived experience caring for older adults with dementia requiring continuous nursing care in LTCFs. A broad, general question was used to begin the interview and avoid any bias or leading answers. Further questions consistent with qualitative data collection methodology, clarified the responses and included the RNs sharing of experiences in a LTCF where the OIG regulations apply.

Data was analyzed through content analysis; a qualitative analysis technique used to classify words in a text into categories (Burns & Grove, 2011). The findings suggest a decrease in APM use among older adults with dementia in LTCFs. Yet the study respondents did not endorse improvements in health outcomes within this population. The proposed study seeks to systematically answer that question: Did the 2011 OIG LTCF regulations lead to improved health outcomes [falls, falls with major injury (fractures), functional decline (change in transfer status) and urinary continence] among LTCF residents?

Methods

Design

The proposed study involved a retrospective, descriptive, secondary data analysis design. Both the proposed predictor (OIG 2011 LTCF regulations) and outcome [falls, falls with major injury (fractures), functional decline (change in transfer status) and urinary continence] variables have already occurred when investigating the impact of governmental regulations on older adults residing in LTCFs across the U.S. Thus, trends in resident health outcomes will be examined before and after the OIG 2011 regulation.

Setting

The OIG 2011 regulations apply to all LTCFs that receive Medicare or Medicaid funding. Therefore, the study setting will include all CMS-certified LTCFs in the U.S. Non-certified CMS LTCFs in the U.S. and those in countries outside the U.S. will be excluded from the study.

Population and Sampling

The study population includes all residents residing in a CMS-certified. An administrative dataset from CMS will be used to access the study population. Administrative data are often associated with the delivery of a service and originate from the operation of administrative systems, including governmental agencies (Connelly et al. 2016). Administrative data is obtained from a known population (i.e., older adults residing in LTCFs) and represents information from an entire population compared to a sample (Connelly et al. 2016). Administrative data allows researchers an opportunity to develop cohorts of individuals and investigate trends in data over time (pre/post

regulations). The national CMS, aggregate data is collected from LTCFs across the U.S. on a quarterly bases (minimum) and was explored for all residents residing in LTCFs.

Measures

Minimum Data Set (MDS) 3.0. Data for the proposed study represent data entered into the MDS 3.0, a federal assessment for individuals residing in LTCFs and receiving funding from Medicare or Medicaid. The MDS 3.0 is the current, standardized assessment for individuals residing in LTCFs and addresses clinical, functional, and psychosocial characteristics (CMS, 2016). The MDS 3.0 identifies variables such as acuity level, diagnosis, treatment, functional status, medications, restraint and alarms, health conditions (including falls and fractures), bowel and bladder, and cognitive patterns. The MDS 3.0 is completed upon admission to a LTCF and performed on a quarterly and annual basis thereafter. The MDS 3.0 assessment is also executed when there are significant changes in the condition of the resident.

The RAND Health Corporation (2008), under a contract with CMS, investigated the clinical relevance and accuracy of the revised MDS 3.0. The final testing of the MDS 3.0 intended to assess and analyze inter-rater reliability between gold-standard (research) nurses and facility nurses using a modified Delphi process. The modified Delphi process accurately predicts health outcomes and is particularly useful when research findings must be translated from narrowly focused studies and generalized to a larger population. The RAND Health Corporation (2008) determined an established increased reliability within the MDS 3.0 when compared to the MDS 2.0. The MDS 3.0 demonstrated excellent or very good reliability when comparing research to facility nurse assessment. The MDS 3.0 requires the assessment to be completed in a shorter amount of time; the

modified Delphi process indicated a 45% increased efficiency among those completing the MDS 3.0. Another important element discovered when evaluating the validity of the MDS 3.0 was the increased validity in the revised fall and balance sections. The average gold-standard kappa was 0.967 and the gold standard to facility-nurse kappa was 0.945. The revised fall section of the MDS 3.0 is more reliable and preferred over the MDS 2.0 by staff who have used both versions of the MDS. Dr. Debra Saliba MD, MPH, Senior Natural Scientist, RAND Corporation reports alphas were not reported as MDS items detect potential conditions among older adults requiring care. The RAND Corporation did not develop or test scales within the MDS (Dr. Saliba personal communication, March 22, 2019).

The MDS 3.0 is completed on all LTCF residents as of October 2010 when the MDS 3.0 replaced the MDS 2.0. One of the advantages of the MDS 3.0 compared to the MDS 2.0 is the continuous (quarterly at a minimum) evaluation of LTCF residents with this standard assessment and corresponding documentation. The MDS 3.0 identifies actual or potential concerns and promotes and maintains transparency regarding quality of care in U.S. LTCFs (as the MDS is submitted to the federal government within 14 days after completion). A major disadvantage of the MDS 3.0 is the quality of data. When comparing MDS 3.0 data and the review of actual medical records, there exists documented error rates as high as 11.65% (Shin & Scherer, 2009).

Outcomes of interest. The variables are based on data available in the MDS 3.0 and supported by literature investigating outcomes associated with APM use among older adults with dementia. When considering a set of study variables, the researcher often evaluates associations between outcome variables (dependent variables) and relevant

predictor variables (independent variables) (Akinwande et al. 2015). Based on the aims of the proposed study, the predictor variable is the OIG 2011 regulations restricting APM use in U.S. LTCFs. The outcome variables included falls, falls with major injury (fractures), functional decline (change in transfer status) and urinary continence among all residents in a U.S. LTCF. Demographic data collected included resident age, sex, race/ethnicity, and dementia diagnosis.

Data Analysis

Results were reported for both before and after the OIG 2011 regulations including age, sex, race/ ethnic background, and diagnosis. For the outcomes of interest [falls, falls with major injury (fractures), functional decline (change in transfer status) and urinary continence], the chi-square test of goodness of fit and linear regression was found to be a suitable method of analyses. The chi-square test requires the researcher to enter observed frequencies corresponding to combinations of levels of relevant factors. Sums of elements within rows and columns are then calculated. The chi-square test was used to examine if the frequency within cells is what would be expected (Preacher, 2019).

The binary or count variables are the outcome variables identified in the study aims. The chi square test is chosen as the data can be expressed in one or more two-by-two tables.

The chi square test is a nonparametric test and does not rely on estimated parameters. Nonparametric tests do not make assumptions related to the distribution of data and are useful if the initial analysis demonstrates the MDS data is not normally distributed (Fabri, 2016). One cannot assume the MDS 3.0 data is normally distributed. A nonparametric approach such as the chi square analysis will demonstrate if there exists a significant trend in falls, falls with major injury (fractures), functional decline (change in transfer

status) and urinary continence. A linear regression test was also chosen as the data represents a dichotomous variable in evaluating trends over time.

Limitations

The proposed study has several limitations, most of which are related to the study design. With a secondary data analysis, the investigator is restricted on the type and amount of available data (Euser et al. 2009). There are other factors that may influence the outcomes of interest that are not documented in the MDS 3.0 or identified by the investigator. The choice of outcome variables is guided by the literature but there may be important variables in the MDS 3.0 which investigators have not yet examined. Another potential limitation of the current study is the quality of data entered into the MDS 3.0 in the clinical setting. The MDS 3.0 data is entered by clinical staff with varying degrees of expertise, education, and experience with MDS 3.0 coding. Berlowitz et al. (2010) summarize research indicating clinical staff poorly identify active diagnosis when completing the MDS 3.0. The quality of MDS 3.0 data will vary depending on those influential factors mentioned previously, and there does exist the possibility of inaccurate data entered into the MDS 3.0.

Potential Barriers to Obtaining De-Identified Data

Complex ethical, social, financial, and technical concerns surround the secondary use of health data and may hinder access to data. A framework to guide and facilitate widespread collection, storage, and transmission of health data provided adequate protection for valid secondary use, but such a framework does not exist. To mitigate this challenge, a thorough Institutional Review Board (IRB) application was submitted to Duquesne University and approval was secured. IRB review ensures human research

protections and HIPAA regulation adherence regarding personal identification information and protections of research subjects from harm.

Chapter Two: Final Manuscript

TRENDS IN LONG-TERM CARE FACILITY RESIDENT OUTCOMES BEFORE
AND AFTER FEDERAL REGULATIONS LIMITED ANTIPSYCHOTIC
MEDICATION: A SECONDARY ANALYSIS

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Author Note

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Abstract

Trends in resident falls did not significantly change, although trends in serious injury from falls declined ten years after regulations restricted antipsychotic medications in long-term care facilities. Trends in functional and continence status worsened after the regulations were implemented.

Key words: antipsychotic medication, long-term care facilities, falls, injury, functioning, continence

Trends in Health Outcomes Before and After Long Term Care Federal Regulations Limited Antipsychotic Medication Use: A Secondary Data Analysis

Approximately 6.5 million Americans currently have dementia, and that number is expected to reach 12.7 million by the year 2050 (Alzheimer's Association, 2022). More than 80% of long-term care facility (LTCF) residents with dementia exhibit neuropsychiatric symptoms (NPS) including agitation, aggression, irritability, and/or apathy (Zuidema et al., 2015). The prevalence of agitation and aggression is 92.34% and 63.46%, respectively among individuals with dementia (Choi et al., 2019). Dementia-related NPS are associated with increased healthcare utilization, morbidity, mortality and poor health outcomes in older adults (Kales et al., 2014) and caregivers (Choi et al., 2019).

Antipsychotic Medications and Neuropsychiatric Symptoms in Dementia

Management of neuropsychiatric symptoms in older adults is a complex task since behavioral and environmental interventions are not always effective in reducing agitation, aggression, irritability, or apathy (Phan et al., 2019). Despite a boxed warning regarding APM use with older adults (United States Food and Drug Administration [FDA], 2005), antipsychotic medications (APMs) continue to be used in the management of NPS among individuals with dementia residing in LTCFs (United States Government Accountability Office, 2015). Because APMs are associated with increased mortality when given to older adults (FDA, 2005), the United States (U.S.) Department of Health and Human Services (HHS), Office of the Inspector General (OIG, 2011), imposed restrictions on APM use for LTCF residents with dementia. The regulations were

informed by studies showing a 1.6 to 1.7 increase in mortality due to cardiac events (heart failure or sudden death) or infections (mostly pneumonia) (FDA, 2005).

Effects of Antipsychotic Medications on Older Adults with Dementia

Studies of APM use in LTCFs suggest that male residents with dementia (Buchanan et al., 2004; Kamble et al., 2008; 2009; Ott et al., 2000) and ambulatory residents of both sexes with dementia receive more APMs than less mobile (dependent) residents with dementia (Miller et al., 2011). The literature also shows that APMs increase the risk of resident falls (French et al., 2007; Frenchman, 2005; Galik et al., 2018; Van Doorn et al., 2003; Wei et al., 2017), fractures (Berry et al., 2018; Huybrechts et al., 2012; Jalbert et al., 2010; Katz et al., 2004), functional decline (Dutcher et al., 2014; King & Mallet, 1991), and urinary incontinence (Brandeis et al., 1997; Zarowitz et al., 2015).

LTCF Regulations and Antipsychotic Medications

According to (LTCF) Code of Federal Regulations (CFR, 2022), §483.25, quality of care includes services (e.g., nursing care) in accordance with professional standards and consideration of resident-centered preferences. Specifically, CFR §483.25 holds LTCFs and those who work in LTCFs accountable to prevent accidents (including falls and fractures), prevent a reduction in mobility (including transfers and ambulation), and restore continence to the maximum degree possible. Federal regulations also evaluate LTCFs on the proficiency to maintain and restore participation in activities of daily living (ADLs, unless a clinical decline precludes one from maintaining independence). The OIG regulations prohibiting the use of APMs for LTCF residents with dementia is in

accordance with the aforementioned regulations since APMs present a known risk of harm to older adults.

Study Purpose

After the APM-restricting regulations were implemented in 2011, APM use in LTCFs decreased from approximately 24% of the residents in 2011 to 14.4% of the residents in 2021 (CMS, 2022). Although an almost 40% reduction in APM use is a step in the right direction, 14.4% of LTCF residents continue to receive APMs for conditions such as dementia, despite the current guidance advising against the use of APMs. No studies in the literature were located that evaluated the specific health effects of the OIG APM-restricting regulations. The study extends the literature by comparing rates of falls, falls with major injury (fractures), functional decline (change in transfer status, how a resident moves between surfaces such as bed, chair, and wheelchair) and urinary continence among LTCF residents in 2011 (when the regulations were initially enacted) and ten years after the LTCF regulations prohibited the APM use for residents with dementia (in 2021).

Method

Study Design

A descriptive, retrospective study design was used to determine if LTCF resident health outcomes improved ten years after 2011 regulations restricted the use of APMs in CMS-certified LTCFs. CMS administrative data from 2011 and 2021 evaluated resident health outcomes, including falls, falls with major injury (fractures), functional status (independent transfers) and urinary continence. The study was approved by the Duquesne University Institutional Review Board.

Population and Setting

Administrative data were obtained from a known population (e.g., individuals residing in LTCFs) and represented the entire population, as compared to a sample or portion of the population (Connelly et al., 2016). Administrative datasets representing all residents living in CMS-certified LTCFs in the U.S. were used for comparing health outcomes of residents in 2011 (when the APM-related regulations were initially enacted), and ten years after the APM-related restrictions were implemented.

Data Source

The variables of interest are documented in the LTCF Minimum Data-Set version 3.0 (MDS 3.0). The MDS 3.0 is a comprehensive and standardized assessment tool for documenting each resident's clinical, functional, and psychosocial status; along with diagnoses, functional status (transfer status), health conditions (falls and fractures), bowel and bladder function (urinary incontinence), and cognitive patterns (CMS, 2016). The MDS 3.0 assessment is completed within 14 days after admission, and again on a quarterly and annual-basis thereafter on all individuals residing in LTCFs that receive funding from CMS. The MDS 3.0 assessment is also executed when there are significant changes in a resident's condition (e.g., change in transfer status). The MDS 3.0 is used to identify actual or potential resident concerns, while maintaining transparency regarding the quality of care in CMS-certified LTCFs.

The RAND Health Corporation, under a contract with the CMS, evaluated the clinical utility and accuracy of the MDS 3.0 (RAND, 2008). When compared to the MDS 2.0 (earlier version), the MDS 3.0 is completed in less time, and is 45% more efficient at identifying resident concerns (RAND, 2008). The MDS 3.0 is also more reliable than the

MDS 2.0 (RAND, 2008). Inter-rater reliability among research nurses and LTCF nurses was excellent or very good (especially in the fall and balance sections) (RAND, 2008). Measures within the MDS 3.0 were not psychometrically evaluated (Dr. Saliba personal communication, March 22, 2019).

Data Analysis

Raw numbers (N) and percentage of the total resident population were used to describe LTCF residents in 2011 and 2021. Health outcomes included falls, falls with major injury (fractures), change in independent transfer (functional status) and urinary continence. Chi-square analyses determined the odds of the resident health outcomes in 2021, given the same health outcomes in 2011. Separate linear regression analyses determined if there was a change in each health outcome over time (over the 41 quarters between 2011 and 2021). In each regression analysis, one health outcome was the dependent variable and time (the 10-year period) was the independent variable. Two-tailed p values less than 0.05 were considered statistically significant.

Results

Characteristics of the LTCF Population

Table I describes the population of LTCF residents in the U.S. when the APM regulations were enacted (2011, Quarter Four) and a decade later (2021, Quarter Four). The LTCF population declined 16.4% from 2011 to 2021. The LTCF population was younger, included more males, and was more racially/ethnically diverse in 2021, compared to a decade earlier. There were 5% fewer LTCF residents with a diagnosis of dementia (Alzheimer's disease or another type of dementia) in 2021, compared to 2011.

Females continued to comprise the majority of LTCF residents in 2021, although the proportion of female to male residents declined over the ten-year period (67% female in 2011 and 61% female in 2021). There was a 6% increase in male population over the ten-year study period, with males comprising 39% of the LTCF population in 2021 (versus 33% in 2011). Over the study time-frame, there was an 8.1% increase in LTCF residents between the ages of 65-74 years old and a 10% decrease in LTCF residents ages 85 years and older.

Comparing the racial/ethnic composition of LTCF residents from 2011 to 2021, there were 0.8% fewer White residents, 0.5% more Black residents, a 0.2% increase in the proportion of both Asian and Hispanic residents, and a 0.1% increase in Native American / Pacific Islander and American Indian/ Alaskan Native residents.

Health Outcomes

The chi-square analyses suggested LTCF residents had the same odds of experiencing the health outcomes in 2021, as they had in 2011. Specifically, LTCF residents are at the same risk for falls, falls with major injury (fractures), functional decline (change in transfer status), and urinary incontinence ten years after the LTCF regulations were enacted there exists a 40% reduction of APM use. Results of the chi-square analyses are listed in Table II.

Despite a 1.3% decline in the proportion of LTCF resident falls from 2011 to 2021 (17.4% of the residents fell in 2011 and 16 % fell in 2021), that trend was not statistically significant. The proportion of the residents experiencing falls with major injury (fractures), changes in functional status (independent transfers), and bladder incontinence were significantly different in 2021, compared to the residents in 2011.

Results of the regression analyses for the remaining health outcomes are described below and presented in Table III.

A small (0.2%) downward trend in the proportion of LTCF residents with fall-related injuries in 2021 (compared to 2011) was statistically significant. In 2011, 3.2% of the residents experienced fall-related resident injuries and in 2021, 3.0% of the residents experienced similar injuries. There was also a significant reduction (4.3% downward trend) in the proportion of residents able to transfer independently in 2021. In 2011, there were 12.1% LTCF residents who were able to transfer independently, compared to 7.8% of the residents in 2021. This represents a significant downward trend in resident's ability to transfer independently from various surfaces such as chair to bed, wheelchair to bed, etc. Regarding continence status, there was a significant downward trend (8% reduction) in the proportion of continent residents in 2021. In 2011, 25.1% of the LTCF residents were continent, compared to 17.7% of LTCF population in 2021. This downward trend indicates an increase in the proportion of residents experiencing urinary incontinence.

Discussion

The LTCF Population

The U.S. LTCF population was smaller, composed of more males, was younger, and more racially and ethnically diverse in 2021, than the LTCF population in 2011. The LTCF population declined 16.4% from 2011 to 2021, while the U.S. population increased by only 0.1% (fewer than one million citizens) in 2020 (U.S. Census Bureau, 2020). The slowest rate of U.S. population growth in the 20th century was from 1918-1919, during the influenza pandemic and World War I (U.S. Census Bureau, 2020). This is noteworthy since approximately 460,000 U.S. deaths were attributed to the COVID-19 pandemic

from January to December 2021 [Centers for Disease Control and Prevention (CDC), 2022]. In 2020, COVID-related deaths in LTCFs accounted for nearly half of the deaths from the virus nationally (Kaiser Family Foundation, 2022).

Pandemic-related deaths in the U.S. were highest among persons aged 85 years or higher (U.S. Census Bureau, 2020). The observed 10% reduction in the proportion of LTCF residents age 85 to 95 years from 2011 to 2021 may be attributed to the COVID-19 pandemic. Over the study time-frame, the fastest growing age-group of LTCF residents was the 65- to 74-year-old age group. This trend is also consistent with the U.S. population, since citizens age 65-and-older increased by 34.2% during the past decade (U.S. Census Bureau, 2020). Growth in this age group contributes to the increase in the national median age from 37.2 years in 2010 to 38.4 years in 2020 (U.S. Census Bureau, 2020). No other age-group experienced growth as much as the 65 to 74 years age group (U.S. Census Bureau, 2020).

The racial and ethnic distribution of LTCF residents in 2021 mirrored that of the U.S. population in 2020, with the exception of White LTCF residents. The U.S. White population increased by 4.3% from 2010 to 2020 (U.S. Census Bureau, 2020), while the proportion of White LTCF residents decreased by 0.8% from 2011 to 2021. In 2021, the ethnic and racial distribution of individuals living in U.S. LTCFs was 77.9% White (non-Hispanic), 14.3% Black, 5.2% Hispanic, 1.9% Asian, 0.4% American Indian/ Alaskan Native, and 0.3% Native Hawaiian /Pacific Islander. From 2010 to 2020, the U.S. population experienced the largest growth among Asian citizens (29.3%), followed by Native Hawaiian and Other Pacific Islander citizen (21%), Hispanic citizens (20%), American Indian and Alaska Native citizens (13.1%), Black citizens (11.6%), and White

citizens (4.3%) (U.S. Census Bureau, 2020). Over the study period (2011 and 2021), the proportion of Black LTCF residents increased by 0.5%, followed by a 0.2% increase in the proportion of Asian and Hispanic residents. The proportion of American Indian / Alaskan Native residents (0.4%), along with Native Hawaiian / Pacific Islander residents (0.3%) remained stable over the study time frame.

Health Outcomes

Results of this study show that the ten-year time span (after APM-restricting regulations were enforced) was not significantly associated with a reduction in resident falls, although there was a significant downward trend in major injuries from falls (e.g., fractures) from 2011 to 2021. This trend is consistent with older adults living in the community. According to an analysis of falls and fall-related injuries among non-institutionalized older adults (ages >65 years), the percentage of falls and fall-related injuries decreased slightly from 2016 to 2018 when compared to data from 2012 to 2016 (Moreland et al., 2020). This is important to note since current fall and fall-related injury prevention measures in LTCFs include decreasing the use of APMs. It is possible that restricting APMs for LTCF residents with dementia resulted in fewer fall-related serious injuries in 2021.

It was hypothesized that the proportion of residents that could transfer independently would significantly increase as APM use decreased in LTCFs (from 2011 to 2021). It was discouraging to learn that the proportion of independent LTCF residents decreased significantly from 2011 to 2021 in this study. Independence in activities of daily living (including transfers) influences an individual's quality of life (McClain et al., 2018). Among older adults, declining physical mobility is associated with a lower quality

of life (Groess et al., 2019) and loss of independence in ADLs is associated with an increase in hospitalizations and mortality (Ankuda et al., 2020). The increase in resident ADL dependence may be due to numerous factors, none of which were accounted for in this study. However, discontinuing APM use (required by CFR §483.25 and described above) may not necessarily restore an individual's maximum level of independence. Restorative and rehabilitation services in LTCFs cannot be underestimated for achieving and sustaining an individual's maximum level of participation in ADLs.

At a time when there was nearly a 40% reduction in APM use in U.S. LTCFs (CMS, 2022), there was also a significant decrease in the proportion of continent LTCF residents. This is also discouraging since urinary incontinence is associated with an increased risk of mortality (Huang et al., 2021) and higher costs of care (Coyne et al., 2014). It is possible that the higher proportion of incontinence is directly related to the increase in assistance with resident transfers. Any increase in dependence (e.g., transfers) may place the LTCF resident at risk for incontinence since the individual would require additional staff support for transfers, toileting (including incontinence care) and personal hygiene. Identifying factors that contribute to urinary incontinence (e.g., inability to transfer to the toilet independently) may help to identify targets for preventive interventions such as scheduled toileting and physical therapy to enhance independent mobility.

Study Limitations

Three study limitations related to the design were identified: the possibility of Type-I errors, the lack of ability to address confounding variables due to aggregate datasets, and the high-cost of purchasing individuals cases of CMS datasets.

Type-I Error

The study findings must be interpreted with caution since we analyzed population data, rather than evaluating data from a random sample of LTCF residents. We analyzed 1,446,226 cases in the 2011 dataset and 1,208,122 cases in the 2021 dataset. Studies with extremely large samples have the ability to detect smaller differences between or within groups as evidenced by statistical significance (Case & Ambrosius, 2007; Hochster, 2008). Although studies may achieve statistical significance, such studies can lack clinical impact (Dahlberg et al., 2020). The study results are generalizable to the entire LTCF population. Causal relationships or associations among the outcomes of interest were not identified.

Confounding Variables

The study results must be interpreted with caution since the publicly available, aggregate, CMS-dataset did not control for possible confounding or intervening variables. Confounding variables (confounders) are related to the outcome of interest, and may account for a portion or all of the relationships between the dependent variable (10 years after the APM-restricting regulations were enacted) and independent variables or resident health outcomes (Koenig et al., 2011). If the relationship between the dependent and independent variable dissipates completely when considering confounders, the dependent variable is not associated with the outcome (Koenig et al., 2011). Without resident-level data on possible confounding variables, the health outcomes observed ten years after the APM restrictions were enacted may be very small. For example, the proportion of LTCF population with urinary continence decreased from 2011 to 2021; indicating that more residents experienced urinary incontinence in 2021. To evaluate if the APM-restrictions

were associated with the higher proportions of residents with urinary incontinence in 2021, it would be important include resident-level data about chronic and acute conditions including medications, cognitive status, functional status, and sensory impairments. If the study had analyzed individual, case data including possible confounding variables from a random sample LTCF residents, a multi-variable regression model would have provided a more trustworthy estimate describing the strength of association between time and resident health outcomes.

Cost of CMS-Data

This study was funded by the Gerontological Advanced Nurse Practice Foundation (Research Award, 2021) and publicly available, aggregate CMS-data were used to answer the research questions. The funds were dedicated to hiring a statistical consultant to assist with the data analyses and interpretation of the study findings. It would have cost more than \$12,000 (USD) to obtain de-identified, resident-level CMS data (personal communication, Steve Beekman MPH, Technical Advisor, Research Data Assistance Center [ResDAC], September 1, 2021). Without resident-level data, one cannot say that a causal relationship exists between the ten-year time interval (when there was a 40% reduction in APM use) and resident health outcomes.

Implications for Future Studies

The study revealed findings that would benefit from further research. Investigating the driving forces behind the steady decline in the LTCF population could reveal facilitators and barriers related to accessing long-term nursing care in the community. It would also be interesting to evaluate the level of culturally-specific care provide to LTCF residents from various racial and ethnic backgrounds. Important insights

can also be gained from exploring the lived experiences of LTCF residents, especially non-White residents.

Although not a study question, examination of the CMS LTLF data showed a disturbing trend that warrants further investigation. The proportion of LTCF residents with a schizophrenia diagnosis nearly doubled ten years after the APM regulations were enacted. It is important to note, the CMS approved APM use for the treatment of chronic psychiatric conditions including Schizophrenia, Schizoaffective Disorder, Bipolar Disorder, Psychosis, Psychotic mood disorders, Huntington's chorea and Tourette's Syndrome (CMS, 2013). When a resident has an appropriate psychiatric diagnosis (e.g., schizophrenia), APM use is justified and the facility does not receive a negative quality rating. This increase in the diagnosis of schizophrenia in LTCFs may be a strategy designed to manage or treat dementia-related NPS without revealing the residents has dementia (instead, giving the resident a diagnose of schizophrenia). It would be interesting to conduct a study related to the accuracy of resident diagnoses. An article in the *New York Times* (September 11, 2021) highlighted this practice (diagnosing LTCF with schizophrenia) and the concern voiced by Medicare advocacy groups.

Reducing APM use may result in an increase in NPS symptoms among residents with dementia and place residents and staff at risk for emotional and physical injury (Simmons et al. 2017). Studies evaluating educational programs addressing resident aggression are necessary in a regulatory environment mandating eventual elimination of APMs when clinically indicated. The Cornell Institute for Translational Research on Aging (CITRA) (2022), has developed a program for LTCF staff to recognize aggression among older adults residing in LTCFs. The program, *Improving Relationships in Long-*

Term Care (IRRL), provides free-educational resources empowering LTCF staff with knowledge regarding older adult aggression, strategies to manage aggression and documentation practices to adhere to reporting guidelines. The educational resources are intended to improve the quality of life for LTCF residents and improve working conditions for LTCF staff. When the APM-restricting regulations were enacted, no resources like the *Improving Relationships in Long-Term Care* program were available to support LTCFs in achieving the goal of the regulation (decreasing APM use) and supporting LTCF staff and residents during this change. Educational initiatives will support the ability to recognize and manage NPS with non-pharmacological interventions and resident-centered care strategies.

Conclusion

This study demonstrated that ten years after the APM restrictions were implemented, there were significantly fewer resident injuries (from falls), significantly more dependent residents (fewer independent transfers), and significantly more incontinent LTCF residents (fewer continent residents). Although the rate of falls in LTCFs decreased over the ten-year period, the trend was not statistically significant. The study was limited by the cost of obtaining data related to confounding variables, although it provides preliminary evidence that LTCF fall and injury prevention strategies may be working. This study also provides preliminary evidence that loss of the resident's functional abilities and continence levels require more attention. Rigorously designed studies using de-identified resident-level data, from a random sample representing all LTCF residents, will provide further insight into these negative health outcomes ten years after the LTCF APM-restrictions were enacted.

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Table I.*Demographic characteristics of CMS-Certified LTCF Residents in 2011 (last quarter) and 2021 (last quarter)*

Characteristic		2011(Q4)	2021(Q4)
Total population (N)		1,446,226	1,208,122
Sex [% (N)]	Male	33 (475085)	39 (469355)
	Female	67 (971141)	61 (738767)
Age [% (N)]	0-30	0.6 (8389)	0.5 (6524)
	31-64	15.0 (216822)	17.5 (211905)
	65-74	14.8 (214797)	22.9 (277143)
	75-84	28.3 (408766)	27.8 (335375)
	85-95	36.2 (524048)	26.8 (323777)
	96+	5.1 (73769)	4.4 (53278)
Race [% (N)]	American Indian/Alaskan Native	0.4 (6221)	0.4 (5794)
	Asian	1.7 (24275)	1.9 (24506)
	Black	13.8(195787)	14.3 (187956)
	Hispanic	5.0 (71235)	5.2 (68809)
	Native Hawaiian/Pacific Islander	0.3 (4046)	0.3(4346)
	White	78.7 (1114758)	77.9 (1026345)
Alzheimer's [% (N)]		15.6 (212154)	11.5 (128522)
Dementia [% (N)]		43.1 (585404)	41.3 (460012)

Table II.

Linear regression analysis of changes in health trends from 2011 to 2021

Independent Variable	p<0.05 (CI)
Falls	0.07
Fall with Major injury	0.008*
Independent mobility	<0.001*
Level of continence	<0.001*

Table III.

Chi-square analysis of outcomes from 2011 to 2021

Independent Variable	OR (95%CI)	P value
Falls	1.0(1.00 to 1.00)	P<0.001
Fall with Major injury	1.0(1.00 to 1.00)	P<0.001
Independent mobility	1.0(1.00 to 1.00)	P<0.001
Level of continence	1.0(1.00 to 1.00)	P<0.001