Title of Project: *Improving Medication Safety in Nursing Home Dementia Care*

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1. Structured Abstract

Purpose: Antipsychotic medications are widely used in nursing homes to manage behavioral and psychological symptoms of dementia, despite increased mortality risk. A national campaign for safer dementia care in US nursing homes was launched in 2012, with accompanying state initiatives, resulting in a 39% reduction in antipsychotic medication prescribing by 2018. To strengthen the evidence base for patient safety interventions in this clinical area and to contribute to a broader understanding of the strategies that are most effective in improving patient-safety practices at scale across large healthcare systems and large numbers of facilities, providers, and patients, we used a mixed-methods approach to examine the effectiveness of national, state, and facility initiatives to reduce antipsychotic prescribing in nursing homes.

Scope: An analysis of national- and state-level changes in use patterns following select quality improvement initiatives to improve understanding of the factors associated with reduction in prescribing during the first 4 years of the campaign.

Methods: We used a mixed-methods strategy, incorporating analyses of administrative and clinical data, state case studies with key informant interviews of state leaders, and facility case studies to examine the features and effectiveness of national, state, and facility initiatives to reduce antipsychotic prescribing.

Results: Our findings suggest that substantial change in prescribing practices is achievable through sustained, data-informed quality improvement initiatives that integrate educational and regulatory interventions, supported by public reporting of quality measures at facility and state levels. Adequate staffing, particularly at the registered nurse level, is also key to support individualized management of symptoms through nonpharmacological strategies.

Key Words: long-term care, nursing homes, dementia, antipsychotic medication, policies, elderly

2. Purpose

This project addressed the critical patient safety challenge of safe management of behavioral and psychological symptoms of dementia (BPSD). Antipsychotic (AP) medications continue to be widely used to manage these symptoms, despite an FDA black box warning based on strong clinical trial evidence of substantially increased mortality. Multiple federal and state initiatives have been undertaken to encourage safer dementia management, with varying degrees of success. However, evidence needed to inform such initiatives is inadequate. Stronger, actionable knowledge on patient, provider, community, and policy influences on treatment patterns; policy-modifiable points of intervention; and effectiveness of alternative strategies for safer use are vital to inform such initiatives. This patient safety challenge prompted multiple calls for action, including an HHS Inspector General Report, leading to the launch early in 2012 by CMS of the National Partnership to Improve Dementia Care in Nursing Homes. The Partnership set an initial goal for 2012 of a 15% reduction in AP use by long-stay residents. As part of the national effort, states initiated campaigns aimed at reducing use through multi-stakeholder educational and other systemic strategies. Clearer understanding of effects of actionable factors, such as facility staff mix, is vital.

To address these multiple safety-related aspects of treatment, we used a mixed-methods strategy combining quantitative analyses of merged datasets with state and facility case studies. We examined patient, facility, community, and policy factors associated with use, and we characterized national and state trends in safety-related dimensions of use. Analyses aimed to inform quality improvement and patient safety initiatives through a clearer understanding of national and state medication use patterns, predictors, trends, and changes during national and state campaigns for safer dementia care; to complement quantitative examination of the outcomes of the national and state campaigns with case studies of selected states and facilities with high success versus those with limited success in reducing AP use in individuals with dementia; to work with stakeholders to help translate project-generated knowledge on effective strategies for systems-based improvements in medication use processes into sustainable policies and practices to improve safe medication use practices; and to disseminate project results and tools through national and state dementia care improvement partnerships.

The broad purposes of the study were at two levels: to inform patient safety interventions in this specific, important clinical area and to utilize this issue as a case study to contribute to broader understandings of the characteristics of effective patient-safety intervention in large systems. The challenge of reducing mortality risks from antipsychotic prescribing in elderly with symptoms of dementia is one of many widespread practices in healthcare that differ from those recommended in evidence-based guidelines and patient-safety recommendations. Quality-improvement initiatives to improve these practices face many barriers to success, including the difficulty of modifying established provider practices; perceptions that alternatives are not available; and family and staff concerns about distressing symptoms. The difficult challenge of changing such practices at scale across large systems is exemplified by the case of initiatives to reduce antipsychotic prescribing in nursing homes, which have had mixed success across countries; examination of these initiatives can shed broader light on effective strategies for systemic change.

3. Scope (Background, Context, Settings, Participants, Incidence, Prevalence)

Safer management of behavioral and psychological symptoms of dementia is a major quality issue in long-term care of older people. Symptoms such as agitation, aggression, crying, cursing, wandering, or threatening others can be highly distressing for staff, other residents, and families, often leading to requests for clinicians to “do something” about these behaviors. The response is often an antipsychotic prescription. However, for frail elderly residents, these medications bring substantial risk. In 2008, the Food and Drug Administration (FDA) imposed a black box warning of increased mortality risk on all antipsychotic medications for elderly patients with dementia, following earlier warnings on second-generation antipsychotics.

The FDA has estimated that such treatment is associated with a 1.6-1.7 times greater risk of death compared with placebo, based on a meta-analysis of 17 double-blind, randomized controlled trials averaging 8-12 weeks with a total of 5,106 patients.[1] In these trials, about 4.5% of drug-treated patients versus 2.6% of placebo-treated patients died, implying about two more deaths per 100 antipsychotic-treated than placebo-treated patients. Other studies support similar estimates of substantially increased mortality through multiple pathways, including stroke, acute myocardial infarction, pneumonia, and other causes,[2,3,4] implying that thousands of residents each year have their lives shortened by antipsychotic use.

Despite the risks, antipsychotics are widely used for nursing home residents with dementia, in the United States and internationally. The gold standard of care for managing symptoms of dementia utilizes behavioral management strategies and environmental modifications, requiring substantial investments in staffing and education.[5]

In the United States, reducing antipsychotic use has been a long-standing policy challenge. The 1987 Nursing Home Reform Act (OBRA-87) sought to reduce both physical restraint and antipsychotic use, referred to as “chemical restraints.” Under OBRA-87, a federally directed, state-operated system of oversight was created. Components included a survey and certification process entailing periodic site visits by regulators, empowered to issue deficiency citations, and subsequently the Minimum Data Set (MDS) system under which facilities provide periodic information on resident characteristics, treatments, and services. MDS data provide the source for public reporting of antipsychotic medication use through the Nursing Home Compare website, sponsored by the Centers for Medicare and Medicaid Services (CMS).

The oversight system created under OBRA-87 had significant initial success in reducing antipsychotic use.[6] During the late 1990s and the 2000s, use increased again as second-generation antipsychotics, perceived as safer, replaced first-generation ones. Increasing evidence of mortality risks with second-generation antipsychotics, culminating in the FDA black box warnings, had only limited impact.[7] By 2011 (fourth quarter), 23.9% of residents were receiving antipsychotic medications (excluding those with schizophrenia, Huntington’s disease, or Tourette’s syndrome).[8]

Persistently high use despite growing evidence of mortality risks led to increasing calls for action.[9,10] Early in 2012, CMS, the major nursing home associations, and other partners jointly launched the Partnership to Improve Dementia Care in Nursing Homes, with an initial goal for 2012 of 15% reduction in antipsychotic use in long-stay residents. To examine change in prescribing during the Partnership campaign, we examined predictors and trends in MDS-reported antipsychotic prescribing. Given concerns that initiatives to reduce antipsychotic prescribing might lead to shifts to sedative-hypnotic medications, we also examined predictors and trends in use of this class of medications.

The campaign, overall, achieved a very substantial level of improvement, despite concerns of many experts and stakeholders that the clinical processes involved in prescribing these medications would be very difficult to change given the distressing nature of the behaviors involved and perceived lack of alternatives. From 2011 through the second quarter of 2018, the rate of prescribing across all long-stay residents declined from 23.9% to 14.6%, a 39% relative reduction. Improvement was quite heterogeneous across states, although all states had some improvement. During the latter part of the period, much of the national improvement was driven by reductions in several large states, including Texas, New York, and California, that had initially been somewhat slower than some smaller states to achieve reduction. The experience of the Texas initiative was identified as a case study of particular interest, as the state achieved a 55% reduction over this timespan, moving from 50th place to 12th place among states. As one of our case study states and as a state that our team had worked with earlier in the project to share evolving information from the study on effective practices in other states, these changes were noteworthy and led us to give particular attention to the strategies used to achieve this improvement. In periodic conference calls with leadership involved in the Texas improvement campaign, we were able to gain insights into the strategies used to improve patient safety across more than 1,200 facilities and almost 100,000 residents scattered across a vast geographical area and to continue to share information on strategies that were showing effectiveness (or lack thereof) in other states, exemplifying the stakeholder-engaged research approach of the project.

4. Methods (Study Design, Data Sources/Collection, Interventions, Measures, Limitations)

We triangulated data from three sources: 1) long-stay nursing home resident assessments linked with facility-level data for virtually all US nursing homes; 2) facility case studies; and 3) state case studies.

Resident and Facility Data. MDS data (2011-2016) were linked with the Certification and Survey Provider Enhanced Reports (CASPER). MDS includes resident demographic information, clinical measures including behavioral symptoms of dementia, and antipsychotic and/or sedative/hypnotic medication administration at the time of assessment. CASPER includes nursing home and aggregate resident characteristics, including ownership, bed size, and nurse staffing. Our final sample included 3,687,901 long-stay residents (2011-2016) in 17,289 facilities.

Project resources supported the updating of previously acquired datasets through 2016. Quite recently, in order to provide analyses that were more recent and captured a later stage of the campaign, we were able to partner with another Rutgers researcher to fund the addition to the project's DUA and data resources of 2016 MDS data for the project. Analyses of the updated 2016 data are continuing.

Using these linked data, we examined variation and change in MDS-reported antipsychotic and sedative/hypnotic prescribing among residents without schizophrenia, Huntington's disease, or Tourette's syndrome.

Inclusion of Priority Populations. Table 1 below shows that the final study population contained extensive representation of women and minorities. In 2016, the study population included approximately 744,000 women, 157,000 African American residents, and 59,000 Hispanic residents.

Facility Case Studies. To better understand decision making and changes in prescribing, we conducted 39 semi-structured interviews at 14 nursing homes in seven states with nursing home staff and prescribing physicians (Arkansas, California, Georgia, Maine, North Carolina, Texas, Wisconsin). Questions focused on the decision-making process, effects of CMS regulation, barriers to change, and sources of improvement.

State Case Studies. For insight on strategies used in state campaigns, we conducted virtual focus group interviews with key informants from public health and government agencies in the seven states where facility case studies were completed. We also used information on state strategies compiled by the Partnership.[7]

5. Results (Principal Findings, Outcomes, Discussion, Conclusions, Significance, Implications)

Nationally, antipsychotic prescribing declined by 29% from 2011-2016 (Table 1). Reduction was particularly substantial for Black (from 21.0% to 13.4%) and Hispanic (from 25.9% to 17.2%) versus non-Hispanic White residents (from 23.2% to 16.8%). Reduction was greater among residents without recorded behavioral symptoms of physical or verbal aggression than among those with these behaviors, suggesting a trend to more-judicious use, more focused on residents with the most severe symptoms.[14] Similarly, reduction was less among residents with recorded bipolar disorder diagnoses than for other residents. These residents, unlike those with schizophrenia, are included in the CMS quality metric for antipsychotic use; however, an FDA indication exists for antipsychotic treatment in bipolar disorder. The proportion of residents with a recorded diagnosis of bipolar disorder increased from 3.3% to 4.1%, which could reflect some degree of “gaming the system” but might also reflect increased recognition of co-occurring conditions.

Among facility characteristics, notable differences included greater reduction in facilities in the highest quartile of acuity-adjusted registered nurse (RN) staffing versus those with the lowest staffing. Non-profit facilities, and those with smaller proportions of Medicaid residents, improved somewhat more than for-profit and Medicaid-dominated facilities in the bivariate analyses. Reduction in sedative-hypnotic use was substantial across all resident and facility characteristics.

In order to examine whether the reduction produced unintended adverse consequences via a shift to other medication classes that were not measured in the quality measures used in the campaign, we examined changes in sedative-hypnotic prescribing over the 2011-2016 period. Such a shift would be very concerning, because sedative-hypnotic medications are increasingly recognized as having important safety risks for frail elderly—for example, increasing the risks of falls that can be catastrophic. Such a shift would imply that facilities “taught to the test” and responded to pressures to reduce antipsychotic prescribing through workarounds that might be just as hazardous—an outcome that might be expected if the initiative failed to achieve buy-in to the overall aim of increased medication safety and was responded to in a mechanical way that was limited to the specific practices being measured. However, we found that, rather than increasing, sedative/hypnotic prescribing decreased over this time period by an even greater proportion, declining by nearly 43%.

Table 1. Changes in the Long-stay Nursing Home Resident Population, Facility Characteristics, and Use of Antipsychotic or Sedative Medications between 2011 and 2016

	Population Characteristics		Antipsychotic Use		Sedative-Hypnotic Use	
	2011	**2016**	**2011**	**2016**	**2011**	**2016**
Resident-level variables	n=1,116,404	n=1,119,889	22.9%	16.2%	6.3%	3.6%
Male	30.8%	33.5%	24.8%	17.4%	6.7%	4.0%
Female	69.2%	66.5%	22.0%	15.6%	6.1%	3.4%
Hispanic	4.7%	5.3%	25.9%	17.2%	7.6%	4.9%
White	78.0%	75.9%	23.2%	16.8%	6.5%	3.7%
Black≤ 55% Medicaid	13.1%	14.0%	21.0%	13.4%	4.9%	2.8%
Medicaid	68.7%	71.8%	22.8%	16.4%	6.2%	3.4%
Physical Aggression	5.3%	4.2%	48.2%	38.2%	4.3%	2.5%
Verbal Aggression	8.4%	7.0%	45.1%	35.0%	6.0%	3.5%
Bipolar Disorder	3.3%	4.1%	66.6%	60.7%	10.5%	6.5%
Dementia	44.8%	46.1%	29.9%	21.0%	4.4%	2.4%
Anxiety	17.7%	15.4%	32.3%	22.1%	3.8%	2.0%
Depression	49.7%	50.5%	27.0%	19.9%	7.3%	4.3%
Facility-level variables	n=15,530	n=15,524				
For Profit	69.1%	69.6%	23.8%	16.8%	6.8%	3.9%
Government	6.6%	7.4%	22.3%	16.8%	5.2%	3.4%
Non Profit	24.3%	23.0%	20.3%	14.3%	5.0%	2.9%
Rural	25.1%	23.1%	23.3%	17.2%	6.2%	3.7%
Urban	74.9%	76.9%	22.7%	15.9%	6.3%	3.6%
High Bed Count	≥ 172 beds	≥ 170 beds	23.2%	16.7%	5.8%	3.3%
Low Bed Count	≤ 96 beds	≤ 95 beds	22.2%	16.1%	6.0%	3.5%
High Medicaid	≥ 77% Medicaid	≥ 76% Medicaid	26.7%	19.7%	6.6%	3.9%
Low Medicaid	≤ 55% Medicaid	≤ 53% Medicaid	19.3%	13.6%	5.8%	3.4%
Acuity adjusted average RN minutes per resident day						
Highest quartile	34 min	50 min	21.1%	14.5%	5.1%	3.0%
Second highest quartile	22 min	33 min	21.9%	15.4%	5.8%	3.3%
Second lowest quartile	17 min	26 min	23.1%	16.3%	6.6%	3.8%
Lowest quartile	12 min	17 min	25.4%	18.3%	7.5%	4.4%
Acuity adjusted average CNA hours & minutes per resident day						
Highest quartile	3.11 hrs	3.18 hrs	22.9%	16.1%	6.8%	3.8%
Second highest quartile	2.48 hrs	2.53 hrs	22.3%	15.3%	6.1%	3.7%
Second lowest quartile	2.17 hrs	2.22 hrs	22.6%	15.9%	5.9%	3.4%
Lowest quartile	1.78 hrs	1.83 hrs	23.6%	17.3%	6.2%	3.5%

Adjusted avg. LPN hours per resident day						
Highest quartile	1.42 hrs	1.57 hrs	23.3%	16.3%	6.9%	4.1%
Second highest quartile	0.98 hrs	1.16 hrs	23.5%	16.7%	6.6%	3.8%
Second lowest quartile	0.87 hrs	0.93 hrs	22.8%	16.0%	6.2%	3.5%
Lowest quartile	0.55 hrs	0.57 hrs	21.8%	15.6%	5.3%	3.0%
Adjusted avg. total RN/LPN/CNA hours per resident day						
Highest quartile	4.40 hrs	4.90 hrs	22.5%	15.7%	6.4%	3.7%
Second highest quartile	3.62 hrs	4.00 hrs	22.4%	15.3%	6.1%	3.6%
Second lowest quartile	3.25 hrs	3.58 hrs	22.8%	16.1%	6.3%	3.5%
Lowest quartile	2.78 hrs	3.05 hrs	23.7%	17.5%	6.3%	3.6%

Table 2a provides summary results of a multivariate, stepped logistic regression analysis of resident and facility characteristics associated with antipsychotic use in 2011 and 2016. In the multivariate model for 2016, antipsychotic use was notably lower among Black residents (OR = 0.737); lower for older residents (OR = 0.796 per 10-year age increment); and much higher, as expected, for residents with physical aggression, verbal aggression, or bipolar disorder. Among facility characteristics, the bivariate association between lower RN staffing and higher antipsychotic use persisted with adjustment for other facility and patient characteristics (OR = 1.139 for lowest vs. highest quartile of RN staffing). Both the resident’s individual Medicaid eligibility and the proportion of Medicaid residents in the facility were associated with greater odds of antipsychotic treatment. Like antipsychotic use, sedative/hypnotic use (Table 2b) was associated with lower RN staffing, White non-Hispanic or Hispanic ethnicity, and for-profit ownership.

Table 2a. Antipsychotic Use in 2011 and 2016—Stepped Logistic Regressions

	Model 1				Model 2				Model 3			
	2011		2016		2011		2016		2011		2016	
	OR, p	95% CI	OR, p	95% CI	OR, p	95% CI	OR, p	95% CI	OR, p	95% CI	OR, p	95% CI
Resident-level variables												
Male vs. Female	1.076 ***	1.066-1.086	1.020 ***	1.009-1.032	1.120 ***	1.108-1.133	1.088 ***	1.074-1.101	1.119 ***	1.106-1.132	1.082 ***	1.069-1.096
Age (10-year increase)	0.884 ***	0.881-0.887	0.837 ***	0.834-0.841	0.806 ***	0.802-0.809	0.783 ***	0.779-0.786	0.823 ***	0.819-0.826	0.796 ***	0.792-0.800
Hispanic vs. White	1.065 ***	1.044-1.087	0.938 ***	0.917-0.959	1.137 ***	1.112-1.163	0.988	0.964-1.014	1.084 ***	1.058-1.111	0.947 ***	0.923-0.972
Black vs. White	0.797 ***	0.786-0.808	0.669 ***	0.658-0.679	0.907 ***	0.894-0.921	0.780 ***	0.766-0.794	0.832 ***	0.818-0.846	0.737 ***	0.723-0.751
Other Race vs. White	0.783 ***	0.765-0.801	0.741 ***	0.723-0.761	0.864 ***	0.842-0.887	0.867 ***	0.843-0.893	0.855 ***	0.832-0.880	0.859 ***	0.835-0.885
Medicaid Insurance	0.991 *	0.981-1.000	1.055 ***	1.043-1.067	0.990	0.980-1.001	1.051 ***	1.037-1.064	1.000	0.989-1.012	1.052 ***	1.038-1.066
Physical Aggression					2.056 ***	2.013-2.099	2.100 ***	2.048-2.153	2.067 ***	2.021-2.114	2.099 ***	2.046-2.152
Verbal Aggression					2.107 ***	2.071-2.143	2.045 ***	2.005-2.087	2.114 ***	2.076-2.154	2.039 ***	1.998-2.081
Bipolar Disorder					7.601 ***	7.422-7.785	8.668 ***	8.482-8.858	7.504 ***	7.314-7.700	8.522 ***	8.337-8.712
Dementia					2.436 ***	2.411-2.462	2.315 ****	2.287-2.344	2.429 ***	2.402-2.457	2.302 ***	2.273-2.331
Anxiety					2.185 ***	2.158-2.212	1.846 ***	1.818-1.873	2.164 ***	2.135-2.193	1.819 ***	1.792-1.846
Depression					1.552 ***	1.536-1.567	1.590 ***	1.571-1.608	1.554 ***	1.537-1.571	1.591 ***	1.572-1.610
ADL Score					0.987 ***	0.986-0.988	0.987 ***	0.986-0.988	0.990 ***	0.989-0.991	0.990 ***	0.989-0.991

Facility-level variables												
For-Profit Ownership									1.111 ***	1.096-1.127	1.073 ***	1.057-1.090
Government Ownership									0.983	0.960-1.007	1.038 **	1.013-1.064
Rural vs. Urban									1.063 ***	1.049-1.077	1.077 ***	1.061-1.092
High vs. Low Medicaid									1.321 ***	1.299-1.342	1.224 ***	1.202-1.246
Lowest vs. Highest RN									1.132 ***	1.114-1.151	1.139 ***	1.119-1.160
Lowest vs. Highest LPN									0.936 ***	0.921-0.951	0.949 ***	0.933-0.966
Lowest vs. Highest Aide									0.986	0.970-1.001	0.990	0.972-1.007
High vs. Low Bed Count									1.017 *	1.001-1.034	1.014	0.997-1.032

Table 2b. Sedative/Hypnotic, Use 2011-2016—Stepped Logistic Regressions

	Model 1				Model 2				Model 3			
	2011		2016		2011		2016		2011		2016	
	OR, p	95% CI	OR, p	95% CI	OR, p	95% CI	OR, p	95% CI	OR, p	95% CI	OR, p	95% CI
Resident-level variables												
Male vs. Female	0.933 ***	0.918-0.949	0.944 ***	0.924-0.965	0.917 ***	0.901-0.933	0.943 ***	0.921-0.965	0.923 ***	0.905-0.940	0.943 ***	0.922-0.965
Age (10-year increase)	0.786 ***	0.782-0.790	0.762 ***	0.757-0.767	0.838 ***	0.833-0.843	0.824 ***	0.818-0.830	0.841 ***	0.835-0.846	0.827 ***	0.821-0.834
Hispanic vs. White	1.021	0.988-1.055	1.120 ***	1.077-1.166	1.111 ***	1.072-1.151	1.286 ***	1.232-1.341	1.066 ***	1.025-1.108	1.272 ***	1.219-1.329
Black vs. White	0.614 ***	0.599-0.630	0.611 ***	0.591-0.631	0.670 ***	0.652-0.689	0.688 ***	0.664-0.713	0.646 ***	0.627-0.665	0.666 ***	0.642-0.691
Other Race vs. White	0.800 ***	0.769-0.832	0.844 ***	0.805-0.885	0.828 ***	0.794-0.864	0.901 ***	0.856-0.949	0.796 ***	0.760-0.834	0.912 ***	0.865-0.961
Medicaid Insurance	0.986	0.970-1.002	0.801 ***	0.784-0.818	1.000	0.983-1.017	0.799 ***	0.782-0.818	1.048 ***	1.028-1.068	0.847 ***	0.827-0.868
Physical Aggression					0.847 ***	0.808-0.888	0.915 *	0.854-0.981	0.864 ***	0.821-0.908	0.921 *	0.859-0.989
Verbal Aggression					1.034 *	1.001-1.068	1.036	0.990-1.085	1.040 *	1.005-1.077	1.047	1.000-1.097
Bipolar Disorder					1.352 ***	1.305-1.402	1.415 ***	1.357-1.475	1.356 ***	1.305-1.409	1.409 ***	1.350-1.470
Dementia					0.613 ***	0.602-0.624	0.572 ****	0.559-0.586	0.611 ***	0.599-0.623	0.571 ***	0.558-0.586
Anxiety					0.607 ***	0.591-0.623	0.592 ***	0.570-0.616	0.595 ***	0.579-0.612	0.586 ***	0.563-0.609
Depression					1.435 ***	1.412-1.459	1.572 ***	1.538-1.607	1.414 ***	1.390-1.439	1.558 ***	1.523-1.593
ADL Score					0.960 ***	0.958-0.961	0.963 ***	0.961-0.965	0.961 ***	0.959-0.962	0.964 ***	0.962-0.966

Facility-level variables												
For-Profit Ownership									1.209 ***	1.181-1.237	1.156 ***	1.123-1.191
Government Ownership									0.991	0.951-1.032	1.120 ***	1.067-1.191
Rural vs. Urban									0.943 ***	0.923-0.963	1.011	0.984-1.038
High vs. Low Medicaid									0.954 ***	0.929-0.979	0.927 ***	0.897-0.958
Lowest vs. Highest RN									1.331 ***	1.296-1.367	1.280 ***	1.238-1.324
Lowest vs. Highest LPN									0.823 ***	0.801-0.844	0.802 ***	0.776-0.829
Lowest vs. Highest Aide									0.831 ***	0.810-0.852	0.915 ***	0.885-0.945
High vs. Low Bed Count									0.981	0.956-1.008	0.953 **	0.922-0.985

Facility Case Studies.

Interviews were completed with 39 nursing home staff and prescribing physicians at 14 nursing homes. In order to maximize the contribution of this qualitative study component to understanding both facilitators and barriers for improvement from the perspective of facility staff and clinicians, facilities were selected purposively to include strong improvers as well as some that had made little improvement. We also took into account inclusion of a diverse range of facility characteristics. First, we consulted with experts at state aging agencies and state nursing home associations in seven states and requested that they send us recommendations of nursing homes that had greatly improved their APM rate or had seen little improvement. These recommendations were then compiled into an Excel file, and two nursing homes in each state were chosen based on organizational data from MDS and CASPER that included profit status, number of certified beds, number of dementia residents, percentage of residents on Medicaid, baseline (2014) antipsychotic use rates, and whether the facility had been cited for F-329 in 2015 (for inappropriate medication use). We aimed for a balanced number of non-profit and for-profit nursing homes as well as large and small nursing homes. Overall, 39 facilities had been recommended to us (n=2 in Arkansas, n=7 in California, n=4 in Georgia, n=7 in Maine, n=6 in North Carolina, n=7 in Texas, and n=9 in Wisconsin). We narrowed this down to 14 facilities, two in each of the seven states. (Note that, in some cases, we selected nursing homes that were not on the initial list, mainly because the NH administrator was unable to give approval in a timely way).

We identified several recurring themes in the case study data that provide additional insight into decision making and change, complementing the quantitative results. First, responses suggested considerable staff and clinician buy-in to the campaign’s overall aim of reducing reliance on antipsychotic use, and that buy-in was an important element in successful change in prescribing practices. Facility staff and prescribers generally acknowledged and appreciated the risks of antipsychotic use and supported the need to reduce use and to treat these medications as a last resort. For patient safety initiatives, these findings highlight the importance of achieving buy-in on the goals of the campaign, not simply provider compliance, in accomplishing sustainable improvement that is focused on the well-being of the patient rather than on finding workarounds to policies perceived as unconstructive.

A second recurring theme was that facilities that achieved improvement emphasized the important role of systematic use of data for quality improvement. For example, respondents reported on internal initiatives to analyze facility prescribing data and distribute results to the staff to support monitoring. A Director of Nursing reported: “*We have a task force that’s working on reducing antipsychotics…we have a dashboard…we have the CASPER report. We run it monthly.”*

Third, consistent with findings from a recent systematic review of decision making for dementia patients,[12] respondents offered strong support for the essential role of collaboration and communication in safe dementia care practices. A recurring theme was that incorporating improved practices into prescribing and medication management processes across multiple levels of decision making required the efforts of interdisciplinary teams including staff at all levels, particularly nursing assistants. This supported our initial hypothesis that engaging multiple actors at multiple points in the medication use process is an important facilitator for success in patient safety initiatives aimed at improving medication use. Related to this, respondents also emphasized the importance of clear communication among staff and with physicians. These results highlight that patient safety improvement is a social process, not simply a series of individual clinician decisions. Educational and regulatory initiatives that encourage multiple actors in the medication use process to interact in reviewing existing prescribing patterns, implementing alternative interventions, and de-prescribing when appropriate contribute to a process of normalization of safer practices that, optimally, contributes to sustained change in medication use.

Fourth, respondents spoke about the challenge of and need for individualized approaches to behavioral issues. For example, a registered nurse noted: *"…a patient in the Alzheimer's unit that kept urinating in the hallway in the floor, around the nurse's cart… they tried redirection, they tried toileting, they tried all kinds of things… And then they have these lights that I bought at Wal-Mart that come on when you walk by, and I stuck it to the back of the bedside commode and he began to use the bedside commode instead of urinating in the hallway.*" These results highlight the contribution of encouraging patient-centered approaches that encourage staff to understand and individually address behaviors rather than simply treating them with medication.

Fifth, to achieve such individualized approaches, respondents perceived a need for more training in use of nonpharmacological strategies for symptom management. Nurses described in-service training and informal advice from other staff as useful but not sufficient to give nursing assistants, and even nurses, needed insight into the sources of dementia patients' agitation and aggression and methods for dealing with these behaviors*: "…ask every nurse in the facility, 'Do you feel you're getting the education you need to assist you when caring for these patients [with dementia]?' Because I bet half of them would say, 'No.'"* These findings also highlight the key role of registered nurses that was identified in the quantitative findings about the effects of RN staffing level on AP use rates. Because RNs play a vital role in guiding care provided by other staff, such as nurses' aides, educating them in strategies for nonpharmacological intervention can help reduce reliance on antipsychotics.

Education on dementia management and the risks of pharmacological strategies was also reported to be important for family members. Respondents noted that, in their concern for an elderly relative's well-being and discouragement over aggressive or agitated behaviors, family members often see antipsychotics as a solution rather than a problem. Family members, as well as staff, are part of the medication use process, as interviews indicated that their requests to "do something" about distressing behaviors, or reluctance to consider medication reduction, can be key barriers to patient safety improvement.

Finally, respondents were generally conscious of, and even supportive of, the changes in CMS regulations on antipsychotics, although some took a rather cautious view of monitoring by surveyors, sometimes seeing the surveyors as too focused on "the numbers" and not conscious of the complexities of reducing antipsychotic medication use. A physician commented*, "[The Director of Nursing] does not want to take admissions for somebody that is on an antipsychotic agent because heaven forbid that will mess their numbers up…she is feeling pressure from the state surveyors and other people…."*

Overall, the interviews suggest that reducing antipsychotic medications is more time and resource intensive than relying on medication, by requiring a person-centered approach. However, the consensus was that, given appropriate staff time, training, and effective communication, individualized reduction of antipsychotic medications is achievable as well as desirable.

State Case Studies. State coalition respondents indicated the importance of multi-modal strategies that involved both state-level interorganizational coordination and training and technical assistance at the facility level. In several states, respondents noted the important role, in sustaining these initiatives, of CMS grants from Civil Monetary Funds (funds derived from penalties paid by facilities for quality and safety violations). State respondents, like those in the facility studies, noted the importance of public reporting of antipsychotic use rates at facility and state levels, included on CMS's Nursing Home Compare website beginning in July of 2012.[13] Public reporting served to define change targets and as a catalyst to action: one respondent from Georgia noted *"the powerful motivator of shame."* As a California respondent stated, *"When you compare people to a benchmark and to their peers and they're not looking too good, that definitely gets their attention."*

Public reporting served as an incentive for improvement at both state and facility levels. Texas used metrics to identify facilities that achieved notable reductions in antipsychotic prescribing whose strategies could be shared with other facilities. Maine similarly identified high-improvement facilities and presented these data to state legislators and local media. Conversely, quality metrics were used to identify facilities in greatest apparent need of support for quality improvement (termed by respondents "low-hanging fruit"). Texas identified the 100 facilities with the highest use of antipsychotics and sent certified letters to their Medical Directors, encouraging them to address the issue. Quality Improvement Organizations (QIOs) and regulators also used metrics to focus their efforts. QIOs assisted nursing homes to collect and interpret facility data over time to support monitoring efforts. These interventions were complemented by an increased regulatory focus on antipsychotic use during regular regulatory site visits (survey and certification process), in which each nursing home is visited periodically by a state survey team. In addition, special site visits focused on reviewing dementia care (focused dementia care surveys) were implemented during 2015 in Texas, California, and other states.

Once facility targets were identified, state coalitions developed or obtained training and technical assistance materials to redefine and normalize prescribing and psychosocial practices that rely on person-centered care principles to manage difficult behavior. These training strategies varied from home-grown pamphlets to materials provided by CMS and to the purchase (using Civil Monetary Penalty funds) of consultation and materials on nonpharmacological strategies. States typically offered in-person trainings and created online repositories for ongoing access by facilities. For individual facilities identified as struggling to achieve improvement, QIOs and other coalition participants provided individual assistance, including onsite training, phone-based technical assistance, and facility-to-facility mentoring programs. In Texas, a designated Quality Monitoring Program (QMP), distinct from the survey process, worked with facilities identified as in need of improvement; technical assistance visits addressed monitoring procedures and staff training on evidence-based practices. To address family fears regarding resident behavior that could be a barrier to de-prescribing, some states developed educational materials for families that could be distributed by facilities.

State respondents also reported the importance of involving members of a variety of professional groups in coalition activities, including physicians and pharmacists. For example, in North Carolina, multiple coalition partners participated in training for facilities, including representatives of the state pharmacy association, medical directors, the ombudsman, the QIO, and CMS. Facility training addressed resources available to support improvement and detailed regulatory changes with which they would be expected to comply. Pharmacists in North Carolina were also highly involved in an effort to improve electronic medical records to allow facilities to easily and quickly identify resident-level information about antipsychotic medication use.

Discussion. Many quality initiatives to increase safety and quality in healthcare have had limited or no success. In contrast, the National Partnership has had substantial impact on a practice that has been widely considered a difficult target to change; that has persisted despite highly credible safety evidence; and that has been a challenge in many countries.[16] What, then, was distinctive about this initiative that helped drive its significant impact? Interventions varied across states, and the factors influencing prescribing across the nation's nursing homes are complex. However, several themes, of general relevance to efforts to influence prescribing in healthcare settings, emerge from the multiple quantitative and qualitative perspectives examined in this mixed-methods study.

First, public reporting of a safe-use metric appears to have been a key element in motivating change at both state and facility levels. As a respondent from Texas noted, *"I think that we all were disgusted with being in last place in the country. We were 51st for a long time."* Public reporting of metrics will likely be a useful tool to motivate further progress and respond to any backsliding.

Second, in the large and complex long-term care system, engagement of multiple stakeholders was vital. This process began at the national level, with leadership from CMS, the national nursing home associations, and other key stakeholders. At the state level, a diverse group of organizations was engaged. States that achieved rapid success, such as North Carolina and Georgia, benefited from already developed working relationships among CMS, the Quality Improvement Organizations (QIOs), statewide provider organizations, and individual facilities. These relationships were marshaled to develop new advisory groups to brainstorm strategies to assist facilities with high antipsychotic use. Although these efforts were typically coordinated by the QIO, they benefited from established collaborations among key stakeholder groups. A North Carolina participant described high rates of attendance at initial rollout trainings in 2012 and explained that this pattern was typical in a state in which *"facilities are very, very interested in being on the cutting edge of things."*

In the largest states, the extended time necessary to engage multiple geographically dispersed stakeholders and facilities emerged as an important theme. Trends in California, Texas, and New York earlier (2012-2015) versus later (2016-2017) in the initiative reflect the challenge of generating change in such large systems. The trajectory of change was slower in these states than in smaller states; each achieved greater relative improvement later in the campaign, improving in rank relative to other states. These results suggest that achieving change in large state systems, with thousands of facilities, requires a sustained multi-year effort to engage the necessary range of stakeholders on a statewide basis. Once these initiatives are incorporated into these large systems, however, the experience of California, Texas and New York suggests that sustained change can be achieved in such systems. However, continuing efforts will likely be required to institutionalize these changes.

Third, integration of educational activities and regulatory oversight contributed to the effectiveness of state initiatives. Initiatives based in the survey and certification system, such as focused dementia care surveys in which antipsychotic prescribing was reviewed in detail (conducted in Texas, California and other states during 2015), contributed to facilities' motivation to incorporate improvement strategies into their operations. Respondents reported that regulatory feedback was most effective when it focused on improving internal review and quality management processes rather than on individual cases. For example, one California respondent noted*: "I'm not sure hitting people with a stick for pharmacological use would be as effective as forcing them to write a plan of a correction for care that is not meeting the standard of individualized dementia care including appropriate activities."* More broadly, consistent with findings from systematic reviews of health system initiatives to change prescribing and other clinical practices,[15,17,18] state-level initiatives appeared to be most successful when they achieved buy-in that the recommended practices were in the best interest of patients and accomplished incorporation of desired practices into established workflows.

Fourth, facilities with the most severe understaffing appeared to have been less able to respond to incorporate the recommended practices into their care processes. In particular, lower registered nurse staffing was associated with greater reliance on antipsychotics. This finding is not surprising in view of the substantial differences in RN staffing reported across staffing quartiles. As shown in Exhibit 2, facilities in the lowest quartile averaged only 17 minutes of RN time per resident day, in contrast to 50 minutes for facilities in the highest quartile. Even in nursing homes staffed at the levels recommended by CMS, there may still not be enough staff time for residents with behavioral symptoms of dementia to receive individualized activities and adequate physical activity during the day. Improving the infrastructure for recruiting and training nursing home volunteers (similar to requirements in the hospice industry) could help improve personalized care for residents with dementia and lead to opportunities for volunteers to join the long-term care workforce.[19]

Implications for the Design of Medication Safety Interventions in Nursing Homes. Results suggest that the federally supervised, state-administered oversight structure for nursing homes created under OBRA-87 appears to have functioned well as a framework within which a campaign to address a specific problematic practice can operate effectively. In this regard, the success in reducing antipsychotic prescribing has similarities to earlier successful initiatives to reduce physical restraints, which, like antipsychotics, require a physician order. Use of physical restraints declined from 41% in the early 1990s[18,19] to current rates of less than 3%.[13] As with reducing antipsychotic use, reducing reliance on physical restraints required deployment of individualized strategies in managing patients with complex behavioral disturbances and communications challenges as well as on changing established mindsets concerning appropriate treatment practices.

In the nursing home setting, deploying alternative nonpharmacological strategies in place of medication-based strategies requires adequate RN staffing for individualized care planning and supervision of direct care staff. As reflected in all but the top quartile of nursing homes, current federal requirements do not ensure that staffing levels adequate to provide safe, individualized care. Stronger requirements and incentives to meet CMS minimum safe staffing guidelines would contribute to safer dementia care. The potential for substitution of pharmacological for psychosocial strategies for managing patients with dementia is heightened in the nursing home setting by misaligned financial incentives, because, for long-term residents, facilities are responsible for staffing costs but not for the costs of medications, typically reimbursed by Medicare. This financial misalignment strengthens the argument for stronger federal staffing requirements and maximal transparency of staffing patterns.

Staffing adequacy is, of course, directly related to Medicaid reimbursement for long-term nursing home care, which varies widely across states and falls far short of Medicare reimbursement for post-acute care provided in the same facilities. In consequence, facilities with the greatest dependence on Medicaid reimbursement are less able to provide the level of staff support necessary to deploy personalized dementia care strategies that minimize reliance on antipsychotics. Although Medicaid-dominant facilities did achieve improvement, they remain more dependent on antipsychotic medications for symptom management. Given financial pressures on state budgets, the long-standing challenge of inadequate Medicaid nursing home rates is unlikely to be solved soon; however, current findings suggest the contribution of this challenge to patient safety problems.

Finally, continued financial and logistical support will likely be needed in order for state quality improvement consortia to sustain their efforts over time. CMS funding from Civil Monetary Funds, reported by some respondents as vital in their consortium's success, will likely be needed on a sustained basis.

Overall, results suggest that safer dementia management, with reduced reliance on antipsychotics, is facilitated by approaches that effectively integrate educational and regulatory elements, public quality measure reporting, and adequate staff resources. Accelerated improvement several years into the campaign in several large states, relative to other states, suggests the importance of a multi-year commitment to improvement initiatives in the larger systems. State and federal initiatives appear to have achieved considerable buy-in on the need to reduce antipsychotic use. Study results indicate that, with a combination of educational and regulatory approaches, multi-stakeholder engagement, and measurement-based accountability, substantial improvement in safe dementia care in nursing homes is achievable. However, sustaining these efforts will require continuing collaborative effort. Adequate RN staffing emerged as a key factor, as facilities with lower staffing levels appeared to be less able to incorporate recommended changes into their operations. The importance of adequate staffing highlights financial concerns regarding the impact of reductions to state Medicaid programs and the potential impact on voluntary efforts, including staffing above minimum levels.

The sustainability of the changes achieved by the campaign remains to be determined.[20,21] Modifying practices in the large and complex long-term care system involves difficult challenges of modifying established workflows and clinical habits. Thus far, the campaign has demonstrated significant staying power and, contrary to some expectation, appears to have generated significant buy-in and incorporation of safer dementia care practices into established workflows. There appear to be grounds for optimism that, if safer dementia care practices become embedded in ongoing care processes and in widely shared understandings of best practices, the campaign can achieve long-term impact. Continued progress will likely require systematic continuing education for the large number of staff and physicians who flow through the long-term care system each year. Continued transparency of practices using public reporting of quality measures will also be important, along with integrated regulatory and educational initiatives to maintain focus on safe practices and adequate staffing resources to provide personalized, patient-centered care.

In terms of implications for patient safety improvement initiatives in other clinical situations, particularly those related to safe medication use, results of the present study are suggestive of elements likely to be key for success of large-scale quality and patient safety initiatives. Broadly, they suggest that these elements include a balance between voluntary and mandatory features that require some level of provider engagement, integrating educational and regulatory components; strategies that achieve provider buy-in; use of public reporting as a motivator; and "normalization" of preferred provider behaviors as accepted best practices within the provider community. Normalization is a complex process that takes place within structures of social influence within provider communities as well as other factors, such as financial incentives, "hassle factors," adequacy of staffing, and the availability of alternatives. Interventions that are cognizant of these factors and that work to leverage these motivators are more likely to achieve sustained impact. Research designs that integrate analyses of administrative data on care practices with methods that provide insight on provider and other stakeholder perspectives, on the actual implementation of the interventions, and on the processes by which normalization does and does not take place in different clinical and organizational settings can contribute in important ways to the building of a stronger knowledge base to inform patient safety initiatives across settings and clinical practices.

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