

# The Quality of Antipsychotic Drug Prescribing in Nursing Homes

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**Background:** The prescribing of antipsychotic drugs has been increasing in nursing homes (NHs) since the availability of second-generation antipsychotic agents, also known as the atypicals, but there is little information on the appropriateness of such prescribing.

**Methods:** A retrospective analysis using the nationally representative data set of the Medicare Current Beneficiary Survey merged to Minimum Data Sets assessments, medication administration records, and Medicare claims. We identified a sample of 2.5 million Medicare beneficiaries in NHs during 2000-2001 (unweighted n=1096) to assess prevalence of antipsychotic use, rates of adherence to NH prescribing guidelines, and changes in behavioral symptoms.

**Results:** Approximately 693 000 (unweighted n=302), or 27.6%, of all Medicare beneficiaries in NHs received at least 1 prescription for antipsychotics during the study period: 20.3% received atypicals only; 3.7%, convention-

als only; and 3.6%, both atypicals and conventionals. Less than half (41.8%) of treated residents received antipsychotic therapy in accordance with NH prescribing guidelines. One (23.4%) in 4 patients had no appropriate indication, 17.2% had daily doses exceeding recommended levels, and 17.6% had both inappropriate indications and high dosing. Patients receiving antipsychotic therapy within guidelines were no more likely to achieve stability or improvement in behavioral symptoms than were those taking antipsychotics outside the guidelines.

**Conclusions:** This study detected the highest level of antipsychotic use in NHs in over a decade. Most atypicals were prescribed outside the prescribing guidelines and for doses and indications without strong clinical evidence. Failure to detect positive relationships between behavioral symptoms and antipsychotic therapy raises questions about the appropriateness of prescribing.

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**A**NTIPSYCHOTIC DRUG PRESCRIBING in nursing homes (NHs) has been rising again after a period of marked decreases.<sup>1</sup> In 1999, 19.4% of NH residents received antipsychotics compared with 16.0% in 1995.<sup>2</sup> Antipsychotics have also become the most costly drug class for Medicaid programs, the main payer of medications prescribed in NHs.<sup>3</sup> In 2001, Medicaid spent over \$3.0 billion for antipsychotic drugs compared with \$2.7 billion for antimicrobial agents, \$2.4 billion for cardiovascular agents, and \$1.8 billion for antidepressants.<sup>3</sup> The reversal in NH prescribing patterns and high Medicaid drug expenditures can be attributed to the availability of second-generation antipsychotic agents, first introduced with clozapine and followed by risperidone, olanzapine, quetiapine fumarate, ziprasidone, and lastly, aripiprazole in 2002. These “atypical” agents have transformed the therapeutic applications of antipsychotics by replacing the older conventional agents and expanding the clinical prerogative to prescribe for indications out-

side those approved by the Food and Drug Administration (FDA).<sup>4</sup> The influence of the atypicals in NHs is especially remarkable because antipsychotic use must adhere to prescribing guidelines of appropriateness that limit off-label use.

The rising use of antipsychotics in NHs raises concerns about the quality of care, especially when discordant with prescribing guidelines. Most atypicals received FDA approval for demonstrated efficacy in schizophrenia, yet they are increasingly prescribed for other conditions with less evidence.<sup>4</sup> In NHs, atypicals are prescribed mainly for the behavioral and psychological symptoms of severe dementia even though the clinical response is undergoing study and preliminary findings are equivocal.<sup>5-10</sup> The safety advantage of the atypicals is also under review. The atypicals share a receptor-blocking profile widely promoted as causing less tardive dyskinesia and other movement disorders compared with the conventional agents; however, clinical trials of atypicals show serious adverse events including falls, somnolence, and abnormal gait.<sup>11-15</sup> In the face of limited evidence, the

wider use of antipsychotics in NHs deserves attention to understand the extent of new indications and new patient populations and the ability of established guidelines to protect NH residents from inappropriate use.

The purpose of this study was to provide a current and comprehensive assessment of antipsychotic prescribing in NHs nationwide. The study aims were to (1) provide prevalence estimates of antipsychotics in Medicare NH population; (2) determine the appropriateness of indications and dosing levels according to NH guidelines; and (3) assess improvement in behavioral symptoms by appropriateness of antipsychotic therapy. Only 2 studies have examined antipsychotic use in NHs since the availability of the atypicals, but they were conducted outside the United States or in a few states.<sup>16,17</sup> Our study used a nationally representative data set with resident-level information drawn from in-person surveys, health and behavioral assessments from the Minimum Data Set (MDS), drug information from the Medication Administration Records (MARs), and diagnostic information from Medicare claims.

The appropriateness of antipsychotic drug prescribing in NHs has been a clinical and political issue since a 1986 report by the Institute of Medicine cited widespread misuse of these agents to sedate or discipline NH residents.<sup>18</sup> The following year, Congress passed the 1987 Omnibus Budget Reconciliation Act (OBRA-87; Pub L No. 100-203) with stipulations for more oversight of psychoactive medications in NHs. Studies conducted on the early effects of Federal efforts found declines ranging from 2% to 41% in the number of NH residents receiving conventional antipsychotics.<sup>1,19-21</sup>

The OBRA-87 statute is still in effect to protect NH residents from receiving inappropriate antipsychotics, and it is implemented through prescribing guidelines with routine updates.<sup>22,23</sup> According to the latest guidance, appropriate antipsychotic prescriptions, either conventional or atypical, must have approved indications from a list of conditions described under "Study Definitions" in the "Methods" section.<sup>23</sup> Antipsychotics may also be appropriately prescribed for delirium or dementia but only if psychotic features or dangerous behaviors are also present. Federal guidelines also stipulate maximum daily doses for all antipsychotics and preclude the use of concurrent antipsychotics. Exceptions to these rules require documentation in the resident's record. If residents receive inappropriate antipsychotics, NHs may be cited by the government for deficient care and incur fines and sanctions.

## METHODS

The study used the 2000-2001 Medicare Current Beneficiary Survey (MCBS), a nationally representative data set on the community-dwelling and institutionalized Medicare population. The MCBS tracks the health care and health status of Medicare beneficiaries through person-level surveys and medical claims records. The survey has a 4-year rotating sample of approximately 12 000 people per year, of which about 900 reside in NHs. For NH residents, the MCBS questionnaire gathers information directly from residents when available and their medical records. Data collected in the survey include demographics, assessments of cognitive and physical functioning, and selected facility characteristics including type of institution and

number of beds. Sampling weights in the MCBS can be used to generate population-level estimates.

Our study linked the MCBS survey to 3 data sets with supplemental information on the NH sample: the Medicare Part A and B claims files, monthly extracts of the MARs, and full MDS records. The Medicare claims are included in the MCBS and each encounter record contains diagnoses coded using the *International Classification of Diseases, Ninth Revision (ICD-9)*. The MARs data set contains monthly extracts of the individual's medication administration records, which are gathered during the MCBS interview. These files can link to the MCBS and are available through special requests to the Centers for Medicare and Medicaid Services (CMS).<sup>24</sup> The MAR data capture the drug name, dose, scheduling, and frequency of administration. The CMS also maintains a third data set on the MCBS NH sample: full MDS records that are available for approved purposes. The MDS assessments occur on admission into the facility, at routine intervals, and when significant changes occur in health. Domains within the MDS include demographics, cognitive and behavioral assessments, evaluations of well-being and physical functioning, and disease diagnoses. The MDS has been shown to provide valid measures of resident health and behaviors.<sup>25</sup>

In summary, each year of the study data set provides 1 MCBS survey interview, a year's worth of Medicare part A and B claims records, approximately 4 MDS assessments (some residents had 21), and up to 12 measures of monthly medication use.

## SAMPLE

We pooled the MCBS NH respondents between 2000 and 2001 for a total sampling pool of 1263 individuals. For persons with observations in both years, we assessed only the first year of observation to produce annual estimates with only unique individuals. Persons were excluded if they had no MDS records ( $n=142$ ), changed residences and therefore had incomplete medication records ( $n=75$ ), or had less than 2 months of observation ( $n=87$ ). The final sample comprised 1096 individuals, weighted to represent 2.5 million NH residents nationwide. Each individual was observed for 2 to 12 months, for a mean  $\pm$  SD of  $10.1 \pm 3.1$  months.

## STUDY DEFINITIONS

Our evaluation consisted of developing measures of the indication and dosing components of the NH guidelines and applying them to the study data set to assess concordance. All definitions for the NH guidelines came from the 2001 CMS/OBRA Interpretive Guidelines.<sup>23</sup> Most measures were constructed as cross-sectional assessments that captured any occurrence during the year except where noted.

Definitions for appropriate indications included the following ICD-9 codes: schizophrenia, 295.1-295.4, 297.7, 295.8, and 295.9; schizoaffective disorder, 295.7; schizophreniform, 295.4; Tourette syndrome, 307.2; Huntington disease, 333.4; psychotic/delusional disorders, 291.x, 293.x, 294.0, 294.8, 294.9, 296.x, 297.x, and 298.x; and dementia, 290.x, 294.1, 331.x, and 797.x or the MCBS question indicating dementia. For residents with dementia, MDS behavioral assessments must also show evidence of verbal or physical aggression or delusions or hallucinations. For residents without these indications, we checked the MDS for behaviors listed in the guidelines as inappropriate for antipsychotic treatment. These included impaired memory, wandering, restlessness, unsociability, uncooperativeness, and indifference to surroundings.

Subjects were identified as taking antipsychotic drugs if they received at least 1 antipsychotic agent during the year, regardless of duration of therapy. (Average annual duration of anti-

**Table 1. Characteristics of Medicare Beneficiaries in NHs by Indications for Use and Receipt of Antipsychotic Therapy, 2000-2001\***

Characteristic	Had Appropriate† Indication for Antipsychotic Therapy		No Appropriate† Indication for Antipsychotic Therapy	
	Received Antipsychotics (A)	No Antipsychotics (B)	Received Antipsychotics (C)	No Antipsychotics (D)
Weighted n (unweighted n)	479 000 (211)	654 000 (290)	214 000 (91)	1 162 000 (504)
Total	42.2	57.7	15.5	84.5
Age, mean, y	80.7	83.7	80.4	82.8
Female sex	66.6	72.1	61.0	71.9
White race	87.9	88.2	89.6	84.3
Diagnostic indicators				
Depression	38.6	43.6	44.7‡	37.5
Schizophrenia	45.4‡	3.9§	0.0	0.0
Dementia	84.0	78.4	58.8‡	39.4
Delusional disorder	17.2‡	9.1	0.0	0.0
Hallucination	13.8‡	3.7§	1.3§	0.0
Anxiety	18.0‡	9.4	14.0§	11.6
Behavioral indicators				
Verbal/physical aggression	48.2‡	30.6	19.5§	4.8
Wandering	29.6‡	12.1	9.0§	4.8
Restlessness	68.9‡	39.4	51.7‡	16.9
Unsociability	39.7‡	27.7	34.2‡	7.5
Uncooperativeness	44.4	37.4	30.4‡	13.7
Indifference	45.2‡	27.7	25.1‡	11.7
Cognitive indicator				
Impaired memory	78.7	81.5	63.1	56.4
Died	21.2‡	31.7	22.7‡	32.9
NH Ownership				
Private profit	73.7	69.9	72.0	72.4
Private nonprofit	18.7	22.8	25.4	20.8
Public	7.2§	7.3§	2.6§	6.6
No. of beds				
<60	6.3§	9.8	6.4§	7.7
60-119	43.2	46.9	36.9	43.5
≥120	50.5	43.3	56.7	48.8
Geographic region				
Northeast	22.9	19.2	23.8	20.9
Midwest	32.3	28.5	24.6	31.7
South	31.1‡	38.3	38.7	31.8
West	13.7	14.0	12.8§	15.6

Abbreviation: NH, nursing home.

\*Data are given as percentage unless otherwise specified. Source: the 2000-2001 Medicare Current Beneficiary Survey.

†Appropriateness based on the NH guidelines.<sup>23</sup>

‡Significant difference at  $P < .05$  (A) vs (B) and (C) vs (D).

§Cell size less than 20.

psychotic use was 6.4 months.) Antipsychotic drugs were further classified as atypical agents or conventional agents.

For dosing compliance, we compared the daily dosing (DD) levels of every antipsychotic to the NH guidelines' geriatric maximum DD recommendations as well as assessed the presence of duplicative antipsychotic therapy. (The NH guidelines stipulate duplicative antipsychotic therapy is a dosing violation.) Daily doses were calculated for each antipsychotic by dividing the quantity dispensed by the number of days in the month. Our calculations excluded PRN medications never administered and did not consider dosage forms, which were often missing. (Frequency of antipsychotic dosage form was 65.4% tablets or capsules, 1.4% intramuscular or intravenous, and 33.3% missing.) Violations required the administered DD to be above guideline levels for at least 2 consecutive months. Excessive dosing was categorized as 101% to 150% above the recommendations or higher. To qualify as duplicative antipsychotic therapy, both atypical and conventional agents must be administered together for at least 2 consecutive months. Sequential therapy

was defined as receiving atypical and conventional agents together for less than 2 consecutive months.

Finally, we analyzed the last MDS assessment of changes in behavioral symptoms compared with 90 days prior (or since the last assessment). This is a global assessment that includes (but is not limited to) wandering, aggression, socially inappropriate behavior, or resistance to care. The MDS reviewers are instructed to make this assessment after reviewing the nursing notes and last quarterly MDS assessment as well as observing the resident and consulting with staff and family members when possible.

## RESULTS

**Table 1** compares all Medicare NH residents in 2000-2001 by evidence of potentially appropriate indications for antipsychotic therapy and whether they received these

**Table 2. Prevalence of Antipsychotic\* Use and Appropriateness† of Daily Dosing Levels, 2000-2001, in 2.5 Million NH Residents‡**

Agent/Therapy	Overall Prevalence	Actual DD Relative to Recommended DD§		
		Within 100%	Exceeds by 101%-150%	Exceeds by >150%
Any antipsychotic agent (n = 693 000)	27.6	71.5	24.3	4.2
With appropriate indication	19.4	68.5	31.5	
No appropriate indication	8.4	75.8	24.2	
Atypical agents (recommended DD,§ mg/d)	23.9	72.5	25.7	1.8
Risperidone (2.0)	15.5	75.0	18.1	6.9
Olanzapine (10.0)	6.9	77.4	16.8	5.8
Quetiapine fumarate (200.0)	2.8	67.8	29.1	3.1
Conventional agents (recommended DD,§ mg/d)	7.3	58.1	20.2	21.8
Haloperidol (4.0)	4.8	60.6	23.4	16.0
Thioridazine hydrochloride (75.0)	1.6	67.0	21.6	11.4
Others	1.5	33.0	18.6	48.4
Sequential antipsychotic therapy	2.3	NA	NA	NA
Duplicative antipsychotic therapy	1.3	0.0	100.0	

Abbreviations: DD, daily dose; NA, not applicable; NH, nursing home.

\*Clozapine, olanzapine, quetiapine fumarate, risperidone, chlorpromazine, fluphenazine hydrochloride, perphenazine, mesoridazine besylate, prochlorperazine maleate, promazine hydrochloride, trifluoperazine hydrochloride, triflupromazine hydrochloride, thioridazine hydrochloride, thiothixene hydrochloride, haloperidol decanoate, loxapine succinate, molindone hydrochloride, and pimozide.

†Source: the 2000-2001 Medicare Current Beneficiary Survey.

‡Data are given as percentage.

§Based on the NH guidelines.<sup>23</sup>

agents. Our weighted estimates indicate approximately 45.3% of the 2.5 million Medicare beneficiaries in NHs had indications appropriate for antipsychotic therapy, of which 42.2% received antipsychotics. Among this group, those using antipsychotics compared with nonusers were more likely to have schizophrenia (45.4% vs 3.9%;  $P < .001$ ), delusional disorders (17.2% vs 9.1%;  $P < .001$ ), hallucinations (13.8% vs 3.7%;  $P < .001$ ), and anxiety (18.0% vs 9.4%;  $P < .001$ ). Behavioral problems were more common among antipsychotic users relative to nonusers, especially physical or verbal aggression (48.2% vs 30.6%;  $P < .001$ ). Nursing home characteristics were similar for both groups except for residence in the South where antipsychotic rates were lower (31.1% vs 38.3;  $P < .001$ ).

More than 200 000 NH residents received antipsychotics but had no appropriate indications for use. These individuals were more likely than other residents without indications for antipsychotic therapy to have depression (44.7% vs 37.5%;  $P < .001$ ) and dementia (58.8% vs 39.4%;  $P < .001$ ). Nonaggressive behavioral problems were also more common in these residents receiving inappropriately prescribed antipsychotics, such as restlessness (51.7%), unsociability (34.2%), uncooperativeness (30.4%), and indifference to their surroundings (25.1%), compared with 16.9%, 7.5%, 13.7%, and 11.7%, respectively, of the residents appropriately not using antipsychotics.

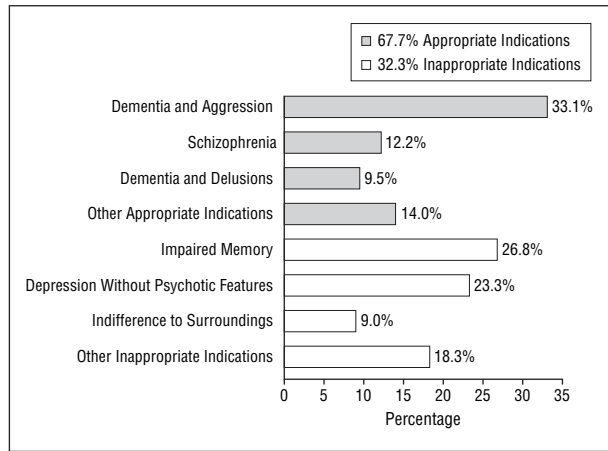
**Table 2** shows that approximately 693 000 NH residents (unweighted  $n = 302$ ) received at least 1 prescription for antipsychotics in 2000-2001. (Average duration of antipsychotic therapy was 6.5 months during the year [data not shown].) More than one third received doses exceeding the NH dosing guidelines. High doses were slightly more common with appropriate indications than with inappropriate ones (31.5% vs 24.2%). Most

antipsychotics prescribed (86.6%) were for the atypical agents, of which risperidone was most common. Almost three quarters (72.5%) of the residents using atypical antipsychotics received daily doses within the NH guidelines for maximum daily doses, 25.7% received doses 101% to 150% above the maximum limit, and about 2% had even higher doses.

About a quarter of antipsychotic users received conventional agents (7.3% of all NH residents). Among the conventionals, haloperidol was the most commonly prescribed. In contrast to the atypicals, dosing of conventional agents more often exceeded the NH guidelines. Only 58.1% of all users of conventional antipsychotics received dosage levels within the recommended maximums. Around 13% of all antipsychotic users (3.6% of all NH residents) received both conventional and atypical agents, of which a third was duplicative therapy.

The indications for use of antipsychotics are displayed in **Figure 1**, of which approximately two thirds (67.7%) were appropriate. The most common reason for appropriately prescribing antipsychotics was dementia with aggressive behaviors (33.1%), followed by schizophrenia (12.2%) and dementia with delusions (9.5%). The other third (32.2%) of NH residents receiving antipsychotics had inappropriate indications. Impaired memory was the most common inappropriate indication (26.8%), followed by depression without psychotic features (23.3%).

**Figure 2** describes changes in behavioral symptoms by appropriateness of antipsychotic drug therapy. Most residents (88.5%) receiving antipsychotics in compliance with the NH guidelines exhibited improved or stable symptoms while 11.5% had worsening symptoms. Residents with antipsychotic therapy with dosing and/or indication violations showed simi-



**Figure 1.** Appropriateness of indications for antipsychotics, 2000-2001 (n=693 000 nursing home residents). Appropriateness is based on the nursing home guidelines.<sup>23</sup> "Other Appropriate Indications" includes psychotic and delusional disorders. "Other Inappropriate Indications" includes insomnia, anxiety, wandering, restlessness, uncooperativeness, and unsociability.

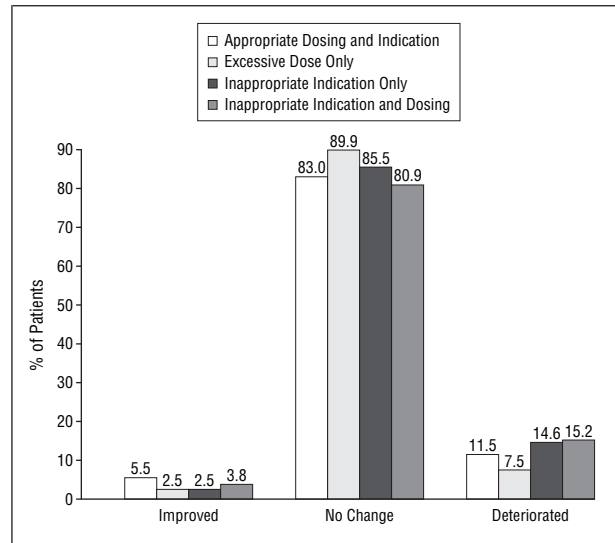
lar levels of behavioral change and no statistically significant differences.

### COMMENT

Our most important finding was the high level of antipsychotic prescribing in NHs: more than 1 of every 4 (27.6%) Medicare beneficiary in an NH received antipsychotics during 2000-2001. This estimate is the highest reported in nearly a decade and is, in fact, within the lower bounds of rates documented prior to the OBRA-87 regulations, which ranged from 20% to 50%.<sup>1,16,20,21</sup> Other recent estimates for comparison are 24.0% in Canada for the years 1998 to 2000, and 18.2% in 5 US states in 1999 and 2000.<sup>16,17</sup> We attribute the high rate detected in this study to an increasing trend in use of atypical antipsychotics in NHs. To test this hypothesis we conducted an ad hoc analysis of atypical use in NHs using previous years of the MCBS and found a nearly doubling of use within 3 years: 12.2% in 1998, 17.3% in 1999, and 21.5% in 2000.

High use does not necessarily indicate misuse; however, our assessment detected high levels of apparent non-compliance with the NH guidelines. This study found over half (58.2%) of the Medicare NH residents who received antipsychotics took doses exceeding maximum levels, received duplicative therapy, or had inappropriate indications according to guideline requirements. Most of the out-of-guideline prescribing was associated with use of antipsychotics for memory problems, nonaggressive behaviors, or depression without psychotic features. These indications were strongly discouraged by a recently convened expert panel on appropriate use of antipsychotics in older adults.<sup>26</sup> The next most common reason for non-compliance (28.5% of cases) was for high doses of antipsychotics, which characterized the care of nearly 197 000 NH residents during the study period. Excessive dosing was more common with conventional agents than with the atypicals (41.9% vs 27.5%).

Our estimate of compliance with recommended indications for antipsychotics (67.7%) compares with the range



**Figure 2.** Change in behavioral symptoms in last 90 days by appropriateness of antipsychotic drug prescribing, 2000-2001 (n=693 000 nursing home residents). Appropriateness is based on the nursing home guidelines.<sup>23</sup> (Source: the 2000-2001 Medicare Current Beneficiary Survey.)

of 16.4% to 91.1% found by Liperoti et al,<sup>16</sup> whose wide estimate accommodates various definitions of allowable indications. Our estimate of compliance with DD levels for antipsychotics (71.8%) is lower than the 90.2% detected by Bronskill et al,<sup>17</sup> a difference possibly due to Canadian policies and the study focus on incidence use.

It is an open question whether the low compliance rates detected in this study represent justifiable differences of opinion between practicing physicians and the NH requirements for appropriate antipsychotic use. Because its original mandate was to reduce the use of chemical restraints, the OBRA-87 NH guidelines are fairly conservative and focus on misuse rather than rules for preferred treatments. A comparison of 2004 consensus recommendations for antipsychotic prescribing in older patients shows no disagreement with the NH guidance.<sup>26</sup> In fact, the consensus panel noted the need for more therapeutic guidance with these agents.

Lastly, our assessment of changes in behavioral symptoms among antipsychotic users should be considered a preliminary finding deserving more investigation. The complexity of caring for this difficult population means that even appropriate prescribing cannot guarantee improvement. Nearly 40% of our study population using antipsychotics still regularly resisted taking medications or eating meals. Nearly as many (38.4%) made disruptive noises such as screaming, disrobed in public, or threw food or feces. Clearly, NH residents and caregivers need more effective therapies for managing behavioral problems and better data to guide appropriate use. The need for high-quality evidence is especially pressing as the proportion of NH residents with serious behavioral problems is growing, from 29% in 1995 to 31% in 1999.<sup>2</sup> Barriers include the lack of consistent outcomes measures in clinical trials studying behavioral therapies in NH populations as well as no clear consensus on measurement thresholds for clinically significant responses.<sup>5</sup> Our study cannot easily explain the lack of improved or stable behavioral patterns with appropri-

ately prescribed antipsychotics. To test for adverse selection, we estimated a logistic model of behavioral deterioration, controlling for demographics, diagnoses, behaviors and residence characteristics. Our analysis still detected no significant differences by prescribing appropriateness. It should be noted, however, that others have also failed to detect improvement in patient outcomes with expanded use of atypical drugs. Duggan<sup>3</sup> found no reduction in admissions to hospitals or long-term care facilities after California Medicaid increased spending on atypical antipsychotics by 670% over 8 years.

Our analysis has several limitations. First, the NH guidelines allow for noncompliance if the documentation clearly states medical necessity, so some antipsychotic prescribing classified as noncompliant here may have been within the guidelines. Second, our study could not distinguish whether compliance with the guidelines varied by symptom severity or if there were cases of dose-induced sedation with antipsychotics. Third, dementia was highly common in the patients who received antipsychotics, and research has detected underestimates with MDS assessments in demented patients.<sup>27</sup> Lastly, our findings may reflect a channeling effect when the most problematic residents are placed in NHs with higher standards of care. Nevertheless, the study's use of a nationally representative data set of MDS records, medication records, Medicare claims, and in-facility surveys provides unparalleled information on the use of antipsychotics by NH residents in the Medicare program.

This research demonstrates, as others have shown, that there are considerable gaps between the medications clinical evidence recommends and the medications clinical practice delivers.<sup>28</sup> In this case, even the established use of prescribing guidelines appears to have had limited ability to rein in the off-label use of atypicals in frail, elderly NH residents. Perhaps this reflects the controversy in restricting antipsychotics through guidelines or formulary policies given the variable responses of patients to this class of medications.<sup>29,30</sup> Nevertheless, this study raises questions about the current uses of antipsychotics in NHs and the role of prescribing guidelines. Now is an opportune time to evaluate this policy as Medicare readies itself to inherit Medicaid's growing costs and concerns over the widespread prescribing of atypicals to frail NH residents.

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