

Does Incorporating Medications in the Surveyors' Interpretive Guidelines Reduce the Use of Potentially Inappropriate Medications in Nursing Homes?

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OBJECTIVES: To quantify the association between including specific medications deemed potentially inappropriate in the surveyors' interpretive guidelines for nursing homes and the prevalence of use.

DESIGN: Quasi-experimental.

SETTING: One thousand one hundred forty-one nursing homes in four U.S. states.

PARTICIPANTS: Residents living in one of the included nursing homes in operation during 1997 (before Beers; n = 130,250) and 2000 (after Beers; n = 164,889).

INTERVENTION: Inclusion of specific medications deemed potentially inappropriate in the surveyors' interpretive guidelines for nursing homes.

MEASUREMENTS: Logistic regression models adjusting for clustering effects of residents residing in homes provided estimates of the relationship between the survey process and use of any medications targeted as potentially inappropriate as part of the survey process, as well as those deemed inappropriate but not included.

RESULTS: The use of any potentially inappropriate medication decreased from 42.5% in 1997 to 39.8% in 2000. After adjustment for resident characteristics, residents were less likely to receive any potentially inappropriate medication (odds ratio (OR) = 0.85, 95% confidence interval (95% CI) = 0.84–0.87), those considered high-severity drugs (those with a high likelihood of a clinically significant adverse event) (OR = 0.67, 95% CI = 0.65–0.69), or Beers' medications not included in the surveyors' guidelines (OR = 0.76, 95% CI = 0.74–0.79) in 2000 than in 1997 after the changes to the drug regulations and interpretive guidelines.

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CONCLUSION: Targeting specific drugs in the surveyor's interpretive guidelines as a method to reduce potentially inappropriate medication use may not produce desired gains in medication-use quality improvement. Alternative strategies for nursing homes should be evaluated. *J Am Geriatr Soc* 55:666–673, 2007.

Key words: nursing homes; medication use; policy

Effective July 1, 1999, the Centers for Medicare and Medicaid Services (CMS) incorporated a modified version of the Beers criteria^{1,2} into the surveyors' interpretive guidelines. In 1991, Beers et al. developed explicit criteria that defined the use of inappropriate medications for older people.¹ These criteria, which were developed using a consensus of internationally recognized experts in geriatric medicine for the elderly population and updated and expanded in 1997,² identified medications that should generally be avoided in older people, doses or frequencies of administrations that should generally not be exceeded, and medications that should be avoided in older persons known to have any of the several comorbidities. A subset of high-severity drugs (those with a high likelihood of causing a clinically significant adverse event) have been included in the category of unnecessary drugs (Tag 329 of the regulations).³ Drugs with a high potential for less-severe adverse outcomes are part of the drug therapy review process conducted by a consultant pharmacist every month (Tag 428/429 of the regulations).³ CMS's decision not to include propoxyphene, oxybutynin, and iron supplementation greater than 325 mg in the surveyors' interpretive guidelines provides a unique opportunity to estimate the relationship between such regulatory approaches and prescribing patterns observed in nursing homes. The hypothesis was that regulatory initiatives aimed at improving pharmaceutical care in nursing homes will promote the reduction of use of specific drugs targeted but will not necessarily diffuse to other medications. Specifically, the use of drugs not included in the interpretive guidelines (and

therefore not subject to regulation) will persist, whereas drugs subject to regulation will decrease in prevalence.

METHODS

The institutional review board of Brown University approved this study.

Minimum Data Set

Data for the current study were from the Systematic Assessment of Geriatric drug use via Epidemiology (SAGE) database.⁴ At the core of SAGE is the Resident Assessment Instrument, with its more than 350-item Minimum Data Set (MDS). CMS mandates MDS assessments at admission, quarterly, and annually. The MDS includes sociodemographic data; information on domains such as cognitive patterns, communication, mood and behavior, physical functioning, and psychosocial well being; and an extensive array of signs, symptoms, syndromes, active clinical diagnoses, and treatments.⁵ A variety of summary scales have been extracted from the MDS, including activities of daily living (ADLs) and the Cognitive Performance Scale.⁶ The validity of these scales has been demonstrated elsewhere.^{7,8}

Operational Expression of the Outcome Variables

The outcome variables were defined using the MDS detailed drug section (Section U), which includes information on residents' medications, including brand or generic name,

dosage, route and frequency of administration, and whether the drug was given as a standing or as-needed order. This section lists all prescription and over-the-counter medications taken by a resident in the 7 days preceding the assessment. The outcome variables were defined to reflect the classifications of medications targeted by the survey process as well as the timing of their inclusion. First, the code captured the drugs included on the Beers list of potentially inappropriate medications that had been included as targeted medications as part of the surveyors' interpretive guidelines since October 1990 (Table 1). A separate outcome variable defined medications targeted in the survey process as of July 1, 1999, and deemed to be high-severity drugs according to Beers under the category of unnecessary drugs (Tag 329). A separate binary variable identified the medications identified by Beers as potentially inappropriate and included in Tag 428/429 of the CMS *Guidance to Surveyors—Long-term Care Facilities*. An additional outcome variable (binary) included medications that CMS did not include in the interpretive guidelines. The following medications deemed potentially inappropriate by Beers criteria were not included in the surveyors' interpretive guidelines: propoxyphene, oxybutynin, and iron supplements at doses greater than 325 mg.

Operational Expression of the Determinant

Implemented in October, 1990, the Omnibus Budgetary Reconciliation Act of 1987 (OBRA 87) states that each

Table 1. Potentially Inappropriate Medications (Included in Beers Criteria [1991, 1997]^{1,2}) and Association with the Nursing Home Surveyors' Interpretive Guidelines

Category on Survey	Survey Description	Beers Classification (1997)	Drugs
Included in guidelines effective 10/1/1990	Unnecessary drugs*	High severity	Flurazepam, meprobamate, lorazepam, oxazepam, alprazolam, temazepam, zolpidem, triazolam, chlordiazepoxide, diazepam, barbiturates (except phenobarbital)
Tag 329 listed in interpretive guidelines effective 7/1/1999	Unnecessary drugs*	High severity	Amitriptyline, chlorpropamide, digoxin (if dose > 0.125 mg per day), disopyramide, doxepin, gastrointestinal antispasmodics (belladonna alkaloids, clindinium, dicyclomine, hyoscyamine, propantheline), meperidine, oral (if started within previous month), methyldopa (if started within previous month), pentazocine, ticlopidine
Tag 428/429 listed in interpretive guidelines effective 7/1/1999	High potential for less-severe adverse outcomes [†]	Mix of high/low severity	Antihistamines (diphenhydramine, chlorpheniramine, hydroxyzine, cyproheptadine, promethazine, tripelemamine, dexchlorpheniramine), dipyrindamole [‡] , ergot mesyloids [‡] (e.g., hydergine [‡]), indomethacin, meperidine, oral (if >1 month), methyldopa (if >1 month), muscle relaxants (carisoprodol, chlorzoxazone, cyclobenzaprine, dantrolene, metaxalone, methocarbamol, orphenadrine) reserpine, [‡] trimethobenzamide
Drugs not included in the guidelines	Not applicable	Low severity	Propoxyphene and combination products, oxybutynin, iron supplements doses > 325 mg

* Defined in the regulations as follows. "An unnecessary drug is any drug when used: in excessive dose (including duplicate therapy), excessive duration, without adequate monitoring or, without adequate indications for its use or, in the presence of adverse consequences which indicate the dose should be reduced or discontinued, or any combinations of the above reasons."

[†] As defined in the Guidance to Surveyors.

[‡] Low-severity drugs according to Beers criteria.

resident's drug regimen must be free from unnecessary drugs.⁹ Specifically, facilities must ensure that residents are not given antipsychotic drugs unless medically necessary to treat a specific condition. Effective July 1, 1999, CMS incorporated a modified version of the Beers criteria^{1,2} into the surveyors' interpretive guidelines. The interpretive guidelines have attempted to specify and standardize the survey process nationally, although individual surveyors still have to apply a degree of personal judgment in assessing deviation from the regulations.

CMS oversees the implementation of the legislation. Pharmacists are required to review all residents' medication on a monthly basis and, through an inspection or survey process, oversee enforcement of these regulations. Performed by state employees (teams of three to four nursing home specialists who have passed a federal test to qualify as a nursing home surveyor), surveys are conducted unannounced on average every 12 months (range 9–15 months) to make sure that the nursing home is meeting state and federal standards (if Medicare/Medicaid certified). The standards define how care must be provided to nursing home residents. Deficiencies range in scope and severity from isolated violations with no actual harm to residents to widespread violations that cause injuries or put residents in immediate jeopardy of harm. In preparation for the survey, team members review the nursing home's background, including previous survey results, complaint investigations, incident reports, and quality indicators. Surveyors observe what is going on in the nursing home; interview residents, family members, and nursing home employees; and read medical records and other documents.

Facilities not meeting the standards have 10 days to respond with a plan of correction and must correct deficiencies. Contravention of the regulations, unless clinical justification is documented, can lead to a range of sanctions, including closure of the facility. A follow-up survey takes place to verify the accurate and timely implementation of the "plan of correction." For the current study, the operational expression of the determinant was based on the dates of data collection. Data from 1997 represented the preimplementation period (to avoid evaluating anticipatory changes in prescribing), and data from 2000 represented the postimplementation period. The first year with complete data after the implementation of the guidelines and the last full year of data available in the SAGE database was 2000. If the changes in the interpretive guidelines were to have an effect, it was hypothesized (on the basis of documented anticipatory changes occurring with the implementation of other regulations (e.g., OBRA 87)) that the effect would have occurred immediately.

Study Sample

Few states systematically collect data for the MDS detailed drug section. For this reason, the current study focused on the MDS data collected on residents of nursing facilities in the states that systematically included these data (Kansas, Maine, Mississippi, and Ohio). There were 1,077,381 MDS records for admission, quarterly, or annual assessments during the study period. Because medication use can vary over time, one assessment was randomly selected per resident ($n = 398,709$) per time period. Residents living in

facilities with valid facility identifiers on the MDS and who systematically documented medication information that appeared to be internally consistent were included ($n = 352,643$). Internal consistency of the data was determined by comparing drug information collected in Section U with specific MDS items regarding drug use. Furthermore, a facility was considered to have consistently completed Section U if at least 95% of residents were taking at least one medication as determined by Section U. To reduce confounding by facility characteristics related to closing and opening of facilities, residents were required to be living in homes that were in operation during both of the time periods under study. The remaining 130,250 residents in 1997 and 164,889 residents in 2000 living in 1,141 nursing facilities constituted the study sample.

MEASURES

Based on previous work,¹⁰ sociodemographic variables (age, race/ethnicity); comorbid conditions (number of comorbid conditions, cardiovascular disease, stroke, hypertension, diabetes mellitus); and measures of physical, cognitive, and social functioning as potential resident-level predictors of use of potentially inappropriate medications were potential confounders. The ADL scale provided a measure of limitation in physical functioning. The ADL scale is based on six levels of self-performance in the areas of dressing, eating, toilet use, bathing, locomotion, transfer, and continence. The Cognitive Performance Scale⁶ is a seven-point ordinal scale that includes two cognitive items (short-term memory and decision-making skills), a measure of communication ability (understood by others), self-performance in eating, and whether the resident is comatose.

Analytic Approach

Correlations between the potential confounders demonstrated that multicollinearity would not threaten the validity of the models. Logistic regression models provided estimates of the independent association between the change in the surveyors' interpretive guidelines and prevalence of medication use while simultaneously controlling for the effects of the case-mix of residents in the facility. Logistic regression models adjusted for the clustering effects owing to the correlation of residents living within the same home using generalized estimating equations in SAS GENMOD (SAS Institute, Inc., Cary, NC). It was assumed that resident characteristics were similarly related to the outcomes across all facilities. The odds ratio (OR) was derived to estimate the association between the surveyors' guidelines and medication use and corresponding 95% confidence intervals (CIs) from the final models. For facility factors predicting treatment patterns, the extent to which the effect of the incorporation of Beers criteria in the surveyors' interpretive guidelines differed according to organizational characteristics was evaluated using methods described by Rothman.¹¹

RESULTS

Characteristics of the 1,141 nursing homes that were included in the study are shown in Table 2. More than 50% had between 81 and 199 beds and were part of chain, almost three-quarters were for profit, and 23.9% had

Table 2. Characteristics of Nursing Facilities (Kansas, Maine, Mississippi, and Ohio) (N = 1,141)

Characteristic	Value
Structural, %	
With certified 81–199 beds	50.8
With certified ≥200 beds	4.9
For profit	73.2
Nonprofit	20.5
Government	6.3
Part of a chain	54.1
Hospital-based facility	7.9
Having any special care unit	23.6
Resource	
With occupancy rate <95%, %	62.4
Source of payment, median ± SD	
Medicare	9.6 ± 16.4
Medicaid	67.5 ± 21.3
Other	22.9 ± 16.7
Staff resource	
Nurse staffing per 100 beds, average ± SD	
Certified nursing assistants	36.0 ± 11.4
Registered and licensed practical nurses	20.0 ± 9.1
Medical director/other physician, %	10.8
Contract pharmacists used, %	60.1
Having physician extenders, %	11.7

Note: Derived from the Online Survey Certification and Automated Record data system.
SD = standard deviation.

special care units. The predominant source of payment was Medicaid (67.5% of facilities). The average number of certified nursing assistants and registered nurses/licensed practical nurses per 100 beds was 36 and 20, respectively; 60.1% of nursing homes used contract pharmacists.

Characteristics of the residents as derived from MDS data in 1997 and 2000 are summarized in Table 3. The two samples were broadly comparable. There were more residents with severe physical and cognitive impairment in 1997 (39.5% and 21.3%, respectively) than in 2000 (34.7% and 17.7%, respectively). Diabetes mellitus and hypertension were more prevalent in residents in 2000 than in 1997.

Changes in the use of potentially inappropriate medications before and after inclusion of the new regulations and interpretive guidelines are shown in Table 4. Overall, there was a reduction in use of any potentially inappropriate medication (Table 1) from 42.5% in 1997 to 39.8% in 2000. For drugs (largely benzodiazepines) that were included in the regulations before 1999, there was an increase in use from 17.9% (1997) to 19.8% (2000). Drugs classified under Tag 329 (unnecessary or high severity) that were included in the revised regulations after 1999 were used less in 2000 than in 1997 (9.3% vs 12.9%). The most notable reductions were in the use of amitriptyline, digoxin (at doses higher than 0.125 mg/d), and ticlopidine. For those classified under Tag 428/429 (high potential for less-severe outcomes and a mix of high/low severity), use remained stable between 1997 (11.4%) and 2000 (11.0%). The most marked reduction was in the use of dipryridamole (1.4% in

Table 3. Characteristics of Nursing Home Residents in Kansas, Maine, Mississippi, and Ohio

Characteristics	1997	2000
	(n = 130,250)	(n = 164,889)
	%	
Female	72.1	70.1
Age		
75–84	35.0	34.9
≥85	42.0	39.0
Minority race/ethnicity	11.4	12.7
Physical functioning		
Moderate impairment	48.2	52.8
Severe impairment	39.5	34.7
Cognitive function		
Moderate impairment	49.1	49.1
Severe impairment	21.3	17.7
Specific diagnoses		
Dementia	36.8	33.7
Alzheimer's disease	15.3	14.6
Parkinson's disease	6.4	6.2
Cancer	9.4	10.8
Diabetes mellitus	22.4	26.4
Cerebrovascular accident	23.9	22.4
Heart failure	25.0	25.8
Coronary artery disease	18.5	16.5
Arrhythmia	14.8	16.9
Hypertension	46.4	54.5
Other cardiovascular disease	24.3	25.7

Note: Characteristics derived from resident-level Minimum Data Set.

1997 to 0.8% in 2000). There was an approximately 2% reduction in use between 1997 and 2000 (10.2% to 8.4%) of propoxyphene and combination products that are classified under the Beers criteria but were not included in the revised guidelines. Residents were less likely to receive any potentially inappropriate medication (adjusted odds ratio (AOR) = 0.85, 95% confidence interval (CI) = 0.84–0.87), less likely to receive medications included in Tag 329 (AOR = 0.67, 95% CI = 0.65–0.69), and less likely to receive Beers' medications not targeted in the survey process (AOR = 0.76, 95% CI = 0.74–0.79) in 2000 than in 1997.

This study evaluated the extent to which reductions in the prevalence of potentially inappropriate medication use identified under Tag 329 differed according to characteristics of the facility related to structural factors (part of chain, size, hospital-based) and staffing resources (physician extender used, full-time physician present, contractual arrangement for pharmacy services). There were no differences in the effect of the regulations on use of potentially inappropriate medications according to staffing resources, although interactions were observed for several structural factors. Figure 1A shows that larger nursing homes experienced greater reductions in the use of medications identified under Tag 329 than smaller nursing homes. Figure 1B shows that free-standing facilities also experienced greater reductions under the regulations than hospital-based facilities.

Table 4. Use of Potentially Inappropriate Medications Before and After Expanded Surveyors' Interpretive Guidelines in Nursing Homes Effective July 1, 1999

Category on Survey	1997 (n = 130,250)	2000 (n = 164,889)
	%	
Any potentially inappropriate medication	42.5	39.8
Included in guidelines 10/1/1990 (unnecessary drugs*; high severity [†])	17.9	19.8
Flurazepam	0.1	0.1
Meprobamate	0.2	0.2
Lorazepam	8.5	9.1
Oxazepam	0.5	0.4
Alprazolam	2.5	3.1
Temazepam	2.1	2.1
Zolpidem	2.3	3.1
Triazolam	0.2	0.1
Chlordiazepoxide	0.3	0.4
Diazepam	1.4	1.2
Barbiturates [‡]	1.7	1.8
Tag 329 - effective 7/1/1999 (unnecessary drugs*; high severity [†])	12.9	9.3
Amitriptyline	3.1	2.5
Chlorpropamide	0.2	0.1
Digoxin (>0.125 mg/d)	5.1	3.9
Disopyramide	0.1	0.1
Doxepin	1.2	0.7
Gastrointestinal antispasmodics (belladonna alkaloids, clindinium, dicyclomine, hyoscyamine, propantheline)	1.4	1.2
Pentazocine	0.1	0.1
Ticlopidine	1.7	0.3
Tag 428/429 - effective 7/1/1999 (high potential for less- severe outcomes*; mix of high/low severity [†])	11.4	11.0
Antihistamines (diphenhydramine, chlorpheniramine, hydroxyzine, cyproheptadine, promethazine, tripelennamine, dexchlorpheniramine)	6.0	6.4
Dipyridamole	1.4	0.8
Ergot mesyloids	0.3	0.2
Indomethacin	0.4	0.3
Meperidine	0.1	0.1
Methyldopa	0.5	0.3
Muscle relaxants (carisoprodol, chlorzoxazone, cyclobenzaprine, dantrolene, metaxalone, methocarbamol, orphenadrine)	1.1	1.1
Reserpine	0.4	0.5
Trimethobenzamide	0.2	0.2
Drugs not included in the guidelines	13.7	11.4
Propoxyphene and combination products	10.2	8.4
Oxybutynin	2.8	2.3
Iron supplements (doses > 325 mg)	1.2	1.0

* Defined in the regulations as follows. "An unnecessary drug is any drug when used: in excessive dose (including duplicate therapy), excessive duration, without adequate monitoring or, without adequate indications for its use or, in the presence of adverse consequences which indicate the dose should be reduced or discontinued, or any combinations of the above reasons."

[†] High/low-severity drugs according to Beers criteria.

[‡] Excludes phenobarbital.

DISCUSSION

To the authors' knowledge, only one study has examined the association between mandated drug regimen reviews and inappropriate prescribing.¹² The current study differs, because the goal was to evaluate the extent to which ex-

panding the surveyors' guidelines for use in U.S. nursing homes to include more potentially inappropriate medications defined using Beers criteria was associated with changes in prevalence of medication use. The findings from the current study are consistent with previous work. Despite the low prevalence of some of the drugs, the analytical

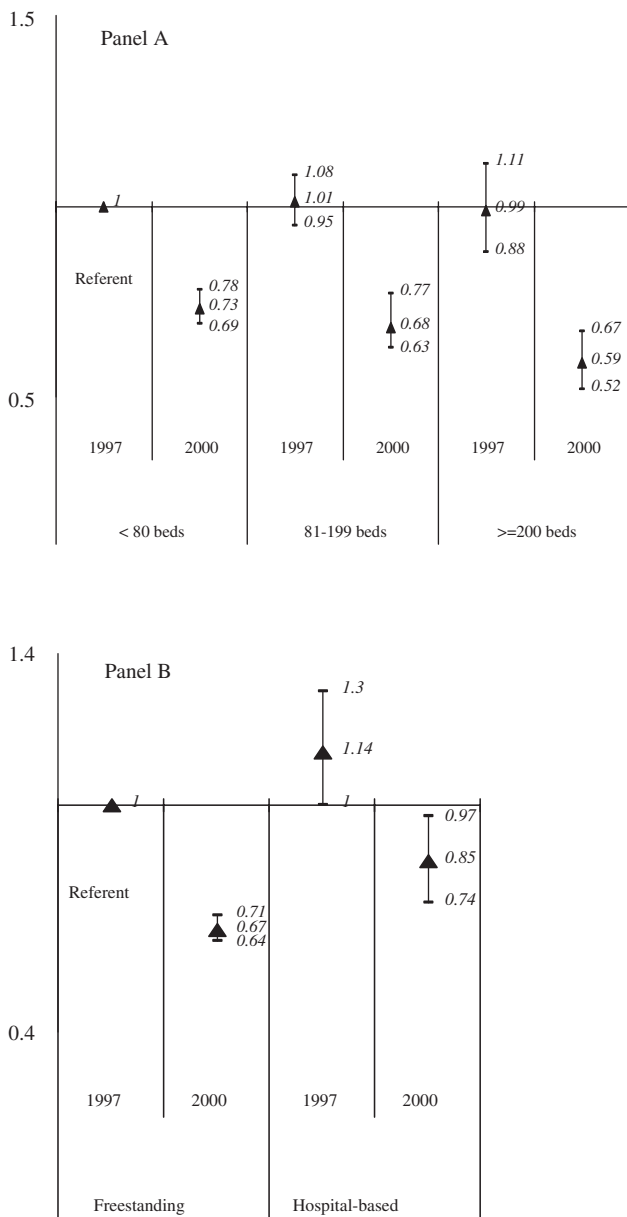


Figure 1. Extent to which reductions in the prevalence of potentially inappropriate medication use identified under Tag 329 differed by size of facility (A) and hospital-based versus freestanding facilities (B). Estimates of prevalence were adjusted for resident and facility characteristics, as shown in Tables 2 and 3 and derived from a logistic regression model.

models demonstrated the lack of an association between incorporating the Beers criteria into the surveyors' interpretive guidelines and changes in prevalence of medication use. Previously, the Nursing Home Reform Act embedded in OBRA 87 reduced the number of prescriptions used by legislating limitations on the use of chemical restraints and requiring extensive documentation justifying the use of psychotropic drugs.^{13,14} However, declines were also observed in the use of medications not targeted by the regulations but considered potentially inappropriate for use in elderly persons.

Several explanations for the findings must be considered. It may be that the postimplementation sampling year (2000) did not permit enough time to observe any changes

that may have occurred. It is unclear whether observed changes in use were due to secular declines in the use of potentially inappropriate medications. Although first appearing in the medical literature in 1991 and updated in 1997, the Beers list has continued to be widely disseminated. It is possible that such widespread dissemination overwhelmed any effect a change in the regulations may have had. It is also possible that the increases in the use of atypical antipsychotics,¹⁵ as well as the increased risk of stroke and death associated with these medications,¹⁶ has influenced the findings of the current study.

With respect to the prevalence of potentially inappropriate medication use and the most commonly used potentially inappropriate medications in nursing homes, the findings are consistent with those of previous reports.^{12,17,18} In concordance with a study based on the 1996 Medical Expenditure Panel Survey Nursing Home Component, a survey of a nationally representative sample of long-term care facilities and residents,¹⁷ the most common drugs in the current study were propoxyphene, diphenhydramine, hydroxyzine, oxybutynin, and amitriptyline. Furthermore, a Canadian study (which does not have equivalent nursing home regulations to those in the United States) showed that the most commonly prescribed inappropriate drugs after nursing home admission were strongly anticholinergic antidepressants (6.4%) and long-half-life benzodiazepines (5.9%).¹⁸ Another Canadian study¹⁹ reported on the use of potentially inappropriate medication (identified from the literature and validated using a modified Delphi method) in older patients in long-term care. More than 50% of treated patients had a potentially inappropriate prescription; the most frequent were for medications for the central nervous system. The patterns of medication use observed in the current study appear similar to previous research despite the differing time frame. The lack of differences may reflect the absence of the introduction of alternative, safer medications for elderly persons.

It may well be that the dual roles of consultant pharmacist (auditor of the drug regimen/potential promoter of certain drugs more cost-effective for their company) in the post-Prospective Payment System era render them ineffective at providing the level of influence in pharmaceutical care that the Nursing Home Reform Act intended, owing to their loss of credibility. Despite these changes to the long-term care pharmacy industry, a recent study revealed that the recommendations made by consultant pharmacists remained consistent with the emphasis provided in the regulations. These included documenting missing information and interventions related to unnecessary drugs, excessive duration, high dose alert, and overuse precautions,²⁰ yet recent research reveals that antipsychotic medication use is at the highest prevalence in the nursing home population (27.6%) and that only 42% were receiving these medications according to prescribing guidelines.¹⁵ In the current study, slight increases in the prevalence of potentially inappropriate medications targeted before the July 1, 1999, CMS guideline expansion were noted. These data suggest that perhaps there is a limit to the effectiveness of consultant pharmacists in the context of the federally mandated drug regimen review. It is possible that pharmacists were focussing on the expansive list of medications and paid less attention to drugs previous targeted. These data

Table 5. Association Between Change in Nursing Home Surveyors' Interpretive Guidelines and Use of Potentially Inappropriate Medications

Inappropriate Medications	Odds Ratio (95% Confidence Interval)	
	Crude	Resident Adjusted*
Any potentially inappropriate medication	0.88 (0.86–0.90)	0.85 (0.84–0.87)
Medications included in the survey process effective 10/1/1990	1.09 (1.07–1.12)	1.07 (1.04–1.10)
Tag 329 included in the survey process 7/1/1999	0.69 (0.67–0.71)	0.67 (0.65–0.69)
Tag 428/429 included in the survey process 7/1/1999	0.96 (0.93–0.99)	0.93 (0.90–0.97)
Medications not included in the survey process	0.79 (0.76–0.81)	0.76 (0.74–0.79)

* Adjusted for resident characteristics shown in Table 2.

also highlight the precarious situation of the nursing home. Depending on the severity of deficiencies cited during the survey process, nursing homes may be subject to a variety of remedies, including denial of Medicare and Medicaid payment for all residents and civil monetary penalties.

Larger facilities and those not affiliated with hospitals also experienced the greatest reductions in use of medications identified under Tag 329—high severity. Previous work¹⁷ determined that smaller nursing homes were less likely to have residents using potentially inappropriate medication use. Authors have speculated that, with fewer beds, it may be easier to coordinate and manage individual care. It is also possible that larger facilities had the most to gain, although previous work has shown that larger homes (>200 beds) were less likely to use antidepressants than mid-sized and smaller homes; this may have been due to an inability to detect depression in homes with many more residents.²¹

These findings should be considered with caution. The analysis was limited to four states, although the aggregate resident and facility characteristics reported in this sample did not differ significantly from those reported for national nursing home statistics.²² To reduce confounding, only facilities present in both 1997 and 2000 were included, although the findings may not be applicable to homes new to the nursing home market. It is possible that the changes observed were caused not by the surveyors' interpretative guidelines but by the introduction of new alternative agents into the market. In the case of indomethacin, alternative pain medications introduced during the study period included celecoxib (December 31, 1998) and rofecoxib (May 20, 1999). Because the change in the use of indomethacin was small during the study period, the introduction of the cyclooxygenase II inhibitors did not appear to influence these results. For oxybutynin, a controlled-release form of oxybutynin entered the market on December 16, 1998, and tolterodine tartrate was released on December 22, 2000. The controlled-release form of oxybutynin was also included in the Tag, and tolterodine tartrate likely did not diffuse to this population (as is typical) for several months after the approval date. As such, neither of these alternatives would have likely influenced the findings. Lastly, the results relating to the Tags are a function of how the guidelines were written at the time of the study. Recently, the interpretive guidelines for F329 have been completely revised, with clarification on several aspects of medication management and the inclusion of a new medication table that details medications that can be problematic in older residents.

CONCLUSION

Medication-related problems that jeopardize patient safety are common in nursing facilities.²³ The Institute of Medicine report entitled *To Err Is Human: Building a Safer Health Care System* reinforces the need for optimizing medication use in a population that is associated with polypharmacy and comorbidities.²⁴ The OIG report, *Prescription Drug Use in Nursing Homes*,²⁵ recommends that "HCFA should require pharmacists' direct input to achieving optimal clinical outcomes for residents." Understanding the contributions and limits of regulatory approaches to promoting safe, rational, and effective medication use in this setting is important. Although regulations may yield some reductions in the use of potentially inappropriate medication use, alternative approaches may have a role to play in improving care and outcomes for these vulnerable individuals. The use of technology in these settings may help achieve the goal.^{26–28} Alternatives may include models of care that enforce greater cooperation and multidisciplinary work.²⁰ Whether the implementation of Part D will provide mechanisms for pharmacists to bill for their services or create more challenges for delivering quality pharmaceutical care to nursing home residents remains to be seen.

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REFERENCES

1. Beers MH, Ouslander JG, Rollinger I et al. Explicit criteria for determining inappropriate medication use in nursing home residents. *Arch Intern Med* 1991;151:1825–1832.
2. Beers MH. Explicit criteria for determining potentially inappropriate medication use by the elderly. An update. *Arch Intern Med* 1997;157:1531–1536.
3. Clark TR. *Nursing Home Survey Procedures and Interpretive Guidelines*. Alexandria, VA: American Society of Consultant Pharmacists, 1999.
4. Gambassi G, Landi F, Peng L et al. Validity of diagnostic and drug data on standardized nursing home resident assessments: Potential for geriatric pharmaco-epidemiology. *Med Care* 1998;36:167–169.
5. Minimum Data Set Plus Training Manual. Natick, MA: Eliot Press, 1991.

6. Morris JN, Fries BE, Mehr DR et al. MDS Cognitive performance scale. *J Gerontol* 1994;49:M174–M182.
7. Hawes C, Morris JN, Phillips CD et al. Reliability estimates for the Minimum Data Set for nursing home resident assessment and care screening (MDS). *Gerontologist* 1995;35:172–178.
8. Hartmaier SL, Sloane PD, Guess HA et al. Validation of the minimum data set cognitive performance scale: Agreement with the mini-mental state examination. *J Gerontol A Biol Sci Med Sci* 1995;50A:M128–M133.
9. Omnibus Budget Reconciliation Act 1987. U.S. Congress. Public Law 101–508.
10. Dhall J, Larrat EP, Lapane KL. Potentially inappropriate medication use in nursing homes. *Pharmacotherapy* 2002;22:88–96.
11. Rothman KJ, Greenland S, eds. *Modern Epidemiology*, 2nd Ed. Philadelphia, PA: Lippincott-Raven, 1998.
12. Briesacher B, Limcangco R, Simoni-Wastila L et al. Evaluation of nationally mandated drug use reviews to improve patient safety in nursing homes: A natural experiment. *J Am Geriatr Soc* 2005;53:991–996.
13. Stoudemire A, Smith DA. OBRA regulations and the use of psychotropic drugs in long-term care facilities: Impact and implications for geropsychiatric care. *Gen Hosp Psychiatry* 1996;18:77–94.
14. Elon R, Pawlson LG. The impact of OBRA on medical practices within nursing facilities. *J Am Geriatr Soc* 1992;40:958–963.
15. Briesacher BA, Limcangco MR, Simoni-Wastila L et al. The quality of anti-psychotic drug prescribing in nursing homes. *Arch Intern Med* 2005;165:1280–1285.
16. Liperoti R, Gambassi G, Lapane KL et al. Cerebrovascular events among elderly nursing home patients treated with conventional or atypical antipsychotics. *J Clin Psychiatry* 2005;66:1090–1096.
17. Lau DT, Kasper JD, Potter DE et al. Potentially inappropriate medication prescriptions among elderly nursing home residents. Their scope and associated resident and facility characteristics. *Health Serv Res* 2004;39:1257–1276.
18. Dhalla IA, Anderson GM, Mamdani MM et al. Inappropriate prescribing before and after nursing home admission. *J Am Geriatr Soc* 2002;50:995–1000.
19. Rancourt C, Moisan J, Baillargeon L et al. Potentially inappropriate prescriptions for older patients in long-term care. *BMC Geriatr* 2004;4:9.
20. Lapane KL, Hughes CM. Pharmaceutical care interventions undertaken by pharmacists in the Fleetwood Phase III study. The role of process control. *Ann Pharmacother* 2006;40:1522–1526.
21. Lapane KL, Hughes CM. Which organisational characteristics are associated with increased management of depression using antidepressants in U. S. nursing homes. *Med Care* 2004;42:992–1000.
22. Hughes CM, Lapane KL, Mor V. Influence of facility characteristics on use of antipsychotic medication use in nursing homes. *Med Care* 2000;38:1164–1173.
23. Hanlon J, Schmader K, Ruby C et al. Suboptimal prescribing in older inpatients and outpatients. *J Am Geriatr Soc* 2001;49:200–209.
24. Institute of Medicine. *To Err Is Human: Building a Safer Health Care System*. Washington, DC: National Academy Press, 2000.
25. Office of the Inspector General. *Prescription Drug Use in Nursing Homes. In: Report 2: An Inside View by Consultant Pharmacists* (Report no. OEI-06–96–00081). Washington, DC: Department of Health and Human Services, 1997.
26. Lapane KL, Cameron K et al. Technology for improving medication monitoring in nursing homes. In: Henriksen K, Battles JB, Marks ES et al., eds. *Advances in Patient Safety: From Research to Implementation*, 4, Programs, Tools, and Products (AHRQ Publication no. 05–0021–3). Rockville, MD: Agency for Healthcare Research and Quality, 2005, pp 410–413.
27. Ferris N. *System Uses Quality Data to Improve Health Care* [on-line]. Available at www.governmenthealthit.com/article90512-08-29-05-Web Accessed June 6, 2006.
28. Judge J, Field TS, Deflorio M et al. Prescribers' responses to alerts during medication ordering in the long term care setting. *J Am Med Inform Assoc* 2006;13:385–390.