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HEALTH CARE REFORM

Medicare Part D’s Exclusion of Benzodiazepines and Fracture Risk in Nursing Homes

Becky A. Briesacher, PhD; Stephen B. Soumerai, ScD; Terry S. Field, DSc; Hassan Fouayzi, MS; Jerry H. Gurwitz, MD

Background: Medicare Part D excludes benzodiazepine medications from coverage, and some state Medicaid programs also limit coverage. We assessed whether such policies decrease the risk of fractures in elderly individuals living in nursing homes.

Methods: This is a quasi-experimental study with interrupted time-series estimation and extended Cox proportional hazards models comparing changes in outcomes before and after implementation of Medicare Part D in a nationwide sample of nursing home residents in 48 states. The study included 1,068,104 residents and a subsample of 50,874 residents with fracture data from 1 pharmacy. We assessed monthly prescribing rates of benzodiazepines and potential substitutes from January 1, 2005, through June 30, 2007, and hazard ratios for incident hip fracture and falls, adjusted for age, sex, and race/ethnicity. Estimates were stratified by concurrent Medicaid limits on benzodiazepines: no supplemental coverage (1 state), partial supplemental coverage (6 states), or complete supplemental coverage (41 states).

Results: The no-supplemental-coverage policy resulted in an immediate and significant reduction of 10 absolute points in benzodiazepine use (27.0% to 17.0%) after Medicare Part D was implemented (95% confidence interval, −0.11 to −0.09; \( P < .001 \)). Benzodiazepine use remained stable in the partial-supplemental- and complete-supplemental-coverage states. Hazard ratios for incident hip fracture were 1.60 (95% confidence interval, 1.05 to 2.45; \( P = .03 \)) in the no-supplemental-coverage state after Medicare Part D implementation and 1.17 (95% confidence interval, 0.93 to 1.46; \( P = .18 \)) in the partial-supplemental-coverage states, relative to complete-supplemental-coverage states.

Conclusion: Supplemental drug coverage exclusion policies affect the medication use of nursing home residents and may not decrease their fracture risk.

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care Part D. However, this decrease will be smaller in states with partial supplemental coverage and smallest in states with complete supplemental coverage. Compensatory increases will occur in substitute medications reimbursable by Medicare. Furthermore, a reduction in the risk of falls and hip fractures will be associated with decreases in benzodiazepine use.

### METHODS

#### DESIGN

We used a quasi-experimental research design that used a comparator group and pretests in a longitudinal cohort of NH residents. We compared changes in resident outcomes before and after implementation of Medicare Part D in states with partial or no supplemental coverage for benzodiazepines with the same changes in outcome in states with complete supplemental coverage (comparator).

#### STUDY POPULATION

We analyzed prescription drug–dispensing records merged with Minimum Data Set (MDS) records from January 1, 2005, through June 30, 2007. The prescription data come from more than 2.5 million individuals living in approximately 16,000 NHs across 48 states. These individuals have a variety of prescription drug plans, including private insurance, Medicaid, Medicare Part D, or no drug coverage, but their medications come from 1 pharmacy. The drug-dispensing data include all medications prescribed and administered to residents, including over-the-counter drugs and as-needed medications. Research using these data has been previously described. The data elements include the product identification code (national drug code), date of fill, days’ supply, quantity dispensed, and payment source, as well as basic demographics, limited to sex and age, and the state where the NH was located. Linkable MDS records come from the same source and are available for approximately one-third of individuals with prescription data. The MDS is a nearly universal health assessment tool used in NHs, and it captures more than 300 items with regard to residents’ physical and cognitive functioning. Full assessments occur on admission, with significant change in status, and at annual reevaluations.

For the sample, we excluded individuals who were not Medicare eligible (n=597,211) or observed for less than 4 months (n=1,870,850). Residents whose stay in the NH was less than 4 months may have their medications paid for by Medicare Part A, rather than Part D, as part of bundled per diem payments to the facility. In addition, prior research shows that short-stay residents in NHs differ significantly from long-stay residents. We also identified a subsample of newly admitted NH residents (n=30,874) whose drug-dispensing data were linkable to MDS records that included full assessments of fracture outcomes for selected analyses.

State of residence came from the location of the nursing facility. Each state was characterized by its Medicaid reimbursement policy for benzodiazepines as follows: (1) complete supplemental coverage (41 states), (2) partial supplemental coverage (6 states: Alabama, California, Georgia, Illinois, Kansas, and Missouri), and (3) no supplemental coverage (1 state: Tennessee). Partial supplemental coverage included the following restrictive policies on benzodiazepines: prior authorization, quantity limits, and preferred drug lists. All of the states implemented their benzodiazepine supplemental coverage policy to coincide with initiation of the Medicare Part D program.

### OUTCOME MEASURES

Use of study medications was measured as any dispensing during the month and the average number of prescriptions dispensed per month of use. Benzodiazepines included alprazolam, clonazepam, estazolam, flurazepam, halazepam, lorazepam, oxazepam, quazepam, temazepam, triazolam, chlor Diazepoxide, clorazepate dipotassium, diazepam, and diazepam combinations. Potential substitute medications included the Medicare-covered categories of nonbenzodiazepine sedative/hypnotics (eg, zolpidem tartrate, phenobarbital, eszopiclone, zaleplon, melatonin, and chloral hydrate), other anxiolytic medications (buspirone, hydroxyzine hydrochloride, hydroxyzine pamoate, and meprobamate), and antipsychotic medications (eg, aripiprazole, clozapine, olanzapine, haloperidol, dolapram, decanoate, and haloperidol lactate), as identified in previous research. (A complete list of the drug names is available from the corresponding author.)

Outcomes of interest were measured using the MDS: falls in the past 180 days, hip fractures in the past 180 days, and other fractures in the past 180 days. The MDS documentation of hip fracture has demonstrated high concordance with medical claims data (more than 80%), whereas the documentation of falls has shown fair concordance with medical record abstractions of 65% to 75%.

### STATISTICAL ANALYSIS

We conducted descriptive analyses comparing baseline demographics and drug prescribing before Medicare Part D implementation by state supplemental coverage policy. Interrupted timeseries estimation with segmented regression methods and autoregressive correlations of the first order were used for testing changes in the trend (slope and level) of medication use after the implementation date of the Medicare Part D program and controlling for trends before the policy. The basic model includes a constant summarizing the baseline level and 3 terms. The first term estimates monthly changes per person in the period before the policy, the second estimates the average level change per person in the first month after Medicare Part D implementation, and the third is the trend after Medicare Part D implementation relative to the trend before Medicare Part D implementation. This model tests the population-level effects of Medicare Part D regarding enrollment status, thus avoiding the confounding introduced by comparing effects across nonrandomly assigned groups. We assume the timing of the new Medicare Part D program is independent of the factors that determine treatment assignment and confound simplistic outcome assessments. If Medicare Part D had any effect, the population-level observations after January 1, 2006, would display a distinctly different pattern from the pattern before Medicare Part D implementation. Furthermore, the difference would be greatest where there is no Medicaid supplemental coverage to moderate the effect.

Extended Cox proportional hazards models with Heaviside function were used to estimate hazard ratios for fractures before and after the implementation of Medicare Part D. The basic model includes time-fixed terms for sex, age, race, and ethnicity and a time-varying term for supplemental coverage policy. A Heaviside function is used to provide 2 hazard ratios for supplemental coverage policy that correspond to the intervals before Medicare Part D implementation (January 1 through December 31, 2005) and after Medicare Part D implementation (January 1 through December 31, 2006). Unlike a standard Cox model, this model allows for changes in the proportional hazards over time. All multivariate models were estimated separately for each dependent variable (monthly proportion of residents who received benzodiazepines and each of the substitute drug cat-
categories, monthly average number of prescriptions dispensed, incidence of falls, incidence of hip fracture, and incidence of other types of fractures). All multivariate analyses were conducted with Stata statistical software, version 10.0 (StataCorp LC, College Station, Texas). The institutional review board of the University of Massachusetts Medical School exempted this research from review.

### RESULTS

We identified 1,068,104 long-stay Medicare enrollees in NHs nationwide who generated 145,254,104 prescription records during the study observation. Table 1 gives the characteristics of the study population and the baseline prescribing of the study medications. In 2005, 882,266 (82.6%) of the NH residents in the study lived in states that would offer complete supplemental coverage of benzodiazepines after implementation of Medicare Part D, and 170,105 (15.9%) lived in states offering partial coverage; only Tennessee did not offer any supplemental coverage (15,733 residents [1.5%]). A comparison of age and sex showed similar distributions across the 3 policy groups.

At baseline, the prevalence of the study medications varied by the state’s supplemental coverage policy. In January 2005, the proportion of NH residents in the study who were receiving benzodiazepine therapy was 26.0% in the no-coverage state, 15.6% in complete-coverage states, and 16.4% in partial-coverage states (P < .001). The proportion of NH residents in the study taking nonbenzodiazepine sedative/hypnotics was 4.4% in the complete-coverage states, 4.0% in the partial-coverage states, and 6.4% in the no-coverage state (P < .001). The prevalence of antipsychotic use was 26.6% in complete-coverage states, 33.4% in partial-coverage states, and 29.9% in the no-coverage state (P < .001). Last, the baseline prescribing of other anxiolytics ranged from 3.3% to 3.7% among the 3 groups (P = .56).

Figure 1 shows the changes that occurred in the monthly prevalence of benzodiazepine use and potential substitutes during the observation period. Times-series analyses showed a large and significant decrease of 10 percentage points (27.0% to 17.0%) in the proportion of benzodiazepine recipients immediately after the implementation of Medicare Part D in the no-coverage state (−0.10 change in prevalence; 95% confidence interval [CI], −0.11 to −0.09; P < .001). This large change did not occur in the partial-coverage states (−0.01 change in prevalence; 95% CI, −0.014 to −0.006; P < .001) or the complete-supplemental-coverage states (−0.01 change in prevalence; −0.014 to −0.004; P < .001). The average monthly number of benzodiazepine prescriptions dispensed peruser did not change before and after Medicare Part D in any of the 3 state reimbursement policy groups (data not shown).

Times-series analyses of the reimbursable anxiolytics, sedative/hypnotics, and antipsychotics showed some evidence of potential substitution for benzodiazepines in the no-coverage state after implementation of Medicare Part D (Figure 1). For instance, the use of other anxiolytics immediately increased significantly in 2006 (+0.02 change in prevalence; 95% CI, 0.005 to 0.03; P<.007) in the no-coverage state relative to 2005. The average monthly number of antipsychotics and other anxiolytics dispensed also increased immediately in 2006 in the no-coverage state relative to 2005 (antipsychotics, +0.66 change in monthly fills; 95% CI, 0.65 to 0.67; P < .001; and other anxiolytics, +0.57 change in monthly fills; 0.55 to 0.58; P < .001). In comparison, these changes did not occur in the other states (data not shown).

Table 2 gives the falls and fractures outcomes for the subgroup of newly admitted NH residents. Overall, this group experienced 9426 incident fractures (4632 before Medicare Part D and 4794 after Medicare Part D) and 23,601 incident falls (10,722 before Medicare Part D and 12,879 after Medicare Part D) while observed. Before implementation of Medicare Part D, the rates of fractures were similar to or lower in the no-coverage state.
compared with those in the other states. For instance, in 2005 the rate of hip fractures was 6.4 per 100 person-years in the no-coverage state compared with 8.9 per 100 person-years in the complete-supplemental-coverage states and 9.6 per 100 person-years in the partial-coverage states ($P=0.007$). After implementation of Medicare Part D, the rates of fractures increased significantly in the no-coverage state compared with the rates in the other states. For instance, the rate of hip fractures doubled from 6.4 in 2005 to 12.4 in 2006 per 100 person-years in the no-coverage state. In comparison, there were modest increases of 8.9 in 2005 to 9.9 in 2006 per 100 person-years in the complete-supplemental-coverage states and 9.6 to 10.7 per 100 person-years in the partial-coverage states ($P=0.002$). The incidence rate of falls showed a similar pattern, although all 3 groups experienced increases after implementation of Medicare Part D.

Multivariate analyses for fracture outcomes showed some significant changes in hazard ratios after implementation of Medicare Part D, but none were in the previously hypothesized direction. Where the large decrease in benzodiazepine use occurred (in the no-coverage state), the hazard ratio for incident hip fractures in NHs increased from 0.74 (95% CI, 0.53 to 1.00) before Medicare Part D implementation to 1.60 (1.05 to 2.45; $P=0.03$) after Medicare Part D implementation, compared with the states with stable benzodiazepine use (complete-coverage states) (Figure 2). The hazard ratios for falls did not change. In the partial-coverage states with no change in benzodiazepine use, the hazard ratios for hip fractures did not change.

**Table 2. Fracture Outcomes Before and After Implementation of Medicare Part D, From January 1, 2005, Through December 31, 2006**

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<th>Outcome</th>
<th>Complete Supplemental Coverage</th>
<th>Partial Supplemental Coverage</th>
<th>No Supplemental Coverage</th>
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<td></td>
<td>Before Part D</td>
<td>After Part D</td>
<td>Before Part D</td>
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<tr>
<td></td>
<td>(n=24,521)</td>
<td>(n=21,108)</td>
<td>(n=15,517)</td>
</tr>
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<td>Any incident fractures, No. (%) per 100 person-years</td>
<td>4269 (17.4)</td>
<td>4334 (19.6)</td>
<td>275 (17.7)</td>
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<tr>
<td>Incident hip fractures, No. (%) per 100 person-years</td>
<td>2189 (8.9)</td>
<td>2185 (9.9)</td>
<td>149 (9.6)</td>
</tr>
<tr>
<td>Incident falls, No. (%) per 100 person-years</td>
<td>9753 (39.8)</td>
<td>11,706 (53.0)</td>
<td>739 (47.7)</td>
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In this population-based study, we found an abrupt and large discontinuation of benzodiazepine use in NHs immediately after the exclusion of these agents by Medicare Part D in the state that did not offer supplemental coverage. Furthermore, NH residents in the same state experienced increases in the use of potential substitute agents, although the increases were temporary and not a complete offset. These responses are similar to those documented in the community setting after restrictive drug policies were implemented. To our knowledge, this is the first analysis to demonstrate these relationships in the NH setting. In contrast, NH residents living in states covering all or some portion of benzodiazepines did not experience the same therapy changes observed in the most restrictive state.

We also showed that the large reductions in benzodiazepine use were not associated with decreased risk of fracture outcomes. Previous restrictive drug policies on the prescribing of benzodiazepines, including prescription limits, prior authorization protocols, and surveillance programs, have also failed to produce a reduction in the risk of fracture outcomes. There are several possible explanations for our finding of no reduction in fracture outcomes. Partial supplemental coverage may have been insufficient to reduce benzodiazepine use. Abrupt discontinuation of benzodiazepine use, especially long-term use, can pose risks to residents, including confusion, elevated systolic blood pressure, and, in rare cases, seizures. In ad hoc analysis stratified by duration of benzodiazepine use, we detected abrupt discontinuation in long-term use (120 continuous days or greater of use) and short-term use in our study sample. Finally, benzodiazepines may not be associated with hip fractures, at least not to the extent reported in other studies. At least 7 studies to date, including studies with prospective cohort and longitudinal, quasi-experimental designs, have failed to find a relationship between benzodiazepine use and fracture risk.

Limitations of the study include the following. First, our analyses were limited to NH residents whose prescriptions were filled by one long-term-care pharmacy. However, our study reflects the observed experiences of nearly half the entire US Medicare population living in NHs. Second, we did not have information on some potentially important clinical factors relating to fracture risk. Third, we did not have information on whether the reduced benzodiazepine use was clinically appropriate. This limitation also applies to the prescribing of substitute agents. In ad hoc analyses, we found increases in the prescribing of meprobamate in the no-coverage state, which
is a potentially inappropriate medication for older adults (1.6 dispensings per 1000 NH residents in 2005 vs 0.6 dispensings per 1000 NH residents in 2006). Third, we had MDS data for only one-third of the sample, although we found no relationship between availability of these data and benzodiazepine use. Last, our category of partial supplemental coverage encompassed several restrictive policies that may vary in effects.

Our approach has several strengths. First, we conducted the analyses of changes in benzodiazepine use with interrupted time-series analyses. The interrupted time-series approach is one of the most powerful quasiexperimental designs because it is robust to many of the threats to the validity of weaker observational designs, particularly in unmeasured changes in the composition of the study population and historical changes in benzodiazepine use. We also used an intention-to-treat analysis, without accounting for actual enrollment into Medicare Part D, meaning that we avoided introducing the selection bias inherent in comparing changes in drug prescribing between individuals who participated in Medicare Part D and those who did not. Furthermore, the state-level analysis also minimizes any threats to validity based on preferential prescribing patterns related to resident characteristics.

In conclusion, we found that the Medicare Part D’s reimbursement exclusion of benzodiazepines was associated with a significant and abrupt decrease in prescribing of these agents in NHs, if the state did not mitigate the effect by providing partial or complete supplemental coverage with state funds. The reimbursement restriction was not associated with any advantage in patient safety by reducing falls and fracture risk.

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Author Contributions: All authors had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Briesacher, Soumerai, Field, and Gurwitz. Acquisition of data: Briesacher and Fouayzi. Analysis and interpretation of data: Briesacher, Soumerai, Field, and Fouayzi. Drafting of the manuscript: Briesacher and Fouayzi. Critical revision of the manuscript for important intellectual content: Briesacher, Soumerai, Field, Fouayzi, and Gurwitz. Statistical analysis: Briesacher, Soumerai, and Fouayzi. Obtained funding: Briesacher and Soumerai. Study supervision: Briesacher.

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