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HEALTH POLICY

Entering and Exiting the Medicare Part D Coverage Gap: Role of Comorbidities and Demographics

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BACKGROUND: Some Medicare Part D enrollees whose drug expenditures exceed a threshold enter a coverage gap with full cost-sharing, increasing their risk for reduced adherence and adverse outcomes.

OBJECTIVE: To examine comorbidities and demographic characteristics associated with gap entry and exit.

DESIGN: We linked 2005–2006 pharmacy, outpatient, and inpatient claims to enrollment and Census data. We used logistic regression to estimate associations of 2006 gap entry and exit with 2005 medical comorbidities, demographics, and Census block characteristics. We expressed all results as predicted percentages.

PATIENTS: 287,713 patients without gap coverage, continuously enrolled in a Medicare Advantage Part D (MAPD) plan serving eight states. Patients who received a low-income subsidy, could not be geocoded, or had no 2006 drug fills were excluded.

RESULTS: Of enrollees, 15.9% entered the gap, 2.6% within the first 180 days; among gap enterers, only 6.7% exited again. Gap entry was significantly associated with female gender and all comorbidities, particularly dementia (39.5% gap entry rate) and diabetes (28.0%). Among dementia patients entering the gap, anti-dementia drugs (donepezil, memantine, rivastigmine, and galantamine) and atypical antipsychotic medications (risperidone, quetiapine, and olanzapine) together accounted for 40% of pre-gap expenditures. Among diabetic patients, rosiglitazone accounted for 7.2% of pre-gap expenditures. Having dementia was associated with twice the risk of gap exit.

CONCLUSIONS: Certain chronically ill MAPD enrollees are at high risk of gap entry and exposure to unsubsidized medication costs. Clinically vulnerable populations should be counseled on how to best manage costs through drug substitution or discontinuation of specific, non-essential medications.

KEY WORDS: medicare; health insurance; health care costs; health services research; health economics.

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BACKGROUND

The Medicare Part D Prescription Benefit went into effect January 2006, providing voluntary drug coverage to all Medicare beneficiaries through private plans contracting with Medicare[1,2]. Part D coverage is offered through almost 1900 stand-alone prescription drug plans (PDPs) and over 1000 private Medicare Advantage Part D plans (MAPDs)[3,4]. Improved financial access to medications was expected to improve adherence to drug regimens and outcomes. However, the standard Part D benefit included a coverage gap designed to limit unnecessary utilization[5] and meet budget constraints (Fig. 1). The gap is triggered annually with a threshold level of total participant and health plan costs. While in the gap, beneficiaries are responsible for the full cost of prescription medications until another threshold of annual patient out-of-pocket expenditures is reached and "catastrophic coverage" (95% coverage with 5% coinsurance) begins. Although some plans offer limited gap coverage, in 2008 71% of PDP and 49% of MAPD plans had none[6].

A sizable proportion of patients enter the gap[7] and few reach catastrophic coverage, so in order to manage treatment more efficiently, it is important to understand which Medicare beneficiaries are most likely to fall into the gap, particularly early in the year. Individuals with chronic diseases requiring pharmaceutical therapy are more likely to face long gaps in coverage[8]. However, most studies addressing this issue were based on pre-Part D data[8–10]; thus, they could not account for whether individuals respond to benefit design by limiting drug utilization. Two studies based on post-Part D data did find that patients with certain conditions were more likely to enter the coverage gap, but each study focused on a single condition (end-stage renal disease and atrial fibrillation)[11,12]. The extent to which other comorbidities contribute to gap entry and exit has not yet been established. Identifying specific medical conditions that put beneficiaries at high risk of gap entry, especially early gap entry, and the medications contributing most to pre-gap spending for those beneficiaries, would allow clinicians to better focus discussions with patients early in the benefit year on how to manage their drug costs, e.g., through generic or therapeutic drug substitutions or discontinuation of medications that do not appear to be effective or that have widely recognized, potentially dangerous side effects.

We used 2006 data on Medicare beneficiaries who were continuously enrolled in a large, national for-profit MAPD and subject to the Part D coverage gap to examine associations of medical and psychiatric conditions and demographic characteristics with the risk of gap entry and exit. We also examined which

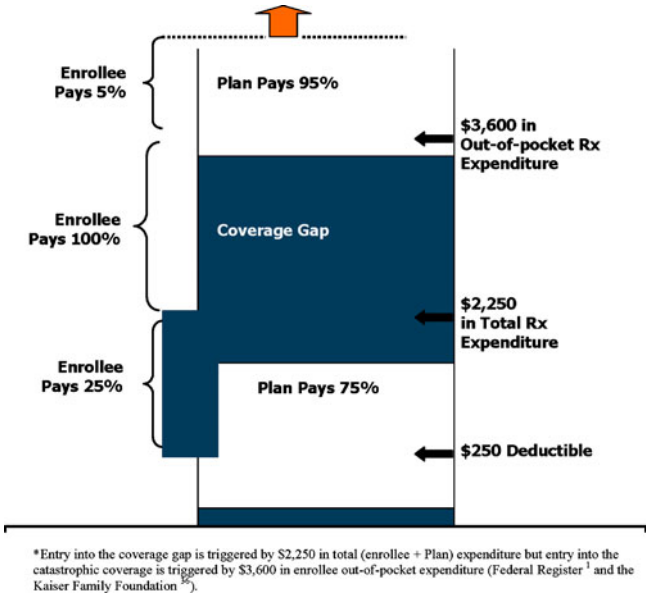

Figure 1. Standard 2006 benefits for Part D*.

medications purchased before gap entry account for the greatest proportion of pre-gap spending.

METHODS

Sources of Data and Sample

Enrollment files and 2005–2006 inpatient, outpatient and Part D pharmacy claims from a large MAPD plan located in eight states were geocoded and linked to 2000 Census block data. Comorbidities were identified using 2005 data; days until gap entry and exit were calculated using 2006 data. The final sample size was 287,713 after excluding beneficiaries who had no 2006 drug fill (N=2,336) or were not continuously enrolled during 2005–2006 (N=145,845); low-income subsidy qualifiers not subject to a coverage gap (N=57,833); those with supplemental retirement benefits (N=111,032), other gap coverage (N=48,373), or an atypical deductible amount (N=13,565); and those missing geocode (N=3,187) or gender (N=1,020).

Measures

We examined whether the beneficiary: (1) entered the gap during 2006; (2) entered the gap within the first 180 days of 2006; and (3) exited the gap before the end of 2006 (among beneficiaries entering the gap during 2006). Predictors included patient sex, age group, and indicators for the conditions listed in Table 1. ICD-9-CM diagnosis codes used to identify conditions were obtained from the Clinical Classifications Software[13]. All models controlled for fixed state effects, urban residence (as a proxy for healthcare supply and geographic proximity to care) and the characteristics of the population in the beneficiary's Census block listed in Table 2.

Statistical Analysis

Separate logistic regressions were estimated for each outcome. We report the average predicted risk differences associated with each comorbidity derived from these models (the mean difference between probabilities predicted with the comorbidity indicator set to 1 vs. 0, holding other covariate values constant at their original values). We simulated 99% confidence intervals (CIs) for these

Table 1. Characteristics of Study Population

	Study population (n=287,713)	National estimates for the population aged ≥65 years (15,16)	NHANES (2005–2006)
Age group:			
65–69	11%	28%	
70–74	24%	23%	
75–79	28%	20%	
80–84	21%	15%	
85+	16%	14%	
Female	60%	58%	49%
Living in urban area	94%	—	
Percent with:			
Diabetes	20%	18%	19%
Hypertension	61%	53%	58%
Hyperlipidemia	45%	—	53%
Coronary artery disease	17%	31%	12%
Mental health condition	8%	—	-
Dementia	4%	—	-
Osteoarthritis	20%	—	52% (arthritis)
Rheumatologic arthritis	2%	—	52% (arthritis)
Non-skin cancer	21%	21%	22% (skin and non-skin)
Chronic obstructive pulmonary disease	15%	10%	6% (emphysema) 8% (chronic bronchitis)
Congestive heart failure	7%	—	10%
Atrial fibrillation/cardiac dysrhythmias	16%	—	-
End-stage renal disease	1%	—	-
Stroke	10%	9%	11%
Peripheral vascular disease	7%	—	-

Key: NHANES = National Health and Nutrition Examination Survey

Table 2. Characteristics of Census-Block Population (N=126,977 Census blocks)

	Mean or %
Median household income of Census block residents	$52843 (SD=$23093)
% Census block residents who:	
Have less than a high school education	26%
Speak no English	2%
Speak English poorly	4%
Speak English well	94%
% Census block residents who are:	
White	77%
African American	6%
Asian	7%
Native American	2%
Other race	11%
Not born in U.S.	16%

risk differences by assuming that coefficient estimates were approximately multivariate normally distributed[14]. Results were similar when using generalized estimating equation models to allow for clustering by census tract.

Our results were not sensitive to changes in the algorithms for assigning comorbidity diagnoses. Therefore, we only report results from the most inclusive algorithm, requiring only one inpatient or outpatient claim with a diagnosis in the given category.

Finally, we explored which medications contributed most to gap entry among patients with the comorbidities most closely associated with gap entry (dementia and diabetes). This was done by rank-ordering the medications used by gap enterers with these comorbidities by the total (plan + patient) pre-gap expenditures associated with each medication.

RESULTS

Population Characteristics

The study population was primarily women (60%) and urban residents (94%) (Table 1). Approximately 50% were 75–84 years old, with an additional 16% over 85. Comorbidities were common, including hypertension (61%), non-skin cancer (21%), diabetes (20%) and coronary artery disease (CAD) (17%). The demographic and comorbidity distributions were similar to 2006 national estimates for older adults, with the exception that our study population was concentrated somewhat more heavily in the older age groups (Table 1)[15,16]. The study population was economically diverse, living in Census blocks whose residents have median household incomes that average $52,843 but with a large standard deviation (Table 2). About one-quarter of Census block residents were non-white and 6% spoke English poorly or not at all. Among this study population, 15.92% entered the coverage gap in 2006, although only 2.56% entered during the first 180 days.

Gap Entry

Table 3, Columns 2 and 3, present the estimated probabilities of any 2006 gap entry. All of the medical conditions had significant positive associations with the risk of gap entry, although the magnitudes varied from modest (e.g., osteoarthritis) to extremely large (e.g., dementia). The risk differences (RDs) are interpreted as percentage point increases. For example, an absolute increase of 18.97% in the risk of gap entry among patients with dementia represents an 18.97 percentage point increase, or more than doubling of the risk of gap entry, relative to the unadjusted risk of 15.92%. Other

Table 3. Differences in Probability of Entry into Medicare Part D Coverage Gap, Entire Sample*

	Gap entry any time during 2006 (unadjusted risk=15.92%)[a]		Gap entry during first 180 days (unadjusted risk=2.56%)	
	Risk difference	99% CI	Risk difference	99% CI
Female	3.98%	3.63%, 4.34%	0.78%	0.62%, 0.94%
Age 70–74	−1.21%	−1.85%, −0.57%	−0.47%	−0.79%, −0.16%
Age 75–79	−1.26%	−1.87%, −0.66%	−0.49%	−0.79%, −0.19%
Age 80–84	−1.04%	−1.61%, −0.22%	−0.62%	−0.94%, −0.32%
Age 85+	−0.91%	−1.61%, −0.22%	−0.73%	−1.06%, −0.41%
Diabetes	11.60%	11.10%, 12.10%	2.60%	2.37%, 2.86%
Hypertension	4.33%	3.95%, 4.70%	0.51%	0.34%, 0.68%
Hyperlipidemia	2.56%	2.19%, 2.91%	0.22%	0.05%, 0.37%
Coronary artery disease	7.21%	6.70%, 7.74%	1.50%	1.28%, 1.75%
Mental health condition	6.29%	5.64%, 6.96%	1.72%	1.43%, 2.04%
Dementia	18.97%	17.80%, 20.15%	6.15%	5.51%, 6.85%
Osteoarthritis	0.73%	0.32%, 1.15%	0.19%	0.01%, 0.38%
Rheumatologic arthritis	4.84%	3.54%, 6.16%	1.67%	1.08%, 2.37%
Non-skin cancer	2.89%	2.47%, 3.31%	0.84%	0.65%, 1.04%
Chronic obstructive pulmonary disease	6.89%	6.38%, 7.43%	1.81%	1.58%, 2.07%
Congestive heart failure	6.44%	5.73%, 7.16%	1.43%	1.13%, 1.74%
Atrial fibrillation	2.36%	1.90%, 2.83%	0.33%	0.14%, 0.53%
End-stage renal disease	8.05%	6.55%, 9.60%	2.14%	1.52%, 2.83%
Stroke	5.61%	5.01%, 6.19%	1.12%	0.87%, 1.37%
Peripheral vascular disease	2.66%	2.05%, 3.29%	0.40%	0.16%, 0.67%

* N=287,713. All estimates were significant at $p \leq 0.01$

[a]*Beneficiaries aged 65–69 are the reference age group. We used logistic regression to model the probability of each outcome, controlling for the full set of comorbidities in addition to a constant term, age group, sex, fixed state effects, urban residence and the percentages of Census block residents who have less than a high school education; are white, African American, Asian, Native American, and another race; and who speak no English or speak English poorly (vs. speak English well). The reference category for each comorbidity is therefore individuals without that particular comorbidity.*

Table 4. Differences in Probability of Exit from Medicare Part D Coverage Gap Among Patients Who Entered the Gap*

	Any 2006 gap exit (unadjusted risk =6.68%)[a]	
	Risk difference	99% CI
Female	0.68%	0.04%, 1.34%
Age 70–74	−0.43%	−1.71%, 0.79%
Age 75–79	0.00%	−1.22%, 1.13%
Age 80–84	−0.51%	−1.79%, 0.67%
Age 85+	−0.54%	−1.88%, 0.69%
Diabetes	2.15%	1.44%, 2.90%
Hypertension	−0.70%	−1.48%, 0.04%
Hyperlipidemia	−1.36%	−2.04%,−0.72%
Coronary artery disease	0.37%	−0.34%, 1.14%
Mental health condition	2.55%	1.62%, 3.58%
Dementia	7.57%	6.17%, 9.15%
Osteoarthritis	0.10%	−0.59%, 0.85%
Rheumatologic arthritis	4.49%	2.39%, 6.98%
Non-skin cancer	1.87%	1.16%, 2.83%
Chronic obstructive pulmonary disease	1.13%	0.40%, 1.95%
Congestive heart failure	2.50%	1.54%, 3.54%
Atrial fibrillation	0.05%	−0.66%, 0.78%
End-stage renal disease	1.76%	0.06%, 3.75%
Stroke	1.23%	0.42%, 2.07%
Peripheral vascular disease	0.37%	−0.52%, 1.36%

* N=45,815

[a]*Beneficiaries aged 65–69 are the reference age group. We used logistic regression to model the probability of the outcome, controlling for the full set of comorbidities in addition to a constant term, age group, sex, fixed state effects, urban residence and the percentages of Census block residents who have less than a high school education; are white, African American, Asian, Native American, and another race; and who speak no English or speak English poorly (vs. speak English well). The reference category for each comorbidity is therefore individuals without that particular comorbidity.*

conditions with strong associations were diabetes (RD=11.60%), end-stage renal disease (RD=8.05%), coronary artery disease (RD=7.21%), chronic obstructive pulmonary disease (RD=6.89%), congestive heart failure (RD=6.44%) and mental health conditions (RD=6.29%). Greater age was associated with significantly lower probability of gap entry, while women had about a one-quarter higher chance of gap entry than men.

Early Gap Entry

Table 3, columns 4 and 5, present similar estimates for early gap entry. The associations remained statistically significant for all comorbidities. Furthermore, while the risk differences were smaller in absolute magnitudes, the *relative* effects were generally larger because the unadjusted risk of early gap entry is only 2.56%. For example, dementia was associated with more than a tripling of the risk of early gap entry (RD=6.15%, implying that overall risk jumps to almost 9%). Diabetes, end-stage renal disease, chronic obstructive pulmonary disease, and rheumatologic arthritis were associated with a doubling or near-doubling of the risk. Associations of early gap entry with sociodemographic characteristics showed patterns similar to any gap entry.

Gap Exit Among Patients Who Entered the Gap

Table 4 presents differences in the conditional risk of gap exit. Among all beneficiaries entering the gap, only 6.68% exited the gap and reached catastrophic coverage by the end of 2006. Predictors of gap exit among gap enterers were slightly different from predictors of gap entry. For example, rheumatologic arthritis increased the likelihood of gap entry by less than one-third, yet almost doubled the conditional likelihood of gap exit. Other comorbidities associated with a substantially higher conditional probability of gap exit were dementia, mental health conditions, congestive heart failure and diabetes.

Medication Use Patterns Among Dementia and Diabetes Patients Entering the Gap

Tables 5 and 6 show the medications that were the most important drivers of gap entry for patients with dementia and diabetes. Of the twelve medications jointly accounting for half of pre-gap drug expenditures, four (donepezil, memantine, galantamine, and rivastigmine) were anti-dementia agents, while another three (risperidone, quetiapine, and olanzapine) were atypical antipsychotics. Notably, 66.32% of dementia patients entering the gap were on at least one anti-dementia drug. As the average cost of these drugs was also high ($4.86 per day), the four dementia drugs together accounted for 32.28% of pre-gap drug expenditures among this subgroup.

Table 5. Medications Contributing Most to Pre-Gap Drug Expenditures of Beneficiaries with Dementia

Medication	Pre-Gap Expenditures for Drug	% of Total Pre-Gap Expenditures	% of Dementia Patients Using Drug Prior to Gap Entry	Average Cost For a 30-Day Supply
Donepezil	$1,902,696	19.58%	49.74%	$145.20
Memantine	$844,794	8.70%	29.80%	$125.10
Clopidogrel	$330,861	3.41%	12.32%	$122.40
Risperidone	$267,247	2.75%	8.60%	$159.90
Quetiapine	$237,272	2.44%	8.95%	$135.30
Pantoprazole	$220,116	2.27%	9.80%	$114.00
Olanzapine	$217,209	2.24%	5.57%	$225.60
Galantamine	$194,508	2.00%	5.38%	$148.50
Rivastigmine	$194,195	2.00%	4.82%	$164.70
Escitalopram	$174,204	1.79%	10.61%	$70.20
Atorvastatin	$170,519	1.76%	9.14%	$85.20
Lovastatin	$150,510	1.55%	18.09%	$29.70

Medications shown account for 50.48% of total pre-gap drug costs among 4,091 patients with dementia who enter the gap in 2006

Table 6. Medications Contributing Most to Pre-Gap Drug Expenditures of Beneficiaries with Diabetes

Medication	Pre-Gap Expenditures for Drug	% of Total Pre-Gap Expenditures	% of Diabetes Patients Using Drug Prior to Gap Entry	Average Cost For a 30-Day Supply
Rosiglitazone	$2,716,653	7.21%	20.54%	$128.40
Clopidogrel	$1,726,883	4.58%	16.43%	$120.90
Metformin	$1,341,259	3.56%	45.69%	$25.20
Pioglitazone	$1,196,860	3.18%	9.81%	$142.20
Atorvastatin	$1,172,725	3.11%	14.95%	$85.50
Lovastatin	$1,080,550	2.87%	29.20%	$31.20
Simvastatin	$969,869	2.57%	10.95%	$127.20
Carvedilol	$868,512	2.30%	9.05%	$100.20
Ezetimibe/Simvastatin combination	$851,199	2.26%	10.65%	$78.90
Pantoprazole	$837,923	2.22%	10.18%	$113.10
Lisinopril	$733,939	1.95%	35.24%	$17.70
Valsartan	$669,291	1.78%	9.97%	$62.40
Amlodipine	$614,675	1.63%	11.13%	$54.90
Insulin glargine	$609,278	1.62%	9.87%	$89.10
Donepezil	$521,810	1.38%	4.17%	$144.60
Glyburide	$511,407	1.36%	21.48%	$20.70
Long-acting Diltiazem	$484,040	1.28%	10.11%	$39.00
Fluticasone and salmeterol inhalation powder	$476,768	1.27%	5.16%	$158.10
Long-acting Nifedipine	$434,152	1.15%	7.12%	$51.30
Risedronate	$387,101	1.03%	5.27%	$73.80
Gabapentin	$358,228	0.95%	8.32%	$53.70

Medications shown account for 49.25% of total pre-gap drug costs among 16,079 patients with diabetes who enter the gap in 2006

Among diabetic patients entering the gap, no single drug accounted for a high proportion of costs. The top three drugs (rosiglitazone, clopidogrel and metformin) accounted for 7.21%, 4.58% and 3.56% of pre-gap expenditures, respectively. Almost half as many patients were using rosiglitazone (20.54%), a third-line oral agent with an average daily cost of $4.28, as were using metformin (45.69%), a first-line agent with an average daily cost of $0.84.

DISCUSSION

One-quarter of Medicare patients who lacked drug coverage in 2005 signed up for a Part D plan in 2006, implying that 3.4 million seniors acquired drug benefits due to the program[7]. Moreover, previously uninsured patients saved 60% of their drug costs through the new benefit[7]. At the same time, the Part D benefit design included a coverage gap to limit the cost of the new drug benefit, as well as provide an incentive to limit overuse of non-essential drugs[5]. Given the heterogeneous need for prescription medications among Medicare beneficiaries, this design may disproportionately penalize populations who already have high costs of care. In addition to putting patients at financial risk, adherence to medication regimens (and as a result, outcomes) may suffer if the 100% cost sharing imposed in the coverage gap discourages compliance[17]. Physicians who make a routine practice of prescribing lower-cost medications first and discontinuing those that do not appear to be effective may not only improve their patients' adherence to more essential medications by keeping them out of the coverage gap, but also avoid exposing their patients to side effects associated with potentially unnecessary medications[18].

To efficiently allocate their time counseling patients about drug costs, physicians need to know which beneficiaries would benefit most from discussions about changing their medication regimens. This study examined the correlates of Medicare Part D coverage gap entry in order to identify subgroups of patients who may be at particular risk of gap entry and hence high out-of-pocket costs that might discourage adherence to drug regimens[19].

Our study found an extremely high risk of gap entry among patients with certain clinical and demographic profiles. Of the conditions studied, dementia had the strongest association with gap entry, followed by diabetes, end-stage renal disease, CAD, COPD and congestive heart failure. We also identified an association of gap entry with female gender, perhaps because women are more likely to seek and adhere to treatment[20]. As an example derived from our data, an average 67-year-old woman with diabetes and a typical set of comorbidities (hypertension, hyperlipidemia, coronary artery disease, depression) would have a 54% probability of falling into the Medicare Part D coverage gap during 2006 and being exposed to the full cost of her medication regime. If this patient fell into the gap, she would have a 11% chance of exiting again and qualifying for catastrophic coverage. In the meantime, however, she would have incurred more than $3,600 in total out-of-pocket drug expenditures. Similarly, the probability of gap entry for a 75-year-old woman with dementia and depression would be 48%, with a conditional probability of gap exit of 20%.

Dementia may prevent patients from optimizing their health-care choices, e.g., leading them or their surrogates to continue to buy brand-name drugs rather than switch to generics or failing to ask about therapeutic substitutes[21]. Alternatively, patients with dementia may be entering the gap earlier because they are using expensive anti-dementia medications. The latter interpretation is supported by the drug utilization patterns observed among dementia patients who entered the coverage gap. The possibility that anti-dementia medications may be causing elderly patients to fall into the Medicare Part D coverage gap is disturbing, given the limited evidence of effectiveness of these drugs[22,23]. Another notable finding was the high use of

atypical antipsychotics such as risperidone, quetiapine, and olanzapine, for which "black box warnings" had been issued as early as 2005 to caution against their use in elderly patients with dementia[24]. More than one-fifth (23%) of dementia patients entering the gap were taking one of these three drugs and this figure rose to 36% among those living in skilled nursing facilities. Less than one-quarter (23%) of these patients had a schizophrenia-related diagnosis. These findings suggest that healthcare providers should make a special effort to assist patients with dementia in making choices about drug treatments to protect their financial as well as clinical interests.

Although the magnitude of its association with gap entry was smaller for diabetes (RD=11.60%) than dementia (RD=18.97), the far higher prevalence of diabetes (20% vs. 4%) implies that the overall system impact is likely to be much greater. Although patterns of medication use among diabetic patients entering the gap raise fewer clinical concerns than those seen among dementia patients, cost considerations remain. Generic substitutes for brand-name drugs are widely available for some classes of diabetes medications (e.g., metformin and sulfonylureas) and even for those with no generic substitutes (e.g., TZDs), therapeutic substitutions are often possible. For example, metformin has an average daily cost less than one-quarter as high as that of rosiglitazone and is usually the first-line agent of choice. Yet in our data, the ratio of metformin to rosiglitazone use was only about 2:1, and 11% of diabetes patients on rosiglitazone were taking it as a single agent, suggesting that in some cases it may have been used as a first-line medication. Thus some patients without contraindications could possibly be switched to metformin.

Our conclusions should be interpreted in light of several study limitations. We may be overstating the associations of gap entry with comorbidities for which claims diagnoses are undercoded and only the most severely ill patients are identified as having the comorbidity[25]. Undercoding may be particularly common for dementia, as Alzheimer's disease alone (accounting for roughly 60% of all dementia) has a prevalence rate of 13% among the elderly. Conversely, inclusion of mild cases for other comorbidities could lead to understating associations with gap entry, because estimates reflect averages across diverse levels of severity.

Our MAPD patients were somewhat older than the national elderly population, suggesting that rates of gap entry and exit could have been higher in our study. We chose to study only MAPD patients, since data for PDP patients (while available to us) were limited to pharmacy claims, which do not provide reliable diagnosis information. Compared with the MAPD patients, on average the PDP patients in our database had similar gender distribution, were three years younger, used about two fewer prescriptions per year, and had lower rates of generic (vs. branded) and mail-order drug use, suggesting that they might be at greater risk of gap entry. Nonetheless, as MAPD plans have more influence than PDP plans on the practice pattern of their physicians, MAPD enrollees are the most likely target population for interventions encouraging physicians to more actively manage the drug utilization of their patients[26].

We use health plan prices and have data from only eight states, predominantly in the western half of the country. Nonetheless, the for-profit MAPD plan we studied is among the largest in the country and the majority of MAPD enrollees are in for-profit plans[27]. Over time patients might become more aware of the coverage gap and modify their behavior accordingly, although several studies show that people still do not understand the gap or make economically preferred choices[28,29]. Finally, medication analyses are inherently a "moving target" because new medications constantly come onto the market, old medications become generic, and new evidence on drug effectiveness and substitutions is disseminated. Thus, findings based on 2006 data should be interpreted in light of any changes to the prescription drug market that may have occurred since then.

Although inadequate drug coverage is hardly unique to the Medicare population and in fact the Part D program greatly improved coverage for many older Americans, its unique "coverage gap" feature does highlight the risks of financial exposure to drug costs. The financial burden associated with coverage gap entry could lead to unacceptable tradeoffs. Studies examining the effect of pre-Part D drug benefit caps found that patients often discontinued use, "stretched" their medications or cut back on other necessities because of cost[30–33]. Part D coverage gap entry also has implications for medication adherence[29] and (since medications are important in controlling chronic conditions) ultimately for health outcomes. Together with the desire of patients to receive more information about management of drug costs from their physicians[34–36], our findings suggest that medication cost counseling interventions focusing on these clinically vulnerable subpopulations may be warranted[37].

Physician-patient discussions about the expense and undesirable side effects of particular medications are one approach to managing outpatient drug therapy and controlling costs. Other systematic strategies might include disease management interventions, monitoring and feedback of physician prescribing patterns, use of formularies with utilization tools (e.g., prior authorization policies), or collaborative care involving pharmacists. A recent systematic review concluded that most of these strategies are moderately effective in changing medication use[38], although tiered formulary interventions may also cause discontinuation of essential and/or cost-effective medications[39] and many of these strategies require an electronic medical record (currently used by only a minority of U.S. physicians[40] in order to optimize results. One possible next step would be to take high-risk patients and randomize them to a high-level organizational intervention to help them better manage their drugs.

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