Published in final edited form as:
Psychiatr Serv. 2009 September ; 60(9): 1169–1174. doi:10.1176/appi.ps.60.9.1169.

Part D and Dual-Eligibles with Mental Illness: Problems Accessing Medications and Use of Intensive Mental Health Services

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Abstract

Objective—This study examined the occurrence of medication access problems and use of intensive mental health services after the transition from Medicaid drug coverage to Part D for dual-eligibles.

Methods—Psychiatrists randomly selected from American Medical Association's Physicians Masterfile reported on experiences in the first twelve months of 2006 of one systematically-selected dual-eligible patient (n=908). Propensity score matching was used to compare use of psychiatric emergency room and inpatient care for individuals who experienced a problem accessing a psychiatric medication after Part D and those who did not.

Results—Approximately 44% of dual-eligible patients were reported to experience a problem accessing medications. The likelihood of having an emergency room visit was significantly higher for those who experienced a problem compared to those who did not (mean OR=1.75, mean p-value=0.003). There was no difference in number of emergency room visits conditional on emergency room use or in hospitalization use.

Conclusions—Many dual-eligible patients experienced difficulty accessing psychiatric medications after Part D's implementation. Patients who experienced difficulties were significantly more likely to use psychiatric emergency room care than patients who did not experience difficulties. While not definitive evidence of a cost offset onto non-drug health care benefits of the switch to Part D for dual-eligibles, these findings raise concerns about potential offsets and possible negative impacts on quality of care. Additional study is needed to understand the full effects of Part D on outcomes and functioning as well as treatment costs for dual-eligibles.

Introduction

Approximately one-third (34%) of individuals dually eligible for Medicare and Medicaid suffer from a mental disorder, and these individuals rely on pharmacotherapy as a key element of mental health treatment.(1) Traditionally, dual-eligibles received coverage for prescription drugs through the Medicaid program. Under the Medicare Prescription Drug Improvement and Modernization Act of 2003, drug coverage for dual-eligibles was shifted from Medicaid to the

new Part D program, and all dual-eligibles were randomly assigned to a private Part D plan. While there have been general concerns about the impact of this change on dual-eligibles, there has been particular concern about how Part D enrollment might affect access to needed psychiatric medications for this population and a desire to monitor the consequences of any disruption to pharmacotherapies that might result in negative clinical outcomes.(2)

To examine the occurrence of medication access problems resulting from the transition to Part D for dual-eligibles, we used psychiatrist reports of the post-Part D experiences of their dual-eligible patients. We compared psychiatric emergency room and inpatient use for patients who experienced a medication access problem after Part D's implementation and similar individuals who did not. We found that individuals experiencing access problems were more likely to receive psychiatric care in the emergency room after Part D's implementation than individuals who did not experience a problem.

Part D for Dual-Eligibles

Dual-eligibles are randomly assigned to a Part D plan with a premium at or below the annual regional benchmark set by the Centers for Medicare and Medicaid Services (CMS) (hereafter, "benchmark plan"). In 2006, there were a total of 409 benchmark plans across the U.S.(3) In the majority of states, there were at least 10 benchmark plans, although that number has decreased in many regions.(3) For example, in 2009, six states have 5 or fewer benchmark plans; Nevada has only one.(3)

Dual-eligibles are permitted to switch monthly to another benchmark plan in their region, and several states provided substantial assistance to help dual-eligibles switch to plans that may be a better match for their medication needs.(4) An estimated 11% of noninstitutionalized dual-eligibles did switch plans in 2006.(5) If a plan's annual premium bid for the coming year exceeds the new benchmark set by CMS, dual-eligibles enrolled in the plan are reassigned to another benchmark plan.

Under Part D, dual-eligibles pay no premiums and only nominal copayments for medications. In 2006, full-benefit dual-eligibles paid $1.00-$2.00 for generics and $3.00-$5.00 for brands, depending on their income. Problems with patients being charged incorrect cost-sharing amounts were, however, documented in the program's initial implementation.(6) While Medicaid regulations stipulate that beneficiaries unable to pay copayments required by their state Medicaid program cannot be denied their prescription medications, there is no such regulation under Part D.

Dual-eligibles are also subject to the formulary and utilization management procedures of the plan in which they are enrolled. Although Part D plans are required to cover only two medications in each drug class, antipsychotics, antidepressants, and anticonvulsants were given special protections under the regulations implemented by CMS. For these classes, plans must cover "all or substantially all drugs," meaning they must cover at least one, but not all, formulations of each molecule in the class. For example, plans must cover either brand Paxil, generic paroxetine, or Paxil CR but are not required to cover all three formulations of paroxetine. However, recent legislation codifying this requirement allows the Secretary of Health and Human Services to specify exceptions that allow Part D plans to exclude a drug in the protected classes from its formulary.(7)

Even though plans were required to include at least one formulation of every drug on the formulary, plans can use various management tools to control utilization of these drugs. For example, a plan can require an enrollee to obtain prior authorization before granting coverage. Alternatively, a plan could require the enrollee to try one or more less expensive medications and document a poor response to these drugs before granting coverage of a more expensive

medication (i.e., step therapy or "fail first" policy). Beneficiaries on established therapies are now exempt from utilization management requirements for medications in these classes, although this policy was not in place when the program was implemented in 2006.(8) Huskamp et al. (2007) found that certain product formulations in these classes were not covered by a number of plans that served dual-eligibles in 2006, and use of prior authorization was common for a minority of plans.(9) Donohue, Huskamp, and Zuvekas (2009) documented that utilization management requirements for atypical antipsychotics, antidepressants, and anticonvulsants have increased since 2006.(2)

Many Medicaid programs use similar management tools to those used by Part D plans (e.g., prior authorization and step therapy) for some medications, and thus the use of certain utilization management methods may not be new to dual-eligibles. However, even if the Part D plan rules are equally restrictive to those used under the state Medicaid program, duals were required to switch to a different set of rules than had applied to them in past. Thus, some patients whose condition was stable on a particular medication may have found that the medication was not covered by their new Part D plan in 2006 or perhaps the plan required the enrollee to obtain prior authorization or undergo step therapy before securing coverage. Some enrollees also may have had difficulty paying the copayments required under Part D.

A transition policy required plans to provide a transition supply of medications during the first 90 days of enrollment, which may have reduced medication access issues during the first few months of implementation. However, despite the transition policy, West and colleagues (2007) documented that a large proportion of dual-eligible patients experienced problems in the first four months of 2006.(10)

Methods

Data

Observational, clinician-reported surveys tracked patient experiences during the first twelve months of Medicare Part D. Data collection consisted of three cross-sectional assessments: January-April 2006, May-August 2006, and September-December 2006. The target population was all practicing psychiatrists in the US with a deliverable address who treated dual-eligible patients. To allow the maximum time for a patient to have experienced an access issue, we used data from the third cycle of data collection (September-December 2006) only.

A total of 5,833 psychiatrists were randomly selected from the AMA's Physicians Masterfile of U.S. psychiatrists (N=55,000). After excluding psychiatrists not currently practicing and those with undeliverable addresses, responses were obtained from 66% of the sample (N=3,361) during the first data collection cycle. Of these respondents, 35% met the study eligibility criteria of treating dual-eligible patients during their last typical work week and participated in this study, providing clinically-detailed data on 1,193 systematically-selected patients. For the third data collection cycle (September-December, 2006), the 1,189 psychiatrists who participated in the first cycle and 1,600 new psychiatrists randomly selected from AMA Physician Masterfile were sampled. Responses were obtained from 68% of previous participants (N=803) and 67% of the new sample (N=914). Of those who responded, 56% met the study eligibility criteria, providing data on 986 systematically-selected patients.

Each psychiatrist was randomly assigned one of 21 start days and times to report on the next dual-eligible patient treated during their last typical work week. For each patient included in the study that the psychiatrist reported on, we obtained information on sociodemographic characteristics, treatment setting, diagnosis, and clinical characteristics as well as data on whether specific medication access problems were experienced. We also obtained information on emergency room visits related to the patient's psychiatric illness and psychiatric

hospitalizations since January 1, 2006. The average patient in the third data collection sample had 42.1 weeks (95% CI=41.8, 42.4) to accrue a medication access problem. Of the 908 patients in our sample, 37 had a psychiatrist who reported on more than one patient (17 psychiatrists reported on two patients and one psychiatrist reported on three patients). All study procedures were approved by APIRE's Institutional Review Board.

Analytical Approach

We first identified a subgroup of patients who experienced a problem accessing a psychopharmacologic medication after Part D's implementation as reported by their psychiatrist. Psychiatrists were asked if the patient experienced the following since January 1, 2006: 1) could not access clinically-indicated medication refills or new prescriptions because they were not covered or approved; 2) was stable on clinically-desired/indicated medication, but switched to a different medication because clinically-preferred medication refills were not covered or approved; or 3) had problems accessing medications because of copayments. If the psychiatrist answered "yes" to any one of these questions, we considered the patient to have experienced a medication access problem.

For this analysis, we excluded nursing home residents (n=31), children under 18 (n=5), and individuals whose only diagnosis was either substance use/dependence, mental retardation, mood disorder not otherwise specified (NOS) or a non-mental health condition (n=8). Thirty-four observations were dropped because of missing age and/or gender. Our final sample size was 908. Of these, 400 experienced a medication access problem according to our criteria.

We used propensity score matching, a method of adjusting for observed characteristics of patients non-randomly assigned to differing interventions,(11) to create pairs of subjects who appear similar in terms of observed characteristics. Each pair included a dual-eligible who had experienced a problem accessing medications and a similar individual who did not. We performed a 1–1 matched analysis without replacement on the basis of the estimated propensity score of each patient. The propensity score model included the following variables: patient sex, patient age group (40 and under, 41–64, or 65 and over), race/ethnicity (white vs. non-white), diagnosis of schizophrenia and/or bipolar disorder versus no such diagnosis, and region (Midwest, South, West, and Northeast).

After creating a matched sample of individuals who did and individuals who did not experience a medication access problem, we estimated two types of multivariate models: 1) logistic regression models of the likelihood of having any emergency room visits and any hospital days for a psychiatric illness since January 1, 2006; and 2) linear regression models of the number of emergency room visits conditional on having any emergency room visits and the number of hospital days conditional on having a psychiatric hospitalization since January 1, 2006. We included as covariates the same variables used in the propensity score matching model to correct for any specification errors in the propensity score models.(12) We also included variables indicating the severity of the patient's symptoms. Physicians were asked to rate the current severity of six symptoms (depressive symptoms, anxiety symptoms, psychotic symptoms, manic symptoms, alcohol/other substance use symptoms, or sleeping problems) as "severe," "moderate," "mild," "none," or "don't know." All models included six dummy variables (one for each symptom) indicating whether the psychiatrist reported that the patient experienced a severe form of the symptom. In addition, the regression models included a variable indicating whether the patient's psychiatrist had reported on more than one patient.

We replicated the propensity score matching 300 times in order to obtain more stable estimates of the parameters. On average, we matched 97% of individuals who experienced an access problem with a similar individual who had not. For each of the 300 sets of matched pairs, we estimated the two multivariate models. We present mean results across the 300 replications.

Results

The dual-eligible patients in our sample were disproportionately female (57%) and 41–64 years of age (62%) (Table 1). Almost three-quarters (74%) were White, while 16% were Black/African American, 7% were Hispanic, and 3% were classified as "other" race/ethnicity. Almost two-thirds (62%) had a diagnosis of either schizophrenia or bipolar disorder.

Among dual-eligible patients in our sample, 318 (35%) were unable to access clinically-indicated refills or new prescriptions because the drugs were not covered or approved, 170 (19%) were stable on a clinically-desired/indicated medication but switched to a different drug because refills were not covered or approved, and 200 (22%) had problems accessing medications because of copayments. As noted above, a total of 400 patients (44%) experienced one or more of these problems. Patients who experienced a medication access problem were more likely to be women, less likely to be diagnosed with schizophrenia, more likely to be diagnosed with major depression or anxiety, and more likely to have severe depressive symptoms, anxiety symptoms, or sleeping problems than patients who did not experience a problem accessing medications (Table 1).

We found that the mean odds ratio of having any emergency room visits was higher for those who experienced a medication access problem relative to similar individuals who did not (OR=1.75, mean p-value=0.003) (Table 2). The mean predicted probability of having an emergency room visit was 0.41 for patients with an access issue versus 0.27 for those with no access issue. Although the likelihood of emergency room use was higher for those with an access issue, there was no statistically significant difference in the number of emergency room visits conditional on having at least one visit between those who did and those who did not experience medication access problems. Neither the likelihood of having any psychiatric hospitalization nor the number of hospital days conditional on having a psychiatric hospitalization were significantly different for those who did and those who did not experience a medication access problem.

Discussion

Dual-eligibles with a psychiatric illness are a particularly vulnerable subgroup of Medicare beneficiaries, and some patient advocates and policymakers were concerned that the shift from Medicaid drug coverage to enrollment in a private Part D plan would result in difficulties accessing medications and possibly negative mental health outcomes for this group. The special protections for medication classes used commonly by individuals with mental disorders were intended to address this concern by guaranteeing formulary coverage of these medications. However, many plans use management tools such as prior authorization and step therapy to control utilization of psychopharmacologic medications. While use of these tools may lead to a more efficient allocation of resources and could possibly result in higher quality of care in some cases, utilization management requirements could also create access issues for enrollees. For example, Soumerai and colleagues' study of the atypical antipsychotic prior authorization and step therapy policies implemented in Maine's Medicaid program indicated these policies were associated with a 29% greater risk of antipsychotic discontinuations compared to a comparison state, with no associated cost savings in drug expenditures.(13) The requirement that all dual-eligibles pay copays to receive medications may also create access issues for some duals.

In fact, we found that almost half of the dual-eligible patients in our sample experienced some form of medication access problem in 2006. Although one might expect rates of access problems to decline over the course of the year, West et al. (2009) found no decline -- in fact, the rate of access problems reported by psychiatrists actually increased slightly as the year

progressed, perhaps due in part to the transition policy.(14) Rates of difficulties accessing medications might also be expected to decrease after the first year of implementation, although a large number of dual-eligibles either switch plans or are reassigned to a different benchmark plan each year. For example, between 2006 and 2007, 1.1 million dual-eligibles were reassigned to another plan when their plan's premium bid exceeded the new benchmark for the coming year; between 2007 and 2008, 2.1 million were reassigned.(3) Thus, during a given year a large proportion of dual-eligibles will likely face different coverage and utilization management requirements under a new plan and thus may be at particular risk for access problems. Access problems may also occur for beneficiaries who remain in the same plan if that plan changes formulary coverage and management procedures over time as permitted.

Although disruptions in medication continuity among psychiatric patients have been shown to be associated with high rates of symptom relapse or exacerbation, hospitalization, and other adverse consequences (15–19), some of the access issues we observed may have been resolved expeditiously, with little harm to the patient. For example, if a claim was initially rejected because prior authorization was required and authorization was granted quickly, the enrollee may have been able to fill the original prescription before a negative health outcome occurred. The timeliness of authorizations has been shown to be critically important for patients with schizophrenia.(20) Consequently, patients who experienced significant disruptions or gaps in medication continuity may have been more likely to relapse and present in the emergency room. Other patients may have switched medications in response to Part D coverage rules, and the effectiveness and/or tolerability of the "new" medication could have been either better or worse for the patient than their "old" drug. Findings from the CATIE study indicate that individuals randomly assigned to olanzapine or risperidone who were continuing with the medication they were taking at baseline had a longer time to discontinuation relative to individuals assigned to switch antipsychotics.(21) The consequences of switching medications may vary, however, based on the nature of the switch (e.g., a therapeutic substitution from one molecule to another versus a generic substitution). We estimated that patients who experienced an access problem were significantly more likely to have an emergency room visit for the treatment of a psychiatric illness, but were not more likely to have a psychiatric hospitalization.

Our findings should be interpreted in the context of several limitations. First, we measure a patient's experience of a medication access problem and the patient's use of psychiatric emergency room and hospital care in the first twelve months after Part D's implementation using reports from their psychiatrist. The psychiatrists may not be aware of all access problems experienced by the patient and all services used, or recall bias could be an issue if the psychiatrist did not provide sufficient documentation in the patient's medical record regarding these issues. We did not have data on the timing of access problems, emergency room use, and hospitalizations within the twelve-month period, which limits our ability to fully examine the relationship between medication access problems and use of these intensive services. Also, the high proportion of patients who experienced medication access problems during the first twelve months of 2006 likely reflects in part the widespread confusion when Part D was first implemented. The relatively high rate of reported access problems motivated us to use propensity score matching to allow us to compare individuals who were similar with respect to observable demographic and clinical characteristics. Second, our propensity score models are only able to reduce differences between the intervention and comparison groups in observed confounders; we are unable to control for differences in unobserved confounders. Third, we do not have information on additional office visits that may have resulted from medication access problems (e.g., a follow-up visit to check on a patient who had to switch medications because of lack of coverage). Finally, the dual-eligible patients we studied were all in the care of a psychiatrist, so our findings may not be generalizable to all dual-eligibles with a psychiatric disorder. However, psychiatrists treat the majority of individuals receiving treatment for

schizophrenia and many individuals with other severe mental illnesses, and a disproportionate share of dual-eligibles suffer from one of these conditions. (22,23)

Conclusions

This study documents various ways that dual-eligible patients with a psychiatric disorder experienced difficulty accessing medications in the first year after their drug coverage was switched to Part D. We found that patients who experienced a medication access problem were more likely to use psychiatric care provided in the emergency room but were not more likely to use inpatient psychiatric care. While not definitive evidence of a cost offset onto non-drug health care benefits of the switch to Part D for dual-eligibles, these findings raise concerns about potential offsets and possible negative impacts on quality of care that should be examined using other data sources, including the Medicare and Medicaid claims, once available. Additional study of the impact of Part D on use of other social services, the criminal justice sector, and, more importantly, the effects on mental health outcomes and functioning for dual-eligibles with psychiatric disorders is also needed.

Acknowledgments

This work was supported by grants from the National Institute of Mental Health (NIMH) (K01MH66109 and 1R01MH069721), a personal services contract from the NIMH, the American Psychiatric Foundation, and unrestricted grants from Astra Zeneca, Bristol Myers Squibb, Eli Lilly, Forest, Janssen, Pfizer, and Wyeth.

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Table 1

Descriptive Characteristics of Sample

Variable	Total Sample (n=908)		Medication Access Issue (n=400)		No Medication Access Issue (n=508)		P-value
	N	%	N	%	N	%	
Age:							.59
40 and Under	217	24%	89	22%	128	25%	
41–64	564	62%	254	64%	310	61%	
65 and Over	127	14%	57	14%	70	14%	
Gender:							.04
Male	394	43%	158	40%	236	47%	
Female	514	57%	242	61%	272	54%	
Race/ethnicity:							.51
White	673	74%	304	76%	369	73%	
Black/African American	145	16%	58	15%	87	17%	
Hispanic	59	7%	27	7%	32	6%	
Other/mixed/unknown	31	3%	11	3%	20	4%	
Diagnosis*:							
Schizophrenia	363	40%	143	36%	220	43%	.02
Major Depression	303	33%	148	37%	155	31%	.04
Bipolar Disorder	207	23%	98	25%	109	22%	.28
Anxiety Disorder	187	21%	94	24%	93	18%	.05
Substance use Disorder	173	12%	41	10%	67	13%	.17
Other	219	24%	89	22%	130	26%	.07
Severe Symptoms*:							
Depressive	130	14%	77	19%	53	10%	<.001
Anxiety	142	16%	79	20%	63	12%	.003
Psychotic	107	12%	47	12%	60	12%	.98
Manic	24	3%	13	3%	11	2%	.31
Alcohol/Other Substance Use	33	4%	13	3%	20	4%	.58
Sleeping Problems	91	10%	58	15%	33	7%	<.001
Treatment Setting:							.001
Public Clinic/Outpatient Facility	321	35%	152	38%	168	33%	
Private Clinic/Outpatient Facility	190	21%	84	22%	104	20%	
Solo or Group Private Office	249	27%	114	29%	135	27%	
Private Inpatient Facility	40	4%	19	5%	21	4%	
Public Inpatient Facility	65	7%	11	3%	54	11%	
Other	43	5%	17	4%	26	5%	
Region							.01
Northeast	268	30%	101	25%	167	33%	
Midwest	224	25%	106	27%	118	23%	
Southeast	293	32%	146	37%	147	29%	
West	123	14%	47	12%	76	15%	
Psychiatric Hospitalization							.42#
Yes	240	26%	111	28%	129	25%	
No	668	74%	289	72%	379	75%	
Mean # days conditional on at least 1	26.3±2.9		19.0± 2.3		32.6±5.0		
Psychiatric Emergency Room Visit							<.001#

Variable	Total Sample (n=908)		Medication Access Issue (n=400)		No Medication Access Issue (n=508)		P-value
	N	%	N	%	N	%	
Yes	300	33%	157	39%	143	28%	
No	608	67%	243	61%	365	72%	
Mean # visits conditional on at least 1	2.2±.1		2.2±.1		2.1±.2		

*The percentages in these categories do not sum to 100 because psychiatrists were permitted to indicate multiple diagnoses and symptoms for their patient.

#These p-values refer to the probability of having either a hospitalization or emergency room visit.

Table 2

Multivariate Results for Individuals Who Experienced a Medication Access Issue Relative to Those who Did Not

	Mean Odds Ratio or Coefficient	Odds Ratio or Coefficient Range	Mean Standard Error of Coefficient	Mean P-value	P-value range	% of P-values ≤0.05
Any Emergency Room Visit	1.75	1.50–2.12	.18	.003	<.001–0.02	100%
# Emergency Room Visits among those with at least 1	.17	.01–.31	.23	.48	.16–.98	0%
Any Hospitalization	1.17	1.02–1.37	.20	0.44	.11–.92	0%
# Hospital Days among those with at least 1	–8.38	−20.04– −1.27	5.13	.15	.01–.73	16%