Suicidality Is Associated With Medication Access Problems in Publicly Insured Psychiatric Patients

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Background: Beginning January 1, 2006, the Medicare Part D prescription drug benefit shifted drug coverage from Medicaid to the new Medicare Part D program for patients who were eligible for both Medicare and Medicaid benefits ("dual-eligibles"). These patients were randomly assigned to a private Part D plan and came under specific formulary and utilization management procedures of the plan in which they were enrolled.

Objective: To examine the relationship between physician-reported medication switches, discontinuations, and other access problems and suicidal ideation or behavior among "dual-eligible" psychiatric patients.

Method: Data were collected in 3 cross-sectional cycles in 2006 (January–April, May–August, and September–December) as part of the National Study of Medicaid and Medicare Psychopharmacologic Treatment Access and Continuity using through-the-mail, practice-based survey research methods. Data from the third cycle, representing all events since January 1, 2006, were used for these analyses. A national sample of psychiatrists randomly selected from the AMA Masterfile provided clinically detailed data on 1 systematically selected, dual-eligible psychiatric patient (N = 908). Propensity score analyses adjusted for patient sociodemographics, treatment setting, diagnoses, and psychiatric symptom severity.

Results: Patients who experienced medication switches, discontinuations, and other access problems had 3 times the rate of suicidal ideation or behavior compared with patients with no access problems (22.0% vs 7.4%, $P < .0001$). Mean odds ratios and excess probabilities were highest for patients who were clinically stable but were required to switch medications (31.8%; mean OR = 4.87, mean $P = 8.92^{-5}$, excess probability = 0.21). Patients who experienced discontinuations (26.4%; mean OR = 2.13, mean $P = 2.12^{-2}$, excess probability = 0.12), other access problems (18.7%; mean OR = 3.01, mean $P = 1.03^{-5}$, excess probability = 0.15), and multiple access problems (22.3%; mean OR = 2.88, mean $P = 4.10^{-5}$, excess probability = 0.14) also had significantly increased suicidal ideation or behavior.

Conclusion: Increased occurrences of suicidal ideation or behavior appear to be associated with disruptions in patient medication access and continuity. Clinicians need to be aware of the possibility of increased suicidality when, for administrative reasons, a clinically stable patient's medication regimen is altered. Dual-eligible psychiatric patients represent a highly vulnerable group with a substantial burden of illness; these findings underscore the need to provide special protections for this population.

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Suicide is a fatal, self-inflicted destructive act with explicit or inferred intent to die.[1] Psychiatric illnesses are the primary distal risk processes that underlie the vast majority of suicide mortality and morbidity[2–12] and are considered to be necessary conditions under which suicidal behaviors may occur.[9,12,13]

Although suicide death is a rare event in the general population,[2,14] suicide morbidity and mortality among psychiatric patients are far from rare and are ongoing concerns in providing adequate care.[6] Appropriate treatment of psychiatric disorders is a central component of suicide prevention.[1,5,7,13] Individuals suffering from comorbid conditions are an especially vulnerable group[3,6,10,15–20] and in need of stable care to facilitate symptom remission, improvement in functioning, and recovery. A key element of treatment for such patients is pharmacotherapy. Compelling evidence demonstrates that appropriate pharmacologic treatment can reduce suicide risk among patients with bipolar illness[21,22] and schizophrenia.[23] At the ecological level, higher rates of prescriptions for selective serotonin reuptake inhibitors have consistently been linked with lower population rates of suicide fatalities in defined geographic regions (eg, Gibbons et al[24]).

Disruptions in treatment access and continuity of care can negatively affect the course of disease in seriously ill psychiatric patients and potentially precipitate adverse clinical and life events.[25–35] Disruption of pharmacologic treatment is of particular concern, as these treatments generally represent first-line, evidence-based interventions for most psychiatric patients. For example, disruptions in medication regimen have been associated with lower patient adherence,[36] increases in adverse events,[25–30] and increased emergency department visits and hospitalization.[37–39] Gaps in medication coverage for patients with schizophrenia have been associated with increased symptom exacerbation,[35] likelihood of relapse,[40] increased hospitalization,[34,35] and homelessness.[35] There is also evidence that switching antipsychotic medications for clinically stable patients with chronic schizophrenia is associated with greater side effects and higher discontinuations than maintaining patients on stable medication regimens.[41] While there are compelling clinical reasons for modifying a patient's medications to personalize treatment (eg, Quitkin et al,[42] Stroup et al,[43] Fava et al[44]), the practice of switching medications for nonclinical reasons has received limited attention.

With few exceptions, most studies of discontinuity in pharmacotherapy have not addressed suicidality, and systematic data examining the relationship between medication disruptions, switches, or other access problems and suicidality have been limited. There is increasing interest in understanding how medication access problems and other treatment discontinuities may affect suicidal ideation or behavior among psychiatric patients. The American Psychiatric Association has called attention to the potential harmful effects of treatment disruption in its Practice Guideline for the Assessment and Treatment of Patients with Suicidal Behaviors.[45] Changes in treatment access have been linked with both suicide mortality[31–33] and morbidity.[29] West et al[29] examined the experiences of a large sample of psychiatric patients in the first 4 months following the implementation of the Medicare Part D prescription drug benefit on January 1, 2006. The investigators found a 22% increase in suicidal ideation or behavior among patients who experienced disruptions in continuity of care as reported by physicians. It is not clear whether this group was disproportionately affected, however, as data were not available on adverse events among patients who did not experience problems with medication access. The goal of the current study is to examine more fully the relationship between medication switches, discontinuations, and other access problems and suicidal ideation or behavior among psychiatric patients using more extensive data, in order to identify potential avenues for prevention.

METHOD

Procedures

The implementation of the Medicare Part D prescription drug benefit under the Medicare Prescription Drug Improvement and Modernization Act of 2003 provided a unique opportunity to conduct a naturalistic study of the potential association of suicidality with changes in medication access. The Medicare Part D prescription drug benefit shifted drug coverage from Medicaid to the new Medicare Part D program for patients eligible to receive benefits from both Medicare and Medicaid ("dual eligibles"), beginning January 1, 2006. This policy affected approximately 2 million patients with mental and addictive illnesses.[29] All dually eligible patients were randomly assigned to a private Part D plan and came under specific formulary and utilization management procedures of the plan in which they were enrolled. Antipsychotics, antidepressants, and anticonvulsants are given special protections, in that plans are required to cover at least 1, but not all, formulations of each molecule in the class. In an effort to control potentially high costs, however, plans employ various formulary and utilization management tools to influence use.[46–49] Strategies may include, for example, prior authorization, switching to a generic drug, or an approach such as step therapy/"fail first," which requires enrollees to document a poor response to 1 or more less-expensive medications before they are granted coverage of a more expensive one.

Data for the current study were collected as part of the National Study of Medicaid and Medicare Psychopharmacologic Treatment Access and Continuity. The data collection procedures have been described in detail elsewhere.[29,30] Briefly, a national sample of psychiatrists provided information on dual-eligible psychiatric patients. Through-the-mail, practice-based survey research methods were used and included a $75 check in the study mailing as incentive to increase response. Data were collected in 3 cross-sectional cycles in 2006: January–April, May–August, and September–December. Each cycle covered the preceding time period that began January 1, 2006, with the third cycle covering January–December; response rates ranged from 66% to 75%. Across all 3 cycles, a total of 1,490 individual psychiatrists reported clinically detailed data on 1 systematically selected patient with dual eligibility. Data from the third and final data collection cycle, reported by 967 psychiatrists, were used for the analyses presented here.

Data included patient sociodemographic characteristics, patient diagnoses, current symptoms and symptom severity, patient's prescription drug plan features during the period covered by the data collection cycle, any disruptions in the patient's medication access or continuity since January 1, 2006, the extent and type of any disruption, and any adverse events since January 1, 2006. Adverse events included increased medication side effects, emergency room visits, psychiatric hospitalization, homelessness, incarceration, violent ideation or behavior, and suicidal ideation or behavior. The study was approved by the institutional review board of the American Psychiatric Institute for Research and Education.

Analyses

A patient was considered to have switched medications for administrative reasons if the physician reported that the patient was stable on treatment with a clinically desired or indicated medication, but was required to switch to a different medication because clinically preferred medication refills were not covered or approved. A patient was considered to have discontinued a medication if the physician reported that the medication was discontinued or temporarily stopped because of drug coverage, management or administration issues, or copayments. A patient was considered to have experienced suicidal ideation or behavior if the physician answered "yes" to the question, "Since January 1, 2006, has this patient had an increase in suicidal ideation or behavior?" Patients under 18, those missing information on sex or age, patients with diagnoses of alcohol/drug abuse only or personality disorders only, and patients in nursing homes were excluded from the analyses. The final sample size was 908.

Sociodemographic and clinical characteristics and medication access problems for patients with and without physician-reported suicidal ideation or behavior were compared using χ^2 tests. Estimates were weighted to the target population, dual-eligible psychiatric patients in the United States. Weights were based on the probability of selection of the psychiatrist and the number of dual-eligible patients in the psychiatrists' caseloads. Propensity score analyses[50] adjusted for selected characteristics by creating matched pairs

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of patients who differed on whether they had (cases) or had not (noncases) experienced a medication access problem, to determine whether one group was more likely to also have experienced increased suicidal ideation or behavior. The propensity score models matched patients on sex; age group (< 25, 26–40, 41–55, 56–64, or 65 years and over); race (white vs nonwhite); diagnosis of schizophrenia and/or bipolar disorder versus no such diagnosis; severity of current depressive, anxiety, psychotic/manic, alcohol/substance use, and sleep symptoms (none, mild, moderate, severe); and region (Midwest, South, West, and Northeast). This approach was used to estimate the difference in the probability of increased suicidal ideation or behavior between patients who had experienced a medication access problem and those who had not; it was also used to calculate odds ratios (ORs). Four models were estimated, 2 for specifically operationalized medication access problems (medication switch and medication discontinuation), 1 for all other medication access problems not including switches or discontinuations, and a fourth that included any medication access problem. To tighten the confidence intervals of the effect parameters, the analyses were replicated 150 times for each model. We report the average of these estimated parameters.

RESULTS

Weighted distributions of sociodemographic characteristics for US dual-eligible psychiatric patients with and without suicidal ideation or behavior during the study period are shown in Table 1. Overall, 56% (weighted) of the patients were female; the majority were white (71%) and 55 years of age or younger (70%). More patients (weighted frequency 31%) were seen by psychiatrists practicing in the South, and fewer (19%) were seen by psychiatrists practicing in the West; 51% were treated in a public clinic or outpatient facility.

There were no significant differences between patients with and without suicidal ideation or behavior on age, race, or treatment setting. There were significant differences by sex, with more females than males experiencing suicidal ideation or behavior, and by region, with a higher proportion of patients treated in the Midwest and a lower proportion treated in the Northeast having an increase in suicidality.

Forty-five percent (weighted) of all patients had a diagnosis of schizophrenia, 32% had a diagnosis of major depression, and nearly half (45%) had more than 1 diagnosis. Three out of 4 (76%) suffered from general medical conditions. Sixty-two percent of all patients experienced 1 or more medication access or continuity problem in the period since Medicare Part D was implemented.

Weighted distributions of clinical characteristics for dual-eligible patients with and without suicidal ideation or behavior reported during the study period are shown in Table 2. Overall, nearly 16% (weighted) of patients had an increase in suicidal ideation or behavior reported during the past year. Patients with and without suicidal ideation or behavior did not differ significantly on the most frequent psychiatric diagnoses or on presence of general medical conditions. There were significant differences between groups on other psychiatric disorders, number of psychiatric diagnoses, symptom severity, other adverse events, and medication access problems. Patients who experienced increased suicidal ideation or behavior were significantly more likely to have a psychiatric diagnosis other than the most frequent ones reported, to have more than 1 psychiatric diagnosis, and to be rated by their physicians as having severe symptoms of depression and anxiety and severe sleep problems. These patients were also significantly more likely to have experienced other adverse events in addition to suicidal ideation or behavior. Weighted frequencies ranged from 21% for increased violent ideation or behavior to 36% for significantly worsened medication side effects. The rates of suicidal ideation or behavior in patients with medication access problems were 3 times higher than for patients with no access problems (22.0% vs 7.4%, $P < .0001$).

Patients who experienced medication access problems had increased probabilities of suicidal ideation or behavior regardless of the type of access problem (Table 3). The excess probabilities ranged from 12% to 21%; all associations were highly significant (P values for ORs shown in column 5). Excess probabilities and mean odds ratios were highest for patients who were clinically stable but were required to switch medications (mean OR = 4.87). Thirty-two percent

Table 1. Weighted[a] Percentage of Clinician-Reported, Dual-Eligible Patients[b] With and Without Suicidal Ideation or Behavior by Sociodemographic Characteristics

		No Suicidal Ideation or Behavior		Suicidal Ideation or Behavior		
Characteristic	Total n	n	%[a]	n	%[a]	*P*
All patients	908	764	84.3	144	15.7	
Sex						.0037
Female	514	427	81.1	87	18.9	
Male	394	337	88.3	57	11.7	
Age						.3570
≤ 25 y	21	15	80.9	6	19.1	
26–40 y	196	165	87.1	31	12.9	
41–55 y	423	350	83.3	73	16.7	
56–64 y	153	129	80.3	24	19.8	
≥ 65 y	115	105	87.8	10	12.2	
Race						.2062
Nonwhite	228	192	86.7	36	13.3	
White	680	572	83.3	108	16.7	
Region						.0081
Northeast	268	238	89.6	30	10.4	
Midwest	224	176	78.2	48	21.9	
South	293	249	85.9	44	14.1	
West	123	101	82.3	22	17.7	
Treatment setting						.8080
Public clinic/outpatient facility	319	274	83.4	45	16.6	
Private clinic/outpatient facility	189	151	82.2	38	17.8	
Solo or group private office	248	219	86.6	29	13.4	
Private inpatient facility	40	30	88.9	10	11.1	
Public inpatient facility	65	51	84.5	14	15.5	
Other	43	39	83.3	8	16.7	

[a]Weighted for the probability of selection of the psychiatrist and the number of dual-eligible patients in the psychiatrists' caseloads.
[b]Patients eligible for coverage under both Medicare and Medicaid.

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Table 2. Weighted[a] Percentage of Clinician-Reported, Dual-Eligible Patients[b] With and Without Suicidal Ideation or Behavior by Clinical Characteristics

Characteristic	Total n	No Suicidal Ideation or Behavior n	No Suicidal Ideation or Behavior %[a]	Suicidal Ideation or Behavior n	Suicidal Ideation or Behavior %[a]	*P*
All patients	908	764	84.3	144	15.7	
Diagnosis						
Schizophrenia	363	303	84.6	60	15.4	.7970
Bipolar disorder	207	172	82.3	35	17.7	.4390
Major depression	303	253	83.6	50	16.4	.7027
Anxiety disorders	187	156	85.1	31	14.9	.7492
Alcohol use disorder	53	43	86.7	10	13.3	.6122
Other substance use disorder	60	50	84.4	10	15.6	.9864
Other disorder[c]	243	202	77.9	41	22.1	.0028
No. of disorders						.0005
Exactly 1 disorder	504	435	87.9	69	12.1	
More than 1 disorder	404	329	79.2	75	20.8	
Severe symptoms[d]						
Depressive	130	73	58.3	57	41.7	<.0001
Anxiety	142	95	66.6	47	33.4	<.0001
Psychotic/manic	119	87	82.8	32	17.2	.6044
Alcohol/other substance use	33	22	76.1	11	23.9	.2346
Sleep problems	91	58	57.0	33	43.0	<.0001
Medication access issue	516	401	78.1	115	22.0	<.0001
General medical condition	686	572	83.9	114	16.1	.6250
Other adverse events						
Any psychiatric hospitalization	240	335	74.6	87	31.3	<.0001
Emergency department visit for psychiatric illness	300	153	68.7	96	29.1	<.0001
Patient homeless for ≥48 h	59	204	71.0	23	31.6	.0009
Patient detained or incarcerated in jail or prison	48	36	68.4	15	24.0	.1419
Significantly worsened clinical symptomatology	290	33	76.0	112	32.9	<.0001
Significantly worsened medication side effects	72	178	67.1	29	35.7	<.0001
Increase in violent ideation or behavior, or patient physically injured by another person	85	43	64.3	29	20.8	.1044
Any other adverse event	469	56	79.2	134	25.4	<.0001

[a]Weighted for the probability of selection of the psychiatrist and the number of dual-eligible patients in the psychiatrists' caseloads.
[b]Patients eligible for coverage under both Medicare and Medicaid.
[c]Personality disorder, n = 28; other depressive disorder, n = 20; dementia, n = 14; disorder groups or not grouped, n = 39.
[d]Physicians rated patient symptoms as none, mild, moderate, or severe.

of these patients experienced suicidal ideation or behavior, compared with 12% of patients not required to switch. Patients whose medication was discontinued or temporarily stopped had more than twice the odds of suicidality than did patients with no medication access problem (mean OR = 2.13). Patients who experienced 1 or more medication access problems had nearly 3 times the odds of suicidality than did patients with no medication access problem (mean OR = 2.88).

DISCUSSION

This study examined the relationship between medication switches, discontinuations, and other medication access problems and physician-reported suicidal ideation or behavior. Our findings indicated strong and consistent relationships between access problems and suicidal ideation or behavior. Physicians reported that more than 1 in 5 patients who had any medication access problems also experienced suicidal ideation or behavior. Among patients who were specifically required to switch medications because their clinically preferred medication was not covered by their prescription drug benefit, nearly 1 in 3 experienced suicidal ideation or behavior.

The consequences of breaks in medication regimens for seriously ill psychiatric patients are well known.* The current naturalistic study confirms and extends previous work in this area in several ways. First, most studies of the consequences of medication disruption have examined outcomes such as emergency department visits[35,37–39] or hospitalization[34,35,37–39]; a handful have also examined clinical outcomes such as symptom exacerbation.[26,27,35,40] The current study is one of the few to show that suicidality can also be a potential consequence of medication disruption or a change in medication that is not clinically indicated.

Second, previous findings from studies of medication disruptions were derived primarily from studies of patients with schizophrenia or bipolar disorder,† small samples,[26,40,51] or clinical trial data.[26,27,41–44,52] Our naturalistic study provides evidence from a large and clinically diverse population of patients, seen in a wide range of clinical settings, that switching or discontinuing medications for nonclinical reasons may place vulnerable patients at greatly increased risk for destabilization and serious adverse events such as suicidality. Our findings on patients who did not experience suicidal ideation or behavior also provide evidence to support continuity of current medication regimens in patients who are clinically stable.

Third, most studies of treatment discontinuation have been conducted from the perspective of the individual patient and have focused on patient nonadherence as a major reason for medication disruption (eg, Lacro et al[53]). Some investigators have recently argued that nonadherence to treatment is multidimensional and can occur for a variety of reasons other than being a willful choice of the patient.[34,51,54,55] The current study, through physician-reported data, provides further evidence that potential factors at the systems level may contribute to medication nonadherence, disruptions in medication regimen, and clinical consequences for patients and need to be considered.

The current findings are consistent with the stress-diathesis model, which suggests that higher risk for suicidal outcomes is associated with a greater number of stressors and a greater burden of illness.[12,56–59] In our study, patients with increased suicidality were significantly more likely to have an increased burden of illness as indicated by more than 1 diagnosis, high rates of symptom severity, and more than 1 medication access problem. Although such multiple stressors present considerable challenges to patient care, they

*References 29, 30, 34, 35, 37, 39, 40.
†References 26, 27, 34, 35, 37, 40, 47, 51, 52.

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Table 3. Physician-Reported Medication Access Problems and Suicidal Ideation or Behavior in Dual-Eligible Psychiatric Patients[a]

Medication Access and Continuity Problem	Increase in Suicidal Ideation or Behavior, Unweighted % (SE)[b]	Mean Predicted Probability of Increased Suicidal Ideation or Behavior[c]	Excess Probability[c]	Mean OR[c] (OR range)	Mean *P* Value of OR[c] (range)
Patient was stable on clinically desired/ indicated medication, but required to switch to different medications because clinically preferred medication refills were not covered or approved			0.208	4.87 (2.8–11.7)	8.92^{-5} (4.2^{-8}–6.6^{-4})
Yes (n = 170)	31.8 (3.6)	0.306			
No (n = 738)	12.2 (1.2)	0.098			
Medication was discontinued/temporarily stopped because of drug coverage, management/administration issues, or copayments			0.124	2.13 (1.4–4.0)	2.12^{-2} (3.7^{-5}–1.7^{-1})
Yes (n = 197)	26.4 (3.1)	0.259			
No (n = 711)	12.9 (1.3)	0.135			
Medication access problems other than switches or discontinuations[d]			0.149	3.01 (2.56–3.41)	1.03^{-5} (2.2^{-7}–1.3^{-4})
Yes (n = 246)	18.7 (2.5)	0.226			
No (n = 662)	7.14 (1.3)	0.077			
One or more medication access/continuity problems			0.139	2.88 (2.43–3.46)	4.10^{-5} (3.5^{-7}–4.0^{-4})
Yes (n = 516)	22.3 (1.8)	0.219			
No (n = 392)	7.4 (1.3)	0.080			

[a]Patients eligible for coverage under both Medicare and Medicaid.
[b]Estimated using unweighted χ^2.
[c]Estimated using propensity score models; 150 repetitions were conducted for each model. Cases and noncases were matched on sex, age, race, symptom severity, schizophrenia or bipolar diagnosis, and region.
[d]Other access problems: patients could not access clinically indicated medications or doses because they were "off label," patient had problems accessing benzodiazepines because they were not covered or approved, clinically indicated and preferred medications could not be prescribed because they were not covered or approved, patient could not access clinically indicated medication refills or new prescriptions because they were not covered or approved, a medication not clinically preferred had to be prescribed because of drug coverage or management issues, or patient had problems accessing medications because of patient copayments.

also present multiple opportunities to intervene to reduce risk and ease the burden of illness. One promising direction for preventing a suicidal outcome may be to reduce stressors for vulnerable patients when treatments are changed for administrative rather than clinical reasons. Clinicians need to be aware of the possibility of increased suicidality when a clinically stable patient's medication regimen is altered and carefully monitor any switches in medications or other disruptions in medication continuity.[26,27,41]

Taken together, our findings support the recent call[60] for improvement of mental health services through approaches from a variety of perspectives and point to the need to revise administrative policies related to medication access for seriously ill psychiatric patients. Prescription drug policies are largely driven by economic considerations,[47,48] and it is likely that the majority of patients in the general population may not be adversely affected by changes in their medications. Dual-eligible psychiatric patients, however, represent a highly vulnerable group with a substantial burden of illness, and our findings underscore the need to provide special protections for this population.

Limitations

The findings of the current study should be interpreted with several important limitations in mind. First, information on patient experiences was derived from physician reports; it was not possible to validate the data against other sources of information such as chart reviews or administrative claims data. Second, clinicians were asked to report on increases in "suicidal ideation or behavior" as 1 item rather than providing separate reports for suicidal thinking, nonsuicidal self-injury, and suicidal self-injurious behaviors. It was not possible to determine, therefore, what proportion of patients experienced any level of suicidal ideation only, what proportion injured themselves without intent to die, and what proportion injured themselves with intent to die, ie, made a suicide attempt. Future work needs to separately ascertain suicidal thinking, nonsuicidal self-injury, and suicidal behaviors in order to examine whether disruptions in medication access may be more likely to be associated with some self-injurious behaviors or suicidal outcomes but not others. Third, access problems could have triggered increased patient contact, making the physician more likely to detect suicidal ideation. Fourth, this study could not address temporal sequence or causality, since the data were retrospective and collected in cross-sectional assessments. It was not possible, therefore, to ascertain whether medication access problems occurred before the observed increases in patient suicidal ideation or behavior, nor was it possible to determine whether patients with a prior history of suicidality were more likely to experience suicidality during the reporting period. A causal relationship between medication access problems and suicidality cannot be established on the basis of our data. We can only note that there was a strong association between medication access problems and clinician-reported increases in patient suicidal ideation or behavior within the reporting period, a finding that merits further investigation with longitudinal data.

CONCLUSION

The observational findings reported here have important implications for suicide prevention in clinical settings and merit further investigation. While the sequence of events is unknown and causality cannot be established with these data, the fact remains that increased occurrence of a serious clinical outcome—suicidal ideation or behavior—was significantly associated with disruptions in patient medication access and continuity that were previously attributed specifically to prescription drug coverage and management. Awareness that this potential set of circumstances at the systems level may affect highly vulnerable individuals provides important opportunities for preventive intervention. Whether patients with elevated rates of suicidal thinking or behavior are at greater risk for medication access problems, or whether access problems put severely ill patients at greater risk for suicidal outcomes, the observed link with administrative procedures suggests that prescription drug coverage and management policies that are sensitive to the needs of the most vulnerable patients may potentially ease suffering and ultimately save lives.

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