

SPECIAL ARTICLE

Effect of a Mental Health “Carve-Out” Program on the Continuity of Antipsychotic Therapy

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ABSTRACT

BACKGROUND

On July 1, 1996, as a cost-containment strategy, Tennessee’s expanded Medicaid program, TennCare, rapidly shifted the provision of mental health services to a fully capitated, specialty “carve-out” program, TennCare Partners. We studied the effect of this transition on the continuity of antipsychotic therapy among patients with severe mental illness who had previously adhered to treatment.

METHODS

Study patients were 21 to 64 years of age, were enrolled throughout the study period, and had adhered to antipsychotic therapy during a 6-month base-line period that preceded the 12 months of study follow-up. The study population included 4507 patients whose follow-up began on the day the change was implemented (the post-transition cohort) and 3644 patients whose follow-up began one year earlier (the pretransition cohort). We compared the two cohorts in terms of the loss of continuity of antipsychotic therapy (missed treatment for more than 60 days during follow-up) and the mean number of days of antipsychotic therapy during follow-up.

RESULTS

As compared with the pretransition cohort, the post-transition cohort had increased odds of loss of continuity (a multivariate odds ratio of 1.18 [95 percent confidence interval, 1.07 to 1.30], $P=0.001$) and a shorter mean duration of antipsychotic therapy (a mean reduction of 4.2 days [95 percent confidence interval, 1.7 to 6.7], $P=0.001$) during follow-up. This difference was most pronounced among high-risk patients (those requiring the administration of extended-release [depot] injections of antipsychotic medications or who had been hospitalized for psychosis) at base line, for whom continuity was most important (odds ratio for loss of continuity, 1.79 [95 percent confidence interval, 1.45 to 2.22]; $P<0.001$; mean reduction in the number of days of antipsychotic therapy, 14.4 days [95 percent confidence interval, 9.4 to 19.4]; $P<0.001$). These patients had decreased use of antipsychotic drugs immediately after the transition; the lower level persisted throughout the 12 months of follow-up.

CONCLUSIONS

These findings underscore the need to ensure that shifts to widely used carve-out programs, which are designed primarily to contain costs, do not adversely affect clinical outcomes.

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FEDERAL, STATE, AND LOCAL GOVERNMENTS pay for more than two thirds of the costs of mental health care. State Medicaid programs now deliver a substantial fraction of this government-financed care.¹⁻⁴ “Carve-out” programs, which transfer the responsibility for mental health services to specialty behavioral health organizations,^{2,5} have become increasingly attractive to states as a cost-containment strategy.^{2,3,6} Although there is some evidence that these programs reduce costs,^{1,7-9} there are conflicting data on their effects on clinical outcomes in vulnerable populations of patients who are eligible for Medicaid.^{1,10}

On July 1, 1996, Tennessee’s expanded Medicaid program, TennCare, implemented a carve-out program for mental health and substance-abuse care, TennCare Partners.¹¹ Responsibility for the provision of services was rapidly transferred to two newly created behavioral health organizations. Anecdotal reports suggest that there were serious disruptions of patients’ care, which were attributed to both intrinsic flaws in the new policy and problems with the change in policy.¹¹

We evaluated the effect of this transition on one important clinical outcome: the continuity of antipsychotic therapy among patients with severe mental illness. Long-term antipsychotic therapy is the cornerstone of the management of chronic psychotic disorders. The practice guidelines for the treatment of schizophrenia from the American Psychiatric Association suggest that patients with multiple episodes should receive antipsychotic maintenance therapy for “at least five years and possibly indefinitely.”¹² Patients who are in remission for more than 2 years have a greater-than-50-percent risk of relapse within 12 to 24 months if they discontinue therapy¹² — more than twice the risk among those who continue therapy.^{13,14} Patients who do not adhere to treatment have elevated risks of acute psychotic episodes and hospitalization.^{13,15} Once lost, adherence may be difficult to reestablish, and the ensuing clinical deteriorations may not be reversible.

METHODS

THE TRANSITION TO A BEHAVIORAL HEALTH ORGANIZATION

Just before the change was implemented, TennCare¹⁶ served 1.4 million traditional Medicaid enrollees and uninsured, working poor people through 13 managed-care organizations. Enrollees who

were 21 to 64 years of age were eligible for mental health services that included medically necessary prescription drugs, up to 45 outpatient visits per year (\$100,000 worth over the patient’s lifetime), and up to 30 days per admission or 60 days per year for inpatient stays. Traditional state and local safety-net providers furnished services for severely ill patients in excess of the TennCare limits.¹¹

Subsequently, mental health services for moderately to severely ill patients were “carved out” to one of two behavioral health organizations.¹¹ Benefits were expanded to include unrestricted coverage for medically necessary services, furnished through the provider networks of the behavioral health organizations. These organizations assumed complete financial risk and received payment solely on the basis of the number of covered Medicaid enrollees. Payments previously made to safety-net providers became part of the funding package for the behavioral health organizations.

STUDY COHORTS

Study data were obtained from the TennCare program’s enrollment file and files that documented encounters between patients and physicians.¹⁷ Information about medications was obtained from records of filled prescriptions in files on pharmacy encounters,¹⁷⁻²¹ with information on the drug dispensed, the dose, and the number of days of supply. There was no evidence that the transition led to changes in the quality of pharmacy-related data. Encounter files for inpatient stays, outpatient visits, and long-term care facilities included the dates of the encounters and diagnoses. We used files from which personal identifiers had been deleted, and the study was thus classified as exempt from the requirement for informed consent by the Vanderbilt Committee for the Protection of Human Subjects.

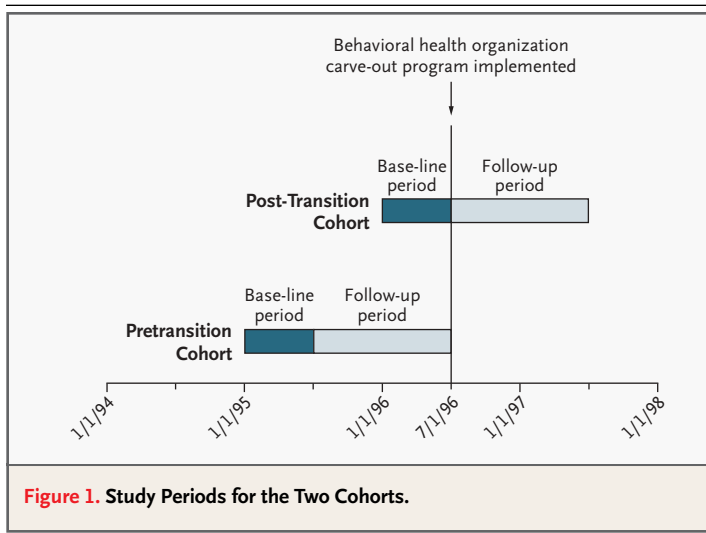
We identified two cohorts: one that might have been affected by the change (the post-transition cohort) and one that, during the one-year follow-up period, was unaffected by it (the pretransition cohort) (Fig. 1). Each cohort included patients 21 to 64 years of age who were enrolled in TennCare for the entire study period and excluded patients from one small managed-care organization that had had problems with providing complete pharmacy data to TennCare.

The post-transition cohort (Fig. 1) consisted of patients with adherence to antipsychotic therapy during the 6-month (182-day) base-line period ending June 30, 1996, the day before the change was

implemented. In order to be included in the study, these patients had to have used antipsychotic drugs during both the first week and the last week of this period, so that we could ensure that drug use had not either just begun or just ended. Adherence throughout the base-line period was defined as the receipt of at least 5 months (150 days) of therapy during this period, with use of medication for the 14 days preceding and including June 30, 1996. In order to exclude patients with less severe mental illness, we required that the average daily dose of antipsychotic medication be at least 100 mg of thioridazine (Mellaril, Novartis) or its equivalent.²² Outcomes were measured for the cohort's follow-up year, July 1, 1996, through June 30, 1997. The pretransition cohort was defined similarly (Fig. 1), except that all dates were relative to June 30, 1995, so that both the base-line and follow-up periods occurred before the carve-out program was implemented.

A total of 365,687 persons 21 to 64 years of age were continuously enrolled in TennCare during the post-transition period, and 431,212 were continuously enrolled during the pretransition period. Of these persons, 17,968 during the post-transition period (4.9 percent) and 19,539 during the pretransition period (4.5 percent) had some use of antipsychotic drugs during the base-line period. Of these patients, 4507 during the post-transition period (25.1 percent) and 3644 during the pretransition period (18.6 percent) met the criteria for adherence to antipsychotic therapy and doses of drugs. There were 1808 patients in both cohorts, although for different periods.

We identified two other groups for analysis. Although we assumed that patients with six months of continuous use of antipsychotic medication in moderate-to-high doses had severe mental illnesses and thus should have therapy continued indefinitely, this assumption may have been invalid for a few patients. We therefore identified patients in the cohorts for whom continuation was almost certainly essential: those who required the administration of extended-release (depot) antipsychotic medications during the base-line period (the only reason for which would be to ensure adherence) or who were hospitalized with a diagnosis of psychosis during this period (1108 patients in the post-transition cohort and 862 patients in the pretransition cohort). We also analyzed the effect of the transition on patients with long-term use of antipsychotic drugs at base line for whom continuation



was essential but who were ineligible for the study because of poor adherence (31 to 149 days of use during the base-line period, with some use during the last month) — a total of 864 patients during the post-transition period and 1042 during the pretransition period.

STUDY OUTCOMES AND ANALYSIS

Loss of continuity was defined as more than 60 missed days of antipsychotic therapy during the year of follow-up. We estimated the change after the transition by calculating the odds ratio for loss of continuity in the post-transition cohort relative to the pretransition cohort. A secondary study outcome was the relative change in the number of days of antipsychotic therapy during the year of follow-up, calculated as the difference between the mean number of days in the post-transition cohort and the mean number in the pretransition cohort. We also used this measure, defined on a monthly basis, in a time-series analysis²³ of the temporal relation between the change in policy and antipsychotic therapy.

We assessed a broad measure of the continuity of outpatient therapy. We identified all cohort members with a primary diagnosis of mental illness and at least one base-line visit to a physician, excluding encounters for laboratory tests or radiology (709 patients in the post-transition cohort and 520 in the pretransition cohort) and then calculated the odds of a subsequent visit to the same physician during the follow-up year.

Measures of the effect of the transition were estimated on the basis of multivariate (logistic-regression and ordinary-regression) repeated-measures

Table 1. Base-Line Characteristics of the Patients in the Post-Transition and Pretransition Cohorts.

Characteristic	Post-Transition Cohort (N = 4507)	Pretransition Cohort (N = 3644)
Demographic characteristics		
Mean age (yr)	42.9	42.7
Male sex (%)	48.7	49.4
Black race (%)	32.5	30.3
Enrollment in TennCare due to disability (%)	90.9	91.6
Residence in a standard metropolitan statistical area (%)	62.5	62.2
Antipsychotic therapy		
Any (mean no. of days)	172.6	171.4
Haloperidol (mean no. of days)	39.2	39.6
Thioridazine (mean no. of days)	22.7	23.8
Thiothixene (mean no. of days)	18.9	21.8
Haloperidol decanoate (mean no. of days)	18.4	16.6
Fluphenazine enanthate (mean no. of days)	14.3	14.7
Fluphenazine decanoate (mean no. of days)	15.5	15.7
Risperidone (mean no. of days)	18.1	10.6
Mean dose of antipsychotic drugs (mg of thioridazine or equivalent)	534.5	558.2
Heterocyclic antidepressant (mean no. of days)	33.6	33.1
Selective serotonin-reuptake inhibitors (mean no. of days)	17.8	18.3
Trazodone (mean no. of days)	11.7	11.3
Benzodiazepines (mean no. of days)	25.4	24.7
Lithium (mean no. of days)	22.5	22.4
Anticonvulsants (mean no. of days)	41.0	36.5

analyses that assumed an exchangeable correlation structure. The model included age, sex, race, residence or nonresidence in a long-term care facility, base-line dose of antipsychotic drugs, type of antipsychotic drugs (atypical or other), and four predefined base-line risk factors that indicated either greater severity of illness or a history of poorer adherence. These factors were a history of hospital admission for mental illness, a history of two or more outpatient visits for mental illness, a history of use of depot antipsychotic medication, and a history of missing more than 14 days of antipsychotic therapy.

All statistical analyses were performed with SAS software, version 8.2 (SAS Institute). All reported P values are two-sided.

RESULTS

STUDY POPULATION

The cohorts identified after and before the change to behavioral health organizations had similar characteristics at the beginning of follow-up (Table 1). The mean age of all patients was 43 years; 49 percent of the patients were male, 32 percent were black, 62 percent lived in a standard metropolitan statistical area, and 91 percent were enrolled in TennCare because of disability.

ANTIPSYCHOTIC THERAPY

During the 6-month base-line periods, patients in the post-transition and pretransition cohorts re-

Table 1. (Continued.)

Characteristic	Post-Transition Cohort (N = 4507)	Pretransition Cohort (N = 3644)
Other medical treatment		
Any cardiovascular drug (%)	28.7	27.5
Any antimicrobial drug (%)	40.1	40.2
Any gastrointestinal drug (%)	16.6	18.2
Any antidiabetic drug (%)	9.1	8.9
Mean no. of outpatient visits for somatic illness	2.7	2.7
Any hospitalization for somatic illness (%)	8.6	11.1
Residence in long-term care facility (%)	3.8	2.4
Continuity of therapy		
Continuation of antipsychotic therapy deemed essential (%)	24.6	23.7
Risk factors for noncontinuity (%)		
Any	49.1	49.0
Gap in antipsychotic therapy of >14 days	19.8	23.4
Use of depot injections of antipsychotic drugs	22.7	22.2
≥2 Outpatient visits for mental illness	16.1	14.5
Inpatient stay for mental illness	4.1	3.6
1 Risk factor	37.4	36.6
2 Risk factors	9.9	10.3
≥3 Risk factors	1.8	2.1

ceived antipsychotic therapy for a mean of 172.6 and 171.4 days, respectively. Use of individual drugs was similar in the two cohorts, except that there was greater use of the atypical antipsychotic risperidone in the post-transition cohort (18.1 days of use, as compared with 10.6 days in the pretransition cohort). The mean dose of antipsychotic drugs was 534.5 mg of thioridazine or the equivalent in the post-transition cohort and 558.2 mg of thioridazine or the equivalent in the pretransition cohort. Members of the cohorts had frequent use of other psychoactive drugs, including antidepressants, benzodiazepines, lithium, and anticonvulsants. There was considerable somatic illness at base line, but its frequency did not vary materially according to the cohort (Table 1).

In a total of 1108 patients in the post-transition cohort (24.6 percent) and 862 patients in the pretransition cohort (23.7 percent), continuation of antipsychotic therapy was deemed to be essential (Ta-

ble 1). In both cohorts, 49 percent of the patients had one or more of the base-line factors that were hypothesized to indicate a high risk of loss of continuity. A total of 37 percent of the combined cohorts had exactly one such factor, 10 percent had exactly two, and 2 percent had three or more.

EFFECT OF THE TRANSITION

The shift to the provision of mental health services by behavioral health organizations was accompanied by a reduction in the continuity of antipsychotic therapy (Table 2). The proportions of patients in the post-transition and pretransition cohorts who missed more than 60 days of antipsychotic therapy were 26.5 percent and 24.5 percent, respectively, with a multivariate odds ratio of 1.18 for the post-transition cohort (95 percent confidence interval, 1.07 to 1.30; P=0.001). Similarly, the post-transition cohort had a smaller mean number of days of antipsychotic therapy (mean number in the post-

Table 2. Continuity of Antipsychotic Therapy during the Follow-up Year.*

Variable	Missed >60 Days of Antipsychotic Therapy				Mean No. of Days of Antipsychotic Therapy			
	Post-Transition Cohort	Pre-transition Cohort	Odds Ratio (95% CI)	P Value	Post-Transition Cohort	Pre-transition Cohort	Post-Transition Cohort minus Pretransition Cohort (95% CI)	P Value
All patients	26.5	24.5	1.18 (1.07 to 1.30)	0.001	314	317	-4.2 (-6.7 to -1.7)	0.001
Need for continuation of therapy								
Probable	25.5	25.8	1.04 (0.93 to 1.16)	0.49	315	315	-0.8 (-3.7 to 2.0)	0.57
Essential	29.4	20.3	1.79 (1.45 to 2.22)	<0.001	311	324	-14.4 (-19.4 to -9.4)	<0.001
Any predefined risk factor	31.1	26.0	1.39 (1.21 to 1.60)	<0.001	308	315	-8.5 (-12.2 to -4.7)	<0.001
Gap in antipsychotic therapy of >14 days								
No	22.7	21.5	1.10 (0.98 to 1.23)	0.11	319	321	-2.8 (-5.5 to -0.2)	0.04
Yes	41.8	34.2	1.36 (1.12 to 1.66)	0.002	293	302	-8.4 (-14.9 to -2.0)	0.01
Use of depot injections of antipsychotic drugs								
No	25.8	25.8	1.06 (0.95 to 1.18)	0.33	314	315	-1.4 (-4.2 to 1.5)	0.35
Yes	28.7	19.9	1.79 (1.44 to 2.23)	<0.001	313	325	-13.7 (-18.8 to -8.6)	<0.001
No. of outpatient visits for mental illness								
<2	26.0	24.4	1.16 (1.04 to 1.29)	0.006	315	317	-3.5 (-6.2 to -0.8)	0.01
≥2	28.7	24.8	1.28 (0.98 to 1.67)	0.07	309	315	-7.6 (-14.6 to -0.6)	0.03
Hospitalization for mental illness								
No	26.0	24.3	1.17 (1.06 to 1.29)	0.002	315	317	-3.9 (-6.5 to -1.4)	0.002
Yes	37.0	30.3	1.39 (0.84 to 2.32)	0.20	297	304	-8.2 (-25.2 to 8.8)	0.34
No. of risk factors								
0	22.0	23.0	0.98 (0.85 to 1.13)	0.78	320	319	-0.1 (-3.5 to 3.3)	0.95
1	28.3	25.2	1.26 (1.08 to 1.49)	0.005	312	316	-5.8 (-9.9 to -1.7)	0.005
2	37.8	27.5	1.75 (1.28 to 2.38)	<0.001	299	311	-13.8 (-23.3 to -4.3)	0.004
≥3	51.8	33.8	2.02 (1.02 to 4.01)	0.04	275	302	-21.0 (-44.5 to 2.4)	0.08

* Odds ratios for missing more than 60 days of antipsychotic therapy in the post-transition cohort as compared with the pretransition cohort, as well as the differences in the mean number of days of antipsychotic therapy, were calculated on the basis of multivariate repeated-measures analysis. CI denotes confidence interval.

transition cohort minus mean number in the pretransition cohort, -4.2 [95 percent confidence interval, -6.7 to -1.7]; P=0.001).

High-risk patients for whom the continuation of therapy was deemed to be essential had the most pronounced loss of continuity (Table 2). Among such patients in the post-transition cohort, 29.4 percent missed more than 60 days of antipsychotic therapy, as compared with 20.3 percent in the pretransition cohort (multivariate odds ratio, 1.79 [95 percent confidence interval, 1.45 to 2.22]; P<0.001). There was a similar difference in the mean number of days of antipsychotic therapy (mean in the

post-transition cohort minus mean in the pretransition cohort, -14.4 [95 percent confidence interval, -19.4 to -9.4]; P<0.001). In contrast, among the remainder of patients, there was no significant difference between cohorts in either the loss of continuity (multivariate odds ratio for the post-transition cohort, 1.04 [95 percent confidence interval, 0.93 to 1.16]; P=0.49) or the mean number of days of antipsychotic therapy (mean in the post-transition cohort minus mean in the pretransition cohort, -0.8 [95 percent confidence interval, -3.7 to 2.0]; P=0.57).

The deterioration in continuity after the change

to behavioral health organizations increased according to the number of base-line risk factors (Table 2). As the number of risk factors (0, 1, 2, or 3 or more) increased, so did the odds of a loss of continuity after the transition; the multivariate odds ratios were 0.98 (95 percent confidence interval, 0.85 to 1.13), 1.26 (95 percent confidence interval, 1.08 to 1.49), 1.75 (95 percent confidence interval, 1.28 to 2.38), and 2.02 (95 percent confidence interval, 1.02 to 4.01), respectively ($P=0.01$ for linear trend). There was a similar pattern for the mean number of days of use of antipsychotic drugs during follow-up ($P=0.03$ for linear trend) (Table 2).

Among patients for whom the continuation of therapy was deemed essential, the reduction in the use of antipsychotic drugs in the post-transition cohort occurred immediately after the change in the provision of services and persisted through month 12 of follow-up (Fig. 2). This reduction was most pronounced during the last six months of follow-up ($P=0.02$). In contrast, for the remainder of patients, the difference in the number of days of antipsychotic therapy varied from month to month, in some months favoring the post-transition cohort.

There was evidence that the continuity of outpatient care decreased after the transition was implemented. Among patients in the post-transition cohort who had had at least one outpatient visit for mental illness at base line, 35.7 percent visited the same physician practice during the follow-up year — a significantly lower proportion than the 44.0 percent among similar patients in the pretransition cohort (multivariate odds ratio for a visit to the same practice in the post-transition cohort, 0.63 [95 percent confidence interval, 0.50 to 0.80]; $P<0.001$).

The continuity of antipsychotic therapy did not significantly improve after the transition for those patients not qualifying for the primary study cohorts because of poor adherence at base line. During the year of follow-up, the proportion that missed more than 60 days of therapy was 92.9 percent among those whose follow-up began after the transition, as compared with 91.8 percent among those whose follow-up began one year earlier, with a multivariate odds ratio of 1.16 (95 percent confidence interval, 0.83 to 1.64; $P=0.38$).

DISCUSSION

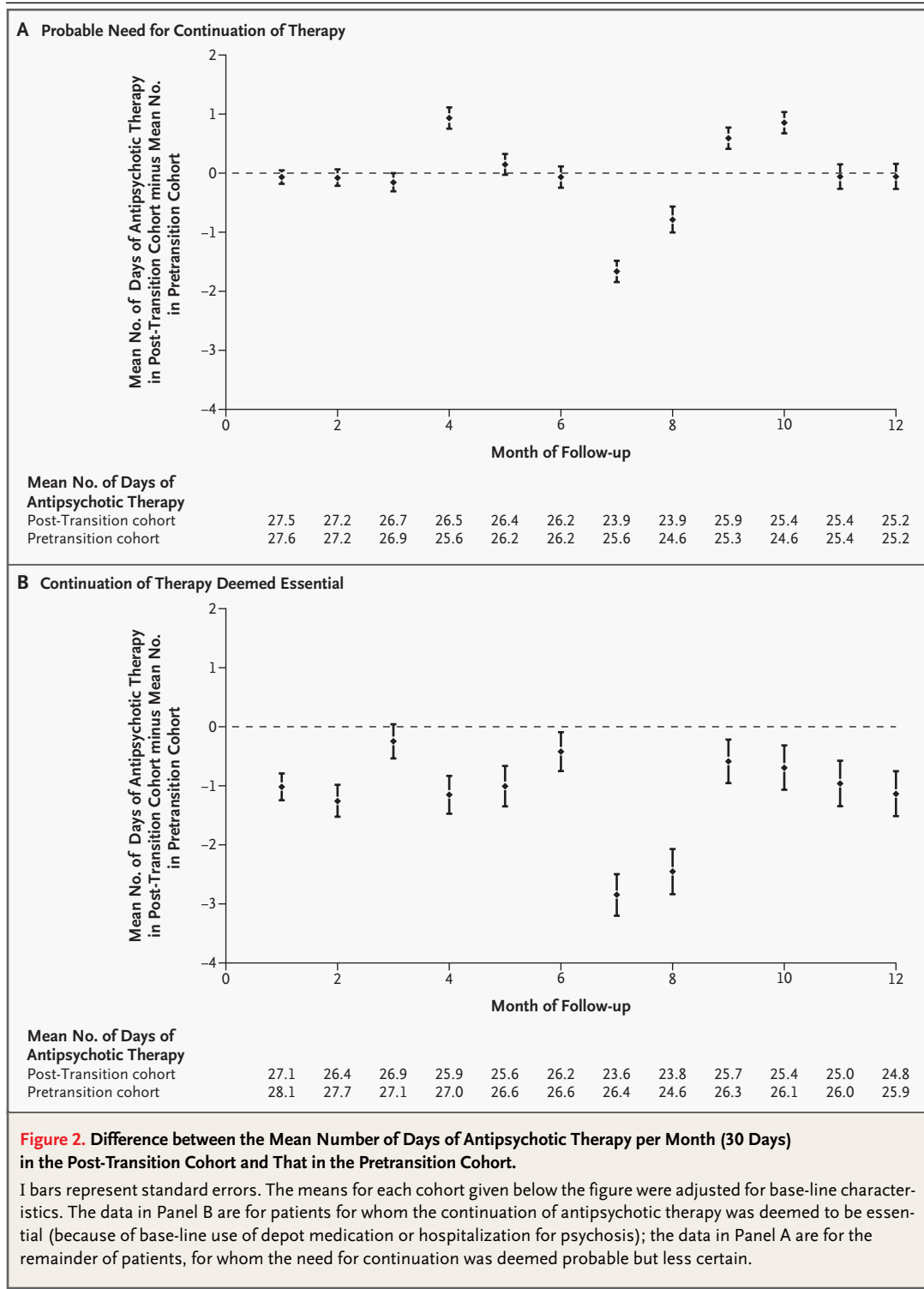
In the two very similar cohorts of patients with long-term adherence to the use of antipsychotic medication, the cohort affected by the change to the spe-

cialty carve-out program had an 18 percent increase in the odds of loss of continuity of therapy. Among high-risk patients for whom such continuity was essential, the increase was 79 percent. Among these patients, the reduction in use of antipsychotic therapy occurred immediately after the transition was implemented and persisted throughout the first year after the transition. Similar high-risk patients who were not included in the primary study cohorts because they had poor adherence at base line did not have improved continuity after the transition.

Were the study findings attributable to a secular trend of poorer adherence to antipsychotic therapy? The reduction in the continuity of therapy immediately after the transition argues against this possibility. Furthermore, both the growing awareness of the importance of regular pharmacotherapy in patients with schizophrenia²⁴ and the introduction of the better-tolerated atypical antipsychotic drugs²⁵⁻²⁷ that dramatically improve compliance²⁸ should have resulted in a trend of better adherence to therapy. Thus, our findings may underestimate the effect of the transition on the continuity of antipsychotic therapy.

Our use of the continuity of antipsychotic therapy as the study outcome had several important advantages. Long-term adherence to antipsychotic therapy is the cornerstone of contemporary management of psychoses, and patients who stop therapy have a markedly increased risk of exacerbation of disease.¹³⁻¹⁵ Unlike outpatient and inpatient services, eligibility for pharmacy services was unchanged by the shift to the carve-out program. Changes in pharmacotherapy could be detected immediately after the transition, without the lag time necessary for delayed or infrequent outcomes. This close temporal association is evidence that changes were due to the change in policy itself rather than to other secular trends.²⁹ However, this retrospective study could not assess changes in the symptoms of disease, the most important clinical outcome.

Was the post-transition reduction in the continuity of antipsychotic therapy no more than the effect of a badly managed transition?²¹ It is difficult, in a study in a single state, to separate the effects of the policy itself from those of its implementation. However, although we are not able to determine whether the continuity of treatment was adversely affected by the model of care, some evidence suggests that the carve-out model itself could have unfavorably affected vulnerable patients with severe mental illness.



The carve-out model requires that patients use a restricted network of providers that have contracts with the behavioral health organization. Some patients thus had to change physicians, not only at the time of the shift to the carve-out program, but also whenever the network of providers changed. In Tennessee, this requirement was reported to have caused some severing of relationships between patients and their long-term health care providers and the closure of historically large practices.¹¹ These changes are consistent with the 37 percent reduction in the odds of one measure of continuity of outpatient care after the transition.

The carve-out model gave the behavioral health organizations complete exposure to financial risk, with no adjustment for the case mix, thus providing a powerful incentive to curtail services. This effect was reported to have substantially reduced the amount of reimbursements to providers in the network of the behavioral health organizations, who, in turn, were forced to close their practices or reduce the size of their staff.¹¹ For patients who were obliged to turn to different providers operating with a smaller staff, services designed to enhance adherence, such as the provision of reminders to patients or the scheduling of transportation, might have been curtailed. Such a possibility would be consistent with our finding that patients whose history showed difficulty with adherence to treatment and who thus might have benefited the most from these ancillary services were affected the most by the change in policy. On the other hand, because adherence to antipsychotic therapy should avert psychiatric hospitalizations, behavioral health organizations should have a financial incentive to provide services aimed at increasing adherence.

Although some of the disruptions caused by the shift to a carve-out policy may have been short-term problems, the loss of continuity among vulnerable patients may have persisted. Clinical experience suggests that patients with psychoses are particularly vulnerable to disruption of the process of care. Once adherence is lost, it may be very difficult to reestablish. Indeed, although the program disruptions in Tennessee were most intense during the first six months,¹¹ we found that the reduction in continuity persisted unchanged for at least a full year.

In 2000, an estimated 68 percent of persons with health insurance in the United States received mental health benefits through carve-out programs,³⁰ as did the enrollees of 16 state Medicaid programs.³¹ The primary focus of the relatively new behavioral health organization industry, with \$3 billion in annual revenues and nearly 4000 different carve-out “products,” is cost containment: 71 percent of the plans offered in 2000 involved a partial or full shifting of financial risk to the behavioral health organizations, whereas only 16 percent reduced the amount of payments if quality or other performance standards were not met.³⁰ The findings of our study suggest that higher priority must be given to ensuring that carve-out programs do not disrupt the continuity of care, either during transitions or during steady-state operation. Ultimately, proponents of carve-out and other cost-containment strategies should provide evidence that these programs do not adversely affect either the continuity of care or other clinical outcomes.

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