Limiting Access to Psychiatric Services Can Increase Total Health Care Costs

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Restricted access to health care services and medication is associated with overall higher utilization and higher health care costs. Although randomized controlled trials (RCTs) are regarded as the best method of determining whether a treatment strategy does more good than harm, clinical practice improvement (CPI) methods may be a more effective way of achieving superior medical outcomes for the least cost over the course of a patient's care. The Managed Care Outcomes Project, a large-scale CPI study, tracked detailed factors regarding medical care, patients, and outcomes from different managed care settings. Results showed that cost-containment strategies employed by various health maintenance organizations were associated with poor treatment outcomes for patients and in fact *increased* total health care costs. Psychiatric illnesses were underdiagnosed, and care ranged from patients receiving psychiatric medications without a psychiatric diagnosis to patients with a psychiatric diagnosis receiving no psychiatric treatment at all. Cost-containment strategies appeared to limit psychiatric referrals, frequency of psychiatric visits, and use of certain antidepressants (i.e., selective serotonin reuptake inhibitors). Further, the severity of the primary physical illness in the study population was associated with greater psychiatric illness. The fact that treatment was inconsistent and frequently inappropriate shows the need for better diagnostic and management protocols.

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A ccording to the U.S. Department of Health and Human Services,¹4 of the 10 leading causes of disability in the United States and other developing countries are mental disorders—major depression, bipolar disorder, schizophrenia, and obsessive-compulsive disorder. Depression alone imposes an enormous burden on society; the economic impact in the United States on an annual basis was reported to total approximately \$44 billion in 1993.² Of this total, 28% was attributed to direct costs, such as inpatient and outpatient care, partial care, and pharmaceutical costs. Pharmaceutical costs represented just 3% of the total cost of depression.

With the costs of medical care ever rising, instituting practices that promote good health at the least cost is an attractive approach. The intent of health maintenance organizations (HMOs) is to provide comprehensive health services to an enrolled group of subscribers who pay a fixed premium (capitation fee) to belong.³ The emphasis is on maintaining the health of the enrollees as well as treating their illnesses. The anticipated financial outcome of HMOs is better control of costs and saving money. In instituting anticipated money-saving protocols, however, access to best care for many patients has been restricted and overall costs have actually increased. Costs in the form of more patient visits to physicians, more emergency room visits, more hospitalizations, greater estimated cost of prescriptions per year, and greater total number of prescriptions per year have resulted.

My colleagues and I have previously reported the results of a large clinical practice improvement (CPI) study.⁴⁻⁶ The naturalistic design of our CPI study allowed us to collect and analyze a wide variety of data that would not have been available via the traditional randomized controlled trial (RCT) research method. Because an understanding of the differences and similarities between RCT and CPI methodologies may be helpful to the interpretation of our data, I will first provide a comparison of these 2 methods and then briefly describe the Managed Care Outcomes Project. Finally, on the basis of all of the data collected, the effects of limiting access to health care services—mental health services, in particular—are reviewed.

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CPI vs. RCT: A COMPARISON

CPI is a method for analyzing the content and timing of individual steps of a health care process in order to determine how to achieve superior medical outcomes for the least necessary cost over the course of a patient's care.⁵ CPI methodology consists of recording detailed information about the patient care process (management strategies, interventions, and medications), controlling for differences in patient illness and characteristics (e.g., disease category, severity of disease, and overall course of disease and treatment), and determining which treatments and management strategies are associated with optimal outcomes (e.g., clinical outcomes, health status, cost of care, length of hospitalizations, and number of health care encounters) for particular medical conditions. CPI provides protocols of greater specificity than can be attained by traditional outcomes research.

RCTs, on the other hand, involve collecting information in a prospective fashion, which controls for some aspects of bias. At the same time, however, the limited patient eligibility serves to alter the population characteristics from those found in actual treatment settings and often eliminates patients, for example, with secondary problems or more severe disease.

Comparisons of the results of the 2 methodologies reveal several differences. RCTs involve rigorous exclusionary criteria; usually fewer than 15% of people with a given medical condition are eligible to enter the study. With CPI methods, all patients qualify and the study design adjusts for severity and measures (rather than excludes) anything that might make patients differ. RCTs examine one variable at a time; CPI examines all variables. RCTs cost in the millions7; CPI studies cost in the thousands. RCTs are based on controlled conditions; CPI is based on everyday clinical practice. RCTs usually involve new treatments where the risks are high, the hypothesis is clear, and alternatives are discrete (yes-no). RCTs are not dependent on local knowledge, confounders are not interesting, and effects are small. With CPI methods, the risks are small and manageable (care strategies are already in practice), hypotheses are many and often vague, and the alternatives are not discrete. Local knowledge contributes, confounders are interesting and frequently affect outcomes, and the effects are large. CPI connects outcomes with detailed processes and adjusts for severity of illness.

Several studies^{8–10} have confirmed that on average, despite their differences, results of observational CPI studies are remarkably similar to those of the RCTs. Concato et al.⁸ searched databases (MEDLINE 1991–1995) for RCTs and observational studies on the same clinical topics. They then compared the results of the original reports (5 clinical topics; 99 reports) according to research design and concluded that well-designed observational studies do not systematically overestimate the magnitude of the effects of treatment

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as compared with RCTs on the same topic. Benson and Hartz⁹ came to the same conclusion. Of the 19 clinical topics (136 reports) compared in their study, only 2 of the nonrandomized studies had results that fell outside the 95% CI of the effect found by RCTs. These results suggest a relatively high concordance between randomized and nonrandomized studies. A recent study by Ioannidis et al.¹⁰ comparing results on 45 medical topics (408 reports) with binary outcomes revealed a very good correlation between the summary odds ratios of the randomized and nonrandomized studies. Despite the fact that Ioannidis et al. found higher rates of discrepancies in comparisons, the correlation coefficient between the treatment effect in nonrandomized studies and RCTs was 0.75 (p < .001). When retrospective studies were excluded, the correlation coefficient became 0.83 (p < .001). Not every RCT on the same topic comes to the same conclusion, but the variation in findings among RCTs on the same topic is of the same size as the variation in findings between RCTs and observational studies.

Both study designs are necessary and complementary methodologies. RCTs are necessary to show whether a treatment is safe and effective. CPI studies are necessary to determine for whom a treatment is most beneficial. The significance of the similarities between RCT and CPI research methods cannot be underestimated because they have a direct effect on health care policy, specifically the relationship between formulary restrictions and overall health care costs.

MANAGED CARE OUTCOMES PROJECT

In 1996, my colleagues and I⁴⁻⁶ reviewed a year's worth of data on the care of thousands of typical patients treated by their regular doctors across multiple managed care organizations. Health care services used were compared with cost-containment efforts by the HMO. This study involved approximately 13,000 outpatients from 6 HMOs across the United States. Patients in 5 disease groups (ear infection, arthritis, hypertension, asthma, and stomach ulcers) were enrolled in the study. During the course of the year, this group represented more than 99,000 office visits, 480 emergency room visits, 1000 hospitalizations, and over 240,000 30-day equivalent prescriptions.

Differences between HMOs played a major part in outcome analyses. For example, one site had no formularies at all, while other sites had more or fewer of the available drugs that had been approved by the Food and Drug Administration (FDA) for each disease area. Some sites were very restrictive in one illness category but very lenient in another.

After controlling for severity and other variables (Table 1), patients with no restrictions used fewer prescriptions over the year, and patients with more restrictions used more prescriptions over the year. The less restrictive, the

Cost-Containment			
Patient Variable	Practice Variable	HMO Site Variable	
Severity of patient illness	Second-opinion requirements	Physician payment method	
Age and gender	Strictness of site's gatekeeper	HMO profit status	
Time in study	Strictness of case management	Geographical location	
Number of physicians	Drug and visit copays		
seen by patient	Restrictions of formulary		
	Extent of generic drug use		
^a Based on Horn et al. ^{4,12}			
Abbreviation: HMO = heal	th maintenance organization.		

Table 2. Psychiatric Diagnoses and Psychiatric Drug Use in Patients With Either Psychiatric Diagnosis (Coded) or Psychiatric Drug Use^a

Psychiatric Drug Use		
No	Yes	Total
0	2668	2668
4 (15%)	23 (85%)	27
58 (27%)	154 (73%)	212
17 (63%)	10 (37%)	27
79 (25%)	235 (75%)	314
	No 0 4 (15%) 58 (27%) 17 (63%)	No Yes 0 2668 4 (15%) 23 (85%) 58 (27%) 154 (73%) 17 (63%) 10 (37%)

^b49 patients had more than one diagnosis.

Abbreviation: NOS = not otherwise specified.

Figure 1. Proportion of Patients With Diagnosed Depression and/or Antidepressant Therapy Treated by a Specialty



lower the cost; the more restrictive, the higher the cost. In addition, patients with restricted formularies had increased visits to physicians, more emergency room visits, more hospitalizations, greater numbers of prescriptions per year, and greater estimated cost of prescriptions.⁴

PSYCHIATRIC FINDINGS

Although psychiatric conditions were not included as 1 of the 5 primary medical conditions of interest for the

overall study, data that included psychiatric diagnoses, signs and symptoms of mood or other psychiatric disorders, prescriptions for psychiatric medications, and provider accessed were collected as a natural course of the CPI study design. Of the nearly 13,000 patients studied, 3199 either had a coded psychiatric diagnosis or were taking a psychiatric medication at some time during the year.⁵ A total of 2668 patients without a coded psychiatric diagnosis were receiving a psychiatric medica-

tion. Of the 531 patients who had a psychiatric diagnosis, 373 (70%) were receiving a psychiatric agent. The most common diagnosis was depression not otherwise specified (depression NOS), which accounted for 314 of the diagnoses (Table 2).⁵ Of those with depression NOS, 235 (75%) were receiving psychiatric medication. Of the 212 patients with diagnoses of major/neurotic depression, 154 (73%) were receiving psychiatric medication.

With regard to antidepressant agents, 1067 patients were receiving antidepressant therapy without a psychiatric diagnosis code for depression.⁵ Of the 212 patients with a diagnosis of major depression, 128 (60%) were receiving antidepressant therapy. Because of specialty care limitations, very few patients with a diagnosis of depression or being treated with antidepressants were seen by a mental health provider (Figure 1).¹¹

Treatment for psychiatric disorders varied greatly among patients. Of the 3199 patients who either had a psychiatric diagnosis or were receiving psychiatric medications, 306 (9.6%) had visited a psychiatrist at least once, 3005 (93.9%) had visited a primary care physician at least once, and 1545 (48.3%) had visited other medical or surgical specialists.⁵ Patients who had visited a psychiatrist at least once over the course of the year had more severe illness as assessed by the sum of the Ambulatory Patient Severity (APS) visit scores for all visits over the year^{4,12} than did those who did not visit a psychiatrist. The mean APS yearly sum score for patients who visited a psychiatrist was 89.3, compared with a mean yearly sum score of 81.9 for those who had visited another provider. Patients without a psychiatric diagnosis who were receiving psychiatric medication very rarely visited a psychiatrist, and even patients with a psychiatric diagnosis who did or did not receive psychiatric medication averaged fewer than 2 psychiatric visits per year.

Patients with a psychiatric comorbidity were seen more frequently in their doctor's offices and were prescribed considerably more nonpsychiatric medications.⁵ In other words, rather than reducing costs by limiting access to mental health services, costs actually increased because patients used more nonpsychiatric drugs, required more nonpsychiatric visits, and had more nonpsychiatric emergency room visits and hospitalizations. If the psychiatric problem is not adequately addressed, patients are seen over and over again.

At the time of our study, selective serotonin reuptake inhibitors (SSRIs) tended to be restricted and so usage was extremely low; tricyclic antidepressants (TCAs) and benzodiazepines were the most frequently prescribed psychiatric medications. Of the patients in our study who received antidepressant medication, 263 received an SSRI, 792 received a TCA, and 126 were switched from a TCA to an SSRI.5 The mean APS score at the initial visit was higher among SSRI recipients (11.0) than among TCA recipients (10.6), indicating that those patients given SSRIs were somewhat sicker than those given TCAs at their initial visit. Patients switched from TCAs to SSRIs had even more severe illness (initial visit APS score of 12.3). However, SSRI recipients had a significantly lower mean number of HMO visits during the year compared with TCA recipients (9.5 vs. 10.0). Patients who were switched from TCA to SSRI treatment averaged 12.5 visits during the year. Mean sum APS score over the course of the year was lower among the SSRI recipients than among the TCA recipients (74.7 vs. 77.6); mean APS score among patients switched from TCA to SSRI treatment was highest (96.1).

Many patients with mood disorders had no psychiatric medications recorded. Some patients had taken both newer (e.g., SSRIs) and older medications throughout the year; others had taken older medications only or newer medications only. Interestingly, the number of office visits among patients prescribed the newer antidepressants only (9.2 visits) was significantly less than patients using no psychiatric medications (12.2 visits), using both old and new antidepressants (12.0 visits), or using only old antidepressants (10.4 visits). In fact, patients who received psychiatric care and were using the newer drugs had lower overall utilization of all health care services.

Regardless of the initial choice of antidepressant, patients switched to another antidepressant are in treatment longer and are seen in their doctor's office more than patients who do not switch medication. In a retrospective chart review, Nurnberg et al.¹³ found that of 214 patients started on an SSRI, approximately one quarter (17% to 28%) switched to another antidepressant agent during the course of their treatment. The duration of treatment for those patients whose SSRI was changed increased substantially (54% longer) as well as the number of office visits (40% more visits) compared with patients who completed treatment with their initial agent.

Because elderly patients often take multiple medications and metabolize them differently, choice is especially important in formularies that serve this group. Data from a large, long-term care study¹⁴ collected during 1996 and 1997 from 109 long-term care facilities across the United States supported the use of SSRIs to improve patient outcomes and control costs. Approximately 800 elderly residents in this study suffered from agitation in dementia.

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About one third of them took no psychiatric medication at all. Of the remaining cohort, about one third received antipsychotics, about one third received antidepressants, and about one third received antianxiety agents. Combination therapy—in particular, the combination of an SSRI plus either an antianxiety agent or an antipsychotic agent—was associated with significantly fewer hospitalizations, significantly fewer episodes of urinary incontinence, and the development of significantly fewer pressure ulcers.

Health care plan administrators often enact formulary restrictions in an effort to control costs.¹⁵ A strong relationship between formulary restrictiveness and increased resource use for all levels of illness severity was evident in our study.⁴ Sites that most severely restricted formularies often had double the use of health care services versus sites with no formulary restrictions. The single site that had no formulary almost always had lowest use of health care services. These results suggest that physician groups using restricted formularies are putting their patients at risk for increased office visits and in some cases increased emergency room visits and hospitalizations.

Primary care physicians are being driven to make treatment decisions on the basis of which medication is on the formulary list, and there is pressure to limit the number and duration of visits to psychiatrists.¹⁵ To comply with restricted formularies, clinicians sometimes employ the "step" method for treating an illness. That is, once they have made a diagnosis, they consult the formulary list and select the medication(s) available at the lowest cost. If the medication is not effective, they move down the list to the next one and so on until the patient's symptoms subside. By design, the step method increases the number of visits and, concurrently, medication costs. Further, if a clinician feels it is in the best interest of the patient to go outside of the formulary list, obtaining preauthorization to use nonformulary therapy is burdensome and time consuming.

A recent study reported some of the pitfalls of limiting access to treatment with SSRIs.¹⁵ SSRIs are not interchangeable. Patients who discontinue one SSRI for lack of tolerability or response can generally be treated effectively with another. Having several antidepressant agents to choose from allows more options to continue treating patients. Antidepressant agents represent < 10% of total direct costs of depression.

A larger study than ours confirmed our findings that limiting access is associated with higher utilization.¹⁶ During the HMO Medicare enrollment period of January through December 1994, nearly 23,000 patients aged \geq 65 years old were seen in 1 of 3 multispecialty physician medical groups. Two of the physician medical groups followed provisions for a capitation on drugs implemented through a formulary; one did not. Controlling for age, gender, and severity of illness, ordinary least square regression estimates for mean total health care costs were 10% higher and pharmaceutical costs were 20% higher in the pharmaceutical capitation group than in the nonpharmaceutical capitation group. Further, a greater percentage of the patients in the capitation group had pharmaceutical expenditures compared with patients in the non-pharmaceutical capitation group. Lower costs were seen at 6 months in the group with no formulary and no capitation. Curtailing access to medication via costcontrol mechanisms can adversely affect other health care utilization (e.g., additional office visits for dose titration or monitoring, increased emergency room and hospital visits, and the addition of concomitant medications) and thereby increase total health care costs.^{4,16-18} Thus, individual capitation of any health care component may not be the best approach to controlling costs or assuring quality.¹⁶

Observational studies that focus on patient details, treatments, and outcomes have led to the implementation of treatments that are best for specific types of patients. Further, discerning patient treatment needs in this way has been associated with a 30% to 50% decrease in the cost of health care.^{19,20} Some managed care organizations have dropped restrictive formularies on the basis of such data.

CONCLUSION

The various managed mental health care costcontainment practices of risk-benefit analysis, provider usage, manipulation of supply and demand, determination of medical necessity, and formulary restrictions have adversely affected quality of care. Cost-containment strategies in the HMOs my group studied appeared to have strongly limited referral to psychiatrists. Patients referred to psychiatrists had more severe psychiatric illness; however, even those patients averaged a very small number of visits per year as part of their treatment. Patients prescribed SSRIs had more severe illness at presentation but subsequently averaged fewer visits and lower severity scores over the course of the year. Patients who were switched from TCA to SSRI treatment had the greatest initial severity of illness, greatest mean severity, and greatest mean number of visits. Finally, mean severity of the primary illnesses analyzed in the Managed Care Outcomes Project was markedly increased in patients who had a psychiatric diagnosis.

Given the wide use of psychiatric medications without psychiatric diagnoses, however, it appears that psychiatric illness, particularly depression, in the ambulatory patient population is substantially underdiagnosed. Additionally, a significant proportion of patients with psychiatric diagnoses are not receiving psychiatric medication.

Reporting costs and setting limits are results of the way HMOs typically manage their budgets. Many large HMOs separate their budgets in a silo fashion (i.e., the person in charge of the drug budget is different from the person in charge of the visit budget who is different from the person in charge of the hospitalization budget, and so on). By managing health care dollars in compartments like this, no one has the overall pharmacoeconomic perspective, so total health care costs actually escalate.²¹ Further, by focusing primarily on the direct cost of medication, the savings in indirect costs (i.e., greater overall benefits of effectively treating depression) may be overlooked.²² For example, the greater cost of SSRIs may be counterbalanced by increased productivity and quality of life. Therefore, spending more on pharmaceuticals may actually lower overall costs.

These findings suggest a need for a system of disease or case management that uses cost-containment tools developed from studying medical care as an interrelated system. The system should comprehensively evaluate the impact of cost-containment practices on all components of care and overall quality of care. Questions of efficacy, effectiveness, and availability must be considered as part of the pharmacoeconomic evaluation. Efficacy data are available typically in the form of published RCTs, whereas effectiveness data are often not available when formulary decisions are being made. The net result is that many costcontainment policy decisions have had serious unintended effects that have affected the health of individuals and increased expenditure in the overall budget, which basically offset any savings in the drug budget. Improved mental health services are dependent upon redefining mental health problems and understanding inequities created by limiting access to services.

REFERENCES

- National Institute of Mental Health. The numbers count: mental disorders in America. Bethesda, Md: US Dept of Health and Human Services, National Institute of Mental Health; 2003
- Greenberg PE, Stiglin LE, Finkelstein SN, et al. The economic burden of depression in 1990. J Clin Psychiatry 1993;54:405–418
- Carlson G. What is a health maintenance organization? Available at: http://www.outreach.missouri.edu/hes/fmhlth/whatishmo.htm. Accessed July 11, 2003
- Horn SD, Sharkey PD, Tracy DM, et al. Intended and unintended consequences of HMO cost-containment strategies: results from the Managed Care Outcomes Project. Am J Managed Care 1996;2:253–264
- Horn SD. Overcoming obstacles to effective treatment: use of clinical practice improvement methodology. J Clin Psychiatry 1997;58(suppl 1): 15–19
- Horn SD, Sharkey PD, Phillips-Harris C. Formulary limitations and the elderly: results from the Managed Care Outcomes Project. Am J Managed Care 1998;4:1105–1113
- Lohr KJ, Brook RH, Kamberg C, et al. Rand health insurance experiment. Med Care 1986;24:S72–S87
- Concato J, Shah N, Horwitz RI. Randomized, controlled trials, observational studies, and the hierarchy of research designs. N Engl J Med 2000;342:1887–1892
- Benson K, Hartz AJ. A comparison of observational studies and randomized, controlled trials. N Engl J Med 2000;342:1878–1886
- Ioannidis JPA, Haidich AB, Pappa M, et al. Comparison of evidence of treatment effects in randomized and nonrandomized studies. JAMA 2001;286:821–830
- Bartels SJ, Horn SD, Sharkey PD, et al. Treatment of depression in older primary care patients in health maintenance organizations. Int J Psychiatry Med 1997;27:215–231
- Horn SD, Sharkey PD, Gassaway J. Managed Care Outcomes Project: study design, baseline patient characteristics, and outcome measures. Am J Managed Care 1996;2:237–247

- Nurnberg HG, Thompson PM, Hensley PL. Antidepressant medication change in a clinical treatment setting: a comparison of the effectiveness of selective serotonin reuptake inhibitors. J Clin Psychiatry 1999;60: 574–579
- Horn SD, Bender SA, Bergstrom N, et al. Description of the National Pressure Ulcer Long-Term Care Study. J Am Geriatr Soc 2002;50:1816–1825
- Hensley PL, Nurnberg HG. Formulary restrictions of selective serotonin reuptake inhibitors for depression: potential pitfalls. Pharmacoeconomics 2001;19:973–982
- Popovian R, Johnson KA, Nichols MB, et al. The impact of pharmaceutical capitation to primary medical groups on the health care expenditures of Medicare HMO enrollees. J Managed Care Pharm 1999;5:414–419
- Soumerai SB, Ross-Degnan D, Avorn J, et al. Effects of Medicaid drugpayment limits on admission to hospitals and nursing homes. N Engl J

Med 1991;325:1072-1077

- Soumerai SB, McLaughlin TJ, Ross-Degnan D, et al. Effects of limiting Medicaid drug-reimbursement benefits on the use of psychotropic agents and acute mental health services by patients with schizophrenia. N Engl J Med 1994;331:650–655
- Horn SD, ed. Clinical Practice Improvement Methodology: Implementation and Evaluation. New York, NY: Faulkner & Gray; 1997
- Willson DF, Horn SD, Hendley JO, et al. The effect of practice variation on resource utilization in infants hospitalized for viral lower respiratory illness (VLRI). Pediatrics 2001;108:851–855
- Johnson JA, Friesen E. Reassessing the relevance of pharmacoeconomic analyses in formulary decisions. Pharmacoeconomics 1998;13:479–485
- Guze BH. Selective serotonin reuptake inhibitors: assessment for formulary inclusion. Pharmacoeconomics 1996;9:430–442