The Effects of Primary Care Depression Treatment on Patients' Clinical Status and Employment

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Objective. To evaluate the effects of depression treatment in primary care on patients' clinical status and employment, over six months.

Data Sources/Study Setting. Data are from a randomized controlled trial of quality improvement for depression that included 938 adults with depressive disorder in 46 managed primary care clinics in five states.

Study Design. Observational analysis of the effects of evidence-based depression care over six months on health outcomes and employment. Selection into treatment is accounted for using instrumental variables techniques, with randomized assignment to the quality improvement intervention as the identifying instrument.

Data Collection/Extraction Methods. Patient-reported clinical status, employment, health care use, and personal characteristics; health care use and costs from claims data.

Principal Findings. At six months, patients with appropriate care, compared to those without it, had lower rates of depressive disorder (24 percent versus 70 percent), better mental health-related quality of life, and higher rates of employment (72 percent versus 53 percent), each $p < .05$.

Conclusions. Appropriate treatment for depression provided in community-based primary care substantially improves clinical and quality of life outcomes and employment.

Key Words. Depression, effectiveness, instrumental variables, employment

This study examines the effects of evidence-based depression treatment, delivered under naturalistic primary care practice conditions, on health and employment outcomes at six months. Depressive disorders are highly prevalent in the general population and in primary care (Kessler et al. 1994) and are leading causes of disability and reduced quality of life worldwide (Ormel and Costa e Silva 1995; Murray and Lopez 1996). Depression disorders and mental illness generally appear to reduce employment rates and productivity (e.g., Ruhm 1992; Ettner et al. 1997; Marcotte et al. 2000; Kessler and Frank 1997; Wells et al. 1988; Broadhead et al. 1990; Martin et al. 1996). Annual social costs attributable to affective disorders in the

United States were \$44 billion in 1990 (Rice et al. 1993; Greenberg et al. 1993), mostly due to societal costs of morbidity.

Effective treatment of depression could thus have major public health benefits (Neugebauer 1999). Yet despite availability of efficacious treatments, that is, antidepressant medications and psychotherapies, and of national practice guidelines (e.g., Depression Guidelines Panel 1993; American Psychiatric Association 1993), rates of appropriate treatment for depression remain low nationally, particularly in primary care where only about a quarter of depressed patients receive appropriate care (Young et al. 2001; Ormel et al. 1991; Katon et al. 1992; Regier et al. 1993; Wells et al. 1996, 1999).

One reason for low treatment rates could be clinician and patient uncertainty over whether benefits of treatment suggested by clinical trials can be realized under naturalistic community practice conditions. Clinical trials randomly assign treatments that are free to patients and are provided by expert clinicians under standardized protocols, but in community practice patients receive nonstandardized treatments from their usual providers under a variety of payment and management conditions (Schulz et al. 1995; Wells 1999a). Clinical trials also typically contain disproportionately fewer patients with medical comorbidities, and fewer racial and ethnic minorities, than are typically seen in primary care (Schulz et al. 1995; Wells 1999a). We attempt to address these information gaps here by focusing on treatment outcomes under naturalistic practice conditions.

Declining insurance coverage for mental health care suggests that public commitment may be low for improving treatment rates for depression (Hay Group 1998). This could be partly due to uncertainty among policymakers about whether treatments that improve clinical outcomes also improve societal outcomes such as employment (e.g., Mintz, Mintz, and Phipps 1992). Prior research has documented improvement in self-rated work functioning (Mintz, Mintz, Arruda, and Hwang 1992; Berndt et al. 1999). However, these changes in patient reports could reflect changes in mood rather than in actual

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work functioning, at least in part. We know of no prior evidence regarding the effects of depression treatment on employment per se, which we examine here.

Obtaining data on treatment outcomes in usual care is difficult because randomized trials that have strong internal validity often modify usual practice conditions, while observational studies are subject to strong selection bias (Sturm and Wells 1995). This study relies on instrumental variables analysis, a technique that supports causal inference when selection bias is present (Angrist et al. 1996; Heckman 1996; Heckman 1997; Sturm 1998; Newhouse and McClellan 1998). We use data from a randomized trial of quality improvement interventions for depression in which naturalistic practice conditions were preserved, that is, usual providers, patients, payment mechanisms, and patient and provider choice of treatment. We use intervention status as the instrument, allowing us to plausibly meet the strict assumptions that have limited application of this method in medicine and public health. The interventions improved quality of care, clinical quality of life, and employment outcomes for depressed patients over 12 months (Wells et al. 2000); but here we focus on outcomes of appropriate treatment per se, which many patients did not receive even under the interventions.

METHODS

Design and Subjects

Partners in Care (PIC) was designed both as a randomized trial of practice-initiated quality improvement interventions versus usual care, and an observational study of outcomes of appropriate treatment. This was achieved by designing an intervention that encouraged appropriate treatment through provider training and additional practice resources, without assigning a level or type of treatment as in a traditional efficacy trial. The study was conducted in six diverse, nonacademic managed primary care organizations (Wells 1999b; Wells et al. 2000). Forty-six of 48 primary care practices and 181 of 183 clinicians participated. Practices were matched into blocks of three clusters, based on factors that might affect baseline quality of care or intervention response: clinician specialty mix, distribution of patient socioeconomic and demographic characteristics, and presence of onsite mental health clinicians. Within blocks, practices were randomized to usual care or one of two quality improvement (QI) programs designed to increase rates of appropriate care.

Study staff screened 27,332 consecutive patients in participating practices over five to seven months. Patients were eligible if they intended

to use the clinic during the next twelve months and screened positive for depression, using items from the World Health Organization's twelve-month Composite International Diagnostic Interview (CIDI) (WHO 1997). Patients were positive if they reported at least one week of depression in the last 30 days, plus two weeks or more of depressed mood or loss of interest in pleasurable activities or persistent depression over the year. Positive predictive value of the screener compared to the full CIDI for depressive disorder is 55 percent (Wells 1999). Patients were ineligible if under age 18, not fluent in English or Spanish, or lacking insurance coverage for the therapists trained for the intervention.

Of the 27,332 patients completing the screener, 3,918 were potentially eligible. Of the 2,417 patients present to confirm insurance eligibility (some left), 241 were ineligible. Of eligibles who read the informed consent, 1,356 (70 percent) enrolled. For comparability with treatment trials, this study evaluates patients with current symptoms of depression and current or lifetime major depression or dysthymia by the CIDI ($N = 1,093$). The analytic sample is 938 patients (86 percent of those enrolled) who completed the six-month follow-up survey.

Quality Improvement Interventions

The two QI interventions were designed to be practice-initiated. Organizations committed to the interventions by providing local interdisciplinary teams who were trained to implement the QI activities. The teams were provided with patient and clinician education materials. Local practice nurses were trained to provide patient assessment and to educate and motivate patients for treatment (Rubenstein 1999). One intervention supported the same nurses to provide six or twelve months of medication follow-up (randomized at the patient level) through telephone contacts or visits, and the other intervention trained local therapists in group and individual Cognitive Behavioral Therapy. These therapists were available to intervention patients at reduced copay. All patients could have other types of psychotherapy for usual copays. Usual care practices only received written depression treatment guidelines by mail. In all intervention conditions, patients and providers made their own treatment decisions and use of intervention resources was optional (Rubenstein et al. 1999). All educational materials presented antidepressants and psychotherapy as equally efficacious for most patients. The study and intervention design is described elsewhere (Wells 1999b; Rubenstein et al. 1999; Wells et al. 2000).

MEASURES

Appropriate treatment in the first six-months of follow-up was measured by survey items that assessed whether the respondent had four or more specialty counseling visits or used antidepressant medication for any amount of time or above the minimum dosage recommended in the Agency for Health Care Policy and Research (AHCPR) practice guidelines (Depression Guidelines Panel 1993b), adapted to include newer antidepressant medications. We note that most patients either had appropriate care or almost no mental health care. In particular, 90 percent of those using appropriate medication during the period used it for six months; similarly, the mean number of visits among patients with at least four therapy visits was 12.5 (SD = 10.4), while for other patients the mean was 0.4 (SD = 0.8).

Health outcomes at six months include: probable depressive disorder, based on a repeat of the screener items; and the global mental health scale (MCS-12) of the SF-12 (Ware et al. 1995). In addition, we analyzed patients' self-reported employment status at six months.

Covariates collected at baseline include age, sex, marital status, education, household wealth, employment status, ethnicity, medical comorbidity, depressive disorder status, health-related quality of life, practice site, and presence of comorbid anxiety disorder (Table 1). We also controlled for the number of days between enrollment and the follow-up survey.

DATA ANALYSIS

We used univariate and bivariate analyses to describe the sample and compare patients who did or did not receive appropriate care in the first six months. We used multivariate regression models to examine the effects of appropriate care on outcomes. We expected that unobserved differences by treatment status would remain even after controlling for baseline patient characteristics. We used the method of instrumental variables to account for these differences (Angrist et al. 1996; Heckman 1996; Heckman 1997; Sturm 1998; Newhouse and McClellan 1998). This method relies on identification of an "instrument" that predicts the probability of treatment, but which has no independent effect on outcomes except through treatment; this approach helps to separate the effect on outcomes due to treatment from the effect due to unobserved characteristics.

Table 1: Patient Characteristics

Sample Size		Total 938	Appropriate Care		T-Statistic*	P-Value*
			Yes 440	No 498		
Randomization (Instruments)	Control clinic	32.6%	24.5%	39.0%	−4.327	0.000
	Medication QI clinic	30.3%	35.4%	26.2%	2.898	0.004
	Therapy QI clinic	37.1%	40.0%	34.8%	1.537	0.124
Demographics	Female	73.4%	77.8%	69.9%	2.512	0.012
	Mean age	43.3	44.2	42.5	1.656	0.098
	Married	53.0%	53.0%	53.0%	0.003	0.997
	Less than high school graduate	18.7%	13.8%	22.7%	−2.939	0.003
	High school graduate	29.2%	27.7%	30.3%	−0.813	0.416
	Some college	31.9%	33.9%	30.3%	1.148	0.251
	College graduate	20.2%	24.6%	16.7%	3.044	0.002
	White	61.5%	71.4%	53.7%	5.120	0.000
	Hispanic	30.1%	19.9%	38.1%	−5.467	0.000
	Black	6.3%	6.1%	6.5%	−0.196	0.845
	Other race/ethnicity	2.1%	2.6%	1.7%	0.984	0.325
	Wealth percentile rank	49.3%	50.9%	47.9%	1.476	0.140
	Employed at baseline	65.8%	62.5%	68.3%	−1.725	0.085
Health status	Double depression	15.2%	21.2%	10.4%	4.105	0.000
	Single depression	57.1%	59.9%	54.8%	1.487	0.137
	Lifetime disorder	27.8%	18.8%	34.9%	−5.087	0.000
	Anxiety at baseline	49.2%	56.6%	43.4%	3.685	0.000
	Mean MCS-12 score	34.2	32.4	35.5	−4.435	0.000
	Mean PCS-12 score	45.0	43.8	45.9	−2.667	0.008
	No chronic diseases	21.4%	21.0%	21.8%	−0.286	0.775
	1 chronic disease	23.9%	22.5%	25.1%	−0.816	0.415
	2 chronic diseases	19.6%	19.2%	19.9%	−0.250	0.802
	3+ chronic diseases	35.1%	37.3%	33.3%	1.210	0.226
Survey period	Mean days since screening	240.9	235.5	245.2	−3.426	0.001
Outcomes at six months	Appropriate treatment	44.2%	100.0%	0.0%		
	Appropriate medication	*36.9%*	*78.6%*			
	Appropriate counseling	*27.1%*	*57.7%*			
	Mean Mental HRQOL (MCS-12)	39.341	38.272	40.188	−2.296	0.022
	Probable disorder	49.0%	48.7%	49.2%	−0.148	0.883
	Employed	63.3%	58.4%	67.3%	−2.817	0.005

* *Note.* Test of difference between treatment and no treatment groups.

We used randomized intervention status (case versus control) as the instrument, which meets the conditions for valid instruments specified by Angrist et al. (1996): (1) random assignment; (2) the instrument affects treatment rates ("nonzero average causal effects"); (3) the instrument is unlikely to affect outcomes except through treatment ("exclusion restriction"); (4) outcomes for one patient are unlikely to be affected by outcomes for other patients ("stable unit treatment value"); and (5) patients with positive outcomes in usual care would likely have positive outcomes under the intervention ("monotonicity"). Each assumption seems plausible here.

We estimated a multivariate regression with each outcome as the dependent variable, controlling for whether patients received appropriate care and the covariates above; and we estimated a second regression with appropriate care as the dependent variable, controlling for intervention status and the covariates. For dichotomous outcomes (probable disorder, employment), these equations were estimated simultaneously using a bivariate probit specification (Greene 1990). For the continuous MCS-12, these equations were estimated simultaneously using two-stage least squares (Greene 1990; Hausman 1975).

We present outcomes adjusted for all covariates. We used the parameter estimates from the regressions and each individual's actual value for covariates to generate predicted values under the scenario that the patient received appropriate care, and then under the scenario without appropriate care. After that, we averaged the predictions across individuals under each scenario.

Although patients were clustered within providers and clinics, intraclass correlations are close to zero. For this reason, and because we know of no standard methods to account for clustering in instrumental variables models, we report results unadjusted for cluster effects. We weighted the data for the probability of selection at screening and for nonresponse at follow-up. We used multiple imputation for missing data at the item level (Rubin 1987; Schafer 1997). We use two-tailed tests with alpha = 0.05; while we have two clinical outcomes, findings are in a consistent direction, so formal correction for multiple comparisons is too conservative.

RESULTS

About 44 percent of patients received appropriate care during follow-up. As reported previously (Wells et al. 2000), patients in usual care practices were less likely than those in intervention practices to have appropriate care (Table 1). Patients with and without appropriate care differed in baseline

characteristics (Table 1). Patients receiving appropriate care were more likely to be female, better educated, and white. Perhaps more important for this analysis, patients with appropriate care were sicker at baseline: they had worse average quality of life scores ($p<0.01$) and were more likely to have current depressive disorder ($p<0.001$) and comorbid anxiety disorder ($p<0.001$). They also had lower employment rates ($p<0.10$) at baseline.

Table 1 also reports a simple bivariate comparison of outcomes at six months by treatment status. On average, patients who received appropriate care have worse mental health quality of life scores at six months ($p<0.05$) and are less likely to be employed ($p<0.01$). There is no bivariate association between treatment status over six months and remission.

These findings indicate that there is substantial selection into treatment: patients who were relatively sick at baseline were more likely to receive appropriate care in the subsequent six months. After accounting for patient covariates and selection into treatment through the instrumental variables method, appropriate treatment, relative to no or inappropriate treatment, improved both health outcomes and employment status (Table 2), each $p<0.05$. For example, only 24 percent of patients who received appropriate care were still depressed at six months (i.e., a 76 percent remission rate), but 70 percent of patients without appropriate care still had significant symptoms (i.e., a 30 percent remission rate) ($p<0.01$). Furthermore, 72 percent of patients who received appropriate care were employed at six months, compared with 53 percent of those who received no or inappropriate treatment ($p<0.01$).

DISCUSSION

Our findings suggest that evidence-based care for depression, when received by diverse patients in community-based settings under usual practice conditions, decreases the personal and societal burdens of depression. Improvements span clinical outcomes, quality of life, and employment status, and effects are substantively large.

From a policy perspective, it may be useful to think of our results as the average benefit that could be attained with current treatment methods if quality improvement efforts were successfully implemented for all eligible primary care depressed patients. This is a useful perspective for anticipating the consequences for public health of broad dissemination and implementation of quality improvement interventions for depression. We note that, technically, the instrumental variables method identifies the effects of

Table 2:   Predicted Outcome at Six Months, by Appropriate Care Status

		(95% CI)	*T-statistic**	*P-value**
Global Mental HRQOL (MCS-12)				
No appropriate care	32.5	*(26.2 38.9)*		
Appropriate care	47.9	*(39.7 56.2)*	2.081	0.037
Percent with probable disorder				
No appropriate care	70.0%	*(58.3% 81.7%)*		
Appropriate care	23.6%	*(9.5% 37.8%)*	− 3.297	0.001
Percent employed				
No appropriate care	52.5%	*(41.7% 63.4%)*		
Appropriate care	72.2%	*(65.3% 79.1%)*	2.917	0.006

* *Note*: Tests difference versus "no appropriate care," based on treatment coefficient.

treatment for patients who are likely to receive care under the intervention but not under usual care; effectiveness may be different for patients who are very likely to be treated under any practice conditions and those who are unlikely to be treated under any circumstances (Harris and Remler 1998).

Our results inform public policy debates about the desirability of parity of coverage for mental health and physical health care, by underscoring the real-world effectiveness of appropriate depression care. The results regarding employment status may be particularly useful, since this outcome has not been examined in clinical trials. Strikingly, the estimated increase in employment due to treatment is very similar to the estimated decrease in employment due to depression reported elsewhere (e.g., Marcotte et al. 2000). Our results also inform clinical practice goals by suggesting that the effectiveness of appropriate treatment as provided in community practice is comparable to that observed for standardized treatments in clinical trials, that is, remission rates greater than 70 percent for appropriate treatment and under 40 percent for no or inappropriate treatment. Thus, providers and patients no longer have to take it on faith that findings of efficacy studies for depressive disorders apply in community practice.

To put our findings in perspective, we estimate that the direct outpatient care costs of providing appropriate depression treatment over a six-month period are at most $2,134 (95 percent CI $1,898–2,371) compared with costs of $459 (95 percent CI $520–668) for patients without appropriate care. The mean difference of about $1,500 is similar to the cost of more intensive, effective quality improvement interventions for depression in primary care (Simon et al. 2001).

Our study has important limitations. While we studied a diverse range of managed care practices, different findings could apply for other practices. We had moderately high dropout rates in early enrollment. Our definition of appropriate treatments is somewhat below full guideline recommendations. We rely on self-report measures of treatment; prior studies have found moderate to high correlation between automated pharmacy data and patients reports of antidepressant use (Katon et al. 1996; Saunders et al. 1998). However, in the instrumental variables framework, random error in measuring treatment does not bias the estimates of treatment effectiveness (Fuller 1987; Bound et al. 1999). Our dichotomous treatment measure assumes that treatment below the threshold has no effect on outcomes, and treatment above the threshold has no additional value. If these assumptions are violated, the estimated treatment effectiveness may be higher or lower than the true effect.

The treatment effectiveness we report could reflect not just the effects of appropriate treatment per se (i.e., medication and/or psychotherapy), but whatever else patients might have received with that treatment because of the interventions (Newhouse and McClellan 1998). However, there is little evidence that aspects of care other than specific treatments substantially improve outcomes for depressed patients (Wells et al. 1996; Depression Guidelines Panel 1993a, 1993b; Schulberg et al. 1996; Attikson and Zich 1990; Brown et al. 1995).

Our study provides a hopeful message that the burden of illness from depression can be substantially reduced through provision of appropriate care under current practice conditions in managed primary care. Policymakers and other stakeholders wishing to reduce depression's public burden should consider promoting quality improvement interventions that enable clinicians to provide appropriate care and depressed patients and their families to seek it.

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