Randomized Trial of a Depression Management Program in High Utilizers of Medical Care

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Background: High utilizers of nonpsychiatric health care services have disproportionally high rates of undiagnosed or undertreated depression.

Objective: To determine the impact of offering a systematic primary care–based depression treatment program to depressed “high utilizers” not in active treatment.

Design: Randomized clinical trial.

Setting: One hundred sixty-three primary care practices in 3 health maintenance organizations located in different geographic regions of the United States.

Patients: A group of 1465 health maintenance organization members were identified as depressed high utilizers using a 2-stage telephone screening process. Eligibility criteria were met by 410 patients and 407 agreed to enroll: 218 in the depression management program (DMP) practices and 189 in the usual care (UC) group.

Intervention: The DMP included patient education materials, physician education programs, telephone-based treatment coordination, and antidepressant pharmacotherapy initiated and managed by patients’ primary care physicians.

Main Outcome Measures: Depression severity was measured using the Hamilton Depression Rating Scale (Ham-D) and functional status using the Medical Outcomes Study 20-item short form (SF-20) subscales. Outpatient visit and hospitalization rates were measured using the health plan’s encounter data.

Results: Based on an intent-to-treat analysis, at least 3 antidepressant prescriptions were filled in the first 6 months by 151 (69.3%) of 218 of DMP patients vs 35 (18.5%) of 189 in UC (P<.001). Improvements in Ham-D scores were significantly greater in the intervention group at 6 weeks (P = .04), 3 months (P = .02), 6 months (P<.001), and 12 months (P<.001). At 12 months, DMP intervention patients were more improved than UC patients on the mental health, social functioning, and general health perceptions scales of the SF-20 (P<.05 for all).

Conclusion: In depressed high utilizers not already in active treatment, a systematic primary care–based treatment program can substantially increase adequate antidepressant treatment, decrease depression severity, and improve general health status compared with usual care.

Arch Fam Med. 2000;9:345-351

Depression among primary care patients is associated with significant functional impairment, lost productivity, and use of health services. Epidemiologic studies consistently demonstrate that approximately 10% of primary care patients suffer from significant depressive disorders. Depressed primary care patients report poorer quality of life, greater impairment of daily functioning, and more disability and/or lost productivity because of illness. Use of general medical services by depressed primary care patients is 50% to 100% higher than utilization by similar patients without depressive illness. The economic burden of depression in primary care (in terms of increased health care utilization and lost productivity) vastly exceeds the resources currently devoted to treatment.

Among primary care patients with clinically significant depression, as many as half go unrecognized. Fewer than half of patients with recognized depression receive treatment of proven efficacy and of those who do obtain treatment, half or fewer receive levels of treatment consistent with expert guidelines. These high rates of underrecognition and undertreatment are especially concerning given the strong evidence for the efficacy of both pharmacotherapy and depression-specific psychotherapy. A series of recent randomized trials have demonstrated that systematic efforts to provide high-quality depression treatment can significantly improve clinical outcomes. These studies show that depression treatment effectiveness can be increased by using careful monitoring of patients and active involvement of specially trained clinicians.
SUBJECTS AND METHODS

The study was conducted within selected primary care clinics of 3 large prepaid health plans representing 3 geographic regions (Midwest, Northwest, and New England) in the United States: DeanHealth Plan (DHP), Wisconsin; Group Health Cooperative of Puget Sound (GHC), Washington; and Harvard Pilgrim Health Care (HPHC), Massachusetts. Both HPHC and GHC are not-for-profit health maintenance organizations (HMOs); DHP is a for-profit HMO. DeanHealth Plan has 175,000 members, GHC has 450,000 members, and the staff model division of HPHC has 300,000 members. The study protocol was approved by the institutional review boards of all 3 HMOs. Computerized databases from participating physician practices in all 3 HMOs were used to identify health plan members aged 25 to 63 years with continuous health plan enrollment for the previous 2 years. Members in this sample with ambulatory visit counts above the 85th percentile for both of the 2 previous years were considered high utilizers. For screening purposes, ambulatory office visits were defined as primary care visits, medical specialty visits, and walk-in clinic visits. Ambulatory office visits did not include emergency department visits, all mental health provider visits, routine obstetric visits, physical therapy/occupational therapy visits, optometry visits, x-ray/diagnostic visits, home health visits, telephone contacts, chiropractic visits, and allergy injections. Computerized record data were then used to assess the following exclusion criteria: recent treatment for alcohol or other substance abuse; past treatment for schizophrenia or bipolar disorder; life-threatening medical disorders (eg, metastatic malignant neoplasm); or active treatment for depression. Active treatment was defined as current specialty mental health treatment or minimal adequate trial of antidepressant medication. Minimal adequate trial was defined as an antidepressant prescription(s) filled in the past 90 days with at least 30 days of an adequate dose based on American Psychiatric Association guidelines.

We used a 2-stage telephone-screening process to identify those high utilizers likely to benefit from depression treatment. The first screening call included a modified version of the Structured Clinical Interview for DSM-IV (SCID) to identify 1,463 enrollees who screened positive for either major depression or major depression in partial remission. Of these, 1,205 enrollees agreed to complete a second telephone interview to assess depression severity using the 17-item Hamilton Depression Rating Scale (Ham-D). Potential study subjects were excluded if they had a Ham-D score less than 15 or met any of the following conditions: contraindications to taking an antidepressant, receiving treatment by a psychiatrist within the past 4 months, pregnancy, planned pregnancy within the next year, breastfeeding, positive screen for alcohol abuse, and intent to disenroll from the HMO.

The 163 participating physician practices were randomly assigned to either the DMP (n = 82) or usual care (UC; n = 81) groups. While randomization of physicians occurred prior to recruitment, study personnel at each site were not informed of an individual patient’s assignment until that patient had completed the enrollment process. Eligible and consenting patients from the practices of UC physicians were informed that telephone screening suggested depression and were advised that care was available with their primary care physician. Patients from the practices of DMP physicians were invited to participate in the protocol described below. All analyses classified patients according to the original assignment of their primary care physicians, regardless of the treatment actually received.

The principal elements of the DMP were physician education, patient education, antidepressant treatment, and treatment coordination. Prior to patient enrollment, all physicians in the DMP group participated in a standardized 2-hour training program focused on the initial assessment of depression and the initiation of pharmacotherapy. At each health plan, 1 or 2 psychiatrists were identified as consultants for the DMP. At the time of enrollment, all study patients in practices of the DMP group physicians were asked to schedule an evaluation visit with their primary care physician. Prior to this visit, patients received a booklet created for the study “Depression Isn’t Just a Mental Problem” and videotaped educational materials from the treatment coordinator designed to increase acceptance of depression treatment. At the initial visit, primary care physicians confirmed the diagnosis of depression, assessed contraindications to pharmacotherapy, and (if indicated) recommended antidepressant treatment. Patients who had psychotic symptoms, mania, or acute suicidality were immediately referred to psychiatrists.

Primary care physicians were advised to follow a specific pharmacotherapy algorithm, but were allowed to adjust treatment according to individual clinical need. The treatment algorithm recommended that patients who had previously been successfully treated and tolerated an...
implemented in most managed health care systems. Results of the screening program (prevalence of depression, association of depression with functional impairment, and increased utilization) are described in a separate publication. This article uses data from the randomized trial to examine the impact of the DMP on treatment discontinuation. In addition, treatment coordinators contacted DMP patients for telephone monitoring of treatment adherence; treatment response (based on administration of the 17-item Ham-D), and medication adverse effects after 2 and 10 weeks (and, if needed, after 18, 30, and 42 weeks). Treatment coordinators did not have access to the Ham-D scores generated by the blinded raters. The coordinators all had bachelor’s or master’s degrees and at least some clinical mental health experience. Data from this monitoring program, as well as recommendations for adjustments in treatment, were provided to treating primary care physicians after each monitoring contact. A written response was generated if the subject was doing well and a call to the physician was placed if the subject was not doing well. The study physicians did not have to acknowledge receipt of written messages. Study psychiatrists had ongoing contact with all intervention group primary care physicians via periodic case reviews and as-needed telephone consultation. A psychiatric consultation visit was strongly encouraged for all DMP patients not doing well. The study physicians did not have appointments for patients who had a full year of health plan coverage were included in the analysis of outpatient visits and inpatient stays.

Primary care treatment was supported by an ongoing program of monitoring, feedback, and as-needed specialty consultation. Coordinators reviewed DMP patient prescription refills and office visits to identify unplanned treatment discontinuation. In addition, treatment coordinators contacted DMP patients for telephone monitoring of treatment adherence; treatment response (based on administration of the 17-item Ham-D), and medication adverse effects after 2 and 10 weeks (and, if needed, after 18, 30, and 42 weeks). Treatment coordinators did not have access to the Ham-D scores generated by the blinded raters. The coordinators all had bachelor’s or master’s degrees and at least some clinical mental health experience. Data from this monitoring program, as well as recommendations for adjustments in treatment, were provided to treating primary care physicians after each monitoring contact. A written response was generated if the subject was doing well and a call to the physician was placed if the subject was not doing well. The study physicians did not have to acknowledge receipt of written messages. Study psychiatrists had ongoing contact with all intervention group primary care physicians via periodic case reviews and as-needed telephone consultation. A psychiatric consultation visit was strongly encouraged for all DMP patients not responding to treatment by 10 weeks and for patients with more complicated depression (e.g., major psychiatric comorbidity, past treatment failures). While UC patients could self-refer to any specialty services normally available to health plan members, no additional monitoring, case management, or psychiatric liaison services were provided.

All patients in both the DMP and UC groups were contacted for blinded telephone assessments 6 weeks, 3 months, 6 months, and 12 months after randomization. These assessments included a second administration of the Ham-D, a patient-rated 7-point scale of overall improvement since enrollment (patient global improvement score), and the Medical Outcomes Study 20-item short form (SF-20) functional status questionnaire. Health care utilization was collected from the HMOs’ automated claims databases for 1 year before and 1 year after study randomization. Outpatient visits were defined as unique patient, provider, and date of services for all clinic or outpatient hospital encounters, excluding visits to departments of radiology, pathology, and anesthesiology. Specialty mental health outpatient visits are defined as those visits provided by a mental health specialist and include visits to the psychiatrists involved in the study. Hospital admissions are defined as a stay in the hospital requiring at least 1 night’s stay, with stays not separated by at least 1 outpatient day considered a single admission. Only people who had a full year of health plan coverage were included in the analysis of outpatient visits and inpatient stays.

Participants provided informed consent to participate prior to the initial telephone screening, prior to the second-stage screening, and prior to enrollment in the randomized trial. The DMP patients provided additional informed consent to participate in the treatment program. An independent data safety committee monitored unblinded patient outcomes and adverse events throughout the study.

Primary comparisons of the DMP and UC groups were based on change scores (follow-up minus baseline scores) using an intent-to-treat approach. Estimation was done by analysis of variance with robust or sandwich estimates for the variance/covariance matrix corrected for intracluster correlation at the patient level. We also obtained very similar estimates controlling for site, age, sex, and baseline mental and physical health status, using a random-effects generalized least-squares estimator, generalized estimating equations for the health status measures, and negative binomial regression for outpatient visits and inpatient stays (not shown). For simplicity, we report the analysis of variance results on change scores, with robust estimates of the inference statistics and corrected for intraclass correlation among patients of the same physician.
Demographic and Patient Characteristics*  

<table>
<thead>
<tr>
<th></th>
<th>DMP (n = 218)</th>
<th>UC (n = 189)</th>
<th>P†</th>
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<tbody>
<tr>
<td>Age, y, mean (95% CI)</td>
<td>45.6 (44.0-47.1)</td>
<td>45.4 (43.9-46.9)</td>
<td>.89</td>
</tr>
<tr>
<td>Female, % (95% CI)</td>
<td>76.6 (70.9-82.4)</td>
<td>78.3 (71.7-84.9)</td>
<td>.69</td>
</tr>
<tr>
<td>White, % (95% CI)</td>
<td>87.6 (82.4-92.8)</td>
<td>77.3 (70.5-84.0)</td>
<td>.02</td>
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<tr>
<td>Married, % (95% CI)</td>
<td>71.1 (64.6-77.6)</td>
<td>65.6 (58.8-72.5)</td>
<td>.25</td>
</tr>
<tr>
<td>Years of education, mean (95% CI)</td>
<td>13.6 (13.4-13.9)</td>
<td>13.8 (13.4-14.1)</td>
<td>.52</td>
</tr>
<tr>
<td>Depression status, % (95% CI)</td>
<td>Current: 64.7 (59.4-70.0)</td>
<td>63.5 (56.4-70.6)</td>
<td>.79</td>
</tr>
<tr>
<td></td>
<td>Partial remission: 35.3 (30.0-40.6)</td>
<td>36.5 (29.4-43.6)</td>
<td>.79</td>
</tr>
<tr>
<td>SF-20 subscales, mean (95% CI)</td>
<td>Ham-D: 19.1 (18.7-19.6)</td>
<td>19.2 (18.7-19.7)</td>
<td>.75</td>
</tr>
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<td></td>
<td>MHI-5: 47.4 (44.7-50.0)</td>
<td>48.5 (45.7-51.4)</td>
<td>.56</td>
</tr>
<tr>
<td></td>
<td>GHP: 37.4 (34.2-40.6)</td>
<td>38.6 (34.8-42.4)</td>
<td>.64</td>
</tr>
<tr>
<td></td>
<td>PF: 54.6 (50.2-58.9)</td>
<td>50.4 (45.6-55.1)</td>
<td>.20</td>
</tr>
<tr>
<td>Patient seeing mental health provider (last 2 y), % (95% CI)</td>
<td>33.9 (27.8-40.1)</td>
<td>34.4 (27.2-41.6)</td>
<td>.93</td>
</tr>
<tr>
<td>Inadequate trial of antidepressant (last 90 d), % (95% CI)</td>
<td>24.3 (18.5-30.1)</td>
<td>13.8 (7.7-19.8)</td>
<td>.01</td>
</tr>
</tbody>
</table>

* DMP indicates depression management program; UC, usual care; SF-20, Medical Outcomes Study 20-item short form; Ham-D, Hamilton Depression Rating Scale; MHI-5, mental health inventory 5; GHP, general health perception; CI, confidence interval; and PF, physical functioning.  
† P values for individual variables are unadjusted for multiple comparisons. An overall F test of DMP vs UC for all variables was not significant (P = .13).

Of the 218 patients in the DMP, 198 scheduled and 189 completed the first physician visit and 166 started the RHYTHMS program. A treatment coordinator telephone contact was made at 2 weeks (177 patients), 10 weeks (194 patients), 18 weeks (131 patients), and 30 weeks (90 patients), for an average of 2.7 contacts per DMP patient. Computerized administrative databases were examined to determine the treatment actually received by DMP and UC patients. The DMP patients were much more likely to receive adequate antidepressant treatment. Pharmacy refill data for the 6-month period after enrollment indicated that 179 (82.1%) of 218 DMP patients and 61 (32.3%) of 189 UC patients filled at least 1 antidepressant prescription (P < .001); 151 (69.3%) of 218 DMP patients and 35 (18.5%) of 189 UC patients had filled at least 3 antidepressant prescriptions (P < .001) (Figure 2). The mental health treatment provided in both groups was given largely in primary care. At least 1 specialty mental health visit was made by only 39 (27.1%) of 218 DMP patients and 32 (16.9%) of 189 UC patients (P = .03). Only 29 (13.3%) of 218 DMP patients vs 18 (9.5%) of 189 UC patients made 3 or more specialty mental health visits in the first 6 months (P = .29).

Patients assigned to the intervention group experienced significantly better outcomes at every follow-up assessment. Improvements in Ham-D scores were significantly greater in the DMP than in the UC group: −3.3 vs −2.0 at 6 weeks (P = .04); −5.6 vs −3.9 at 3 months (P = .02); −7.3 vs −4.0 at 6 months (P < .001); and −9.2 vs −5.6 at 12 months (P < .001). The difference between DMP and UC groups increased significantly over time (P = .005) (Figure 3). At 12 months, 108 (53.2%) of 203 DMP patients had responded (defined as at least 50% reduction in Ham-D scores from baseline) compared with 58 (32.8%) of 177 UC patients (P < .001), and 92 (45.3%) of 203 DMP patients were in remission (defined as a Ham-D score < 7) compared with 49 (27.7%) of 177 UC patients (P < .001). Forty-one (23.2%) of 177 UC patients vs 26 (12.8%) of 203 DMP patients reported an increase in Ham-D scores (an increase indicates worse health) from baseline to 12-month assessment (P = .01). One hundred seventeen (57.6%) of 203 DMP patients rated themselves as “much” or “very much” improved at 12 months compared with 60 (33.7%) of 178 UC pa-
patients (P<.001), concordant with the Ham-D results. At 12 months, DMP patients reported significantly better social functioning, mental health, and general health perceptions than UC patients on the SF-20 (P<.05 for all), but not on physical functioning, role functioning, and pain perception (Figure 4). Given the baseline imbalance in the proportion of patients receiving recent inadequate antidepressant treatment, the above analyses were repeated, excluding all patients receiving inadequate antidepressant treatment during the 90 days prior to enrollment. Results were nearly identical.

Comparing the year before randomization with the year after randomization, mean visit counts in DMP increased by 1.6 visits (18.4 to 19.9 visits), 0.5 of which was attributable to a single case. Mean visit counts in UC decreased by 2.0 visits (19.4 to 17.4 visits). The change in visits did differ significantly between groups (P=.02). Outpatient visits included nonphysician encounters, such as physical therapy and speech therapy. Comparing the year before randomization with the year after randomization, mean inpatient admissions in the DMP group increased by 0.04 (0.23 to 0.27 admissions) and mean inpatient admissions in the UC group decreased by 0.08 (0.26 to 0.18 admissions). The change in inpatient admissions between groups was not significantly different (P=.09).

COMMENT

Depressed high-utilizer patients not already in active treatment who received the DMP had significantly better clinical outcomes and improved general health status compared with patients who received UC. The effectiveness of the DMP in this real world clinical setting is notable, given that some DMP patients did not pursue treatment and some UC patients received adequate treatment through the usual channels. The results show that the DMP did not decrease outpatient visits compared with UC and our estimate is actually a relative increase in outpatient visits. While the study protocol recommended 9 or more outpatient visits for initiating and monitoring depression treatment, the DMP group increased by only 1.6 visits, while the UC group decreased by 2.0 visits, suggesting that most visits for depression could be combined with other visits.

The following limitations should be considered when generalizing the results of this study. First, the UC patients may have been more likely to seek depression treatment than usual because the telephone screeners recommended that they contact their physicians. At the exit interview, 74 (41.6%) of 178 UC patients reported they took action in some way based on this recommendation. The low rate of specialty mental health visits and prescription of antidepressants in the UC group suggests that this had a limited effect. Because of this limitation, the study results probably represent a lower bound of the impact of the intervention. Second, the initial imbalance of more DMP patients than UC patients having an inadequate antidepressant trial prior to entering the study could have affected the results. This seems unlikely, as the results did not change when randomized patients on inadequate antidepressant trial at baseline were excluded from the analyses. Third, because the study was not powered to detect a change in inpatient admissions, we cannot determine whether the intervention affected inpatient utilization. Fourth, the 1-year study period may have been too short to capture the full benefit of the DMP intervention. The difference in Ham-D scores between the DMP and UC groups was greatest at the 12-month assessment point. Fifth, care must be taken in generalizing these results to depressed populations other than high utilizers.

How substantial is the effect of the DMP intervention? One way to assess the impact of the DMP is to consider the number of patients with depression who would need treatment in the DMP group to achieve 1 more remission than would occur in the UC group. Based on our data, this number needed to treat was 5:1. This ratio compares favorably with the 9:1 number of patients with diastolic blood pressure of 115 to 129 mm Hg needed to treat to achieve 1 less stroke, myocardial infarction, or death.37 Another way to assess the DMP is to compare it with efficacy studies of antidepressants vs placebo. The differences of 17.6% in remission rates and 3.6 in Ham-D scores between the DMP and UC groups in this study is similar to the difference seen between efficacious antidepressant and placebo in clinical trials.38-42

Figure 3. Patients’ scores on the Hamilton Depression Rating Scale (Ham-D) during the 12-month study. The P values were based on the change in scores since the baseline assessment.

Figure 4. Change in patients’ scores on the Medical Outcomes Study 20-item short form (SF-20) subscales after receiving either the depression management program (DMP) or usual care (UC) for 12 months. The P value was based on the change in scores since the baseline assessment.
While the difference between the DMP and UC patients in mean Ham-D scores is similar to that between active treatment and placebo groups in other primary care studies, and specialty studies, rates of response and remission in both groups seem low. This study used a 2-stage screening process that required a diagnosis of depression at the first call and a Ham-D severity greater than or equal to 15 at the second call 2 weeks later. Requiring participants to have depressive symptoms that persisted over time may have decreased the number of patients likely to spontaneously recover. The DMP patients on average took longer to respond to treatment than has been seen in clinical trials. One reason is that time zero was defined as the date of study enrollment, not the first physician visit, which was at least 2 weeks later. Another reason may be that high utilizer patients have more medical and psychiatric comorbidity, which has been shown to be associated with delayed onset of treatment response and lower response rates.

Most DMP patients (69.3%) received at least adequate antidepressant treatment (defined here as 3 or more antidepressant prescriptions) during the first 6 months of the study, even though the large majority of DMP patients (72.9%) received no specialty mental health treatment. This is consistent with the intervention’s goal of providing primary care–based treatment for the majority of depressed patients and increasing the intensity of specialty care for nonresponding patients.

Our randomized trial of a multicomponent intervention does not allow specific conclusions regarding the benefits of individual intervention components. However, considering our findings along with those of other primary care intervention studies suggests some general conclusions. Several programs limited to physician training or depression screening have not improved patient outcomes. Common elements of effective programs include guideline-based treatment, organized follow-up care, and active monitoring of patient outcomes.

Our findings suggest that real-world primary care physicians can deliver effective depression treatment, if those physicians are supported by organized systems for patient education, proactive psychiatric consultation for nonresponders, physician education, and patient monitoring. Previous studies of programs that focused solely on increasing recognition of depression have not demonstrated differences in patient outcomes. The DMP tested in this study was not as tightly controlled as previous successful primary care interventions, but it was more intensive than several earlier unsuccessful programs. The successful programs described by Katon et al. and Schulberg et al. all involved direct treatment by specially trained study personnel. In the study by Katon et al., mental health specialists participated in the care of all patients. Schulberg et al. used 2 different systematic depression treatment programs for patients in primary care that were more effective than UC. The major difference between the DMP used in this study and the successful Katon and Schulberg models is that patient’s depression treatment in the DMP was based with their own primary care physician.

The DMP used in this study could be a model for use with high utilization patients in many health care organizations. The DMP treatment model has the advantage of being initiated by the patient’s own primary care physician. In addition, it encourages integration of medical and psychiatric treatment. Another substantial advantage is that patient visit and pharmacy tracking programs already present in many existing managed care organizations will facilitate the implementation of the DMP. Further research will be needed to determine the effectiveness of this systematic treatment model in other depressed populations.

Accepted for publication October 27, 1999.

Funded by a grant from Pfizer Pharmaceuticals Inc, New York, NY (Drs Katzelnick, Simon, and Pearson).

We thank the members of the study’s data safety and monitoring board: David DeMets, PhD (chair), James Jefferson, MD, William McKinney, MD, Colleen McHorney, PhD, and Jeff Douglas, PhD, and advisory committee: Jonathan Borus, MD (chair), Donald Klein, MD, and Herbert C. Schulberg, PhD. We also thank Wilma Harrison, MD, and Robert Miceli, PhD, for their assistance in designing the study.

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