The 'Usual Care' of Major Depression in Primary Care Practice

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Objective: To determine how primary care physicians treat patients with major depression in the course of routine practice and the degree to which such practice produces outcomes anticipated with interventions recommended by the Agency for Health Care Policy and Research Depression Guideline Panel.

Design: Prospective cohort study.

Settings: Academically affiliated ambulatory family practice centers and internal medicine clinics in urban neighborhoods of Pittsburgh, Pa.

Patients: Ninety-two patients who were seen in primary care practices and who met criteria for a current major depression as determined by the Diagnostic Interview Schedule and a psychiatrist's assessment.

Intervention: Physicians were informed of the patient's psychiatric diagnosis, and were urged to treat it in whatever manner and for whatever duration they deemed appropriate (ie, with "usual care").

Main Outcome Measures: The treatments that were provided, the patients' clinical course, and the relationship between the type of treatment and clinical course.

Results: Health center records indicated that 67 patients (73%) received a depression-specific treatment in the 8 months following study entry. A majority of the total cohort were prescribed an antidepressant drug. Of the 92 patients, 18 (20%) were asymptomatic at 8 months (Hamilton Rating Scale for Depression score, ≤7). The treatment pattern was not clearly related to the clinical course.

Conclusions: The recovery rates for the patients with major depression who were treated with usual care in routine primary care practices were lower than those anticipated from treatments consistent with the Agency for Health Care Policy and Research guidelines. Further studies of the caregiving elements that influence the effectiveness of depression-specific treatments of patients in primary care settings are needed.

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STUDIES CONDUCTED in the United States[1,2] and elsewhere[3,4] have indicated that depression is commonly treated in primary care settings. These findings assume particular significance in light of the Agency for Health Care Policy and Research (AHCPR) Depression Guideline Panel's conclusion[5] that most episodes of major depression can be treated successfully by family physicians and general internists. Given this expectation, the question arises as to whether the usual clinical practice of primary care physicians conforms to guideline principles and whether it achieves successful outcomes. These concerns are becoming increasingly important as third-party payers shift mental health services to generalists whose costs are only 33% to 50% of those incurred by specialists.[6]

Prior reports of "usual care" (UC) indicate that while antidepressant medications typically are the physician's treatment of choice,[7-11] practices of prescribing vary widely.[2,8,10,12-18] When criteria approximating the guidelines were applied to judge whether the medication was prescribed at the minimally sufficient dosage and duration that were thought to be needed to achieve therapeutic benefits, pharmacotherapy by primary care physicians was found "adequate" for no more than half of the patients who received it.[12,14,19-23] Many primary care physicians also counsel depressed patients,[24] with 30% to 40% of such patients being offered a psychosocial intervention in the generalist's office.[10,18] However, the nature and quality of counseling that primary care physicians provide their depressed patients are unknown. The total number of visits made by depressed patients to a primary care physician during a 12-month period specifically for the treatment of a mood disorder was found to range from 2.1 to 3.7[18,22]; these numbers are insufficient for

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PATIENTS AND METHODS

DESIGN AND SAMPLE SELECTION

The prospective cohort study reported here is part of an RCT of treatments of major depression conducted in Pittsburgh, Pa, between April 1991 and December 1994, at 4 ambulatory general medical facilities that serve largely lower socioeconomic class urban populations and that are affiliated with family practice or internal medicine residency training programs. As we have reported previously,[26] the potential subjects were patients aged 18 to 65 years who presented in the waiting rooms at these sites, were not being treated for depression, and were not pregnant. The patients were assessed through a multiphase evaluation to identify those who met diagnostic and severity criteria for major depression and to exclude those with medical (eg, organic mood syndrome) or psychiatric illness (eg, active substance abuse) that would contraindicate randomization to 1 of the study's 3 treatment cells (ie, interpersonal psychotherapy, nortriptyline hydrochloride pharmacotherapy, and a physician's UC). Depressed patients with contraindications (eg, serious suicidality) to treatment in these outpatient general medical settings were also excluded. In this manner, a total of 283 patients were identified as being eligible for the University of Pittsburgh Biomedical Institutional Review Board–approved protocol; 276 (97.5%) provided informed consent for and received a randomized treatment assignment. Subsequently, 92 patients were randomized back to their regular health center physician for UC; 20 (22%) and 72 (78%) of the 92 patients were treated by faculty and residents, respectively.

UC PROTOCOL

Researchers informed the physicians of all patients who were randomized to UC verbally and by letter that their patients had been diagnosed as having current major depressive disorder, and the physicians were urged to treat it. Patients were similarly so informed about their diagnosis and urged to discuss treatment options with their physicians. While provision of this information to the physician and patient is a marked deviation from UC necessitated by ethical considerations, the intervention in other respects approximated routine physician practice in nonresearch circumstances. Thus, the type and extent of depression-specific treatment that physicians provided to their patients and referral to a mental health specialist turned on the physicians' autonomous judgments of whether and how to treat a mood disorder. Consultations with psychiatrists were available to all primary care physicians, and on-site referrals to psychologists and social workers could be made daily.

INSTRUMENTS

The nature of UC was determined in 2 ways. First, research associates abstracted the patients' health center records to identify services documented in the 8 months after randomization to UC. When antidepressants were prescribed, physician investigators (M.R.B., E.R., and C.P.S.) judged the adequacy of the dosage and its duration according to standards recommended by the AHCPR Depression Guideline Panel.[5] Second, physicians who were treating patients with UC completed questionnaires after office visits for both study and nonstudy patients; the physicians described their view of the encounter's purpose, its level of clinical difficulty, and the type of intervention provided to the patient. Physicians also completed a research questionnaire 8 months after a patient's randomization that documented their judgments about the patient's diagnosis, treatment, and clinical course.

A patient's level of depressive symptoms was measured at baseline with the Center for Epidemiologic Studies–Depression[27] questionnaire and, at periodic intervals during the next 8 months, with the Hamilton Rating Scale for Depression (HRS-D)[28] and the Beck Depression Inventory.[29] The general level of functioning was evaluated at these same time points with the Global Assessment Scale.[30] A history of other lifetime psychiatric disorders (Axis I) or personality disorders (Axis II) was assessed with the Diagnostic Interview Schedule[31] and the Structured Clinical Interview for *DSM-III-R* Personality Disorders,[32] respectively. These instruments were administered by clinical evaluators who were blind to a patient's treatment assignment after achieving interrater reliabilities that exceeded 0.90. The severity of a patient's medical illness was assessed with the Duke Severity of Illness Checklist[33] by nurses who abstracted the patient's medical record and rated each of the assigned diagnoses with regard to symptom level, complications, prognosis, and treatability.

DATA ANALYSIS

The frequency with which primary care physicians provided depression-specific treatment as part of their UC of major depression was calculated based on the information recorded in the patient's medical record and physicians' responses to a questionnaire that was developed by the researchers. A physician's professional status (faculty or resident) was found to be unrelated to the treatment pattern, possibly because residents routinely presented their cases to health center faculty who served as preceptors and influenced treatment decisions. The subsequent analyses, therefore, combine data found for the 14 faculty and 55 resident physicians who treated the 92 patients randomized to UC. A patient's clinical outcome at 8 months was analyzed in 2 ways: (1) the percentage reduction in the severity of the depressive episode as determined by change of the HRS-D score from baseline, and (2) recovery from the episode (ie, whether the HRS-D score could be classified as asymptomatic within the convention recommended by Frank et al[34]).

the frequent contacts and monitoring as recommended by the AHCPR Depression Guideline Panel[5] for either counseling or medication.

Despite numerous reports about the nature of UC, little is known about its clinical outcome. Scott and Freeman[23] found that "routine GP [general practitioner] care" was less effective than the interventions provided by a psychiatrist at 4 weeks after the start of treatment but not 18 weeks later. Intriguingly, the "adequacy" of antidepressant medications that were taken by patients who received routine care from a general practitioner was unrelated to the outcome found by Scott and Freeman.[23] In the 2 randomized trials conducted by Katon et al[21,22] in an urban health maintenance organization, signifi-

Table 1. Baseline Clinical Characteristics of Patients Randomized to Usual Care (N=92)*

Scale	No. of Patients	Mean (SD)
CES-D	92	38.0 (8.4)
HRS-D	92	23.4 (5.3)
BDI	77	27.3 (9.7)
GAS	79	48.8 (6.9)
DUSOI	92	34.4 (15.4)

*CES-D indicates Center for Epidemiologic Studies–Depression questionnaire; HRS-D, Hamilton Rating Scale for Depression; BDI, Beck Depression Inventory; GAS, Global Assessment Scale; and DUSOI, Duke Severity of Illness Checklist.

Table 2. Primary Treatments of Depression Provided to Patients at Health Centers Within 8 Months of Randomization

Treatment	No. (%) of Patients	Mean No. of Visits*	% Clinical Improvement†
No treatment, diagnosis only	25 (27)	0.1	44.2
Referral only	3 (3)	1.0	50.0
Counseling only	10 (11)	2.2	23.2
Antidepressant medications only	25 (27)	3.3	42.6
Antidepressant medications combined with counseling	29 (32)	4.8	48.4
Total	92 (100)	...	...

*To generalists and mental health specialists (analysis of variance: $F=29.2$; df=4, 87; $P=.001$).

†Percentage of reduction in Hamilton Rating Scale for Depression score between baseline and month 8 (analysis of variance: $F=1.29$; df=4, 87; $P=.28$).

cantly fewer patients with major depression who received UC from a primary care physician improved after 7 months compared with those who received treatments that conformed with guideline standards. Rost et al[19] similarly determined from their study of rural practices that only 31.6% of patients recovered from this disorder after 5 months of UC.

These earlier studies point to gaps between the UC provided by generalists and the guideline principles for treating depression, and provide limited data regarding the effectiveness of UC. In this article, we examine whether the nature and outcome of UC services are related by using data gathered during a randomized control trial (RCT) that compared the effectiveness of a primary care physician's UC with that of an antidepressant medication and short-term psychotherapy that was provided within highly standardized protocols.[25] The UC treatment arm constituted a naturalistic study within the clinical trial, and data about it provide an unusual opportunity to examine the relevance of AHCPR treatment guidelines.

RESULTS

PATIENT CHARACTERISTICS

With regard to the sociodemographic characteristics of the 92 patients, their mean age was 38.6 years, 80 (87%) were female, 49 (53%) were white, 25 (27%) were married, 78 (85%) had completed a high school or higher level of education, and 38 (41%) were employed in full- or part-time jobs.

Table 1 presents the clinical characteristics of the 92 patients (internal medicine, 44; family practice, 48) who were randomized to UC. The cohort's depressive severity at baseline as measured by the Center for Epidemiologic Studies–Depression questionnaire, HRS-D, and Beck Depression Inventory was high, and its overall level of functioning as measured by the Global Assessment Scale was poor. Almost one half of the patients had previously obtained psychiatric treatment (outpatient, 41 patients [45%]; inpatient, 20 patients [22%]), and more than one half met criteria for lifetime episodes of other psychiatric or personality disorders (Axis I, 74 patients [80%]; Axis II, 70 patients [76%]) according to the *Diagnostic and Statistical Manual of Mental Disorders, Third Edition, Revised.*[35]

MEDICAL CHART–RECORDED UC INTERVENTIONS

A depression-specific treatment, including referral to a mental health facility, was recorded in the medical record for 67 (73%) of the patients during the 8 months after study entry (**Table 2**). Of the 92 patients randomized to UC, 54 (59%) were prescribed antidepressant medications, and almost one third had notations that indicated that counseling was provided in addition to such a drug. A small number (10 [11%]) of the UC patients received counseling but no pharmacotherapy. Continuous treatment during the 8-month observation period was documented in the medical record for only one third of the 67 (73%) patients who received any treatment. Two thirds of the patients who were provided any treatment received it only during delimited intervals during the 8-month period. The frequency of visits by the patients to their primary care physicians or mental health specialists for depression-specific treatment ranged from 0.1 for patients who were provided no such treatment to 4.8 for those who received both medication and counseling ($F=29.2$; $df=4, 87$; $P<.001$).

Patient variables were found to be unrelated to the treatment pattern. Patients who were prescribed medications (n=54) and those who were not (n=38) could not be distinguished at baseline on any of 6 demographic and 12 clinical variables (including depressive severity). Internists and family physicians actively treated similar percentages of the patients randomized to them (75% and 71%, respectively). However, treatment patterns differed significantly by specialty ($\chi^2=12.3$; $P=.02$); more internists provided counseling alone, while more family physicians combined counseling with medication.

Since medication constituted the primary care physicians' key approach to treating depression, we reviewed the specific drugs that were prescribed by them. Sixty-three percent of the prescriptions were for tricyclic antidepressants; the numbers (percentages) of patients treated with these drugs were as follows: nortriptyline, 27 (39%); amitriptyline hydrochloride, 8 (11%); imipramine hydro-

chloride, 6 (8.6%); desipramine hydrochloride, 2 (2.9%); and doxepin hydrochloride, 1 (1.4%). Thirty-one percent of the prescriptions were for selective serotonin-reuptake inhibitors; 13 (19%), 7 (10%), and 2 (2.9%) of the patients were treated with fluoxetine hydrochloride, sertraline hydrochloride, and paroxetine, respectively. Six percent of the prescriptions were for a heterocyclic antidepressant (ie, 4 patients [5.7%] received trazodone hydrochloride). When judged against the recommendations of the AHCPR Depression Guideline Panel,[5] 44 (82%) of the 54 patients were prescribed an antidepressant at a therapeutic dosage level and for the minimal 4-week period deemed necessary for the short-term phase of the treatment. However, only 23 (52%) of these 44 patients received the antidepressant at a dosage level and for the minimal 4-month period recommended for the continuation phase of the treatment. Thus, 23 (43%) of the 54 patients who were prescribed any antidepressant received it within current state-of-the-art guidelines.

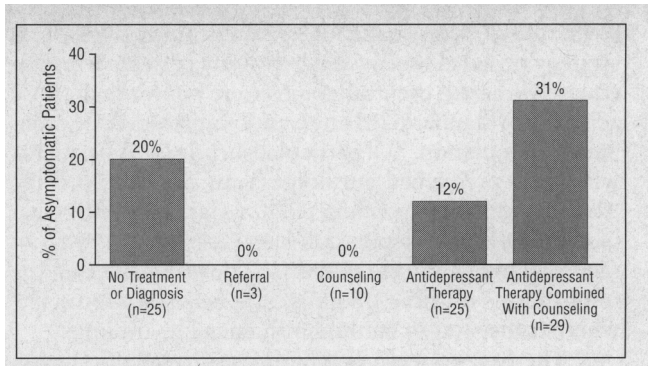
PHYSICIANS' PERCEPTIONS OF UC INTERVENTIONS

Physicians who treated patients, randomized to UC, completed a brief form, developed by the investigators, that described the nature of office visits with these patients and with a randomly selected sample of nonstudy patients who were seen on the same day. Physicians completed forms for 143 (51.6%) of the 277 visits that patients made during the 8 months after assignment to UC and for 500 randomly selected visits made to them by nonstudy patients during this same period. The mean length of an office visit, as reported by physicians, was longer for patients randomized to UC than for nonstudy patients (25.1 vs 21.2 minutes; $t=12.7$; $df=1$; $P<.001$). Physicians indicated that the primary focus of a visit was psychological for 92 (64.3%) of the 143 sessions for patients who received UC but only for 40 (8%) of the 500 interactions with nonstudy patients.

Primary care physicians maintained the responsibility for the continuity of a patient's UC. Eight months after a patient's assignment, physicians completed a questionnaire that was developed by the investigators who inquired about the diagnosis, treatment, and clinical course of the patient. Although researchers had informed physicians that the patient was depressed at entry to the study, physicians stated that only 68% of the patients were depressed at any point during the 8-month study period. Nevertheless, primary care physicians reported that they personally provided or arranged depression-specific treatment for 79% of patients. According to the physicians, 60% of all patients were prescribed medication, 72% were provided counseling (as defined by the respondents), and 60% were additionally referred to a mental health specialist. At the 8-month follow-up, physicians thought that 30% of the patients remained depressed and that 22% had recovered; they were uncertain about the clinical status of the remaining 48% of these patients.

UC INTERVENTION AND CLINICAL OUTCOME

The relationship between a patient's treatment pattern and clinical outcome was assessed in 2 ways. First, we examined the type of treatment recorded in the medical chart and the degree of improvement in depressive severity from baseline to month 8 (as measured by the HRS-D scores at these 2 time points). The mean reduction in depressive severity for the total group was 43%; the differences among treatment patterns were not significant (Table 2). Second, complete recovery from the depressive episode was measured using the convention of Frank et al[34] (ie, achievment of an HRS-D score <7). The **Figure** indicates that the treatment pattern was significantly related to this more stringent outcome measure. At 8 months, 31% of the patients who received antidepressant medication combined with counseling were asymptomatic. However, no patient who was provided only counseling had recovered at this time point—an outcome that was possibly influenced by the fact that all had lifetime histories of anxiety disorder (particularly panic), which is a risk factor for a poorer depressive course.[36]



The percentages of patients who were treated with usual care and who were judged to be asymptomatic at month 8 in relation to the primary treatment pattern during the preceding months ($\chi^2=17.9$; $P=.02$).

The relationship between the intensity of intervention and outcome also was examined by comparing the clinical course of the 23 patients who were prescribed antidepressants at a dosage and duration consistent with AHCPR[5] standards with that of the 25 patients whose records revealed no depression-specific treatment during the 8-month study period. The 2 groups had similar depressive severity at baseline (mean HRS-D scores of 23.0 and 22.6, respectively) that improved at equivalent rates during the succeeding months. Eight months after randomization, no differences in the level of improvement were found between patients who were prescribed adequate medication and those who received no depression-specific treatment (mean HRS-D scores of 13.6 and 12.4, respectively). Thus, both subgroups of patients achieved the same 43% reduction in the severity of their depression, and the same 20% to 22% recovery rate (HRS-D score, ≤7). Of interest is that this recovery rate was significantly poorer than that achieved by patients who were assigned to the standardized nortriptyline arm of the larger RCT (ie, 48% for the intent-to-treat cohort and 67% for the patients who completed treatment).[37]

COMMENT

The present research data extend the findings from earlier studies of the primary care physician's UC of major depression by relating the type and quality of services that

constitute UC with a patient's 8-month clinical status. This strategy revealed that even when study patients were adequately treated, their outcomes were poorer than those achieved by standardized interventions provided to a comparable population.[37] Of particular surprise is that patients who were prescribed antidepressants according to the AHCPR guideline[5] recommendations fared no better than patients for whom depression-specific treatment was not recorded in health center charts. Before considering the implications of these findings, it is necessary to review whether the study's method influenced its findings.

The first concern is whether a physician's awareness of the patient's diagnosis of major depression and the study's other treatments altered his or her typical management of a depressive episode. The available data suggest that this was not the case. Physicians did not consider 32% of their patients to be depressed even when they were informed of this diagnosis; this is a disagreement rate comparable with that obtained in other recent studies.[15,38] As for the treatment patterns recorded by physicians in medical records, our findings that 59% of the patients were prescribed antidepressants and 42% were provided counseling (Table 2) is also consistent with treatment patterns reported in the previously cited studies.

A manner wherein the protocol does appear to have influenced UC at the study sites was the physicians' choice of drug therapy when they were prescribing an antidepressant. We found that 39% of such prescriptions were for nortriptyline; this is a rate that far exceeded its typical 10% use in primary care practice.[39] However, only 10 (37%) of 27 nortriptyline prescriptions conformed with the AHCPR guideline standards for adequate dosage and duration with this medication. Although physicians may find it easier to prescribe the selective serotonin-reuptake inhibitor drugs at therapeutic dosages and durations,[14,21] data are still lacking as to whether such prescribing practices improve outcomes in routine primary care practice.

A second methodological concern is the validity of data abstracted from the medical record, particularly with regard to the differential recording of certain psychiatric services. On the one hand, physicians' responses to the investigators' questionnaires, as well as data in the medical record, both indicated that approximately 60% of the patients randomized to UC were prescribed antidepressant drugs. On the other hand, physicians self-reported counseling 72% of their UC patients; however, they noted this intervention in only 42% of the charts (Table 2). Even if the physician's self-report is the more accurate measure, the frequency with which psychosocial interventions were provided to patients fell short of the number deemed necessary to achieve clinical improvement in the depressive episode.[5] In our study, the patients who were provided counseling alone had a mean of 2.2 treatment visits and those who received counseling combined with a medication had a mean of 4.8 treatment visits with their primary care physicians and mental health specialists during the 8-month study period. This compares with the mean of 13.8 visits provided to patients in the standardized psychotherapy condition of the RCT and the 9.8 visits provided to those in the standardized pharmacotherapy condition.

A third methodological concern is whether the recruitment of a cohort of patients with extensive psychiatric and general medical comorbidity reduced the effectiveness of UC. A comparison of patients who did and did not recover revealed the prevalence of other psychiatric disorders and personality disorders to be the same among the 2 subgroups. However, the severity of general medical illness was greater at baseline among nonrecovered than recovered patients (mean Duke Severity of Illness Checklist score, 36.6 vs 28.4; $t=5.3$; $df=1$; $P=.02$). Since antidepressant medication was the modal treatment that was provided to patients, the nonrecovered subgroup possibly tolerated the drugs more poorly because of general medical complications. This raises the question of whether a selective serotonin-reuptake inhibitor drug that produces fewer troublesome side effects than nortriptyline would achieve better clinical outcomes with patients who experience more severe levels of medical morbidity.

A fourth methodological concern is that the study was conducted in academic practices; hence, its findings may not generalize to nonacademic settings. We would note, however, that our academically affiliated study sites function as primary care rather than specialty referral practices. Patients typically are followed up by the same physician, who, while often a house officer, has access to on-site psychiatric consultation that is a service unavailable in most community practices. Nevertheless, replication of this study in nonacademic community practices is necessary and recommended.

Given that antidepressant medications constituted the treatment that was most prescribed by primary care physicians, how well did their use conform with state-of-the-art recommendations? Physicians typically prescribed these drugs at dosage levels and for durations that they believed would be adequate to achieve an initial therapeutic benefit. However, only 43% of the prescriptions were continued for the additional period needed to forestall a relapse (ie, ≥4 months). Thus, educational efforts (eg, the "collaborative management" program developed by Katon et al[22] with primary care physicians) should note the value of extending the duration of pharmacotherapy at the dosage level that achieved asymptomatic remission if patients are to recover fully from and avoid relapse of the depressive episode.

Having made this recommendation, we recognize that patients who received pharmacotherapy judged adequate for dosage and duration and patients who and were prescribed pharmacotherapy judged inadequate or provided no depression-specific treatment had similarly low 8-month recovery rates (22% and 20%, respectively). It may be that patients who were prescribed adequate courses of antidepressant medications failed to comply with the treatment; we lacked such information as pill counts or drug levels for this group. Nevertheless, the similar finding by Scott and Freeman[23] and Simon et al[40] that clinical outcome in routine primary care practice was unrelated to the adequacy of an intervention raises the question of what features of a depression-specific treatment are critical to its effectiveness. For example, we know that patients who are educated in the use of antidepressants are more likely to comply than patients who are not provided this information.[41] It is also conceivable that a subgroup of patients with major depression may recover from the episode without treatment, and that the decision by the study's primary care physicians not to intervene actively was clinically appropriate.

To our knowledge, there has been little research in primary care practices to determine the validity of the AHCPR treatment guidelines; the principles and outcome indexes were largely derived from RCTs that were conducted in psychiatric settings. The present findings suggest the need for additional studies of the caregiving elements that influence the effectiveness of pharmacotherapy in a routine primary care practice (eg, the patient's willingness to be treated for depression and concern about stigma, the specific treatment that the patient wishes to receive, and his or her adherence to treatment recommendations). Research also is needed about the complex nature of the encounter between the physician and the depressed patient[42,43] (eg, the type of education that physicians provide patients about their depressive disorder, the frequency with which physicians contact patients to whom they have prescribed antidepressants, their knowledge of whether the medication is producing disturbing side effects, the degree to which physicians emphasize the need to comply with dosing schedules and convey optimism to the patient about recovery). These treatment elements were intrinsic to the "clinical management" within which standardized pharmacotherapy was practiced in this RCT[44] and that conducted by the National Institute of Mental Health, Rockville, Md,[45] and likely potentiated the drug's biochemical actions by enhancing patients' adherence. If particular elements in this approach are atypical or difficult to implement in primary care practice, new approaches consistent with this setting should be tested.

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