ORIGINAL ARTICLES

A Randomized Trial Using Computerized Decision Support to Improve Treatment of Major Depression in Primary Care

Bruce L. Rollman, MD, MPH, Barbara H. Hanusa, PhD, Henry J. Lowe, MD, Trae Gilbert, MA, Wishwa N. Kapoor, MD, MPH, Herbert C. Schulberg, PhD

OBJECTIVE: **To examine whether feedback and treatment advice for depression presented to primary care physicians (PCPs) via an electronic medical record (EMR) system can potentially improve clinical outcomes and care processes for patients with major depression.**

DESIGN: **Randomized controlled trial.**

SETTING: **Academically affiliated primary care practice in Pittsburgh, PA.**

PATIENTS: **Two hundred primary care patients with major depression on the Primary Care Evaluation of Mental Disorders (PRIME-MD) and who met all protocol-eligibility criteria.**

INTERVENTION: **PCPs were randomly assigned to 1 of 3 levels of exposure to EMR feedback of guideline-based treatment advice for depression: ''active care'' (AC), ''passive care'' (PC), or ''usual care'' (UC).**

MEASUREMENTS AND MAIN RESULTS: **Patients' 3- and 6-month Hamilton Rating Scale for Depression (HRS-D) score and chart review of PCP reports of depression care in the 6 months following the depression diagnosis. Only 22% of patients recovered from their depressive episode at 6 months (HRS-D $\leq$7). Patients' mean HRS-D score decreased regardless of their PCPs' guideline-exposure condition (20.4 to 14.2 from baseline to 6-month follow-up; $P < .001$). However, neither continuous (HRS-D $\leq$7: 22% AC, 23% PC, 22% UC; $P = .8$) nor categorical measures of recovery ($P = .2$) differed by EMR exposure condition upon follow-up. Care processes for depression were also similar by PCP assignment despite exposure to repeated reminders of the depression diagnosis and treatment advice (e.g., depression mentioned in $\geq$3 contacts with usual PCP at 6 months: 31% AC, 31% PC, 18% UC; $P = .09$ and antidepressant medication suggested/prescribed or baseline regimen modified at 6 months: 59% AC, 57% PC, 52% UC; $P = .3$).**

CONCLUSIONS: **Screening for major depression, electronically informing PCPs of the diagnosis, and then exposing them to evidence-based treatment recommendations for depression via EMR has little differential impact on patients' 3- or 6-month clinical outcomes or on process measures consistent with high-quality depression care.**

KEY WORDS: **major depression; PRIME-MD; primary care; electronic medical records; clinical practice guidelines; intervention.**
J GEN INTERN MED 2002;17:493–503.

Major depression is among the most common problems encountered in primary care, affecting 6% to 10% of all patients who present in this setting.[1] Depressed patients experience at least as much physical and social dysfunction as those experiencing chronic physical conditions such as hypertension, diabetes, arthritis, and back pain.[2–4] Moreover, depression worsens the prognosis for other coexisting medical problems and may even lead to suicide.[5,6] Unfortunately, poorer than expected outcomes are consistently reported for depressed patients treated by primary care physicians (PCPs).[7,8] In part, this may be related to PCPs' low rate of recognizing depression and/or a lack of awareness about and failure to implement effective, guideline-based interventions.[9,10]

With the aim of improving the quality of medical care in routine practice, automated, interactive, data-driven electronic medical record (EMR) systems are currently in use that can prompt physicians to perform empirically validated patient-specific actions according to programmable rules. Physicians utilizing various EMR systems have been found to make fewer prescription,[11] test,[12] and antibiotic ordering errors,[13] and are more likely to order recommended preventive and disease management care than practitioners using non-automated records.[14–20] However, few studies have reported clinical outcomes when an EMR system is used to treat a chronic medical problem,[21,22] or a psychiatric disorder.[23]

The EMR's technical features and effectiveness in altering provider behavior through timely reminders make it an attractive modality for improving the quality of care

Received from the Division of General Internal Medicine, Center for Research on Health Care, (BLR, BHH, WNK), the Center for Biomedical Informatics (HJL), and the Department of Psychiatry, Western Psychiatric Institute and Clinic (TG), University of Pittsburgh School of Medicine, Pittsburgh, Pa; and the Department of Psychiatry, Weill Medical College, Cornell University (HCS), White Plains, NY.

Presented in part at the 13th National Institute of Mental Health International Conference on Mental Health Problems in the General Health Sector, Washington, D.C., July 12, 1999.

Address correspondence and requests for reprints to Dr. Rollman: University of Pittsburgh Medical Center, Center for Research on Health Care, Suite E-820, 200 Lothrop St., Pittsburgh, PA 15213-2582 (e-mail: rollmanbl@msx.upmc.edu).

and subsequent clinical outcomes for major depression in primary care practice. Previously, we reported that PCPs respond quickly when electronically informed of their patients' depression diagnosis (median response time: 1 day), and that when PCPs electronically indicated their agreement with the diagnosis, they were more likely to make a notation of depression in their patients' medical record and to initiate treatment for the depressive episodes at 1 month than were PCPs who disagreed with the diagnosis.[24] Still, it remains unclear whether electronic reminders presented to PCPs can actually improve patient outcomes for depression and if so, whether varying the presentation of guideline-based treatment recommendations to PCPs via EMR will improve outcomes compared to screening and feedback of the diagnosis alone.

We also reported that electronic feedback of guideline-based treatment advice for depression to PCPs had no differential impact on care processes for treating depression at 1 month following our screening procedure.[24] However, this finding should not be extrapolated to subsequent outcomes because EMR systems capable of delivering persisting, organized, and brief periodic reminders of guideline-based care could improve provider and patient adherence with appropriate care over time and thereby improve clinical outcomes. We, therefore, hypothesized that providing continuing guideline-based patient-specific treatment advice and other computerized decision support to the PCP via EMR is more likely to improve 6-month patient outcomes and care processes for depression than screening and electronic feedback of the depression diagnosis alone. We also examined the effect on our outcome measures of varying the intensity of guideline-based treatment recommendations to PCPs so as to identify the most efficient strategy for providing guideline-based advice electronically.

METHODS

Study Site

This research was conducted at the University of Pittsburgh School of Medicine's main urban practice, at which faculty physicians provide primary care. This practice is staffed by 19 PCPs board-certified in internal medicine who typically see 10 to 15 patients per half-day, with appointments scheduled at 45-minute intervals for new patients and at 15-minute intervals for returning ones.

Nine months prior to implementing our electronic guideline for major depression, Logician (Version 4.2; MedicaLogic, Beaverton, Ore)[25] was installed as the ambulatory EMR for this practice. Following each patient encounter, physicians either typed their clinical impressions directly into the EMR or dictated them into the Medical Center's central transcription service for later transcription and uploading into the EMR. In addition, physicians entered and maintained electronically their patients' problem, medication, and allergy lists.

PCPs could obtain instant access to their patients' medical information via computer terminals placed in the examination rooms, common clinic work areas, or their own office located away from the practice site. PCPs were also given a printed summary of each patient's medical problems, medications, and various care recommendations on a paper encounter form generated by the EMR for each office visit. This form was also used by clinicians to record notes and update patient information for later dictation and/or direct input into the EMR.

Participants

Primary Care Physicians. Using a protocol approved by the Institutional Review Board of the University of Pittsburgh, we recruited PCPs approximately 1 month preceding patient recruitment. Study investigators (BLR, WNK, HCS) presented highlights of the Agency for Health Care Policy and Research's (AHCPR) Depression Panel's Guideline[26] and then introduced the study to PCPs at an hour-long journal club–style conference. All 17 protocol-eligible PCPs (100%) (BLR and WNK were ineligible) subsequently provided informed consent for study participation and completed a self-report baseline assessment packet. PCPs were stratified by their number of half-day clinic sessions per week and then, within each strata, randomly assigned to one of the 3 EMR system exposure conditions (see below, Intervention Conditions) prior to the start of patient recruitment. This procedure was performed by the study statistician (BHH) using an SPSS routine (version 9.0; SPSS, Inc., Chicago, Ill) that randomly chose PCPs without replacement. Given the nature of our interventions, PCPs were not blinded to their assignment condition.

Primary Care Patients. All patients ages 18 to 64 presenting at the study site were screened for major depression with the self-administered Patient Questionnaire (PQ) portion of the Primary Care Evaluation of Mental Disorders (PRIME-MD),[27] which they completed prior to meeting with their PCP as part of routine practice. If the patient screened positive for a mood disorder on the PQ and had: (1) no obvious dementia, psychotic illness, or unstable medical condition; (2) two or fewer positive responses on the CAGE alcohol screening questionnaire[28] included on the PQ; (3) no previous enrollment in the protocol; and (4) no language or other communication barrier, a research assistant sought the patient's written consent to administer the Mood Module component of the PRIME-MD to ascertain the presence of a Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV) diagnosis of major depression.

When the PRIME-MD Mood Module assessment identified a current major depression, the research assistant asked the patient to provide a second written informed consent for the full clinical protocol. Each patient's clinical eligibility for the study was confirmed with a 40- to 60-minute baseline telephone assessment by an investigator

(TG) and a chart review by a physician-investigator (BLR). In addition to the exclusion criteria described previously, the protocol also required that the patient: (1) have a 17-item Hamilton Rating Scale for Depression (HRS-D)[29] score $\geq$12; (2) report no alcohol or other substance abuse disorder within the past 2 months; (3) have no history of bipolar disorder; (4) have no active suicidal ideation; (5) be medically stable as determined from a medical record review and the baseline telephone assessment; (6) have no plans to leave the study practice within the next 6 months; and (7) not presently be receiving treatment for depression from a mental health professional.

Electronic Notification of the Depression Diagnosis Procedure

When a patient was identified by the Mood Module as having a major depression, PCPs were notified via an interactive e-mail alert ("flag") generated through our EMR system and via an electronic letter signed by the study investigators. These messages generally were transmitted to the PCP within 1 business day of the patient's being diagnosed with a major depression. PCPs were asked to indicate whether they "agreed," "disagreed," or were "unsure" of the PRIME-MD depression diagnosis. They were also asked to electronically "sign" the letter to acknowledge its receipt, much as they would acknowledge a consult letter from another health care professional.

If the PCP agreed with the psychiatric diagnosis, a researcher entered "major depression" into that patient's electronic problem list and forwarded a flag to the clinic's scheduling secretary. This message requested that the patient be scheduled or rescheduled for a follow-up visit with the PCP within 4 weeks of the PRIME-MD assessment, if such an appointment was not already entered into the practice's electronic scheduling system. If the PCP electronically expressed uncertainty about the depression diagnosis, the researcher replied with a new flag inquiring whether the patient could be scheduled to return within a 4-week period so that the PCP could again consider the diagnosis. When the PCP indicated disagreement with the depression diagnosis, another interactive e-mail message was sent following the patient's next visit. Repeat reminders were automatically generated if the PCP did not respond to an e-mail message within 3 business days. The diagnosis of "major depression" was only added to a patient's electronic problem list when the PCP agreed with the PRIME-MD diagnosis.

Intervention Conditions

Characteristics of the 3 EMR conditions to which PCPs were randomized are presented in Table 1. "Usual care" (UC) clinicians and PCPs in the other EMR conditions who disagreed or were unsure of a patient's depression diagnosis received no additional patient-specific treatment advice or reminders of care over the course of follow-up.

Table 1. Characteristics of the EMR Interventions

PCP Exposed to:	1 Usual Care	2 Passive Care	3 Active Care
Notification of depression diagnosis via EMR	X	X	X
Depression diagnosis on patient encounter form		X	X
Patient-specific, guideline-based treatment advice on patient encounter form			X

EMR, electronic medical record; PCP, primary care physician.

"Passive care" (PC) PCPs were provided a reminder of their patients' depression diagnosis on the paper encounter form generated for each patient visit. This message encouraged the PCP to treat the depressive episode but offered no details on how to do so ("This patient diagnosed with major depression. Properly treated, depressive episodes remit sooner."). The message additionally suggested that the PCP mouse-click on a computer desktop icon if he/she wished to obtain further advice for treating depression. Doing so launched a Web browser offering the PCP detailed information for treating depression based on the AHCPR's depression treatment guideline[26] from an Intranet site developed for use in this study. PC PCPs were not exposed to any other intervention prompts nor were they advised about when to (re)schedule their patients' follow-up appointments.

"Active care" (AC) PCPs who agreed with the diagnosis were exposed to 1 or more patient-specific advisory messages on the paper encounter form generated for viewing at the time of the clinical encounter. These messages were based upon the AHCPR's practice guideline[26] and modified for electronic dissemination via our EMR system.[30] Their content varied in keeping with a PCP's earlier actions as entered into the EMR system (e.g., the patient was prescribed an antidepressant medication or referred to a mental health specialist). The clinician could also view these messages online at any time. Most advisory messages concluded with a suggestion that the clinician mouse-click on the computer desktop icon to obtain further treatment advice from our Intranet site. AC PCPs were also periodically exposed to prompts offering to schedule a follow-up appointment with their study patients. This occurred whenever the interval between follow-up appointments exceeded twice the time interval recommended by the AHCPR guideline for a given treatment phase as determined by a researcher's review of the clinicians' encounter notes.

Technical limitations within our EMR system precluded automatically launching or removing depression treatment protocols at specified time intervals in response to mental health referrals, events described in clinicians' free-text notes (e.g., the patient is experiencing a medication side effect), or according to physicians' randomization status in

our study. Therefore, a trained research assistant reviewed each patient's electronic medical record and launched or removed various advice statements ("macros") according to predefined criteria so as to simulate an "automated" experience for study clinicians. The research assistant was instructed to review each AC patient's electronic medical record and the computerized appointment schedule on a weekly basis to monitor for any changes in clinical activity. Thus, we were able to adjust our advice messages to pertinent clinical events according to information entered by the PCP into the EMR system, but were unable to do so at the time of the patient encounter. Further details on how we converted the AHCPR Depression Care guidelines to an electronic format have been described elsewhere.[30]

Patient Assessment

All study participants were contacted shortly after recruitment to confirm their protocol eligibility and to conduct a standardized telephone assessment by an interviewer who was blinded to the randomization status of a patient's PCP. These interviews assessed depression severity (HRS-D),[29] quality of life (SF-12),[31] history of past treatment for depression, comorbid anxiety disorder (PRIME-MD),[27] satisfaction with the PCP and the depression care received, as well as such sociodemographic information as age, race, gender, education, and employment status. Medical comorbidity was assessed at baseline through a review of each patient's EMR and paper chart (including non-University patient records, consult letters, etc.) for 6 months prior to the PRIME-MD date. The measure used was a simple count of the number of International Classification of Diseases, Ninth Revision (ICD-9) diagnoses assigned at each timepoint. The same blinded interviewer (TG) readministered the HRS-D at 3 and 6 months following study enrollment.

The indicators of PCP depression care at 3 and 6 months following screening with the PRIME-MD included the mean number of office visits and total contacts (including the screening visit), proportion of patients with $\geq$3 contacts, proportion of patients with $\geq$3 contacts where depression or depression treatment was mentioned, and PCP reports of counseling, prescribing of antidepressant medications, and referring their patient to a mental health specialist. Contacts included both office visits and telephone communications between the PCP and the patient that were documented in the EMR. These measures were advocated by the AHCPR's Depression Panel's treatment recommendations for intensity of clinical follow-up (e.g., 3 or more contacts within a 90-day period),[26] and are similar to those recently reported by other effectiveness trials designed to improve the quality of primary care for major depression.[7,32,33]

The type of depression-specific treatment recommended to the patient by the PCP and the number and timing of follow-up visits were abstracted directly from data entered into the EMR. Two trained nurses who were blinded to the randomization status of a patient's PCP reviewed each study patient's medical records. One nurse reviewed a printed copy of every patient's medical record collected from the study clinic, University medical center, and from specialists and non-University providers where applicable, and then completed a detailed structured abstract. Each completed abstract was then reviewed by the other nurse for completion and accuracy. Discrepancies between nurse-abstractors were brought to the attention of an investigator (BLR or BHH) for adjudication.

Statistical Analyses

Our prestudy sample size estimates were based on a 3-group design to detect a 30% difference in the proportion of patients recovered (65% vs 35%) with $\alpha = 0.05$ (2-tailed) and $\beta = 0.20$. Because the PCP was our unit of randomization, with patient outcomes nested under the PCP, we needed to increase the required sample size to account for the dependence of observations. Using an extension from 2 to 3 groups of Donner et al.'s method for dealing with dependent observations[34] with $\kappa = 0.05$, we estimated that 72 observations per group were needed.

The primary outcome measures were a patient's depression status at 3 and 6 months as measured by the 17-item HRS-D, and PCP reports of depression care in the 6 months following the date of screening with the PRIME-MD. Changes in the continuous HRS-D score from baseline to 3 and 6 months and categorized HRS-D score at 6 months were used as measures of depression recovery. We examined outcomes for all patients with an intent-to-treat analyses, as well as analyses limited to patients whose PCP had agreed with the depression diagnosis. Because our findings were unchanged by the latter approach, we only present the intent-to-treat analyses involving our full study cohort. Patient variables across the 3 levels of EMR notification were compared with χ^2 analyses. Patients' clinical status assessed with a categorized HRS-D score at 6 months was analyzed with a likelihood ratio χ^2. Changes in the continuous HRS-D scores were compared across intervention groups using random effects regression. The interaction of intervention group $\times$ time was the primary test of the impact of the study interventions on patient outcomes.

We used regression analyses to compare continuous measures (e.g., number of visits) across intervention groups and likelihood ratio χ^2 tests to compare categorical measures (e.g., proportion of patients prescribed antidepressants) across intervention groups. All analyses are adjusted for the clustering of patients under each PCP and were performed with either SPSS version 9.0 or STATA (version 6.0; Stata Corp., College Station Tex).

RESULTS

We approached 9,513 patients aged 18 to 64 between April, 1997 and December 1998 and asked them to complete the PRIME-MD PQ (Figure 1). A total of 8,302

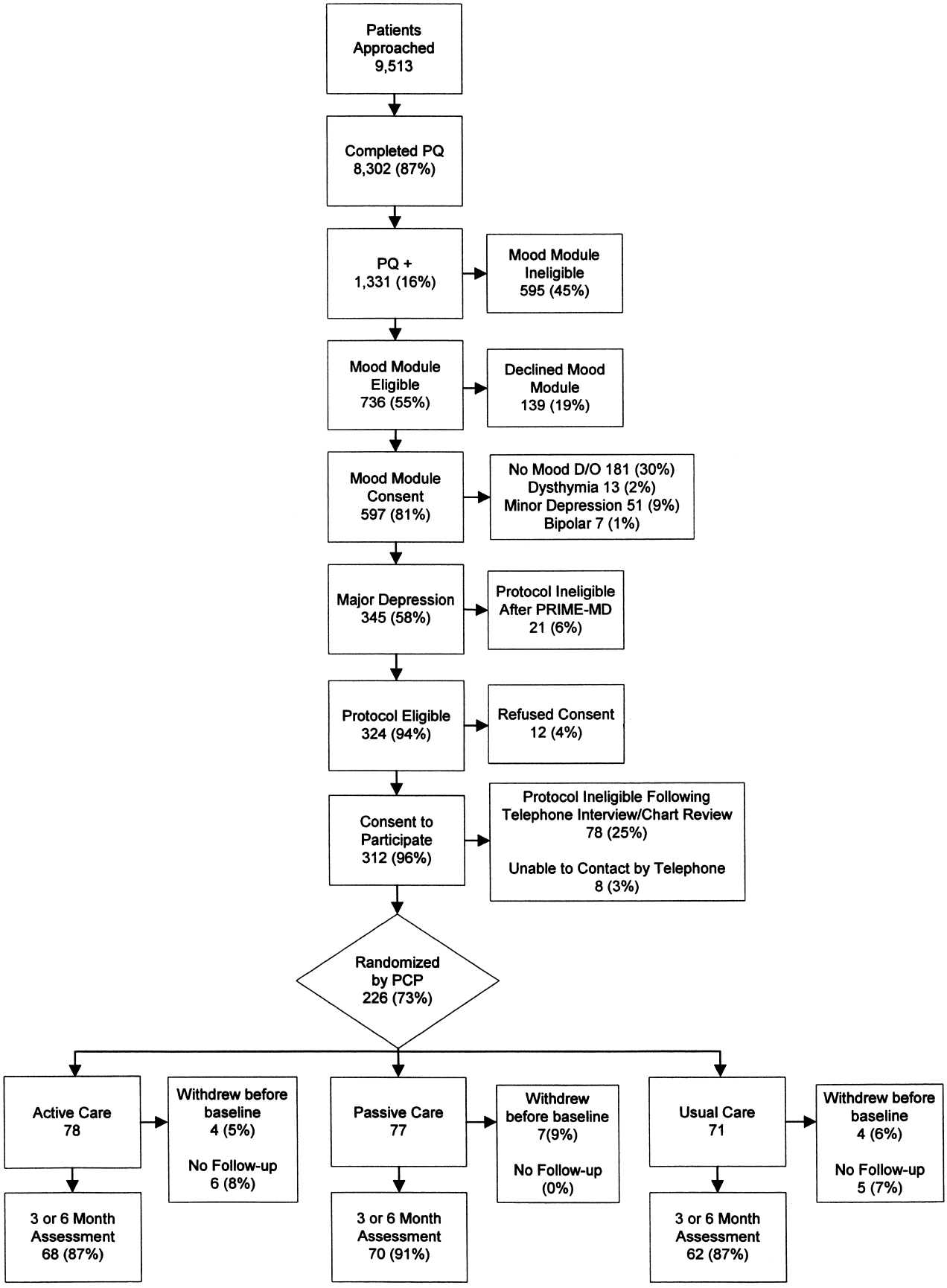

FIGURE 1. Patient recruitment.

patients (87%) did so, of whom 1,331 (16%) screened positive (PQ+) for a mood disorder. After a research assistant performed a preliminary review of the PQ+ patients' medical records, 736 (55%) were judged potentially protocol eligible, 597 (81%) completed the Mood Module, and 345 (58%) met DSM-IV criteria for a current episode of major depression. Of this group, 99 were found protocol ineligible, 12 declined to enroll in the treatment phase; we were unable to contact 8 patients to perform a baseline assessment and to confirm protocol eligibility despite multiple phone calls and follow-up postcards. The remaining 226 patients were included in the study in a manner consistent with their PCPs' earlier randomization assignment. Consequently, 78 patients were assigned to AC, 77 to PC, and 71 to UC. However, 15 (6%) of these 226 patients later withdrew their protocol consent when contacted for a telephone assessment. Of the remaining 211 patients who completed our baseline assessment, 192 (91%) had a 3-month follow-up interview, 193 (91%) had a 6-month follow-up interview, and 185 (88%) had interviews at both times. Our analyses focus on the 200 patients (95%) who completed either our 3- or 6-month telephone assessment.

Table 2 presents demographic and clinical characteristics of our study patients at baseline. Their mean age was just under 44 years (range, 19 to 64), 70% were female, and 73% were white. Although patients in our 3 EMR groups were similar on most sociodemographic variables and clinical characteristics, PC patients were more likely to be female, older, and married. There were no baseline differences between groups in measures of depression severity (HRS-D), SF-12 scores, medical comorbidity, presence of a comorbid anxiety disorder, or history of prior treatment for depression. At 3 months following the date of screening with the PRIME-MD, PCPs agreed with the finding of major depression for their patients 78% of the time. The proportion of agreement did not differ between intervention conditions.[24]

Figure 2 displays the longitudinal HRS-D scores for our full study cohort by intervention arm. Although patients' mean HRS-D scores decreased from baseline to 3- and 6-month follow-up regardless of their PCPs' guideline exposure condition (20.4 to 14.4 and 14.2, respectively; F test of the interaction of assessment time by intervention group [$F_{2,379} = 90.7$; $P < .001$]), neither overall nor categorical measure of recovery differed by EMR exposure condition or from our UC control condition ($F_{4,379} = 0.42$; $P = .80$). Moreover, there were no differences in the categorical measures of recovery at 6 months among our 3 PCP exposure groups (χ^2 [$df = 4$] = 5.63; $P = .2$) (Table 3). Thus, our "active" and "passive" electronic feedback and guideline dissemination strategies were no more effective at altering our main clinical outcome measure than was our "usual care" control condition.

We then examined whether our intervention affected various caregiving practices consistent with the AHCPR's

Table 2. Patient Demographics, Clinical History, and Satisfaction and Physician Responses to EMR Notification of the Depression Diagnoses Generated by the PRIME-MD

	Total (*N* = 200)	Active Care (*n* = 68)	Passive Care (*n* = 70)	Usual Care (*n* = 62)	*P* Value
Sociodemographic variables					
Mean age, y	43.9	44.2	46.4	40.8	.03
Female gender, *n* (%)	141 (70)	38 (56)	57 (81)	46 (74)	.003
White race, *n* (%)	145 (73)	48 (71)	50 (71)	47 (76)	.9
Education, *n* (%)					
≤High school	36 (18)	10 (15)	15 (21)	11 (18)	.2
Some college	96 (48)	40 (59)	27 (39)	29 (47)	
≥College degree	68 (34)	18 (26)	28 (39)	22 (36)	
Marital status, *n* (%)					
Single	59 (30)	25 (37)	12 (17)	22 (36)	.05
Married	77 (39)	22 (32)	35 (51)	20 (33)	
Separated/divorced/widowed	62 (30)	21 (31)	23 (33)	19 (31)	
Employment, full-time, *n* (%)	108 (54)	36 (53)	33 (47)	39 (63)	.2
Baseline clinical variables					
Mean Hamilton Rating Scale for Depression	20.4	19.7	20.7	20.7	.50
Mean SF-12 PCS Score	43.9	42.1	43.1	46.7	.1
Mean SF-12 MCS Score	34.3	35.6	33.4	33.8	.4
Past treatment for depression, *n* (%)	96 (48)	28 (41)	38 (56)	29 (47)	.2
Comorbid anxiety disorder, *n* (%)	72 (36)	25 (37)	26 (37)	21 (34)	.9
2+ comorbid medical conditions, *n* (%)	113 (57)	38 (56)	44 (63)	31 (50)	.3
At screening, *n* (%)					
Patient was returning to usual PCP	122 (61)	44 (65)	48 (69)	30 (48)	.08
Patient was seeing PCP for first visit	66 (32)	22 (32)	17 (24)	24 (39)	
Patient did not see usual PCP	15 (8)	2 (3)	5 (7)	8 (13)	

EMR, electronic medical record; PRIME-MD, primary care evaluation of mental disorders; PCS, physical component summary; MCS, mental component summary; PCP, primary care physician.

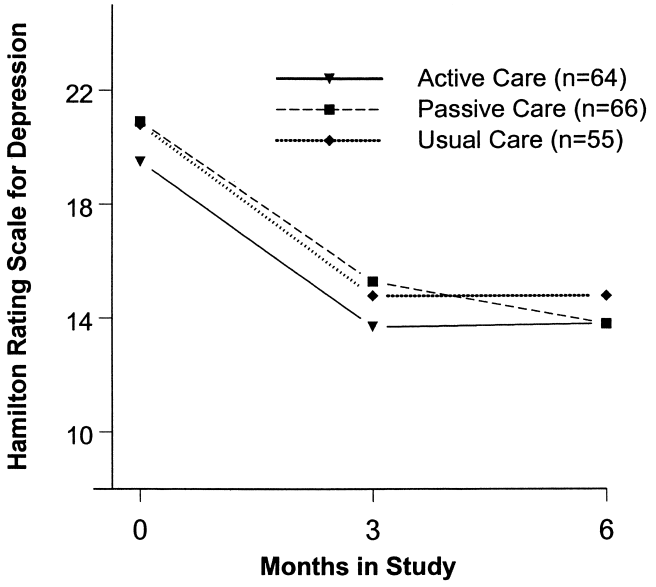

FIGURE 2. Hamilton Rating Scale for Depression for baseline, 3, and 6 months.

Depression Panel's Guideline. As portrayed in Table 4, patients of PCPs randomized to either AC or PC had both more office visits ($P = .02$) and were more likely to have ≥ 3 contacts with their usual PCP ($P = .03$) over the course of our 6-month follow-up interval than did patients in the UC condition. At 3 months following the PRIME-MD's administration, 51% of patients had seen their PCPs 3 or more times, 76% of PCPs mentioned depression in their EMR notes at least once, 21% had mentioned depression at least 3 times, and 17% had treatment for depression explicitly mentioned in 3 or more PCP contacts. However, these care process measures for depression did not differ by method of PCP exposure to guideline-based care. Although rates for each of these measures increased slightly at 6 months, again, there were no differences among the PCP exposure groups.

At 3 months, PCPs had prescribed an antidepressant for 50% of their patients while they continued their patients' pre–PRIME-MD dosage of antidepressant for another 11%. By 6 months, PCPs had prescribed an antidepressant medication for 56% of their patients and 66% of patients had used any antidepressant medication. PCPs prescribed a serotonin-reuptake inhibitor 94% of the time when using antidepressant pharmacotherapy.

Few PCPs documented counseling their patients for depression (20% at 3 months and 22% at 6 months) or had encouraged or referred them to seek care from a mental health specialist (27% at 3 months and 33% at 6 months). Of the patients referred to a mental health specialist, the vast majority also received at least 1 prescription for antidepressants (74% at 3 months and 83% at 6 months). Again, there were no differences among the PCP intervention groups in their use of antidepressants or mental health specialty care for depressed patients. Similar analyses limited to the 158 (78%) patients whose PCPs agreed with the diagnosis also indicated no significant differences in care provided across intervention groups (data not shown).

DISCUSSION

This study investigated whether screening primary care patients for major depression, electronically informing PCPs of the diagnosis, and providing evidence-based treatment recommendations for depression using an EMR system could improve the quality of patient care and 6-month clinical outcomes. We found no improvement in the depression recovery rate for our entire cohort, or any subgroup of it, when compared to previously reported outcomes for "usual care" in primary care randomized clinical trials for treating major depression.[7,32,33,35] Varying the intensity of electronic feedback to study PCPs did have a statistically significant effect on the mean number of follow-up visits at 6 months. However, we found no differential impact on recovery or on various depression care process measures compared to the impact of simple screening and feedback of the diagnosis alone. Thus, our findings are consistent with trials of other screening and non-electronic feedback strategies to improve the quality of primary care for major depression.[36–38]

It is generally accepted that feedback delivered via a well-implemented EMR system can improve the process of care by prompting receptive physicians to perform "1-time" actions such as ordering a mammogram, lipid profile, or flu vaccine, particularly when the feedback must be acknowledged.[39,40] Yet, as in this report, investigators attempting to improve outcomes for such chronic conditions as congestive heart failure[21] and diabetes[22] using EMR systems and repeated reminders also found little or no measurable impact on clinical outcomes despite earlier positive reports on the effectiveness of these systems.[41]

Table 3. Depression Status at 6 Months by Method of PCP Exposure to EMR Feedback

Depression Status	Total ($N = 193$)	Active Care ($n = 65$)	Passive Care ($n = 69$)	Usual Care ($n = 59$)
Asymptomatic (HRS-D 0–7), *n* (%)	43 (22)	14 (22)	16 (23)	13 (22)
Partially symptomatic (HRS-D 8–11), *n* (%)	40 (22)	14 (22)	16 (23)	10 (17)
Symptomatic (HRS-D $\geq$12), *n* (%)	110 (57)	37 (57)	37 (54)	36 (61)

Likelihood ratio $\chi^2(df = 4) = 5.63$; P = .22.

PCP, primary care physician; EMR, electronic medical record; HRS-D, Hamilton Rating Scale for Depression.

Table 4. Care Processes in the 6-Month Period Following Depression Screening by Method of PCP Exposure to Guideline-based Care

Care Process	Total (*N* = 200)	Active Care (*n* = 68)	Passive Care (*n* = 70)	Usual Care (*n* = 62)	*P* Value
At 3 months					
Mean office visits with usual PCP	2.19	2.41	2.24	1.87	.05
Mean contacts with usual PCP*	2.71	2.88	2.61	2.61	.8
Mean contacts with any PCP*	2.97	3.15	2.83	2.92	.8
≥3 contacts with usual PCP*, *n* (%)	102 (51)	39 (57)	35 (50)	28 (45)	.6
Depression mentioned in any contact with usual PCP*, *n* (%)	153 (76)	51 (75)	57 (81)	45 (73)	.6
Depression mentioned in ≥3 contacts with usual PCP*, *n* (%)	41 (21)	18 (27)	14 (20)	9 (15)	.5
Depression treatment mentioned in ≥3 contacts with usual PCP*, *n* (%)	34 (17)	14 (21)	12 (17)	8 (13)	.8
PCP counsels patient for depression, *n* (%)	41 (20)	16 (23)	13 (19)	12 (19)	.9
Antidepressant medication suggested/prescribed or baseline regimen modified, *n* (%)	100 (50)	37 (54)	35 (50)	28 (45)	.2
Antidepressant medication baseline regimen continued without modification, *n* (%)	22 (11)	8 (12)	11 (16)	3 (5)	
Antidepressant medication not offered, *n* (%)	78 (39)	23 (34)	24 (34)	31 (50)	
Mental health referral suggested, *n* (%)	54 (27)	14 (21)	21 (30)	19 (31)	.6
At 6 months					
Mean office visits with usual PCP	2.95	3.31	3.09	2.40	.02
Mean contacts with usual PCP*	3.78	4.01	3.70	3.61	.6
Mean contacts with any PCP*	4.32	4.68	4.10	4.18	.4
≥3 Contacts with usual PCP*, *n* (%)	115 (58)	45 (66)	44 (63)	26 (42)	.03
Depression mentioned in any contact with usual PCP*, *n* (%)	161 (80)	54 (79)	61 (87)	46 (74)	.3
Depression mentioned in ≥3 contacts with usual PCP*, *n* (%)	54 (27)	21 (31)	22 (31)	11 (18)	.09
Depression treatment mentioned in ≥3 contacts with usual PCP*, *n* (%)	43 (22)	16 (24)	16 (23)	11 (18)	.9
PCP counsels patient for depression, *n* (%)	44 (22)	17 (25)	14 (20)	13 (21)	.9
Antidepressant medication suggested/prescribed or baseline regimen modified, *n* (%)	112 (56)	40 (59)	40 (57)	32 (52)	.3
Antidepressant medication baseline regimen continued without modification, *n* (%)	20 (10)	8 (12)	9 (13)	3 (5)	
Antidepressant medication not offered, *n* (%)	68 (34)	20 (29)	21 (30)	27 (44)	
Mental health referral suggested, *n* (%)	65 (33)	18 (26)	25 (36)	22 (35)	.3

* *Includes telephone calls.*
PCP, primary care physician.

We previously reported that PCPs respond quickly to electronic feedback of their patients' diagnosis of major depression, and that response rates and agreement with the diagnosis increased with repeated electronic reminders and as PCPs became more comfortable with feedback.[24] That finding was consistent with another report that electronic feedback increases the rate at which PCPs document depression in their clinical notes compared to PCPs who are not electronically informed of the diagnosis.[23] However, even valid and pertinent EMR reminders for appropriate depression care must compete for physician attention with overt patient concerns (e.g., fatigue, insomnia, and back pain) plus the routine primary care tasks (e.g., cancer screening and managing cardiovascular disease) to be performed within the limitations of the typical 15-minute primary care encounter. Addressing these presenting complaints and somatic symptoms can distract busy PCPs from counseling their patients for depression or from delivering appropriate care.[42] Indeed, if the 6-month clinical outcomes or care processes measures for patients of PCPs randomized to either guideline exposure condition were significantly improved compared to those of "usual care" patients, one might conclude that repeated electronic reminders are necessary to alter PCP behavior and improve patient outcomes beyond that which occurs within 1 month.[24]

Management of a chronic medical condition also typically requires the physician to adjust initial treatment in keeping with the patient's subsequent experience and clinical outcome. Unfortunately, contemporary EMR systems cannot collect such data and subsequently present the physician with new treatment recommendations at the time of a follow-up clinical encounter. Effective treatment of chronic conditions requires a greater level of patient participation than does passive receipt of a 1-time recommendation for an immunization or a blood test.[43] However,

depressed individuals are often nonadherent with recommended care[8,44] and EMR systems that typically provide feedback to the physician are unable to directly activate patients to participate in their own treatment.

To the best of our knowledge, this is the first report of clinical outcomes and care processes resulting from providing PCPs with electronic feedback and ongoing treatment advice for patients with major depression or any other psychiatric condition. The validity and generalizability of our findings are strengthened by: (1) application of an evidence-based treatment guideline intended for use in primary care settings and converted to an electronic format[30]; (2) use of a commercially available EMR system running on the widely available Windows-PC computer platform; (3) administration of a depression case-finding instrument designed for use in a busy primary care setting[27]; (4) rapid feedback of the depression diagnosis to the PCP shortly after each patient's visits; (5) requiring that physicians electronically acknowledge receipt of the depression diagnosis and respond appropriately[40]; (6) limiting study participation to board-certified physicians and their patients; and (7) sufficient sample size to address our research hypothesis with adequate power and consideration of the dependence of observations under each physician.[34]

Despite these design strengths, our negative findings must be interpreted cautiously, since our study was conducted within a single, large, academically affiliated primary care practice. Yet, we are unaware of any published report indicating that patients with psychiatric distress treated by "academic" PCPs achieve clinical outcomes dissimilar to those of patients managed by "nonacademic" PCPs. We also note that although only 5 to 6 PCPs were assigned to each EMR exposure condition, we found no evidence that a single PCP unduly weighted the results for any study group.

It is also unclear whether our findings were related to the EMR's lack of effectiveness, a problem with the guideline's translation into an electronic form,[45] competing patient and provider agendas within a limited time encounter, nonadherence with our electronic prompts and reminders for care or another barrier to the use of computers by study clinicians, failure by study patients to accept their PCPs' treatment recommendations for depression, or some other limitation. Still, few PCPs documented discussing depression with their patients 3 or more times, counseling them, or advising them to see a mental health specialist for care at either 3 or 6 months following screening with the PRIME-MD. Although PCPs may deliberately choose not to document such behavior in the medical record because of stigma or some other reason,[46] our chart review indicated that the majority of patients were prescribed an antidepressant at both 3- and 6-month follow-up. Further analyses of specific PCP behaviors in response to the electronic prompts and of patients' responses to PCP recommendations are needed to address these issues.

It is conceivable that contamination of our intervention by PCPs randomized to different guideline exposure conditions compromised our ability to detect significant intergroup differences. For example, although encouraged by the investigators not to do so, study PCPs may have discussed our treatment advice with each other. Still, the recovery rate of UC patients was similar to that experienced by the UC cohort in a report from Schulberg et al.[47] Patients may also have seen a PCP on the date of the PRIME-MD who was not their usual PCP, may have switched providers within the group practice, or may have seen another PCP, who had been randomized to a different study condition, when their own PCP was unavailable (e.g., on vacation). However, we found that just 8% of study patients saw a PCP other than their usual provider on the date of the PRIME-MD's administration, and switching PCPs while remaining within the group practice was uncommon (<10%). Moreover, one third of those who switched providers when their own PCP was unavailable met with a PCP randomized to the same EMR exposure condition as their assigned PCP.

Given rapid advances in the capabilities of computer software and hardware systems, investigators using newer and more powerful EMR systems might obtain a different result than ours. Contemporary EMR systems cannot automatically identify a mental illness, as they can an abnormal laboratory result or drug–drug interaction. Therefore, the need to systematically screen patients for depression either in person,[48] by telephone,[49] or following initiation of treatment is necessary, unless the EMR is programmed to expose physicians to treatment advice following entry of critical information into the system (e.g., physician prescribes antidepressant pharmacotherapy).[32] Still, it is difficult to convert the subtleties of a paper-based treatment guideline to algorithmic form that can be interpreted by a computer system.[30] Contemporary EMR systems, such as the one used in our study site, are unable to interpret uncoded information entered as unstructured text (e.g., clinical impressions, oral recommendations, etc). To be clinically feasible, algorithm branch points must hinge on information routinely entered in the EMR system (e.g., medications, appointment dates, etc.). Although our use of the EMR was a hybrid, in that some functions were automated while others were simulated to meet the needs of a clinical trial and overcome the limitations of our EMR system, this requirement may limit the patient specificity and pertinence of computer-generated recommendations to typical care.[30,45] Future EMR systems might overcome this challenge and better involve patients in their own care[43] by requiring them to enter data into the EMR such as weight, blood pressure, blood glucose, and self-reported depressive symptoms via e-mail or over a secure Internet connection prior to their encounter with a physician. Nevertheless, despite developments in artificial intelligence, it will be difficult to imbue a computer with clinical reasoning or the logic to interpret human emotion and provide patient-specific empathy and counseling at the

time of the clinical encounter comparable to that of a trained physician.

In conclusion, we were unable to demonstrate that screening patients for major depression, electronically informing PCPs of the diagnosis, and exposing them to evidence-based treatment recommendations for depression via an EMR system improved either clinical outcomes or various care processes for depression at 6 months following our screening procedure. Our findings are consistent with other recent reports suggesting that contemporary EMR systems are more effective at triggering "1-time" events than for ongoing management of a chronic medical condition. Given the persistent need for physicians to remain current and to provide high-quality care, and given steady declines in the real costs of computer technology, studies attempting to improve the effectiveness of care for chronic medical conditions with increasingly sophisticated EMR systems remain necessary. We encourage efforts that incorporate the key principles of delivering effective chronic illness care, particularly improved care coordination and patient self-management support that activates patients to participate in their own care.[43]

The authors gratefully acknowledge the contributions of Bea Herbeck Belnap, PhD for her critical review of this manuscript and helpful comments.

This work was supported by AHCPR Grant R01 HS09421.

REFERENCES

1. Katon W, Schulberg HC. Epidemiology of depression in primary care. Gen Hosp Psychiatry. 1992;14:237–47.
2. Broadhead E, Blazer D, George L, Tse C. Depression, disability days, and days lost in a prospective epidemiologic survey. JAMA. 1990;264:2524–8.
3. Wells KB, Stewart A, Hays RD, et al. The functioning and well-being of depressed patients. Results from the Medical Outcomes Study. JAMA. 1989;262:914–9.
4. Hays RD, Wells KB, Sherbourne CD, Rogers W, Spritzer K. Functioning and well-being outcomes of patients with depression compared with chronic general medical illnesses. Arch Gen Psychiatry. 1995;52:11–9.
5. Katon W, Sullivan MD. Depression and chronic medical illness. J Clin Psychiatry. 1990;51:3–11.
6. Lin EH, Von Korff M, Wagner EH. Identifying suicide potential in primary care. J Gen Intern Med. 1989;4:1–6.
7. Schulberg HC, Block MR, Madonia MJ, et al. The 'usual care' of major depression in primary care practice. Arch Fam Med. 1997;6:334–9.
8. Simon GE, VonKorff M. Recognition, management, and outcomes of depression in primary care. Arch Fam Med. 1995;4:99–105.
9. Schulberg HC, Katon W, Simon GE, Rush AJ. Treating major depression in primary care practice: an update of the Agency for Health Care Policy and Research Practice Guidelines. Arch Gen Psychiatry. 1998;55:1121–7.
10. Perez-Stable EJ, Miranda J, Munoz RF, Ying YW. Depression in medical outpatients. Underrecognition and misdiagnosis. Arch Intern Med. 1990;150:1083–8.
11. Garrett LE Jr, Hammond LE, Stead WW. The effects of computerized medical records on provider efficiency and quality of care. Methods Inf Med. 1986;25:151–7.
12. Young DW. Improving the consistency with which investigations are requested. Med Inform (Lond). 1981;6:13–7.
13. Pestotnik SL, Classen DC, Evans RS, Burke JP. Implementing antibiotic practice guidelines through computer-assisted decision support: clinical and financial outcomes. Ann Intern Med. 1996;124:884–90.
14. McDonald CJ. Protocol-based computer reminders, the quality of care and the non-perfectability of man. N Engl J Med. 1976;292:1351–5.
15. Safran C, Rind DM, Davis RB, et al. Guidelines for management of HIV infection with computer-based patient's record. Lancet. 1995;346:341–6.
16. McAlister NH, Covvey HD, Tong C, Lee A, Wigle ED. Randomized controlled trial of computer assisted management of hypertension in primary care. BMJ. 1986;293:670–4.
17. Barnett GO, Winickoff RN, Morgan MM, Zielstorff RD. A computer-based monitoring system for follow-up of elevated blood pressure. Med Care. 1983;21:400–9.
18. McDonald CJ, Hui SL, Tierney WM. Effects of computer reminders for influenza vaccination on morbidity during influenza epidemics. MD Comput. 1992;9:304–12.
19. Dexter PR, Wolinsky FD, Gramelspacher GP, et al. Effectiveness of computer-generated reminders for increasing discussions about advance directives and completion of advance directive forms. A randomized, controlled trial. Ann Intern Med. 1998;128:102–10.
20. Dexter PR, Perkins S, Overhage JM, Maharry K, Kohler RB, McDonald CJ. A computerized reminder system to increase the use of preventive care for hospitalized patients. N Engl J Med. 2001;345:965–70.
21. Tierney W, Overhage J, Murray M, et al. Effects of computerized guidelines for outpatient management of ischemic heart disease and heart failure. J Gen Intern Med. 1999;14(suppl 2):125.
22. Karson A, Kuperman G, Horsky J, Fairchild D, Fiskio J, Bates D, Patient-specific computerized outpatient reminders to improve physician compliance with computerized guidelines. J Gen Intern Med. 2000;15(suppl 1):126.
23. Cannon DS, Allen SN. A comparison of the effects of computer and manual reminders on compliance with a mental health clinical practice guideline. J Am Med Inform Assoc. 2000;7:196–203.
24. Rollman BL, Hanusa BH, Gilbert T, Lowe HJ, Kapoor WN, Schulberg HC. The electronic medical record: a randomized trial of its impact on primary care physicians' initial management of major depression. Arch Intern Med. 2001;161:189–97.
25. Burger M. Logician, ver 4.2. JAMA. 1997;278:1380–2.
26. Agency for Health Care Policy and Research. Depression in Primary Care, Vol. 1. Detection and Diagnosis; Vol. 2. Treatment of Major Depression. Rockville, Md: U.S. Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research; 1993.
27. Spitzer RL, Williams JBW, Kroenke K, et al. Utility of a new procedure for diagnosing mental disorders in primary care: the PRIME-MD 1000 study. JAMA. 1994;272:1749–56.
28. Ewing JA. Detecting alcoholism: the CAGE questionnaire. JAMA. 1984;252:1905–7.
29. Potts MK, Daniels M, Burnam MA, Wells KB. A structured interview version of the Hamilton Depression Rating Scale: evidence of reliability and versatility of administration. J Psychiatr Res. 1990;24:335–50.
30. Rollman BL, Gilbert T, Lowe HJ, Kapoor WN, Schulberg HC. The electronic medical record: its role in disseminating depression guidelines in primary care practice. Int J Psychiatry Med. 1999;29:267–86.
31. Ware JE Jr, Kosinski M, Keller SD. A 12-item short-form health survey: construction of scales and preliminary tests of reliability and validity. Med Care. 1996;34:220–33.
32. Simon GE, VonKorff M, Rutter C, Wagner E. Randomised trial of monitoring, feedback, and management of care by telephone to

improve treatment of depression in primary care. BMJ. 2000;320:550–4.
33. Wells KB, Sherbourne C, Schoenbaum M, et al. Impact of disseminating quality improvement programs for depression in managed primary care: a randomized controlled trial. JAMA. 2000; 283:212–20.
34. Donner A, Birkett N, Buck C. Randomization by cluster: sample size requirements and analysis. Am J Epidemiol. 1981;114:906–14.
35. Katon W, Von Korff M, Lin E, et al. Collaborative management to achieve treatment guidelines. Impact on depression in primary care. JAMA. 1995;273:1026–31.
36. Linn LS, Yager J. The effect of screening, sensitization and feedback on notation of depression. J Med Educ. 1980;55:942–9.
37. Shapiro S, German PS, Skinner EA, et al. An experiment to change detection and management of mental morbidity in primary care. Med Care. 1987;25:327–39.
38. Magruder-Habib K, Zung WW, Feussner JR. Improving physicians' recognition and treatment of depression in general medical care. Results from a randomized clinical trial. Med Care. 1990;28: 239–50.
39. Balas E, Weingarten S, Garb C, Blumenthal D, Boren S, Brown G. Improving preventive care by prompting physicians. Arch Intern Med. 2000;160:301–8.
40. Litzelman DK, Dittus RS, Miller ME, Tierney WM. Requiring physicians to respond to computerized reminders improves their compliance with preventive care protocols. J Gen Intern Med. 1993;8:311–7.
41. Hunt DL, Haynes RB, Hanna SE, Smith K. Effects of computer-based clinical decision support systems on physician performance and patient outcomes. JAMA. 1998;280:1339–46.
42. Rost K, Nutting P, Smith J, Coyne JC, Cooper-Patrick L, Rubenstein L. The role of competing demands in the treatment provided primary care patients with major depression. Arch Fam Med. 2000;9:150–4.
43. Wagner EH, Austin BT, Von Korff M. Organizing care for patients with chronic illness. Milbank Q. 1996;74:511–44.
44. Lin EH, Von Korff M, Katon W, et al. The role of the primary care physician in patients' adherence to antidepressant therapy. Med Care. 1995;33:67–74.
45. Tierney WM, Overhage JM, Takesue BY, et al. Computerizing guidelines to improve care and patient outcomes: the example of heart failure. J Am Med Inform Assoc. 1995;2:316–22.
46. Rost K, Smith R, Matthews DB, Guise B. The deliberate misdiagnosis of major depression in primary care. Arch Fam Med. 1994;3:333–7.
47. Schulberg HC, Block MR, Madonia MJ, et al. Treating major depression in primary care practice. Eight-month clinical outcomes. Arch Gen Psychiatry. 1996;53:913–9.
48. Spitzer R, Kroenke K, Williams J. Validation and utility of a self-report version of the PRIME-MD. The PHQ Primary Care Study. JAMA. 1999;282:1737–44.
49. Kobak KA, Taylor LH, Dottl SL, et al. A computer-administered telephone interview to identify mental disorders. JAMA. 1997;278: 905–10.