ORIGINAL ARTICLES

Improving Depression Outcomes in Community Primary Care Practice

A Randomized Trial of the QuEST Intervention

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OBJECTIVE: **To determine whether redefining primary care team roles would improve outcomes for patients beginning a new treatment episode for major depression.**

DESIGN: **Following stratification, 6 of 12 practices were randomly assigned to the intervention condition. Intervention effectiveness was evaluated by patient reports of 6-month change in 100-point depression symptom and functional status scales.**

SETTING: **Twelve community primary care practices across the country employing no onsite mental health professional.**

PATIENTS: **Using two-stage screening, practices enrolled 479 depressed adult patients (73.4% of those eligible); 90.2% completed six-month follow-up.**

INTERVENTION: **Two primary care physicians, one nurse, and one administrative staff member in each intervention practice received brief training to improve the detection and management of major depression.**

MAIN RESULTS: **In patients beginning a new treatment episode, the intervention improved depression symptoms by 8.2 points (95% confidence interval [CI], 0.2 to 16.1; *P* = .04). Within this group, the intervention improved depression symptoms by 16.2 points (95% CI, 4.5 to 27.9; *P* = .007), physical role functioning by 14.1 points (95% CI, 1.1 to 29.2; *P* = .07), and satisfaction with care (*P* = .02) for patients who reported antidepressant medication was an acceptable treatment at baseline. Patients already in treatment at enrollment did not benefit from the intervention.**

CONCLUSIONS: **In practices without onsite mental health professionals, brief interventions training primary care teams to assume redefined roles can significantly improve depression outcomes in patients beginning a new treatment episode. Such interventions should target patients who report that antidepressant medication is an acceptable treatment for their condition. More research is needed to determine how primary care teams can best sustain these redefined roles over time.**

KEY WORDS: **primary care; depression; outcomes; quality.**
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Researchers have tested a range of interventions to improve primary care management of major depression to address the poor outcomes these patients often achieve.[1–6] The most successful of these interventions have utilized mental health professionals as part of multifaceted interventions to provide extended consultation on medication management[7–9] or to provide psychotherapy in the primary care setting.[10,11] While impressive, these models may be difficult to disseminate widely since only one third of primary care physicians work in practices with onsite mental health professionals.[12] In addition, few practices without onsite mental health professionals have reimbursement arrangements to support collaborative care. More transportable interventions have trained primary care nurses/extenders to monitor medication response[13,14] or to provide brief psychotherapy.[15,16] Building on these latter studies, we tested the Quality Enhancement by Strategic Teaming (QuEST) intervention. The QuEST intervention redefined roles across the primary care team to improve the detection and management of major depression without the assistance of an onsite mental health professional. Incorporating strengths from effectiveness studies, we tested the intervention with primary care professionals in community practices caring for patients meeting criteria for major depression, the population described in the Agency for Health Care Policy and Research (AHCPR) Guidelines.[17,18]

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The primary objective of the study was to evaluate the effect of the QuEST intervention on the process and outcomes of care provided to this heterogeneous group of primary care patients with major depression. We anticipated the intervention would be more effective in improving outcomes among patients beginning a new treatment episode, because patients who remained depressed after treatment might be more treatment-resistant. Neither the AHCPR Guidelines nor the QuEST intervention provided evidence-based recommendations for treatment-resistant patients since efficacy trials are only now beginning to define the treatment these patients need. Because patient treatment preferences have a significant impact on the quality of care depressed primary care patients receive,[19] we also anticipated that the intervention's effect on outcomes would be more observable in the patients who reported at baseline that antidepressant medication was an acceptable treatment for their problem.

METHODS

Our methods, which have been described in detail elsewhere,[20] are summarized here. Following approval by the Human Research Advisory Committee of the University of Arkansas for Medical Sciences and the Colorado Multi-Institutional Review Board, the research team conducted the study in 12 community primary care practices, none of which employed onsite mental health professionals. The 12 practices were matched into 6 blocks by depression treatment practice patterns before 1 practice from each block was randomly assigned to receive the enhanced care intervention.

The goal of the QuEST intervention was to increase the proportion of primary care patients with current major depression who completed a course of pharmacotherapy and/or psychotherapy concordant with AHCPR Guidelines.[18] The intervention encouraged physicians to select the type of treatment the patient preferred (except in relatively rare instances where the preferred treatment was contraindicated), but did not require physicians to deliver guideline-concordant care. Before patient recruitment began, two physicians and one nurse from each enhanced care practice participated in a series of four 90-minute conference calls over a 2-month period. One nurse from each enhanced care practice completed an 8-hour session to train her to provide the clinical services described below. One administrative staff person from each enhanced and usual care practice completed an 8-hour training session in patient recruitment using two-stage screening.[21,22] Total training costs for physicians, nurses, and administrative staff averaged $4,661 per enhanced care practice.[20]

Administrative staff persons from enhanced and usual care practices recruited 479 subjects meeting DSM-IIIR criteria for major depression in the past 2 weeks[20] before patients saw the doctor at the index visit. Study criteria did not exclude depressed patients currently under treatment. If enhanced care physicians concurred with the diagnosis, they asked patients to schedule a return visit in the next week. Immediately before this return visit, the nurse in enhanced care practices re-assessed each patient's depressive symptoms, provided education about preferred treatments, asked patients to complete homework assignments to increase/maintain their readiness to engage in active treatment,[23] and arranged a subsequent time to follow up with the patient. Patients then proceeded to see the physician who initiated and/or adjusted treatment as needed in this return visit. Nurses used a similar protocol to follow patients over the next 8 weeks. Logs documented that nurses conducted at least one session with 221 (92.5%) patients in the enhanced care condition, contacting patients an average of 5.2 times (SD, 1.9) during the first 8 weeks following the index visit.[20] After training was completed, we estimate that practices spent an average of $12 in administrative staff time to identify each patient meeting study criteria for major depression and an average of $61 to deliver the intervention to each depressed patient participating in the program.[20] Usual care physicians were not informed which patients were participating in the study, nor did usual care nurses meet on a regular basis with depressed patients.

All data at baseline and at 6-month follow-up were collected by telephone using structured instruments administered by an independent member of the research team. Subjects completed baseline interviews an average of 8.4 days following the index visit, before new treatments could be expected to have a substantial effect on patient symptoms. The interviewer was blinded to the subject's condition except in 5 follow-up interviews when the interviewer needed to contact the practice to get updated locator information. Major variables in the study were operationalized as follows:

Process of Care

We evaluated whether patients received pharmacotherapy and psychotherapy concordant with AHCPR guidelines from patient reports at 6-month follow-up. Pharmacotherapy was defined as guideline-concordant if the patients reported that they had taken an antidepressant medication at or above the minimum dose (available from the authors on request) for at least 3 months using a series of questions demonstrated to have excellent test–retest reliability.[24] We used 3 months as the minimum acceptable duration in order to compare our results to previous interventions[7] and to be congruent with a critical component of the National Committee for Quality Assurance's Health Plan Employer Data and Information Set (HEDIS) performance measure for antidepressant medication management. We defined guideline-concordant psychotherapy as making 8 or more specialty care visits which included counseling over a 6-month period. This operationalization is more successful in capturing evidence-based recommendations about the quantity of

psychotherapy needed to improve depression outcomes[25,26] than in measuring variations in the quality of psychotherapy patients received. Primary care referral to a mental health specialist was measured by asking patients whether a medical provider had recommended they go to another doctor or therapist for counseling or treatment during the past 6 months.

Outcomes of Care

Depression severity was measured by a modified 23-item Center for Epidemiologic Studies — Depression scale (mCES-D).[27] The scale was constructed by removing 7 CES-D items that did not directly parallel DSM-IV criteria for major depression and creating an additional 10 items to measure DSM-IV criteria not assessed in the original CES-D. The modified scale was then standardized on a 100-point scale with high scores reflecting more severe depressive symptoms. Physical role functioning was measured by a 100-point subscale of the SF-36[28] that was scored so that higher scores indicated better functioning. Satisfaction was measured by asking patients, "How satisfied were you with the health care available to you for personal or emotional problems in the past 6 months?", dichotomizing responses on a 5-point scale to satisfied versus neutral/dissatisfied.[7]

Covariates

Sociodemographic and clinical covariates were collected for each subject at baseline. Sociodemographic covariates in the analyses included age, gender, minority status (minority vs not), education (high school graduate vs not), employment for pay (full/part-time vs not), marital status (currently married vs not), and annual income adjusted by family size. Clinical covariates included physical comorbidity, dysthymia during the past year, and role functioning. Physical comorbidity was measured by summing the number of 14 chronic physical conditions the subject reported at baseline, and coded as two or more, one, or zero comorbidities. Dysthymia was measured by meeting criteria on the World Health Organization-Composite International Diagnostic Interview (WHO-CIDI) for dysthymia[21] within the last year. Role functioning was measured by three items on the SF-36 scale[28] measuring perceived limitations in usual daily activities in the past month related to emotional problems.

We conducted intent-to-treat analyses, comparing process and outcome measures of interest between enhanced and usual care patients stratified by recent treatment, controlling for all covariates noted above. We used SAS 8.0 to run multilevel (hierarchical) models[29] in which patients were nested within physicians and physicians were nested within practices to account for any intraclass correlation at the physician and practice levels. When the multilevel model indicated that there was no variation in the outcome of interest by practice and physician, the model simplified to the usual fixed effects regression model. We evaluated the effect of the intervention by generating a predicted value of the dependent variable (change in scores created by subtracting 6-month responses from baseline scores) for each individual—first as an enhanced care subject and then as a usual care subject—to standardize the intervention comparison to the characteristics of the complete analytic sample, and then averaged across individuals. To test our hypotheses, we stratified the sample to test the model in patients beginning a new treatment episode and in patients recently treated. Patients were characterized as beginning a new treatment episode if they reported they had not taken antidepressant medication in the past month or made one or more specialty care visits in the past 6 months. Patients beginning a new treatment episode were stratified a second time by whether they accepted antidepressant medication before the intervention began. We determined that we needed to recruit 480 patients (half of whom we expected would be beginning a new treatment episode) to have more than 85% power to detect an intervention effect of 0.40 on depression severity using a two-sided t-test of $P < .05$ when we analyzed the two groups separately.

RESULTS

Patient Participants

As Figure 1 displays, administrative staff recruited 73.4% (479/653) of patients identified as eligible into the study. Subjects in the study were 42.6 years old (SD, 13.1) on average, 83.9% female, 15.7% minority, 79.1% high school educated, 55.5% employed full or part time, 84.1% health insured, and reported an average of 6.7 of the 9 DSM-IIIR criteria in the past 2 weeks. Compared to eligible non-participants, the 479 participants were younger (42.6

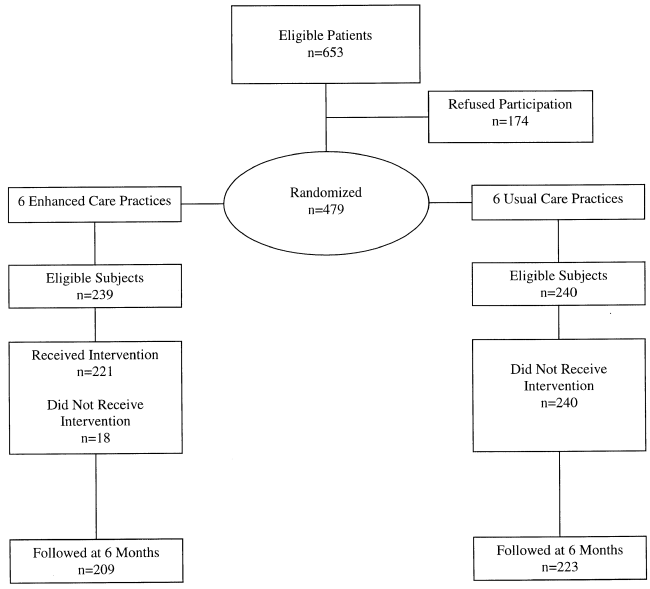

FIGURE 1. Profile of randomized controlled trial.

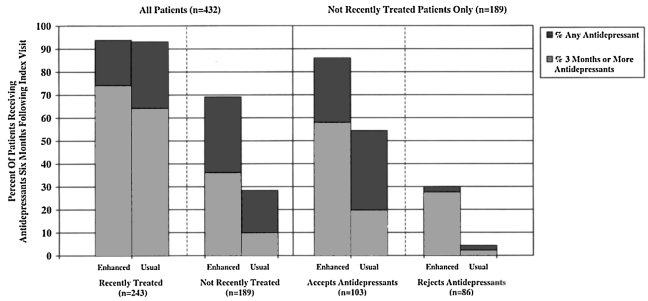

FIGURE 2. Intervention effects on pharmacotherapy.

years compared to 45.6 years, $P = .03$), more likely to be minority (15.7% vs 8.0%, $P = .01$), more likely to be female (83.9% vs 73.6%, $P = .003$), and reported more symptoms (6.7 symptoms compared to 6.4, $P = .02$). Compared to the 240 subjects in usual care practices, the 239 subjects in the enhanced care practices were younger (41.4 vs 43.9, $P = .04$), reported lower incomes per household member ($8,982 vs $11,917, $P = .02$), and had somewhat fewer comorbid physical conditions (1.9 vs 2.2, $P = .08$). The research team collected 6-month data on 90.2% (432/479) of the baseline cohort at follow-up. Compared to the 47 patients lost to follow-up, the 432 patients completing follow-up were clinically and sociodemographically similar except that each additional year of age decreased the odds of dropout by 4% ($P = .002$).

Intervention Effects on the Process of Care

We evaluated the intervention's effect on pharmacotherapy and psychotherapy in two patient groups: patients beginning a new treatment episode and recently treated patients.

Pharmacotherapy in Patients Beginning a New Treatment Episode. As Figure 2 displays, the intervention increased any pharmacotherapy (69.1% vs 28.3%; odds ratio [OR] = 5.59; $P = .0001$) and guideline-concordant pharmacotherapy (36.1% vs 9.8%; OR = 5.13; $P = .0003$) in patients beginning a new treatment episode. Within this group, the intervention increased any pharmacotherapy (86.0% vs 54.4%; OR = 4.93; $P = .007$) and guideline-concordant pharmacotherapy (57.9% vs 19.6%; OR = 6.14; $P = .003$) in patients who reported that antidepressant medications were an acceptable treatment. The intervention unexpectedly increased any pharmacotherapy (30.0% vs 4.35%; OR = 9.74; $t = 2.31$; $P = .02$) and guideline-concordant pharmacotherapy (27.5% vs 2.2%; OR = 17.9; $t = 2.06$; $P = .04$) in patients who reported that antidepressants were *not* an acceptable treatment.

Pharmacotherapy in Recently Treated Patients. The intervention had no effect on any pharmacotherapy or guideline-concordant pharmacotherapy in recently treated patients. Of note, 72.8% of patients in the recently treated group reported taking guideline-concordant doses of antidepressant medication during the month before the index visit.

Psychotherapy in Patients Beginning a New Treatment Episode. The intervention failed to increase psychotherapy referral (22.7% vs 14.1%; OR = 1.83; $P = .21$) or guideline-concordant psychotherapy (3.1% vs 1.1%; OR = 3.48; $P = .33$) in patients beginning a new treatment episode, regardless of whether they accepted antidepressant medication.

Psychotherapy in Recently Treated Patients. While the intervention had no effect on psychotherapy referral (51.8% vs 45.0%; OR = 1.31; $P = .32$), it did increase guideline-concordant psychotherapy (31.3% vs 19.1%; OR = 1.93; $P = .05$) in recently treated patients.

Guideline-concordant Pharmacotherapy and/or Psychotherapy. The intervention increased the odds of guideline-concordant pharmacotherapy and/or psychotherapy in patients beginning a new treatment episode (42.3% vs 12.0%; OR = 5.68; $P = .0001$). The intervention had no effect on this measure in the recently treated group (82.1% vs 74.8%; OR = 1.54; $P = .31$).

Table 1. Intervention Effects on Depression Severity

	All Patients ($n = 432$)				Beginning New Treatment Episode ($n = 189$)			
	Recently Treated ($n = 243$)		Beginning New Treatment Episode ($n = 189$)		Accepts Antidepressants ($n = 103$)		Rejects Antidepressants ($n = 86$)	
	Enhanced	Usual	Enhanced	Usual	Enhanced	Usual	Enhanced	Usual
Baseline mCESD	56.9	57.4	55.1	52.7	57.9	53.6	50.8	52.1
Six month mCESD	42.4	46.4	33.4	39.2	31.5	43.4	35.5	35.7
Decrease in mCESD	14.5	11.0	21.7	13.5	26.4	10.2	15.3	16.4
Decrease in mCESD attributable to intervention	3.5		8.2*		16.2**		−1.1	

* $P < .05$.
** $P < .01$.

Intervention Effects on the Outcomes of Care

We evaluated the effect of the intervention on change in depression symptom severity, physical role functioning, and satisfaction with care available for emotional problems in patients beginning a new treatment episode and in recently treated patients.

As Table 1 shows, the intervention increased improvement in depressive symptoms by 8.2 points (95% CI, 0.2 to 16.1; $P = .04$, a 15% reduction in baseline symptoms equivalent to a 0.43 effect size) in patients beginning a new treatment episode. The improvement in depressive symptoms occurred primarily in patients who reported antidepressant medications were acceptable. These patients reported a 16.2-point improvement in depressive symptoms (95% CI, 4.5 to 27.9; $P = .007$), a 27% reduction in baseline symptoms equivalent to a 0.83 effect size), a 14.1-point improvement in physical functioning (95% CI, −1.1 to 29.2; $P = .07$) and significantly enhanced satisfaction with care ($P = .02$). The intervention diminished physical functioning by 20.3 points in patients who rejected antidepressant medication (95% CI, −1.32 to −39.2; $P = .03$) but had no effect on any other outcome.

The intervention had no effect on any outcome in recently treated patients.

DISCUSSION

The purpose of this study was to test a transportable intervention of modest cost to enhance guideline-concordant care for major depression in patients visiting primary care clinics that did not employ an onsite mental health specialist. The QuEST intervention increased the proportion of depressed patients who received care as recommended in the guidelines by 1) engaging patients beginning a new treatment episode to take a 3-month course of antidepressant medication and 2) encouraging patients who were symptomatic despite treatment at baseline to seek extended specialty care counseling.

As we hypothesized, the QuEST intervention improved outcomes in depressed patients beginning a new treatment episode, primarily in those patients who initially noted antidepressant medication was an acceptable treatment. Among this subgroup (which constitutes approximately 24% of depressed patients in the practices we studied), depressive symptoms diminished by 27% on average. Enhanced satisfaction with care and somewhat improved physical functioning were also reported. The QuEST intervention's effect on treatment response in these patients is comparable to early collaborative care interventions[7,30] and greater than other primary care nurse interventions[13] tested in this subgroup.

The intervention did not improve outcomes in patients who reported that antidepressant medication was *not* an acceptable treatment at the beginning of a new treatment episode (a subgroup which constitutes approximately 20% of depressed patients in the practices we studied). Although the training encouraged the primary care team to initiate the treatment the patient preferred, many enhanced care patients who initially reported that antidepressant medication was not an acceptable treatment were convinced to start pharmacotherapy anyway. Depression symptoms in both the enhanced and usual care conditions improved more than 30% in this subgroup; however, physical role functioning declined in enhanced care patients, perhaps in part due to medication side effects. Patient attitudes regarding antidepressant medication appear to identify a subgroup of patients whose depressive symptoms improve over 6 months with usual care[31] and whose physical functioning declines with additional emphasis on pharmacotherapy. Longitudinal studies indicate that while many untreated primary care patients with major depression temporarily improve, they are vulnerable to relapse within one year.[1] Rather than actively encouraging patients who do not want antidepressant medication to begin a course of pharmacotherapy, primary care teams may achieve more over the long run by educating these patients to seek help from the primary care physician or a specialty care counselor as soon as patients feel their symptoms may warrant treatment.

As we suspected, the intervention did not improve outcomes in patients who were depressed despite recent treatment, even though it did encourage these patients to make extended specialty care visits with counseling as the guidelines encourage.[18] Depressive symptoms in this subgroup (constituting approximately 56% of patients in the study) declined less than 20% despite the fact that three out of four patients completed a course of care in seeming accordance with the guidelines. Several explanations for this high rate of continuing symptoms with or without the intervention deserve further exploration. First, because the study was designed to answer other research questions, it is possible that we did not have sufficient power to observe the impact these additional specialty care counseling visits had on outcomes. Second, enhanced care patients who received this additional counseling may not have received evidence-based psychotherapy, because many of the mental health professionals who provide counseling to depressed patients were trained before the efficacy of specific psychotherapeutic approaches for depression was firmly established. Third, patients who fail medication trials may benefit from trying a different antidepressant more than from referral for specialty care psychotherapy, given the evidence from a recent study on the treatment of persistent depression.[32] We also recognize that there may be no known effective medication or psychotherapy treatments for this sizable number of primary care patients who remain symptomatic after multiple treatments. These non-responders may represent the accumulation over time of the 25% of primary care patients whose depression fails to respond despite compliance to high quality medication management[7,10] and/or psychotherapy regimens.[10]

We believe our findings have strong internal validity because we utilized a randomized block design to evaluate

the intervention's ability to improve the process and outcomes of care with an intent-to-treat analysis. We cannot, however, identify which component(s) of the intervention account for the improved outcomes we observed, although previous experimental research[33,34] allows us to confidently rule out that feeding back the diagnosis alone had an impact on outcomes. Future investigations can address this limitation by employing richer experimental designs to determine which components of quality care interventions are essential to improve outcomes. Because patients in this study were members of more than 250 health plans, we had to rely on 6-month recall to identify the type and amount of pharmacotherapy and psychotherapy patients received. The measurement error associated with this strategy limits our ability to draw definitive comparisons about pharmacological treatment received compared to previous studies which were able to abstract pharmacy records[7] or get biological confirmation of medication compliance.[10] Similarly, we recognize that effectiveness studies lack validated methods for rating the quality of psychotherapy in routine care settings. Despite these drawbacks, self-reported process indicators should not seriously bias experimental comparisons within our study. The high rates of guideline-concordant care we observed in usual care patients highlight the difficulty in relying exclusively on an experimental design to determine whether the AHCPR guidelines are appropriate and effective. Supplementary as-treated analyses will be useful in drawing more precise conclusions about the effectiveness of the AHCPR guideline recommendations.

The external generalizability of our findings is strengthened because we tested the intervention on a clinically and sociodemographically diverse group of primary care patients targeted by the AHCPR guidelines. Our recruitment methods identified 7.0% of patients screened at the time of a visit as meeting the study's eligibility criteria for major depression, well within the 4.8% to 8.6% prevalence range for major depression reported across multiple primary care settings.[17] In addition, we tested the intervention in an organizationally diverse group of primary care practices across the country. Physician-nurse teams in these practices successfully incorporated the intervention into their daily clinical responsibilities, logging an average of 5.2 contacts for 92% of enhanced care patients. It is important to note, however, that primary care teams in our study could not continue systematic screening, education, and monitoring after the study ended because of competing demands for the staff's attention.[20] This 'finding' suggests that managed care plans that deliberately shift responsibility for depression management from specialty settings to primary care practice need to reallocate (rather than reabsorb) part of the specialty care budget to primary care practice so that primary care teams can systematically identify depressed patients, educate them about their treatment options, and monitor their response over time; otherwise, such a shift in responsibility may well result in suboptimal health and economic outcomes.[35]

While the QuEST intervention can enhance the ability of primary care teams without onsite mental health professionals to treat patients beginning new episodes of care for depression, analyses comparing this intervention to a number of alternative models in the field are planned to identify the most cost-effective methods to improve care. As these findings demonstrate, the field will only be able to make meaningful comparisons using statistical adjustments to compare interventions in clinically and attitudinally similar patient populations. These studies should also evaluate the effect of primary care depression interventions on physical disease outcomes to explore whether focusing on depression treatment promotes better or worse outcomes for the range of health problems patients bring to the visit.

Thus, this trial demonstrates that in practices employing no onsite mental health professional, a brief structured intervention encouraging primary care teams to enhance medication management of patients beginning a new treatment episode for depression will improve outcomes for patients who accept antidepressant medication at baseline. Patients who reject antidepressant medication appear to improve over the short-term with the treatment provided by usual care. Supplementing high quality primary care depression treatment with psychiatric consultation may be critical to improving outcomes in patients whose depression persists despite guideline-concordant care.

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