

# A CQI Intervention To Change the Care of Depression: A Controlled Study

**CONTEXT.** Although new strategies for managing depression in primary care (e.g., nurse telephone calls, collaborative care) have been shown to be effective, no models are available for their systematic implementation in the “real world.”

**OBJECTIVE.** To test whether a continuous quality improvement (CQI) intervention could be used to implement systems in primary care clinics to improve the care and outcomes for patients diagnosed with depression.

**DESIGN.** Before–after study with concurrent controls.

**INTERVENTION.** A multidisciplinary team from the three intervention clinics developed and implemented a graded set of five care management options, ranging from watchful waiting (nurse telephone call in 4 to 6 weeks) to mental health management, which clinicians could order for their patients with depression.

**SETTING.** 9 primary care clinics in greater Minneapolis–St. Paul, Minnesota.

**PATIENTS.** Outpatients 18 years of age and older whose primary care clinic visit included an International Classification of Diseases, 9th revision, code for depression and who completed baseline and 3-month follow-up surveys before and after the intervention.

**MAIN OUTCOME MEASURES.** Measures of process of care (follow-up depression visits to physician, mental health visits, follow-up telephone calls) and outcomes of care (improved depression symptoms over 3 months, satisfaction with care).

**RESULTS.** Although the CQI team appeared to function well, only 30 of the 257 patients identified from depression-coded visits for this study were referred to the new system during the 3-month evaluation period. In both the intervention and control clinics, follow-up visits, mental health referrals, and follow-up telephone calls did not improve significantly from the preintervention levels of about 0.5 for a primary care visit, 0.4 for a mental health visit, or 0.1 for a follow-up phone call per person. The same was true of patient outcomes: The proportion of patients in the intervention and control clinics who had improved depression symptoms and those who were very satisfied with their depression care did not change significantly from the preintervention levels of 43% and 26%, respectively.

**CONCLUSIONS.** Our attempt to improve the primary care management of depression failed because physicians used the new order system so infrequently. Whether a greater leadership commitment to change or a different improvement process would alter our findings is an open question.

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## ORIGINAL ARTICLE

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**A**growing body of evidence suggests that a variety of primary care management strategies can improve outcomes for depressed patients.<sup>1-6</sup> One example, collaborative care, which includes frequent visits with both a primary care physician and psychiatrist, continued surveillance of adherence to medication, and patient education, has shown improved medication adherence and depression outcomes for patients with major depression.<sup>1</sup> Problem-solving therapy by primary care physicians (e.g., six sessions lasting a total of 3.5 hours) has also been shown to work about as well as antidepressant medications in randomized trials.<sup>2, 3</sup> Three randomized trials have reported that systematic supportive follow-up telephone calls by nurses or other non-mental health professionals can improve depression more than usual care.<sup>4-6</sup> Hunkeler and colleagues' study<sup>4</sup> highlighted the importance of nurse follow-up by showing that patients receiving nurse telephone calls had greater improvement in their depression despite no change in adherence to antidepressant medications.

While the preceding studies suggest that these effective management strategies should be incorporated into primary care,<sup>7</sup> this does not typically happen. The basic challenge is creating and maintaining a system that ensures that these strategies are adopted in real life, without the artificial support of a research project. Many studies suggest the need for building an organized office system to improve preventive services or chronic disease.<sup>8-13</sup> Studies of guideline implementation prove that the usual strategies to change the behavior of individual clinicians are weak or ineffective and that organizational change is needed.<sup>14</sup> Educational strategies directed at physicians have minimal or no effect on depression care, although they may be useful supplements to more broadly based change efforts.<sup>15-18</sup> RAND's recent randomized, controlled effectiveness trial for organizational change involved six managed care plans as collaborating sponsors of change in 30 primary care clinics.<sup>19, 20</sup> In this trial, an intervention consisting of institutional commitment, training to set up the system, training of staff nurses to provide follow-up, and development of patient registries improved depression and work productivity. This intervention was called a quality improvement (QI) program, but because the actual change process was not described it is hard to know how much of the change was due to research personnel.<sup>21-24</sup>

Our multispecialty care system has been concerned about the cost and quality of care for depression. Although our recent effort to move mental health therapists into primary care clinics probably improved care,<sup>25</sup> this care was still neither systematic nor comprehensive. Aware of the importance of an office-systems approach, organizational leaders used modern QI methods to design and imple-

ment a depression care system.<sup>7</sup> We conducted a controlled trial called DIAMOND (Depression Is A MANageable Disorder) to evaluate this system in three volunteer intervention primary care clinics and six similar control clinics. We hypothesized that depressed patients in intervention clinics would have greater improvements in the process of care (e.g., appropriate follow-up, mental health referral) and outcomes (e.g., depression symptoms, satisfaction with care). To make this trial closer to real-life conditions, the evaluation focused on all patients who had received a diagnosis of depression rather than those who were screened and cared for by a research protocol.

## Methods

### Overview

We designed a nonrandomized, before-after study of a continuous quality improvement (CQI) intervention with concurrent controls. **Figure 1** shows the overall design and patient recruitment for the study. The care system being studied has 18 primary care clinics in the metropolitan Twin Cities (Minneapolis and St. Paul) area of Minnesota. Specialty mental health care is provided in off-site mental health facilities and by mental health therapists who work part-time in primary care clinics.<sup>26</sup> The medical group's leader for primary care recruited three clinics by asking the clinic leaders for volunteers. Six clinics were selected as controls because they had similar on-site mental health professionals, similar numbers of primary care clinicians, and similar geriatric populations.

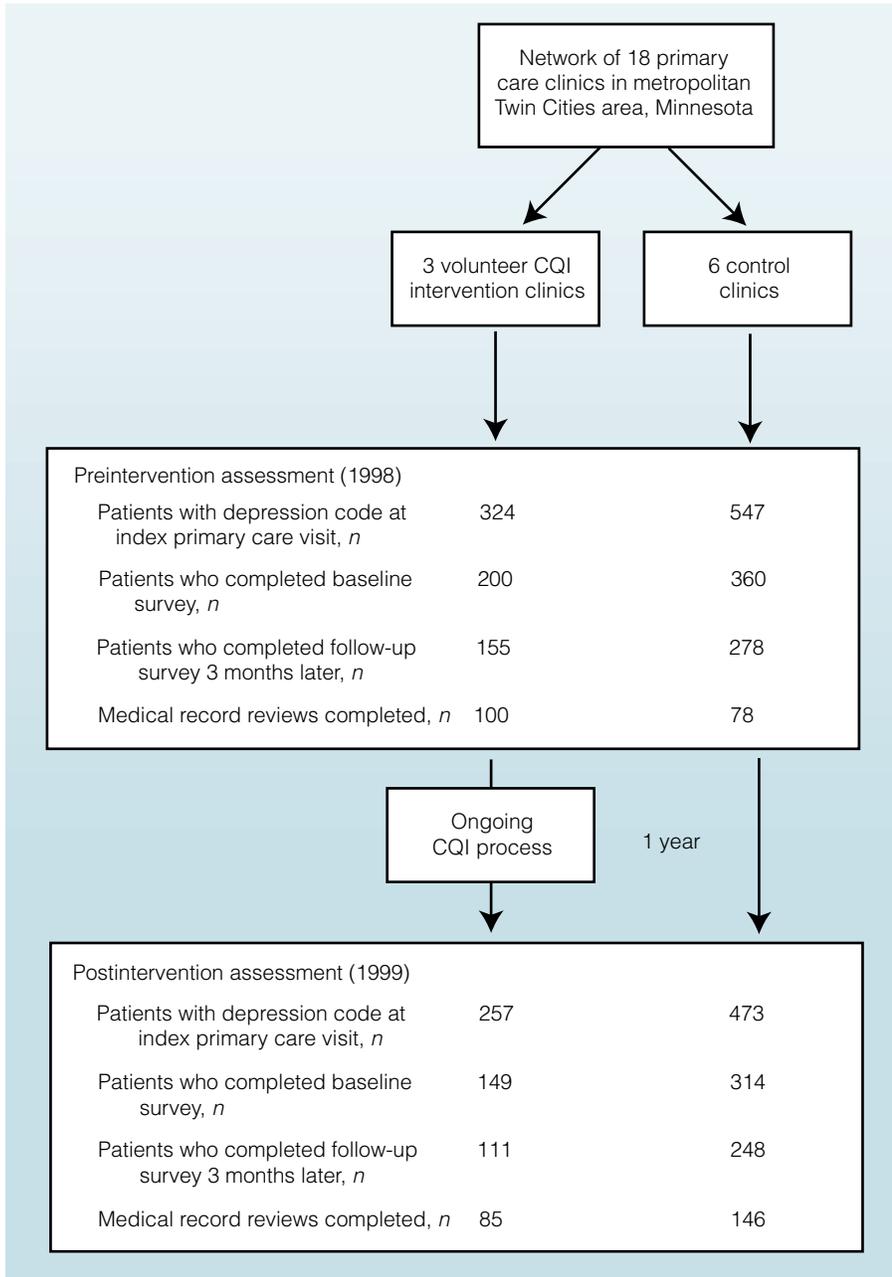
### Intervention

#### Change Process

Medical group leaders for primary care and mental health served on the project steering committee. Medical and administrative leaders from each intervention clinic were invited to four to five meetings and received periodic updates. We created a depression QI team that included two members from each of the three clinics (a physician, a psychiatric nurse, a nursing supervisor, a receptionist, a triage nurse, and a rooming nurse), an experienced QI leader, and an experienced facilitator.

After conducting a simple patient survey-chart audit and a staff survey to understand what areas of the current care process needed improvement, the team modified tools developed by the project steering committee. Instead of developing and implementing a whole new system (as would have been the case with earlier QI methods), each change was tested on a small scale in one of the three clinics, measured where possible, revised, and gradually expanded into other clinics—this process is the rapid-cycle testing approach to implement change gradually.<sup>23</sup> Seven

**FIGURE 1. Study design.**  
CQI = continuous quality improvement.



months after beginning, the QI team and the medical group leaders held all-staff clinic orientation meetings, and thereafter the team worked on identified problems.

### **New Care Management Options**

The key problem identified was the need for a more systematic way to ensure follow-up, coordination, and patient support. To address this need, we developed a graded set of five care management options (Table 1). The idea was to make it easy for physicians to match the patient with the appropriate option and to clarify the physician, nurse, and patient roles. Two of these options provided new ways to follow patients not wanting medical treatment.

### **Systems To Support the Options**

The team created the following systems for physicians, patients, and nurses to facilitate the use of the new management options.

1. To inform physicians about the care options, we created and distributed a brief physician manual to explain the options, and we posted chart reminder systems on examination room walls. We also tried to make it simple for physicians to initiate the chosen option for an individual patient. All a physician had to do was write the appropriate letter (A through E, per Table 1) on the slip normally used to communicate follow-up appointments to the receptionist.

TABLE 1

## New Care Management Options That Physicians Could Order for Their Patients with Depression

| CARE OPTION                 | PATIENT NEEDS  | CLINICIAN ROLE  | NURSE ROLE*   |
|-----------------------------|--|---|---|
| A. Watchful waiting         | Does not want or need any treatment  | None unless a need develops   | Telephone call in 4–6 weeks to see if patient wants help                |
| B. Self-management support  | Prefers to manage own treatment  | Follow-up visit in 6–8 weeks  | Telephone call at 2 and 4 weeks   |
| C. Care guidance            | Requires medications or physician counseling                               | Physician manages care  | Telephone call 1 week after each visit                                  |
| D. Collaborative care       | Requires help from both physician and mental health therapist              | Physician and therapist alternate visits and provide complementary care | Telephone call 1 week after each visit                                  |
| E. Mental health management | Requires consult or transfer of care to external mental health specialists | Provide personal physician care   | Telephone call 1 week later and then as needed to maintain coordination |

\*Telephone call responsibilities described in more detail in the text.

2. A preassembled patient education packet about depression, the care options, and the resources available was created for patients.

3. One or two registered nurses in each clinic were given 8 hours of training, a manual, and clear descriptions of their role to support effective patient self-care. Their role was to provide encouragement and information about resources, facilitate follow-up and communication, monitor depression, alert the clinician to problems and progress, and assure a documented care plan. We provided nurses with telephone scripts, charting formats, a computer scheduling system to remind them about the timing of follow-up calls, and a summary of antidepressant medication information (e.g., key dosages, side effects).

### Evaluation

Processes and outcomes of care were assessed in different samples of patients before and after the intervention. In 1998 (before the intervention), we identified a cross-section of adults (18 years of age and older) with an index visit during a 3-month interval to one of the nine study clinics. Inclusion criteria were a primary care clinician visit; an International Classification of Diseases, 9th revision, code for depression at that visit; and no code for schizophrenia, dementia, or chemical dependence in the past year. We repeated this process 1 year later to select patients for the postintervention sample. Preintervention participants were excluded from the postintervention sample.

Consecutive patients meeting these criteria were mailed a baseline, pretested questionnaire within 1

week of their primary care clinic visit. Accompanying the questionnaire was information stating that a \$5 coupon for groceries would be sent on receipt of the completed survey. This was followed by a postcard reminder in 1 week, a repeated questionnaire in 3 weeks, and up to six telephone calls. Rates of response to these baseline surveys did not differ for intervention and control clinics. Overall response rates for the nine clinics were 64% before and 63% after the intervention (adjustment for undeliverable questionnaires or ineligible participants increased these rates to 70% and 68%).

We mailed a follow-up questionnaire to each of these patients 3 months later and used the identical strategy to maximize response rates. We had complete follow-up data on 155 intervention and 278 control patients before the intervention and on 111 intervention and 248 control patients after the intervention (**Figure 1**). Thus, the overall completion rates for the nine clinics were 50% before and 49% after the intervention (adjusted rates, 52% and 53%). The only significant difference between responders and nonresponders (persons who did not respond to either the baseline or follow-up surveys) was that nonrespondents tended to be somewhat younger.

To ascertain process of care (e.g., follow-up visits), all patients who returned the follow-up questionnaire were asked to give written informed consent for medical record reviews. We attempted to review all charts of consenting respondents from the intervention clinics (100 reviewed before and 85 reviewed after the inter-

TABLE 2

**Definitions and Data Sources for Measures Used\***

| VARIABLES                                  | DEFINITION   | DATA SOURCE                     |
|--|--|---------------------------------|
| Intervention uptake                        | Eligible patients in postintervention period for whom new order system was used  | Administrative computer records |
| Process measures                           |  | Chart audits                    |
| Depression follow-up visits with physician | Mean number of visits per person   |                                 |
| Mental health visits                       | Mean number of visits per person   |                                 |
| Follow-up telephone calls                  | Mean number of calls per person  |                                 |
| Outcome measures                           |  | Follow-up patient surveys       |
| Depression symptoms                        | Percentage of patients improved, defined as: reporting resolution of at least 2 symptoms (out of 11) from baseline to 3-month follow-up, calculated from change in CES-D depression score  |                                 |
| Satisfaction with care                     | Percentage of patients very satisfied according to the question, "During the past 3 months, how dissatisfied or satisfied were you with the care for depression or other personal or emotional problems?" Possible response choices included very dissatisfied, dissatisfied, neither dissatisfied nor satisfied, satisfied, very satisfied, or not applicable |                                 |

\*CES-D = Center for Epidemiological Studies–Depression.

vention) and a random sample of charts from consenting respondents from control clinics (78 reviewed before and 146 reviewed after the intervention).

## Measures

Table 2 provides definitions and data sources for the measured used.

### Intervention Uptake

Using an administrative database, we could identify the number of patients for whom any of the new management options were ordered.

### Process Measures

The chart audit measured documentation of follow-up visits, mental health visits, and nurse telephone calls in the 3 months after the index primary care visit before and after the CQI intervention, as well as the presence of care plans, medications, and interprofessional communication. The audit form was pretested and modified. Two experienced auditors used the final form to review 20 charts and demonstrated high interrater reliability.

### Outcome Measures

At baseline, patients completed an 11-page, 49-item baseline questionnaire that assessed the two main outcome measures: depression severity (the Center for Epidemiological Studies–Depression [CES-D] short-form depression screen)<sup>27, 28</sup> and satisfaction with care of depression ("During the past 3 months, how dissatisfied or satisfied were you with the care for depression or other personal or emotional problems?"). The survey also asked about demographic characteristics, chronic health problems, and the 12-item short-form (SF-12) health status measures.<sup>29</sup> The 3-month follow-up questionnaire included 25 items that assessed depression severity (CES-D short form) and satisfaction with care. The CES-D short-form depression screen was coded by using an algorithm from Garfein and Herzog.<sup>28</sup> We considered patients to have "improved depression" when at least 2 of the 11 CES-D symptoms had resolved from baseline to follow-up.

### Analysis

We conducted both univariate and multivariate regression analyses to determine whether the intervention and

control clinics were equivalent before the intervention and whether any changes from preintervention to postintervention were statistically significant. Multivariate analyses were adjusted for whether this was a new case of depression, depression severity at baseline, history of depression, age, sex, and other chronic conditions. Significance for comparisons of the change in intervention clinics to the change in control clinics was assessed by using the Breslow–Day test for homogeneity of the odds ratio (SAS, SAS Institute, Cary, NC).<sup>30</sup>

## Results

### Clinics and Patient Characteristics

As shown in **Table 3**, the characteristics of the clinics involved in this study did not substantially differ. Similarly, **Table 4** shows that there were no significant differences between patients in the intervention and control clinics who were eligible for the trial at baseline. Seventy-nine percent of patients had positive findings on screening for depression symptoms at the time of the baseline index visit. The patients receiving diagnostic codes for depression in these clinics are predominantly older women with relatively low self-rated health.

### Intervention Process

The combined clinic QI team functioned well. At least five of the six clinic members attended and expressed a high level of interest and commitment for the 13 one-

hour meetings that occurred during the development and implementation period. However, attendance and interest subsequently diminished for the two team members from the least involved clinic.

### Intervention Uptake

The computer system used to track and schedule patients for the follow-up telephone calls from the nurse care manager allowed us to know how many patients were referred to the new care system. During the 3-month evaluation period after the intervention, the new order system was used for 54 patients from the intervention clinics. However, only 30 of these patients were included in the 257 patients selected for evaluation, presumably because 24 patients did not receive a clinician code for depression. The most commonly ordered care options were “care guidance” (physician care with nurse telephone call after each visit) and “collaborative care” (alternating physician and therapist with nurse telephone call after each visit). Physician use of the order system varied by clinic. At clinic X, where the physician team member practiced, most physicians (7 of 8) used the new system. At clinics Y and Z, however, fewer physicians (1 to 2 of 9 to 12) used the system, and none of the physician leaders used the system for their own patients. The nurse practitioner at every clinic participated.

As has been described in more detail in another report,<sup>31</sup> interviews with physicians and staff in the intervention clinics revealed that almost none of the

**TABLE 3**  
**Characteristics of the Intervention and Control Clinics\***

| CHARACTERISTIC                                 | INTERVENTION CLINICS<br>(n = 3) | CONTROL CLINICS<br>(n = 6) |
|--|---------------------------------|----------------------------|
| <b>Staffing</b>                                |                                 |                            |
| <b>Adult primary care clinicians</b>           |                                 |                            |
| Number   | 10 (8–12)                       | 8 (3–15)                   |
| FTE  | 8.5 (6.5–10.3)                  | 6.6 (3.0–10.7)             |
| Mental health professionals (FTE) <sup>†</sup> | 0.82 (0.68–1.0)                 | 0.84 (0.5–1.5)             |
| <b>Patient population</b>                      |                                 |                            |
| Adult patients (age >15 y), n                  | 12,863 (11,491–14,864)          | 11,376 (7172–18,377)       |
| Elderly patients (adults >64 y), %             | 9% (7%–11%)                     | 11% (9%–14%)               |
| <b>Prevalence and treatment of depression</b>  |                                 |                            |
| Adults with ICD-9 code for depression, %       | 2.3% (2.2%–2.5%)                | 2.4% (2.1%–2.7%)           |
| Depressed adults taking antidepressants, %     | 86% (80%–89%)                   | 86% (80%–89%)              |

\*Values are expressed as the mean (range). FTE = full-time equivalent; ICD-9 = International Classification of Diseases, 9th revision.

<sup>†</sup>Each clinic had approximately two mental health professionals.

TABLE 4

**Characteristics of Baseline Patients before the Intervention\***

| CHARACTERISTIC                        | INTERVENTION PATIENTS<br>(n = 200) | CONTROL PATIENTS<br>(n = 360) |
|---------------------------------------|------------------------------------|-------------------------------|
| <b>Age</b>                            |                                    |                               |
| 18–40 y                               | 29%                                | 27%                           |
| 41–60 y <sup>†</sup>                  | 42%                                | 39%                           |
| > 60 y <sup>†</sup>                   | 29%                                | 34%                           |
| <b>Women</b>                          | 72%                                | 70%                           |
| <b>Working full-time</b>              | 42%                                | 45%                           |
| <b>Education &gt; high school</b>     | 36%                                | 37%                           |
| <b>Married</b>                        | 53%                                | 59%                           |
| <b>Household income &lt; \$25,000</b> | 29%                                | 23%                           |
| <b>General health fair or poor</b>    | 31%                                | 31%                           |
| <b>Depressed (score ≥ 6 on CES-D)</b> | 79%                                | 79%                           |

\*CES-D = Center for Epidemiologic Studies–Depression; NS = not significant.

<sup>†</sup>P value < 0.05; otherwise not significant.

respondents felt there was a critical need to improve the follow-up care of patients with depression. For example, one nonuser physician said, “I don’t use the DIAMOND system—I don’t need it because my patients are doing okay.” Some physicians also felt that the new DIAMOND system was too complex. One physician reported that “I couldn’t remember the letters or what they stood for. . . . It was a wonderful idea—and if I was more involved and understood it more, I would have paid more attention.”

When members of the clinic CQI team were confronted with evidence of this lack of uptake, they preferred to resort to personal contacts and exhortation and resisted the idea of instituting automatic ways of including patients with depression in the nurse-care-manager follow-up.

#### **Effect of Intervention on Process and Outcomes of Care**

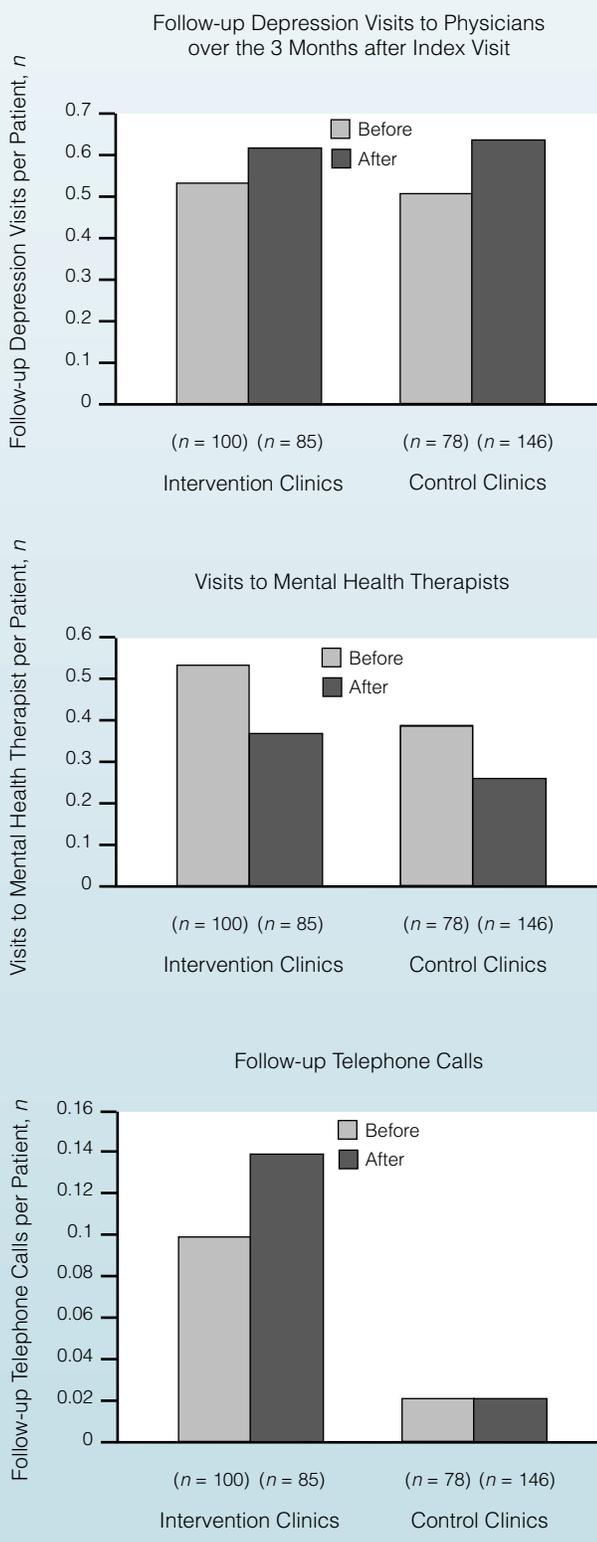
Figures 2 and 3 show the key process and outcome variables at baseline as well as changes over time. Changes in these variables were not significantly greater in intervention clinics. Follow-up visits, mental health referrals, and follow-up telephone calls did not improve significantly from the baseline levels of about 0.5 for a primary care visit, 0.4 for a mental health visit, or 0.1 for a follow-up phone call per person. Other variables (not shown)

reflecting clinician actions to recommend follow-up, make referrals, or provide information also did not significantly differ. The same was true for measures of patient satisfaction with various aspects of care. The charts of only 4 preintervention and 11 postintervention patients documented any provision of educational resources. The same was true of care outcomes, where baseline levels of depression improvement (42.5%) and satisfaction with care (25.8% highly satisfied) did not change significantly. The multivariate analyses were similar and confirmed the lack of any significant differences.

### **Discussion**

On the basis of the data we collected, this intervention did not significantly affect the care process or outcomes for patients in the clinics volunteering to improve depression care. The consistency of results over a wide variety of measures suggests that this lack of demonstrated effect is not due to insufficient evaluation scope. Instead, it is attributable to the inclusion of too few patients in the intervention. The small numbers of intervention patients in the evaluation pool make it impossible to even assess the effects of the intervention on the patients who we know were included in it.

Why did this effort fail? There are several explanations. One is that the physicians in these clinics do not seem to have viewed the new care system as a major



**FIGURE 2. Comparison of process measures at intervention and control clinics before and after the introduction of continuous quality improvement intervention based on chart review.**

advance.<sup>31</sup> Physicians interested in more comprehensive depression care already had recently acquired access to

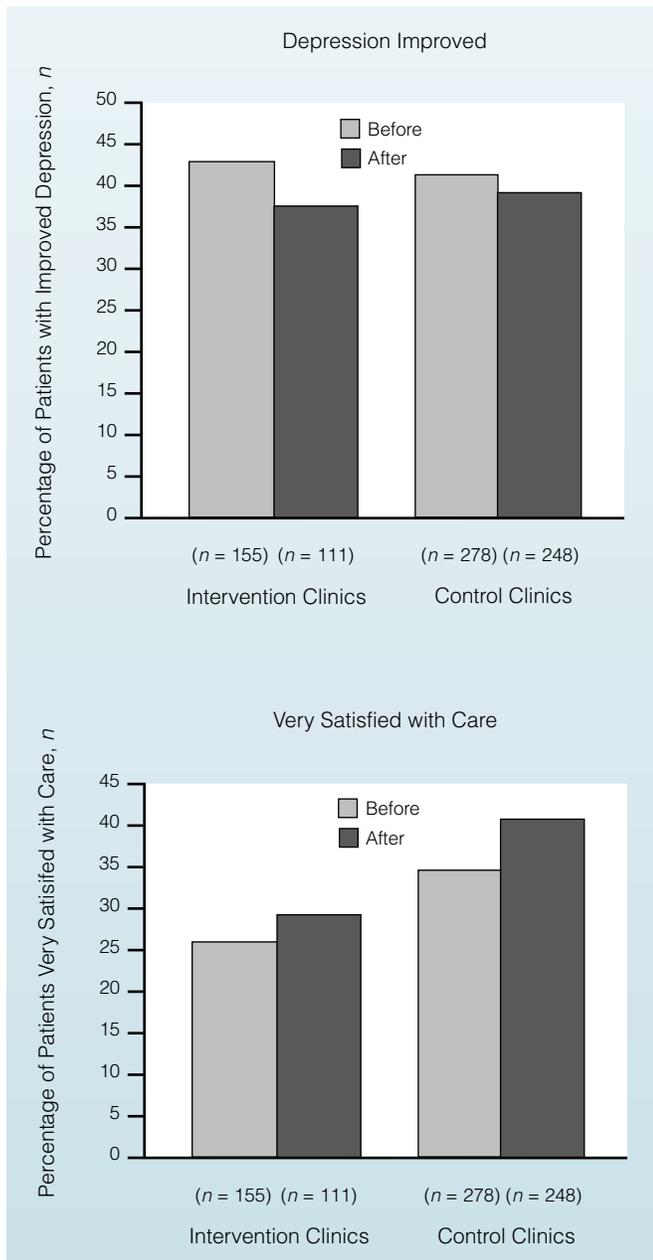
on-site mental health therapists, and the graded-care options with nurse follow-up telephone calls were seen by some as confusing and unnecessary rather than complementary.

Limited physician buy-in heightened the second problem—our system still required that physicians initiate the intervention for their depressed patients. Although this required little effort, physicians still needed to identify a specific treatment option from among the five that were available and to request it for their patients. It is now clear that long-established habits, time pressures, an apparently complex concept, and less-than-enthusiastic support for the new team approach to care were barriers to even this simple step. Moreover, clinic staff are reluctant to introduce changes that would automatically bypass this physician barrier.

Probably the most important limiting factor was that leadership at both the medical group and clinic levels only passively supported this change effort. The effort was one of many pilot initiatives for an organization undergoing major external and internal turmoil. Despite verbal support from most of the clinic leaders, their attention was distracted by multiple conflicting agendas and initiatives, with no clear organizational focus except to try to stem a serious physician morale problem. It is telling that no patients were referred for DIAMOND care by the physician leaders of two of the intervention clinics and only a few were referred by the other leader. We believe that efforts to fundamentally redesign the care delivery system must be one of a few vital initiatives that are seen by leadership at all levels as crucial to the survival and prosperity of the organization.

Two previous trials of CQI-based interventions to improve adherence to guideline care for depression have also failed to demonstrate any significant change, including any real uptake of the CQI-designed improvement strategies.<sup>32–34</sup> In an article analyzing the reason for the failure of his trial, Goldberg concluded that their results emphasize the difficulty of curbing longstanding clinical habits.<sup>35</sup> He suggested that one solution to the problems of CQI is to simplify the work of a CQI team by providing them with both the data they need and the changes to be made. However, the other trial made the more cogent point that “CQI teams cannot, by themselves, eliminate fundamental resource constraints, competing resource needs . . . decades-old barriers . . . or inefficiencies in basic organizational structures.” To this we would add that successful CQI efforts must be part of a major organizational change effort.

We have conducted the only major randomized, controlled trial of CQI in normal primary care clinics with project Improving Prevention Needs Organization, Vision, and Empowerment (IMPROVE).<sup>36</sup> This



**FIGURE 3.** Comparison of selected intervention and control clinic outcome variables before and after the intervention.

trial also failed to demonstrate greater improvement in delivery rates for preventive services, despite apparent enthusiasm and prolonged hard work by most of the clinic process improvement teams. In the DIAMOND trial, we felt that we had corrected most of the problems that had contributed to the failure of the IMPROVE trial.<sup>37</sup>

In their recent systematic review of evidence on the impact of CQI in clinical practice, Shortell and colleagues<sup>38</sup> concluded that the following three conditions must exist for successful CQI change to occur: 1) The application must be clearly formulated and focused on

areas of real importance to the organization; 2) the organization must have capable leadership and be truly prepared to make a change; and 3) the external environment must be conducive to the change.

In conclusion, this trial supports a growing body of evidence that redesign of front-line care delivery for any purpose is difficult under the best of circumstances. However, in the absence of a high level of tension for change and a leadership determined to make the change successfully, such an undertaking may be futile.

## Take-Home Points

- Although new strategies for managing depression in primary care (e.g., nurse telephone calls, collaborative care) have been demonstrated to be effective, they are mostly underused and no models exist for their systematic implementation in the “real world.”
- We conducted a before–after study of three volunteer intervention clinics and six control clinics in the greater Minneapolis–St. Paul area to learn whether a CQI intervention improved the processes and outcomes of care for patients with depression.
- The CQI intervention clinic team implemented a new set of five management options (e.g., watchful waiting, collaborative care) that physicians could order for their patients with depression, and the team trained a nurse manager to conduct telephone follow-up.
- Physicians rarely used the new order system for their patients with depression. Process of care (follow-up physician visit, mental health referral, or nurse telephone calls) and outcomes (patients reporting improved depression on a survey) did not significantly change in either the intervention or the control clinic.

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