

# Primary care

## Re-engineering systems for the treatment of depression in primary care: cluster randomised controlled trial

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### Abstract

**Objective** To test the effectiveness of an evidence based model for management of depression in primary care with support from quality improvement resources.

**Design** Cluster randomised controlled trial.

**Setting** Five healthcare organisations in the United States and 60 affiliated practices.

**Patients** 405 patients, aged  $\geq 18$  years, starting or changing treatment for depression.

**Intervention** Care provided by clinicians, with staff providing telephone support under supervision from a psychiatrist.

**Main outcome measures** Severity of depression at three and six months (Hopkins symptom checklist-20): response to treatment ( $\geq 50\%$  decrease in scores) and remission (score of  $< 0.5$ ).

**Results** At six months, 60% (106 of 177) of patients in intervention practices had responded to treatment compared with 47% (68 of 146) of patients in usual care practices ( $P=0.02$ ). At six months, 37% of intervention patients showed remission compared with 27% for usual care patients ( $P=0.014$ ). 90% of intervention patients rated their depression care as good or excellent at six months compared with 75% of usual care patients ( $P=0.0003$ ).

**Conclusion** Resources such as quality improvement programmes can be used effectively in primary care to implement evidence based management of depression and improve outcomes for patients with depression.

### Introduction

Depression is frequently treated in primary care,<sup>1</sup> yet there are barriers to its effective management.<sup>2-3</sup> Recent randomised controlled trials have shown benefits for patients with depression from increased telephone support, better cooperation between primary care and mental health professionals, and more systematic follow up.<sup>4-6</sup> Some of these changes are costly, however, and their implementation has required intensive support from research teams. Changes have also proved difficult to sustain outside externally funded research.<sup>7</sup>

We developed and tested a model of evidence based management of depression that could be widely

disseminated. We hypothesised that implementation would improve targeted processes for management of depression and improve outcomes at six months.

### Methods

We recruited five healthcare organisations (three medical groups and two health plans) across the United States. To be eligible, each needed to be affiliated with at least 10 primary care practices, have an established quality improvement programme, and be willing to sustain and disseminate our model if it added value at reasonable cost. Methods are described in detail elsewhere.<sup>8</sup>

Leaders of the five organisations invited the affiliated practices to participate. Sixty practices were identified. An evaluation centre randomised these practices after stratification by healthcare organisation. The practices were paired on the basis of clinicians' specialty (internal medicine or family practice), number of clinicians, onsite mental health care, and distance from the organisation's central office. Within pairs, practices were randomly assigned to treatment by flip of a coin.

### Participant flow and follow up

Between February 2002 and February 2003 the clinicians identified patients aged 18 years or older who were starting or changing treatment for depression. The evaluation centre determined diagnoses using a structured interview.<sup>9</sup> The severity of depression was assessed with the Hopkins symptom checklist-20, with a score of 0.5 or more required for enrolment.<sup>10</sup>

Patients were excluded if they were unobtainable for an evaluation interview within 14 days of their index visit, were pregnant, or had suicidal thoughts, schizophrenia, bipolar disorder, post-traumatic stress disorder, or a substance misuse disorder (see [bmj.com](http://bmj.com) for flow of patients through the trial).

### Treatment groups

The intervention concerned a systematic approach to the assessment and management of depression by the



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clinician, with a centrally based care manager providing telephone support for patients.<sup>11</sup> The patient health questionnaire-9 was used to aid in diagnosis, to monitor treatment response, and to guide changes in treatment.<sup>9 12 13</sup>

Patients received a follow up telephone call from the care manager one week after their initial visit. Thereafter they were telephoned monthly and as needed until remission. At the monthly calls the questionnaire was re-administered. The clinician was provided with the reports.

Psychiatrists employed by the organisations supervised the care managers through weekly telephone contact. During these contacts, the care managers presented both new patients and follow up contacts. Based on responses to the questionnaire, the psychiatrist could suggest changes either through the care manager or by contacting the clinician. The clinicians were able to contact the psychiatrists for informal telephone advice. (See *bmj.com* for details on training.)

Clinicians in the practices allocated to usual care took part in a 45-60 minute programme on diagnosis of depression and assessment of suicidal thoughts.

#### Blinding, data collection, and statistical analysis

Interviewers were blind to study group assignment, followed computer aided scripts, and had no knowledge of the purpose of the study or of the intervention. The Hopkins symptom checklist-20 was used to assess the severity of depression. The interviewers also asked about current drugs, recent care, and satisfaction with care.

We used means (standard deviations) for continuous variables and percentages for categorical variables. Our primary outcomes included depressive symptoms (scores on the Hopkins symptom checklist-20), response to treatment (50% or more reduction in depression score from baseline), and remission (<0.5 depression score). The process of treatment was analysed for several variables (see *bmj.com*).

We used linear mixed effects regression models, including both fixed and random effects, to analyse the effect of the intervention on continuous outcomes. We analysed the effect of the intervention on binary outcomes with generalised linear mixed effect models with a logit link. We fitted the mixed effects using SAS Proc mixed and Proc nlmixed.

We fitted a random intercept model that included the fixed effects of depression severity at baseline,

intervention, and time. We also fit models of a two way interaction (intervention by time) for both the continuous and binary outcomes. Further, we tested a three way interaction among intervention, time, and baseline depression scores by testing intervention by time interaction effect within each stratum defined by baseline scores of more than two.

## Results

The characteristics of the practices and patients were well balanced (see *bmj.com*). The mean depression score on the Hopkins symptom checklist-20 for the total sample was 2.01, which is consistent with moderate to severe symptoms. According to the mental disorders patient health questionnaire<sup>14</sup>, 47% of usual care patients and 51% of intervention patients (P=0.42) had generalised anxiety, panic disorder, or both.

Compared with the usual care clinicians the intervention clinicians more often asked patients about suicidal thoughts, offered educational materials, and assisted in setting self management goals. Intervention patients also received more follow up by visits or telephone and were significantly more likely at both three and six months to report receiving good or excellent care. The patterns of management did not differ significantly. No adverse events were reported.

The table presents depression scores, response, and remission based on intention to treat. Intervention patients had better outcomes on all measures at both follow up intervals. Although mean depression scores declined among patients in both groups, the decline was significantly greater in intervention patients: the intervention sizes on the Hopkins symptom checklist were 0.23 at three months and 0.29 at six months.

A mean of 20 minutes was expended for each telephone call, including record keeping. The clinicians reported negligible time demands from the model aside from administrative duties such as obtaining consent.

## Discussion

Enhanced management of depression can improve outcomes for patients when implemented through quality improvement resources increasingly available to community practices. Depressed patients in our intervention practices reported significantly milder symptoms of depression and had higher response and

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Clinical outcomes for patients being managed for depression with evidence based model or usual care. Values are percentages (number of patients/total number) unless stated otherwise

Outcomes	Intervention patients	Usual care patients	Between group difference or odds ratio (95% CI)*	P value
Mean (SD) severity of depression†:				
Baseline	2.04 (0.66)	1.98 (0.65)	0.15 (-0.03 to 0.33)	0.105
3 months	1.16 (0.80)	1.29 (0.76)	-0.16 (-0.32 to -0.002)	0.048
6 months	0.97 (0.80)	1.09 (0.74)	-0.20 (-0.39 to -0.014)	0.036
Response‡:				
3 months	53.0 (97/183)	34.2 (52/152)	2.2 (1.4 to 3.4)	0.001
6 months	59.9 (106/177)	46.6 (68/146)	1.7 (1.1 to 2.7)	0.021
Remission§:				
3 months	26.2 (48/183)	16.5 (25/152)	2.1 (1.2 to 3.7)	0.018
6 months	37.3 (66/177)	26.7 (39/146)	1.9 (1.2 to 3.3)	0.014

\*Adjusted for variability in practices. All patients have at least 0.5 score on Hopkins symptom checklist-20 at baseline.

†Scores on Hopkins symptom checklist-20.

‡At least 50% decrease in depression score from baseline.

§Score of <0.5 on Hopkins symptom checklist-20.

remission rates at follow up than patients in the usual care practices.

We identified elements that possibly influence clinical outcomes. The intervention patients had more telephone contacts and more visits. Intervention patients reported that the clinicians were more likely to assess suicide risk, offer educational materials, and assist with self management goals. Counselling and adherence to antidepressants were similar between the groups, suggesting that specific but modest support for patients results in better outcomes for depression and higher patient ratings for quality of care.

Although clinical outcomes were enhanced, these effects were modest. At least four features of our study may help to explain this. Firstly, rather than identifying potentially ambivalent patients through screening, all patients were identified during routine care by the clinicians, had accepted the diagnosis of depression, and had agreed to be managed with drugs or by counselling. Secondly, the usual care clinicians performed well on process and outcome measures compared with those in other trials,<sup>15 16</sup> creating a high standard of comparison. Thirdly, there was potential for attenuation of the intervention tasks compared with their direct implementation by researchers using a strict protocol.<sup>17</sup> Finally, our intervention was modest compared with other recent large trials.<sup>16 18 19</sup>

Although remission rates at six months indicate that most patients had at least partial symptoms, these patients continued to receive support and may have improved further.

We suggest that by recruiting 60 practices in diverse locations, our trial extends the generalisability of earlier findings on efficacy of telephone support and primary care specialty cooperation beyond special settings. Many of these earlier studies took place in health maintenance organisations, academic sites, or veterans administration practices.<sup>20-24</sup> Our trial adds to this knowledge by showing that modest resources delivered through established programmes can approach outcomes achieved by more research intense, resource rich interventions.

The generalisability of our findings to primary care is constrained because the practices had access to established quality improvement programmes and care management staff, resources which are becoming more widely, but not yet universally, available. Primary care trusts in the United Kingdom may be able to assume this function, and in some countries professional societies and regional health authorities could play a part.

Our model for depression produced significantly better outcomes and more favourable patient responses on quality of care than usual care. The model requires only modest changes from practices and creates a framework to study long term sustainability and dissemination of evidence based care.

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### What is already known on this topic

Trials have shown improved outcomes for depression in primary care patients using models for the management of chronic illness

These models involve more systematic follow up and monitoring, patient telephone support, and cooperation between primary care and psychiatry

Implementation of these models has usually depended on research teams and has not been sustainable when research support ends

### What this study adds

Evidence based models of depression management can be implemented in primary care with support from existing quality improvement resources

These models can improve outcomes for depression

manuals and other resources are available at [www.depression-primarycare.org/clinicians/re\\_engineering/](http://www.depression-primarycare.org/clinicians/re_engineering/)

Contributors: See [bmj.com](http://bmj.com)

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Competing interests: AJD has received honorariums from Forest Laboratories and Pfizer and has consulted for Wyeth Pharmaceuticals. TEO has received honorariums from Pfizer for presenting at two conferences on primary care education. JWWJr has received honorariums from GlaxoSmithKline, Pfizer, and Wyeth-Ayerst and has received funding from Eli Lilly and Pfizer. MLB has received an unrestricted education grant from Janssen Pharmaceuticals. KR has been reimbursed by Forest Pharmaceuticals for attending a symposium. KK has received research support and honorariums from Eli Lilly and Wyeth and honorariums from Pfizer. PAN has been funded by Eli Lilly to study patient perceptions of the options for hormone replacement therapy as presented by primary care clinicians.

Ethical approval: Our study was approved by the committees for the protection of human participants at Dartmouth Medical School, Weill Medical College of Cornell University, and participating organisations.

- Regier DA, Narrow WE, Rae DS, Manderscheid RW, Locke BZ, Goodwin FK. The de facto US mental and addictive disorders service system. Epidemiologic catchment area prospective 1-year prevalence rates of disorders and services. *Arch Gen Psychiatry* 1993;50:85-94.
- Ford DE. Managing patients with depression: is primary care up to the challenge? *J Gen Intern Med* 2000;15:344-5.
- Nutting PA, Rost K, Dickinson M, Werner JJ, Dickinson P, Smith JL, et al. Barriers to initiating depression treatment in primary care practice. *J Gen Intern Med* 2002;17:103-11.
- Von Korff M, Goldberg D. Improving outcomes in depression. *BMJ* 2001;323:948-9.
- Rost K, Smith J. Retooling multiple levels to improve primary care depression treatment. *J Gen Intern Med* 2001;16:644-5.
- Gilbody S, Whitty P, Grimshaw J, Thomas R. Educational and organizational interventions to improve the management of depression in primary care: a systematic review. *JAMA* 2003;289:3145-51.
- Lin EH, Simon GE, Katon WJ, Russo JE, Von Korff M, Bush TM, et al. Can enhanced acute-phase treatment of depression improve long-term outcomes? A report of randomized trials in primary care. *Am J Psychiatry* 1999;156:643-5.
- Dietrich AJ, Oxman TE, Williams JW, Kroenke K, Schulberg HC, Bruce M, et al. Going to scale: re-engineering systems for primary care treatment of depression. *Annals Fam Med* 2004;2:301-4.
- Spitzer RL, Kroenke K, Williams JB. Validation and utility of a self report version of PRIME-MD: the PHQ primary care study. Primary care evaluation of mental disorders patient health questionnaire. *JAMA* 1999;282:1737-44.

- 10 Lipman RS, Covi L, Shapiro AK. The Hopkins symptom checklist (HSCL)—factors derived from the HSCL-90. *Affect Disord* 1979;1:9-24.
- 11 Oxman TE, Dietrich AJ, Williams JW Jr, Kroenke K. A three-component model for reengineering systems for the treatment of depression in primary care. *Psychosomatics* 2002;43:441-50.
- 12 Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. *J Gen Intern Med* 2001;16:606-13.
- 13 Kroenke K, Spitzer RL. The PHQ-9: a new depression diagnostic and severity measure. *Psychiatr Annals* 2002;32:509-21.
- 14 Spitzer RL, Williams JB, Kroenke K, Linzer M, deGruy FV 3rd, Hahn SR, et al. Utility of a new procedure for diagnosing mental disorders in primary care. The PRIME-MD 1000 study. *JAMA* 1994;272:1749-56.
- 15 Badamgarav E, Weingarten S, Henning J, Knight K, Hasselblad V, Gano A, et al. Effectiveness of disease management programs in depression: a systematic review. *Am J Psychiatry* 2003;160:2080-90.
- 16 Unutzer J, Katon W, Callahan CM, Williams JW Jr, Hunkeler E, Harpole L, et al. Collaborative care management of late-life depression in the primary care setting: a randomized controlled trial. *JAMA* 2002;288:2836-45.
- 17 Eisenberg JM, Power EJ. Transforming insurance coverage into quality health care: voltage drops from potential to delivered quality. *JAMA* 2000;284:2100-7.
- 18 Wells KB, Sherbourne C, Schoenbaum M, Duan N, Meredith L, Unutzer J, et al. Impact of disseminating quality improvement programs for depression in managed primary care: a randomized controlled trial. *JAMA* 2000;283:212-20.
- 19 Bruce ML, Ten Have TR, Reynolds CF 3rd, Katz I, Schulberg HC, Mulsant BH, et al. Reducing suicidal ideation and depressive symptoms in depressed older primary care patients: a randomized controlled trial. *JAMA* 2004;291:1081-91.
- 20 Katon W, Von Korff M, Lin E, Walker E, Simon GE, Bush T, et al. Collaborative management to achieve treatment guidelines. Impact on depression in primary care. *JAMA* 1995;273:1026-31.
- 21 Katon W, Von Korff M, Lin E, Simon G, Walker E, Unutzer J, et al. Stepped collaborative care for primary care patients with persistent symptoms of depression: a randomized trial. *Arch Gen Psychiatry* 1999;56:1109-15.
- 22 Simon GE, Von Korff 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.
- 23 Hunkeler E, Meresman J, Hargreaves W, Fireman B, Berman W, Kirsch A, et al. Efficacy of nurse telehealth care and peer support in augmenting treatment of depression in primary care. *Arch Fam Med* 2000;9:700-8.
- 24 Hedrick SC, Chaney EF, Felker B, Liu CF, Hasenberg N, Heagerty P, et al. Effectiveness of collaborative care depression treatment in veterans' affairs primary care. *J Gen Intern Med* 2003;18:9-16.

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## Commentary: Can care management enhance integration of primary and specialty care?

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Dietrich et al report a randomised controlled trial in which community practices implemented enhanced care for depressive illness.<sup>1</sup> The programme was a quality improvement initiative of the participating healthcare organisations, not a stand alone intervention provided by the researchers. Key elements included telephone follow up of patients by a care manager, support of the care manager and the primary care clinician by a psychiatrist, and increased attention to patient education and goal setting by the primary care clinician. The magnitude of benefits was comparable to those of some previous effectiveness trials in which interventions were delivered by researchers.<sup>2</sup> On completion, the organisational changes were extended to additional practices in the participating organisations.

Evidence that depression outcomes can be improved through systematic changes in delivery of care is now compelling.<sup>2,3</sup> This study shows that community practices are able to implement and sustain improvements when offered a standardised care management programme and adequate support. Other chronic conditions that would benefit from such programmes include congestive heart failure, diabetes, and asthma.

As healthcare organisations consider implementing care management programmes, this study highlights three key points: the programme was standardised, but implementation was customised to each setting by the organisations; the care manager—a centralised resource not located in the primary care clinic—managed patients in collaboration with the clinician, who retained overall responsibility for patient care; a psychiatrist supervised the care manager, provided guidance to the clinician through the care manager, and advised the clinician directly as needed.

As a package, the introduction of a care management programme facilitated key changes in how patients, allied health professionals, clinicians, and specialists worked together to improve patient outcomes. By serving as a communication link, care managers can potentially bridge the ever widening gap

in coordination of care between clinicians and specialists.<sup>4</sup> In an era when technological progress has accelerated medical specialisation, ageing populations with multiple chronic conditions need integration of health care more than ever. Primary care clinicians will either embrace new ways of integrating care for their patients or continue to struggle with the onslaught of too many patients, seen in too little time, with seemingly disparate and disconnected needs. By enhancing communication and follow up, care managers may play a vital part in enhancing continuity of care, efficiently integrating the roles of the specialist and the primary care clinician.

Whether and how care management will be implemented on a mass basis is not settled. Should each major disease have its own care manager? Programmes of proved effectiveness have typically targeted individual chronic conditions, but this may not be the best path to integrating care for patients with multiple chronic conditions. It is heartening to learn that a centralised care management programme for depression, linked to primary care, could be successfully implemented and sustained in diverse community practices, but whether and how care management will be integrated into routine practice for the range of conditions that might benefit from enhanced follow up and coordination of care remains an open and critically important issue.

Competing interests: MVK gave an invited lecture on pain and depression at the European Society of Psychosomatic Research with support from Eli Lilly.

- 1 Dietrich A, Oxman TE, Williams JW, Schulberg HC, Bruce ML, Lee PW, et al. Re-engineering systems for the treatment of depression in primary care: cluster randomised controlled trial. *BMJ* 2004;329:602-5.
- 2 Gilbody S, Whitty P, Grimshaw J, Thomas R. Educational and organizational interventions to improve the management of depression in primary care: a systematic review. *JAMA* 2003;289:3145-51.
- 3 Von Korff M, Goldberg D. Improving outcomes in depression. *BMJ* 2001;323:948-9.
- 4 Katon W, Von Korff M, Lin E, Simon G. Rethinking practitioner roles in chronic illness: the specialist, primary care physician, and the practice nurse. *Gen Hosp Psychiatry* 2001;23:138-44.

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