Collaborative Care for Bipolar Disorder: Part I. Intervention and Implementation in a Randomized Effectiveness Trial

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Outcome for bipolar disorder remains suboptimal despite the availability of efficacious treatments. To improve treatment effectiveness in clinical practice, a Veterans Affairs study team created a care model conceptually similar to the lithium clinics of the 1970s but augmented by principles of more recent collaborative care models for chronic medical illnesses. This intervention consists of improving patients' self-management skills through psychoeducation; supporting providers' decision making through simplified practice guidelines; and enhancing access to care, continuity of care, and information flow through the use of a nurse care coordinator. In this article, which is part I of a two-part report, the authors summarize the conceptual background and development of the intervention, describe the design of a three-year, 11-site randomized effectiveness trial, and report data describing its successful implementation. Trial design emphasized aspects of effectiveness to support generalizability of the findings and eventual dissemination of the intervention. Part II (see companion article, this issue) reports clinical, functional, and overall cost outcomes of the trial. (*Psychiatric Services* 57:927–936, 2006)

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Bipolar disorder is common—from 1 to 6 percent lifetime prevalence in the United States (1,2)—and chronic. It is characterized by recurring manic and depressive symptoms and often psychosis (3). The disorder is associated with high suicide rates (4) and substantial social dysfunction (3), ranking sixth as a cause of disability worldwide (5). It may be the most expensive mental disorder for U.S. private behavioral health plans (6) and employers (7). Lifetime total costs per patient exceed $250,000 (8), with up to 70 percent of direct treatment costs generated outside the mental health sector (9).

As with other chronic medical illnesses, the cornerstone of managing bipolar disorder is evidence-based pharmacotherapy (10,11); however, undertreatment in ordinary clinical practice is an endemic problem (12–14). The President's New Freedom Commission report noted that fragmented care, suboptimal clinical outcomes, substantial functional deficits, and high costs characterize all severe and persistent mental illnesses, including bipolar disorder (15). The Institute of Medicine has recognized that these characteristics also describe other chronic medical illnesses (16,17).

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Underscoring the problems associated with undertreatment, the low medication response rates in recent real-world clinical trials for depression (18,19), schizophrenia (20), and bipolar disorder (21) indicate that more comprehensive approaches for such illnesses are warranted. The development of structured psychotherapies for bipolar disorder, including cognitive-behavioral therapy (22–25), family therapy (26), and psychoeducation (27,28), is promising, although effectiveness appears limited for persons with greater impairment (25).

Moreover, promising treatments for chronic conditions do not easily move from initial clinical trials to general practice for mental illnesses (29–31) or other medical illnesses (16,32,33). The dearth of evidence-based interventions applicable for the public sector is particularly notable; less than 3 percent of mental health clinical trials have been conducted in such settings (34). How, then, can outcome be improved for individuals with bipolar disorder under real-world clinical conditions, particularly in the public sector?

In this article we summarize the conceptual background and development of an intervention model for the treatment of bipolar disorder, describe the design of a three-year, 11-site randomized effectiveness trial, and report data describing its successful implementation.

Intervention development

In 1992 we evaluated treatment needs for individuals with bipolar disorder at our Department of Veterans Affairs medical center (VAMC). Comorbidity was common, and the population tended to be poor, have chronic disabilities, and be without families or social support networks. Without funding to develop a mobile treatment team or wraparound services such as a program for assertive community treatment (35–37), we were limited to reorganizing existing outpatient clinic–based services.

Given the available literature on interventions for chronic illness, we recognized that our intervention would need to address three factors (38). First, the intervention should accommodate severely ill patients with comorbidities, who are common in clinical practice but typically excluded from clinical trials (39). Second, the intervention should minimize the provider-based variability typical of medical-surgical (40–42) and mental health (43) care. Evidence-based clinical practice guidelines could reduce such provider-based variability, but they have not been well implemented under naturalistic conditions (44). Third, the intervention should minimize the substantial system-related barriers characteristic of chronic care (32,33,45, 46) to allow providers and patients to come together for timely, proactive illness management.

After a literature review, consultation with experts in bipolar disorder, and discussion with patients, we identified two main conceptual models (13). First, in the 1970s lithium clinics supported the transition from predominantly or exclusively psychotherapeutic treatment to a medical model of treatment for bipolar disorder (47–51). These clinics were organized around medication delivery, typically by a team consisting of a psychiatrist and support staff, with an emphasis on standardized care. Patient education was critical; provision of information was often supplemented by support groups to facilitate destigmatization, peer-based learning, and mutual support. Our specific orientation toward patient education derived from nursing practice, which has long emphasized patient education and collaborative decision making (52,53). The value of a collaborative patient-centered approach was underscored by the feedback we received from patients and has been documented recently in formal studies (54,55).

Second, we became aware of the chronic care models being developed for chronic medical illnesses by Wagner, Von Korff, and others (32,33,56, 57). These models recognize that chronic illnesses are inadequately treated, despite the availability of efficacious medications. They emphasize anticipatory, patient-centered care by addressing four aspects of

clinical care. Patient self-management skills are enhanced via education and collaborative goal setting. Provider decision making is supported by expert guidance, which may range from provision of practice guidelines to facilitated specialist consultation. Information flow is facilitated through various methods, ranging from development of complex electronic infrastructure to use of support staff to ensure that the clinician is provided with adequate patient data during the encounter. Work role redesign for both physician and support staff is typically required to achieve these changes.

The central focus of chronic care models, based on principles of social learning and self-regulation theories (56), is to reorganize medical care to support an effective partnership between clinicians and patients to improve outcomes relevant to patients (58). A recent review indicates that such interventions improved process or outcome measures in 32 of 39 clinical trials. All five trials that used all four components showed benefit. Notably, 19 of 20 interventions with a patient self-management component were effective (30).

We therefore defined the collaborative chronic care model as "an organization of care that emphasizes the patient's development of illness management skills and supports provider capability and availability in order to engage patients in timely, joint decision making about their illness" (13). The model articulates "chronic" care not in any pessimistic sense but rather to emphasize ongoing, anticipatory (rather than reactive, crisis-oriented) management (32,33, 56,57). In fact, the strong emphasis on patient-centered collaboration anticipates current wellness and recovery orientations (55).

On the basis of these considerations, we organized a team-based intervention (57) that consisted of patient psychoeducation to improve self-management skills, simplified clinical practice guidelines, and use of a nurse care coordinator working in collaboration with a supervising psychiatrist to enhance continuity of care and information flow as described in detail below. We conducted a population-based, quasi-experimental study (59) with 103 veterans with bipolar disorder at our VAMC, excluding only those with dementia. Bipolar care was transferred to the intervention; no other existing care was changed, and specialty care referrals were made as clinically indicated. Compared with baseline, bipolar-specific pharmacotherapy increased without increased side effects, and patient satisfaction increased dramatically; the intervention retained more than 90 percent of participants at one year. Among those hospitalized in the prior year, psychiatric hospital days declined to 57 percent, and direct treatment costs were reduced by 65 percent.

On the basis of these data, in 1996 the VA Cooperative Studies Program (CSP) funded a three-year, multisite randomized controlled trial to test this model (CSP 430). Our hypotheses (38) were that, compared with usual care, the intervention would improve clinical outcome, with gains maximal over years 2 and 3; reduce total direct (mental health plus medical-surgical) treatment costs from the VA's economic perspective over three years; and improve functional outcome by the third year. The lag time to response would be consistent with preliminary data (59,60) and characteristic of social learning theory (56).

Effectiveness trial design

Emphasizing effectiveness

Intervention effects commonly are attenuated when moving from initial testing by expert hands in highly selected samples to testing with other clinicians and less restrictive samples (16,17,38,45,61–64). The initial efficacy approach emphasizes internal validity of the trial to isolate treatment effects under ideal conditions. The latter effectiveness approach, like practical clinical trials (65,66), emphasizes external validity—the applicability of results to the settings in which the intervention will be applied. Unfortunately, only a minority of mental health clinical trials adequately address external validity characteristics (67). Accordingly, the study design committee emphasized such effectiveness characteristics from the outset, addressing four interrelated aspects of protocol design: sample, intervention, assessment methods, and data analysis (38).

Sample

A high priority was to recruit a sample that would resemble typical public-sector patients, particularly those receiving care in the VA system. We thus required a *DSM-IV* diagnosis of bipolar disorder via structured interview (68) but employed broad inclusion and minimal exclusion criteria, including those with comorbid illnesses and excluding only those for whom the protocol would not be feasible or relevant, such as patients with dementia (69) (see box on the next page). Potential participants were identified during acute hospitalization for bipolar disorder and randomly assigned at discharge to either continue usual outpatient care or receive care in the intervention clinic for three years. Randomization was stratified on the basis of receipt of living support services (group homes, for example).

Site recruitment is frequently not reported in clinical trials but is an important determinant of external validity (45). We solicited participation from all VAMCs through their research offices. We established two criteria for site selection: VAMCs must have 24-hour emergency service access, and they must not be in the bottom quartile nationally of mental health visits per patient per year. Following these criteria ensured that we would not be comparing the intervention with substandard care while allowing us to draw from a heterogeneous group of VAMCs. Among 50 responses, 12 VAMCs were chosen to ensure diversity of geographic location, urban as well as rural location, size, mission (historically general as well as neuropsychiatric), and prior research productivity. The intervention development site (59) was excluded. One site (large, urban, high research productivity) and its data were dropped at midstudy because of irregularities in data collection.

Intervention

The Bipolar Disorders Program intervention (13,38,59) consists of an outpatient clinic "specialty team" of a

Cooperative Studies Program 430 Inclusion and Exclusion Criteria

Inclusion criteria

- Diagnosis of bipolar disorder type I or II by criteria on the Structured Clinical Interview for Axis I DSM-IV Disorders (68). All psychiatric and medical comorbidities were allowed except as specified below.
- Index episode of manic, major depressive, or mixed episode, by *DSM-IV* criteria, requiring hospitalization on an acute psychiatric ward
- At least two hospitalizations on acute psychiatric wards more than three months apart over the prior five years

Exclusion criteria

- Moderate to severe dementia, with a Mini-Mental State Examination score of ≤26 (69).
- Unresolved substance intoxication or withdrawal
- Hospitalization on chronic or acute psychiatric wards for six or more months in the past year
- Ongoing enrollment in mental health programs with a mobile outreach component in which clinical caregivers deliver services to the patient in the community
- Terminal medical illness with less than three years of expected longevity
- Unable or unwilling to give informed consent or in other ways unable to complete study requirements
- Participation in another concurrent experimental mental health or medical-surgical treatment protocol

psychiatrist and a nurse care coordinator (57). Specifically, staffing requires a .5 full-time-equivalent (FTE) nurse and a .25 FTE psychiatrist for 45 to 50 patients. (We included in this caseload additional patients with bipolar-spectrum disorders who were not randomly assigned to the intervention.) The Bipolar Disorders Program is situated in the mental health outpatient clinic, without after-hours availability or mobile community outreach. All bipolar-specific care is provided in the intervention, but no other care is changed. For example, specialty mental health treatment (psychotherapy and substance treatment) is continued, and other referrals are made if clinically indicated. Similarly, enrollment in primary care and collaboration with medical providers are emphasized.

Three intervention components address patient, provider, and system aspects of care. Each component is specified in a detailed manual (available from the first author).

To enhance illness self-management skills, the Bipolar Disorders Program nurse care coordinator enrolled participants in group psychoeducation in the first months of care in the intervention. This Life Goals Program stresses identification of personal symptom profiles, early warning symptoms, and triggers. It uses "personal cost-benefit analyses" and group feedback to improve coping responses and develop collaborative action plans with providers (60,70,71). The Life Goals Program goes beyond one-way information transfer and stimulates active self-management and collaborative activities (13,58).

Simplified VA Bipolar Clinical Practice Guidelines (72) offer expert guidance to providers for decision making. We reasoned that access to specialty consultants (often called "collaborative care" or "stepped care" in primary care studies) would not regularly be available at all VAMCs. We thus decided to rely on published guidelines that were distilled to a single reference algorithm and six-page manual (13). The algorithm focuses on the endemic underrecognition and undertreatment of mood episodes (12–14) and stresses identification of episodes and subsyndromal symptoms and their aggressive treatment. The algorithm specifies classes of medications to use (for example, antimanics and antidepressants) rather than sequencing individual agents (such as lithium or paroxetine) to allow for patient-centered collaborative decision making that is based on efficacy and side effects. Preliminary data indicated that the algorithm increased bipolar-specific pharmacotherapy across four VAMCs (13). The practice guidelines were updated throughout the study as new medications demonstrated efficacy for bipolar disorder.

System reorganization to improve access to and continuity of care and information flow is implemented by using a nurse care coordinator to augment the psychiatrist's effort. The nurse's access and continuity manual considers three types of contacts. "Backbone scheduled care" consists of regularly scheduled appointments for monitoring the patient regardless of clinical status. "Demand-responsive services" are requested by patients for issues that cannot wait until the next scheduled appointment—for example, to alleviate side effects, address nonresponse to a change in medication, or help with crisis management. Nurse care coordinators provide same-day telephone response and next-business-day clinic visits on demand, similar to what are now called "open access" clinics (73). "Outreach and inreach contacts" include, respectively, aggressive follow-up for missed appointments and liaison with other providers during admissions and emergency room visits or for care coordination. These activities involve collaborating with mental health and medical-surgical providers (concerning, for example, substance relapse, hypertension, obesity, and confusion over medical medications). Nurse care coordinators also facilitate information flow to the psychiatrist by providing patient assessments, implementing reminders for guideline-based monitoring, and tracking laboratory values. We took this low-technology approach to information flow—one not dependent on electronic medical record or specialized information-processing technology—so that the intervention could be disseminated even to small non-VA sites.

Consistent with our effectiveness orientation, we balanced the need for intervention fidelity (internal validity) with training and monitoring that would be typical of other VA specialty programs (external validity) (13). We conducted two-day clinical training at the start of the study. During the study, new nurses completed one-day on-site training, and psychiatrists re-

Table 1

Operationalization of the Cooperative Studies Program (CSP) 430 Bipolar Disorders Program and comparison to usual Veterans Affairs (VA) care

Chronic care model domain[a]	CSP 430 Bipolar Disorders Program	Usual VA care for bipolar disorder
Patient self-management enhancement	Psychoeducation via Life Goals Program[b]	Psychiatrist's choice
Provider decision support	Simplified VA Bipolar Clinical Practice Guidelines (one-page distillation with manual)	Psychiatrist's choice after nationwide release of VA Bipolar Clinical Practice Guidelines
Delivery system redesign and facilitation of information flow	Nurse care coordinator and manual-based access and continuity procedures	Usual access and continuity
Scheduled care	With nurse care coordinator, psychiatrist as needed during program clinic hours	With psychiatrist or therapists, per individual individual clinician's choice
Unscheduled care	Next business day with nurse care coordinator or psychiatrist as needed	Psychiatrist's choice if available, otherwise emergency services
Telephone contacts	Same day with nurse care coordinator, and with psychiatrist as needed	With psychiatrist if available, otherwise emergency services
Missed appointments	Outreach by nurse care coordinator	Psychiatrist's choice
Liaison to other medical, surgical, and mental health providers	Communication via nurse care coordinator	Psychiatrist's choice
Hospitalizations	Inpatient liaison for treatment plan and follow-up coordination by nurse care coordinator	Psychiatrist's choice
Information flow	Augmentation by nurse care coordinator to to psychiatrist	Standard use of paper or computerized medical records

[a] See references 32, 33, 56, and 57.
[b] See references 60 and 70.

ceived telephone training. Nurses were trained to criterion and monitored in the Life Goals Program (60). Regular conference calls and newsletters provided updates on treatment guidelines, aided discussion of difficult cases, and reviewed access and continuity issues.

Fidelity monitoring avoided intense scrutiny of practice style (such as chart reviews or audiotaping) and relied instead on continuous quality improvement methods using audit-feedback monitoring (74,75). Three parameters were chosen: caseload, completion of phase I of the Life Goals Program, and the "critical service encounter" index. Each Bipolar Disorders Program was expected to maintain a caseload of 45 to 50 patients (including patients with bipolar disorder who were randomly selected for the intervention plus others who were not part of the protocol). Participants were to complete phase I of the Life Goals training within the first 12 months of enrollment in the intervention. The critical service encounter index was constructed as follows to measure access to care and continuity of care. Ideally, all unscheduled mental health contacts ("critical service encounters") should be with a Bipolar Disorders Program or other ongoing mental health provider, rather than with an emergency room, medication refill clinic, or other triage visit. The critical service encounter index was therefore calculated by dividing the number of unscheduled contacts outside of the Bipolar Disorders Program or other ongoing providers by all unscheduled contacts (including unscheduled contacts with intervention staff or other ongoing providers). We expected that the critical service encounter index would remain below 10 percent. Monitoring data were fed back to the sites in monthly newsletters and conference calls.

Usual care

Participants who were randomly assigned to usual care continued with their previous psychiatrist or were assigned one if new to the VA. Clinicians caring for usual-care participants and clinicians for the intervention each received intake data according to the Structured Clinical Interview for DSM-IV. No intervention clinicians cared for participants enrolled in usual care. To avoid a Hawthorne effect (inducing a change in behavior simply by monitoring), no monitoring of usual care was undertaken. However, process parameters for evaluating characteristics of usual care (for example, collaborative practice style and number of ambulatory visits) were collected for secondary analyses.

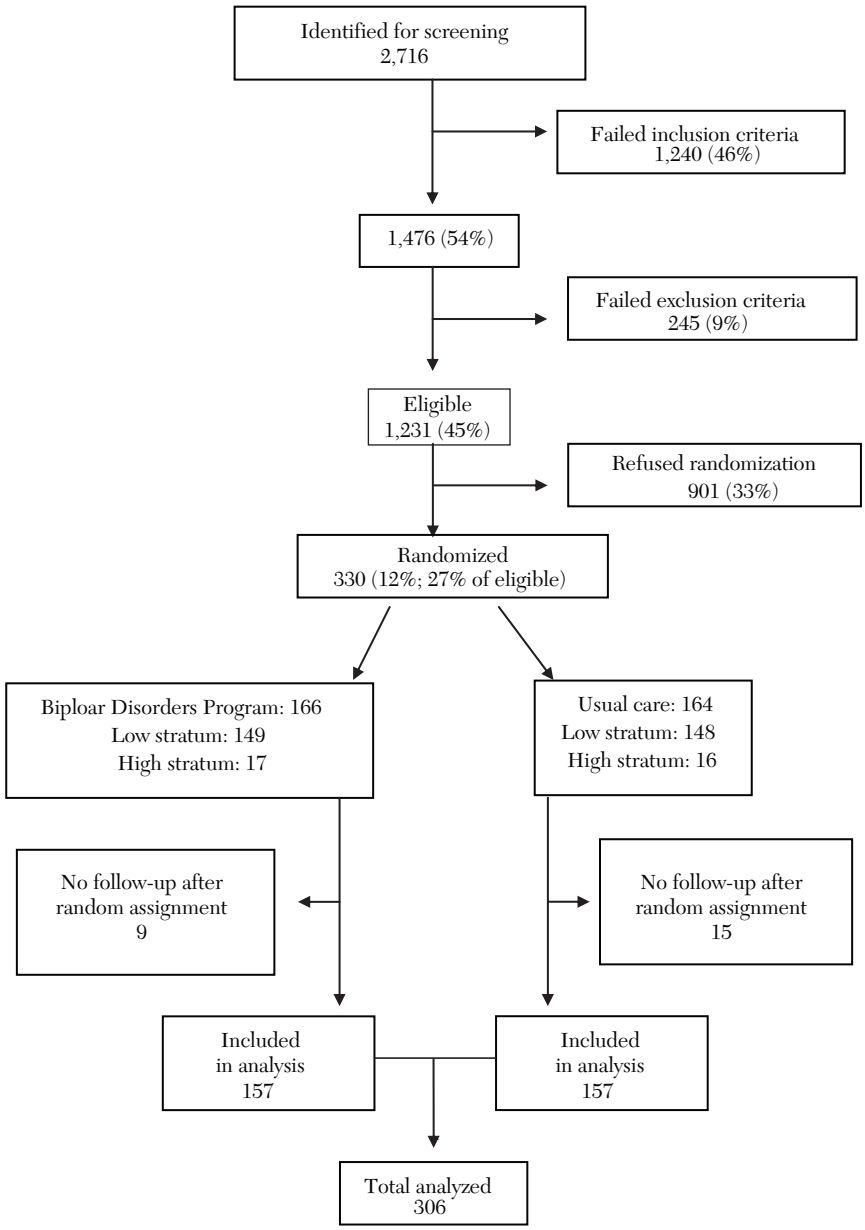
Intervention components are compared with usual care in Table 1. Three clinical vignettes are available as online supplements to this article to qualitatively illustrate participation in the intervention (see ps.psychiatryonline.org).

Assessment

The effectiveness orientation requires outcome assessment with minimal respondent burden, preferably

Figure 1

Participant screening and enrollment flow diagram[a]



[a] Per CONSORT (Consolidated Standards of Reporting Trials) guidelines. For the study, 330 participants were randomly assigned, which represents 12 percent of those screened and 27 percent of those meeting inclusion and exclusion criteria (330 of 1,231). Participants did not meet inclusion criteria if they did not meet *DSM* criteria for bipolar disorder or current episode requiring admission to an acute psychiatric ward (N=597) or if they did not meet prior hospitalization criteria of at least two acute psychiatric hospitalizations separated by at least three months over the prior five years (N=902). Patients did not meet exclusion criteria if they had a Mini-Mental State Examination score below 26 (N=20), could not be reevaluated after substance detoxification (N=31), were hospitalized for more than six months over the prior year (N=18), were treated in community or mobile mental health programs (N=28), had terminal illness with less than three years' life expectancy (N=16), were unable to give informed consent (N=115), or were enrolled in other research programs (N=32). Stratification was based on whether the participant resided in an assisted living facility (high stratum) or lived independently (low stratum). Analyses were based on data from 306 participants.

with data that can be provided by proxy where necessary (38). The outcome battery was administered in 45 to 75 minutes every eight weeks and covered clinical and functional outcome, quality of life, non-VA clinical service use, and selected process measures as detailed in a companion article in this issue of *Psychiatric Services* (76). Preliminary work indicated that completion of the assessment was tolerated well, with over 90 percent of desired data collected and high correlations between participant data and proxy data (77).

Because participants could not be blinded to the intervention, we could not guarantee blinding of the research assistants. However, assessments were scripted, and interviewers were trained to criterion and reassessed regularly (38). Furthermore, a "firewall" was established between research assistants and clinicians to allow communication of participant information only in situations of acute danger to the participant or to others. This prevented clinical information from biasing research evaluations (internal validity) and prevented the research assistant from inadvertently acting as a case manager, which would not be part of the intervention when disseminated (external validity).

Cost data were collected from the economic perspective of the VA. Perspective in cost analyses indicates whose dollars are being counted (78). Our primary cost hypothesis focused on costs to the payer, the VA (rather than all societal costs). Thus all treatment costs (inpatient, outpatient, pharmacy, other; mental health, medical-surgical, other) were included; lost wages and other indirect costs were not. Over 90 percent of service contacts in our preliminary study were within the VA system (59), so we used the VA National Patient Care Database and Pharmacy Benefits Management Package (www.virec.research. med.va.gov/datasourcesname/datanames.htm) to identify patient-specific costs. This source of data was supplemented by participant report of non-VA service use at bimonthly interviews, an interval for which recall remains intact (59).

Data analysis

Data-analytic approaches in an effectiveness trial must reflect real-world considerations of treatment effects and be able to deal with heterogeneous individuals who may periodically be lost to follow-up (38). Although analytic techniques are described in detail in the companion to this article (76), note here that our a priori hypotheses aimed to help de-

Table 2

Sample characteristics and comparison of Veterans Affairs Cooperative Studies Program 430 (VA CSP 430) with recent, large randomized controlled trial and cohort samples of patients with bipolar disorders

Variable	VA CSP 430 (N=306)		Other randomized controlled trial samples			Cohort samples	
				Texas Medication Algorithm Project (N=409)[a]			
	Value[b]	% (for N)	Group Health (N=441)[c]	Intervention	Control	Stanley Foundation Network (N=261)[d]	STEP-BD Network (N=1,000)[e]
Demographic							
Age (mean±SD)[f]	46.6±10.1		44.2±13	38.3±10.6	39.7±10.0	43.1±1.3	41±12.6
Female (%)[g]	28	9	68	72	63	56	59
Minority (%)[g]	71	23	12	41	38	7	11
Education <12 years	18	6	—	—	—	2	4
Clinical							
Bipolar type I (%)	265[h]	87	76	—	—	81	71
Age at onset (mean±SD)	21.0±9.0		—	—	—	22.9±10.4	17.4±8.6
Current psychosis (%)	101	34	14	—	—	59[i]	—
Index episode							
Mixed (%)	69	21	—	—	—	—	7
Manic (%)	102	34	14	—	—	—	30
Depressed (%)	135	45	35	—	—	—	31
Lifetime suicide attempt (%)[f]	211	65	—	—	—	19	36
Substance use disorder [f]							
Current (%)	103	34	7	39[j]	55[k]	4	12
Lifetime (%)	219	72	—	—	—	42	48
Anxiety disorder							
Current (%)	115	38	—	—	—	30	31
Lifetime (%)	130	43	—	—	—	42	51
Active medical comorbidities (median)[l]	2 (1, 3)		—	1 (0, 1)	1 (0, 1)	—	—
Depressive episodes, past year (median)[l]	3 (1, 6)		—	—	—	—	2.3±3.7
Number of manic episodes, past year (median)[l]	3 (1, 8)		—	—	—	—	2.1±3.9
Functional (%)							
Marital status other than married or widowed	214	70	73	73	—	55	62
Nonindependent living	31	10	—	—	—	—	—
Homeless	40	13	—	—	—	—	—
Unemployable	166	54	37	73	74	6	22
Disability pension	87	28	—	49	49	—	—
Treatment							
Hospitalization rate[m]	5.3±5.5		10	—	—	29	—
<12 months with current psychiatrist	172	62	—	—	—	—	—

[a] See reference 81. This study enrolled participants with either bipolar type I or schizoaffective disorders. Values are reported separately for the study's two treatment arms.

[b] N, mean, or median

[c] See references 82 and 83.

[d] See references 84 and 85.

[e] Systematic Treatment Enhancement Program for Bipolar Disorder; see references 86 and 87.

[f] The intervention sample, compared with usual care, was somewhat older (48.10±4 compared with 44.6±9.4; t=3.52, df=304, p<.001); less likely to have had a prior suicide attempt (88 of 156, or 56 percent, compared with 112 of 148, or 76 percent; χ^2=12.5, df=1, p<.001); and more likely to have had a substance use disorder diagnosis at some time (102 of 157, or 65 percent compared with 117 of 148, or 79 percent; χ^2=7.4, df=1, p=.006), although current substance use disorder prevalence did not differ.

[g] The overall study sample had a higher proportion of women, African Americans, and Hispanics than the veteran population nationally (11).

[h] Remainder (N=41, 13 percent) with bipolar type II disorder

[i] Over the lifetime

[j] Percent positive on the screening instrument, not on the clinical diagnosis; 31 percent alcohol and 8 percent drug dependence.

[k] Percent positive on the screening instrument, not on the clinical diagnosis; 42 percent alcohol and 13 percent drug dependence.

[l] Numbers in parentheses indicate quartiles.

[m] For this study the rate is the mean±SD number of psychiatric hospitalizations over the prior five years. For the Group Health study the rate is the percentage of the sample hospitalized in the prior year. For the Stanley Foundation study the rate is the number of participants with at least five lifetime hospitalizations.

tect change over time rather than acutely, as medical chronic care investigators have done (79). Thus our focus was long-term "illness load" (77,80) rather than time to remission or time to first relapse, and statistical techniques were designed to handle intermittent missing data with mixed-effects models.

How successfully was the effectiveness trial implemented?

Sample

The protocol randomly assigned 330 participants, and outcome data were collected for 306 (93 percent). Flow of participants throughout the study is illustrated in Figure 1 according to CONSORT (Consolidated Standards of Reporting Trials) guidelines, and participant characteristics are summarized in Table 2. As can be seen, in comparison with other large samples of patients with bipolar disorder (81–87), our sample was somewhat older, severely ill, and highly complex. Participants had high rates of hospitalization, prior suicide attempts, substance and anxiety disorders, and active medical illnesses. Most were without families and unemployable, and 13 percent were homeless. The proportion of women and minorities matched or exceeded rates in the veteran population (38).

Intervention

Fidelity monitors indicated excellent implementation of the intervention, including the median monthly caseload of 47 (quartiles 41 and 48) and Life Goals Program completion by one year for 78 percent of the sample (quartiles 74 and 82). The critical service encounter index (see above for calculation) was 8 percent (quartiles 8 and 11); that is, 92 percent of unscheduled care was provided by the intervention or other ongoing clinicians, indicating excellent access and continuity.

Staff turnover during study years (1997 through 2003) resulted in 17 nurses and 25 psychiatrists staffing the 11 Bipolar Disorders Programs. Thus the intervention was well implemented despite typical staff turnover, suggesting that trial results reflect principles of treatment rather than skills of a small number of devotees.

Assessment

Despite the complexity of the population we studied, intake diagnostic reliability was excellent for mood, anxiety, and substance diagnoses, including differentiation of bipolar from substance-induced symptoms (Cramér's V=.91 to 1.00). Follow-up clinical and functional measures had similarly high interrater reliability (intraclass correlations of .82 to .91).

Conclusions

The Bipolar Disorders Program intervention is a collaborative chronic care model with conceptual roots in lithium clinics and medical chronic care models. The program provides a highly specified, manual-based intervention. However, unlike typical efficacy interventions, which are designed for maximal effect in select samples with less regard for complexity or cost, this intervention was developed for eventual dissemination. The randomized controlled trial was designed from an effectiveness perspective to maximize the likelihood that trial results would resemble those seen when disseminated. This developmental strategy anticipated subsequent arguments that interventions should be developed from the outset with consideration for their eventual dissemination (45).

The intervention was then tested in a multisite trial that emphasized effectiveness aspects to maximize generalizability of results. The trial recruited a complex sample typical of the population treated in VAMCs and successfully assessed participants over a three-year period with a low-burden assessment battery. The companion article in this issue (76) reports the results of this clinical trial.

Acknowledgments

This study was funded by Department of Veterans Affairs Cooperative Studies Program 430. The authors especially thank Nancy M. Shea, R.N., M.S., Tracy Wyrostek, Christina Moniz, Tara Burke, Erinn Dawson, M.A., Eileen Richardson, and G. F. Kimpton for their assistance. Additional acknowledgments are available in the online supplement to this article at ps.psychiatryonline.org. Some of the findings in this article were presented at the annual meeting of the American College of Neuropsychopharmacology, held in San Juan, Puerto Rico, December 12–16, 2004, and at the 18th Mental Health Services Research Conference, held by the National Institute of Mental Health in Washington, D.C., July 18–19, 2005.

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