An Evidence Synthesis of Care Models to Improve General Medical Outcomes for Individuals With Serious Mental Illness: A Systematic Review

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ABSTRACT

Objective: To conduct a systematic review of studies of interventions that integrated medical and mental health care to improve general medical outcomes in individuals with serious mental illness.

Data Sources: English-language publications in MEDLINE (via PubMed), EMBASE, PsycINFO, and the Cochrane Library, from database inception through January 18, 2013, were searched using terms for our diagnoses of interest, a broad set of terms for care models, and a set of terms for randomized controlled trials (RCTs) or quasi-experimental design. Bibliographies of included articles were examined for additional sources. ClinicalTrials.gov was searched using the terms for our diagnoses of interest (*serious mental illness*, *SMI*, *bipolar disorder*, *schizophrenia*, or *schizoaffective disorder*) to assess for evidence of publication bias and ongoing studies.

Study Selection: 4 RCTs were included from 1,729 articles reviewed. Inclusion criteria were RCT or quasi-experimental design; adult outpatient population with 25% or greater carrying a diagnosis of schizophrenia, schizoaffective disorder, or bipolar disorder; intervention with a stated goal to improve medical outcomes through integration of care, using a comparator of usual care or other quality improvement strategy; and outcomes assessing process of care, clinical outcomes, or physical functioning.

Data Extraction: A trained researcher abstracted the following data from the included articles: study design, funding source, setting, population characteristics, eligibility and exclusion criteria, number of subjects and providers, intervention(s), comparison(s), length of follow-up, and outcome(s). These abstracted data were then overread by a second reviewer.

Results: Of the 4 studies reviewed, 2 good-quality studies (according to the guidelines of the Agency for Healthcare Research and Quality) that evaluated processes of preventive and chronic disease care demonstrated positive effects of integrated care. Specifically, integrated care interventions were associated with increased rates of immunization and screening. All 4 RCTs evaluated changes in physical functioning, with mixed results: 2 studies demonstrated small improvements in the physical health component of the 36-Item Short-Form Health Survey (SF-36) and the 12-Item Short-Form Health Survey, and 2 studies demonstrated no significant difference in SF-36 scores. No studies reported on clinical outcomes related to preventive care or chronic medical care.

Conclusions: Integrated care models have positive effects on processes of preventive and chronic disease care but have inconsistent effects on physical functioning for individuals with serious mental illness. The relatively small number of trials and limited range of treatment models tested and outcomes reported point to the need for additional study in this important area.

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Individuals with serious mental illness have shortened life expectancies relative to the general population[1,2] to an extent that is not explained by unnatural causes such as suicide or accidents. Epidemiologic studies[3–6] have estimated the life expectancy of individuals with schizophrenia to be 10 to 25 years less than the general population. One study[7] estimated the overall economic impact of schizophrenia, including health care costs, disability payments, lost productivity, and law enforcement costs, to be $62.7 billion annually in the United States. Patients with bipolar disorder are estimated to have the highest total health care costs of any mental illness,[8,9] with up to 70% of these costs in non–mental health settings.[10,11] Given these issues, methods to improve outcomes and efficiency of services for individuals with serious mental illness are pressing priorities.

Individuals with serious mental illness have higher rates of illnesses such as infectious disease,[12] diabetes,[13–15] respiratory illness,[16] and cardiovascular disease[17,18] than the general population. Modifiable risk factors for poor health, such as smoking,[19] obesity,[20,21] alcohol and substance abuse,[22] and lack of exercise,[23] are highly prevalent in individuals with serious mental illness—as are obstacles to optimal health care, such as poverty,[24] homelessness,[25] and social isolation.[26]

Multiple studies show that general medical care for individuals with serious mental illness is not provided in concordance with current guidelines, as evidenced by reduced receipt of preventive medical services[27,28] and lower quality of chronic disease management for illnesses such as diabetes[29,30] and cardiovascular disease[31] as well as acute illnesses such as myocardial infarction.[32] In addition, the antipsychotic medications often prescribed for people with serious mental illness are associated with increased risk of sudden death,[33] hyperglycemia,[34] hyperlipidemia,[35] and weight gain.[36]

The term *serious mental illness* has been defined in multiple ways that include groupings

of diagnoses and ratings of functional impairment. Because ratings of illness severity and functional impairment are not often reported in studies of general medical care in individuals with serious mental illness, we used psychiatric diagnoses as the best available proxy. Given our interest in individuals with the greatest barriers to care and highest acuity of psychiatric treatment, we focused on schizophrenia, schizoaffective disorder, and bipolar disorder as representative of the more severe serious mental illnesses.

In this systematic review, we sought to evaluate models of care that integrate medical and mental health services to improve general medical outcomes in individuals with serious mental illness. We were interested in integration for people whose psychiatric disability causes the greatest barriers to general medical care and for whom the site of greatest interaction with health care is the psychiatric setting.

Clinical Points

- Interventions that aimed to integrate medical care and mental health care demonstrated generally positive effects on process of care for patients with serious mental illness, specifically, demonstrating improvements in immunization rates, cancer screening, and selected screening for cardiovascular disease.
- Care models with limited to moderate integration of medical and mental health care can lead to improvements in process of care when fully integrated models are infeasible.

METHOD

This review was commissioned by the Evidence-based Synthesis Program in the Department of Veterans Affairs (VA) after a formal topic nomination and prioritization process that included representatives from relevant entities within the VA Central Office. Key questions were developed in consultation with these stakeholders. This article is a summary of a more detailed internal report prepared for the VA. The final key questions were as follows:

Key Question 1

What types of care models have been evaluated prospectively that integrate mental health care and primary medical care with the goal of improving general medical outcomes for individuals with serious mental illness?

Key Question 2

Do models of integrated care for individuals with serious mental illness improve the process of care for preventive services (eg, colorectal cancer screening) and chronic disease management (eg, annual eye examination in patients with diabetes mellitus)?

Key Question 3 (3a and 3b)

(3a) Do models of integrated care for individuals with serious mental illness improve general functional status outcomes (eg, as measured by the 36-Item Short-Form Health Survey [SF-36]) or disease-specific functional status outcomes (eg, as measured by the Seattle Angina Questionnaire) related to medical care for chronic medical conditions such as diabetes mellitus, hypertension, or heart failure?

(3b) Do models of integrated care for individuals with serious mental illness improve clinical outcomes related to preventive services (eg, influenza rates) and chronic medical care (eg, kidney disease, amputations, retinopathy in patients with coexisting diabetes mellitus)?

We developed and followed a standard protocol for all steps in preparation of this review, adhering to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[37]

Study eligibility criteria (Table 1) were developed on the basis of several considerations. The diagnoses of bipolar disorder, schizoaffective disorder, and schizophrenia were used as proxies for serious mental illness, with a goal of focusing on articles assessing patients with the most severe mental illness and therefore the greatest barrier to medical care, as discussed in the introduction. This rationale is supported by an analysis of a nationally representative survey[38] that showed that individuals with psychotic disorders and bipolar disorder, but not major depression, were less likely than the general population to have a primary care provider, even after controlling for demographics, income, and insurance status. Furthermore, the National Advisory Mental Health Council definition of serious mental illness automatically classified individuals diagnosed with schizophrenia, schizoaffective disorder, bipolar disorder, or autism within the past year as meeting criteria for serious mental illness without requiring further evidence of functional impairment.[39] There is also a large body of literature[40,41] and subsequent reviews[42,43] describing efforts to integrate primary and mental health care for individuals with unipolar depression and anxiety disorders.

Data Sources

We searched for English-language publications in MEDLINE (via PubMed), EMBASE, PsycINFO, and the Cochrane Library whose span of coverage ranged from database inception through January 18, 2013. Search terms included terms for our diagnoses of interest, a broad set of terms for care models, and a set of terms for randomized controlled trials (RCTs) or quasi-experimental studies adapted from the Cochrane Effective Practice and Organization of Care Search.[44–47] We supplemented electronic searching by examining the bibliographies of the included studies and other review articles. Finally, we searched ClinicalTrials.gov using the terms *serious mental illness*, *SMI*, *bipolar disorder*, *schizophrenia*, or *schizoaffective disorder* to assess for evidence of publication bias (completed, unpublished studies) and ongoing studies that may fill gaps in the evidence.

Table 1. Summary of Study Inclusion and Exclusion Criteria

Study Characteristic	Inclusion Criteria	Exclusion Criteria
Study design	RCT or quasi-experimental study defined as nonrandomized cluster controlled trial, controlled before-and-after study, or interrupted time series	Non–English language publication Cross-sectional and other observational designs not listed as included
Population	Adults ≥ 18 years of age with schizophrenia, schizoaffective disorder, or bipolar disorder A sample described as persons having severe mental illness (based on low functional status and chronicity) and with at least 25% diagnosed as having schizophrenia, schizoaffective disorder, or bipolar disorder	Primary substance abuse
Interventions	Interventions with a stated goal to improve general medical care or outcomes through an integrated model *and* either one of the following: 1. A system redesign that adds care provider(s) to directly address or coordinate mental and general medical care 2. Interventions that do not add providers but include at least 3 of the following elements: • decision support • information systems • self-management support • team care • enhanced communications between mental health providers and general medical providers	Interventions designed to be implemented primarily in the community (nonmedical settings) Interventions designed to affect only 1 specific outcome or aspect of general medical health (eg, weight loss or smoking cessation)
Comparators	Usual care or other quality improvement strategy	None
Outcomes	Process of care measures for preventive services (eg, influenza vaccination rate) or chronic disease management (eg, lipid screening or glucose control in a patient with diabetes mellitus) Clinical outcomes (eg, rate of influenza infection) Physical functioning (SF-36 physical component) or disease-specific symptoms measured by a validated instrument (eg, Seattle Angina Questionnaire)	Only measures of mental health care processes, symptom status, or functional status
Setting	Outpatient primary care or mental health clinic settings	Hospital-based (inpatient) settings Community-based settings (eg, senior centers, homeless shelters)

Abbreviations: RCT = randomized controlled trial, SF-36 = 36-Item Short-Form Health Survey.

Study Selection and Data Extraction

Using the study eligibility criteria, 2 reviewers assessed the resulting list of titles and abstracts. We then retrieved the full-text articles for potentially relevant references. A trained researcher abstracted data from these articles; a second reviewer overread the abstracted data. We resolved any disagreements about the included articles or abstracted data by consensus among the first and second reviewer or by obtaining a third reviewer's opinion when consensus could not be reached. We abstracted study design, funding source, setting, population characteristics, subject eligibility and exclusion criteria, number of subjects and providers, intervention(s), comparison(s), length of follow-up, and outcome(s) for each included study.

Intervention characteristics were categorized using Wagner's Chronic Care Model[48,49] and representative elements of the Patient-Centered Medical Home (PCMH).[50] Wagner's Chronic Care Model is a concrete guide for management of chronic illness in primary care based on literature review and expert advisory panel input,[48] and it is supported by at least 32 studies showing improved diabetes management and 18 studies showing decreased health care costs.[49] The chronic care model classifies health care elements into 6 domains: health system, delivery system design, decision support, clinical information systems, self-management support, and the community.[49] The PCMH enhances the fundamental tenets of primary care: access, comprehensiveness, integration, and relationship.[50] With the exception of the health system, we used the domains of the chronic care model along with representative elements of PCMH implementation—a primary treating clinician, team-based care, and methods to enhance access to care—for categorization. *Primary treating clinicians* were defined as clinicians responsible for coordinating and monitoring care and included physicians, advanced practice providers, and care managers. Enhanced access included interventions such as colocation of mental health and primary care services, multiple modes of access such as via telephone or computer, and same-day or next-day appointments.

There are many possible indicators of process of care. In literature on integrated care implementation, including the studies reviewed here, process of care is frequently assessed in regard to general preventive interventions and evidence-based interventions for chronic disease management. When data on immunizations and cancer screening were available separately, we grouped these data into the general category of preventive services outcomes. In some cases, preventive and chronic disease outcomes were reported only in aggregate form.

We assessed the risk of bias pertaining to key questions 2 and 3 using the key quality criteria described in the Agency for Healthcare Research and Quality *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*,[51] adapted for this specific topic, and assigned a summary

quality score of good, fair, or poor to individual RCTs. To facilitate critical analysis, we constructed summary tables showing the study characteristics and results for all included studies, organized by key question, intervention, or clinical condition, as appropriate. We compiled a summary of findings for each key question or clinical topic and drew conclusions based on qualitative synthesis of the findings. There was an insufficient number of studies to perform a meta-analysis. We assessed the overall quality of evidence for outcomes using a method developed by the Grades of Recommendations, Assessment, Development, and Evaluation Working Group,[52] which classifies the grade of evidence as high, moderate, low, or insufficient.

RESULTS

Our initial search identified 1,729 articles, of which 1,669 were excluded by title and abstract review. A total of 60 articles were pulled for full-text review. Fifty-three of these articles were excluded for the following reasons: not serious mental illness = 11, not outpatient = 2, not RCT = 15, not integrated care = 16, no medical outcomes = 6, not peer-reviewed = 2, or not Westernized culture = 1. We identified a total of 7 articles for inclusion in the current review, representing 4 RCTs.

Additionally, our search of www.clinicaltrials.gov identified 2,635 potentially relevant trials. Of these, 10 were ongoing RCTs addressing integrated care interventions in individuals with serious mental illness. No completed, unpublished trials were identified; thus, we found no evidence in this database of publication bias.

Key Question 1: Models of Care

Basic characteristics of the included studies are summarized in Table 2. Four good-quality RCTs (891 subjects) met eligibility criteria; no quasi-experimental studies met eligibility criteria. The proportion of patients with the psychiatric diagnoses of interest (schizophrenia, schizoaffective disorder, and bipolar disorder) varied in each study, with 2 samples[53–57] consisting entirely of patients with bipolar disorder, and another sample[58] with 50% carrying the diagnoses of interest. The fourth study[59] reported that 21% of the participants had a diagnosis of schizophrenia, 13% had a diagnosis reported as major affective disorder, and 9% had a diagnosis reported as *other*. Although this study did not explicitly report 25% of patients with the diagnoses of interest, it was decided after some discussion among reviewers that the targeted population was consistent with the inclusion criteria. This decision was based on the 22% of patients with major affective disorder or *other* diagnosis (potentially bipolar disorder or schizoaffective disorder) and the report that 76% of participants had "severe psychiatric illness" by the criteria of the National Advisory Mental Health Council.[39]

Three studies[55,57–59] tested interventions specifically aimed at improving general medical outcomes, while 1 study[53] focused primarily on psychiatric pathology but included an emphasis on primary care enrollment and collaboration. Care management or care coordination was a common element in the studies; only 1 study employed colocation of medical and psychiatric services.

Three studies[53,55,57,59] were conducted in VA outpatient mental health settings, and 1 study[58] was conducted in an urban community mental health center. Samples in VA settings had relatively few female participants (ranging from 0.8% to 9%), while almost one-half the sample was female in the urban community mental health center study. Participants were, on average, midlife adults; mean ages ranged from 45 to 55 years. Follow-up varied from 24 to 156 weeks. Wagner's Chronic Care Model and the PCMH informed the classification of the models that were used in the included studies (summarized in Table 3). Two studies[53–57] were explicitly based on Wagner's model. A third study[58] also utilized Wagner's principles, while the fourth study[59] did not state a clear theoretical model on which it was based.

As required in our inclusion criteria, all the interventions were based primarily in a mental health setting, but integration of general medical services varied from services contiguous with the mental health clinic[59] to care management provided from remote locations.[53–57] Three studies[53–58] relied on research funds to pay the key study intervention staff, while 1 study[59] was conducted in a setting in which the psychiatry service paid the salaries of the study intervention staff through clinic funds. The spectrum of clinical disciplines employed in the interventions of the 4 RCTs was relatively narrow and limited to those trained traditionally with a primary biomedical orientation (eg, physicians, nurses, nurse practitioners). All the study interventions employed team-based care—at least to the extent of collaboration by multiple providers to help patients with their mental health and general medical problems. None of the studies used fully integrated teams of mental health and general medical providers working closely together with regular team meetings.

Key Question 2: Effects on Process of Care

Two good-quality trials[58,59] provided data relevant to key question 2. Process of care outcomes are summarized for preventive services and chronic disease management in Table 4. We rated the overall strength of evidence for key question 2 as moderate. At baseline, the quality of general medical care was low, leaving ample room for intervention effects. In both studies,[58,59] a high proportion (52%–54%) of medical diagnoses were not documented previously in the medical record, and, in 1 study,[59] only about 20% of recommended preventive services had been provided prior to study start.[58]

In both studies,[58,59] the intervention improved preventive care as measured by receipt of immunizations and screening tests. Druss and colleagues[59] reported higher influenza vaccination rates in the intervention group versus usual-care group ($P = .006$), while more subjects in usual care versus intervention received the pneumococcal vaccination ($P = .006$). This latter difference was not statistically significant in the subgroup with an indication for pneumococcal vaccination.

Table 2. Summary of Included Studies

Study	Design	Subjects: Disorder	Subjects: Demographics	Funding	Setting	Intervention Summary	Follow-Up	General Medical Outcomes	Quality
Druss et al, 2001[59]	RCT with usual-care control (N = 120)	Schizophrenia: 21% PTSD: 29% Major affective disorder: 13% Substance use: 28% Other: 9% "Severe psychiatric illness" by NAMHC criteria: 76%	Gender: 0.8% female Mean age: 45.2 ± 8.2 y Race: 70% white	VA Research and Development/ local clinic funds	VA outpatient mental health	Colocated general medical clinic with care provided by a nurse practitioner with supervision from a family practitioner; care coordination provided by a nurse	52 weeks	US Preventive Services Task Force indicators; general medical service use	Good
Bauer et al, 2006[53,54] Kilbourne et al, 2009[56] (VA Cooperative Study)	RCT with usual-care control (N = 306)	Bipolar disorder type I: 87% Bipolar disorder type II: 13%	Gender: 9% female Mean age: 46.6 ± 10.1 y Race: 23% "minority"	VA Research and Development	VA outpatient mental health	Specialty team of psychiatrist and nurse care manager, including self-management support, decision support, emphasis on primary care enrollment and collaboration	156 weeks	SF-36 physical health	Good
Kilbourne et al, 2008[55,57]	RCT with usual-care control (N = 58)	Bipolar disorder type I: 76% Bipolar disorder type II: 7% Bipolar disorder NOS: 17%	Gender: 9% female Mean age: 55.3 ± 8.4 y Race: 10% African American	VA Research and Development	VA outpatient mental health	Bipolar disorder medical care model consisting of 4 sessions of self-management support, nurse care management, guideline implementation related to cardiovascular risk factors	24 weeks	SF-12 quality of life–physical health WHO-DAS	Good
Druss et al, 2010[58]	RCT with usual-care control (N = 407)	Schizophrenia/ schizoaffective disorder: 36.4% Bipolar disorder: 13.1% PTSD: 5.1% Depression: 45.2% Other: 0.3% Co-occurring substance use disorder: 26%	Gender: 48.4% female Mean age: 46.7 ± 8.1 y Race: African American: 77.4% Hispanic or Latino: 1.5% White: 21.1%	National Institute of Mental Health	Urban community mental health center	Nurse care management with self-management, liaison, and case management components	52 weeks	RAND Community Quality Index SF-36 Framingham Cardiac Index	Good

Abbreviations: NAMHC = National Advisory Mental Health Council, NOS = not otherwise specified, PTSD = posttraumatic stress disorder, RCT = randomized controlled trial, SF-12 = 12-Item Short-Form Health Survey, SF-36 = 36-Item Short-Form Health Survey, VA = Veterans Affairs, WHO-DAS = World Health Organization–Disability Assessment Schedule.

Table 3. Severe Mental Illness Intervention Characteristics Informed by Wagner's Chronic Care Model[a]

Study	Primary Provider	Team-Based	Enhanced Access	Self-Management Support	Decision Support	Delivery System	Information Systems	Community Linkages
Druss et al, 2001[59]	Primary care: yes Psychiatric care: per usual care procedures	Supervising family practitioner and nurse practitioner; liaison with mental health providers	Primary care appointments scheduled to immediately follow mental health appointments when possible	None reported	None reported	Colocation of mental health and primary care services	VA computerized record (both study arms)	None reported
Bauer et al, 2006[53,54] Kilbourne et al, 2009[56] (VA Cooperative Study)	Primary care: per usual care procedures Psychiatric care: nurse care manager for bipolar disorder–specific care; otherwise, per usual care procedures	Primary care: emphasis on primary care enrollment and collaboration; otherwise, per usual care procedures Psychiatric care: "specialty team" composed of a psychiatrist and nurse care coordinator	Nurse care manager provided same-day telephone and next-business-day clinic appointments	Psychoeducational program (Life Goals Program) primarily addressing bipolar disorder symptoms	Simplified VA Bipolar Clinical Practice Guidelines for providers	Care management; Bipolar Disorders Program	VA computerized record (both study arms)	None reported
Kilbourne et al, 2008[55,57]	Primary care: per usual care procedures Psychiatric care: nurse care manager as first response for bipolar disorder–specific care; otherwise, per usual care procedures	Nurse care manager provided liaison between existing providers	None reported	Four-session group lead by nurse care manager	Continuing medical education and guidelines; pocket cards for medical and mental health providers related to cardiovascular risk factor management	Care management; Bipolar Disorder Medical Care Model	VA computerized record (both study arms)	None reported
Druss et al, 2010[58]	Primary care: per usual care procedures Mental health care: per usual care procedures	Nurse care manager provided liaison between mental health and medical providers	None reported	Care manager provided motivational interviewing, development of action plans, and coaching	None reported	Care management	None reported	Public transportation and child care

[a]Definitions of model elements: *primary provider:* clinician responsible for coordinating and monitoring care, ie, physician, advanced practice provider, registered nurse; *team-based:* group of providers, led by the primary provider, who share responsibility for care across several elements of the health care system; *enhanced access:* interventions to increase access to primary provider, such as colocation, multiple modalities of contact, same day appointments[50]; *self-management support:* collaboratively helping patients acquire skills, providing self-management tools and assessing problems and accomplishments; *decision support:* evidence-based clinical practice guidelines integrated into daily practice , reminders, access to specialty providers; *delivery system:* practice teams with a clear division of labor; *information systems:* computerized records systems, including reminders, feedback to physicians, clinical registries of patients with a given chronic condition; *community linkage:* connections with community resources, ie, exercise programs, senior centers, education classes, case management.[48]

Abbreviation: VA = Veterans Affairs.

Table 4. Process of Care Outcomes for Preventive Care and Chronic Disease Management (Key Question 2)

Study	Design (follow-up)	Intervention Summary	Preventive Care				Chronic Disease Management	
			Immunizations		Screening Procedures			
			Intervention	Control	Intervention	Control	Intervention	Control
Druss et al. 2001[59] (additional preventive care results reported)	RCT (52 weeks)	Colocated general medical clinic with care provided by a nurse practitioner with supervision from a family practitioner; care coordination provided by a nurse	Flu: 32.2% Pneumovax: 11.9%	Flu: 11.5% Pneumovax: 32.8%	Hemoccult: 49.2% Digital rectal examination: 65.9% Flexible sigmoidoscopy: 33.9%	Hemoccult: 44.3% Digital rectal examination: 44.3% Flexible sigmoidoscopy: 14.8%	Diabetes screening: 71.2% Cholesterol screening: 79.7% Weight measured: 84.7% Smoking education: 84.7%	Diabetes screening: 45.9% Cholesterol screening: 57.4% Weight measured: 59.0% Smoking education: 63.9%
Druss et al. 2010[58] (additional preventive care results reported)	RCT (52 weeks)	Nurse care management with self-management, liaison, and case management components	24.7%[a]	3.8%[a]	50.4%[b]	21.6%[b]	Proportion of indicated services received for cardiovascular disease: 34.9%[c] Framingham Cardiac Index: 6.9%	Proportion of indicated services received for cardiovascular disease: 27.7%[c] Framingham Cardiac Index: 9.8%

[a]Rate reported is percentage of recommended immunizations performed (influenza; hepatitis B; measles, mumps, and rubella; pneumococcal bacterial infection; tetanus-diphtheria; and varicella).
[b]Rate reported is percentage of recommended screening tests performed (cholesterol, fecal blood, human immunodeficiency virus, sigmoid, and tuberculosis).
[c]Rate reported is the proportion of indicated services received for cardiovascular disease among the subset with at least 1 cardiometabolic condition (diabetes, hypertension, hypercholesterolemia, or coronary artery disease).
Abbreviation: RCT = randomized controlled trial.

Selected screening tests were also more likely to be performed in the intervention group than in the usual-care group: digital rectal examination ($P = .005$) and flexible sigmoidoscopy ($P = .01$).[59] The investigators also reported a nonsignificant difference favoring the intervention for hemoccult testing ($P = .10$). In the more recent study,[58] a broader set of general medical process measures were evaluated. Immunization outcomes were reported as the proportion of recommended services received. The intervention group was more likely to receive indicated vaccinations than the usual-care group ($P < .001$). In addition, other recommended screening services (cholesterol, fecal occult blood, human immunodeficiency virus, sigmoidoscopy, and tuberculosis testing) were completed more frequently in the intervention group than the usual-care group ($P < .001$).[58] The effects of the intervention on chronic disease management focused on process outcomes relevant to cardiovascular disease risk. Druss and colleagues[59] reported significantly higher rates in the intervention group for weight measurement, diabetes screening, cholesterol screening, and smoking cessation education during the 12-month study period. In the later study,[58] Druss and colleagues found higher rates of indicated services for cardiovascular disease ($P = .03$) in the intervention group in an a priori analysis of a prespecified subset of 202 subjects who had 1 or more cardiometabolic conditions. In the subset with blood tests available (n = 100), the Framingham Cardiac Index (a measure of the 10-year risk of myocardial infarction or coronary-related death) was also significantly lower at study end in the intervention group ($P = .03$), with the intervention group's index improving and the usual-care group's index worsening during the course of the study. However, an analysis that adjusted for baseline cardiovascular risk did not show a statistically significant change in risk between groups.

Key Question 3: Effects on Functional Status and Clinical Outcomes

All 4 included studies reported data relevant to key question 3a (summarized in Table 5). Of these, 3 studies used the SF-36,[60–62] and 1 used the 12-Item Short-Form Health Survey (SF-12).[63] Neither disease-specific symptom scales nor disease-specific functional status scales were reported in any of the studies. We rated the overall strength of evidence for key question 3a as moderate. Regarding key question 3b, we did not identify published trials or quasi-experimental studies that examined clinical outcomes relating to preventive services. We rated the strength of evidence as insufficient for this question.

Of the 3 studies using the SF-36, Druss and colleagues[59] reported scores at 52-week follow-up on the physical health component. Mean scores were higher for the intervention group than for the usual-care group. The difference in change between the 2 groups was significant ($P < .001$), with subjects in the integrated-care clinic scoring 4.7 points higher than baseline on the physical component summary score, compared to a 0.3-point decline from baseline in the score of subjects in the general medicine clinic. Investigators in the VA Cooperative Study[53,54,56] reported no statistically significant difference at 3-year follow-up between the bipolar collaborative chronic care model and the usual-care groups on the SF-36 physical health component. Similarly, a later study by Druss and colleagues[58]

Table 5. Outcome Summary for Key Question 3

Study	Follow-Up	Intervention Versus Control Outcome (SF-36 or SF-12 score)
Druss et al, 2001[59]	52 weeks	SF-36 physical component: mean (SD), 50.9 (7.1) versus 45.3 (9.7); $P < .001$ for difference in change scores using baseline, 6-month, and 12-month assessments
Bauer et al, 2006[53,54] Kilbourne et al, 2009[56] (VA Cooperative Study)	156 weeks	SF-36 physical component: mean, 43.4 (95% CI, 42.4–44.4) versus 42.9 (95% CI, 41.9–43.9)
Kilbourne et al, 2008[55,57]	12 weeks 24 weeks	SF-12 physical component: mean (SD), 38.5 (8.4) versus 33.9 (8.6); P = NR SF-12 physical component: mean (SD), 37.0 (7.3) versus 35.1 (7.7); P = NR; difference in repeated-measures analysis of changes in scores using baseline, 3-month, and 6-month assessments: $\beta = 2.5$ (95% CI, 0.5–4.9; $P = .04$)
Druss et al, 2010[58]	52 weeks	SF-36 physical component: mean (SD), 37.1 (11.5) versus 34.7 (11.9); $P = .08$; difference in change scores: "not significant," P = NR

Abbreviations: NR = not reported, SD = standard deviation, SF-12 = 12-Item Short-Form Health Survey, SF-36 = 36-Item Short-Form Health Survey, VA = Veterans Affairs.

did not report a statistically significant difference between the mean scores of the intervention group versus usual-care group on the SF-36 physical health component, although their findings exhibited a trend toward significance ($P = .08$); they also noted that the difference in change between the 2 group scores was not statistically significant. Kilbourne and colleagues[55,57] used the physical health component of the SF-12 to report functional outcomes after 24 weeks of the bipolar disorder medical care model versus usual care. Change in SF-12 scores from baseline to 24-week follow-up differed significantly between the intervention and control groups ($P = .04$).

DISCUSSION

We evaluated 4 RCTs that were similar in many ways, demonstrating a limited variety of approaches to improve general medical care for individuals with serious mental illness. Three studies[53,55,58] were theoretically based on Wagner's Chronic Care Model. Elements of the PCMH, such as having a primary treating provider, team-based care, and enhanced access, were not robustly employed. On the spectrum of limited (eg, communication between providers) to fully integrated (eg, shared development and implementation of treatment plans), the interventions ranged from limited to moderately integrated. Of the 4 included RCTs, 2 studies[58,59] involving 527 patients addressed outcomes of process of care for preventive services and chronic disease management. Both of these studies—one[59] employing colocated primary and mental health care at a VA facility and the other[58] employing care management to facilitate care among mental health and primary care providers who remained organizationally and physically separate in an urban community setting—demonstrated generally positive effects on immunization rates, cancer screening, and selected screening for cardiovascular disease.

All 4 RCTs,[53,55,58,59] involving 891 patients, reported effects on general functional status outcomes, but none investigated disease-specific functional status outcomes or clinical outcomes related to preventive services. Two RCTs,[55,59] both conducted in VA settings, demonstrated small, statistically significant improvements in physical functioning at follow-up periods ranging from 12 to 52 weeks, while 2 other RCTs[53,58] did not find statistically significant improvements.

This systematic review demonstrates key gaps regarding the integrated care interventions evaluated. First, the key intervention components remain uncertain, in part due to lack of diversity in the types of integration models tested, but also because none of the studies permitted disaggregation of intervention effects for each intervention component. In addition, 2 studies focused entirely on individuals with bipolar disorder; therefore, greater uncertainty exists about intervention effects for individuals with other serious mental illnesses. In addition, we found no studies reporting on disease-specific functional outcomes or clinical outcomes related to preventive services. Follow-up for functional outcomes varied from 24 to 156 weeks, with 3 studies having follow-up of 52 weeks or less; interventions could be expected to require longer follow-up in order to demonstrate positive effects on physical functioning. Effects of interventions that are part of routine care rather than an RCT remain uncertain.

Only 4 studies employing a limited range of approaches to integration of care met our study selection criteria, demonstrating that the improvement of general medical outcomes in individuals with serious mental illness is an understudied area. Still, these RCTs provided useful findings for several of our key questions, findings that should be considered by policymakers and for prioritizing future research. The identified studies maintained mental health settings as the central point of care, with services augmented by either colocated general medical services or placement of care managers in the mental health setting. Given the intensity of psychiatric services often required for a population with serious mental illness, this approach may be logical; however, studies in which psychiatric services were provided to augment general medical services in the general medical setting were not identified. It is also notable that none of the studies implemented a full chronic care or PCMH model, and the interventions were moderately

integrated at best. The positive outcomes of these studies, despite low fidelity to complete models, indicate the utility of assessing the effectiveness of implementing 1 or 2 components of the chronic care model in systems that may not have the resources to implement the model fully. Further educational interventions to guide primary care providers in deciding which components of an integrated model could be most effectively incorporated into their specific practice may also be beneficial.

Importantly, 3[53,55,59] of the 4 RCTs were conducted in the VA system, where a range of medical services is generally offered on site. Integration and colocation approaches may be easier to implement in VA settings. The VA population is significantly skewed toward men aged in their 40s and 50s. This fact may limit the generalizability of these data to young adult, female, or elderly populations. It should also be noted that the VA is a single-payer health care system that may have inherently different barriers to care than a community-based system involving third-party payment. Further controlled trials of integrated care models outside of the VA could focus on some of these differences.

Another important limitation is that the term *serious mental illness* varies in definition, an issue that makes it challenging to study this population through systematic reviews. *Serious mental illness* is not a Medical Subject Headings (MeSH) search term. Although we used broad and sensitive search strategies across multiple databases and augmented the searches by reviewing the bibliographies of selected articles, our search strategy may still have missed relevant articles. By design, our review did not address disparities in quality of care received by individuals with serious mental illness in general medical inpatient settings, which has been shown in studies of myocardial infarction[32] and in receipt of and outcomes after nonemergency surgical procedures.[64]

There are clear implications for future research relating to models of integration of care in this population. Although the interventions studied have been informed by the chronic care model, elements such as decision support, shared decision making, self-management support related to chronic medical conditions, and community linkages were not consistently and robustly included. If the conceptual model were broadened to include elements of PCMH, then additional elements such as designated care teams, shared medical appointments, home telemonitoring, test and referral tracking, and performance monitoring might be tested. Future research could focus on existing models of integration (such as the VA mental health–primary care program) as well as the proposal of new RCTs with diversity of design, longer follow-up, a broad range of patient diagnoses, and comprehensive outcomes including distal clinical outcomes such as disease-specific symptom measures or disease-specific or all-cause mortality rates. With cardiovascular disease being a main source of morbidity and mortality, particularly in individuals with serious mental illness, a focus on this category of disease is important. However, greater variety of chronic disease outcomes is missing in the literature.

Individuals with various psychiatric diagnoses within this broad group may have differences in their experience of general medical care, leading to disparate outcomes among those groups. While some methods to improve integration of care for individuals with serious mental illness may be generalized among diagnostic entities, some may need to be specific to the psychiatric diagnostic group, and future research should examine this issue. The RCTs that met our criteria had only 19% of the total sample population with diagnoses of schizophrenia or schizoaffective disorder—another gap in the research. It is notable that there is significant diversity within populations with serious mental illness, and many individuals have additional characteristics that contribute to even greater disparities in health care access. The reviewed studies noted their populations to be underinsured, have low socioeconomic status, have functional and cognitive limitations, have significant comorbid substance use disorders, and have trouble accessing transportation.[57,58] Subgroup analysis of the differing effects of collaborative interventions based on region, ethnicity, or language is an important area for future research. This information would assist health care systems in implementing interventions best tailored to the population served. In addition, while we limited studies in this review to those conducted in traditional mental health outpatient settings, services delivered in the community may also be important to improving general medical care in this population and should be investigated.

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