

Effects of Care Models to Improve General Medical Outcomes for Individuals With Serious Mental Illness

September 2011

Prepared for:

Department of Veterans Affairs Veterans Health Administration Health Services Research & Development Service Washington, DC 20420

Prepared by:

Evidence-based Synthesis Program (ESP) Center Durham Veterans Affairs Healthcare System Durham, NC John W. Williams Jr., MD, MHSc, Director

Investigators:

Principal Investigator: Daniel W. Bradford, MD, MPH

Co-Investigators:

Monica N. Slubicki, MD Jennifer McDuffie, PhD Amy Kilbourne, PhD John W. Williams Jr., MD, MHSc

Research Associate: Avishek Nagi, MS

Medical Editor: Liz Wing, MA



PREFACE

Health Services Research & Development Service's (HSR&D's) Evidence-based Synthesis Program (ESP) was established to provide timely and accurate syntheses of targeted healthcare topics of particular importance to Veterans Affairs (VA) managers and policymakers, as they work to improve the health and healthcare of Veterans. The ESP disseminates these reports throughout VA.

HSR&D provides funding for four ESP Centers and each Center has an active VA affiliation. The ESP Centers generate evidence syntheses on important clinical practice topics, and these reports help:

- develop clinical policies informed by evidence,
- guide the implementation of effective services to improve patient outcomes and to support VA clinical practice guidelines and performance measures, and
- set the direction for future research to address gaps in clinical knowledge.

In 2009, the ESP Coordinating Center was created to expand the capacity of HSR&D Central Office and the four ESP sites by developing and maintaining program processes. In addition, the Center established a Steering Committee comprised of HSR&D field-based investigators, VA Patient Care Services, Office of Quality and Performance, and Veterans Integrated Service Networks (VISN) Clinical Management Officers. The Steering Committee provides program oversight, guides strategic planning, coordinates dissemination activities, and develops collaborations with VA leadership to identify new ESP topics of importance to Veterans and the VA healthcare system.

Comments on this evidence report are welcome and can be sent to Nicole Floyd, ESP Coordinating Center Program Manager, at nicole.floyd@va.gov.

Recommended citation: Bradford DW, Slubicki MN, McDuffie JR, Kilbourne AM, Nagi A, Williams JW Jr. Effects of Care Models to Improve General Medical Outcomes for Individuals With Serious Mental Illness. VA-ESP Project #09-010; 2011

This report is based on research conducted by the Evidence-based Synthesis Program (ESP) Center located at the Durham VA Medical Center, Durham, NC, funded by the Department of Veterans Affairs, Veterans Health Administration, Office of Research and Development, Health Services Research and Development. The findings and conclusions in this document are those of the author(s) who are responsible for its contents; the findings and conclusions do not necessarily represent the views of the Department of Veterans Affairs or the United States government. Therefore, no statement in this article should be construed as an official position of the Department of Veterans Affairs. No investigators have any affiliations or financial involvement (e.g., employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties) that conflict with material presented in the report.

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EVIDENCE REPORT

INTRODUCTION

Individuals with serious mental illness (SMI) 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. Epidemiological studies have estimated the life expectancy of individuals with schizophrenia to be 10 to 25 years less than the general population.³⁻⁶ Increased morbidity of both chronic and acute illnesses in individuals with SMI also reduces quality of life and increases the overall burden of disability beyond that of the SMI itself. SMIs have an overwhelming economic impact, as measured by direct and indirect costs, including health care costs, disability payments, lost productivity, and law enforcement costs. For example, one study estimated annual costs due to schizophrenia to be \$62.7 billion annually in the U.S.,⁷ and patients with bipolar disorder are estimated to have the highest total health care costs of any mental illness^{8,9} with up to 70 percent of these costs in non–mental health (e.g., primary care) settings.^{10,11} Given these issues, methods to improve general medical services for individuals with SMI is a pressing priority.

BACKGROUND

The issues that influence general medical outcomes for individuals with SMI are complex and overlapping and likely vary by disease state. Relevant factors can be categorized to include population characteristics, contextual and system factors, provider factors, and community resources. Interventions aimed at improving general medical outcomes in this population could be directed at any one, or several, of these factors.

The populations of individuals with SMI have consistently shown 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 SMI—as are obstacles to optimal health care such as poverty, ²⁴ homelessness, ²⁵ and social isolation. ²⁶

Multiple studies show diminished guideline concordance of general medical care provided to individuals with SMI, 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 disease³¹ as well as acute illnesses such as myocardial infarction.³² In addition, psychiatric medications can be risk factors for poor health given the association with some pharmacological treatments and medical outcomes such as increased risk of sudden death,³³ hyperglycemia,³⁴ hyperlipidemia,³⁵ and weight gain.³⁶

Effectiveness of Health Care Providers

The effectiveness of health care providers in optimizing general medical outcomes in individuals with SMI depends on multiple factors, including the type and level of training for working with this complex population, attitudes and beliefs about individuals with SMI, and knowledge of specific issues affecting individuals with SMI. The range of professionals involved with providing psychiatric care to patients with SMI includes disciplines with little or no training in

medical issues. Among physician mental health providers (i.e., psychiatrists), general medical training is typically limited to less than 6 months of direct service in internal medicine settings. Further, general medical providers usually have limited experience working with patients with SMI. Although combined training programs, such as those in psychiatry and internal medicine, produce physicians who are well trained to address both medical and psychiatric problems, there are relatively few of these programs—only 17 in the U.S.³⁷—so graduates of such programs represent a small minority of those who provide general medical services along with SMI care.

Settings of Care

The characteristics of various sites of care where individuals with SMI receive general medical services affect the general medical outcomes of this population. Individuals with SMI may receive psychiatric and general medical care at sites separated by geography, organization, financing, and/or culture.³⁸ While integration of mental health and primary care services has been implemented in some settings for depressive and anxiety disorders, general medical and psychiatric services typically are received at different sites for individuals with SMI. Payment structures may not incentivize collaboration of care among medical and psychiatric care providers, making the increased time challenging for this important element of care. Even in integrated systems with single payers, medical and psychiatric care systems may be held accountable for outcomes that sometimes lead to conflicting medical decisions (e.g., psychotropic medication choice may lead to improved psychiatric symptom control while worsening metabolic indices).

Supportive Services

A further impact to general medical outcomes in persons with SMI may be the availability of various types of supportive services that facilitate overall well-being and access to care. While it has not been systematically studied to this point, the availability of housing, intensive case management services, and employment support would be expected to positively influence adherence to recommendations and the ability of persons with SMI to access general medical care.

Integration of Care

In this evidence synthesis, we sought to elucidate the best ways to integrate medical and mental health care to improve general medical outcomes in individuals with SMI. We were interested in understanding methods of integration of care for those 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. The term "serious mental illness" has been defined multiple ways and includes groupings of diagnoses and ratings of functional impairment, such as the Global Assessment of Functioning. Because the rating of illness severity—particularly those elements (e.g., cognitive functioning, communication abilities) that are most likely to have an impact on the quality of general medical healthcare received—is rarely reported in studies of general medical care in persons with SMI, we used reported psychiatric diagnoses as the best available proxy.

For this review, we chose to focus on the mental disorders of schizophrenia, schizoaffective disorder, and bipolar disorder as representative of the more serious mental illnesses. Lending support to this decision are the results of an analysis of a nationally representative survey³⁹

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showing 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. Another factor in this choice was the large body of literature^{40,41} and subsequent reviews^{42,43} that have described efforts to integrate primary and mental health care for individuals with unipolar depression and anxiety disorders.

Throughout health care systems, including the Veterans Health Administration (VHA), there is increasing emphasis on the patient-centered medical home (PCMH);^{44,45} however, the ways this model will be implemented in the care of individuals with SMI remain unclear. The organization of service delivery for individuals with SMI may be the most modifiable of the many factors that impact general medical outcomes in this population. In addition, components may be added to the delivery of care to enhance medical outcomes, such as patient self-management interventions, decision support, and shared medical records. In this review, we sought to evaluate models of care designed to improve general medical outcomes among individuals with SMI.

METHODS

TOPIC DEVELOPMENT

This review was commissioned by the Department of Veterans Affairs' Evidence-based Synthesis Program. The topic was selected after a formal topic nomination and prioritization process that included representatives from the Office of Mental Health Services, Health Services Research and Development, the Mental Health Quality Enhancement Research Initiative (QUERI), and the Office of Mental Health and Primary Care Integration.

The final key questions (KQs) were:

- **KQ 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 (SMI)?
- **KQ 2.** Do models of integrated care for individuals with SMI improve the process of care for preventive services (e.g., colorectal cancer screening) and chronic disease management (e.g., annual eye examination in patients with diabetes mellitus [DM])?
- **KQ 3.** (3a) Do models of integrated care for individuals with SMI improve general functional status outcomes (e.g., as measured by SF-36) or disease-specific functional status outcomes (e.g., Seattle Angina Questionnaire) related to medical care for chronic medical conditions such as DM, hypertension, or heart failure? (3b) Do models of integrated care for individuals with SMI improve clinical outcomes related to preventive services (e.g., influenza rates) and chronic medical care (e.g., kidney disease, amputations, retinopathy in patients with coexisting DM)?
- **KQ 4.** What are the gaps in evidence for determining how best to integrate care to improve general medical outcomes for individuals with SMI?

ANALYTIC FRAMEWORK

We developed and followed a standard protocol for all steps of this review. Our approach was guided by an analytic framework adapted from a previously developed behavioral model for vulnerable populations.⁴⁶ Figure 1 shows the analytic framework.

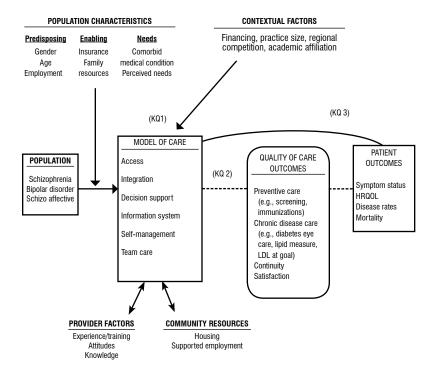


Figure 1. Analytic framework for general medical outcomes for SMI

SEARCH STRATEGY

We searched for English-language publications in MEDLINE® (via PubMed®), Embase®, PsycINFO®, and the Cochrane Library from database inception through March 10, 2011. Search terms included terms for schizophrenia and bipolar disorder; 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.⁴⁷⁻⁵⁰ The search strategies were developed in consultation with a master librarian. The search terms and MeSH headings for the search strategies appear in Appendix A. 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" or "SMI" to assess for evidence of publication bias (completed but unpublished studies) and ongoing studies that may fill gaps in evidence.

STUDY SELECTION

Using prespecified inclusion/exclusion criteria (Appendix B), two reviewers assessed the lists of titles and abstracts from the databases for further review. Full-text articles of potentially relevant abstracts were retrieved for further review. To be included in our evidence report, a study had to (1) be a randomized controlled trial (RCT) or quasi-experimental study design, (2) evaluate a care model designed to integrate mental and general medical care, (3) include a sample of adult patients with SMI (i.e., schizophrenia, bipolar disorder, schizoaffective disorder) or who met the definition of SMI based on low functional status (e.g., by Global Assessment of Functioning score) and (4) report a relevant outcome. If both preliminary and final reports were published, the final data analysis was utilized. The eligibility criteria are described in detail in Table 1.

Table 1. Summary of 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	Primary substance abuse
	A sample described as persons having SMI (based on low functional status and chronicity) and at least 25% are diagnosed with schizophrenia, schizoaffective disorder, or bipolar disorder	
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	Interventions designed to be implemented primarily in the community (nonmedical settings) Interventions designed to affect only one
	(1) a system redesign that adds care provider(s) to directly address or coordinate mental and general medical care	specific outcome or aspect of general medical health (e.g., weight loss or smoking cessation, etc.)
	(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 	
Comparators	Usual care or other quality improvement strategy	None
Outcomes	Process of care measures for preventive services (e.g., influenza vaccination rate), or chronic disease management (e.g., lipid screening or glucose control in a patient with diabetes mellitus)	Only measures of mental health care processes, symptom status, or functional status
	Clinical outcomes (e.g., rate of influenza infection)	
	Physical functioning (SF-36 Physical Component) or disease-specific symptoms (e.g., Seattle Angina Questionnaire) measured by a validated instrument	
Setting	Outpatient mental health	Hospital-based (inpatient) settings
		Community-based settings (e.g., senior centers, homeless shelters)

DATA ABSTRACTION

A trained researcher abstracted data from published articles and reports into a data abstraction form; a second reviewer overread the abstracted data. We resolved disagreements by consensus among the first and second reviewer or by obtaining a third reviewer's opinion when consensus could not be reached. We abstracted the following data for each included study:

- study design
- setting
- population characteristics
- subject eligibility and exclusion criteria
- number of subjects and providers
- intervention(s)
- comparison(s)
- length of followup
- outcome(s)

Intervention characteristics were categorized using the chronic care model and selected elements of the patient centered medical home. The chronic care model classifies health care elements into six domains: health system, delivery system design, decision support, clinical information systems, self-management support, and the community.⁵¹ With the exception of health system factors (e.g., quality-based incentives), we used these domains along with the following PCMH elements: a primary treating clinician, team-based care, and methods to enhance access to care.

We grouped immunizations and cancer screening into the general category of preventive services outcomes. For chronic disease care processes, we prioritized those with an established link to clinical outcomes (e.g., blood pressure control in patients with diabetes mellitus). Some care processes (e.g., cholesterol measurement) could be classified as preventive screening or chronic disease management. When these outcomes were reported separately, we grouped them according to our analytic framework, but in some cases we could not follow this approach because preventive and chronic disease outcomes were reported only in aggregate form.

QUALITY ASSESSMENT

We assessed the risk of bias pertaining to KQs 2 and 3 using the key quality criteria described in the Agency for Healthcare Research and Quality (AHRQ) *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*, ⁵² adapted for this specific topic (Appendix C). For RCTs, we abstracted data on adequacy of randomization and allocation concealment, comparability of groups at baseline, blinding, completeness of followup and differential loss to followup, whether incomplete data were addressed appropriately, validity of outcome measures and completeness of outcomes reporting, and conflict of interest. Using these data elements, we assigned a summary quality score of Good, Fair, or Poor to individual RCTs. We assessed studies for applicability to U.S. Veterans.

DATA SYNTHESIS

We constructed summary tables showing the study characteristics and results for all included studies, organized by KQ, intervention, or clinical condition, as appropriate. We critically

analyzed studies to compare their characteristics, methods, and findings. We compiled a summary of findings for each KQ or clinical topic and drew conclusions based on qualitative synthesis of the findings. There were not sufficient studies to perform quantitative synthesis (meta-analysis).

RATING THE BODY OF EVIDENCE

We assessed the overall quality of evidence for outcomes using a method developed by the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) Working Group,⁵³ which classified the grade of evidence across outcomes according to the following criteria:

- High—Further research is very unlikely to change our confidence on the estimate of effect.
- Moderate—Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
- Low—Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
- Insufficient—Evidence on an outcome is absent or too weak, sparse, or inconsistent to estimate an effect.

PEER REVIEW

A draft version of this report was reviewed by technical experts as well as clinical leadership, and their comments are provided in Appendix D.

RESULTS

LITERATURE FLOW

We reviewed 1598 titles and abstracts from the electronic search and an additional 24 from reference mining for a total of 1622 references. After applying inclusion/exclusion criteria at the abstract level, 1565 references were excluded. We retrieved 57 full-text articles for further review, after which another 50 articles were excluded. We identified a total of seven articles for inclusion in the current review, representing four RCTs. Four articles contained the main outcomes of the RCTs, and three articles, referred to as "companion articles," contained additional data pertinent to the four RCTs. We grouped the studies by KQ. Figure 2 details the exclusion criteria at the full-text level and the number of articles related to each of the KQs.

Additionally, our search of www.clinicaltrials.gov identified 208 potentially relevant trials. Of these, four were RCTs and one was a non-RCT of integrated care treatments for individuals with SMI. One of these trials was completed, published, and identified in our MEDLINE search.⁵⁴ The other four studies have yet to be completed. Since we did not identify any registered and completed but unpublished trials, there was no evidence in this database of publication bias. The identified trial studies, along with one additional observational study identified through contacts with experts, are summarized in KQ 4.

Figure 2 illustrates each step of our literature search process. Appendix E provides a complete listing of articles excluded at the full-text stage, with reasons for exclusion.

Excluded at title/abstract level = 1565 Search results = 1622 references* references Excluded = 50 references Not SMI = 11 Pulled for full-text review = 57 references Not outpatient = 2 Not RCT = 14 Not integrated care = 15 No medical outcomes = 5 Not peer-reviewed = 2 Not Westernized culture = 1 Included 7 articles representing 4 unique studies KQ3 KQ₁ KQ2 KQ4 4 studies + 4 studies + 4 studies + 4 studies + 3 companion articles 3 companion articles 3 companion articles 3 companion articles *Search results from PubMed (1016), PsychInfo (453), Cochrane (129), and manual (24) were combined.

Figure 2. Literature flow diagram

Abbreviations: KQ = key question; RCT = randomized controlled trial; SMI = serious mental illness

STUDY CHARACTERISTICS

Basic characteristics of the included studies are summarized in Table 2. Four good-quality RCTs (891subjects) met eligibility criteria; no quasi-experimental studies met eligibility criteria. The psychiatric diagnoses of interest (schizophrenia, schizoaffective disorder, and bipolar disorder) varied in proportion in each study, with two samples⁵⁵⁻⁵⁹ entirely consisting of patients with bipolar disorder and another sample⁶⁰ with 21 to 34 percent carrying the diagnoses of interest. Another study⁵⁴ included 49 percent with the diagnoses of interest. Druss and colleagues (2001)⁵⁴ reported that 72 to 80 percent of the sample had "severe psychiatric illness" as defined by criteria of the National Advisory Mental Health Council.⁶¹

Three studies^{54,57,59,60} tested interventions specifically aimed at improving general medical outcomes, while one study⁵⁵ 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 one study employed co-location of medical and psychiatric services.

Three studies^{55,57,59,60} were conducted in VA outpatient mental health settings, and one study was conducted in an urban community mental health center.⁵⁴ Samples in VA settings had relatively few female participants (ranging from 0.8 to 29%) while almost one-half the sample was female in the urban community mental health center study. Participants were, on average, mid-life adults; mean ages ranged from 47 to 55 years of age. Followup varied from 24 to 156 weeks. A summary of the detailed quality assessment of the studies is found in Appendix C.

Table 2. Summary of included studies

Study	Design	Sub	pjects	Setting	Intervention summary	Followup	General medical outcomes	Quality
		Disorder	Demographics					
Druss et al., 2001 ⁶⁰	RCT with usual care control N = 120	 Schizophrenia: 21% PTSD: 29% Major affective disorder: 13% Substance use: 28% "Severe psychiatric illness" by NAMHC criteria: 76% 	 Gender: 0.8% female Mean age (yr): 45.2 +/- 8.2 Race: 70% white 	VA outpatient mental health	Co-located general medical clinic with care provided by a nurse practitioner with supervision from a family practitioner. Care coordination provided by a nurse.	52 wk	U.S. Preventive Services Task Force indicators; general medical service use	Good
Bauer et al., 2006 ^{55,56} Kilbourne et al., 2009 ⁵⁸ (VA Cooperative Study)	RCT with usual care control N = 306	Bipolar disorder type I: 87% Bipolar disorder type II: 13%	 Gender: 28% female Mean age (yr): 46.6 +/- 10.1 Race: 71% "minor-ity" 	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 wk	SF-36 Physical Health	Good
Kilbourne et al., 2008 ^{57,59}	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 (yr): 55.3+/- 8.4 Race: 10% African American	VA outpatient mental health	Bipolar disorder medical care model consisting of 4 sessions self-management support, nurse care management, guideline implementation related to cardiovascular risk factors	24 wk	SF-12 quality of life–physical health; WHO-DAS	Good
Druss et al., 2010 ⁵⁴	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 (yr): 46.7 +/- 8.1 Race: 77.4% African American Hispanic or Latino: 1.5% White: 21.1% 	Urban community mental health center	Nurse care management with self-management, liaison, and case management components	52 wk	RAND Community Quality Index; SF- 36; Framingham Cardiac Index	Good

Abbreviations: NAMHC = National Advisory Mental Health Council; PTSD = posttraumatic stress disorder; RCT = randomized controlled trial; SF-36 = Short Form-36; VA = Veterans Affairs; WHO-DAS = World Health Organization—Disability Assessment Schedule; wk = week/weeks

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 (SMI)?

Studies of Efficacy

Our review identified four RCTs that met our inclusion criteria. Classification of the models of care used in these studies was informed by Wagner's Chronic Care model. 51,62-64 The models of care used in two studies 55-59 were explicitly based on Wagner's model. A third study 54 also utilized these principles, while the fourth study 60 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 clinic⁶⁰ to care management provided from remote locations.⁵⁵⁻⁵⁹ Three studies⁵⁴⁻⁵⁹ relied on research funds to pay the key staff used for the study intervention, while one study⁶⁰ was conducted in a setting where the psychiatry service paid the salaries of the staff involved in the intervention through clinical funds. The spectrum of clinical disciplines employed in the interventions of the four RCTs was relatively narrow and limited to those trained traditionally with a primary biomedical orientation (e.g., 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.

In Table 3 and the paragraphs that follow, each intervention is summarized relative to the components of Wagner's Chronic Care Model.

Table 3. SMI intervention characteristics informed by Wagner's Chronic Care Model

Study				Model elements				
	Primary provider	Team-based	Enhanced access	Self-management support	Decision support	Delivery system	Information systems	Community linkages
Druss et al., 2001 ⁶⁰	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 im- mediately follow mental health appointments when possible	None reported	None reported	Co-location of mental health and primary care services	VA computer- ized record (both study arms)	None reported
Bauer et al., 2006 ^{55,56} Kilbourne et al., 2009 ⁵⁸ (VA Coopera- tive 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" comprised 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 manage- ment; Bipolar Disorders Program	VA computer- ized record (both study arms)	None reported
Kilbourne et al., 2008 ^{57,59}	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 be- tween existing provid- ers	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 manage- ment; Bipolar Disorder Medi- cal Care Model	VA computer- ized record (both study arms)	None reported
Druss et al., 2010 ⁵⁴	Primary care and mental health care: per usual care procedures	Nurse care manager provided liaison be- tween mental health and medical providers	None reported	Care manager pro- vided motivational interviewing, devel- opment of action plans, and coaching	None reported	Care manage- ment	None reported	Public trans- portation and child care

Abbreviations: VA = Veterans Affairs

Druss and colleagues (2001)⁶⁰ conducted a good-quality RCT evaluating a co-located, integrated medical clinic contiguous with the existing mental

health outpatient clinic versus usual care in a VA medical center. Continuity of primary medical care was provided by a team that included a nurse practitioner who was supervised by a family practitioner, a nurse case manager, and an administrative assistant. The family practitioner acted as a liaison between the physicians in the medical and psychiatry services. Enhanced access was provided by reminder calls, followup after missed appointments, and efforts to schedule primary care visits immediately following mental health visits. Providers in both the intervention and usual care arms of the study had access to the VA's electronic medical record system including records from all care in the VA system. The study intervention did not include additional decision support or community linkages. This study intervention was not reported as being designed according to an explicitly stated theoretical model.

Investigators in the VA Cooperative Study^{55,56,58} conducted a multisite, good-quality RCT to evaluate the effectiveness of the Bipolar Collaborative Chronic Care Model versus usual care in 11 VA medical centers. The delivery system was a "specialty team" located in the outpatient mental health setting and consisted of a psychiatrist who worked in collaboration with the nurse care coordinator. The nurse care coordinator provided enhanced access to mental health care with same-day telephone visits and next-business-day clinic visits. While focused primarily on management of bipolar disorder symptoms, the study intervention also emphasized enrollment in primary care and collaboration with medical providers 55 utilizing the nurse care manager. Selfmanagement support, focused on bipolar disorder, was provided through a psychoeducational group (Life Goals Program) led by the nurse care coordinator over the first year of the intervention. Decision support, again primarily related to bipolar disorder, was implemented by providing the psychiatrists a one-page summary and a six-page manual of the VA Bipolar Clinical Practice Guidelines. Providers in both the intervention and usual care arms of the study had access to the VA's electronic medical record system. The study intervention did not include community linkages. This study intervention was based on Wagner's Chronic Care Model and also drew on elements from the PCMH with a stated patient-centered focus on care for bipolar disorder.

Kilbourne and colleagues (2008)^{57,59} conducted a good-quality RCT that evaluated an intervention using existing services for medical and psychiatric care in a VA medical center mental health outpatient setting augmented by the bipolar disorder medical care model, emphasizing self-management, care management, and guidelines implementation compared to usual care. The intervention began with providing four 3-hour sessions aimed at enhancing selfmanagement of bipolar disorder along with general medical issues relevant to cardiovascular disease. Upon completion of these sessions, nurse case managers provided continuous care management by acting as a liaison among patients and existing medical and psychiatric providers. Decision support was implemented through two 1-hour continuing medical education sessions for providers of medical and psychiatric care focused on the unique aspects of cardiovascular risk factors in individuals with bipolar disorder as well as strategies for managing these risk factors based on the American Diabetes Association and American Heart Association guidelines. Pocket cards were also provided to reinforce material in these sessions. Providers in both the intervention and usual care arms of the study had access to the VA's electronic medical record system including records from all care in the VA system. The study intervention did not include elements of enhanced access or community linkages. The study intervention was based largely on Wagner's Chronic Care Model.

Druss and colleagues (2010)⁵⁴ conducted a good-quality RCT evaluating medical care management using a registered nurse care manager in an urban community mental health center setting compared to usual care. The nurse care manager functioned not as a member of a team, but rather served as a liaison between medical and mental health providers. Patient self-management skills were supported through motivational interviewing, development of action plans, and coaching to help patients become more active in their own health care. Participants were linked to community resources for child care and public transportation to appointments. The study did not report that access to primary care providers was explicitly enhanced, though system level barriers were addressed by assisting eligible patients to enroll in entitlement programs. The study intervention did not include additional decision support or enhancement of information systems.

Summary of Findings

The four studies represented in our review were similar in many ways, showing a relatively limited variety of approaches to improving general medical care. All studies used nurse care or case managers to some extent to augment or facilitate care provided by physicians or nurse practitioners. Notably, disciplines such as psychologists, with expertise in facilitating behavior change, and nutritionists were not incorporated into the models tested. As described above, three of the four studies had substantial basis in the Chronic Care Model, but elements of PCMH, such as having a primary treating provider, team-based care, and enhanced access, were not robustly employed. Three of the four studies were set in the VA system, while one was a non-VA study.

KEY QUESTION 2. Do models of integrated care for individuals with SMI improve the process of care for preventive services (e.g., colorectal cancer screening) and chronic disease management (e.g., annual eye examination in patients with diabetes mellitus [DM]?

Studies of Efficacy

Two good-quality trials^{54,60} provided data relevant to KQ 2. Process of care outcomes are summarized for preventive services (Table 4) and chronic disease management (Table 5). At baseline, the quality of general medical care was low, leaving ample room for intervention effects. In both studies, a high proportion (52 to 54%) of medical diagnoses were not documented previously in the medical record, and in one study,⁶⁰ only about 20 percent of recommended preventive services had been provided prior to study start.⁵⁴

In both studies, the intervention improved preventive care as measured by receipt of immunizations and screening tests. Druss and colleagues $(2001)^{60}$ reported higher influenza vaccination rates in the intervention versus usual care group (32.2% versus 11.5%, p = 0.006), while more subjects in usual care versus intervention received the pneumococcal vaccination (32.8% versus 11.9%, p = 0.006). This latter difference was not statistically significant in the subgroup with an indication for pneumococcal vaccination.

Selected screening tests were also more likely to be performed in the intervention group than in the usual care group: digital rectal examination (69.5% versus 44.3%, p = 0.005) and flexible sigmoidoscopy (33.9% versus 14.8%, p = 0.01). The investigators also reported a nonsignificant difference favoring the intervention for hemoccult testing (49.2% versus 44.3%,

p=0.10). In the more recent study, 54 a broader set of general medical process measures were evaluated. Immunization outcomes were reported as the proportion of recommended services received (influenza; hepatitis B; measles, mumps, and rubella; pneumococcal; tetanus-diphtheria; and varicella). The intervention group was more likely to receive indicated vaccinations than the usual care group (24.6% versus 3.8%, p < 0.001). In addition, other recommended screening services (cholesterol, fecal occult blood, HIV, sigmoidoscopy, and tuberculosis testing) were completed more frequently in the intervention than usual care group (50.4% versus 21.6%, p < 0.001). 54

The effects of the intervention on chronic disease management focused on process outcomes relevant to cardiovascular disease risk. Druss and colleagues (2001)⁶⁰ reported significantly higher rates in the intervention group for weight measurement, diabetes screening, cholesterol screening, and smoking education. In the intervention group, these services were provided to 71.2 to 84.7% percent of the subjects by study end compared to 45.9 to 63.9 percent in the usual care group. In the later study, ⁵⁴Druss and colleagues found higher rates of indicated services for cardiovascular disease (34.9 versus 27.7%, p = 0.03) in the intervention group in an analysis established a priori of a subset of 202 subjects who had one or more cardiometabolic conditions (diabetes, hypertension, hypercholesterolemia, or coronary artery disease). In the subset with blood tests available, the Framingham Cardiac Index (a measure of the 10-year risk of myocardial infarction or coronary-related death) was also significantly lower in the intervention group at study end (6.9 versus 9.8%, p = 0.03), 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.

Table 4. Process of care outcomes for preventive care (KQ 2)

Study	Design	Intervention summary		Prever	ntive care	
			Immuniz	zations	Screening	g procedures
Druss et al., 2001 ⁶⁰ (additional preventive care results reported)	RCT	Co-located general medical clinic with care provided by a nurse practitioner with supervision from a family practitioner. Care coordination provided by a nurse.	Intervention • Flu: 32.2% • Pneumovax: 11.9%	Control • Flu:11.5% • Pneumovax: 32.8%	Intervention Hemoccult: 49.2% Digital rectal exam: 65.9% Flexible sigmoidoscopy: 33.9%	Control Hemoccult: 44.3% Digital rectal exam: 44.3% Flexible sigmoidoscopy: 14.8%
Druss et al., 2010 ⁵⁴ (additional preventive care results reported)	RCT	Nurse care management with self-management, liaison, and case management components.	Intervention 24.7% ^a	Control 3.8%ª	Intervention 50.4% ^b	<u>Control</u> 21.6% ^b

^aRate reported is percentage of recommended immunizations performed (influenza; hepatitis B; measles, mumps, and rubella; pneumococcal bacterial infection; tetanus-diphtheria; and varicella).

Abbreviation: RCT = randomized controlled trial

Table 5. Process of care outcomes for chronic disease management (KQ 2)

Study	Design	Intervention summary	Chronic disease r	management
			Intervention	Control
Druss et al., 2001 ⁶⁰	RCT	Co-located general medical clinic with care provided by a nurse practitioner with supervision from a family practitioner. Care coordination provided by a nurse.	 (At 12 mo) 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 ⁵⁴	RCT	Nurse care management with self-management, liaison, and case management components.	 Proportion of indicated services received for cardiovascular disease: 34.9%^a Framingham Cardiac Index: 6.9% 	 Proportion of indicated services received for cardiovascular disease: 27.7% Framingham Cardiac Index: 9.8%

^aRate reported is the proportion indicated of services received for cardiovascular disease among the subset with at least one cardiometabolic condition (diabetes, hypertension, hypercholesterolemia, or coronary artery disease).

Abbreviation: RCT = randomized controlled trial

^bRate reported is percentage of recommended screening tests performed (cholesterol, fecal blood, HIV, sigmoid, and tuberculosis).

Summary of Findings

Only two of the four studies identified for this review reported on measures relevant to KQ 2. Generally, the study interventions improved process measures for preventive services, and cardiovascular disease management. However, some measures represented a "low bar," such as measuring weight rather than evaluating the quality of care for weight control. Other measures of relevant care processes (e.g., physical activity counseling) were not reported. Although rates of recommended services were improved by the intervention, they remained suboptimal in all groups at study end.

KEY QUESTION 3. (3a) Do models of integrated care for individuals with SMI improve general functional status outcomes (e.g., as measured by SF-36) or disease-specific functional status outcomes (e.g., Seattle Angina Questionnaire) related to medical care for chronic medical conditions such as DM, hypertension, or heart failure? (3b) Do models of integrated care for individuals with SMI improve clinical outcomes related to preventive services (e.g., influenza rates) and chronic medical care (e.g., kidney disease, amputations, retinopathy in patients with coexisting DM)?

Studies of Efficacy

Four good-quality studies met our criteria for KQ 3a. All studies measured general functional status outcomes, described in Table 6. Of these, three used the SF-36 item Short-Form Survey⁶⁵⁻⁶⁷ and one used the SF-12 item Short-Form Survey.⁶⁸ Neither disease-specific symptom scales nor disease-specific functional status scales were reported in any of the studies. In addition, none of the four trials met our criteria for KQ3b by reporting clinical outcomes related to preventative services (e.g., incidence of influenza illness) or chronic medical care (e.g., diabetic retinopathy). Brief descriptions of relevant outcomes for each study are described below. Table 7 summarizes outcomes.

Druss and colleagues $(2001)^{60}$ reported scores at 52-week followup on the physical health component of the SF-36 Short-Form Survey. Mean scores were higher for the intervention than for usual care group (50.9 [SD 7.1] versus 45.3 [SD 9.7], p = NR). The difference in change between the two groups was significant (t_{170} = 3.7, P<0.001), with subjects in the integrated care clinic scoring 4.7 points higher than baseline in the physical component summary score compared to a 0.3 point decline from baseline in the score of subjects in the general medicine clinic. Higher scores indicated better functional status, and a five-point difference is generally considered a clinically important difference.

Kilbourne and colleagues (2008)^{57,59} used the physical health component of the SF-12 Short-Form Survey to report functional outcomes after 24 weeks of the bipolar disorder medical care model versus usual care. The bipolar disorder medical care intervention did not address general medical problems directly but emphasized enrollment in and collaboration with primary care. Change in SF-12 scores from baseline to 24-week follow up differed significantly between intervention and control groups (intervention change in score = 0.8 [SD 6.7] versus control

change in score -0.6 [SD 6.6]; p = 0.04).

Investigators in the VA Cooperative Study^{55,56,58} as well as Druss and colleagues (2010)⁵⁴ also reported on functional outcomes using the SF-36 questionnaire. In the VA Cooperative Study, there was no statistically significant difference at 3-year followup between the Bipolar Collaborative Chronic Care Model and usual care groups on the SF-36 physical health component (mean = 43.4, 95% confidence interval [CI], 42.4 to 44.4 versus mean = 42.9, 95% CI, 41.9 to 43.9). Similarly, Druss and colleagues (2010)⁵⁴ did not report a statistically significant difference between the mean scores of intervention versus usual care group on the SF-36 physical health component, although their findings exhibited a trend toward significance. At 1-year followup, SF-36 physical component scores were 37.1 (SD 11.5) and 34.7 (SD 11.9) for the medical care management and usual care groups respectively (p = 0.08). They also noted that the difference in change between the two group scores was not statistically significant (intervention group +1.9% versus usual care group -2.8%). This Druss study was the only one of the four reviewed that focused on an urban community mental health center and did not include veterans.

Table 6. Outcome measures

Measure	General class	Items measured	Scoring range; population mean (SD)	Direction for better outcomes
SF-36	36-item Short Form Health Survey	Physical functioning, role limitations due to physical health problems, bodily pain, general health	0 to 100; 50 (10)	Higher scores indicate better outcomes
SF-12	12-item Short Form Health Survey	Physical functioning, role limitations due to physical health problems, bodily pain, general health	0 to 100; 50 (10)	Higher scores indicate better outcomes

Table 7. Outcome summary for KQ 3

Study	Followup	Intervention versus control outcome
Druss et al., 200160	52 weeks	SF-36 physical component: mean 50.9 (SD 7.1) vs. 45.3 (SD 9.7); p <0.001 for difference in change scores using baseline, 6-month and 12-month assessments
Bauer et al., 2006 ^{55,56} Kilbourne et al., 2009 ⁵⁸ (VA Cooperative Study)	156 weeks	SF-36 physical component: mean 43.4 (95% CI, 42.4 to 44.4) vs. 42.9 (95% CI, 41.9 to 43.9)
Kilbourne et al., 2008 ^{57,59}	12 weeks 24 weeks	SF-12 physical component: mean 38.5 (SD 8.4) vs. 33.9 (SD 8.6), p = NR SF-12 physical component: mean 37.0 (SD 7.3) vs. 35.1 (SD 7.7), p = NR; difference in change scores using baseline, 3 month and 6 month assessments: 2.5, 95% CI, 0.5 to 4.9
Druss et al., 2010 ⁵⁴	52 weeks	SF-36 physical component: mean 37.1 (SD 11.5) versus 34.7 (SD 11.9); p < 0.08; difference in change scores: "not significant," p value not reported

Abbreviation: CI = confidence interval; NR = not reported; p = probability; SD = standard deviation; SF = Short Form

Summary of Findings

In summary, the findings from two good-quality RCTs provided support for small improvements in general functional outcomes at followup periods ranging up to 52 weeks. Two other RCTs did not find statistically significant differences using similar health outcome survey measures when comparing integrated care to usual care. Thus, effects on physical function appear small and inconsistent. However, interventions varied in their focus on care processes that could be expected to improve physical function. Followup periods ranged from 24 to 156 weeks, and interventions that focus primarily on preventive care could be expected to require long followup periods to show positive effects on physical functioning. Three of the four studies were conducted in the VA system, with two of three VA studies demonstrating improvements in general functional outcomes. Given the range of medical services generally offered on site at VA health care locations, integration and collocation approaches may be easier to implement, and VA interventions generalize more easily to VA settings.

We did not identify published trials or quasi-experimental studies examining clinical outcomes relating to preventative services.

KEY QUESTION 4. What are the gaps in evidence for determining how best to integrate care to improve general medical outcomes for individuals with SMI?

Only four trials, comprising 891 individuals, were identified by this review. The relatively small number of trials and limited range of outcomes reported make definitive conclusions difficult. Further, the small number of trials makes it difficult to identify the key elements of the interventions. We summarize the gaps in evidence in Table 8 and then discuss these gaps further.

Table 8. Summary of gaps in evidence

The key intervention components are uncertain.

There is greater uncertainty about intervention effects for individuals with SMIs other than bipolar disorder

Effects on clinical outcomes have not been studied.

Sustainability of intervention effects is uncertain.

Effects of interventions (effectiveness) are uncertain when part of routine care rather than part of an RCT.

Effects of current VA delivery models are uncertain, including primary care services co-located in the mental health setting and assertive community treatment.

There is uncertainty about effects of current VA programs to improve mental health outcomes of veterans with SMI (e.g., assertive community treatment) that theoretically may have beneficial effects on general medical outcomes.

Abbreviation: RCT = randomized controlled trial; SMI = serious mental illness; VA = Veterans Affairs

The four RCTs included in our review, as reported in KQ 1, offered interventions with multiple components—with all components offered to those receiving the intervention. These study designs did not permit disaggregation of intervention effects for each intervention component.

Because two studies focused entirely on individuals with bipolar disorder, the proportion of studies with other SMIs was relatively few, with just 19 percent of the overall samples identified as having schizophrenia or schizoaffective disorder. The two studies that included individuals with SMI other than bipolar disorder did not provide subgroup analyses by diagnosis, so possible differences in the efficacy of the study interventions between diagnostic groups is unknown. Global Assessment of Functioning was reported in only one trial and only by study assignment group, so it was not possible to determine the overall number of individuals who met our study criteria based on level of functioning.

None of the four trials provided information on general medical outcomes, such as rates of diabetic neuropathy, influenza, or myocardial infarction, that occurred in study populations either during the delivery of the study intervention or in follow-up. While many measures selected for process of preventive care and quality of chronic disease management are known to be correlated with clinical outcomes, absence of this information is a substantial gap in the evidence. It may be possible, particularly for the three studies conducted in VA settings, to obtain additional follow-up data on general medical outcomes on study subjects.

Three of the four studies^{54,57,60} evaluated interventions implemented at only one site. Only one study⁶⁰ explicitly stated that existing staff or resources were used in the study intervention, with the other trials delivering interventions with staff funded with research grants. Therefore, the RCTs reviewed primarily provided evidence regarding efficacy of the study interventions under ideal and closely controlled conditions. Information about the effectiveness of these interventions when implemented in existing programs was lacking.

All of the studies included in this review were RCTs with randomization at the patient level. No studies were identified using other designs stated in our inclusion criteria, such as cluster randomized trials, nonrandomized cluster controlled trials, controlled before-and-after studies, or interrupted time series designs. These additional designs can yield different types of information from the patient-level RCT, given that they are most often conducted in natural environments, thus producing fewer threats to external validity. For example, three of the four RCTs were conducted in single sites where motivation of the researchers and clinicians was likely to be high. Multisite designs might provide broader information on the effectiveness of the interventions in more naturalistic settings.

Two models of delivery of care that have already been implemented in the VA are relevant to our study questions: programs with co-located mental health and primary care and assertive community treatment programs. Mental health—primary care programs, which serve veterans with SMI in a clinic organized under the mental health service and are often co-located with mental health clinics, have been implemented in 10 out of 107 VA medical centers, based on a national survey of mental health leaders. After adjustment for organizational and patient-level factors, analyses of data from these programs showed that patients from co-located clinics received better quality of care compared with those without co-location on four of nine indicators. The study showed a need for additional chronic disease management strategies in

these co-located clinics, given that HgA1c was actually less well controlled in these clinics compared to those without co-location. Another study using VA data in these co-located clinics, compared to those without co-location, showed a significant reduction in hospitalizations for ambulatory care—sensitive conditions.^{69,70} Additional evaluation of these programs, even retrospectively, has the potential to provide valuable information relevant to our study questions, including filling some of the gaps in evidence identified here (e.g., lack of quasi-experimental designs, broader diversity of included subjects based on diagnosis, and reporting of general medical outcomes).

Assertive community treatment—implemented in the VA as Mental Health Intensive Case Management (MHICM)—has been shown to be effective in reducing symptom severity and inpatient psychiatric utilization among individuals with SMI; client-reported housing, quality of life, satisfaction with services are improved.⁷¹ Though these programs, and their evaluation, to date have been focused on mental health outcomes, case managers do facilitate receipt of primary care services to varying degrees—yet general medical outcomes of patients receiving MHICM and other assertive community treatment implementations have been largely unreported.

It is notable that the collaborative care models for bipolar disorder employed in two of the studies ^{55,57} have gained sufficient evidence to be included in the recommendations of two recent clinical treatment guidelines. ^{72,73} Still, the impact of these models on general medical outcomes remains an area where additional study is needed.

Our search of www.clinicaltrials.gov identified three RCTs and one observational study evaluating integrated approaches to addressing the general medical needs of individuals with SMI. One of these studies is being conducted in VHA. These studies are summarized in Table 9.

Table 9. Ongoing studies evaluating integrated approaches

Study title	VA/DOD population?	Intervention	Comparator	Sponsor and ClinicalTrials.gov ID number	Funding start and stop date	Status
Life Goals Behavioral Change to Improve Outcomes for Veterans With Serious Mental Illness	Y	Behavioral: life goals collaborative care	Usual care	Department of Veterans Affairs NCT01244854	October 2010 to December 2011	Enrolling by invitation
Treatment of Metabolic Syndrome in a Community Mental Health Center	N	IMBED: active comparator—a primary care provider Liaison: Active comparator—a medical case manager	Treatment as usual; no intervention	The University of Texas Health Science Center at San Antonio NCT01115114	January 2009 to September 2012	Recruiting
The Medical HOME Study	N	Care team	No intervention; referral only	National Institute of Mental Health NCT01228032	April 2010 to January 2015	Recruiting
Non-RCT	•					
Reduction of Cardiovascular Risk in Severe Mental Illness (RISCA-TMS)	N	Nurse-administered lifestyle counseling	None	Consorci Hospitalari de Vic NCT01182012	August 2010 to December 2012	Recruiting
Benefits of a Primary Care Clinic Co- located and Integrated in the Mental Health Setting for Veterans with Serious Mental Illness	Y	Enrollment in a co- located, integrated primary care clinic in the mental health outpatient unit	Subject is own comparator; timeseries design	Systems Outcomes and Quality in Chronic Disease and Rehabilitation; Providence VA Medical Center	Unfunded	Completed; manuscript in press

Abbreviations: RCT = randomized controlled trial

SUMMARY AND DISCUSSION

A key observation that emerges from this review is that integration of care for the purpose of improving general medical outcomes in individuals with SMI is an understudied area, with only four RCTs meeting our study criteria. Further, these studies tested a limited range of approaches to integrating care. Despite these limitations, these four studies provided useful findings for several of our key questions. These findings and the overall strength of evidence are summarized and discussed by key question.

SUMMARY OF EVIDENCE BY KEY QUESTION

Table 10. Strength of evidence by key question

Key question	Strength of evidence	Summary
KQ 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 (SMI)?	Not relevant to KQ 1	 4 good-quality studies Conclusions: The degree of integration of care ranged from limited to moderate. The range of integrated care models tested was relatively limited. Many PCMH elements were not included in tested models. A broader range of disciplines should be included in future evaluations of integrated care models.
KQ 2. Do models of integrated care for individuals with SMI improve the process of care for preventive services (e.g., colorectal cancer screening) and chronic disease management (e.g., annual eye examination in patients with diabetes mellitus [DM])?	Moderate	2 good-quality studies Conclusions:
KQ 3. (3a) Do models of integrated care for individuals with SMI improve general functional status outcomes (e.g., as measured by SF-36) or disease-specific functional status outcomes (e.g., Seattle Angina Questionnaire) related to medical care for chronic medical conditions such as DM, hypertension, or heart failure?	Moderate for KQ 3a Insufficient for KQ 3b	4 good-quality studies for KQ 3a; no studies reported data relevant to KQ 3b Conclusions: • Studies reported inconsistent effects on physical functional status. Two studies showed small, positive effects, and two showed no statistically or clinically significant benefit. • No study reported effects on disease-specific functional status or clinical outcomes.
(3b) Do models of integrated care for individuals with SMI improve clinical outcomes related to preventive services (e.g., influenza rates) and chronic medical care (e.g., kidney disease, amputations, retinopathy in patients with coexisting DM)?		

Key question	Strength of evidence	Summary
KQ 4. What are the gaps in evidence for determining how best to integrate care to improve general medical outcomes for individuals with SMI?	Not relevant to KQ 4	 4 good-quality studies Conclusions: There was little diversity in the types of models tested, with most models based on Wagner's Chronic Care Model. Elements of PCMH, other than those that overlap with the chronic care model, were not generally evaluated. Other than cardiovascular disease, greater variety of chronic disease outcomes is missing in the literature. There was relatively little evidence regarding individuals with schizophrenia and related psychotic disorders.

Abbreviation: DM = diabetes mellitus; KQ = key question; PCMH = patient-centered medical home; SF = Short Form; SMI = serious mental illness

KQ 1

For KQ 1, four RCTs (represented by seven articles) evaluated approaches to integrated care and most commonly were theoretically based on the chronic care model. All integrated care models were set in mental health specialty settings, had additional personnel, and used care management or care coordination as a key strategy. Only one study used co-located mental health and general medical services. Self-management support was a component in three of the four studies, but only one study used decision support for general medical care.

Within VHA, general medical and psychiatric services are most often provided in settings that are organizationally and geographically distinct. Integrating these services for patients with SMI has the potential to improve outcomes. At the simplest level, the integration of mental and physical health care takes place when specialty mental health and general medical providers collaborate to address the mental and physical health needs of their patients. Broadly speaking, integration can occur in two ways: specialty mental health care being introduced into general medical settings or general medical care being introduced into specialty mental health settings. A robust literature shows that integrating mental health services into primary care improves mental health outcomes. In contrast, few trials have tested approaches to integrating care to improve general medical outcomes for patients with SMI. On the spectrum of limited integration (e.g., communication between providers) to fully integrated (e.g., shared development and implementation of the treatment plan), the interventions tested range from limited ^{55,56,58} to moderately integrated. ⁶⁰

Although these interventions have been informed by the chronic care model, elements such as decision support, shared decisionmaking, self-management support related to chronic medical conditions, and community linkages have not been commonly 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. Implementing the PCMH in VHA—known as the Patient Aligned Care Team (PACT)—provides a potential opportunity to test these models for individuals with SMI. The locus of care for such a model for individuals with SMI is yet to be determined. The studies identified maintained mental health settings as the central point of

care with services either augmented in these settings by co-located general medical services, or by placing care managers in the mental health setting to facilitate care in the general medical setting. Given the intensity of psychiatric services often required and provided in this population, this may be a logical approach; however, studies where psychiatric services were provided to augment general medical services in the general medical setting were not identified. It is possible that the general medical and mental health needs of some individuals with SMI can be adequately provided within the context of PACT, but this model of care has not yet been formally evaluated. Finally, by emphasizing the team-care approach essential to PACT, these models could test multidisciplinary teams that include nutritionists and psychologists or health educators to address needed behavior changes. Consistent with the transformation of VA mental health services towards a recovery orientation, peer support interventions may also be useful, with one pilot study showing benefit for patient activation and number of primary care visits in a study of veterans with SMI.⁷⁴

Another potential strategy that does not appear to have been studied is the training of mental health professionals to directly manage some common general medical illnesses. It is possible that this strategy could improve general medical outcomes in individuals with SMI without increasing the burden on primary care services. However, interventions that attempt to improve mental health care through training primary care providers have been largely ineffective.

KQ₂

Two good-quality trials involving 527 patients reported outcomes relevant to KQ 2. These studies showed generally positive effects on immunization rates, cancer screening, and selected screening for cardiovascular disease. We rated the strength of evidence for these outcomes as moderate. However, important cancer-screening practices (e.g., mammography, pap smears) and chronic disease care unrelated to cardiovascular disease were not studied.

When examined in detail, these studies showed important differences in intervention design, with Druss and colleagues (2001)⁶⁰ co-locating primary care services in the mental health setting in a VA medical center and Druss and colleagues (2010)⁵⁴ providing care management in an urban community mental health center to facilitate care with various primary care providers in the community. In the later study, primary care providers were organizationally and physically separate from the community mental health center. These studies provide evidence that integrated care models can improve preventive services and chronic disease management as compared with usual care—one in an integrated system and one in a nonintegrated system. Both studies included a broad range of individuals with SMI. Given the theoretical reasons, as shown in our analytic framework, for differential effects by specific mental illnesses, social support systems, and severity of chronic medical illnesses, larger studies in multiple sites would be helpful to further understand the impact of integrated care models on these outcomes for individuals with SMI.

KQ3

For KQ 3, four good-quality trials reported inconsistent effects on physical components of functional status. Two studies showed small, positive effects, and two showed no statistically or clinically significant benefit. We rated the strength of evidence for the finding of no to small

positive effects on physical functioning as "moderate." No study reported disease-specific functional status or clinical outcomes. We rated the strength of evidence "insufficient" for these outcomes.

Integrated care models, ranging from limited to moderate levels of integration, had inconsistent effects on the physical component of functional status for individuals with SMI. Additional studies may help to clarify these mixed results. Interventions that are more tailored to specific disease states, or utilize greater levels of integration and organizational support may be required to produce more robust effects on functional status. That there were no studies providing data on clinical outcomes, such as disease-specific or all-cause mortality rates, is a significant gap in the literature. However, numerous studies among the general population have demonstrated strong links between process measures for prevention and chronic disease management and improvement in clinical outcomes. Given the size and duration of studies required to demonstrate differences in ultimate clinical outcomes for these issues, studies that assess well-established intermediate outcomes may be adequate, particularly given potentially higher priority gaps in the literature. In addition, there is not a strong reason to believe that process outcome linkages would differ for the general and SMI populations. However, incorporation of disease-specific symptom and physical function measures would be feasible and should be strongly considered in future trials.

KQ 4

Among the four studies reviewed, there was relatively little diversity in the types of models tested, with most models based on Wagner's Chronic Care Model. Elements of PCMH, other than those that overlap with the chronic care model, were not generally evaluated. Other models, including community-based care approaches may hold promise but were not evaluated in this review. At this early stage in the development of interventions to improve general medical outcomes, researchers and policymakers should remain open to alternative models.

With cardiovascular disease being a main source of morbidity and mortality in the general population and particularly in individuals with SMI, the focus on this category of disease is important. However, a greater variety of chronic disease outcomes is missing in the literature. Finally, there was relatively little evidence regarding individuals with schizophrenia and related psychotic disorders.

Important gaps in the literature were identified in our review. These gaps are further discussed in the Recommendations for Future Research section below.

LIMITATIONS

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 MeSH search term, making searches of electronic databases challenging. 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. Three of the four studies were conducted in VA settings, possibly limiting applicability outside of nonintegrated health care systems.

In addition to the above limitations, our methodological approach had important strengths. First, limiting our review to evidence gleaned from clinical trials and quasi-experimental studies allowed us to focus on quality over quantity when examining this relatively undeveloped body of research. In addition, our evidence synthesis was guided by a carefully designed standardized protocol, including a systematic search of research databases and relevant bibliographies, double data abstraction, and use of validated criteria to assess the quality of identified studies. Further, we searched for evidence of publication bias in ClinicalTrials.gov. In sum, this was a highly structured and systematic review of the extant evidence.

RECOMMENDATIONS FOR FUTURE RESEARCH

The combination of the known gaps in the quality of general medical care and subsequent outcomes in this population, together with the few relevant studies identified, confirms the importance of future research in this area. Proven interventions that close gaps in quality and can be implemented widely are needed. The ultimate goal is to improve general medical outcomes for individuals with serious mental illnesses; however none of the studies identified reports distal clinical outcomes, such as disease-specific symptom measures or disease-specific or all-cause mortality rates. Future research should include longer-term follow up and patient important clinical outcomes, particularly in the absence of a strong process – outcome association for intermediate outcomes.

SMIs encompass a wide variety of psychopathologies. Individuals with various psychiatric diagnoses within this broad group may, by virtue of the nature of their psychiatric symptoms, have differences in their experience of general medical care, leading to disparate outcomes among these subgroups. Individuals with bipolar disorder comprised two of the four studies identified here. A considerable amount of research has been conducted in the VHA and elsewhere that demonstrates significant disparities in outcomes and quality measures for individuals with other disorders, including and perhaps especially, schizophrenia and related disorders. Yet, studies here included a relatively small number of individuals with these disorders identified, with no analyses conducted by subgroup. While some methods to improve integration of care for individuals with SMI may be generalized among these diagnostic entities, some may need to be more specific to the psychiatric diagnostic group. Future research could focus on integration of psychiatric and general medical care for individuals with schizophrenia and related disorders as well as other diagnostic subgroups.

With the exception of the study by Bauer and colleagues (2006),^{55,56,58} all of the identified studies were conducted in one site, and all of the studies identified used clinical staff funded through research studies. Larger studies in more naturalistic, real-world settings are needed to evaluate the effectiveness, as opposed to efficacy, of the strategies tested. The models used in the studies in this review could be described broadly as:

- 1. Co-location of primary care services in the mental health setting.⁶⁰
- 2. Optimization of treatment for psychiatric illness through collaborative care in the mental health setting with enhanced enrollment in and collaboration with primary care. 55,56,58
- 3. Modification of the collaborative care model for psychiatric illness to specifically address common general medical issues seen in individuals with SMI.^{57,59}

4. Nurse care management, focused on general medical issues, provided in the mental health setting to increase information exchange, access to primary care, and collaboration with primary care providers.⁵⁴

The VA Cooperative Studies Program provides an valuable infrastructure for testing the effectiveness of larger scale implementation of these models, perhaps using RCTs with randomization at the site level. A large multicenter study might also allow for disaggregation of effects of various model components.

While our systematic review intentionally excluded interventions delivered in the community, the mental health outcomes associated with assertive community treatment emphasize the effectiveness of community-based interventions in this population. Assertive community treatment, implemented in the VA as Mental Health Intensive Case Management, operates under multiple principles, including that most services are provided within the team as opposed to being brokered out to other providers. The inclusion of a primary care provider, integrated into the workings of an assertive community treatment team, has not been studied as a platform for delivery of primary care services to this population. The model used in Druss and colleagues (2010)⁵⁴ could be applied to the assertive community treatment model, with case managers having increased emphasis on coordination of services for general medical illnesses and disease registries implemented to assure preventive services are delivered. 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.

Additional sites of delivery of mental health services focusing on individuals with SMI could potentially be targets for studying the addition of services oriented toward general physical health. For example, in the VA, Psychosocial Rehabilitation and Recovery Centers (PRRCs) provide treatment and rehabilitation services to Veterans with SMI. The addition of primary care services and the impact of wellness-oriented activities could be studied in PRRCs. Also, some VA Community Based Outpatient Centers (CBOCs) have developed integrated care programs. There may be a ready opportunity to conduct a high-quality observational study comparing these centers to CBOCs without integrated care programs.

By design, our review did not address disparities in quality of care received by individuals with SMI in general medical inpatient settings. Gaps in quality of care may also exist in inpatient care received by individuals with SMI, as has been shown for myocardial infarction³² and in receipt of and outcomes after nonemergency surgical procedures.⁷⁵ These issues were beyond the scope of the current review but may be important topics for future systematic reviews.

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