Evidence-based Synthesis Program

# A HSR&D

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

#### EXECUTIVE REPORT

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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.

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## **EXECUTIVE SUMMARY**

#### BACKGROUND

Individuals with serious mental illness (SMI) have shortened life expectancies relative to the general population to an extent that is not explained by unnatural causes such as suicide or accidents. Numerous studies show higher rates of acute and chronic illnesses, lower quality general medical care and worse outcomes in individuals with SMI. 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 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 this review, we sought to evaluate models of care designed to improve general medical outcomes among individuals with SMI. We conducted a systematic review of the peer-reviewed literature to answer the following key questions (KQs):

**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?

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.

#### **METHODS**

We searched for English-language publications in MEDLINE<sup>®</sup> (via PubMed<sup>®</sup>), Embase<sup>®</sup>, PsycINFO<sup>®</sup>, 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. 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.

Titles, abstracts, and articles were reviewed in duplicate by investigators trained in the critical analysis of literature. 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. Study characteristics, patient characteristics, and outcomes were extracted by trained research staff. 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*: 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.

#### **DATA SYNTHESIS**

We constructed summary tables showing the study characteristics and results for all included studies, organized by KQ. We critically analyzed studies to compare their characteristics, methods, and findings. We compiled a summary of findings for each KQ and drew conclusions based on qualitative synthesis of the findings. There were not sufficient studies to perform quantitative synthesis (meta-analysis). We graded the strength of evidence for KQ 2 and KQ3 using principles from the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) Working Group. This approach assesses the strength of evidence for each critical outcome by considering risk of bias, consistency, directness, precision, and publication bias. After considering each domain, a summary rating of "high," "moderate," "low," or "insufficient" strength of evidence was assigned.

#### **PEER REVIEW**

This draft version of the report will be reviewed by technical experts as well as clinical leadership, and their comments will be considered in the final report.

#### RESULTS

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. No non-RCT studies met eligibility criteria.

Of the four RCTs, three were set in the VA facilities and one was set in a community mental health center. Because two studies focused entirely on individuals with bipolar disorder, the proportion of subjects with other SMIs was relatively low, with just 19 percent of the overall samples identified as having schizophrenia or schizoaffective disorder.

**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)?

Four RCTs evaluated approaches to integrated care; most studies were theoretically based on Wagner's Chronic Care Model. All integrated care models were set in mental health specialty settings, added new 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. 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 to moderately integrated.

The four studies represented in our review were similar in many ways, showing a relatively limited variety of approaches to improving general medical care for individuals with SMI. Notably, professionals 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 the patient-centered medical home (PCMH), such as having a primary treating provider, team-based care, and enhanced access, were not robustly employed.

**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])?

Two good-quality RCTs involving 527 patients reported outcomes relevant to this question. Compared to usual care, interventions showed generally positive effects on immunization rates, cancer screening, and selected screening for cardiovascular disease in nonintegrated care systems. We rated the strength of evidence for these outcomes as moderate. However, some measures represented a "low bar," such as measuring weight rather than evaluating the quality of care for weight control, and important cancer-screening practices (e.g., mammography, pap smears) and chronic disease care unrelated to cardiovascular disease were not studied.

**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)?

Four good-quality RCTs, involving 891 subjects, reported effects on functional status outcomes, but no studies reported effects on clinical outcomes. Compared to usual care, integrated care in two RCTs showed small, statistically significant improvements in physical functioning

at followup periods ranging from 12 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 26 to 156 weeks, and interventions that focused primarily on preventive care could be expected to require long followup periods in order to show positive effects on physical functioning. Interventions that are more tailored to specific disease states or that utilize greater levels of integration and organizational support may be required to produce more robust effects on functional status.

Three of the four studies were conducted in the VA system, with two of three VA studies demonstrating improvements in physical functioning. Given the range of medical services generally offered on site at VA healthcare locations, integration and collocation approaches may be easier to implement in VHA than many other health care systems.

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

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. Given the high prevalence of cardiovascular disease in individuals with SMI, the focus on process of care for cardiovascular disease is important. However, effects of integrated care on a broader range of preventive and chronic disease services and, importantly, clinical outcomes is needed. Finally, relatively few individuals with schizophrenia and related psychotic disorders were included in these studies, and it is uncertain if the positive effects would be replicated in these patients.

Our search of ClinicalTrials.gov found three ongoing RCTs and one ongoing non-RCT evaluating care models for individuals with SMI.

The following table summarizes the key gaps in evidence.

Key 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.