



Evidence Brief: Use of Patient Reported Outcome Measures for Measurement Based Care in Mental Health Shared Decision-Making

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PREFACE

The VA Evidence-based Synthesis Program (ESP) was established in 2007 to provide timely and accurate syntheses of targeted healthcare topics of particular importance to clinicians, managers, and policymakers as they work to improve the health and healthcare of Veterans. QUERI provides funding for four ESP Centers, and each Center has an active University affiliation. Center Directors are recognized leaders in the field of evidence synthesis with close ties to the AHRQ Evidence-based Practice Centers. The ESP is governed by a Steering Committee comprised of participants from VHA Policy, Program, and Operations Offices, VISN leadership, field-based investigators, and others as designated appropriate by QUERI/HSR&D.

The ESP Centers generate evidence syntheses on important clinical practice topics. These reports help:

- Develop clinical policies informed by evidence;
- Implement 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.

The ESP disseminates these reports throughout VA and in the published literature; some evidence syntheses have informed the clinical guidelines of large professional organizations.

The ESP Coordinating Center (ESP CC), located in Portland, Oregon, was created in 2009 to expand the capacity of QUERI/HSR&D and is charged with oversight of national ESP program operations, program development and evaluation, and dissemination efforts. The ESP CC establishes standard operating procedures for the production of evidence synthesis reports; facilitates a national topic nomination, prioritization, and selection process; manages the research portfolio of each Center; facilitates editorial review processes; ensures methodological consistency and quality of products; produces “rapid response evidence briefs” at the request of VHA senior leadership; collaborates with HSR&D Center for Information Dissemination and Education Resources (CIDER) to develop a national dissemination strategy for all ESP products; and interfaces with stakeholders to effectively engage the program.

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

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EXECUTIVE SUMMARY

Key Messages

- This rapid review found no studies of the specific VA-recommended approach of using any of 4 recommended patient-reported outcome measures (PROMs) for implementing measurement based care (MBC) in the context of shared decision-making in mental health. However, we identified other promising approaches to use of PROMs for MBC in mental health.
- Inadequate measurement of MBC’s hypothesized mechanism of action (*eg*, detection of non-response and change in treatment plan) and MBC protocol fidelity are the greatest weaknesses of the evidence base.
- New research would be more meaningful if it evaluated the specific VA-recommended MBC approach, improved on identified methodological limitations, evaluated a wider range of clinically meaningful outcomes, and simultaneously compared MBC use under 2 or more implementation strategies that are feasible for a wider range of care settings.

Measurement based care (MBC) is a care delivery approach involving the regular use of standardized measures in routine mental health care to identify individuals not improving as expected and to prompt treatment changes. In the US Department of Veterans Affairs (VA), MBC is specifically defined as: (1) Collect = use of “reliable, validated, clinically appropriate measures at intake and at regular intervals”, (2) Share = “results from the measures are immediately shared and discussed with the Veteran and other providers involved in the Veteran’s Care”, and (3) Act = “Together, providers and Veterans use outcome measures to develop treatment plans, assess progress over time, and inform shared decisions about changes to the treatment plan over time”. As of January 2018, the Joint Commission requires MBC use in all mental health treatment programs accredited under behavioral health standards both within and outside of VA. As MBC delivery has varied widely and shown equally variable clinically meaningful effects across studies, guidance is needed on which specific delivery approaches may operate most effectively and why.

This rapid evidence synthesis builds on recent conflicting reviews by adding 14 new studies and focusing on the subset of approaches with the most clinically meaningful and highest-strength evidence and with the most relevance to the specific approach currently recommended by VA.

Despite the large volume of new studies, identification of the most promising delivery approaches for VA remains difficult, because the methodological quality of the evidence remains low, no studies were in Veterans, no studies evaluated the specific approach currently recommended by VA, and effects on other important clinical outcomes, patient satisfaction with

Background

The ESP Coordinating Center (ESP CC) is responding to a request from the Office of Mental Health and Suicide Prevention (OMHSP) for an evidence brief on measurement based care (MBC) practices in mental health care, specifically in the context of using standardized patient-reported outcome measures in shared decision-making with individual Veterans. Findings from this evidence brief will be used to inform guidance for MBC within the VHA.

Methods

To identify studies, we searched MEDLINE®, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, and other sources up to August 2018. We used prespecified criteria for study selection, data abstraction, and rating internal validity and strength of the evidence. See our PROSPERO protocol for our full methods.



care processes, and adverse effects or unintentional consequences remain unknown. The greatest weaknesses of this evidence are that 1) it lacks measurement of the hypothesized mechanism of action (eg, detection of non-response and change in treatment plan) and 2) it lacks information about MBC protocol fidelity.

The most promising MBC approach we identified was when MBC was used in a single Norwegian general outpatient psychiatric clinic in the course of an intense implementation strategy including extensive training provided by the PROMs tool creators, use of technology-assisted automated risk scoring, and strong management advocacy including moral and financial support for providers (48% vs 33%; OR 1.91; 95% CI 0.88 to 4.15; P = 0.1025; NNT = 7, Executive Summary Table). Key strengths of this study that increase our confidence that the mechanisms of effect could be specifically attributed to MBC are that it took extra measures to minimize confounding due to therapist variability and clients' pretreatment distress levels and better protected against lack of blinding by using an independent outcome assessment measure. However, its use of a not-yet-VA-recommended assessment tool and an intense implementation facilitation strategy raises concerns about the feasibility of its widespread use across VA nationally in different clinical settings with variable resources.

The effects of MBC on suicide behavior, functioning, and quality of life are largely unknown. In addition to clinical outcomes, although it has been suggested that MBC has the potential to improve patient satisfaction with care and treatment adherence, and to reduce no-shows and drop-outs, to date there is limited randomized controlled trial evidence to support these proposed benefits.

The potential benefits of MBC have been best shown in populations with anxiety and/or depressive disorders. MBC has also shown some promise in couples' therapy and in inpatient treatment of eating disorders, but not for outpatient treatment of eating disorders, the specific symptoms of schizophrenia, or for patients in severe psychiatric crisis seeking emergency help. We found no studies of MBC in PTSD, bipolar disorder, or for suicide prevention.

MBC is a complex, multicomponent, multidisciplinary, and nuanced care delivery process that can represent a major change to practice. However, it is inherently difficult to study because there are so many more sources of heterogeneity and confounding – system, provider, patient, MBC approach – than with a single intervention, such as with a new antidepressant. New research would be more meaningful if it adequately addressed a broader range of sources of confounding, demonstrated that MBC shortened time to identifying patients at risk of important below-expected progress, and improved the types of treatment plan changes made in the context of shared decision-making using a wider range of instruments (ie, VA-recommended instruments) and under implementation strategies that are feasible for a wider range of care settings.

Executive Summary Table: Summary of Findings

Key Question 1: Effectiveness of Measurement Based Care Delivery Practices	
E	<p><i>Clinically Significant Improvement in Overall Distress</i></p> <p>54% of studies reported a clinically meaningful response with MBC. Best evidence from Brattland et al 2018 with 93% PCOMS administration fidelity.</p> <p>Evidence: 13 RCTs¹⁻¹³</p>

E *Suicide Behavior, Functioning, and Quality of Life*
 MBC improved quality of life in 1 of 3 studies. No studies reported on suicide behavior and functional outcomes.
Evidence: 3 RCTs¹⁴⁻¹⁶

E *Satisfaction with Care*
 Improvement in satisfaction in a study of patients with schizophrenia or related psychotic disorders and no change or decreased satisfaction in 2 studies of patients with primarily anxiety and/or depressive disorders.
Evidence: 3 RCTs¹⁵⁻¹⁷

≈ *No-shows, Drop-outs, Medication Adherence*
 No change in attendance rates in 4 studies. No studies reported on no-shows or medication adherence.
Evidence: 4 RCTs^{10,14,18,19}

Key Question 2: Adverse Effects and Unintended Consequences of Measurement Based Care

? *Unknown*
Evidence: None

Key Question 3: Outcomes of Measurement Based Care Delivery Practices in Specific Populations

á *Couples Therapy*
 Improved rate of reliable or clinically significant change with MBC.
Evidence: 2 RCTs^{2,9}

E *Eating Disorders*
 Increased rates of clinically significant improvement in inpatient care and improved dietary restriction behaviors in outpatient individual CBT, but no improvement in outpatient group psychotherapy.
Evidence: 3 RCTs^{10,14,19}

E *Schizophrenia*
 Improvement in quality of life, patient satisfaction, and health and social needs, but not schizophrenia symptoms.
Evidence: 1 RCT¹⁶

â *Severe Psychiatric Crisis*
 Less improvement in outcomes patients receiving MBC.
Evidence: 1 RCT²⁰

Abbreviations: RCT=randomized controlled trial; MBC=measurement based care; CBT=cognitive behavioral therapy; PCOMS=Partners for Change Outcome Management System

EVIDENCE BRIEF

INTRODUCTION

PURPOSE

The ESP Coordinating Center (ESP CC) is responding to a request from the Office of Mental Health and Suicide Prevention (OMHSP) for an evidence brief on measurement based care (MBC) delivery practices in mental health care, specifically in the context of using standardized patient-reported outcome measures in shared decision-making with individual Veterans. The OMHSP will use findings from this evidence brief to inform guidance for MBC within the VHA.

BACKGROUND

Some research suggests that symptom deterioration in patients with mental health conditions may not always be easy for clinicians to detect.²¹ Systematic use of standardized patient-reported outcome measure (PROMs) instruments to augment clinical judgment in routine mental health care is increasing.²² The practice of systematically administering PROMs to monitor progress and using their results to inform treatment decisions is typically referred to as Measurement Based Care (MBC).^{23,24} “MBC is designed to optimize the efficiency, accuracy, and consistency of symptom assessment in order to maximize the likelihood that nonresponse to treatment is detected by the provider.”²³ Other proposed benefits of MBC include its potential to enhance the therapeutic relationship, improve treatment adherence, focus collaboration, create a more informed, engaged, and activated patient, facilitate communication between providers, and support quality improvement efforts.²²

Some leading theories about how MBC might work include that the feedback influences the providers to improve care consistent with best practice guidelines (Feedback Intervention Theory), and improves performance when “novel information about performance, especially errors, is provided in a timely manner” (Contextual Feedback Theory), and that the process of feeding back the test results to the patients *itself* has a therapeutic effect (Feedback Intervention Theory).^{25,26} The elements necessary to support these proposed mechanisms include: (1) use of a valid instrument that accurately distinguishes between people making expected progress from those that are not by comparing progress with norms or expected response, (2) the instrument has to provide targeted and actionable information about people who are progressing at a below-average pace that is accessible at the time of the clinical encounter, and (3) the provider has to adhere to the MBC model and have the ability and desire to readily initiate specific improvements in treatment that are consistent with best practice guidelines.²³

Numerous validated symptom rating instruments exist that may be appropriate and useful for measuring mental health symptoms in MBC.²³ For depression symptoms, the 9-item Patient Health Questionnaire (PHQ-9) is commonly recommended as a brief and practical option.²³ For example, the VA MBC Initiative currently recommends the PHQ-9 along with 3 other measures selected by the Military and Veterans Mental Health Interagency Task Force – the Generalized Anxiety Disorder (GAD-7), PTSD Checklist (PCL-5), and Brief Addition Module (BAM) – as measures that address prevalent and high-impact psychological health conditions, are easily administered across settings, and are reliable and valid.^{27,28} Other transdisciplinary instruments have been developed that are specifically designed for collecting and using patient feedback in

behavioral healthcare services. Two instruments commonly used in MBC studies which can also be used in the VA are the Partners for Change Outcomes Management System (PCOMS) and the Outcome Questionnaire (OQ-45). Evaluation of their performance characteristics found high internal consistency and adequate concurrent validity, both with each other and other measures, including the Symptom Checklist-90 and the Depression Anxiety Stress Scale.²⁹⁻³² The PCOMS assesses outcomes and process with 2 brief, transtheoretical, 4-item scoring scales (range 0 to 10 for each item, total score of 40 for each scale). The Outcome Rating Scale (ORS) focuses on treatment outcomes and is designed to be used at the beginning of each session, and the Session Rating Scale (SRS) focuses on therapeutic alliance and is designed to be used after each session.^{29,31} Patients are asked to place a hash mark on four different 10-centimeter visual analog scales representing different areas of functioning and therapeutic alliance.³³ Based on these scales, a progress curve is manually or electronically charted with a dotted line representing expected trajectory of change. Patients can be classified as “Deteriorating: dropping 5 points”, “No Change: no reliable change after 3 sessions”, “Reliable Change: gain of 5 points”, and “Clinically Significant Change: gain of 5 points and passing the cut-off score of 25”, and corresponding recommendations to clinicians are provided based on patient classification.²

The OQ-45 is a 45-item global distress scale with 3 subscales (symptom distress, interpersonal relations, and social role) and was the first instrument designed to monitor patient functioning at each session.^{34,35} This tool identifies patients who are not-on-track (NOT) and provides clinical support tools to measure the therapeutic alliance, readiness for client change, and social support level to assist in evaluating treatment progress.³² Each of the 45 items is scored on a 5-point scale with a total score range from 0 to 180. Patients reaching an improvement of 14 points are considered to meet the cut-off of the Reliable Change Index and patients with an overall score of 63 or less are considered to be in normal range. Based on patient’s trajectory and change, feedback is presented in 4 color codes: White feedback: patient is in normal range, Green feedback: rate of change is adequate, Yellow feedback: rate of change is less than adequate, Red feedback: patient is not making expected level of progress.³⁶

MBC has been used as one component in various complex multi-component care management and/or collaborative mental health care models, along with treatment planning according to a recommended algorithms, the addition of mental health specialist case managers to the treatment team, and patient education.³⁷⁻³⁹ MBC use is also currently supported in a number of published guidelines. In 2011, the National Institute for Health and Care Excellence (NICE) issued a depression guideline that recommends considering using a validated measure to evaluate treatment, recording the results, and using them to adjust treatment.⁴⁰ In 2012, the Institute of Medicine (IOM) advised that the Department of Defense (DoD) and Department of Veterans Affairs (VA) move toward MBC for posttraumatic stress disorder (PTSD).⁴¹ As part of their formal, national MBC in Mental Health Initiative, VA has implemented MBC nationally as a standard of care in mental health *specifically for use in the context of shared decision-making*. In VA, shared decision-making is an important element in their overall patient-centered approach to mental health. Thus, in the VA setting, MBC is specifically defined as: (1) Collect = use of “reliable, validated, clinically appropriate measures at intake and at regular intervals”, (2) Share = “results from the measures are immediately shared and discussed with the Veteran and other providers involved in the Veteran’s Care”, and (3) Act = “Together, providers and Veterans use outcome measures to develop treatment plans, assess progress over time, and inform shared decisions about changes to the treatment plan over time.”⁴² As of January 1, 2018, the Joint

Commission requires all programs accredited under behavioral health standards within and outside of VA to start using MBC.⁴³

However, implementing MBC can be challenging^{22,44} because MBC systems are complex and can vary widely with respect to the measures used, format of measures (*ie*, paper and pencil vs electronic), frequency of administration, intensity level of feedback given (*ie*, none, to provider, patient, or both), format of feedback (*ie*, verbal, narrative printed materials, graphical printed materials), opportunities for discussion (*ie*, none, unstructured, or structured), and/or levels of inclusion in treatment decisions (*ie*, none, unstructured, or structured use of a formal clinical support tool).⁴⁵ Purposes of PROM use in mental health care can also vary from quality improvement, to use as a tool to facilitate communication among multidisciplinary teams, to a decision aid to promote patient-centered care.⁴⁶ A 2015 scoping study proposed a typology of 5 MBC categories based on level of intensity of feedback, from 1 = no feedback provided to the clinician or patient to 5 = PROM results reported back to the clinician and client, with a formal procedure in which a discussion of PROMs can affect subsequent treatment.⁴⁷

Practical concerns about MBC have also been a challenge to its implementation. For example, surveys exploring attitudes about MBC found that front-line VA providers' perceptions of the clinical utility of MBC were generally positive, but may vary by provider type (*ie*, psychiatrist, nurses, social workers, psychologists)⁴⁸ and that public mental health service workers perceive a need for more training.⁴⁹ Additionally, in a 2015 survey of barriers to MBC implementation, providers indicated that reasons for not using measures included that they didn't have time, there was no way to keep track of scores, and they weren't easily accessible.²⁴ Providers also may dislike systematic PROM use to assess response for reasons such as worry they undermine professional autonomy or intrude in sensitive consultations or skepticism about motives.^{50,51} Also, if viewed as evaluative, providers may interpret MBC as threatening and view it with fear and mistrust.⁴⁴

Recent literature reviews on MBC's general effectiveness have been mixed. For example, a 2015 review that grouped studies into 5 categories based on feedback intensity level (1 = no feedback to 5 = feedback to clinician and client, with a formal procedure in which a discussion of PROMs can affect subsequent treatment) and qualitatively evaluated results for each category found that "PROM feedback appears to be more effective when integrated in a formalized and structured manner" (category 5).⁴⁵ However, as that review was for scoping purposes only and did not include any critical appraisal of how well studies controlled for potential biases, the validity of its conclusions about MBC's effects on patient outcomes are unclear. In contrast, a 2016 good-quality Cochrane review that did consider risk of bias but lumped all the studies together regardless of MBC approach found that MBC has not been conclusively shown to improve mean symptom scores over no MBC after 1-6 months (standardized mean difference -0.07, 95% CI -0.16 to 0.01, N=3696).⁵² Finally, the most recent 2018 review specifically of using the OQ-45 or PCOMS in psychotherapy found that "two-thirds of studies found that routine outcome monitoring-assisted psychotherapy was superior to treatment-as-usual", but it also did not consider variation in the risk of bias of the primary studies.⁵³ MBC's impact on patient outcomes and its exact mechanism(s) have been difficult to study. Identification of key components have been difficult to identify among mixed findings because of multiple potential sources of heterogeneity and confounding, including wide diversity in approaches used across studies, patient factors (*eg*, illness severity and duration, comorbidities, previous experience with MBC), provider factors (*eg*, attitudes, training, experience, management approach, accreditation,

adherence to MBC), and treatment type (eg, psychotherapy, pharmacotherapy, education, further testing).

As previous reviews have had mixed findings and none have provided sufficient guidance specifically about MBC as used in shared decision-making, the approach endorsed by VA, to advance previous work we conducted a rapid evidence review to evaluate the effectiveness and harms of MBC in mental health shared decision-making.

SCOPE

This evidence brief will address the following key questions and inclusion criteria:

Key Questions

Key Question 1: What is the effectiveness of measurement based care delivery practices in mental health care?

Key Question 2: What are the adverse effects and unintended consequences of using measurement based care delivery practices in mental health care?

Key Question 3: Do the effectiveness and/or adverse effects of using measurement based care delivery practices in mental health care vary by patient demographics (gender, race, *etc*) or mental health characteristics/diagnoses (psychoses, addiction, PTSD, suicide risk, *etc*)?

Eligibility Criteria

The ESP included studies that met the following criteria:

- **P**opulation: Adults receiving mental health treatment
- **I**ntervention: Measurement based care as used in treatment monitoring (not screening), specifically including collection of standardized patient reported outcome measures, sharing of results with the patient AND provider, AND shared decision-making (including treatment planning). We did not include studies that used MBC as just one of many “extras” within a broader bundled intervention model because they do not allow evaluation of the individual contribution of the MBC component outside of the bundled model.
- **C**omparator: Any comparator that does not include measurement based care
- **O**utcomes:
 - Clinically relevant improvement in mental health symptom scores, suicide (attempts, ideation), functioning, health-related quality of life, patient satisfaction, care processes (no-show rates, drop-out from care, medication adherence, *etc*)
 - Adverse effects/unintended consequences (number and type of psychotropic drug side-effects)
- **T**iming: Any

- **S**etting: Any
- **S**tudy design: Any, but may prioritize to accommodate timeline using a best-evidence approach

METHODS

To identify articles relevant to the key questions, our research librarian searched Medline, PsycINFO, CENTRAL, and Google Scholar from 1/1/2015 through 11/16/2018, using terms for psychotherapy, feedback, and patient-reported outcomes (see Supplemental Materials for complete search strategies). We relied on the 2016 Cochrane review by Kendrick et al for identification of studies published through 2014.⁵² Additional citations were identified from hand-searching reference lists and consultation with content experts. We limited the search to published and indexed articles involving human subjects available in the English language. Study selection was based on the eligibility criteria described above. Titles and abstracts were reviewed by one investigator and checked by another (sequential review). Full-text articles were sequentially reviewed by 2 investigators. All disagreements were resolved by consensus.

We rated the internal validity of studies only for the subset of studies that used MBC approaches most relevant to the specific approach currently recommended by the VA that at least included collecting and sharing of feedback with patients. To rate the internal validity, we used a subset of items from the Cochrane's Risk of Bias Tool,⁵⁴ that focused on randomization adequacy, balance of baseline characteristics, control for confounding variables, and adequacy of fidelity to the MBC protocol. We abstracted data from all included studies and results for each included outcome. All data abstraction and internal validity ratings were first completed by one reviewer and then checked by another. All disagreements were resolved by consensus.

We informally graded the strength of the evidence based on the AHRQ Methods Guide for Comparative Effectiveness Reviews, by considering risk of bias (includes study design and aggregate quality), consistency, directness, and precision of the evidence.⁵⁵ Ratings typically range from high to insufficient, reflecting our confidence that the evidence reflects the true effect. For this review, we applied the following general algorithm: evidence comprised primarily of RCTs with high risk of bias received ratings of 'insufficient'; evidence consisting of a single fair- to good-quality RCT received a rating of 'low strength'; and evidence consisting of multiple, consistent, precise, fair- to-good quality RCTs received a rating of 'moderate strength' or 'high strength'. We found no 'high-strength' evidence, but this generally would have been comprised of multiple, good-quality, precise RCTs.

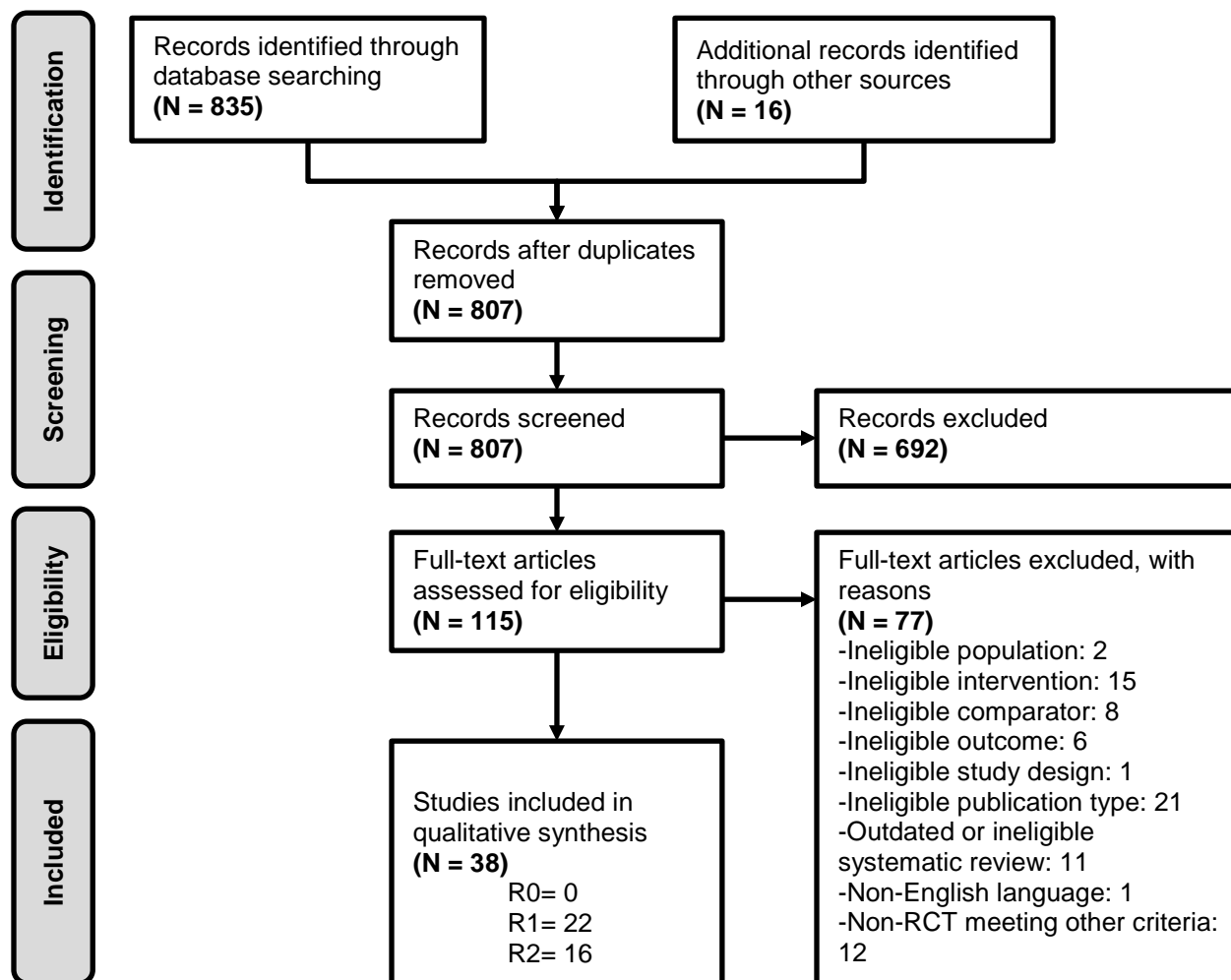
Where studies were appropriately homogenous, we synthesized outcome data quantitatively using Microsoft® Excel® for Windows (2016) to estimate pooled effects. Where meta-analysis was not suitable due to limited data or heterogeneity, we synthesized the evidence qualitatively.

The complete description of our full methods can be found on the PROSPERO international prospective register of systematic reviews (<http://www.crd.york.ac.uk/PROSPERO/>; registration number CRD42018107202). A draft version of this report was reviewed by peer reviewers as well as clinical leadership. Their comments and our responses are presented in the Supplemental Materials.

RESULTS

LITERATURE FLOW

Figure 1. Literature Flowchart



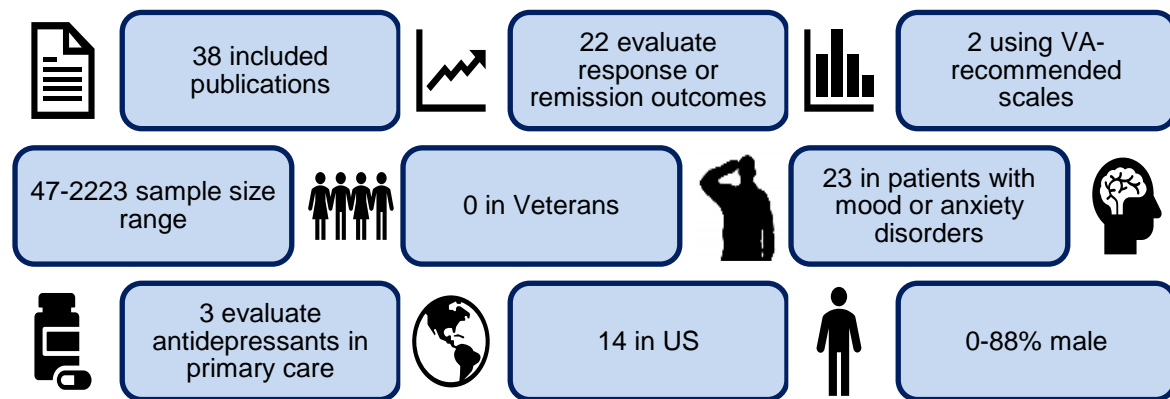
R0 = Explicitly describes all 3 components of the specific VA-recommended MBC approach with shared decision-making (collect, share, and act with shared decision-making)
 R1 = Collection of PROMs data + standard procedure or guidance to share/discuss feedback with patients and/or act, but not clearly with shared decision-making
 R2 = Collection of PROMs with no standard procedure or guidance for sharing/discussing feedback with patients or acting with or without shared decision-making

LITERATURE OVERVIEW

Searches resulted in 807 unique and potentially relevant articles. We included 38 studies.^{1-20,34,56-72} No studies described use of explicit shared decision-making (see Figure 1 for specific criteria). Twenty-two studies were categorized as R1.^{1-20,63,68} Sixteen studies were categorized as R2.^{34,56-62,64-67,69-72} For our synthesis, we focused on studies with at least a standard procedure for sharing

and discussing feedback with patients (R1). For a list of ongoing and excluded studies, see Supplemental Materials. Figure 2 provides details about key study characteristics.

Figure 2. Selected Study Characteristics



MBC Approaches and Applicability to MBC in Shared Decision-making

In general, findings from MBC studies are most applicable to populations with anxiety and/or depressive disorders as implemented into general outpatient treatment settings. Additionally, some studies focused on more specific populations including eating disorders,^{10,14,19} relationship issues,^{2,9} schizophrenia,¹⁶ and severe psychiatric crisis.²⁰ Although the number of MBC RCTs is increasing, the available evidence likely has unclear applicability to the specific practice of using any of the 4 VA-recommended tools for MBC in the context of shared decision-making in primary care mental health integrated care management models such as are primarily used in VA. This is because we found no studies that used an MBC approach as specifically defined by VA (*ie*, collect, share, and act with shared decision-making) in a care management setting, only one study in a military/Veteran population,⁶⁹ and only 2 studies that used any of the VA-recommended MBC tools (PHQ9 and GAD7).^{13,15} Studies collected PROMS data, but typically either (1) combined that with guidance on how to share feedback with clients and made suggestions on how to act, which may or may not have included shared decision-making, or (2) did not provide explicit guidance on if/how to share and act on feedback. For example, in the RCT with the potential to be the most relevant to Veterans in terms of population characteristics – the only study in a military population, many of whom were returning Veterans from Iraq and Afghanistan – applicability is still limited because the MBC approach involved only giving PROMs results to therapists with no sharing with participants and no attempt to monitor therapist behavior regarding PROMs use for informing treatment planning.⁶⁹ Similarly, although a 2015 RCT by Guo et al⁶³ is frequently cited as providing strong evidence of MBC's benefits, its findings also likely have limited applicability to MBC in shared decision-making because it was unclear whether MBC ratings were shared with the patients and clinicians made treatment decisions strictly based on an explicit and fixed dosing schedule of either paroxetine or mirtazapine, which did not appear to incorporate patient preference.⁶³

Methodological Quality

The methodological quality of the MBC literature remains low, making it difficult to attribute treatment effects to specific mechanisms of MBC. Low methodological quality is primarily due to (1) the lack of adequate information about the actual use of MBC or the quality of its implementation, (2) lack of information about potential for confounding due to between-group heterogeneity in provider characteristics (*ie*, experience, competence, treatment models, case mix, training, and attitudes toward MBC), patient illness severity and duration, comorbidities, previous experience with MBC, intensity of psychotherapy (*ie*, frequency and duration) and concomitant treatments (*ie*, pharmacotherapy, education, further testing), and (3) lack of use of an independent instrument to corroborate progress in the feedback group that was based on the feedback instrument alone. Only 5 RCTs reported on MBC fidelity.^{3,6,18,20,68} Among those, they generally only reported on administering the PROMs (*ie*, administered every session in 93% of patients,³ or 67% of therapists reported applying PCOMS adequately in > 70% of sessions²⁰) and did not provide information about if and how they used the PROMs in treatment decisions. To control for provider variability, 3 studies randomized by provider^{8,16,68} but typically little information was provided about patient characteristics and even less was provided about treatment type and/or intensity. Finally, as blinding the patients and therapists to whether or not they are in the feedback group in MBC studies is not feasible, there exists an inherently increased risk of more favorable outcomes in the feedback group due to expectations alone and the potential for more attention in general. Additionally, the feedback group is at risk of further favoring because patients may be extra motivated to improve when informed of scores indicating lower improvement than perceived as expected. Therefore, to better protect against this bias, use of another independent outcome measure to corroborate progress should be used as assessed by a blinded outcome assessor and without discussion by the therapist or client. However, only a single study used blinded outcome assessors¹⁹ and one study assessed outcomes using an independent instrument.³

Strength of Evidence

Our confidence in the strength of the findings on MBC's effects is generally low because studies did not directly assess MBC as defined by the VA, they had serious methodological weaknesses as discussed above, and most MBC approaches were evaluated by single-study evidence bases (unknown consistency in direction and/or magnitude of effect).

KEY QUESTION 1: What is the effectiveness of measurement based care delivery practices in mental health care?

Clinically Significant Improvement in Overall Distress

MBC's effects are mixed across studies that evaluated approaches that included collect and share components and encouraged but did not monitor acting on results (Table 1). For example, among the 14 studies that reported rates of patients with a clinically meaningful response, 57% of MBC approaches resulted in statistically significantly improved outcomes.^{1-3,8-10,12,63} However, determining what MBC conditions are most effective was difficult due to heterogeneity across studies in multiple patient, provider, setting, and implementation approach factors.

Among the studies demonstrating clinically important improvements, 2 studies stand out as providing the strongest support for MBC.^{3,63} First is a 2018 RCT of 170 mostly women with

mood and anxiety disorders seen in a hospital-based outpatient psychiatric clinic in Norway.³ In this RCT, under ideal implementation circumstances, MBC resulted in a small but significant improvement in outcomes over treatment as usual ($d = 0.26$), with improvements increasing over time. The advantage remained even after adjustments for therapist variability and clients' pretreatment distress levels. What makes this possibly the best evidence we have are the following important strengths of this RCT: (1) high PCOMS measure administration fidelity was documented (93%), (2) an independent measure of symptom and function was used to assess outcome, (3) therapists were regularly trained and supervised (*ie*, obligatory 1-day face-to-face training twice a year given by developers of PCOMS system and training and supervision sessions once each month), (4) patients' diagnoses were reliable based on use of a valid and standardized tool (M.I.N.I International Neuropsychiatric Interview), and (5) some potential confounding was minimized through adjustment for therapist variability and clients' pretreatment distress levels. However, the strength of these findings is still limited by important methodological weaknesses common to this body of evidence. Weaknesses include not adequately minimizing other sources of potential bias including variation between groups in specific types or dose of psychotherapy, medical treatment, or treatment outside the clinic, if/how PCOMS results were discussed, if/how subsequent treatment changes were made, and the lack of blinding of outcome assessors. Additionally, this RCT involved use of a highly intensive implementation strategy that included highly trained experts who received extensive training provided by PCOMS creators and extensive implementation support that included minimization of provider paperwork burden through use of technology-assisted automated risk scoring and management that advocated PCOMS and provided moral and financial support. It is unclear whether implementation of the intensive implementation strategy used in this RCT would be feasible in more typical clinical settings with fewer implementation resources.

Second is the 2015 RCT by Guo et al,⁶³ which is frequently cited as providing strong evidence of MBC's benefits. This RCT of 120 outpatients with moderate to severe major depressive disorder treated with a fixed dosing schedule of paroxetine or mirtazapine at a university-affiliated teaching hospital in China found that after 24 weeks, MBC with the Quick Inventory of Depressive Symptomatology-Self-Report (QIDS-SR) led to significantly greater rates of remission than usual care (Chinese version of the 17-item Hamilton Depression Rating Scale [HAM-D] score ≤ 7 , 73.8% vs 28.8%, $P < 0.0001$). The greatest strengths of this study are that it is the best example we identified of a design that better isolates MBC's effects through explicit documentation of the stepped-care treatment algorithm used, which included specific medication choices. It also took measures to minimize performance and measurement biases through using blind raters to assess outcome and ensured high fidelity to MBC protocol via external compliance monitoring. However, its findings likely have limited applicability to the specific approach of using MBC in shared decision-making because it was unclear whether MBC ratings were shared with the patients, and clinicians made treatment decisions strictly based on an explicit and fixed dosing schedule of either paroxetine or mirtazapine, which did not appear to incorporate patient preference.

Suicide Behavior, Functioning, Quality of Life

The effects of MBC on suicide behavior, functioning, and quality of life are largely unknown. We did not identify any studies that reported on suicide behavior and real-life functional outcomes (*eg*, days missed from work). MBC significantly improved quality of life in only one¹⁶ of 3 studies that assessed quality of life outcomes using various instruments (*eg*, MANSA=

Manchester Short Assessment of Quality of Life,¹⁶ EQ-5D-5L= EuroQol Quality of Life Scale,¹⁵ and WHO-5 score = WHO-Five Well-Being Index).¹⁴ However, serious methodological weaknesses – primarily lack of MBC fidelity assessment – preclude reaching any conclusions based on this evidence. Also, as the findings of improved quality of life came from a population with a primary diagnosis of schizophrenia or related psychotic disorder, they have unclear applicability to patients with more commonly diagnosed mental health conditions, such as mood and anxiety disorders.

Satisfaction with Care

Evidence on satisfaction with care is very limited.¹⁵⁻¹⁷ Among patients with schizophrenia or related psychotic disorders, MBC significantly improved treatment satisfaction after 12 months as measured using the Client Satisfaction Questionnaire (CSQ) (adjusted mean 25.99 points vs 25.15, adjusted mean difference 0.92, 95% CI 0.22 to 1.56).¹⁶ However, in patients with more commonly diagnosed mental health conditions, MBC either did not change satisfaction with care¹⁷ or actually decreased patient satisfaction.¹⁵

No-shows, Drop-outs, Medication Adherence

There is little evidence to suggest that MBC improves care processes. No RCT reported medication use and/or adherence outcomes or no-show rates. Among 4 RCTs that reported attendance outcomes, all consistently found that MBC did not improve rates of attendance.^{10,14,18,19}

Table 1. Characteristics of Studies with Feedback to Patient and Clinician and Discussion

Author Year Sample Size Country	Population characteristics	General treatment type	Setting	Outcome assessment & feedback tool	Clinically significant change in outcome? ^b	Significant improvement in distress/ function?	Fidelity or adherence to intervention
Amble 2014 ¹ ^a N=259 Norway	Mixed mood and anxiety disorders	Mental health outpatient and inpatient treatment	Outpatient and inpatient psychiatric clinics	OQ-45	Yes 22.9% FB vs 13.9% TAU	NA	NR
Anker 2009 ² N=410 Norway	Relationship issues	Couples therapy	Outpatient community family counseling clinic	PCOMS ORS/SRS	Yes 66.7% FB vs 39.1% TAU (P=0.01)	NA	NR
Brattland 2018 ³ N=170 Norway	Mixed mood and anxiety disorders	Mental health outpatient treatment	Hospital-based mental health outpatient clinic	PCOMS BASIS-32	Yes 58.2% FB vs 36.2% TAU	NA	Yes, administered as intended for all but 6 cases
Davidson 2017 ¹⁴ N=159 Denmark	Eating disorders	Group and individual therapy	Outpatient psychotherapy center	PCOMS ORS/SRS	NR	No	NR
De Jong 2014 ⁴ ^a N=604 Netherlands	Mixed mood and anxiety disorders	Mental health outpatient treatment	Mental health care institutions or private practices	OQ-45	No 43% FBTP vs 38% FBT vs 37% TAU	Mixed	NR
Delgadillo 2018 ¹³ N=2,223 England	Depression	CBT and depression counseling	8 National Health Service primary care sites	PHQ-9 GAD-7	No OR 1.2 (95% CI 0.85 to 1.17)	Mixed	NR
Guo 2015 ⁶³ N=120 China	Depression	Mental health outpatient treatment and antidepressant medication (paroxetine or mirtazapine)	Outpatient, university affiliated teaching hospital	HAM-D QIDS-SR	Yes 73.8% FB vs 28.8% TAU	NA	Yes 99.8% FB vs 99.7% TAU
Hawkins 2004 ⁵ ^a N=201 USA	Mixed mood and anxiety disorders	Mental health outpatient treatment	Outpatient, hospital- based psychotherapy clinic	OQ-45	No 23% FBTP vs 10% FBT vs 10% TAU	Yes	NR

Kellybrew-Miller 2017 ⁶ N=162 USA	Mixed mood, anxiety, and substance disorders	Mental health outpatient treatment	Outpatient community mental health centers	PCOMS ORS/SRS	No 33% FB vs 25% TAU (P>0.05)	Yes	Yes, 67.2% of integrity checklists completed
Kendrick 2017 ¹⁵ N=47 England	Depression	Mental health outpatient treatment	General practice clinics	PHQ-9 PYCHLOPS DTAS BDI-II primary outcome	NR	Mixed	NR
McClintock 2017 ¹⁸ N=79 USA	Depression	Mental health outpatient treatment	University health center	CFF	NR	No	Yes, therapist rating of “frequently discuss feedback” mean 4.67 (scale 1-5)
Murphy 2012 ^{7 a} N=110 Ireland	Mixed mood and anxiety disorders	Mental health outpatient treatment	University counselling service	PCOMS ORS	No 61.0% FB vs 47.1% TAU (P>0.05)	No	NR
Priebe 2007 ¹⁶ N=507 6 European countries	Schizophrenia or related disorder	Mental health outpatient treatment	Multidisciplinary comprehensive care programs for people with severe and enduring mental illness	DIALOG	NR	Mixed	NR
Puschner 2007 ⁶⁸ N=294 Germany	Mixed mood and anxiety disorders	Psychiatric inpatient treatment	University hospital psychiatric inpatient unit	EB-45 (German version of OQ-45)	NR	No	Yes, 80% completion rate
Reese 2010 ^{9 a} N=92 USA	Couples seeking therapy	Couples therapy	Graduate training clinic for marriage and family therapy	PCOMS ORS/SRS	Yes 48.1% FB vs 26.3% TAU (P=0.02)	NA	NR
Reese 2009 ^{8 a} N=148 USA	University students and marriage and family therapy counseling clients	Marriage and family therapy and psychological therapy	University counseling center and graduate marriage and family therapy clinic	PCOMS ORS/SRS	Yes Study 1: 80% FB vs 54.2% TAU (P<0.05)	NA	NR

					Study 2: 66.7% FB vs 41.4% TAU (P<0.05)		
Rise 2016 ¹⁷ N=75 Norway	NR	Mental health outpatient treatment	Outpatient unit in mental health hospital	PCOMS ORS/SRS	NR	No	NR
Schmidt 2006 ¹⁹ N=61 UK	Eating disorders	CBT	Eating disorder specialist unit	TREAT-EAT, SEED, HADS	NR	Mixed	NR
Simon 2012 ^{11 a} N=370 USA	Mixed mood and anxiety disorders	Individual psychotherapy	Hospital-based outpatient psychotherapy clinic	OQ-45 and ASC	No 45.11% FB vs 6.1% TAU (P=0.1)	Yes	NR
Simon 2013 ¹⁰ N=141 USA	Eating disorders	Individual and group psychotherapy	Inpatient eating disorder clinic	QO-45 and ASC	Yes 52.95% FB vs 28.6% TAU (P=0.01)	NA	NR
Slone 2015 ¹² N=84 USA	NR	Group therapy	University counseling center	PCOMS ORS/SRS	Yes 41.9% FB vs 29.3% TAU (P=0.05)	NA	NR
van Oenen 2016 ²⁰ N=287 Netherlands	Severe psychiatric crisis	Various: behavioral, pharmacotherapy, psycho-education, outreach	Emergency outpatient crisis clinic	PCOMS ORS/SRS	NR	No	Yes, 67% of therapists reported adequate PROMs in > 70% of sessions

^aIncluded in Kendrick 2016 systematic review; ^bClinically significant change, recovery, or response as defined by feedback tool

Abbreviations: ASC=Assessment for Signal Cases, BDI-II= Beck Depression Inventory 2nd edition, CBT=Cognitive Behavioral Therapy, DIALOG= computer-mediated intervention structuring patient-clinician dialogue, DTAS= Distress Thermometer Analogue Scale, FB=feedback, FBTP=feedback to patient and therapist, FBT=feedback to therapist, HADS=Hospital Anxiety and Depression Scale, HAM-D= Hamilton Depression Rating Scale, LOS=length of stay, NR=not reported, OQ-45=Outcome Questionnaire 45, PCOMS=Partners for Change Outcome Management System, PHQ-9=Patient Health Questionnaire 9, PSYCHLOPS= psychological outcomes profile, PROMs=patient-reported outcome measures, QIDS-SR= Quick Inventory of Depressive Symptomatology–Self-Report, SEED=Short Evaluation of Eating Disorders, TAU=treatment as usual, TREAT-EAT=TREAT-EAT Outcome Monitoring Questionnaire

KEY QUESTION 2: What are the adverse effects and unintended consequences of using measurement based care delivery practices in mental health care?

We found no studies that evaluated adverse effects or unintended consequences of using MBC.

KEY QUESTION 3: Do the outcomes of using measurement based care delivery practices in mental health care vary by patient demographics or mental health characteristics/diagnoses?

Evidence is insufficient to determine whether the effectiveness and/or adverse effects of using measurement based care delivery practices in mental health care vary by patient demographics (gender, race, *etc*), mental health characteristics/diagnoses (psychoses, addiction, PTSD, suicide risk, *etc*), or MBC approaches. This is because studies generally did not formally evaluate effects in subgroups and qualitatively isolating effects in any particular characteristic is not possible due to the extensive heterogeneity on all other characteristics. Below we report findings from studies that evaluated some less-common specific populations or used VA-recommended assessment instruments (PHQ-9, GAD-7, PCL-5, and BAM).

Diagnostic Subgroups

Although the majority of studies involved the most common mental health disorders in adults of anxiety and depression, a few studies focused on MBC in treatment for relationship issues,^{2,9} eating disorders,^{10,14,19} schizophrenia,¹⁶ and severe psychiatric crisis.²⁰ Among these, MBC showed the most promise for consistently improving outcomes in couples therapy.^{2,9}

For couples therapy either in an outpatient community family counseling clinic in Norway (N=410)² or at a graduate training clinic in the US (N=92),⁹ 2 RCTs provided consistent evidence that MBC increases the rate of the composite outcome of patients with either a “reliable change” or a “clinically significant change” (Table 1), as well as rates of couples with clinically significant change as assessed by the ORS (38.5% vs 10.7%, ESP-calculated OR 5.77, 95% CI 2.73 to 12.20, P < 0.0001, NNT=3).^{2,9}

For eating disorders, MBC showed potential benefit when used to supplement inpatient treatment¹⁰ or a guided outpatient individual cognitive behavioral self-help program,¹⁹ but not in the context of outpatient group psychotherapy (Table 1).¹⁴ Evidence was strongest in the inpatient setting¹⁰ as use of the OQ system in 141 females with eating disorders in inpatient care significantly increased rates of clinically significant improvement (52.95% vs 28.6%). In the study of using MBC to supplement a guided outpatient individual cognitive behavioral self-help program in the UK, MBC significantly improved dietary restriction behaviors, but not bingeing, vomiting, or exercise behaviors.¹⁹ However, we cannot attribute any of these improvements directly to MBC, as fidelity to its intended use was not assessed and an independent instrument was not used to assess outcome.

For schizophrenia, as described above, MBC in patients with schizophrenia or related psychotic disorders may improve some patient outcomes – quality of life, client satisfaction with care, health and social needs (CANSAS - Camberwell Assessment of Need Short Appraisal Schedule)

– but not the negative, positive, or overall specific symptoms of schizophrenia as measured by the Positive and Negative Syndrome Scale (PANSS).¹⁶

There is low-strength evidence that MBC does not benefit patients in severe psychiatric crisis seeking emergency psychiatric help (Table 1).²⁰ When PCOMS was administered adequately in a majority of sessions in an outpatient emergency center in Amsterdam over 3 months, patients receiving MBC actually improved less than those receiving treatment as usual.²⁰ Study authors hypothesized that this may be because people have a reduced ability to reflect during crisis, that the high severity of symptoms interfere with the intended effects of feedback, and that the high intensity of treatment as usual did not leave a lot of room for improvement. We do have some confidence that the findings can be attributed to MBC as there was verification that 67% of therapists reported adequate use of PCOMS in at least 70% of sessions.

We did not identify any studies that focused on demographic subgroups such as women, race/ethnicity, age, and/or period of service or diagnostic subgroups such as high risk for suicide or PTSD.

Use of VA-recommended Scales

We only identified 2 RCTs that used an MBC approach including any of the VA-recommended instruments (Table 1).^{13,15} Both had mixed findings across outcomes. Between them, the best evidence was provided by the 2018 RCT by Delgadillo et al,¹³ which was far larger than the 2017 RCT by Kendrick et al¹⁵ (N=2,233 vs N=47) and all other available RCTs. In the Delgadillo 2018 RCT, 2,233 patients with depression who were undergoing a stepped-care approach to CBT and depression counseling as part of the Improving Access to Psychological Therapies (IAPT) program at 8 National Health Service primary care sites in England were administered the PHQ-9 and GAD-7 to record weekly patient progress using an electronic clinical record system. The electronic system included comparison of progress to expected treatment response curves for comparable patient groups and automatic generation of risk signals to alert therapists of patients who were not responding as expected. While this MBC approach did not significantly improve the odds of reliable improvement in the full sample (68% vs 60%, OR 1.21, 95% CI 0.85 to 1.71) or the not-on-track subsample (61% vs 52%, OR 1.32, 95% CI 0.93 to 1.89) (both adjusted for therapist effects), it did reduce odds of reliable deterioration (OR 0.68, 95% CI 0.48 to 0.94, ESP-calculated inverse of control vs feedback group reported in publication). Strengths of this RCT include that it controlled for therapist variability by randomizing by therapist and further including adjustment for therapist variability in their multilevel model, it minimized potential for confounding by ruling out variability in treatment intensity and patient clinical characteristics, and it included a feature to reduce bias in MBC performance by providing a 6.5-hour training program. However, as with the majority of the other RCTs, we still have much uncertainty about whether the mechanism of the potential benefit is specific to MBC and was not influenced by expectations due to lack of blinding or use of an independent outcome assessment tool, as the study authors indicated that they “did not have the resources to closely monitor competence in treatment delivery or in feedback use”.

We did not identify any RCTs that have used PCL-5 or BAM for MBC.

SUMMARY AND DISCUSSION

This rapid review built on previous evidence synthesis work^{23,45,52} by adding 14 new studies and identifying the delivery circumstances under which MBC has the most reliable evidence of operating most effectively. Our review found that MBC can lead to clinically meaningful improvements in patient outcomes under certain circumstances. The most reliable evidence^{3,6,18,20} points to use of the PCOMS to routinely monitor outcomes in outpatient treatment of anxiety and mood disorders as the most promising approach when paired with a high-intensity implementation strategy (clinically significant improvement for MBC vs usual care: 48% vs 33%, OR 1.91, 95% CI 0.88 to 4.15, P = 0.1025, NNT= 7).³ As the effectiveness of this MBC approach was demonstrated to increase over time, likely it was the intense and sustained implementation efforts – which appeared more intense than in other applications – that led to its success. PCOMS and the OQ-45 have also shown some promise for use in other diagnostic subgroups including couples therapy^{13,32} and inpatient treatment of eating disorders,¹⁰ but not for improving specific symptoms of schizophrenia,¹⁶ or for patients in severe psychiatric crisis seeking emergency help.²⁰

Our findings differ somewhat from previous reviews^{23,45,52} and this is likely due to differences in scope and methodology. For example, our findings are less favorable compared to the 2017 review by Fortney et al²³ which broadly stated that “virtually all randomized controlled trials with frequent and timely feedback of patient-reported symptoms to the provider during the medication management and psychotherapy encounters significantly improved outcomes.” While we agree that some randomized controlled trials did demonstrate improvement, we disagree with the implication that all improvements are equally clinically meaningful, reliable, and universally applicable. Alternatively, while we completely agree with the suggestion from the 2016 Cochrane review by Kendrick et al that “more research of better quality is needed”, our findings are slightly more positive than theirs, which broadly stated that “we found insufficient evidence to support the use of routine outcome monitoring using PROMs in the treatment of common mental health disorders in terms of improving patient outcomes or in improving management.”⁵² This is largely because the RCT we highlighted above as potentially representing the most promising MBC approach was not yet available at the time of the 2016 Cochrane review.

LIMITATIONS

Despite a large volume of new evidence in the past few years, significant limitations remain in study methodology, applicability to Veterans, and the clinical relevance of the findings. First, regarding study methodology, the main limitation of this evidence was the lack of reporting on the competence and actual delivery of the MBC components of sharing and acting. No study reported the rates in which PROMs were shared, and if and how they were used in making treatment management decisions. The only aspect of fidelity assessed was the collection of patient measures, which was only reported in a quarter of studies (5/21)^{3,6,18,20,68} using variable methods with unclear clinical meaningfulness (*ie*, “67% of therapists reported applying PCOMS adequately in > 70% of sessions”).²⁰ This is important because it prevents us from determining if and how any improvements in clinically important outcomes were actually specifically due to improved management or were nonspecifically due to extra attention that could be achieved with other approaches to enhancing care delivery – such as care management.

Second, we are unclear about the applicability of the findings in this review to the approach of interest of using MBC in shared decision-making within an integrated primary care mental health care management model such as primarily used in VA. This is because we found no studies that used an MBC approach as specifically defined by VA (*ie*, collect, share, and act with shared decision-making), only 1 study in a military/Veteran population,⁶⁹ and only 2 studies that used any of the VA-recommended MBC tools (PHQ9 and GAD7),^{13,15} and the most promising approach used a highly intensive implementation strategy that included specific practical, technical, and structural components that may not be equally accessible across the diverse range of VA settings. The fact that there is a lack of data on using MBC in shared decision-making is not a weakness of the literature in general. The issue is more about its unclear relevance to the current VA-recommended approach of using MBC in shared decision-making, which is an important element in the VA model of MBC, as it is part of their overall patient-centered approach to mental health care in general. Additionally, because the integrated primary care mental health care management model widely used in VA already provides a great deal of multimodal care, it is unclear whether MBC added to the VA model would provide the same level of benefit as it has when added to single treatment modalities delivered in general mental health settings (*ie*, psychotherapy alone).

Third, the clinical relevance of the findings in this review are largely unknown. Key to determining the clinical utility of using MBC to guide mental health management is to demonstrate improvements across numerous outcomes including improved management (*ie*, increased identification of at-risk patients, improved treatment change decisions), reduced duration of treatment, remission, suicidal behavior, quality of life, functional capacity, adverse effects and unintended consequences, patient satisfaction, and care processes, and to demonstrate these benefits are sustainable beyond 6 months. However, research to date has primarily focused on mean improvement in symptom scores, which aren't always indicators of clinically meaningful improvement, and little other data is yet available.

The primary limitations of our findings related to our review methods include (1) our literature search and (2) our scope. First, although our search included multiple databases, our shortened timeframe precluded searching a more exhaustive range of sources. Also, searching for literature is a common challenge in reviews of complex multicomponent health care delivery models because of the many dimensions and inconsistent terminology used in the studies.⁷³ We addressed this challenge by including a wider than usual variety of terminology in our search strategy, as well as using a wider than usual range of grey literature searching. However, there is a risk that we may have missed additional relevant studies. Regarding our scope, because we focused on the subset of highest-quality studies that reported the most clinically meaningful patient outcomes that were most relevant to the current specific VA-recommended MBC approach, this may limit the generalizability of our findings to a broader range of users.

FUTURE RESEARCH IMPLICATIONS

Although this review identified a particular MBC approach as most promising for use in outpatient mental health management of patients with anxiety and/or mood disorders, we suspect it was its intense and sustained implementation efforts that largely led to its success and are concerned that a barrier to its likewise broad success in VA is that the specific practical, technical, and structural components it involved may not be equally accessible across all VA settings. Better understanding of implementation factors that can support MBC implementation

in a broad range of settings is key to increasing its successful uptake consistent with VA's national initiative.

Another challenge in MBC is how to pick an instrument that is valid, brief, actionable, easily understood, and sensitive to change among the multitude that exist that may be appropriate and useful. The VA MBC Initiative currently formally recommends 4 measures (PHQ-9, GAD-7, PCL-5, BAM). While few studies used any of these 4 VA-recommended measures (PHQ-9, GAD-7, PCL-5 and BAM), we acknowledge that their strong psychometric properties and successful use in other complex care models, such as collaborative care, provide a solid rationale for their use for MBC in shared decision-making. However, the most direct evidence of their effects for MBC in shared decision-making would come from a study that evaluated their use specifically in this way. While the VA currently recommends PHQ-9, GAD-7, PCL-5, and BAM, however, adoption of other measures is welcomed. The PCOMS and OQ-45 may be appealing because they are the most widely studied in MBC in mental health RCTs and have the unique features of including assessment of the therapeutic alliance and are accompanied by systems that use large databases to develop predictive models to automatically classify treatment response as inadequate or deteriorating. Also, research has shown that electronic administration of instruments may be preferred as it is acceptable to consumers, highly correlated with pen and paper administration, and be more efficient.⁷⁴ Further, to facilitate future analysis to improve understanding of MBC's effects, where applicable, the ability to enter PROMs data into the electronic medical records would be ideal. However, facilitating electronic administration and incorporating additional PROMs into institution-specific software programs that support MBC and interface with electronic medical records can be costly and time consuming, and decisions about their incorporation have to take into account other priorities both within MBC and in other VA-wide initiatives.

Thus, the potential for variation in success based on differences in instrument choice, format of results delivery (*ie*, automated vs manual paper and pencil) and intensity, frequency, and nature of education and training (*ie*, standardized face-to-face trainings vs webinars vs self-directed study) are important to consider. Other proposed provider-level barriers to MBC implementation include lack of time, inaccessibility of scores,²⁴ worry that MBC undermines professional autonomy or intrudes in sensitive consultations,^{50,51} and MBC being viewed as evaluative and threatening.⁴⁴ It is encouraging to see the ongoing study by Wray et al²² that is focused on evaluating implementation facilitation by directly comparing 2 implementation approaches in VA: an implementation facilitation strategy involving use of an "external facilitator and MBC experts who work with intervention sites to form a quality improvement team, develop an implementation plan, and identify and overcome barriers to implementation" versus standard VA national support. Studies such as this are expected to be key in better supporting MBC's success. Other potential areas of study include approaches that compare different specific results formats, education and training, and provider incentives. Additionally, to increase the clinical relevance of evidence and demonstrate sustainability of MBC practices, longer-term studies are needed that evaluate a wider range of outcomes beyond mean changes in symptoms scores that go beyond 6 months.

Although we identified some ongoing MBC research (see Supplemental Materials), with the exception of one study by Metz et al which is expected to report on patient adherence to treatment and quality of life, it is not clear that any other studies will directly and sufficiently address existing gaps. Therefore, concerted research of better quality is still needed in the

specific limitation areas we outlined in detail above, including study methodology, applicability to Veterans, and the clinical relevance of the findings. For example, the 2015 RCT by Guo et al,⁶³ which is frequently cited as providing strong evidence of MBC's benefits, is the best example we identified of a design that better isolates MBC's effects through explicit documentation of the stepped-care treatment algorithm used, which included specific medication choices. It also took measures to minimize performance and measurement biases through using blind raters to assess outcome and ensured high fidelity to MBC protocol via external compliance monitoring.⁶³

CONCLUSIONS

Effectiveness of the specific VA-recommended approach of using any of 4 recommended PROMs for implementing MBC in the context of shared decision-making in mental health is unknown. We identified other promising approaches to use of PROMs for MBC in general mental health settings, but raise important questions about their applicability and implementation feasibility into heterogenous VA primary care mental health integrated care settings. New research would be more meaningful if it evaluated the specific VA-recommended MBC approach, improved on identified methodological limitations, evaluated a wider range of clinically meaningful outcomes, and simultaneously compared MBC use under 2 or more implementation strategies that are feasible for a wider range of care settings.

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Operational Partners

Operational partners are system-level stakeholders who have requested the report to inform decision-making. They recommend Technical Expert Panel (TEP) participants; assure VA relevance; help develop and approve final project scope and timeframe for completion; provide feedback on draft report; and provide consultation on strategies for dissemination of the report to field and relevant groups.

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Peer Reviewers

The Coordinating Center sought input from external peer reviewers to review the draft report and provide feedback on the objectives, scope, methods used, perception of bias, and omitted evidence. Peer reviewers must disclose any relevant financial or non-financial conflicts of interest. Because of their unique clinical or content expertise, individuals with potential conflicts may be retained. The Coordinating Center and the ESP Center work to balance, manage, or mitigate any potential nonfinancial conflicts of interest identified.

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