**National Quality Forum—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** 0712

**Measure Title**: Depression Utilization of the PHQ-9

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Click here to enter composite measure #/ title

**Date of Submission**: 12/2/2016

Please Note: Text in black is from our last submission and supports depression monitoring in adults. The direction of the evidence has not changed since the previous endorsement, but we have added evidence that supports including adolescents in the measure. This new content is in red text.

|  |
| --- |
| **Instructions**  *For composite performance measures:*  *A separate evidence form is required for each component measure unless several components were studied together.*  *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*   * Respond to all questions as instructed with answers immediately following the question. All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed. * If you are unable to check a box, please highlight or shade the box for your response. * Maximum of 10 pages (*incudes questions/instructions*; minimum font size 11 pt; do not change margins). ***Contact NQF staff if more pages are needed.*** * Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx). |

|  |
| --- |
| **Note: The information provided in this form is intended to aid the Steering Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.** 1a. Evidence to Support the Measure Focus The measure focus is evidence-based, demonstrated as follows:   * Health outcome: [**3**](#Note3) a rationale supports the relationship of the health outcome to processes or structures of care. Applies to patient-reported outcomes (PRO), including health-related quality of life/functional status, symptom/symptom burden, experience with care, health-related behavior. * Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4)that the measured intermediate clinical outcome leads to a desired health outcome. * Process: [**5**](#Note5) a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured process leads to a desired health outcome. * Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured structure leads to a desired health outcome. * Efficiency: [**6**](#Note6) evidence not required for the resource use component.   **Notes**  **3.** Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.  **4.** The preferred systems for grading the evidence are the U.S. Preventive Services Task Force (USPSTF) [grading definitions](http://www.uspreventiveservicestaskforce.org/uspstf/grades.htm) and [methods](http://www.uspreventiveservicestaskforce.org/methods.htm), or Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org/publications/index.htm).  **5.** Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.  **6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework: Evaluating Efficiency Across Episodes of Care](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx); [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)). |

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*)

Outcome

Health outcome: Click here to name the health outcome

Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors*

Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

Process: Administration of a Patient Reported Outcome (PRO), the Patient Health Questionnaire tool PHQ-9, to patients with major depression and dysthymia

Structure: Click here to name the structure

Other: Click here to name what is being measured

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**HEALTH OUTCOME/PRO PERFORMANCE MEASURE**  *If not a health outcome or PRO, skip to* [*1a.3*](#Section1a3)

**1a.2.** **Briefly state or diagram the path between the health outcome (or PRO) and the healthcare structures, processes, interventions, or services that influence it.**

**1a.2.1.** **State the rationale supporting the relationship between the health outcome (or PRO) to at least one healthcare structure, process, intervention, or service (*i.e., influence on outcome/PRO*).**

*Note: For health outcome/PRO performance measures, no further information is required; however, you may provide evidence for any of the structures, processes, interventions, or service identified above.*

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**intermediate outcome, PROCESS, or STRUCTURE PERFORMANCE measure**

**1a.3.****Briefly state or diagram the path between structure, process, intermediate outcome, and health outcomes**. Include all the steps between the measure focus and the health outcome.

Please note that this process measure for administration of the PHQ-9 depression tool, a PROM that is validated for both the assessment and diagnosis of depression as well as for monitoring ongoing outcomes of treatment, is a PAIRED process measure with RELATED measures of depression remission (PHQ-9 < 5) and depression response (PHQ-9 is improved by > 50%) at six and twelve months. To quote a NQF Behavioral Steering Committee member as these measures were initially endorsed “the best way to avoid being measured is to never give the PHQ-9”. This process measure allows an understanding of the use of the tool in the target population, promotes frequent and follow-up contact with patients whose score indicates a need for treatment and serves as a catalyst in a collaborative care model for patients with major depression or dysthymia. It is estimated that up to 90% of patients diagnosed with depression and anxiety are treated solely in primary care. [NICE National Institute Health and Care Excellence United Kingdom 2011]

**1a.3.1.** **What is the source of the systematic review of the body of evidence that supports the performance measure?**

Clinical Practice Guideline recommendation – ***complete sections*** [***1a.4***](#Section1a4)***, and*** [***1a.7***](#Section1a7)

US Preventive Services Task Force Recommendation – ***complete sections*** [***1a.5***](#Section1a5) ***and*** [***1a.7***](#Section1a7)

Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*) – ***complete sections*** [***1a.6***](#Section1a6) ***and*** [***1a.7***](#Section1a7)

Other – ***complete section*** [***1a.8***](#Section1a8)

*Please complete the sections indicated above for the source of evidence. You may skip the sections that do not apply.*

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION**

**1a.4.1.** **Guideline citation** (*including date*) and **URL for guideline** (*if available online*):

Depression, Adult in Primary Care

Institute for Clinical Systems Improvement (ICSI) September 2013

<https://www.icsi.org/guidelines__more/catalog_guidelines_and_more/catalog_guidelines/catalog_behavioral_health_guidelines/depression/>

Adolescents:

Guidelines for Adolescent Depression in Primary Care (GLAD-PC): I. Identification, Assessment, and Initial Management (2007) - <http://pediatrics.aappublications.org/content/120/5/e1299.short>

Guidelines for Adolescent Depression in Primary Care (GLAD-PC): II. Treatment and Ongoing Management (2007) - <http://pediatrics.aappublications.org/content/120/5/e1313>

**1a.4.2.** **Identify guideline recommendation number and/or page number** and **quote verbatim, the specific guideline recommendation**.

Adults:

There are several references related to the effectiveness of collaborative care, assessing patients with a standardized instrument for ongoing monitoring of depression symptoms and treatment effectiveness, the importance of follow-up care and measurement of treatment effectiveness.

Guideline Aims (pg. 7)

* Improve communication between the primary care physician and the mental health care clinician (if patient is co-managed). *(Annotations #4, 8, 12)*
* Increase the percentage of patients with major depression or persistent depressive disorder who have improvement in outcomes from treatment for major depression or persistent depressive disorder. *(Anno­tations #8, 9)*
* Increase the percentage of patients with major depression or persistent depressive disorder who have a follow-up to assess of response to treatment. *(Annotations #8, 10)*

Select excerpts from guideline annotation # 8 Comprehensive Treatment Plan with Shared Decision Making (pages 38 to 52)

Collaborative Care Model and Improved Patient Outcomes (pg.38)

A collaborative care approach is recommended for patients with depression in primary care (High Quality Evidence, Strong Recommendation).

More than 37 randomized controlled trials have demonstrated the effectiveness of the collaborative care model, in which primary care treatment of depression is provided by a team (depression care manager, primary physician, consulting psychiatrist, others). The work group recommends three key references *(Gilbody, 2006 [Meta-analysis]; Hunkeler, 2006 [High Quality Evidence]; Katon, 1999 [High Quality Evidence])*. This model has demonstrated improvement in treatment adherence, patient quality of life and depression outcomes. (pg.38)

In the Prevention of Suicide in Primary Care Elderly: Collaborative Trial (PROSPECT) study, suicidal ideation rates declined in patients receiving care based on treatment guidelines and use of a care manager *(Bruce, 2004 [High Quality Evidence])*. (pg.39)

In the Improving Mood Providing Access to Collaborative Treatment (IMPACT) study, 1,801 primary care patients were randomly assigned to collaborative care or usual care. Intervention subjects had less suicidal ideation at 6 and 12 months, and there were no completed suicides for either group in 18 months *(Unützer, 2006 [High Quality Evidence])*. (pg.39)

The use of a collaborative care model can help with medication compliance, by providing closer follow-up than is possible without a care manager. Three or more follow-up visits in the first three months reduced the risk of relapse/recurrence of depression, as did continuous use of antidepressants *(Kim, 2011 [Low Quality Evidence])*. Care management facilitates continuous use of antidepressants, by providing close follow-up and early intervention when side effects occur. (pg.38)

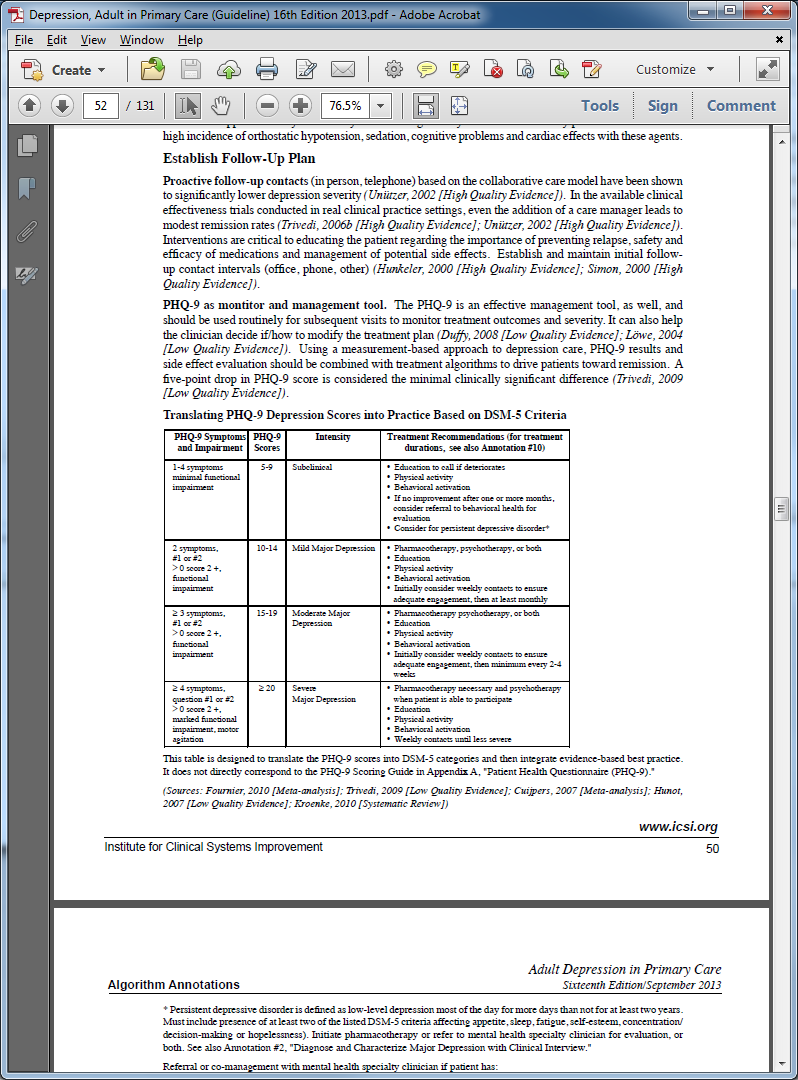
Establish a Follow-up Plan and PHQ-9 as a monitor and manage tool. (pg. 38)

Clinicians should establish and maintain follow-up with patients (Low Quality Evidence, Strong Recommendation).

Proactive follow-up contacts(in person, telephone) based on the collaborative care model have been shown to significantly lower depression severity *(Unützer, 2002 [High Quality Evidence])*. In the available clinical effectiveness trials conducted in real clinical practice settings, even the addition of a care manager leads to modest remission rates *(Trivedi, 2006b [High Quality Evidence]; Unützer, 2002 [High Quality Evidence])*. Interventions are critical to educating the patient regarding the importance of preventing relapse, safety and efficacy of medications and management of potential side effects. Establish and maintain initial follow-up contact intervals (office, phone, other) *(Hunkeler, 2000 [High Quality Evidence]; Simon, 2000 [High Quality Evidence])*. (pg. 50)

The PHQ-9 is an effective management tool, as well, and should be used routinely for subsequent visits to monitor treatment outcomes and severity. It can also help the clinician decide if/how to modify the treatment plan *(Duffy, 2008 [Low Quality Evidence]; Löwe, 2004 [Low Quality Evidence])*. Using a measurement-based approach to depression care, PHQ-9 results and side effect evaluation should be combined with treatment algorithms to drive patients toward remission. A five-point drop in PHQ-9 score is considered the minimal clinically significant difference *(Trivedi, 2009 [Low Quality Evidence])*. (pg. 50)

If the primary care clinician is seeing some improvement, continue working with that patient to increase medication dosage or augment with psychotherapy or medication to reach remission. This can take up to three months. Don't give up on the patient whether treating in primary care or referring. Stay connected through consultation or collaboration, and take the steps needed to get the patient to remission. This can take longer and can take several medication interventions or other steps. The STAR\*D study has shown that primary care can be just as successful as specialty care *(Trivedi, 2006a [High Quality Evidence])*.



Adolescents:

The GLAD-PC guidelines emphasize providing frequent follow-up for adolescent patients with depression and routine assessment of depressive symptoms to measure treatment effectiveness. Similar to the literature supporting the collaborative care model for depression management in adults, the GLAD-PC guidelines recommend collaboration between the PCP and mental health providers and resources, with co-management of patients across settings. Relevant recommendations from the *Identification, Assessment, and Initial Management* and *Treatment and Ongoing Management* guidelines are quoted.

Identification, Assessment, and Initial Management

*Recommendation 1: …Clinicians should assess for depressive symptoms on the basis of diagnostic criteria established in the DSM-IV or International Classification of Diseases, 10th Revision (grade of evidence: B; strength of recommendation: very strong) and should use standardized depression tools to aid in the assessment (grade of evidence: A; strength of recommendation: very strong).*

PC clinicians should probe for the presence of any of several depressive disorders, including MDD, dysthymia, and depression not otherwise specified by using systematic, rigorous assessment methods. Standardized instruments should be used to help with diagnosis but should not replace direct interview by the clinician.87-89

*Recommendation 3: The PC clinician should establish relevant links/collaboration with mental health resources in the community (grade of evidence: B; strength of recommendation: very strong)…*

A major gap in the management of chronic disorders in young people is the lack of linkages between relevant services that make up the system of care for an individual youth.103 Furthermore, family-based interventions have been shown to help youth with mental illness.104 Therefore, establishing relevant links/collaboration with mental health resources in the local community, including peer support groups, advocacy groups, and traditional community- or hospital-based mental health services whenever these services are available, is essential to ensure timely and effective access to needed services.8,105

Treatment and Ongoing Management

*Recommendation 1: Systematic and regular tracking of goals and outcomes from treatment should be performed, including assessment of depressive symptoms and functioning in several key domains: home, school, and peer settings (grade of evidence: D; strength of recommendation: very strong).*

Goals should include both improvement in functioning status and resolution of depressive symptoms…Evidence from large RCTs demonstrates that depressive symptoms and functional impairments may not improve at the same rate with treatment.23,26 Therefore, symptoms and functioning should be tracked regularly during the course of treatment with information gathered from both the patients and their families when possible. According to expert consensus, patients should be seen within 1 week of the initiation of treatment. At every visit, clinicians should inquire about ongoing depressive symptoms, risk of suicide, possible adverse effects from treatment (including the use of specific adverse-effect scales), adherence to treatment, and new or ongoing environmental stressors. Regardless of the length of treatment, all patients should be monitored on a monthly basis for 6 to 12 months after the full resolution of symptoms.19

*Recommendation 4: PC clinicians should actively support depressed adolescents who are referred to mental health to ensure adequate management (grade of evidence: D; strength of recommendation:*

*very strong). PC clinicians may also consider sharing care with mental health agencies/professionals when possible (grade of evidence: B; strength of recommendation: very strong). Appropriate roles and responsibilities regarding the provision and coordination of care should be communicated and agreed upon by the PC clinician and the mental health specialist (grade of evidence: D; strength of recommendation: very strong).*

PC clinicians should continue follow-up with adolescents with depression who have been referred to mental health services for assessment and/or management. When possible, PC clinicians may consider sharing management of depressed adolescents with mental health agencies/professionals. There is emerging evidence from the adult literature about the greater effectiveness of “shared-care” models for the management of depression in the PC setting.67-72,79-81 Similar evidence from case reports in the pediatric literature is emerging.82

**1a.4.3.** **Grade assigned to the quoted recommendation with definition of the grade:**

Adults:

Overall review of the evidence in two areas of this extensive guideline demonstrate strong recommendations for both a collaborative care model approach to improve patient outcomes and a key clinical process of establishing and maintaining follow-up with adult patients with depression. Collaborative care models demonstrate a high quality rating of evidence and strong recommendations for use in clinical practices. Additionally, support for the impact of collaborative care models in the treatment of depression is demonstrated by Cochrane review noted briefly in 1a.6. In this review, which contained 47 random control trials measuring depression outcomes with patient reported outcome tools, 26 (55%) used the PHQ-9 either for measuring depression outcomes or for denominator criteria for inclusion. While the overall categorization of evidence for the recommendation to establish a follow-up plan and the use of the PHQ-9 patient reported outcome tool as a means to monitor and manage the patient has a low quality rating, it comes with several high quality evidence studies and a strong recommendation (evidence consistently demonstrates benefit outweighs harm) for its use in clinical practice (pg. 5).

Rationale for Use of GRADE:

ICSI Guideline for Adult Depression in Primary Care utilizes the GRADE methodology for literature review.

GRADE has advantages over other systems including the current system used by ICSI. Advantages include

* developed by a widely representative group of international guideline developers;
* explicit and comprehensive criteria for downgrading and upgrading quality of evidence ratings;
* clear separation between quality of evidence and strength of recommendations that includes a transparent process of moving from evidence evaluation to recommendations;
* clear, pragmatic interpretations of strong versus weak recommendations for clinicians, patients and policy-makers;
* explicit acknowledgement of values and preferences; and
* explicit evaluation of the importance of outcomes of alternative management strategies.

| **Category** | **Quality Definitions** | **Strong Recommendation** | **Weak Recommendation** |
| --- | --- | --- | --- |
| **High Quality Evidence** | Further research is very unlikely to change our confidence in the estimate of effect. | The work group is confident that the desirable effects of adhering to this recommendation outweigh the undesirable effects. This is a strong recommendation for or against. This applies to most patients. | The work group recognizes that the evidence, though of high quality, shows a balance between estimates of harms and benefits. The best action will depend on local circumstances, patient values or preferences. |
| **Moderate Quality Evidence** | Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. | The work group is confident that the benefits outweigh the risks but recognizes that the evidence has limitations. Further evidence may impact this recommendation. This is a recommendation that likely applies to most patients. | The work group recognizes that there is a balance between harms and benefits, based on moderate quality evidence, or that there is uncertainty about the estimates of the harms and benefits of the proposed intervention that may be affected by new evidence. Alternative approaches will likely be better for some patients under some circumstances. |
| **Low Quality Evidence** | 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 or any estimate of effect is very uncertain. | The work group feels that the evidence consistently indicates the benefit of this action outweighs the harms. This recommendation might change when higher quality evidence becomes available. | The work group recognizes that there is significant uncertainty about the best estimates of benefits and harms. |

Adolescents:

In the GLAD-PC guidelines, each of the recommendations was graded on the basis of the level of supporting research evidence from the literature and the extent to which experts agreed that it was highly appropriate in primary care. The level of supporting evidence for each recommendation was based on the Oxford Centre for Evidence-Based Medicine grades of evidence (A–D) system.a Recommendation strength based on expert consensus was rated in 4 categories: very strong (>90% agreement), strong (>70% agreement), fair (>50% agreement), and weak (>50% agreement).

Grades of A, B and D were assigned to the recommendations in 1a.4.2. For all recommendations, the strength of the recommendation was rated “very strong”.

|  |  |
| --- | --- |
| **A** | **consistent level 1 studies** |
| **B** | **consistent level 2 or 3 studies or extrapolations from level 1 studies** |
| C | level 4 studies or extrapolations from level 2 or 3 studies |
| **D** | **level 5 evidence or troublingly inconsistent or inconclusive studies of any level** |

a<http://www.cebm.net/ocebm-levels-of-evidence/>; <http://www.cebm.net/wp-content/uploads/2014/06/CEBM-Levels-of-Evidence-2.1.pdf>

**1a.4.4. Provide all other grades and associated definitions for recommendations in the grading system.** (*Note: If separate grades for the strength of the evidence, report them in section 1a.7.*)

**1a.4.5. Citation and URL for methodology for grading recommendations** (*if different from 1a.4.1*)**:**

**1a.4.6. If guideline is evidence-based (rather than expert opinion), are the details of the quantity, quality, and consistency of the body of evidence available (e.g., evidence tables)?**

Yes **→ *complete section*** [***1a.7***](#Section1a7)

No **→ *report on another systematic review of the evidence in sections*** [***1a.6***](#Section1a6) ***and*** [***1a.7***](#Section1a7)***; if another review does not exist, provide what is known from the guideline review of evidence in*** [***1a.7***](#Section1a7)

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**1a.5.** **UNITED STATES PREVENTIVE SERVICES TASK FORCE RECOMMENDATION**

**1a.5.1.** **Recommendation citation** (*including date*) and **URL for recommendation** (*if available online*):

**1a.5.2.** **Identify recommendation number and/or page number** and **quote verbatim, the specific recommendation**.

**1a.5.3.** **Grade assigned to the quoted recommendation with definition of the grade**:

**1a.5.4. Provide all other grades and associated definitions for recommendations in the grading system.** (*Note: the* *grading system for the evidence should be reported in section 1a.7.*)

**1a.5.5. Citation and URL for methodology for grading recommendations** (*if different from 1a.5.1*)**:**

***Complete section*** [***1a.7***](#Section1a7)

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**1a.6. OTHER SYSTEMATIC REVIEW OF THE BODY OF EVIDENCE**

**1a.6.1.** **Citation** (*including date*) and **URL** (*if available online*):

**Collaborative care for depression and anxiety problems**- Cochrane Review June 2012

Janine Archer, Peter Bower, Simon Gilbody, Karina Lovell, David Richards, Linda Gask, Chris Dickens, Peter Coventry. http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006525.pub2/abstract

Note: Of the random control trials included in this Cochrane review, 47 studies dating from 1993 to 2012 utilized a standardized tool to assess the patient’s depression symptoms. 16 RCT’s used the PHQ-9 PROM to assess patient outcomes, while an additional 10 used the PHQ-9 as part of study inclusion criteria.

**Collaborative care for people with depression and anxiety**

Collaborative care has been tested with patients in a number of countries and health care systems, but it is not clear whether it should be recommended for people with depression or anxiety.

79 randomised controlled trials (RCTs) (90 comparisons) including 24,308 patients worldwide, comparing collaborative care with routine care or alternative treatments (such as consultation-liaison) for depression and anxiety were included in this systematic review. Most of the studies focused on depression and the evidence suggests that collaborative care is better than routine care in improving depression for up to two years. Collaborative care increases the number of patients using medication in line with current guidance, and can improve mental health related quality of life. Patients with depression and anxiety treated with collaborative care are also more satisfied with their treatment.

The results of primary analyses demonstrated significantly greater improvement in depression outcomes for adults with depression treated with the collaborative care model in the short-term (SMD -0.34, 95% CI -0.41 to -0.27; RR 1.32, 95% CI 1.22 to 1.43), medium-term (SMD -0.28, 95% CI -0.41 to -0.15; RR 1.31, 95% CI 1.17 to 1.48), and long-term (SMD -0.35, 95% CI -0.46 to - 0.24; RR 1.29, 95% CI 1.18 to 1.41). However, these significant benefits were not demonstrated into the very long-term (RR 1.12,

95% CI 0.98 to 1.27).

Authors’ conclusions:

Collaborative care is associated with significant improvement in depression and anxiety outcomes compared with usual care, and represents a useful addition to clinical pathways for adult patients with depression and anxiety.

**1a.6.2.** **Citation and** **URL for methodology for evidence review and grading** (*if different from 1a.6.1*)**:**

***Complete section*** [***1a.7***](#Section1a7)

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**1a.7. FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE supporting the measure**

*If more than one systematic review of the evidence is identified above, you may choose to summarize the one (or more) for which the best information is available to provide a summary of the quantity, quality, and consistency of the body of evidence. Be sure to identify which review is the basis of the responses in this section and if more than one, provide a separate response for each review.*

Depression, Adult in Primary Care

Institute for Clinical Systems Improvement (ICSI) September 2013

<https://www.icsi.org/guidelines__more/catalog_guidelines_and_more/catalog_guidelines/catalog_behavioral_health_guidelines/depression/>

**1a.7.1.** **What was the specific structure, treatment, intervention, service, or intermediate outcome addressed in the evidence review?**

Processes: Establish a follow-up plan and use the PHQ-9 as a monitor and management tool.

Comprehensive treatment plan.

**1a.7.2.** **Grade assigned for the quality of the quoted evidence with definition of the grade**:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Topic** | **Quality of Evidence** | **Recommendations** | **Strength of Recommendation** | **Relevant References** |
| Establish follow-up plan. Use of PHQ-9 as monitor and management tool | Low | Clinicians should establish and maintain follow-up with patients. | Strong | *Trivedi, 2009; Trivedi, 2006; Löwe, 2004; Unützer, 2002; Duffy, 2008; Hunkeler, 2000; Simon, 2000* |
| Comprehensive treatment plan | High | A collaborative care approach is recommended for patients with depression in primary care. | Strong | *Katon, 2008; Hunkeler, 2006; Unützer, 2006; Gilbody, 2006; Unützer, 2002; Katon, 1999;* |

GRADE Definitions:

Low Quality of Evidence: 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 or any estimate of effect is very uncertain.

Strong Recommendation: The work group feels that the evidence consistently indicates the benefit of this action outweighs the harms. This recommendation might change when higher quality evidence becomes available.

**1a.7.3. Provide all other grades and associated definitions for strength of the evidence in the grading system.**

**1a.7.4.** **What is the time period covered by the body of evidence? (*provide the date range, e.g., 1990-2010*). Date range**: 2000 - 2009

**QUANTITY AND QUALITY OF BODY OF EVIDENCE**

**1a.7.5.****How many and what type of study designs are included in the body of evidence**? (*e.g., 3 randomized controlled trials and 1 observational study*)

| **Author** | **Publication** | **Evidence Grade** | **Type of Study** |
| --- | --- | --- | --- |
| *Unützer, 2002* | Unützer J, Katon W, Callahan CM, et al. Collaborative care management of late-life depression in the primary care setting: a randomized controlled trial. *JAMA* 2002;288:2836-45. | High | RCT |
| *Trivedi, 2006* | Trivedi MH, Fava M, Wisniewski SR, et al. Medication augmentation after the failure of SSRIs for depression. *N Engl J Med* 2006a;354:1243-52. | High | RCT |
| *Hunkeler, 2000* | Hunkeler EM, Meresman JF, Hargreaves WA, et al. Efficacy of nurse telehealth care and peer support in augmenting treatment of depression in primary care. *Arch Fam Med* 2000;9:700-08. | High | RCT |
| *Simon, 2000* | Simon GE, Van Korff M, Rutter C, Wagner E. Randomised trial of monitoring, feedback, and manage­ment of care by telephone to improve treatment of depression in primary care. *BMJ* 2000;320:550-54. (High Quality Evidence) | High | RCT |
| *Trivedi, 2009* | Trivedi MH. Tools and strategies for ongoing assessment of depression: a measurement-based approach to remission. *J Clin Psychiatry* 2009;70:26-31. | Low | Observ |
| *Löwe, 2004* | Löwe B, Unützer J, Callahan CM, et al. Monitoring depression treatment outcomes with the patient health questionnaire-9. *Med Care* 2004;42:1194-1201. | Low | Cohort |
| *Duffy, 2008* | Duffy FF, Chung H, Trivedi M, et al. Systematic use of patient-rated depression severity monitoring: is it helpful and feasible in clinical psychiatry? *Psychiatric Services* 2008;59:1148-54. | Low | Cohort |

**1a.7.6.** **What is the overall quality of evidence across studies in the body of evidence**? (*discuss the certainty or confidence in the estimates of effect particularly in relation to study factors such as design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population*)

There are several studies with a high quality evidence rating and random control trials evaluated in the systematic review completed by the ICSI guideline work group, but some lower quality observational studies as well, leading to an overall lower quality of evidence rating, but with a strong recommendation for inclusion in clinical practice.

**ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE**

**1a.7.7.** **What are the estimates of benefit—magnitude and direction of effect on outcome(s) across studies in the body of evidence**? (*e.g., ranges of percentages or odds ratios for improvement/ decline across studies, results of meta-analysis, and statistical significance*)

The ICSI guideline work group, in its review of all available literature, determined that there was benefit in the ongoing follow-up with patients with major depression and recommend the use of the PHQ-9 tool for both monitoring and the management of depression symptoms.

**1a.7.8.** **What harms were studied and how do they affect the net benefit (benefits over harms)?**

Not available.

**UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE**

**1a.7.9.** **If new studies have been conducted since the systematic review of the body of evidence, provide for each new study: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review**.

The effectiveness of the collaborative care model for depression has also been demonstrated in the adolescent population. Richardson et al. (2014) conducted a randomized controlled trial to examine the collaborative care model vs usual care for treating adolescents with depression. Results demonstrated that adolescents treated with a collaborative care intervention vs usual care had greater improvement in depressive symptoms at 12 months. The PHQ-9 tool was used to assess the outcome of remission for this study. Using this outcome, the study found that adolescents treated with the collaborative care intervention were significantly more likely to achieve depression remission at both 6 months (OR = 5.2, 95% CI, 1.6-17.3; P = .007) and 12 months (OR = 3.9, 95% CI, 1.5-10.6; P = .007).

Richardson, Laura P., Evette Ludman, Elizabeth McCauley, Jeff Lindenbaum, Cindy Larison, Chuan Zhou, Greg Clarke, David Brent, and Wayne Katon. "Collaborative care for adolescents with depression in primary care: a randomized clinical trial." Jama 312, no. 8 (2014): 809-816.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**1a.8 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

**1a.8.1** **What process was used to identify the evidence?**

**1a.8.2.** **Provide the citation and summary for each piece of evidence.**