Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

Adult depression in primary care.

Bibliographic Source(s)

Trangle M, Gursky J, Haight R, Hardwig J, Hinnenkamp T, Kessler D, Mack N, Myszkowski M. Adult depression in primary care. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2016 Mar. 131 p. [394 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Trangle M, Dieperink B, Gabert T, Haight B, Lindvall B, Mitchell J, Novak H, Rich D, Rossmiller D, Setterlund L, Somers K. Major depression in adults in primary care. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2012 May. 119 p.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- May 10, 2016 – Olanzapine : The U.S. Food and Drug Administration (FDA) is warning that the antipsychotic medicine olanzapine can cause a rare but serious skin reaction that can progress to affect other parts of the body. FDA is adding a new warning to the drug labels for all olanzapine-containing products that describes this severe condition known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).
- May 3, 2016 – Aripiprazole (Abilify, Abilify Maintena, Aristada) : The U.S. Food and Drug Administration (FDA) is warning that compulsive or uncontrollable urges to gamble, binge eat, shop, and have sex have been reported with the use of the antipsychotic drug aripiprazole (Abilify, Abilify Maintena, Aristada, and generics). These uncontrollable urges were reported to have stopped when the medicine was discontinued or the dose was reduced. These impulse-control problems are rare, but they may result in harm to the patient and others if not recognized.

Recommendations

Major Recommendations

Note from the National Guideline Clearinghouse (NGC) and the Institute for Clinical Systems Improvement (ICSI): The recommendations for the diagnosis and treatment of major depression in adults in primary care are presented in the form of a table with a list of evidence-based recommendations and an algorithm with 12 components, accompanied by detailed annotations. The algorithm is provided in the original guideline document (see the "Guideline Availability" field).

Quality of evidence (Low Quality, Moderate Quality, and High Quality) and strength of recommendation (Weak or Strong) ratings are defined at the end of the "Major Recommendations" field.

Screening

Recommendation: Clinicians should routinely screen all adults for depression using a standardized instrument. (Quality of Evidence: Low; Strength of Recommendation: Strong)

- Benefit: There is evidence that screening adults who one suspects as being depressed improves outcomes. There is low to moderate evidence that screening all adults, pregnant and postpartum women improves outcomes even in the absence of treatment protocols, care managers and specialty trained providers. There is less evidence supporting this recommendation with geriatric patients. The benefit is that one would be finding and treating many more depressed patients and improving their outcomes/functioning not only for depression but for the other medical diseases with depression as a comorbidity. There is also some evidence that this might save overall medical costs for depressed patients. The optimum interval at which to screen for depression is unknown; more evidence for all populations is needed to identify ideal screening intervals.
- Harm: The only harm identified is the cost of screening patients who are not depressed.
- Benefit-Harms Assessment: Although direct evidence of the isolated health benefit of depression screening in primary care is weak, the totality of the evidence supports the benefits of screening in pregnant and postpartum and general adult populations, particularly in the presence of additional treatment supports such as treatment protocols, care management and availability of specially trained depression care providers. Evidence is least supportive of screening in older adults, where direct evidence is most limited.
- Relevant Resources: O'Connor et al., 2016; Kroenke et al., 2010; Duffy et al., 2008; Gilbody et al., 2006; Rush et al., 2003.

Diagnosis

Recommendation: Clinicians should use the *Diagnostic and Statistical Manual of Mental Disorders, 5th Edition* (DSM-5) criteria to determine diagnosis of major depression, persistent depressive disorder, other specified depressive disorder, and unspecified depressive disorder. (Quality of Evidence: Guideline; Strength of Recommendation: Strong)

- Benefit: Proper use of diagnostic criteria assists in accurately diagnosing and directing the treatment plan toward appropriate evidence-based interventions.
- Harm: There is a risk of exclusively utilizing the criteria in a checklist manner, which could lead to inappropriate diagnosis and treatment.
- Benefit-Harms Assessment: With proper training and education, the proper use of the diagnostic criteria from the DSM-5 aids in driving the correct diagnosis and proper evidence-based interventions, which outweighs any potential harm.
- Relevant Resources: American Psychiatric Association, 2013.

Treatment

Major Depressive Disorder Treatment Recommendation 1

Consider combining pharmacotherapy and psychotherapy treatments for patients with major depressive disorder when practical, feasible, available and affordable. (Quality of Evidence: Moderate; Strength of Recommendation: Weak)

- Benefit: The preponderance of moderate quality literature shows that outcomes are better when pharmacotherapy and psychotherapy treatments are combined than either treatment alone.
- Harm: The potential negative cumulative impact of time away from work and family to do psychotherapy, office visits to do psychotherapy, and potential side effects of medications could affect the patients.
- Benefit-Harms Assessment: When balancing better outcomes of the combined treatment with negative impacts of treatment on patients, the group felt the benefits of combined treatment outweigh the potential harms.
- Relevant Resources: Cuijpers et al., 2014; Hollon et al., 2014; Peeters et al., 2013; Spijker et al., 2013; van Hees et al., 2013; Cuijpers et al., 2012; Jakobsen et al., 2012; Guidi et al., 2011; Oestergaard & Møldrup, 2011; Cuijpers et al., "Adding," 2009; Cuijpers et al., "Psychotherapy," 2009; de Maat et al., 2008.

Major Depressive Disorder Treatment Recommendation 2

When unable to do combined therapy due to patient preference or availability/affordability of the treatments:

1. Consider starting with psychotherapy for mild to moderate major depression
2. Consider starting with pharmacotherapy for severe major depression

(Quality of Evidence: Moderate; Strength of Recommendation: Weak)

- Benefit: Generally, the evidence shows that both medication and therapy are reasonably effective. For mild to moderate major depression, psychotherapy alone may lengthen the time to relapse and patients may be more successfully withdrawn from the medications. For severe major depression, it appears that medications have a significantly higher effect size than psychotherapy.
- Harm: For mild to moderate major depression, disruptions include taking time for office visits to do psychotherapy, and time away from work and family. For severe major depression, these are the potential side effects of medications.
- Benefit-Harms Assessment: Even though the quality of the majority of individual articles are moderate to high, the overall literature is quite weak in documenting harms, availability and costs to the individual patient. There was no scientific or easy way to directly compare the benefits to costs. The seasoned clinicians in the group chose to go with the benefits in terms of somewhat better outcomes based upon the literature but qualify this by making the recommendations weak. This is an area where shared decision-making is likely to be especially valuable.
- Relevant Resources: Cuijpers et al., 2015; Kuyken et al., 2015; Biesheuvel-Leliefeld et al., 2014; Menchetti et al., 2014; Steinert et al., 2014; Cuijpers et al., 2013; Piet & Hougaard, 2011; Segal et al., 2010; Dobson et al., 2008

Pure Dysthymia Treatment Recommendation

Consider starting with medication in pure dysthymia patients. The work group feels that it is reasonable to consider stepped care, which includes augmenting medications and adding psychotherapy for patients who don't improve. (Quality of Evidence: High; Strength of Recommendation: Strong)

- Benefit: Antidepressant treatment of pure dysthymia outperforms both placebo and psychotherapy in acute trials and can begin to reverse the symptoms, suffering and impairment of a condition that can go on for decades left untreated.
- Harm: A significant percentage of patients will fail to respond and require additional treatment. For those who ultimately require a trial of psychotherapy and benefit from it, starting medication first will have represented a delay in receiving effective care. Antidepressants and augmenting agents have side effects and adverse interactions with other drugs. It is not clear how long to continue psychotherapy that has not yet started to work.
- Benefit-Harms Assessment: Evidence supports starting with antidepressant medication, and one can choose later to add psychotherapy for those who fail to respond or recover. It is reasonable to start with antidepressant medication since it tends to work more quickly than psychotherapy. Access to high-quality psychotherapy is not available in many primary care settings.
- Relevant Resources: Kriston et al., 2014; von Wolff et al., 2013; Cuijpers, 2012; Levkovitz, Tedeschini, & Papakostas, 2011; Cuijpers et al., 2010; Cuijpers et al., "Is psychotherapy," 2009; Imel et al., 2008; Markowitz et al., 2005; Browne et al., 2002.

Chronic Major Depression Treatment Recommendation

For patients with chronic major depression, start with combined antidepressant medication and psychotherapy. (Quality of Evidence: High; Strength of Recommendation: Strong)

- Benefit: Antidepressant treatment with psychotherapy outperforms either treatment as monotherapy and more rapidly begins the process of reversing symptoms, suffering and functional impairment in a condition that can go on for decades untreated. Psychotherapy can produce quality-of-life improvements and lower health and human services costs.
- Harm: Combined medication and psychotherapy increase short-term costs. Access to high-quality psychotherapy is not available in many primary care settings. In a 2000 study of chronic major depression, which excluded pure dysthymic disorder, the overall drop-out rate was the same for the three treatment groups, but reasons for dropping out varied. More patients dropped out of the medication-alone arm because of adverse events, and more psychotherapy patients withdrew consent because therapy was too time consuming, they did not want psychotherapy, or they wanted medication. This highlights the need to consider patient preferences. The benefits of psychotherapy are delayed and may cause some patients to give up on it prematurely.
- Benefit-Harms Assessment: The chronic nature of persistent depressive disorder, which produces serious life consequences that are often underestimated, justifies the combination of medication and psychotherapy. In the 2000 study, those in the combined treatment group had fewer dropouts than the medication-alone group due to adverse events (14% vs. 7%). There is some evidence that although benefits of

psychotherapy are delayed, they continue even after psychotherapy is stopped.
- Relevant Resources: Kriston et al., 2014; Weirsma et al., 2014; Spijker et al., 2013; Cuijpers et al., 2012; Cuijpers et al., 2010; Kocsis et al., "Cognitive," 2009; Imel et al., 2008; Browne et al., 2002.

Comprehensive Treatment Plan with Shared Decision-Making

Collaborative Care Model

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

- Benefit: Collaborative care model has demonstrated improvement in treatment adherence, patient quality of life and depression outcomes. It has demonstrated beneficial impact on direct and indirect economic benefits. Evidence suggests the collaborative care model is also effective for depression during pregnancy and postpartum period.
- Harm: There are challenges in providing the collaborative care model, such as identifying depressed patients, identifying care managers with the right experience and background, establishing the responsibilities and scope of practice of the care managers, whether to locate care managers in a clinic versus centrally based, determining the level of psychiatric supervision, seeking adequate reimbursement for services provider to ensure program sustainability, and feasibility of small clinics to employ on-site mental health specialists or full-time care managers.
- Benefit-Harms Assessment: Collaborative care has shown to improve patient outcomes and provider satisfaction while decreasing cost outweighing the challenges of implementing a collaborative care program.
- Relevant Resources: Fortney et al., 2013; Archer et al., 2012; Katon & Seelig, 2008; Gjerdingen & Yawn, 2007; Belnap et al., 2006; Gilbody et al., 2006; Hunkeler et al., 2006; Simon et al., 2001; Katon et al., 1999.

Educate and Engage Patient

Recommendation: Before initiating treatment, it is important to establish a therapeutic alliance with the patient regarding diagnosis and treatment options (in which there is overlap in the patient's and clinician's definition of the problem and agreement on which steps are to be taken by each). (Quality of Evidence: Low; Strength of Recommendation: Strong)

- Benefit: Therapeutic alliance is a potent predictor of treatment outcomes whether the treatment is psychotherapy or pharmacotherapy. Patient participation in shared decision-making improves adherence to treatment and clinical outcomes. When patients express a treatment preference, the use of that treatment, whether psychotherapy or pharmacotherapy, predicts a positive outcome.
- Harm: A therapeutic alliance can take time to develop, and time is difficult to find in a busy clinical practice. If treatment is delayed because of an uncertain alliance or initiated before an alliance is attained, it could adversely affect outcomes. Difficult experiences with the treatment of depression may cause clinicians to avoid treating depressed patients.
- Benefit-Harms Assessment: The benefits of a therapeutic alliance in terms of improved patient outcomes more than offsets the investment of time.
- Relevant Resources: Kocsis et al., "Patient," 2009; Loh et al., 2007; Krupnick et al., 1996.

Follow-Up

Establish Follow-Up Plan

Recommendation: Clinicians should establish and maintain follow-up with patients. (Quality of Evidence: High; Strength of Recommendation: Strong)

- Benefit: Appropriate, reliable follow-up is highly correlated with improved response and remission scores. It is also correlated with the improved safety and efficacy of medications and helps prevent relapse.
- Harm: Potential harms may include added expense and unnecessary visits.
- Benefit-Harms Assessment: Benefits appear to outweigh potential harms by a wide margin.
- Relevant Resources: Trivedi et al., 2006; Unützer et al., 2002; Hunkeler et al., 2000; Simon et al., 2000.

Pregnant and Postpartum Women

Recommendation: Clinicians should screen and monitor depression in pregnant and postpartum women. (Quality of Evidence: Low; Strength of Recommendation: Strong)

- Benefit: Untreated prenatal depression has been associated with negative pregnancy outcomes such as poor maternal self-care, poor

nutrition, preterm labor and low birth weight, as well as negative effects on children such as developmental delay and cognitive impairment. There is low to moderate evidence that screening pregnant and post-partum women improves outcomes even in the absence of treatment protocols, care managers and specialty trained providers. The benefit is that by screening patients, one would be finding and treating many more patients with depression.

- Harm: The only harm identified is the cost of screening patients who are not depressed.
- Benefit-Harms Assessment: Although direct evidence of the isolated health benefit of depression screening in primary care is weak, the totality of the evidence supports the benefits of screening in pregnant and postpartum women, particularly in the presence of additional treatment supports such as treatment protocols, care management, and availability of specially trained depression care providers.
- Relevant Resources: O'Connor et al., 2016; Yonkers et al., 2009; Vesga-López et al., 2008; Gjerdingen & Yawn, 2007; Gaynes et al., 2005.

Definitions

Quality of Evidence and Strength of Recommendations

Category	Quality Definitions	Strong Recommendation	Weak Recommendation
High Quality Evidence	Further research is very unlikely to change 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 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 benefit, 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 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.

Clinical Algorithm(s)

A detailed and annotated clinical algorithm for adult depression in primary care is provided in the original guideline document (see the "Guideline Availability" field).

Scope

Disease/Condition(s)

- Major depression
- Persistent depressive disorder including pure dysthymia

Guideline Category

Counseling

Diagnosis

Evaluation

Management

Screening

Treatment

Clinical Specialty

Family Practice

Internal Medicine

Obstetrics and Gynecology

Psychiatry

Psychology

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Health Care Providers

Health Plans

Hospitals

Managed Care Organizations

Nurses

Physician Assistants

Physicians

Psychologists/Non-physician Behavioral Health Clinicians

Social Workers

Guideline Objective(s)

To assist primary care in developing systems that support effective assessment, diagnosis and ongoing management of initial and recurrent major depression and persistent depressive disorder in adults age 18 years and over and assist patients to achieve remission of symptoms, reduce relapse and return to previous level of functioning

Target Population

Adults age 18 and over with suspected or established diagnosis of major depression and persistent depressive disorder

Note: This guideline does not address the pediatric population. Diagnoses with significant overlap of symptoms outside the scope of this guideline include anxiety disorder, adjustment disorder and bipolar disorder.

Interventions and Practices Considered

Diagnosis/Evaluation/Screening

1. Standardized screening instrument for depression if suspected
2. Diagnosis and characterization of major depression using the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5) or clinical criteria
3. Screening and monitoring depression in pregnant and postpartum women

Treatment/Management

1. Combining pharmacotherapy and psychotherapy treatments for patients with major depressive disorder
2. Treatment considerations for pure dysthymia (medication, stepped care)
3. Comprehensive treatment plan with shared decision-making
    - Use of collaborative care approach
    - Patient education and engagement
4. Establishing and maintaining follow-up

Major Outcomes Considered

- Sensitivity and specificity of screening tools
- Risk for and rate of suicide or suicide attempts
- Rates of remission, recurrence, relapse, response to treatment, and recovery
- Quality of life and functioning
- Adverse effects of treatment options

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search

A consistent and defined literature search process is used in the development and revision of Institute for Clinical Systems Improvement (ICSI) guidelines. Two literature searches were conducted for this guideline. The searches were conducted in PubMed, Ovid and PsycINFO.

The first search included systematic reviews, meta-analyses, randomized controlled trials and observational studies from January 2013 to February 2015. The search was limited to adults over 18 years of age. The search excluded animal studies and non-English language studies. The terms included screening; patient health questionnaire-9 (PHQ-9); insomnia; therapeutic alliance in depressed patients; psychotherapies; antidepressants; implementation and best practices; special populations and disparities; telepsychiatry and outcomes; complementary medicine; integrated care, coordinated care, collaborative care; continuity of patient care, follow-up, office visits and frequency; effective treatments for adults with major depression who also have diabetes; prevalence and treatment of depression in patients who had stroke; after care; follow-up; remission; remission induction; functional impairment; cognitive impairment; genomics, genetics and pharmacogenetics; shared decision-making; and TMS (transcranial magnetic stimulation).

The second literature search was specific to treatment recommendations for major depressive disorder and persistent depressive disorder and included systematic reviews, meta-analyses and randomized controlled trials. It covered the period between January 2005 and September 2015 and was limited to adults over 18 years of age. The search excluded animal studies and non-English language studies. The terms included treatment, treatment outcomes and multiple treatment comparison; psychological treatment and supportive therapy, cognitive behavioral therapy; antidepressant agents, pharmacotherapy and drug therapy; combined treatment; duration of treatment, acute phase, continuation phase, maintenance phase; depression and major depression; dysthymia disorder and persistent depressive disorder, chronic depression and chronic major depression.

In addition to the literature searches, articles were obtained by work group members and ICSI staff. Those vetted by the work group were included in the guideline when appropriate.

Number of Source Documents

284 potential articles were identified from the initial two literature searches; 394 articles from all sources were included as references, 55 of which support formal recommendations.

See the "Study Selection Flowchart" companion document (see the Availability of Companion Documents" field) for the flow of studies through the selection process.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of Evidence and Strength of Recommendations

Category	Quality Definitions	Strong Recommendation	Weak Recommendation
High Quality Evidence	Further research is very unlikely to change 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 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 benefit, 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 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.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Evidence is reviewed using Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology. Evidence is reviewed for quality utilizing explicit and comprehensive criteria for downgrading and upgrading quality of evidence ratings.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Document Development and Revision Process

The development process is based on a number of long-proven approaches and is continually being revised based on changing community standards. The Institute for Clinical Systems Improvement (ICSI) staff, in consultation with the work group and a medical librarian, conduct a literature search to identify systematic reviews, randomized clinical trials, meta-analysis, other guidelines, regulatory statements and other pertinent literature. This literature is evaluated based on the GRADE methodology by work group members. When needed, an outside methodologist is consulted.

The work group uses this information to develop or revise clinical flows and algorithms, write recommendations, and identify gaps in the literature. The work group gives consideration to the importance of many issues as they develop the guideline. These considerations include the systems of care in our community and how resources vary, the balance between benefits and harms of interventions, patient and community values, the autonomy of clinicians and patients and more. All decisions made by the work group are done using a consensus process.

ICSI's medical group members and sponsors review each guideline as part of the revision process. They provide comment on the scientific content, recommendations and implementation strategies. This feedback is used by and responded to by the work group as part of their revision work. Final review and approval of the guideline is done by ICSI's Committee on Evidence-Based Practice. This committee is made up of practicing clinicians and nurses, drawn from ICSI member medical groups.

Implementation Recommendations and Measures

These are provided to assist medical groups and others to implement the recommendations in the guidelines. Where possible, implementation strategies are included that have been formally evaluated and tested. Measures are included that may be used for quality improvement as well as for outcome reporting. When available, regulatory or publicly reported measures are included.

Document Revision Cycle

Scientific documents are revised as indicated by changes in clinical practice and literature. ICSI staff monitors major peer-reviewed journals for any pertinent evidence that would affect a particular guideline and recommendation.

Rating Scheme for the Strength of the Recommendations

See the "Rating Scheme for the Strength of the Evidence" field.

Cost Analysis

Cost-effectiveness Impact of Collaborative Care Models

In a collaborative care model, the primary treatment for depression is provided by a multidisciplinary team. Most studies have concluded that creating and implementing a collaborative care model will increase effectiveness – producing significant and sustained gains in "depression-free days." The six-month and one-year studies show increased cost to the outpatient care system. This is balanced by continuous accumulation of clinical and economic benefits over time. One of the factors is the decrease in the utilization of general medical services in patients with chronic medical comorbidities. The two-year studies show mixed results possibly indicating a turning point, and the only longer-term study conducted was the Improving Mood-Promoting Access to Collaborative Treatment (IMPACT) study. This was a well-done study analyzing the costs of performing collaborative care for one year over a four-year period. The study illustrated a cost savings of $3,363 per patient over the four-year period.

Almost all the studies done on this aspect have compared enhanced/collaborative care with care as usual. Typically, enhanced care has involved creating a list of depressed patients under treatment, having a care manager provide education, calling or meeting with patient periodically to ensure compliance with medications and/or psychotherapy, and reliably ensuring follow-up visits and measurement of outcomes. Some have involved varying participation of physicians, behavioral health professionals and/or patients.

Workplace Impact of Collaborative Care Models

Randomized controlled trials looked at cost of doing enhanced care and specifically tallied decreases of "absenteeism" and improved work performance (which means that employees are present and effectively achieving good work results, sometimes referred to as decreasing "presenteeism"). Some studies monetized the results and compared them to usual care. The significance of these studies and this analysis is that in the United States, depression costs employers $24 billion in lost productive work time.

In two randomized controlled trials, employers received significant return on investment (ROI) from collaborative care treatment of depression by increasing productivity/decreasing absenteeism in the workplace. Increased productivity ranged from 2.6 hours to 5.6 hours per week after one year. Studies going out to two years showed continued gains in year two.

Several of the articles recommend consideration of coverage of collaborative care to ensure better patient outcomes and the ROI illustrated.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The Institute for Clinical Systems Improvement (ICSI) seeks review from members and the public during the revision process.

Member Review

All ICSI documents are available for member review at two points in the ICSI revision process. The ICSI Response Report is sent to members at the beginning of a document revision. The goal of this report is to solicit feedback about the guideline, including but not limited to the algorithm, content, recommendations and implementation. Members are also welcome to participate in the public comment period (see below).

The work group would like to thank the following organizations for participating in the Adult Depression in Primary Care pre-revision review:

- Fairview Health Services
- HealthPartners Health Plan
- Mayo Clinic

Public Comment

ICSI makes a draft of the guideline available to the public on the ICSI Web site. The public is invited to comment in an effort to get feedback prior to its finalization. All comments will be reviewed by the ICSI facilitator and work group members when needed. The ICSI work group may or may not make changes to the guideline based on public comment responses.

The work group would like to thank all those who took time to thoughtfully and thoroughly review the draft and submitted comments for the Adult Depression in Primary Care guideline.

Document Approval

Each document is approved by the Committee for Evidence-Based Practice (CEBP).

The committee will review and approve each guideline/protocol, based on the following criteria:

- The aim(s) of the document is clearly and specifically described.
- The need for and importance of the document is clearly stated.
- The work group included individuals from all relevant professional groups and had the needed expertise.
- Patient views and preferences were sought and included.
- The work group has responded to all feedback and criticisms reasonably.
- Potential conflicts of interest were disclosed and do not detract from the quality of the document.
- Systematic methods were used to search for the evidence to assure completeness and currency.
- Health benefits, side effects, risks and patient preferences have been considered in formulating recommendations.

- The link between the recommendation and supporting evidence is clear.
- Where the evidence has not been well established, recommendations based on community practice or expert opinion are clearly identified.
- Recommendations are specific and unambiguous.
- Different options for clinical management are clearly presented.
- Clinical highlights and recommendations are easily identifiable.
- Implementation recommendations identify key strategies for *health care systems* to support implementation of the document.
- The document is supported with practical and useful tools to ease *clinician* implementation.
- Where local resource availability may vary, alternative recommendations are clear.
- Suggested measures are clear and useful for quality/process improvement efforts.

Once the document has been approved, it is posted on the ICSI Web site and released to members for use.

Evidence Supporting the Recommendations

References Supporting the Recommendations

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Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Accurate diagnosis and appropriate management of primary care patients with major depression or persistent depressive disorder

See the "Benefits" and "Benefits-Harms Assessment" sections in the "Major Recommendations" field for additional benefits of specific interventions.

Potential Harms

See the "Benefits-Harms Assessment" sections in the "Major Recommendations" field for analysis of benefits and harms of specific interventions. See also the "Treatment" section in the original guideline document for specific side effects and drug interactions, as well as the subgroups most likely to be harmed.

Contraindications

Contraindications

It is important for light therapy treatment to utilize equipment that eliminates ultraviolet frequencies and produces bright light of known spectrum and intensity. For these reasons, use of client-constructed light therapy units is contraindicated.

Qualifying Statements

Qualifying Statements

- The information contained in this Institute for Clinical Systems Improvement (ICSI) Health Care Guideline is intended primarily for health professionals and other expert audiences.
- This ICSI Health Care Guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients and families are urged to consult a health care professional regarding their own situation and any specific medical questions they may have. In addition, they should seek assistance from a health care professional in interpreting this ICSI Health Care Guideline and applying it in their individual case.
- This ICSI Health Care Guideline is designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and is not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition.

Implementation of the Guideline

Description of Implementation Strategy

Implementation Recommendations

Prior to implementation, it is important to consider current organizational infrastructure that address the following:

- System and process design
- Training and education
- Culture and the need to shift values, beliefs and behaviors of the organization

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline. The following points have not been updated during this revision.

- Detection and diagnosis
  - Systems in place to reliably determine if a patient is depressed
  - Use of *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5) criteria and structured questionnaires (such as Patient Health Questionnaire-9 [PHQ-9])
- Patient-centered care, education and self-management programs
  - Structured attention to patient preferences
  - Patient and family education materials/protocols
  - Patient self-management skills such as journal writing or self-monitoring
  - When appropriate, encourage family or loved ones to attend appointments for patient support and advocacy
  - Involving families as well in care management programs
  - Care manager role to coordinate the disease management for patients with depression including such things as patient contacts, education, self-management tools and tips
- Mental health/behavioral medicine specialist involvement
  - Shared care — collaborative care between behavioral health specialists and primary care clinicians in the primary care setting. Care manager and/or primary care clinician consulting with psychiatry on a regular basis regarding the case load of patients with depression managed in the depression care management program
  - Appointment availability — access to behavioral health in timely manner
- Outcomes measurement
  - Build in plans for outcome measures as well as ongoing process measures
  - Response rate to various treatments
  - Remission rates — improvement in response is stable over time
- Systems to coordinate care, ensure continuity and keep clinicians informed of status
  - Build automated processes for the first four core elements wherever possible
  - Reduce dependence on human behavior to ensure delivery of patient care processes
  - Use of components of the chronic care model for depression care (e.g., use of registries, community outreach)
  - Structured frequent monitoring and follow-up with patient
  - Nurse/care manager phone care and use of other modalities for patient follow-up

Implementation Tools

Chart Documentation/Checklists/Forms

Clinical Algorithm

Quality Measures

Quick Reference Guides/Physician Guides

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Related NQMC Measures

Adult depression in primary care: percentage of patients with a diagnosis of major depression or persistent depressive disorder with documentation of DSM-5 criteria at the time of the diagnosis.

Adult depression in primary care: percentage of patients who commit suicide at any time while managed in primary care.

Adult depression in primary care: percentage of patients who are screened for substance use disorders with an appropriate screening tool.

Adult depression in primary care: percentage of patients with type 2 diabetes with documentation of screening for major depression or persistent depressive disorder using either PHQ-2 or PHQ-9.

Adult depression in primary care: percentage of patients with cardiovascular disease with documentation of screening for major depression or persistent depressive disorder using either PHQ-2 or PHQ-9.

Adult depression in primary care: percentage of patients who had a stroke with documentation of screening for major depression or persistent depressive disorder using either PHQ-2 or PHQ-9.

Adult depression in primary care: percentage of patients with chronic pain with documentation of screening for major depression or persistent depressive disorder using either PHQ-2 or PHQ-9.

Adult depression in primary care: percentage of perinatal patients with documentation of screening for major depression or persistent depressive disorder using either PHQ-2 or PHQ-9.

Adult depression in primary care: percentage of patients with major depression or persistent depressive disorder whose primary care records show documentation of any communication between the primary care clinician and the mental health care clinician.

Adult depression in primary care: percentage of patients who have had a response to treatment at six months (+/- 30 days) after diagnosis or initiating treatment, e.g., had a PHQ-9 score decreased by 50% from initial score at six months (+/- 30 days).

Adult depression in primary care: percentage of patients who have reached remission at six months (+/- 30 days) after diagnosis or initiating treatment, e.g., had any PHQ-9 score less than 5 at six months (+/- 30 days).

Adult depression in primary care: percentage of patients of patients who have had a response to treatment at 12 months (+/- 30 days) after diagnosis or initiating treatment, e.g., had a PHQ-9 score decreased by 50% from initial score at 12 months (+/- 30 days).

Adult depression in primary care: percentage of patients who reached remission at 12 months (+/- 30 days) after diagnosis or initiating treatment, e.g., had a PHQ-9 score less than 5 at 12 months (+/- 30 days).

Adult depression in primary care: percentage of patients whose symptoms are reassessed by the use of a quantitative symptom assessment tool (PHQ-9) at six months (+/- 30 days) after diagnosis or initiating treatment.

Adult depression in primary care: percentage of patients whose symptoms are reassessed by the use of a quantitative symptom assessment tool (such as PHQ-9) at 12 months (+/- 30 days) after diagnosis or initiating treatment.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Trangle M, Gursky J, Haight R, Hardwig J, Hinnenkamp T, Kessler D, Mack N, Myszkowski M. Adult depression in primary care. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2016 Mar. 131 p. [394 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2016 Mar

Guideline Developer(s)

Institute for Clinical Systems Improvement - Nonprofit Organization

Guideline Developer Comment

The Institute for Clinical Systems Improvement (ICSI) is comprised of nearly 50 medical group and hospital members representing 9,000 physicians in Minnesota and surrounding areas, and is sponsored by three nonprofit health plans. For a list of sponsors and participating organizations, see the see the ICSI Web site .

Source(s) of Funding

- The Institute for Clinical Systems Improvement (ICSI) provided the funding for this guideline revision. ICSI is a not for profit, quality improvement organization based in Bloomington, Minnesota. ICSI's work is funded by the annual dues of the member medical groups and three sponsoring health plans in Minnesota. Individuals on the work group are not paid by ICSI, but are supported by their medical group for this work.
- ICSI facilitates and coordinates the guideline development and revision process. ICSI, member medical groups, and sponsoring health plans review and provide feedback, but do not have editorial control over the work group. All recommendations are based on the work group's independent evaluation of the evidence.

Guideline Committee

Adult Depression in Primary Care Work Group

Composition of Group That Authored the Guideline

Work Group Members: Michael Trangle, MD (*Work Group Leader)* (HealthPartners Medical Group and Regions Hospital) (Psychiatry); Daniel

Kessler, LP (Allina Medical Clinic) (Psychology); Jeffrey Hardwig, MD (Essentia Health) (Psychiatry); Todd Hinnenkamp, RN (Essentia Health) (Internal Medicine); Robert Haight, PharmD, BCPP (Fairview Health Services) (Pharmacy); Mioki Myszkowski, MD (Mayo Clinic) (Family Medicine); Nicky Mack, RN (North Memorial Health Care) (Family Medicine); Jeffrey Gursky, MD (Olmsted Medical Center) (Psychiatry); Jodie Dvorkin (Institute for Clinical Systems Improvement [ICSI]) (Project Manager/Health Care Consultant); Senka Hadzic (ICSI) (Clinical Systems Improvement Facilitator)

Financial Disclosures/Conflicts of Interest

The Institute for Clinical Systems Improvement (ICSI) has long had a policy of transparency in declaring potential conflicting and competing interests of all individuals who participate in the development, revision and approval of ICSI guidelines and protocols.

In 2010, the ICSI Conflict of Interest Review Committee was established by the Board of Directors to review all disclosures and make recommendations to the board when steps should be taken to mitigate potential conflicts of interest, including recommendations regarding removal of work group members. This committee has adopted the Institute of Medicine Conflict of Interest standards as outlined in the report Clinical Practice Guidelines We Can Trust (2011).

Where there are work group members with identified potential conflicts, these are disclosed and discussed at the initial work group meeting. These members are expected to recuse themselves from related discussions or authorship of related recommendations, as directed by the Conflict of Interest committee or requested by the work group.

The complete ICSI policy regarding Conflicts of Interest is available at the ICSI Web site .

Disclosure of Potential Conflicts of Interest

Jeffrey Gursky, MD (Work Group Member)
Department Chair of Psychiatry and Psychology, Olmsted Medical Center
National, Regional, Local Committee Affiliations: None
Guideline Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

Robert Haight, PharmD, BCPP (Work Group Member)
Psychiatric Clinical Specialist, Pharmacy, Fairview Health Services
National, Regional, Local Committee Affiliations: None
Guideline-Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: Paid expert testimony for the State of Minnesota. On request case, consulting for specific patient cases involving psychiatric medications to be reviewed by various departments.

Jeffrey Hardwig, MD (Work Group Member)
Psychiatrist, Essentia Health
National, Regional, Local Committee Affiliations: None
Guideline Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

Todd Hinnenkamp, RN, NC (Work Group Member)
Nurse Clinician, Internal Medicine, Essentia Health
National, Regional, Local Committee Affiliations: None
Guideline Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

Daniel Kessler, LP (Work Group Member)
Lead Psychologist, Allina Medical Clinic – Part of Allina Health
National, Regional, Local Committee Affiliations: Minnesota Psychological Association
Guideline Related Activities: None

Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

Nicki Mack, RN (Work Group Member)
Care Navigator, North Memorial Health Care
National, Regional, Local Committee Affiliations: None
Guideline Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

Mioki Myszkowski, MD (Work Group Member)
Mayo Clinic
National, Regional, Local Committee Affiliations: None
Guideline Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

Michael Trangle, MD, (Work Group Leader)
Senior Medical Director for Behavioral Health Services, Psychiatry, HealthPartners Medical Group and Regions Hospital
National, Regional, Local Committee Affiliations: None
Guideline Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Trangle M, Dieperink B, Gabert T, Haight B, Lindvall B, Mitchell J, Novak H, Rich D, Rossmiller D, Setterlund L, Somers K. Major depression in adults in primary care. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2012 May. 119 p.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available for purchase from the Institute for Clinical Systems Improvement (ICSI) Web site . Also available to ICSI members for free at the ICSI Web site and to Minnesota health care organizations free by request at the ICSI Web site .

Availability of Companion Documents

The following companions are provided to those who access the guideline (see the "Guideline Availability" field):

- Adult depression in primary care. Executive summary. Bloomington (MN): Institute for Clinical Systems Improvement; 2016 Mar. 3 p.
- Adult depression in primary care. Evidence table. Bloomington (MN): Institute for Clinical Systems Improvement; 2016 Mar. 3 p.
- Adult depression in primary care. Study selection flowchart. Bloomington (MN): Institute for Clinical Systems Improvement; 2016 Mar. 1 p.
- Scientific document overview. Bloomington (MN): Institute for Clinical Systems Improvement; 2016 Feb 22. 4 p.

Additionally, the following are available in the appendices of the original guideline document:

- Aims and Measures (quality measures)
- Patient Health Questionnaire (PHQ-9)
- ICSI Shared Decision-Making Model

- Specialized Therapies
- Special Populations

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI on April 30, 1999. The information was verified by the guideline developer as of April 30, 1999. This summary was updated on December 4, 2002. The updated information was verified by the guideline developer on December 24, 2002. This summary was updated again on August 17, 2004. This summary was updated by ECRI on August 15, 2005, following the U.S. Food and Drug Administration advisory on antidepressant medications. This summary was updated by ECRI on October 3, 2005, following the U.S. Food and Drug Administration advisory on Paxil (paroxetine). This summary was updated by ECRI on December 12, 2005, following the U.S. Food and Drug Administration advisory on Paroxetine HCL - Paxil and generic paroxetine. This summary was updated by ECRI on June 13, 2006. This summary was updated by ECRI on November 22, 2006, following the FDA advisory on Effexor (venlafaxine HCl). This summary was updated by ECRI Institute on July 6, 2007. The updated information was verified by the guideline developer on September 13, 2007. This summary was updated by ECRI Institute on November 9, 2007, following the U.S. Food and Drug Administration advisory on Antidepressant drugs. This summary was updated by ECRI Institute on January 10, 2008, following the U.S. Food and Drug Administration advisory on Carbamazepine. This summary was updated by ECRI Institute on July 18, 2008. This summary was updated by ECRI Institute on May 1, 2009 following the U.S. Food and Drug Administration advisory on antiepileptic drugs. This summary was updated by ECRI Institute on December 22, 2009 and November 10, 2010. This summary was updated by ECRI Institute on May 20, 2011 following the U.S. Food and Drug Administration advisory on antipsychotic drugs. This summary was updated by ECRI Institute on September 21, 2011. This summary was updated by ECRI Institute on April 16, 2012 following the updated U.S. Food and Drug Administration advisory on Celexa (citalopram hydrobromide). This summary was updated by ECRI Institute on August 3, 2012. This summary was updated by ECRI Institute on January 23, 2013 following the U.S. Food and Drug Administration advisory on Zolpidem containing products. This summary was updated by ECRI Institute on January 23, 2014. This summary was updated by ECRI Institute on May 22, 2014 following the U.S. Food and Drug Administration advisory on Eszopiclone (Lunesta). This summary was updated by ECRI Institute on May 24, 2016 following the U.S. Food and Drug Administration advisory on Olanzapine. This summary was updated by ECRI Institute on May 31, 2016 following the U.S. Food and Drug Administration advisory on Aripiprazole (Abilify, Abilify Maintena, Aristada). This summary was updated by ECRI Institute on September 13, 2016. The updated information was verified by the guideline developer on December 13, 2016.

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