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

**Measure Number** (*if previously endorsed*)**:** #0004

**Measure Title**: Initiation and Engagement of Alcohol and Other Drug Abuse or Dependence Treatment

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** n/a

**Date of Submission**: 11/1/2018

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| **Instructions**  *Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.*  *Complete* ***EITHER 1a.2, 1a.3 or 1a.4*** *as applicable for the type of measure and evidence.*  *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.*   * 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. * Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx). |

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| **Note: The information provided in this form is intended to aid the Standing 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:   * Outcome: [**3**](#Note3) Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias. * 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. * For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful. * Process measures incorporating Appropriate Use Criteria: See NQF’s guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.   **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 Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org) and/or modified GRADE.  **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

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.* (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

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

Process: This measure assesses the degree to which the organization initiates and engages members identified with a need for alcohol and other drug (AOD) abuse and dependence services and the degree to which members initiate and continue treatment once the need has been identified.

Appropriate use measure: Click here to name what is being measured

Structure: Click here to name the structure

Composite: Click here to name what is being measured

**1a.2** **LOGIC MODEL** Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient’s health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

The intended result of this process measure is to identify members with diagnosed substance abuse and dependence and assess if they initiate treatment, including Medication Assisted Treatment (MAT), within 14 days of their diagnosis and engage in ongoing care within 34 days of initiation.

The presumed pathway from process to outcomes is as follows:

1. Patient (13 years or older) diagnosed with substance abuse or dependence.
2. Patient initiates treatment through an inpatient AOD admission, outpatient visit, intensive outpatient encounter, partial hospitalization, telehealth or medication assisted treatment (MAT) within 14 days of the diagnosis
3. Patient completes two or more additional AOD treatment services or MAT within 34 days of the initiation visit.
4. Patient successfully engages in treatment (intermediate step), which supports a pathway to treatment completion and substance abuse and dependence recovery or appropriate ongoing management (desired outcome).

**1a.3** **Value and Meaningfulness:**  **IF** this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

N/A

**\*\*RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) \*\***

**1a.2** **FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.**

**1a.3.****SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for intermediate outcome, PROCESS, or STRUCTURE PERFORMANCE measures, including those that are instrument-based) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.**

**What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)**

☐ Clinical Practice Guideline recommendation (with evidence review)

☐ US Preventive Services Task Force Recommendation

☐ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

☐ Other

***Table 1: Clinical Practice Guideline 1***

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | * Practice Guideline for the Treatment of Patients with Substance Use Disorders: Second Edition * American Psychiatric Association * 2006 * Work Group on Substance Use Disorders, Kleber H.D., R.D. Weiss, R.F. Anton, B.J. Rounsaville, T.P. George, E.C. Strain, S.F. Greenfield, D.M. Ziedonis, T.R. Kosten, G. Hennessy, C.P. O'Brien, H.S. Connery HS, American Psychiatric Association Steering Committee on Practice Guidelines, McIntyre J.S., S.C. Charles, D.J. Anzia, J.E. Nininger, I.A. Cook, P. Summergrad, M.T. Finnerty, S.M. Woods, B.R. Johnson, J. Yager, R. Pyles, L. Lurie, C.D. Cross, R.D. Walker, R. Peele, M.A. Barnovitz, S.H. Gray, J.P. Shemo, S. Saxena, T. Tonnu, R. Kunkle, A.B. Albert, L.J. Fochtmann, C. Hart, D. Regier. (2006). *Treatment of patients with substance use disorders, second edition.* American Psychiatric Association. Am J Psychiatry 163(8 Suppl):5-82. * <https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/substanceuse.pdf> |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | **2. Psychiatric management ([I]Recommended with substantial clinical confidence)**  “Psychiatric management is the foundation of treatment for patients with substance use disorders [I]. Psychiatric management has the following specific objectives: motivating the patient to change, establishing and maintaining a therapeutic alliance with the patient, assessing the patient’s safety and clinical status, managing the patient’s intoxication and withdrawal states, developing and facilitating the patient’s adherence to a treatment plan, preventing the patient’s relapse, educating the patient about substance use disorders, and reducing the morbidity and sequelae of substance use disorders. Psychiatric management is generally combined with specific treatments carried out in a collaborative manner with professionals of various disciplines at a variety of sites, including community-based agencies, clinics, hospitals, detoxification programs,  and residential treatment facilities. Many patients benefit from involvement in self-help group meetings, and such involvement can be encouraged as part of psychiatric management.”  **3. Specific treatments**  “The specific pharmacological and psychosocial treatments reviewed below are generally applied in the context of programs that combine a number of different treatment modalities.”  **a) Pharmacological treatments ([I]Recommended with substantial clinical confidence)**  “Pharmacological treatments are beneficial for selected patients with specific substance use disorders  [I]. The categories of pharmacological treatments are 1) medications to treat intoxication and  withdrawal states, 2) medications to decrease the reinforcing effects of abused substances, 3) agonist  maintenance therapies, 4) antagonist therapies, 5) abstinence-promoting and relapse prevention  therapies, and 6) medications to treat comorbid psychiatric conditions.”  **b) Psychosocial treatments (All [I]Recommended with substantial clinical confidence)**  “Psychosocial treatments are essential components of a comprehensive treatment program [I].  Evidence-based psychosocial treatments include cognitive-behavioral therapies (CBTs, e.g., relapse prevention, social skills training), motivational enhancement therapy (MET), behavioral therapies (e.g., community reinforcement, contingency management), 12-step facilitation (TSF), psychodynamic therapy/interpersonal therapy (IPT), self-help manuals, behavioral self-control, brief interventions, case management, and group, marital, and family therapies. There is evidence to support the efficacy of integrated treatment for patients with a co-occurring substance use and psychiatric disorder; such treatment includes blending psychosocial therapies used to treat specific substance use disorders with psychosocial treatment approaches for other psychiatric diagnoses (e.g., CBT for depression).”  **Alcohol Use Disorder**  **Pharmacological Treatments (All [I]Recommended with substantial clinical confidence or II] Recommended with moderate clinical confidence):** “Specific pharmacotherapies for alcohol-dependent patients have well-established efficacy and moderate effectiveness. Naltrexone may attenuate some of the reinforcing effects of alcohol [I], although data on its long-term efficacy are limited. The use of long-acting, injectable naltrexone may promote adherence, but published research is limited and FDA approval is pending. Acamprosate, a γ-aminobutyric acid (GABA) analog that may decrease alcohol craving in abstinent individuals, may also be an effective adjunctive medication in motivated patients who are concomitantly receiving psychosocial treatment [I]. Disulfiram is an effective adjunct to a comprehensive treatment program for reliable, motivated patients whose drinking may be triggered by events that suddenly increase alcohol craving [II].” **NOTE: Please see below for APA 2017 clinical practice guideline on pharmacological treatment for alcohol use disorder.**  **Psychosocial Treatments:** “Psychosocial treatments found effective for some patients with an alcohol use disorder include MET [I], CBT [I], behavioral therapies [I], TSF [I], marital and family therapies [I], group therapies [II], and psychodynamic therapy/IPT [III]. Recommending that patients participate in self-help groups, such as Alcoholics Anonymous (AA), is often helpful [I].”  **Opioid Use Disorder**  **Pharmacological Treatments (All [I]Recommended with substantial clinical confidence):** “Maintenance treatment with methadone or buprenorphine is appropriate for patients with a prolonged history (>1 year) of opioid dependence [I]. The goals of treatment are to achieve a stable maintenance dose of opioid agonist and facilitate engagement in a comprehensive program of rehabilitation [I]. Maintenance treatment with naltrexone is an alternative strategy [I], although the utility of this strategy is often limited by lack of patient adherence and low treatment retention.”  **Psychosocial Treatments:** “Psychosocial treatments are effective components of a comprehensive treatment plan for patients with an opioid use disorder [II]. Behavioral therapies (e.g., contingency management) [II], CBTs [II], psychodynamic psychotherapy [III], and group and family therapies [III] have been found to be effective for some patients with an opioid use disorder. Recommending regular participation in self-help groups may also be useful [III].” |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | Authors did not specifically grade the evidence used to inform each recommendation statement. However, they provided a grading system for each individual reference cited throughout their guideline (below) based on the type of clinical study included as a supporting document.  “The following coding system is used to indicate the nature of the supporting evidence in the summary recommendations and references:  [A] Double-blind, randomized clinical trial. A study of an intervention in which subjects are prospectively followed over time; there are treatment and control groups; subjects are randomly assigned to the two groups; both the subjects and the investigators are blind to the assignments.  [A] Randomized clinical trial. Same as above but not double-blind.  [B] Clinical trial. A prospective study in which an intervention is made and the results of that intervention are tracked longitudinally; study does not meet standards for a randomized clinical trial.  [C] Cohort or longitudinal study. A study in which subjects are prospectively followed over time without any specific intervention.  [D] Case-control study. A study in which a group of patients is identified in the present and information about them is pursued retrospectively or backward in time.  [E] Review with secondary data analysis. A structured analytic review of existing data, e.g., a meta-analysis or a decision analysis.  [F] Review. A qualitative review and discussion of previously published literature without a quantitative synthesis of the data.  [G] Other. Textbooks, expert opinion, case reports, and other reports not included above.” |
| Provide all other grades and definitions from the evidence grading system | See “grade assigned to the evidence associated with the recommendation with the definition of the grade” for information about each article reviewed that met inclusion criteria for this guideline. |
| Grade assigned to the **recommendation** with definition of the grade | “Each recommendation is identified as meriting one of three categories of endorsement, based  on the level of clinical confidence regarding the recommendation, as indicated by a bracketed  Roman numeral after the statement.”  **Recommendation 2:** [I]Recommended with substantial clinical confidence.  **Recommendation 3a (Pharmacologic Treatments):** [I]Recommended with substantial clinical confidence.  **Recommendation 3b (Psychosocial Treatments):** [I]Recommended with substantial clinical confidence.  Further broken down by diagnosis:  **Alcohol Use Disorder: Pharmacological Treatments** (All [I]Recommended with substantial clinical confidence or II] Recommended with moderate clinical confidence)  **Alcohol Use Disorder: Psychosocial Treatments:** [I]Recommended with substantial clinical confidence or [III] May be recommended on the basis of individual circumstances.  **Opioid Use Disorder: Pharmacological Treatments** (All [I]Recommended with substantial clinical confidence)  **Opioid Use Disorder: Psychosocial Treatments:** [I]Recommended with substantial clinical confidence), [II] Recommended with moderate clinical confidence, or [III] May be recommended on the basis of individual circumstances. |
| Provide all other grades and definitions from the recommendation grading system | None. |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | * Authors included 1,063 studies that met inclusion criteria for this guideline after reviewing 89,231 references populated using a structured literature search in PubMed. * “[Authors completed] A comprehensive literature review to identify all relevant randomized clinical trials as well as less rigorously designed clinical trials and case series when evidence from randomized trials was unavailable.” For additional details about the types of studies included as citations for this guideline, see “grade assigned to the evidence associated with the recommendation with the definition of the grade.” |
| Estimates of benefit and consistency across studies | Across included studies, guidelines for the treatment of those with substance use disorders agree that psychosocial care, and in many cases, also pharmacological treatments, are an effective way to reduce morbidity and mortality. |
| What harms were identified? | N/A |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | No. The conclusions drawn from this systematic review remain relevant and current, except as superseded by more recent guidance below specific to alcohol use disorder. |

***Table 2: Clinical Practice Guideline 2***

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | * Practice Guideline for the Pharmacological Treatment of Patients with Alcohol Use Disorder * American Psychiatric Association * 2018 * Reus, V. et al. (2018). Practice Guideline for the Pharmacological Treatment of Patients with Alcohol Use Disorder*. American Journal of Psychiatry, 175(1), 86-90. doi:*10.1176/appi.ajp.2017.1750101 * https://psychiatryonline.org/doi/pdf/10.1176/appi.books.9781615371969 |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | “Statement 8. APA recommends (1C) that patients with alcohol use disorder have a documented comprehensive  and person-centered treatment plan that includes evidence-based nonpharmacological and pharmacological  treatments.”  “Statement 9. APA recommends (1B) that naltrexone or acamprosate be offered to patients with moderate to severe  alcohol use disorder who  • have a goal of reducing alcohol consumption or achieving abstinence,  • prefer pharmacotherapy or have not responded to nonpharmacological treatments alone, and  • have no contraindications to the use of these medications.”  “Statement 10. APA suggests (2C) that disulfiram be offered to patients with moderate to severe alcohol use disorder  who  • have a goal of achieving abstinence,  • prefer disulfiram or are intolerant to or have not responded to naltrexone and acamprosate,  • are capable of understanding the risks of alcohol consumption while taking disulfiram, and  • have no contraindications to the use of this medication.”  “Statement 11. APA suggests (2C) that topiramate or gabapentin be offered to patients with moderate to severe alcohol use disorder who  • have a goal of reducing alcohol consumption or achieving abstinence,  • prefer topiramate or gabapentin or are intolerant to or have not responded to naltrexone and acamprosate,  and  • have no contraindications to the use of these medications.” |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | Statement 8: “A” rating for evidence: High confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of effect.  Statement 9: “B” rating for evidence: Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.  Statement 10: “C” rating for evidence: Low confidence that the evidence reflects the true effect. Further research is likely to change our confidence in the estimate of effect and is likely to change the estimate.  Statement 11: “C” rating for evidence: Low confidence that the evidence reflects the true effect. Further research is likely to change our confidence in the estimate of effect and is likely to change the estimate. |
| Provide all other grades and definitions from the evidence grading system | N/A |
| Grade assigned to the **recommendation** with definition of the grade | Statement 8 and Statement 9: “1” Recommendation: APA recommends with confidence that the benefits of the intervention clearly outweigh harms.  Statement 10 and Statement 11: “2” Suggestion: APA suggests the that although the benefits of the statement are still viewed as outweighing the harms, the balance of benefits and harms is more difficult to judge, or either the benefits or the harms may be less clear. With a suggestion, patient values and preferences may be more variable, and this can influence the clinical decision that is ultimately made. |
| Provide all other grades and definitions from the recommendation grading system | N/A |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | The Agency for Healthcare Research and Quality (AHRQ) systematic review “Pharmacotherapy for Adults With Alcohol-Use Disorders in Outpatient Settings” is the source of evidence used for the development of this guideline. This systematic review included 95 randomized clinical trials, accounting for 22,803 patients.  Jonas, D.E., Amick, H.R., Feltner, C., et al. (2014). Pharmacotherapy for Adults With Alcohol Use Disorders in Outpatient Settings A Systematic Review and Meta-analysis. JAMA, 311(18), 1889–1900. doi:10.1001/jama.2014.3628 |
| Estimates of benefit and consistency across studies | The following texts are directly quoted from the APA guideline and summarize the benefits of each recommendation statement as determined by clinical evidence review:  **Statement 8. Evidence-Based Treatment Planning**  “Development and documentation of a comprehensive treatment plan assures that the clinician has considered the available nonpharmacological and pharmacological options for treatment and has identified those treatments that are best suited to the needs of the individual patient, with a goal of improving overall outcome. It may also assist in forming a therapeutic relationship, eliciting patient preferences, permitting education about possible treatments, setting expectations for treatment, and establishing a framework for shared decision-making. Documentation of a treatment plan promotes accurate communication among all those caring for the patient and can serve as a reminder  of prior discussions about treatment.”  “The potential benefits of this recommendation were viewed as far outweighing the potential harms. The level of research evidence is rated as low because no information is available on the harms of such an approach. There is also minimal research on whether developing and documenting a specific treatment plan improves outcomes as compared with assessment and documentation as usual. However, the majority of studies of pharmacotherapy for AUD included nonpharmacological treatments aimed at providing supportive counseling, enhancing coping strategies, and promoting adherence. This indirect evidence supports the benefits of comprehensive treatment planning.”  **Statement 9. Naltrexone or Acamprosate**  “Acamprosate is associated with a small benefit on the outcomes of returning to any drinking and on the number of drinking days (moderate strength of research evidence). Naltrexone is associated with a small benefit on the outcomes of returning to any drinking, returning to heavy drinking, frequency of drinking days, and frequency of heavy drinking days (moderate strength of research evidence).  Evidence is limited, but the use of long-acting injectable naltrexone may have benefits for adherence as compared with oral formulations of naltrexone. In the AHRQ meta-analysis of head to- head comparisons, neither acamprosate nor naltrexone showed superiority to the other medication  in terms of return to heavy drinking (moderate strength of research evidence), return to any drinking (moderate strength of research evidence), or percentage of drinking days (low strength of research evidence). However, in the U.S. COMBINE study (but not the German PREDICT study),  naltrexone was associated with better outcomes than acamprosate.”  “The potential benefits of this recommendation were viewed as far outweighing the potential harms. For both acamprosate and naltrexone, the harms of treatment were considered minimal, particularly compared with the harms of continued alcohol use, as long as there was no contraindication to the use of the medication. The positive effects of acamprosate and naltrexone were small overall, and not all studies showed a statistically significant benefit from these medications. In addition, European studies showed greater benefit of acamprosate than did U.S. studies, and naltrexone exhibited greater effect than acamprosate in the COMBINE trial. Nevertheless, the potential benefit of each medication was viewed as far outweighing the harms of continued alcohol use, particularly when nonpharmacological approaches have not produced an effect or when patients prefer to use one of these medications as an initial treatment option. In addition, it was noted that even small effect sizes may be clinically meaningful because of the significant morbidity associated with AUD. Patients with mild AUD rarely participated in clinical trials of naltrexone and acamprosate pharmacotherapy. Therefore, although they might respond to these medications, patients with mild AUD are not included in this recommendation because of the limited amount of research evidence.”  **Statement 10. Disulfiram**  “Benefits of disulfiram on alcohol-related outcomes were not reported in the AHRQ review. However,  a subsequent meta-analysis (Skinner et al. 2014) that included randomized open-label studies  (low strength of research evidence) showed a moderate effect of disulfiram as compared with no  disulfiram as well as compared with acamprosate, naltrexone, and topiramate. In studies where  medication adherence was assured through supervised administration, the effect of disulfiram was  large (Skinner et al. 2014).”  “The potential benefits of this statement were viewed as likely to outweigh the harms. The strength of research evidence is rated as low because there were insufficient data from double-blind randomized controlled trials (RCTs), and the bulk of the research evidence for benefits and harms was from randomized open-label studies. With carefully selected patients in clinical trials, adverse events were somewhat greater with disulfiram. However, serious adverse events were few and comparable in numbers to serious adverse events in comparison groups consistent with the long history of safe use of disulfiram in clinical practice. Consequently, the potential benefits of disulfiram were viewed as likely to outweigh the harms for most patients given the medium to large effect size for the benefit of disulfiram when open-label studies are considered and particularly compared with the harms of continued alcohol use. In addition, it was noted that even small effect sizes may be clinically meaningful because of the significant morbidity associated with AUD. The strength of the guideline statement (suggestion) was influenced both by the strength of research evidence and by patient preferences related to disulfiram as compared with other interventions.” |
| What harms were identified? | The following texts are directly quoted from the APA guideline and summarize the harms of each recommendation statement as determined by clinical evidence review:  **Statement 8. Evidence Based Treatment Planning**  “The only identifiable harm from this recommendation relates to the time spent in discussion and documentation that may reduce the opportunity to focus on other aspects of the evaluation.”  **Statement 9. Naltrexone or Acamprosate**  “The harms of acamprosate are small in magnitude, with slight overall increases in diarrhea and vomiting as compared with placebo (moderate strength of research evidence). The harms of naltrexone are small in magnitude, with slight overall increases in dizziness, nausea, and vomiting relative to placebo (moderate strength of research evidence). Alterations in hepatic function are also possible with naltrexone, but changes in liver chemistries were not assessed in the AHRQ review. Individuals taking naltrexone would not be able to take opioids for pain, and other treatments for acute pain would be needed. For individuals treated with long-acting injectable naltrexone, pain or induration can occur at the injection site, and access to the medication can be an issue because of geographic- or payment-related issues. With long durations of naltrexone use, individuals lose tolerance to opioids. This can result in overdose and death if large but previously tolerated opioid doses are taken after naltrexone is discontinued. For many other potential harms, including mortality, evidence was not available or was rated by the AHRQ review as insufficient. However, withdrawals from the studies due to adverse events did not differ from placebo for acamprosate (low strength of research evidence) and were only slightly greater than placebo for naltrexone although statistically significant (moderate strength of research evidence).”  **Statement 10. Disulfiram**  “There were insufficient data on harms of disulfiram to conduct a meta-analysis in the AHRQ report.  When randomized open-label studies were included (low strength of research evidence; Skinner et al. 2014), there was a significantly greater number of adverse events with disulfiram than with control conditions. Significant harms have been reported if alcohol-containing products are ingested concomitantly with disulfiram use.” |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | N/A |

***Table 3: Clinical Practice Guideline 3***

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | * The ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use * American Society of Addiction Medicine (ASAM). * June 1, 2015 * American Society of Addiction Medicine (ASAM). (2015). *The ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use.* Retrieved from: https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf?sfvrsn=24 * https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf?sfvrsn=24 |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | *Part 7: Psychosocial Treatment in Conjunction with Medications for the Treatment of Opioid Use Disorder*  (1) “Psychosocial treatment is recommended in conjunction with any pharmacological treatment of opioid use disorder. At a minimum, psychosocial treatment should include the following: psychosocial needs assessment, supportive counseling, links to existing family supports, and referrals to community services.”  (2) “Treatment planning should include collaboration with qualified behavioral healthcare providers to determine the optimal type and intensity of psychosocial treatment and for renegotiation of the treatment plan for circumstances in which patients do not adhere to recommended plans for, or referrals to, psychosocial treatment.”  (3) “Psychosocial treatment is generally recommended for patients who are receiving opioid agonist treatment (methadone or buprenorphine).”  (4) “Psychosocial treatment should be offered with oral and extended-release injectable naltrexone. The efficacy of extended-release injectable naltrexone to treat opioid use disorder has not been confirmed when it has been used as pharmacotherapy without accompanying psychosocial treatment.” |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | ASAM does not provide a rating for their evidence. “These guidelines were developed using the RAND/UCLA Appropriateness Method (RAM) - a process that combines scientific evidence and clinical knowledge to determine the appropriateness of a set of clinical procedures.” |
| Provide all other grades and definitions from the evidence grading system | N/A |
| Grade assigned to the **recommendation** with definition of the grade | ASAM does not provide a rating for recommendation statements. |
| Provide all other grades and definitions from the recommendation grading system | N/A |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | “In total, 49 guidelines were identified and 34 were ultimately included in the analysis.”  “The majority of existing clinical guidelines are based on systematic reviews of the literature including appropriateness criteria used in the RAM. Therefore, the aim of this exercise was not to re-review all of the research literature, but to identify within the existing clinical guidelines how they addressed common questions or considerations that clinicians are likely to raise in the course of deciding whether and how to use medications as part of the treatment of individuals with opioid use disorder.” |
| Estimates of benefit and consistency across studies | “[Across studies included in the recommendations], patients experience improved outcomes after receiving psychosocial treatment, in both individual and group formats, from a variety of approaches. Ancillary drug addiction counseling and mutual-help programs are generally considered beneficial.” |
| What harms were identified? | “Because lack of patient understanding and adherence  may adversely affect outcomes, clinicians should make every  effort to promote the patient’s understanding of, and adherence to, prescribed and recommended pharmacological and psychosocial treatments. Patients should be informed of the risks, benefits, and alternatives to a particular treatment, and should be an active party to shared decision-making whenever feasible.” |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | n/a |

***Table 4: Clinical Practice Guideline 4***

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | * VA/DoD Clinical Practice Guideline for the Management of Substance Use Disorders * Department of Veterans Affairs and Department of Defense * 2015 * 2009 * Department of Veteran Affairs, Department of Defense. (2015). *VA/DoD Clinical Practice Guideline for the Management of Substance Use Disorders.* Washington DC: Department of Veterans Affairs, Department of Defense. * Department of Veteran Affairs, Department of Defense. (2009). *VA/DoD clinical practice guideline for management of substance use disorders (SUD).* Washington (DC): Department of Veteran Affairs, Department of Defense. * https://www.healthquality.va.gov/guidelines/MH/sud/VADoDSUDCPGRevised22216.pdf |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | Recommendation 3: “For patients with a diagnosis of a substance use disorder, we suggest offering referral for specialty substance use disorder care based on willingness to engage in specialty treatment”  Recommendation 5: “For patients with moderate-severe alcohol use disorder, we recommend offering one of the following medications:   * Acamprosate * Disulfiram * Naltrexone- oral or extended release * Topiramate”   Recommendation 7: “For patients with alcohol use disorder we recommend offering one or more of the following interventions considering patient preference and provider training/competence:   * Behavioral Couples Therapy for alcohol use disorder * Cognitive Behavioral Therapy for substance use disorders * Community Reinforcement Approach * Motivational Enhancement Therapy * 12-Step Facilitation”   Recommendation 8: “For patients with opioid use disorder, we recommend offering one of the following medications considering patient preferences:   * Buprenorphine/naloxone * Methadone in an Opioid Treatment Program”   Recommendation 11: “For patients with opioid use disorder for whom opioid agonist treatment is contraindicated, unacceptable, unavailable, or discontinued and who  have established abstinence for a sufficient period of time (see narrative), we recommend offering:   * Extended-release injectable naltrexone”   Recommendation 24: “For patients who have initiated an intensive phase of outpatient or residential treatment, we recommend offering and encouraging ongoing systematic relapse prevention efforts or recovery support individualized on the basis of treatment response.”  VA/DoD 2009: Offer referral to specialty SUD care for addiction treatment if the patient:  • May benefit from additional evaluation or motivational interviewing regarding his/her substance use and related problems  • Has tried and been unable to change substance use on his/her own or does not respond to repeated brief intervention  • Has been diagnosed with substance dependence  • Has previously been treated for an alcohol or other substance use disorder |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | The VA/DoD did not grade the evidence using a separate system from the overall grading of the recommendation. For the recommendation grade, see “Grade assigned to the recommendation with definition of the grade” below. |
| Provide all other grades and definitions from the evidence grading system | N/A |
| Grade assigned to the **recommendation** with definition of the grade | Grading of Recommendations Assessment, Development and Evaluation (GRADE) system to assess the quality of the evidence base and assign a grade for the strength VA/DoD Clinical Practice Guideline for the Management of Substance Use Disorders December 2015 Page 11 of 169 for each recommendation. The following grade assignments were used:  • Strong For (or “We recommend offering this option …”)  • Weak For (or “We suggest offering this option …”)  • Weak Against (or “We suggest not offering this option …”)  • Strong Against (or “We recommend against offering this option …”)  The relative strength of the recommendation is based on a binary scale, “Strong” or “Weak.” A strong recommendation indicates that the Work Group is highly confident that desirable outcomes outweigh undesirable outcomes. If the Work Group is less confident of the balance between desirable and undesirable outcomes, they present a weak recommendation.  Similarly, a recommendation for a therapy or preventive measure indicates that the desirable consequences outweigh the undesirable consequences. A recommendation against a therapy or preventive measure indicates that the undesirable consequences outweigh the desirable consequences.  Grading by Recommendation   * Recommendation 3: Weak for (We suggest offering this option) * Recommendation 5: Strong for (We recommend offering this option) * Recommendation 7: Strong for (We recommend offering this option) * Recommendation 8: Strong for (We recommend offering this option) * Recommendation 11: Strong for (We recommend offering this option) * Recommendation 24: Strong for (We recommend offering this option)   **A** A strong recommendation that the clinicians provide the intervention to eligible patients. Good evidence was found that the intervention improves important health outcomes and concludes that benefits substantially outweigh harm.  **B** A recommendation that clinicians provide (the service) to eligible patients. At least fair evidence was found that the intervention improves health outcomes and concludes that benefits outweigh harm. |
| Provide all other grades and definitions from the recommendation grading system | **C** No recommendation for or against the routine provision of the intervention is made. At least fair evidence was found that the intervention can improve health outcomes, but concludes that the balance of benefits and harms is too close to justify a general recommendation.  **D** Recommendation is made against routinely providing the intervention to asymptomatic patients. At least fair evidence was found that the intervention is ineffective or that harms outweigh benefits.  **I** The conclusion is that the evidence is insufficient to recommend for or against routinely providing the intervention. Evidence that the intervention is effective is lacking, or poor quality, or conflicting, and the balance of benefits and harms cannot be determined. |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | Overall, 135 studies, the majority of which are randomized control trials or systematic reviews, were included in the systematic review used to inform this guideline. |
| Estimates of benefit and consistency across studies | Overall, the authors of this guideline put forth the above recommendations and specifically stated that the benefits of the recommended treatments and protocol outweigh their potential harms. Additionally, the authors discuss not only the benefit for the primary outcome of interest, engaging patients in SUD care, but the improvement in secondary outcomes, such as crime associated with substance use, social engagement and vocational productivity, transmittable diseases, and morbidity. |
| What harms were identified? | Overall, the authors felt that the benefit of treatment, in accordance with the recommendations put forth in the guidelines, outweighed any potential risk. For each of the pharmacotherapies discussed in the guideline, the authors explicitly urge providers to carefully consider the risks and benefits for each individual patient being treated.  With regard to treatment of pregnant women, the authors included the following: “Clinicians should weigh the unknown risks of long-term harm to the fetus from limited exposure to naloxone in the combination product [buprenorphine/naloxone combination product] versus the risks of misuse or diversion posed by prescribing the mono-product to the mother during pregnancy.” |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | n/a |

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**1a.4 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.*

N/A

**1a.4.1** **Briefly SYNTHESIZE the evidence that supports the measure.** A list of references without a summary is not acceptable.

**1a.4.2 What process was used to identify the evidence?**

**1a.4.3.** **Provide the citation(s) for the evidence.**