# REVIEW OF MEDICATION-ASSISTED TREATMENT GUIDELINES AND MEASURES FOR OPIOID AND ALCOHOL USE

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#### **ABSTRACT**

**Summary**: In response to the growing opioid epidemic, the U.S. Department of Health and Human Services (HHS) announced a three-pronged initiative in March 2015 to: (1) improve opioid prescribing practices; (2) increase access to naloxone for overdose management; and (3) expand medication-assisted treatment (MAT) to reduce opioid dependence. In support of the initiative, the HHS Office of the Assistant Secretary for Planning and Evaluation contracted with Mathematica Policy Research to develop a roadmap that identifies concepts for potential quality measures that promote the appropriate use of MAT for opioid use as well as the steps needed to develop those concepts into measures. As a guiding step in roadmap development, clinical MAT guidelines and existing measures related to MAT were reviewed. This report contains the review of clinical MAT guidelines and existing measures.

Major Findings: Twenty-one MAT opioid use guidelines published between 2010 and 2015 were identified. The guidelines were largely developed using a consensus process informed by a literature review. Ninety percent of the guidelines focus on care delivered in the maintenance treatment phase, 62 percent provide information on assessment, and 62 percent address withdrawal management or detoxification. All the guidelines recommend specific medications for use in treatment and about half (57 percent) provide information on medication dosing. Two-thirds of the guidelines provide some information on psychosocial treatment. Contingency management, motivational interviewing, and cognitive behavioral approaches are the most commonly mentioned psychosocial treatments. In addition to the clinical guidelines, ten existing MAT opioid use quality measures were identified -- eight process measures and two patient satisfaction methods. Six of the process measures assess various aspects of pharmacotherapy use, including dosage and frequency of use. One measure explicitly addresses both components of MAT -- pharmacotherapy and psychosocial treatment; however, this measure assesses counseling about these treatment options, rather than utilization of MAT. One measure that was developed for use in inpatient settings has received the National Quality Forum's (NQF's) endorsement.

**Purpose**: This project surveyed existing clinical guidelines and quality measures related to MAT. The summarized information will be used to develop a roadmap that identifies strategies HHS could use to promote the appropriate use of MAT for opioid use.

**Methods**: This project searched for and reviewed existing MAT clinical guidelines, published from 2010 to 2015, in the National Guidelines Clearinghouse, the National Institute for Health and Clinical Excellence, online search engines, and bibliography scans. MAT quality measures were identified from searches in the National Quality Measures Clearinghouse, the NQF's Quality Positioning System, the HHS Measure Inventory, and online search engines.

#### **ACRONYMS**

The following acronyms are mentioned in this report and/or appendices.

AA Alcoholics Anonymous

ADAP Vermont Division of Alcohol and Drug Abuse Programs

ADI Adolescent Diagnostic Interview

AIDS Acquired Immune Deficiency Syndrome

Al-Anon AA-based program of recovery for the families and friends of

alcoholics

ALT Alanine Transaminase blood test

AMDG Washington State Agency Medical Directors' Group

AOD Alcohol or Other Drug AP Attending Provider

APA American Psychiatric Association APQ Alcohol Problems Questionnaire

ART Antiretroviral Therapy

ASAM American Society of Addiction Medicine

ASPE HHS Office of the Assistant Secretary for Planning and

Evaluation

AST Aspartate Aminotrasferase blood test

AUDIT Alcohol Use Disorders Identification Test (screen)

AUDIT-C Alcohol Use Disorders Identification Test Consumption (screen)

BAP British Association for Psychopharmacology

BASIS-24 24-item Behavior and Symptom Identification Scale

BMT Buprenorphine Maintenance Treatment

CAMHS Child and Adolescent Mental Health Service

CBT Cognitive Behavioral Therapy

cc Cubic Centimeter

CDC HHS Centers for Disease Control and Prevention

CHARD Community Health and Resource Director CINA Clinical Institute for Narcotic Assessment

CIWA-Ar Clinical Institute for Withdrawal Assessment for Alcohol-revised

CM Contingency Management

CMAJ Canadian Medical Association Journal

CNCP Chronic Non-Cancer Pain
CNS Central Nervous System
COD Co-Occurring Disorder

COWS Clinical Opiate Withdrawal Scale

CSAT SAMHSA Centers for Substance Abuse Treatment

CVD Cardiovascular Disease

CYP450 Cytochrome P450, a family of isozymes responsible for the

biotransformation of several drugs

DAART Directly Administered Antiretrovical Therapy

DATA Division of Alcohol and Drug Abuse

DEA Drug Enforcement Agency
DoD U.S. Department of Defense

DSM-IV Diagnostic and Statistical Manual of Mental Disorders, 4<sup>th</sup> edition

DSM-IV TR Diagnostic and Statistical Manual of Mental Disorders. 4<sup>th</sup>

edition, text revision

DSM-V Diagnostic and Statistical Manual of Mental Disorders, 5<sup>th</sup> edition

DT Delirium Tremen

EBT Evidence-Based Treatment EHR Electronic Health Record

FDA HHS Food and Drug Administration

FY Fiscal Year

g Gram

GAF Global Assessment of Functioning Scale

GDG Guideline Development Group GGT Gamma-Glutamyl Transferase

GHB Gamma-Hydroxybutyric

GRADE Grading of Recommendations Assessment, Development and

**Evaluation** 

HEDIS Healthcare Effectiveness Data and Information Set HHS U.S. Department of Health and Human Services

HIV Human Immunodeficiency Virus

IDDT Integrated Dual Disorder Treatment

IV Intravenous

kg Kilogram

LDQ Leeds Dependence Questionnaire

MAST-G Michigan Alcohol Screening Test-Geriatric version

MAT Medication-Assisted Treatment

mg Milligram Milliliter

MMSE Mini-Mental State Examination
MMT Methadone Maintenance Treatment

NA Narcotics Anonymous

NCQA National Committee for Quality Assurance
NHMRC National Health and Medical Research Council
NIAAA National Institute on Alcohol Abuse and Alcoholism

NICE National Institute for Clinical Excellence
NOUGG National Opioid Use Guideline Group

NQF National Quality Forum

NSAID Non-Steroidal Anti-Inflammatory Drug

OAT Opiate Agonist Therapy

OBOT Office-Based Opioid Treatment
OOWS Objective Opioid Withdrawal Scale

OST Opioid Substitution Therapy

OTC Over-The-Counter

OTP Opioid Treatment Program

OVHA Office of Vermont Health Access

PAS-45 New York State Office of Alcoholism and Substance Abuse

Service client Discharge Report

PDMP Prescription Drug Monitoring Program

PTSD Post-Traumatic Stress Disorder

QF Quantity Frequency

QT time between the start of the ! wave and the end of the T wave in

the heart's electrical cycle

QTc Corrected QT interval

RCT Randomized Controlled Trial

ROSC Recovery-Oriented Systems of Care

RPT Relapse Prevention Therapy

SADQ Severity of Alcohol Dependence Questionnaire
SAMHSA HHS Substance Abuse and Mental Health Services

Administration

SIMP Structured Intensive Multidisciplinary Program SMART Self-Management and Recovery Training

SMAST-G Short Michigan Alcohol Screening Test-Geriatric version

SOWS Subjective Opioid Withdrawal Scale SPC Summary of Product Characteristics

SROM Slow-Release Oral Morphine
SSRI Suicide Screening Risk Inventory

SUD Substance Use Disorder

TB Tuberculosis

TJC The Joint Commission

UCLA University of California, Las Angeles

UNAIDS Joint United Nations Programme on HIV/AIDS UNDOC United Nations Office on Drug and Crime

UROD Ultra-Rapid-Detoxification

VA U.S. Department of Veterans Affairs VDH Vermont Department of Health VHA Veterans Health Administration

WFSBP World Federation of Societies of Biological Psychiatry

WHO World Health Organization

#### A. INTRODUCTION

Opioid overdoses claim 17,000 American lives annually (ASAM 2015). Deaths by opioid overdose have nearly quadrupled from 1999 to 2013 (CDC 2015). Nearly 2.5 million Americans are currently at risk for overdoses -- 1.9 million are opioid-dependent, and 517,000 are addicted to heroin (ASAM 2015). In response to the growing opioid epidemic, the U.S. Department of Health and Human Services (HHS) announced a three-pronged initiative in March 2015 to: (1) improve opioid prescribing practices; (2) increase access to naloxone for overdose management; and (3) expand medicationassisted treatment (MAT) to reduce opioid dependence (ASPE 2015). MAT is a treatment that combines medication with psychosocial treatment to treat substance use disorders (SUDs). In the United States, three medications are HHS Food and Drug Administration (FDA)-approved to treat opioid use disorders: methadone, buprenorphine and naltrexone. In support of the initiative, the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE) contracted with Mathematica Policy Research to develop a roadmap that identifies concepts for potential quality measures that promote the appropriate use of MAT for opioid use as well as the steps needed to develop those concepts into measures. As a guiding step in roadmap development, we conducted a review of clinical MAT guidelines and existing measures related to MAT. In this report, we briefly summarize the findings from the review.

#### **B. APPROACH TO REVIEW**

Even though the roadmap focuses on MAT for opioid use, we recognize that clinical guidelines and measures related to MAT for alcohol and other SUDs could be useful to guide the approach to developing and implementing MAT measures for opioid use. As such, we searched for and reviewed clinical guidelines that include MAT for opioid and alcohol use published between 2010 and 2015. We identified clinical guidelines through searches of the National Guidelines Clearinghouse, the National Institute for Health and Clinical Excellence (NICE), PubMed, and Google. We identified additional guidelines through bibliography searches of previously identified guidelines. We also searched for measures related to MAT for opioid and alcohol use and other SUDs through searches in the National Quality Measures Clearinghouse, National Quality Forum's (NQF's) Quality Positioning System, HHS Measure Inventory, and Google. In addition, we drew on a review of measures that Mathematica conducted earlier under the same contract.

TABLE 1. Summary of MAT Guidelines for Opioid Use							
Guideline Name (publication year) (appendix table #)	Setting	Stage(s) of Treatment	Strength of Evidence Rated	Includes Specific Medications	Includes Information on Dosing and Frequency	Includes Psychosocial Treatment	
Practice Guidance for Buprenorphine for the Treatment of Opioid Use Disorders: Results of an Expert Panel Process (2015) (A.1) (10 expert panelists were nominated by literature review or by other known experts in the field; represented diverse clinical/research expertise and practice settings.)	Ambulatory care (deliberately broad to apply to a variety of provider settings).	Assessment, maintenance.	Modified RAND/UCLA Appropriateness Method.	Buprenorphine.	Yesboth.	Generic evidence-based treatment recommendation.	
American Society of Addiction Medicine National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use (2015) (A.5)	OTP, OBOT, other outpatient, inpatient.	Assessment, withdrawal management, maintenance.	RAND/UCLA Appropriateness Method used but individual ratings of specific guidelines not provided.	Buprenorphine, methadone, naltrexone.  Clonidine for withdrawal management.	Yesboth.	Generic recommendation that includes assessment of psychosocial needs; individual and/or group counseling; linkages to existing family supports; and referral to community-based services.	
Commonwealth of Australia: National Guidelines for Medication- Assisted Treatment of Opioid Dependence (2014) (A.21)	Generalist settings (general practice and hospital, clinic or community settings not specialized in treatment of alcohol and other drug problems).	Assessment, withdrawal management, maintenance.	NHMRC definitions (4-star rating system).	Buprenorphine, methadone, and naltrexone.  Clonidine and other supplementary medications are mentioned as withdrawal options, but buprenorphine associated with better outcomes.	Yesboth.	Generic statement that cognitive behavioral approaches and CM can increase effectiveness of MAT. Financial management/advice and participation in self-help groups also encouraged.	
World Health Organization: Guidelines for the Identification and Management of Substance Use and Substance Use Disorders in Pregnancy (2014) (A.6)	Primary care, other outpatient settings inferred, inpatient.	Assessment, withdrawal management, maintenance.	GRADE system.	Buprenorphine, methadone.	No.	Recommends CBT, CM and motivational interviewing/enhancement.	
World Health Organization: Consolidated Guidelines on HIV Prevention, Diagnosis, Treatment, and Care for Key Populations (2014) (A.7)	Not specified.	Withdrawal management, maintenance.	GRADE system.	Buprenorphine, methadone.	Yesdosing.	Generic recommendation that includes assessment of psychosocial needs; supportive counseling; linkages to family and community-based services.	

	TABLE 1 (continued)							
Guideline Name (publication year) (appendix table #)	Setting	Stage(s) of Treatment	Strength of Evidence Rated	Includes Specific Medications	Includes Information on Dosing and Frequency	Includes Psychosocial Treatment		
British Association for Psychopharmacology: Updated Guidelines: Evidence-Based Guidelines for the Pharmacological Management of Substance Abuse, Harmful Use, Addiction, and Co- Morbidity: Recommendations from BAP (2012) (A.11)	Not specified but inferred as several.	Withdrawal management, maintenance.	Type of studies and representativeness of population samples considered. Some recommendations based on consensus rather than systematic evidence.	Buprenorphine, methadone, naltrexone.  Diamorphine when methadone/buprenorphine have failed for maintenance.  Lofexide-withdrawal management.	Yesdosing.	Generic recommendation.		
Substance Misuse and Alcohol Use Disorders. In: Evidence-Based Geriatric Nursing Protocols for Best Practice (2008; revised 2012) (A.12)	Office-based practice, state licensed clinics.	Assessment, maintenance.	Ranked by study type, consensus opinion lowest category.	Buprenorphine, methadone, naltrexone.	Yesdosing.	General generic recommendation; for older adults, group psychotherapy using a cognitive behavioral approach suggested.		
World Federation of Societies of Biological Psychiatry: Guidelines for the Biological Treatment of Substance Use and Related Disorders. Part 2: Opioid Dependence (2011) (A.17)	Outpatient, inpatient.	Withdrawal management, maintenance.	Categories of evidence- based upon study type and consistency of results. Recommendation grade based upon evidence level as well as risk-benefit ratio.	Buprenorphine, methadone, naltrexone.  Heroin for maintenance.  Clonidine, lofexide for withdrawal management (less effective than methadone or buprenorphine, useful for hypertensive cases).	Yesdosing.	The following options are mentioned, with a stated variation in the strength of the evidence in support of the options: CM, CBT, family therapy, relapse prevention, self-help groups. MMT can be enhanced when combined with CM, whereas there is no indication that CM increases the efficacy of BMT.		
Guidelines for Improving Entry Into and Retention in Care and Antiretroviral Adherence for Persons with HIV: Evidence-Based Recommendations from an International Association of Physicians in AIDS Care Panel (2012) (A.13)	Not specified.	Maintenance.	Type of study and strength of evidence/limitations considered. Strength of recommendation also considered these factors: magnitude of benefit, magnitude of risks and burdens, costs, and patient/provider values and preferences.	Buprenorphine, methadone.	No.	No.		
Centre for Addiction and Mental Health: Buprenorphine/Naloxone for Opioid Dependence: Clinical Practice Guideline (Canada) (2011) (A.14)	Ambulatory primary care setting, specialized addiction treatment setting.	Assessment, maintenance.	Level of evidence-based upon study design. Expert opinion is a category. Strength of recommendation based upon above.	Buprenorphine, methadone.	No.	No.		
Substance Use in Pregnancy (Canada) (2011) (A.15)	Not specified, but likely outpatient.	Assessment, maintenance, withdrawal management.	Level of evidence-based upon study design. Expert opinion is a category. Strength of recommendation based upon above.	Methadone.	No.	No.		

TABLE 1 (continued)								
Guideline Name (publication year) (appendix table #)	Setting	Stage(s) of Treatment	Strength of Evidence Rated	Includes Specific Medications	Includes Information on Dosing and Frequency	Includes Psychosocial Treatment		
National Opioid Use Guideline Group: Canadian Guideline for Safe and Effective Use of Opioids for Chronic Noncancer Pain (2010) (A.18)	Not specified.	Not specified.	Based upon study type. Expert opinion is a category.	Buprenorphine, methadone.	No.	No.		
Substance Abuse Mental Health Services Administration: Clinical Use of Extended-Release Injectable Naltrexone in the Treatment of Opioid Use Disorder (revised 2015) (A.3)	Several ambulatory care.	Assessment, withdrawal management, maintenance.	No.	Buprenorphine, methadone, naltrexone.	Yesdosing.	Generic recommendation, CM, motivational interviewing suggested to improve treatment adherence.		
Substance Abuse Mental Health Services Administration: Federal Guidelines for Opioid Treatment Programs (2015) (A.4)	OTPs.	Assessment, withdrawal management, maintenance	No.	Buprenorphine, methadone, naltrexone.	Yesdosing.	Generic recommendation.		
Washington State Department of Labor and Industries: Guideline for prescribing opioids to treat pain in injured workers (2013) (A.8)	Community-based settings, inpatient, residential	Withdrawal management, maintenance	No.	Buprenorphine, methadone, naltrexone.  Clonidine for withdrawal management.	No.	Generic statement that psychological treatment like CBT can be provided.		
Colorado Division of Workers' Compensation: Chronic Pain Disorder Medical Treatment Guidelines (2011) (A.16)	Outpatient, licensed methadone and buprenorphine clinics, inpatient.	Assessment, withdrawal management.	No.	Buprenorphine, methadone.*	Yesdosing.	Generic recommendation.		
Vermont Department of Health Division of Alcohol and Drug Abuse Programs, Office of Vermont Health Access: Vermont Buprenorphine Practice Guidelines (2010) (A.20)	Office-based.	Assessment, withdrawal management, maintenance.	No.	Buprenorphine.	Yesboth.	Generic evidence-based recommendations such as CBT, motivation enhancement therapy, dialectical behavioral therapy.		
Institute of Obstetricians and Gynaecologists, Royal College of Physicians of Ireland and Directorate of Strategy and Clinical Care Health Service Executive: Methadone Prescribing and Administration in Pregnancy (2013; revised 2015) (A.2)	Inpatient.	Assessment, withdrawal management, maintenance.	No.	Methadone.	Yesboth.	No.		
Veterans Affairs Administration/ Department of Defense Clinical Practice Guideline for Assessment and Management of Patients At Risk for Suicide (2013) (A.9)	Not specified.	Maintenance.	Ratings not associated with opioid section (but used for other sections).	Methadone.	No.	No.		

	TABLE 1 (continued)								
Guideline Name (publication year) (appendix table #)	Setting	Stage(s) of Treatment	Strength of Evidence Rated	Includes Specific Medications	Includes Information on Dosing and Frequency	Includes Psychosocial Treatment			
Institute for Research, Evaluation and Training in Addictions: Management of Benzodiazepines in Medication-Assisted Treatment (2013) (A.10)	OTPs, outpatient, inpatient.	Assessment, maintenance.	RAND/UCLA Appropriateness Method used (guidelines are not individually rated; they all were deemed appropriate).	Buprenorphine, methadone.	No.	Generic statement that CM can be incorporated and in case of non-compliance, consider providing increased intensity of psychosocial treatment.			
New York State Department of Health: Preconception Care for HIV- Infected Women (2010) (A.19)	Not specified; several settings inferred.	Maintenance.	No.	Methadone.	No.	No.			
* The guideline includes those drugs w	ith FDA-approval in 20	<ol><li>Not all currently record</li></ol>	mmended and FDA-approved dru	igs were approved for use at the time the	guideline was develop	ed.			

### C. SUMMARY OF MEDICATION-ASSISTED TREATMENT

We identified 21 guidelines on MAT for opioid use (Table 1; Appendix A includes the verbatim guidelines) and seven guidelines on MAT for alcohol use (Table 2; Appendix D includes the verbatim guidelines) published between 2010 and 2015. Nearly all of the guidelines were developed through a consensus process and were guided by a literature review. The guidelines vary in their specificity -- some simply identify the appropriate medications to treat opioid/alcohol use (A.9, A.13, A.15, A.18) while others outline important components of treatment, including processes associated with screening and assessment, the identification of appropriate candidates for specific drugs, and considerations for special populations.

TABL	E 2. Summary of	MAT Guidelin	es for Alcoh	ol Use	
Guideline Name (publication year) (appendix table #)	Setting	Stage(s) of Treatment	Strength of Evidence Rated	Includes Specific Medications	Includes Psychosocial Treatment
British Association for Psychopharmacology: Updated Guidelines: Evidence-based Guidelines for the Pharmacological Management of Substance Abuse, Harmful Use, Addiction, and Co-Morbidity: Recommendations from BAP (2012) (B.4)	Several, including ambulatory.	Several.	X	Х*	Х
Substance Misuse and Alcohol Use Disorders. In: Evidence- Based Geriatric Nursing Protocols for Best Practice (2008; revised 2012) (B.5)	Not specified; several settings inferred.	Several.	X	X	X
National Institute for Health and Care Excellence: Nalmefene for Reducing Alcohol Consumption in People with Alcohol Dependence. NICE Technology Appraisal Guidance [TA325] (2014) (B.2)	Not specified; several settings inferred.	Maintenance.	X		Х
World Health Organization: Guidelines for the Identification and Management of Substance Use and Substance Use Disorders in Pregnancy (2014) (B.3)	Inpatient.	Not specified; several stages inferred.	X	X	X
SAMHSA and National Institute on Alcohol Abuse and Alcoholism: Medication for the Treatment of Alcohol Use Disorder: A Brief Guide (2015) (B.1)	Not specified.	Several.		X	Х
NICE: Alcohol-Use Disorders. Diagnosis, Assessment, and Management of Harmful Drinking and Alcohol Dependence (United Kingdom) (2011) (B.6)	Several.	Several.		Х*	Х
Medical Services Commission, British Columbia: Problem Drinking (2011) (B.7) * The guideline also includes drugs n	Ambulatory.	Several.		Х	Х

In some cases, the guidelines provide little information to allow the reader to assess the strength and quality of the evidence used in support of the guideline recommendations. Slightly more than half (61 percent) of the opioid guidelines rated the strength of or include any comment about the level of evidence used to support the guidelines, and guideline developers used different standards in rating the evidence. As indicated by the guideline developers, given the limitations of the current scientific evidence and the need to account for other factors such as feasibility, risk/benefit ratios, patient and provider values and preferences, and costs, nearly all of the guidelines are based upon a blend of expert opinion and scientific rigor.

## D. VARIATION IN KEY FEATURES OF MEDICATION-ASSISTED TREATMENT CLINICAL GUIDELINES

**Stages of Treatment**. Both opioid and alcohol use MAT guidelines tend to focus on stages of treatment -- assessment, withdrawal management (also referred to as detoxification), and maintenance -- whereby the recommended dosage of medication and frequency and intensity of MAT vary with the stage of treatment and the client's needs. All of the guidelines recommend specific medications appropriate for use in a given treatment stage, and some of the guidelines list contraindications with other medications (A.3, A.5, A.10, A.21).

Treatment Setting. In the United States the treatment setting is directly linked to the appropriate use of MAT. Methadone may be prescribed only in opioid treatment programs (OTPs); buprenorphine may be prescribed in OTPs and in office-based opioid treatment (OBOT) settings by certified physicians; and naltrexone may be prescribed by any provider licensed to prescribe medication (42 CFR Part 8; Drug Addiction Treatment Act of 2000). Despite the importance of treatment setting, the clinical guidelines inconsistently provide information on the recommended treatment setting. Several guidelines do not specify the treatment setting or broadly assume the setting to be an outpatient facility.

**FDA-Approved Medications**. Nearly all of the guidelines focus on FDA-approved medications for MAT, but a few also mention other medications, mostly to be used in combination with FDA-approved medications or as a "second tier" treatment if the patient does not respond to the FDA-approved medications. A few guidelines, notably ASAM's 2015 guidelines, recommend the off-label use of clonidine for opioid withdrawal management (A.5, A.8, A.17, A.21); clonidine has been used extensively in the United States for this purpose (A.5). Other medications recommended throughout the collective guidelines included lofexide for opioid withdrawal (approved in the United Kingdom) (A.11, A.17), diamorphine (heroin) for opioid dependence (A.11, A.17), and baclofen and nalmefene (United Kingdom) for alcohol dependence.

**Psychosocial Treatment**. Most of the guidelines contain broad recommendations for psychosocial treatment in conjunction with the use of medications, but they vary in the strength of the recommendations. Among the guidelines that mention specific treatments, contingency management (CM) (A.3, A.6, A.10, A.17, A.21), motivational interviewing (A.3, A.6, A.20), and cognitive behavioral approaches (A.6, A.8, A.12, A.17, A.20, A.21) are most commonly mentioned. These treatments are typically presented as a "menu option" rather than a strong recommendation for or endorsement of the treatment. The lack of strong recommendations for specific evidence-based practices (EBTs) may reflect the state of the evidence in support of psychosocial treatment for MAT. For example, panelists involved in the development of the buprenorphine guideline (A.1) received summaries of the relevant evidence and were then asked to rate guidelines specific to cognitive behavioral therapy (CBT) and CM. Given disagreement over the best type of counseling to accompany buprenorphine treatment, the final guideline included a broad recommendation for EBT. A few guidelines also include statements about the frequency of psychosocial treatment, specifying that it should be more frequent earlier in treatment and may be reduced during the maintenance phase (A.1, A.4). Finally, some guidelines emphasize the importance of linking patients to community-based services (A.4, A.5) and family supports (A.3, A.4, A.5) and supplementing psychotherapy with self-help/mutual-help groups (A.3. A.4, A.12, A.21).

**Diversion, Drug Testing and Compliance**. Several guidelines provided recommendations for addressing diversion (transfer of MAT medications from a licit to an illicit channel of distribution or use) and compliance with treatment as intended. For example, multiple guidelines recommend consulting the Prescription Drug Monitoring Program (PDMP) before induction (initiation of MAT medication) and periodically afterwards to confirm compliance with prescribed drugs and identify unreported use of other drugs (A.3, A.5, A.10, A.20); conducting toxicology tests and urine screens to test for opioids (absence may indicate diversion), benzodiazepines and other substances (A.1, A.3, A.5, A.10, A.20); and conducting recall visits for pill counts (A.3, A.5, A.20).

**Special Populations**. Several guidelines provide information on the use of MAT for opioid and alcohol use in special populations. The guideline information may identify and present targeted opportunities to develop measures that encourage the appropriate use of MAT for these populations. We briefly summarize the relevant recommendations:

**Pregnant Women**. The guidelines consistently recommend that pregnant women should receive opioid MAT during the maintenance phase of treatment rather than during withdrawal management or abstinence (A.2, A.5, A.6, A.7, A.17, A.19, A.21). Most of the guidelines provide information regarding the preferred MAT medications (A.2, A.6, A.14, A.15, A.17, A.19, A.21) and dosage (A.5); however, animal studies have shown an adverse effect on fetuses, and adequate, well-controlled studies in humans have yet to be conducted (A.3). Despite the lack of adequate research to support the use of MAT medication in pregnant women, some of the guidelines suggest that the potential benefits of MAT medications for some pregnant women may outweigh potential risks (A.3, A.4, A.6, A.21). Some guidelines that include pregnant women also

recommend specific treatment settings (A.2, A.6), depending on the phase of MAT treatment and the stage of the woman's pregnancy (A.2, A.5), and emphasize the importance of care coordination (A.2, A.4, A.5, A.21).

Patients with Co-occurring Mental Disorders. Individuals with SUDs often have co-occurring mental health conditions. The guidelines emphasize the importance of screening for mental health conditions as part of the assessment phase of MAT as well as ongoing monitoring of the condition throughout treatment (A.1, A.4, A.5, A.10, A.21). The guidelines recommend either providing a referral for the treatment of the co-occurring condition or treating it on site. In addition, the guidelines provide information on the risk of drug interactions between MAT medications and benzodiazepines, (a medication commonly used to treat anxiety) (A.1, A.3, A.4, A.10, A.21). The guidelines also point to care coordination as an important component of care (A.1, A.4, A.10, A.21).

**Adolescents**. Most of the guidelines provide little information on the use of MAT for adolescents. Buprenorphine, one of the three medications approved by the FDA for use in the treatment of opioid disorders, is the only medication approved by the FDA for use with adolescents. Under certain circumstances and in some states, adolescents age 16 years and older may also receive methadone treatment (Mann, Frieden, Hyde, Volkow, and Koob 2014). The FDA has not approved the use of any of the medications for MAT for alcohol use in adolescents under age 18. The guidelines generally emphasize that treatment should be developmentally appropriate and involve the family.

*HIV Population*. Some of the guidelines emphasize the integration of care for individuals with HIV and opioid use disorder, suggesting that antiretroviral therapy (ART) and opioid maintenance therapy should be offered in the same care setting when possible (A.7, A.13). Guidelines indicate that buprenorphine and methadone are appropriate for patients with HIV (A.7, A.13, A.21), but drug interactions should be monitored (A.21).

**Prison Population**. The recommendations for MAT for incarcerated individuals are similar to those for the general population; that is, all three MAT medications should be considered and accompanied by psychosocial treatment (A.5). The guidelines recommend the initiation of opioid maintenance therapy before prison release to help reduce subsequent overdose-related mortality (A.5, A.7). The guidelines also stress the importance of continuity of care when an individual returns to the community (A.7, A.21).

	TABLE 3.	MAT for Opioid Use M	easures		
Measure	Denominator	Numerator	Setting	Data Source	Developer/Steward
EFFECTIVE CLINICAL CARE					
Initiation of pharmacotherapy upon new episode of opioid dependence	Number of individuals with index visit associated with an opioid dependence diagnosis after 60-day clean period with no SUD claims.	Number of individuals who initiate pharmacotherapy with at least 1 prescription for an opioid treatment medication within 30 days following index visit with a diagnosis of opioid dependence.	Several, including ambulatory care.	Administrative/electronic clinical data.	Washington Circle Group
Use of opioid dependence pharmacotherapy during a measurement year	Number of individuals with any encounter associated with opioid dependence (primary or other) at any time during the measurement year.	Number of individuals with at least 1 prescription for appropriate pharmacotherapy at any time during the measurement year.	Several, including ambulatory care.	Administrative/electronic clinical data.	Washington Circle Group
Maintenance pharmacotherapy for substance abuse	Patients who receive a service-related diagnosis of opioid or alcohol dependence during a specified period.	Those patients in the denominator who receive at least 30 days' treatment with 1 or more appropriate medications (methadone, buprenorphine, or naltrexone for opiate dependence; naltrexone or disulfiram for alcohol dependence) during a specified interval.	Not specified; inferred to include ambulatory settings.	Administrative/paper-based medical records/pharmacy.	APA
OAT as first line of defense for at least 90 days of treatment at beginning of a new treatment episode	Patients with opiate dependence who are initiating OAT within 30 days on or after the start of a new treatment episode.	Patients from denominator receiving 90 doses of OAT in the 90 days following the first dose.	Not specified; inferred to include ambulatory settings.	Administrative/paper-based medical records.	VHA
Duration of OAT for selected SUD patients	Veterans in the SUD cohort with opiate dependence in a new treatment episode undergoing opiate agonist treatment.	Length (in days) of opiate agonist treatment for patients in the denominator in the 12 months following the start of treatment.	Not specified; inferred to include ambulatory settings.	Administrative/paper-based medical records.	VHA

	TABLE 3 (continued)								
Measure	Denominator	Numerator	Setting	Data Source	Developer/Steward				
Maintenance pharmacotherapy for opiate dependence at empirically based dosages: (1) offered; (2) filled; (3) refused medication; or (4) contraindicated	Patients with SUD diagnosis with opiate dependence with a new treatment episode.	Patients from the denominator who were:  (1) Offered methadone or a prescription for buprenorphine at the empirically based dose but did not fill prescription within 30 days on or after the start of the new treatment episode.  OR (2) Offered methadone or a prescription for buprenorphine at the empirically based dose and filled prescription within 30 days on or after the start of the new treatment episode.  OR (3) Offered methadone or a prescription for buprenorphine at the empirically based dose but refused medication within 30 days on or after the start of the new treatment episode.  OR (4) Found to have documentation that prescription is contraindicated within 30 days on or after start of new treatment episode.  OR (5) Found to have no documentation of offer or refusal and no record of prescription being filled.	Not specified; inferred to include ambulatory settings.	Administrative/paper-based medical records.	VHA				
NQF #1664 SUB-3 Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge SUB-3a Alcohol and Other Drug Use Disorder Treatment at Discharge	The number of hospitalized inpatients age 18 years and older identified with an alcohol or drug use disorder.	SUB-3: The number of patients who received or refused at discharge a prescription for medication for treatment of alcohol or drug use disorder OR received or refused a referral for addictions treatment.  SUB-3a: The number of patients who received a prescription at discharge for medication for treatment of alcohol or drug use disorder OR a referral for addictions treatment.	Inpatient.	Electronic clinical data/paper-based medical records.	TJC				

TABLE 3 (continued)								
Measure	Denominator	Numerator	Setting	Data Source	Developer/Steward			
COMMUNICATION AND CARE COORDINATION								
Counseling on psychosocial and pharmacologic treatment options for opioid addiction	All patients age 18 years and older with a diagnosis of current opioid addiction.	Patients who were counseled on psychosocial AND pharmacologic treatment options for opioid addiction within the 12-month reporting period.	Not specified; inferred to include ambulatory settings.	Administrative/paper-based medical records/electronic clinical data.	APA; Physician Consortium for Performance Improvement; NCQA			
PERSON AND CAREGIVER EXPERIENCE OUTCOMES								
HIV ambulatory care satisfaction: Percentage of HIV- positive adult patients in a methadone maintenance program who reported how often the dispensing line was too slow	HIV-positive adult patients age 18 years and older engaged in a methadone maintenance program who completed the survey.	The number of patients who indicated "All of the time," "Most times," "Sometimes," "Rarely," "Never," "Does not apply" to the item, "The dispensing line was too slow."	Several.	Patient survey.	New York State Department of Health AIDS Institute			
HIV ambulatory care satisfaction: Percentage of HIV-positive adult patients who reported whether their substance use counselors explained to them in a way they could understand how their substance use treatment (for example, methadone) and their HIV medications might interact	HIV-positive adult patients age 18 years and older engaged in a substance use treatment program who completed the survey.	The number of patients who indicated "Strongly Disagree," "Disagree," "Strongly Agree," "Does Not Apply" to the item, "My substance use counselors explained to me in a way I could understand how my substance use treatment (for example, methadone) and my HIV medications might interact."	Several.	Patient survey.	New York State Department of Health AIDS Institute			

## E. SUMMARY OF MEDICATION-ASSISTED TREATMENT QUALITY MEASURES

MAT Opioid Use Measures. We identified ten measures (Table 3) that incorporate MAT -- eight process measures (that rely on administrative data and/or medical record review) and two patient satisfaction measures (that rely on patient surveys and are limited to HIV-positive patients). Only one identified measure -- focused on adults discharged from inpatient settings -- has received the NQF's endorsement. Only one measure explicitly addresses both components of MAT -- pharmacotherapy and psychosocial treatment. However, this measures assesses counseling about these treatment options, rather than utilization of MAT. The remaining process measures assess various aspects of pharmacotherapy use, including dosage and frequency of use.

**MAT Alcohol Use Measures**. We identified ten measures specifically related to alcohol that might be useful in the future development of MAT measures for opioid use, three of which assess the provision of MAT at various stages of treatment (e.g., post-discharge, post-withdrawal) (Appendix C provides details of the measures). One measure assessed receipt of evidence-based psychological interventions while the other measures addressed precursors to MAT: screening and brief interventions/counseling. NQF has endorsed four of the ten measures.

Other Related Measures. In addition to the above measures, we identified 58 measures (Appendix D) that reflect concepts that could be applied to MAT or are known to be important supports for MAT. They include, for example, measures related to assessment; screening; and access to, timeliness of, and retention in treatment; use of psychosocial treatment; and care coordination. The measures are largely process measures, and three have received NQF's endorsement.

#### **F. SUMMARY**

The guidelines provide recommendations on the use of MAT across treatment phases with an emphasis on the maintenance phase. Most of the guidelines were developed based upon expert opinion and scientific literature. Some guidelines focus on special populations and over half mention psychosocial treatment. The strength of the recommendation varies from general recommendations to provide psychosocial treatment to suggestions of specific types of psychosocial treatment. The variation in the evidence supporting the guidelines, along with differences in the specificity of the guidelines' recommendations, may present challenges to the development and positioning of measures. Existing measures related to MAT largely focus on receipt of FDA-approved medications over a specified period. None of the identified MAT for opioid use measures assesses the use of pharmacotherapy and psychosocial

treatment. The lack of consensus regarding specific evidence-based psychosocial treatments effective in the treatment of opioid use disorders may contribute to the dearth of quality measures; however, it could also indicate a gap and an opportunity for improving the appropriate use of MAT.

In the next phase of this project, we will use the information gathered to date to identify potential measure concepts and the steps needed to develop the concepts into measures that meet NQF endorsement standards. The selection of the most appropriate guideline(s) to inform development of the measures may depend on the projected treatment setting, phase of treatment, and target population.

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- Office of the Assistant Secretary for Planning and Evaluation (ASPE). ASPE Issue Brief. 2015. "Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths." Available at <a href="https://aspe.hhs.gov/basic-report/opioid-abuse-us-and-hhs-actions-address-opioid-drug-related-overdoses-and-deaths">https://aspe.hhs.gov/basic-report/opioid-abuse-us-and-hhs-actions-address-opioid-drug-related-overdoses-and-deaths</a>.

## APPENDIX A. MEDICATION-ASSISTED TREATMENT FOR OPIOID USE CLINICAL GUIDELINES: EXCERPTS FROM RELEVANT SECTIONS

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TA	BLE A.1. Pract	tice Guidance	for Buprenorp	hine for the Tr	eatment of Opioid	<b>Use Disorders: Results of an Expert Panel</b>	Process	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement		
2015	Ambulatory care (deliberately broad	Literature Review	"Panelists were instructed that a	Yes.	YesGeneric recommendation for	Domain	Median Rating (range)	
	to apply to a variety of provider settings)	pply to a guideline statement should	statement should be considered valid		evidence-based psychosocial treatment; specific therapies specified for patients with	Conduct assessments to determine candidacy for treatment:     1.1. Determine opioid use disorder by DSM-V standards.      1.2. Assess psychiatric history with attention to current	9.0 (8-9) 8.0 (3-9)	
			(a) Adequate		co-occurring psychiatric disorders	compliance with medication.		
			scientific evidence or professional consensus exists			1.3. Assess medical history with attention paid to liver and cardiac status, medications, and seizures.	8.0 (7-9)	
			to support a link between that			1.4. Assess pregnancy status.	9.0 (3-9)	
		practice and a health benefit to the patient with opiate dependence;  (b) A provider with high rates of adherence to that practice would be considered a higher quality provider;  (c) A majority of factors that determine	health benefit to the patient with			1.5. Assess psychosocial supportsemployment, family, housing, 12-step involvement.	8.0 (5-9)	
						1.6. Assess substance use history and current substance use.	9.0 (8-9)	
			high rates of		1.7. Assess treatment historyprevious treatment episodes with buprenorphine, methadone.	8.5 (5-9)		
			practice would be considered a higher quality	practice would be considered a higher quality	practice would be considered a higher quality		1.8. Assess for current opioid agonist treatment by conducting a witnessed urine screen (methadone, buprenorphine, benzodiazepines).	9.0 (5-9)
					1.9. Assess withdrawal status.	9.0 (6-9)		
			factors that			1.10. Assess addiction severity.	8.0 (7-9)	
	ac pr th pr	adherence to the practice are under the influence of the	adherence to the practice are under he influence of the	der		1.11. Assess potential treatment needs in relation to the physician's ability to accommodate them (intensive monitoring, interactions with legal system, employers, others).	8.0 (4-9)	
		9="definitely valid"  Authors noted that the level of evidence to support many of the guidelines was  9="definitely valid"  2. Patients who means to candidates for tree 2.1. Have current or 2.1. Have current or 2.2. If currently on treatment from a means to the guidelines was	1.12. Assess pain.	8.0 (6-9)				
			,			2. Patients who meet the following criteria are considered to be	good	
			the level of			2.1. Have current opioid dependence.	9.0 (3-9)	
					2.2. If currently on methadone, are unable/unwilling to receive treatment from a methadone clinic.	8.0 (7-9)		
			weak.			2.3. Have adequate psychosocial support.	8.0 (1-9)	

				TABLE	A.1 (continued)		
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement	
						Domain	Median Rating (range)
						2.4. Do not have co-occurring mental disorder or COD is stable.	8.0 (1-9)
						2.5. Are not suicidal.	8.5 (4-9)
						2.6. May be pregnant.	8.0 (8-9)
						2.7. Are expected to be reasonably compliant with treatment.	8.0 (5-9)
						Prior to initiation of treatment, patients should complete and contract containing, at a minimum, the following components:     3.1. Discussion of voluntary participation in treatment.	9.0 (7-9)
						3.2. Agreement to notify prescribing physician if they are or plan to become pregnant.	9.0 (8-9)
						3.3. Discussion of the use of other medications.	9.0 (7-9)
						3.4. Discussion of the use of alcohol and illicit drugs.	8.5 (4-9)
						3.5. Agreement to use medications only as prescribed.	9.0 (7-9)
						3.6. Agreement to attend scheduled appointments.	8.0 (6-9)
						3.7. Compliance with required pill counts and drug tests.	9.0 (7-9)
						3.8. Attendance at counseling and other referrals.	9.0 (7-9)
						3.9. Consequences for attending appointments under the influence.	8.0 (3-9)
						3.10. Policies for recovery and relapse.	7.5 (3-9)
						3.11. Consequences for diversion.	9.0 (8-9)
						3.12. Instructions on safe storage of medication.	9.0 (8-9)
						4. Administer appropriate dosing of buprenorphine during ind stabilization, and maintenance phases:	uction,
						4.1. Induction: Ensure that patient is experiencing objective signs of withdrawal.	8.5 (7-9)
						4.2. Induction: Day 2 maximum dose 8-16mg.	8.0 (1-9)

				TABLE	A.1 (continued)		
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement	
						Domain	Median Rating (range)
						4.3. Induction after methadone: Induction for patients coming off methadone should be managed by experienced physicians only.	8.0 (7-9)
						4.4. Induction after methadone: Monitor for withdrawal symptoms. If not observed within 24+ hours after last methadone treatment, wait prior to initiation.	8-0 (4-9)
						4.5. Stabilization: Adjust dose (as needed) in no more than 2-4mg increments/week.	8.0 (2-9)
						4.6. Stabilization: Daily dose has been established when patient is not using illicit opioids, withdrawal symptoms are not present, and the patient is not experiencing cravings.	8.0 (7-9)
						4.7. Maintenance: After a period of time that varies with each patient but should reflect compliance with treatment, a prescription for 30 days may be written.	8.0 (7-9)
						5. Provide or refer to concurrent psychosocial treatment:     5.1. Patients receiving buprenorphine should receive simultaneous psychosocial counseling.	9.0 (3-9)
						5.2. Physicians should establish linkages with a variety of psychosocial supports and be able to refer to qualified providers.	9.0 (7-9)
						5.3. Patients starting buprenorphine should receive an evidence-based psychosocial treatment.	8.0 (7-9)
						5.4. Patients should receive weekly psychosocial therapy appointments during the stabilization phase.	8.0 (1-9)
						5.5. Early in treatment, patients should be contacted if the physician is aware they are non-compliant with psychosocial therapy.	8.0 (7-9)
						5.6. During the maintenance phase, psychosocial therapy can be less frequent than during stabilization.	8.0 (5-9)
						6. Monitor treatment adherence and effectiveness: 6.1. During induction and stabilization phases, conduct weekly urine screens to detect alcohol and other drugs of abuse and the presence of the buprenorphine metabolite.	8.0 (1-9)

				TABLE	A.1 (continued)		
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement	
						Domain	Median Rating (range)
						6.2. During the maintenance phase, conduct biweekly or monthly urine screens to detect alcohol and other drugs of abuse and the presence of the buprenorphine metabolite.	8.0 (1-9)
						7. Discontinue treatment only when the following conditions a	re met:
						7.1. Before discontinuing buprenorphine, patients must express a desire to discontinue.	9.0 (7-9)
						7.2. Before discontinuing buprenorphine, patients must have stable housing and income.	7.5 (1-9)
						7.3. Before discontinuing buprenorphine, patients must have adequate psychosocial support.	8.0 (4-9)
						7.4. Conditions for termination and contingencies for treatment should be outlined in the treatment agreement.	9.0 (8-9)
						8. Provide adequate assessment and treatment for patients will depression and/or anxiety:	th co-occurring
						8.1. Screen for depression and anxiety.	8.5 (7-9)
						8.2. Assess previous history of mental disorders and treatment, focusing on temporal relationship of symptoms to substance use and response to previous treatment.	8.5 (7-9)
						8.3. Assess source of information, quantity, frequency, and time of last use of illicit substances or prescribed psychotropic drugs.	9.0 (7-9)
						8.4. Assess family history of mental disorders.	8.0 (6-9)
						8.5. Assess severity of depression/anxiety.	9.0 (7-9)
						8.6. Reassess symptoms of depression and anxiety with regularity.	9.0 (7-9)
						8.7. Refer to specialized behavioral health care if patient fails to respond to treatment provided by prescribing physician.	9.0 (8-9)
						8.8. Refer to concurrent evidence-based psychosocial treatment, such as CBT, motivational interviewing, relapse prevention, CM, or supportive therapy.	8.5 (3-9)

	TABLE A.1 (continued)								
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement			
						Domain	Median Rating (range)		
						8.9. Refer to 12-step facilitation, such as Dual Recovery Anonymous.	8.5 (2-9)		
						8.10. Once stabilized, if a patient continues to present symptoms of depression and anxiety, consider prescribing medications with low potential for abuse, such as SSRIs or tricyclic antidepressants.	8.0 (5-9)		
						8.11. Consider alternatives to benzodiazepines.	9.0 (8-9)		
						8.11a. Patients should be strongly advised against self-medicating with benzodiazepines.	9.0 (8-9)		
						8.11b. If a patient has a prescription for benzodiazepines at the outset of treatment, use caution taking him or her off of the benzodiazepines and do not discontinue abruptly.	9.0 (7-9)		
						8.12. Integrate treatment for opiate dependence and depression/anxiety to the greatest degree possible, as on-site integrated care is associated with better outcomes than referrals off-site.	9.0 (1-9)		

The full guideline can be found at <a href="http://www.ncbi.nlm.nih.gov/pubmed/25844527">http://www.ncbi.nlm.nih.gov/pubmed/25844527</a>. See <a href="http://www.ccbh.com/providers/phealthchoices/articles/current/buprenorphine.php">http://www.ncbi.nlm.nih.gov/pubmed/25844527</a>. See <a href="http://www.ccbh.com/providers/phealthchoices/articles/current/buprenorphine.php">http://www.ccbh.com/providers/phealthchoices/articles/current/buprenorphine.php</a> for earlier report. Many of these guidelines were a second at the second a

٦	TABLE A.2. Institute of Obstetricians and Gynecologists, Royal College of Physicians of Ireland and Directorate of Strategy and Clinical Care Health Service Executive: Methadone Prescribing and Administration in Pregnancy								
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement			
2013 (revised 2015)	Inpatient	Literature Review	Not rated.	Yes.	No.	TREATMENT FOR OPIOID DEPENDENCE  Key Recommendations:  1. MMT is the treatment of choice for opioid-dependent pregnant women. In adequate doses, methadone provides stability for the woman during pregnancy, avoiding repeated cycles of intoxication and withdrawal that may adversely affect the fetus.  2. Withdrawal from opioids can cause fetal death and preterm delivery. It is important that women who report illicit opiate use are assessed and treated in a timely manner.  3. Clear communication between maternity hospitals and local addiction services is required, particularly in relation to methadone doses and admission/discharge of methadone-maintained women.  4. Initiation of methadone may be required in a maternity hospital to avoid obstetric complications of opioid withdrawal. Careful initiation is required, as the highest risk of overdose mortality is in the first 2 weeks on methadone treatment.  5. A validated scoring tool should be used to assess signs of opioid withdrawal in opioid-dependent pregnant women.  6. Opioid-dependent pregnant women are at risk of under-treatment of peripartum pain.  7. Breastfeeding should be encouraged in women who are stable on MMT unless there are other medical contraindications.  8. The maternal methadone dose should be individually adjusted to control maternal craving or withdrawal symptoms.  Only summary guidelines are presented here. Please see original document for guidance organized based upon clinical scenarios.			
	1. The full guideline can be found at <a href="http://www.emcdda.europa.eu/attachements.cfm/att">http://www.emcdda.europa.eu/attachements.cfm/att</a> 231326 EN IE10 Opiate%20treatment%20in%20Pregnancy.pdf. Many of these guidelines were based upon a consensus process informed by the literature reviews.								

	TABLE	A.3. SAMHSA:	Clinical Use o	of Extended-Re	elease Injectable N	lattrexone in the Treatment of Opioid Use
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
	Several- ambulatory care	Consensus	Not rated.	Yes.	YesRecommendation for CM, relapse prevention counseling, and motivational interviewing as strategies to improve adherence and reduce risk of relapse. Participation in mutual-help groups also suggested.	Clinical Recommendations. Although no definitive research supports which patients benefit most from extended-release injectable naltrexone, patients in the following categories may be good candidates for such treatment.[1]  Patients who have not had treatment success with methadone or buprenorphine: Depending on the reasons for treatment failure, individuals with an opioid use disorder who have not been successfully treated with methadone or buprenorphine may benefit from medically supervised withdrawal followed by a trial of extended-release injectable naltrexone.[51]  Patients who have a high degree of motivation for abstinence: Individuals who are highly motivated to achieve and maintain abstinence from opioids may be good candidates for treatment with extended-release injectable naltrexone.[50] This category includes people who are required to demonstrate abstinence on urine drug screens, such as individuals in programs for impaired health care professionals, parolees, probationers, and airline pilots.[52]  Patients who have been successful on opioid agonists who wish to discontinue agonist therapy or patients who are not interested in agonist therapy to treat their opioid use disorder. Some patients may be successful on agonist treatment and want continued pharmacologic help to prevent relapse but prefer another type of treatment.[51] Other patients may not be interested in agonist therapy.[11] The latter group typically includes individuals who: (1) feel they are discriminated against (or are embarrassed or ashamed) because they are on agonist therapy.[53] or (2) would like to reduce the time devoted to daily or multiple OTP visits per week, as is frequently required for methadone treatment.[1]  Patients who be suitable candidates for treatment with extended-release injectable naltrexone even if past episodes of MAT were not successful.[54] However, experts agree that the following patients are unlikely to do well on extended-release injectable naltrexone:[1]  Patients who do not tolerate extended opioid-

	TABLE A.3. (continued)										
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement					
		or information.	Definition	Medications	Treatment	Patients whose chronic pain requires treatment with opioid analgesics. Treatment with extended-release naltrexone is not a viable option if pain requires chronic opioid therapy.  Patients who have advanced liver disease, impending liver failure, or acute hepatitis. Use of extended-release injectable naltrexone probably is safe in patients with chronic hepatitis B or C provided that the patient is not at the end stage and starting to go into liver failure. Patients with routine elevated liver enzymes usually tolerate naltrexone.  Integrating Pharmacologic and Non-pharmacologic Therapies  Some patients respond to psychosocial interventions or medication therapy alone, but most patients need both. The different approaches (MAT, professional counseling, and mutual-help groups) are complementary. They support the same goals while addressing different aspects of opioid use disorder: neurobiological, psychological, and social.  Offering the full range of effective treatments maximizes patient choice and outcomes, because no single approach is universally successful. Many studies show that the combination of pharmacologic and non-pharmacologic interventions may be more effective than either approach used alone.[55]  Sources of information on psychosocial therapies suitable for patients being treated in medical office settings are shown in Appendix B.  Encouraging Participation in Mutual-Help Programs. The support of a mutual-help group can be critical to long-term recovery. The oldest, best-known, and most accessible mutual-help program for people with an opioid use disorder is offered by NA. Patients may resist attending NA meetings and may fear that disclosure of medication use will make them unwelcome.[26] Although some NA members may have negative attitudes toward medication, the organization itself supports appropriate medication use. Providers should encourage patients to try meetings of different groups until they find 1 that is a good fit. Lists of local meetings to give to patients can be obtained from the NA					
						presence in many communities. Contact information for several groups that may be helpful to patients and their families is provided in Appendix B.  Adolescents. The lack of treatment resources geared specifically to young people					

	TABLE A.3. (continued)										
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement					
						Ample evidence demonstrates the failure of detoxification-only treatments and the high rates of dropout from psychosocial-only treatments on the part of adolescents and young adults. Yet, despite an increasing body of evidence that medications such as buprenorphine, methadone, and naltrexone are effective and easily combined with psychosocial treatments, only buprenorphine is approved by the FDA for the treatment of patients younger than 18, and the safety and effectiveness of buprenorphine hydrochloride sublingual tablets in patients younger than 16 have not been established. Therefore, the best course of action is to refer young patients to an addiction specialist or program with experience in treating adolescents.[5]  Induction Onto Extended-Release Injectable Naltrexone Treatment  The clinician should consider how best to induct a patient into treatment with extended-release injectable naltrexone. Product labeling and standard practice call for 7-10 days of abstinence from short-acting opioids before starting naltrexone.[91] A urine drug screen should be conducted to verify abstinence before beginning induction.[51]  Dosing and Administration. For patients who are appropriate candidates, the recommended dose of extended-release injectable naltrexone is 380mg, delivered intramuscularly approximately every 30 days, alternating buttocks for each subsequent injection. The following cautions should be observed:[1,83,92]  See original guidelines for detailed information on treatment phases, special populations and much more.  Responding to Changes in Treatment Progress. Individuals receiving MAT often demonstrate dramatic improvement in addiction-related behaviors and psychosocial functioning. Such positive changes should be acknowledged and reinforced by the prescribing physician whenever possible.  However, lack of adherence to pharmacologic regimens occurs in a substantial proportion of patients, with some studies reporting that as many as 7 out of 10 patients fail to follow the treatment plan [5] if a patient					

	TABLE A.3. (continued)									
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement				
						Behaviors that violate the treatment agreement or that indicate limited progress in treatment may not constitute grounds for automatic termination of MAT. Such behaviors should trigger a reassessment of the patient's needs and goals and a corresponding revision of the treatment plan. Aberrant or dysfunctional behaviors may indicate the need for more vigorous engagement in peer support, counseling, or psychotherapies or possibly referral to a more structured treatment setting.  Alternative pharmacologic therapies such as methadone or BMT also should be considered for these patients. Such changes should be documented in the patient's medical record.				
1. The f	ull guideline can be fou	nd at <u>http://store.samhs</u>	<u>a.gov/shin/content/SMA</u>	<u> 14-4892/SMA14-4892.</u>	<u>pdf</u> . Text footnotes are from of	original guideline.				

	TABLE A.4. SAMHSA: Federal Guidelines for Opioid Treatment Programs										
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement					
2015	OTP	Consensus	Not graded.	Yes.	YesGeneric recommendation.	Diversion Control (Summary):  Diversion control section recommends regularly monitoring program environment; observing a patient take their dose, including taking a drink and speaking after; random call backs to inventory a patient's take-home doses; opening OTPs on Sundays for a short period to administer medications to patients not ready for an unsupervised dose; contacting other OTPs in geographical area to confirm patient is not enrolled in multiple OTPs; and checking for patient misuse of prescriptions by consulting the PDMP.  Drug Selection Excerpt:  If a patient has a mild or moderate opioid use disorder without meeting criteria for tolerance/withdrawal, opioid agonist medications that will themselves produce physical dependence must be carefully considered due to the difficulty experienced by many of the discontinuation of opioids on which an individual has become physically dependent. Other options such as psychotherapy or antagonist pharmacotherapy such as oral/injectable naltrexone treatment should be considered.  Informed Consent Excerpt:  Inform each patient about all treatment procedures, services, and other policies and regulations throughout the course of treatment. It should also ensure that each patient voluntarily chooses maintenance treatment and that all relevant facts concerning the use of the opioid drug are clearly and adequately explained to the patient.  • Ensure that before medicating the patient the physician receives voluntary, written, program-specific informed consent to treatment with the specific pharmacotherapy ordered by the physician. Within 30 days post-admission, an appropriate program staff member should review informed consent with the patient.  • Inform each patient at admission and upon a 30-day review that the goal of MAT is stabilization of functioning.  • Inform each patient at admission of state-specific requirements and program policies regarding the report of suspected child abuse and neglect, as well as other forms of abuse (e.g., violence against women).  • Incl					

	TABLE A.4 (continued)									
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement				
						Detoxification Excerpt:  Detoxification can be considered the medically supported transition to a medication-free state or to antagonist therapy. Many OTPs do not provide a specific pathway for patients to go directly to a medication-free state because of the notoriously poor outcomes and high incidence of relapse to drug use. Please refer to TIP 43 (http://www.ncbi.nlm.nih.gov/books/NBK64164/pdf/TOC.pdf). With the decreased availability and insurance reimbursement for inpatient detoxification services and the advent of long-acting antagonist therapy, each program should evaluate the need to develop policies and procedures to provide this service so that treatment can be matched to the individual needs and preferences of the patient. Very careful review of the risks and benefits of detoxification must be provided and thorough informed consent obtained from patients choosing this treatment option. Because of the risk of fatal overdose if relapse occurs, detoxification services should be accompanied by relapse prevention counseling, overdose prevention education as well as a naloxone kit (naloxone dose and syringes) or an FDA-approved naloxone auto injector. The treatment and aftercare plans should always include a strategy to transition to MAT if needed.  Psychosocial Excerpts:  Both psychosocial and medical treatment should be of sufficient intensity and duration so as to be effective for each treatment stage. In general, a greater intensity of services is desirable at the beginning of treatment, or when staff members identify a patient's relapse or relapse "trigger" conditions exist. Many patients often need psychosocial services for an extended period of time because of the multiplicity of their problems.  Unless clinically indicated, there should be no limits on patients' duration of treatment or dosage level of medication. Likewise, there should be no limitations on the psychosocial services offered to patients, even when they no longer take medication. Appropriately trained, experienced, and certified or l				

				TABLE	A.4 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
Year	Care Setting		and Rating Scale		•	Furthermore, under the ROSC framework, OTPs provide patients with continuing care. This includes a discharge plan, referrals to continuing outpatient care, procedures that address patients' physical and mental health problems following medically supervised withdrawal, plans for reentry to maintenance treatment if relapse occurs, and ongoing recovery management. OTPs also are encouraged to offer supportive counseling as a transitional service.  Standing Order/Caps Excerpts:  Standing orders regarding the dose, schedule, or re-administration of methadone are not appropriate because of the unique pharmacologic properties, the well-established potential for fatalities in the induction period, and the risk of relapse during medically supervised withdrawal. In an OTP, an unacceptable standing order is any formulaic policy generically applied to all patients meeting specific criteria or in specific situations without evaluation by a physician or other qualified health care provider. Common examples are dose adjustments made solely on the basis of a COWS score and remedicating a patient who vomits after dosing based on the time between dose administration and vomiting using a fixed percentage of the dose.  Program-wide dosage caps or ceilings are contrary to the current state of the medical literature and the principle of individualized treatment. Programs should eliminate their use. In addition, OTPs should avoid establishing procedures or policies that hinder the ability of physicians or authorized health care professionals, as appropriate, to adjust patient dosages whenever the need is indicated.  Aftercare Planning Excerpt:  Aftercare planning should begin upon admission. Taking a recovery oriented approach to care facilitates this process. Aftercare planning should include the need for ongoing management of medical and psychiatric problems. Untreated, these problems are associated with relapse to drug use. Antagonist medications (e.g., extended-release injectable naltrexone) should also be considered for inclusion
						aftercare plans.  Adolescent Excerpt:
						For the purpose of this document, adolescents are defined as youth ranging in age 13-18.
						Programs develop and implement policies to ensure that adolescents are provided with developmentally appropriate treatment and evidence-based psychosocial support, such as family involvement, for that treatment. Screenings and assessments tailored to adolescents ensure that MAT is the most appropriate treatment for these patients.
1. The	full guideline can be fo	und at http://store.samh	sa.gov/shin/content//PE	P15-FEDGUIDEOTP/PE	EP15-FEDGUIDEOTP.pdf.	

Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
2015	OTP, OBOT, outpatient, inpatient	Literature Review	Not rated.  (RAND/UCLA Appropriateness Method used but individual ratings of specific guidelines not provided.)	Yes. Also includes clonidine, which is not FDA-approved.	YesGeneric recommendation.	Part 1: Assessment and Diagnosis of Opioid Use Disorder  Assessment Recommendations  First clinical priority should be given to identifying and making appropriate referral for any urgent or emergent medical or psychiatric problem(s), including drug-related impairment or overdose.  Completion of the patient's medical history should include screening for concomitant medical conditions, including infectious diseases (hepatitis, HIV, and TB), acute trauma, and pregnancy.  A physical examination should be completed as a component of the comprehensive assessment process. The prescriber (the clinician authorizing the use of a medication for the treatment of opioid use disorder) may conduct this physical examination him/herself, or, in accordance with the ASAM standards, ensure that a current physical examination is contained within the patient medical record before a patient is started on a new medication for the treatment of his/her addiction.  Initial laboratory testing should include a complete blood count, liver function tests, and tests for hepatitis C and HIV. Testing for TB and sexually transmitted infections should also be considered. Hepatitis B vaccination should be offered, if appropriate.  The assessment of females presents special considerations regarding their reproductive health. Women of childbearing age should be tested for pregnancy, and all women of childbearing potential and age should be queried regarding methods of contraception given the increase in fertility that results from effective opioid use disorder treatment.  Patients being evaluated for addiction involving opioid use, and/or for possible medication use in the treatment of opioid use disorder, should undergo (or have completed) an assessment of mental health status and possible psychiatric disorders (as outlined in the ASAM standards).  Opioid use is often co-occurring with other substance-related disorders. An evaluation of past and current substance use as well as a determination of the totality of substances that surround the addicti

				TABLE	A.5 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
						<ul> <li>A tobacco use query and counseling on cessation of tobacco products and electronic nicotine delivery devices should be completed routinely for all patients, including those who present for evaluation and treatment of opioid use disorder.</li> <li>An assessment of social and environmental factors should be conducted (as outlined in the ASAM Standards) to identify facilitators and barriers to addiction treatment, and specifically to pharmacotherapy. Before a decision is made to initiate a course of pharmacotherapy for the patient with opioid use disorder, the patient should receive a multidimensional assessment in fidelity with <i>The ASAM Criteria: Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions</i> (the "ASAM Criteria"). Addiction should be considered a biopsychosocial-spiritual illness, for which the use of medication(s) is but only 1 component of overall treatment.</li> </ul>
						Diagnosis Recommendations
						<ul> <li>Other clinicians may diagnose opioid use disorder, but confirmation of the diagnosis by the provider with prescribing authority, and who recommends medication use, must be obtained before pharmacotherapy for opioid use disorder commences.</li> <li>Opioid use disorder is primarily diagnosed on the basis of the history provided by the patient and a comprehensive assessment that includes a physical examination.</li> <li>Validated clinical scales that measure withdrawal symptoms (e.g., the OOWS, the SOWS, and the COWS may be used to assist in the evaluation of patients with opioid use disorder).</li> <li>Urine drug testing during the comprehensive assessment process, and frequently during treatment, is recommended. The frequency of drug testing is determined by a number of factors including: the stability of the patient, the type of treatment, and the treatment setting.</li> </ul>
						TREATMENT FOR OPIOID DEPENDENCE Part 2: Treatment Options
						<ul> <li>The choice of available treatment options for addiction involving opioid use should be a shared decision between clinician and patient.</li> <li>Clinicians should consider the patient's preferences, past treatment history, and treatment setting when deciding between the use of methadone, buprenorphine, and naltrexone in the treatment of addiction involving opioid use. The treatment setting described as Level 1 treatment in the ASAM Criteria may be a general outpatient location such as a clinician's practice site. The setting as described as Level 2 in the ASAM Criteria may be an intensive outpatient treatment or partial hospitalization program housed in a specialty addiction treatment facility, a community mental health center, or another setting. The ASAM Criteria describes Level 3 or Level 4 treatment respectively as a residential addiction treatment facility or hospital.</li> </ul>

				TABLE	A.5 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
						<ul> <li>The venue in which treatment is provided is as important as the specific medication selected. OTPs offer daily supervised dosing of methadone, and increasingly of buprenorphine. In accordance with federal law (21 CFR ASAM National Practice Guideline   May 27, 2015 15 §1306.07), OBOT, which provides medication on a prescribed weekly or monthly basis, is limited to buprenorphine. Naltrexone can be prescribed in any setting by any clinician with the authority to prescribe any medication. Clinicians should consider a patient's psychosocial situation, CODs, and risk of diversion when determining whether OTP or OBOT is most appropriate.</li> <li>OBOT may not be suitable for patients with active alcohol use disorder or sedative, hypnotic, or anxiolytic use disorder (or who are in the treatment of addiction involving the use of alcohol or other sedative drugs, including benzodiazepines or benzodiazepine receptor agonists). It may also be unsuitable for persons who are regularly using alcohol or other sedatives but do not have addiction or a specific SUD related to that class of drugs. The prescribing of benzodiazepines or other sedative-hypnotics should be used with extreme caution in patients who are prescribed methadone or buprenorphine for the treatment of an opioid use disorder.</li> <li>Methadone is recommended for patients who may benefit from daily dosing and supervision in an OTP, or for patients for whom buprenorphine for the treatment of opioid use disorder has been used unsuccessfully in an OTP or OBOT setting.</li> <li>Oral naltrexone for the treatment of opioid use disorder is often adversely affected by poor medication adherence. Clinicians should reserve its use for patients who would be able to comply with special techniques to enhance their adherence (e.g., observed dosing). Extended-release injectable naltrexone reduces, but does not eliminate, issues with medication adherence.</li> </ul>
						DETOXIFICATION     Part 3: Treating Opioid Withdrawal
						<ul> <li>Using medications for opioid withdrawal management is recommended over abrupt cessation of opioids. Abrupt cessation of opioids may lead to strong cravings, which can lead to continued use.</li> <li>Patients should be advised about risk of relapse and other safety concerns from using opioid withdrawal management as standalone treatment for opioid use disorder. Opioid withdrawal management on its own is not a treatment method.</li> <li>Assessment of a patient undergoing opioid withdrawal management should include a thorough medical history and physical examination focusing on signs and symptoms associated with opioid withdrawal.</li> <li>Opioid withdrawal management in cases in which methadone is used to manage withdrawal symptoms must be done in an inpatient setting or in an OTP. For shortacting opioids, tapering schedules that decrease in daily doses of prescribed methadone should begin with doses 20-30mg/day and should be completed in 6-10 days.</li> </ul>

				TABLE	A.5 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
						<ul> <li>Opioid withdrawal management in cases in which buprenorphine is used to manage withdrawal symptoms should not be initiated until 12-18 hours after the last dose of a short-acting agonist such as heroin or oxycodone, and 24-48 hours after the last dose of a long-acting agonist such as methadone. A dose of buprenorphine sufficient to suppress withdrawal symptoms is given (this can be 4-16mg/day) and then the dose is tapered. The duration of the tapering schedule can be as brief as 3-5 days or as long as 30 days or more.</li> <li>The use of combinations of buprenorphine and low doses of oral naltrexone to manage withdrawal and facilitate the accelerated introduction of extended-release injectable naltrexone has shown promise. More research will be needed before this can be accepted as standard practice.</li> <li>The Guideline Committee recommends, based on consensus opinion, the inclusion of clonidine as a practice to support opioid withdrawal. Clonidine is not FDA-approved for the treatment of opioid withdrawal but it has been extensively used off-label for this purpose. Clonidine may be used orally or trans-dermally at doses of 0.1-0.3mg every 6-8 hours with a maximum dose of 1.2mg daily to assist in the management of opioid withdrawal symptoms. Its hypotensive effects often limit the amount that can be used. Clonidine can be combined with other non-narcotic medications targeting specific opioid withdrawal symptoms such as benzodiazepines for anxiety, loperamide for diarrhea, acetaminophen or NSAIDs for pain, and ondansetron or other agents for nausea.</li> <li>Opioid withdrawal management using anesthesia UROD is not recommended due to high risk for adverse events or death. Naltrexone-facilitated opioid withdrawal management can be a safe and effective approach but should be used only by clinicians experienced with this clinical method, and in cases in which anesthesia or conscious sedation are not being employed.</li> </ul>
						TREATMENT FOR OPIOID DEPENDENCE
						<ul> <li>Methadone is a treatment option recommended for patients who are physiologically dependent on opioids, able to give informed consent, and who have no specific contraindications for agonist treatment when it is prescribed in the context of an appropriate plan that includes psychosocial intervention.</li> <li>The recommended initial dose ranges for methadone are from 10-30mg with reassessment in 3-4 hours, and a second dose not to exceed 10mg on the first day if withdrawal symptoms are persisting.</li> <li>The usual daily dosage of methadone ranges 60-120mg. Some patients may respond to lower doses and some patients may need higher doses. Dosage increases in 5-10mg increments applied no more frequently than every 7 days (depending on clinical response) are necessary to avoid over-sedation, toxicity, or even iatrogenic overdose deaths.</li> </ul>

				TABLE	A.5 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
						<ul> <li>The administration of methadone should be monitored because unsupervised administration can lead to misuse and diversion. OTP regulations require monitored medication administration until the patient's clinical response and behavior demonstrates that the prescribing of non-monitored doses is appropriate.</li> <li>Psychosocial treatment, though sometimes minimally needed, should be implemented in conjunction with the use of methadone in the treatment of opioid use disorder.</li> <li>Methadone should be reinstituted immediately if relapse occurs, or when an assessment determines that the risk of relapse is high for patients who previously received methadone in the treatment of opioid use disorder but who are no longer prescribed such treatment.</li> <li>Strategies directed at relapse prevention are an important part of comprehensive addiction treatment and should be included in any plan of care for a patient receiving active opioid treatment or ongoing monitoring of the status of their addictive disease.</li> <li>Switching from methadone to another medication for the treatment of opioid use disorder may be appropriate if the patient experiences intolerable side effects or is not successful in attaining or maintaining treatment goals through the use of methadone.</li> <li>Patients switching from methadone to buprenorphine in the treatment of opioid use disorder should be on low doses of methadone prior to switching medications.</li> <li>Patients on low doses of methadone prior to switching medications.</li> <li>Patients switching from methadone to oral naltrexone or extended-release injectable naltrexone must be completely withdrawn from methadone and other opioids, before they can receive naltrexone. The only exception would apply when an experienced clinician receives consent from the patient to embark on a plan of naltrexone-facilitated opioid withdrawal management.</li> <li>Patients who discontinue agonist therapy with methadone or buprenorphine and then resume opioid use should be made aware of the r</li></ul>

				TABLE	A.5 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
						<ul> <li>Clinicians should observe patients in their offices during induction. Emerging research suggests, however, that many patients need not be observed and that home buprenorphine induction may be considered. Home-based induction is recommended only if the patient or prescribing physician is experienced with the use of buprenorphine. This is based on the consensus opinion of the Guideline Committee.</li> <li>Buprenorphine doses after induction and titration should be, on average, at least 8mg/day. However, if patients are continuing to use opioids, consideration should be given to increasing the dose by 4-8mg (daily doses of 12-16mg or higher). The FDA approves dosing to a limit of 24mg/day, and there is limited evidence regarding the relative efficacy of higher doses. In addition, the use of higher doses may increase the risk of diversion.</li> <li>Psychosocial treatment should be implemented in conjunction with the use of buprenorphine in the treatment of opioid use disorder.</li> <li>Clinicians should take steps to reduce the chance of buprenorphine diversion. Recommended strategies include frequent office visits (weekly in early treatment), urine drug testing, including testing for buprenorphine and metabolites, and recall visits for pill counts.</li> <li>Patients should be tested frequently for buprenorphine, other substances, and prescription medications. Accessing PDMP data may be useful for monitoring.</li> <li>Patients should be seen frequently at the beginning of their treatment. Weekly visits (at least) are recommended until patients are determined to be stable. There is no recommended time limit for treatment.</li> <li>Buprenorphine taper and discontinuation is a slow process and close monitoring is recommended. Buprenorphine tapering is generally accomplished over several months. Patients should be encouraged to remain in treatment for ongoing monitoring past the point of discontinuation.</li> <li>When considering a switch from buprenorphine to naltrexone, 7-14 d</li></ul>

				TABLE	A.5 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
						<ul> <li>Oral naltrexone should be taken daily in 50mg doses, or 3 times weekly in 2 100mg doses followed by 1 150mg dose.</li> <li>Extended-release injectable naltrexone should be administered every 4 weeks by deep intramuscular injection in the gluteal muscle at a set dosage of 380mg/injection.</li> <li>Psychosocial treatment is recommended in conjunction with treatment with naltrexone. The efficacy of naltrexone use in conjunction with psychosocial treatment has been established, whereas the efficacy of extended-release injectable naltrexone without psychosocial treatment has not been established.</li> <li>There is no recommended length of treatment with oral naltrexone or extended-release injectable naltrexone. Duration depends on clinical judgment and the patient's individual circumstances. Because there is no physical dependence associated with naltrexone, it can be stopped abruptly without withdrawal symptoms.</li> <li>Switching from naltrexone to methadone or buprenorphine should be planned, considered, and monitored. Switching from an antagonist such as naltrexone to a full agonist (methadone) or a partial agonist (buprenorphine) is generally less complicated than switching from a full or partial agonist to an antagonist because there is no physical dependence associated with antagonist treatment and thus no possibility of precipitated withdrawal. Patients being switched from naltrexone to buprenorphine or methadone will not have physical dependence on opioids and thus the initial doses of methadone or buprenorphine used should be low. Patients should not be switched until a significant amount of the naltrexone is no longer in their system, about 1 day for oral naltrexone or 30 days for extended-release injectable naltrexone.</li> <li>Patients who discontinue antagonist therapy and resume opioid use should be made aware of the increased risk associated with an opioid overdose, and especially the increased risk of death.</li> <li>Part 7: Psychosocial Treatment in Conjunction with Medications for the Tre</li></ul>

	TABLE A.5 (continued)								
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement			
						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.  Part 10: Special Populations: Adolescents			
						<ul> <li>Clinicians should consider treating adolescents who have opioid use disorder using the full range of treatment options, including pharmacotherapy.</li> <li>Opioid agonists (methadone and buprenorphine) and antagonists (naltrexone) may be considered for treatment of opioid use disorder in adolescents. Age is a consideration in treatment, and federal laws and FDA approvals need to be considered for patients under age 18.</li> <li>Psychosocial treatment is recommended in the treatment of adolescents with opioid use disorder.</li> <li>Concurrent practices to reduce infection (e.g., sexual risk reduction interventions), are recommended as components of comprehensive treatment for the prevention of sexually transmitted infections and blood-borne viruses.</li> <li>Adolescents may benefit from treatment in specialized treatment facilities that provide multidimensional services.</li> <li>See original guidelines for guidelines on other special populations including pregnant women, individuals with pain, and the incarcerated population. Also see original guidelines for more information.</li> </ul>			

<sup>1.</sup> Full guideline can be found at http://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/national-practice-guideline.pdf?sfvrsn=22. Many of these guidelines were based upon a consensus process informed by the literature reviews.

	TABLE	A.6. WHO: Gu	idelines for the	e Identification	n and Management	of Substance Use and SUD in Pregnancy
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
2014	Primary care, other outpatient settings inferred, inpatient	Literature Review	GRADE Working Group Grades of Evidence  High quality: Further research is very unlikely to change confidence in the estimate of effect.  Moderate quality: Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.  Low quality: Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate.  Very low quality: The GDG is very uncertain about the estimate.  Strength of Recommendation	Yes.	YesRecommend CBT, CM and motivational interviewing/enhancement.	Recommendation 1  Health care providers should ask all pregnant women about their use of alcohol and other substances (past and present) as early as possible in the pregnancy and at every antenatal visit. (Strength of recommendation: Strong; Quality of evidence: Low)  See original guidelines for remarks.  Recommendation 2  Health care providers should offer a brief intervention to all pregnant women using alcohol or drugs. (Strength of recommendation: Strong; Quality of evidence: Low)  See original guidelines for remarks.  Recommendation 3  Health care providers managing pregnant or post-partum women with alcohol or other SUDs should offer comprehensive assessment and individualized care. (Strength of recommendation: Conditional; Quality of evidence: Very low)  Remarks  A comprehensive assessment of women using alcohol or drugs in pregnancy and the post-partum period includes an assessment of patterns of substance use, medical or psychiatric co-morbidity, family context, as well as social problems.  Individualized care involves selecting appropriate psychosocial interventions of different intensity based on the particular needs of the pregnant women and the resources available. Psychosocial interventions include a number of psychological treatments and social supports, ranging from lesser to higher intensity. The psychosocial treatment and support referred to in this section is a more intensive set of interventions typically delivered by people with specific training in the management of SUDs, and usually includes repeated contact with the patient. The kinds of specific psychological techniques considered in this category include CBT, CM and motivational interviewing/enhancement. The kinds of social support referred to in this section include assistance with accommodation, vocational training, parenting training, life-skills training, legal advice, home-visiting and outreach.

				TABLE	E A.6 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
			Strong: The GDG was confident that the quality of the evidence of effect.			Despite the benefits of psychosocial treatment outweighing the harms, this recommendation was considered to be conditional given the absence of strong evidence and the potential resource implications.
			combined with			DETOXIFICATION AND TREATMENT FOR OPIOID DEPENDENCE
			certainty about the			Recommendation 5
			values, preferences, benefits and feasibility, made this a recommendation			Pregnant women dependent on opioids should be encouraged to use opioid maintenance treatment whenever available rather than to attempt opioid detoxification. (Strength of recommendation: Strong; Quality of evidence: Very low)
			that should be done in most			Remarks
			circumstances and settings.			Opioid maintenance treatment in this context refers to either MMT or BMT.
			Conditional: There was less certainty about the			Pregnant patients with opioid dependence who wish to undergo detoxification should be advised that relapse to opioid use is more likely following medication-assisted withdrawal than while undertaking opioid maintenance treatment.
			quality of the evidence and values, preferences, benefits and			Such medication-assisted withdrawal from opioids should be attempted only in an inpatient unit, using a gradual reduction in methadone or buprenorphine doses. Inpatient care should also be considered for the initiation and optimization of maintenance treatment.
			feasibility of this recommendation.			Psychosocial treatment should be an integral component of such treatment.
			Thus, there may be circumstances or settings in which it			Pregnant women who fail to complete medication-assisted withdrawal should be offered opioid agonist pharmacotherapy.
			should not apply.			It was decided that this recommendation should be strong despite the low quality of evidence of effectiveness from RCTs, as the rate of relapse to opioid use following detoxification has been shown to be high and the risks of harm to both mother and fetus from failed detoxification are catastrophic compared to the very low risks of harm from opioid maintenance treatment.
						TREATMENT FOR OPIOID DEPENDENCE
						Recommendation 11
						Pregnant patients with opioid dependence should be advised to continue or commence opioid maintenance therapy with either methadone or buprenorphine.  (Strength of recommendation: Strong; Quality of evidence: Very low)

	TABLE A.6 (continued)									
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement				
						Pregnant patients with opioid dependence should be encouraged to commence opioid agonist pharmacotherapy, which should be combined with psychosocial interventions.  Opioid-dependent pregnant women who are already taking opioid maintenance therapy with methadone should not be advised to switch to buprenorphine due to the risk of opioid withdrawal. Pregnant opioid-dependent women taking buprenorphine should not be advised to switch to methadone unless they are not responding well to their current treatment.  In opioid-dependent pregnant women, the buprenorphine mono formulation should be used in preference to the buprenorphine-naloxone formulation.  Regardless of the choice of medication, psychosocial interventions should be an integral component of treatment.  Opioid-dependent pregnant patients who wish to receive opioid antagonist pharmacotherapy should be discouraged from such a choice.  It was decided that this recommendation should be strong despite the low quality of evidence as the rate of relapse to opioid use following detoxification is high and the risks of harm from failed detoxification are catastrophic compared to the small risks of harm from opioid maintenance treatment.  See original guidelines for full guidelines, particularly sections on infants and breastfeeding.				

<sup>1.</sup> Full guideline can be found at <a href="http://www.guideline.gov/content.aspx?id=48894&search=(%22naltrexone%22+OR+%22buprenorphine%22+OR+%22methadone%22">http://www.guideline.gov/content.aspx?id=48894&search=(%22naltrexone%22+OR+%22buprenorphine%22+OR+%22methadone%22</a>). Many of these guidelines were based upon a consensus process informed by the literature reviews.

idated Suideiii	mes on niv P	revention, Diagno	osis, Treatment and Care for Key Populations
Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
Significance of the GRADE Levels of Evidence  High: Further esearch is very inlikely to change confidence in the estimate of effect.  Moderate: Further esearch is likely to have an important impact on confidence in the effect.  Low: Further esearch is very kely to have an important impact on the estimate of effect and is likely to change the estimate.  Very Low: Any estimate of effect is ery uncertain.  Strength of Recommendations or which there is confidence that the lesirable effects of edherence to the ecommendation	Yes.	YesGeneric recommendation.	TREATMENT FOR OPIOID DEPENDENCE  Opioid Substitution Therapy  Recommendations and Guidance  All Key Population Groups  • All people from key populations who are dependent on opioids should be offered OST in keeping with WHO guidance (Strong recommendation, Low quality of evidence) ("WHO, UNDOC, UNAIDS technical guide," 2012; "Tool," Forthcoming; "Guidelines for the psychosocially," 2009), including those in prison and other closed settings ("Interventions to address HIV," 2007).  Additional remarks  • To maximize the safety and effectiveness of OST programmes, policies and regulations should encourage flexible dosing structures, without restricting dose levels or duration of treatment ("Guidelines for the psychosocially," 2009). Usual methadone maintenance doses should be in the range of a minimum of 60-120mg/day, and average buprenorphine maintenance doses should be at least 8mg/day ("Guidelines for the psychosocially," 2009). Take-home doses can be offered when the dose and social situation are stable and when there is little risk of diversion for illegitimate purposes ("Guidelines for the psychosocially," 2009). OST is most effective as a maintenance treatment for longer periods of time (treatment for years may be necessary). Detoxification or opioid withdrawal (rather than maintenance treatment) results in poor outcomes in the long term. However, patients should be helped to withdraw from opioids if it is their informed choice to do so ("Guidelines for the psychosocially," 2009).  • OST should be used for the treatment of opioid dependence in pregnancy rather than attempt opioid detoxification ("Guidelines for the psychosocially," 2009; "Guidelines for identification," 2014).  • Psychosocial support should be available to all opioid-dependent people, in association with pharmacological treatments of opioid dependence. At a minimum this support should include assessment of psychosocial needs, supportive counselling and links to family and community services ("Guidelines for the psychosocially," 2009).  • For
Call the line of t	statement Grade and Rating Scale Definition ignificance of the GRADE Levels of Evidence igh: Further seearch is very nlikely to change onfidence in the stimate of effect.  Inderate: Further seearch is likely to ave an important appact on onfidence in the ffect.  Inderate: Further seearch is likely to ave an important appact on onfidence in the effect.  Inderate: Further seearch is likely to ave an important important impact on the estimate of effect and is likely on change the stimate.  In the estimate of effect is early uncertain.  It rength of ecommendation or or against) is 1 or which there is onfidence that the estimable effects of dherence to the	Statement Grade Ind Rating Scale Definition  Ignificance of the GRADE Levels of Evidence  Igh: Further Issearch is very Inlikely to change Indidence in the Issearch is likely to eave an important impact on Indidence in the Issearch is very Issearch is likely to eave an important impact on Indidence in the Iffect and is likely to change the Issearch is likely to have an inportant impact in the estimate of Iffect and is likely to change the Issearch is very Issea	Statement Grade Ind Rating Scale Definition  Ignificance of the GRADE Levels of Evidence  Igh: Further Individual of Evidence in the Individual of Evidence in Individual of Evidence in Individual of Evidence Individual

				TABLE	A.7 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
			A conditional recommendation (for or against) is 1 for which the quality of evidence may be low or may apply only to specific groups or settings; or the panel concludes that the desirable effects of adherence to the recommendation probably outweigh the undesirable effects or are closely balanced, but the panel is not confident about these trade-offs in all situations.  If implemented, a conditional recommendation should be monitored closely and evaluated rigorously. Further research will be required to address the uncertainties and is likely to provide new evidence that may change the calculation of the balance of trade-			Care settings that provide OST should initiate and maintain ART for eligible people living with HIV ("Consolidated guidelines," 2013).  Related Recommendations and Contextual Issues for Specific Key Population Groups  People in Prisons and Other Closed Settings  Prison authorities in countries where OST is available in the community should urgently introduce OST programmes and expand them to scale as soon as possible ("Interventions to address HIV," 2007).  Countries should affirm and strengthen the principle of providing treatment, education and rehabilitation as an alternative to conviction and punishment for drug-related offences ("WHO, UNODC, UNAIDS technical guide," 2012).  Care should be taken to see that people on OST before entering prisons or other closed settings can continue OST without interruption while imprisoned and when transferred between settings ("Interventions to address HIV," 2007; "Guidelines for the psychosocially," 2009) and can be linked to community-based OST upon release ("Rolling out," 2013).  Provision of OST before release can help reduce overdose-related mortality (Degenhardt et al., 2014).  Transgender People  There is no evidence of drug interactions between OST and medications used for gender affirmation; however, research is very limited.  Adolescents from Key Populations  WHO guidance does not specify age restrictions for OST.  See original guidelines for full guidelines.

				TABLE	A.7 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
			The values and preferences of the end users (key populations), feasibility and cost as well as consideration of potential benefits and harms contribute to determining the strength of a recommendation.			

<sup>1.</sup> Full guideline can be found at <a href="http://www.guideline.gov/content.aspx?id=48766&search=(%22naltrexone%22+OR+%22buprenorphine%22+OR+%22methadone%22">http://www.guideline.gov/content.aspx?id=48766&search=(%22naltrexone%22+OR+%22buprenorphine%22+OR+%22methadone%22</a>). Many of these guidelines were based upon a consensus process informed by the literature reviews.

	TA	BLE A.8. Wash	nington State I		Labor and Industr	ies: Guideline for Prescribing Opioids
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
2013	Community-based	Literature Review	Not graded.	Yes. Also includes	YesSuggested CBT for	DETOXIFICATION
2013	Community-based settings, inpatient, residential	Literature Review	Not graded.	Yes. Also includes clonidine which is not FDA-approved.	YesSuggested CBT for detoxification.	DETOXIFICATION  STEP 1: Discontinuing Opioids in a Community Care Setting  In most cases, workers who are not on chronic high dose opioids or who do not have co-morbid SUD or a significant mental health disorder may be tapered in a straightforward manner. A gradual taper of approximately 10%/week (see AMDG Guideline, Tapering or Discontinuing Opioids and Appendix H at <a href="http://www.agencymeddirectors.wa.gov/Files/OpioidGdline.pdf">http://www.agencymeddirectors.wa.gov/Files/OpioidGdline.pdf</a> External Web site Policy) can be carried out by the AP. Adjuvant agents like clonidine and psychological support such as CBT can be provided to assist with the taper process. The department or insurer may also authorize temporary coverage of buprenorphine or buprenorphine-naloxone to assist with the tapering process (see L&I coverage policy). The AP may also seek consultative assistance from a pain management specialist.  STEP 2: Discontinuing Opioids in an Intensive Setting  For those workers who have failed step 1 or who are at high risk for failure due to high dose, concurrent benzodiazepine use, or co-morbid substance use or mental health disorder, the prescriber should consider seeking consultative assistance from a pain management specialist, a SIMP provider or addiction medicine specialist. Adjuvant agents and psychological support can be provided to assist with the taper process. The department or insurer may also authorize temporary coverage of buprenorphine or buprenorphine-naloxone to assist with the tapering process (see L&I coverage policy). In these situations, formal inpatient detoxification and/or a 4-week SIMP
						treatment program may be required.  Due to the lack of high quality evidence of safety and comparative efficacy, UROD (e.g., within 3 days), using antagonist drugs with or without sedation, will not be covered.  TREATMENT FOR OPIOID DEPENDENCE Additional Services  If a worker has failed Steps 1 and 2, AND meets the DSM-V criteria for opioid use disorder, the department or insurer may cover up to 6 months of addiction treatment through a licensed chemical dependency treatment center as an aid to recovery. A list of treatment centers certified by the Division of Behavior Health and Recovery is
						available at <a href="http://www.dshs.wa.gov/dbhr/dadirectory.shtml">http://www.dshs.wa.gov/dbhr/dadirectory.shtml</a> External Web site Policy.  Refer to the original guideline document for more information about additional services.

	TABLE A.8 (continued)								
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement			
						Treatment Options for Opioid Use Disorder			
						MAT Buprenorphine (Subutex®, Suboxone®) Methadone Naltrexone (Depade®, Revia®, Vivitrol®) Drug-free outpatient treatment Residential treatment			
				3745&search=(%22nalti	rexone%22+OR+%22bupren	orphine%22+OR+%22methadone%22). Many of these guidelines were based upon a			
cons	ensus process informe	d by the literature review	WS.						

	TABLE A.9. VA/DoD: Clinical Practice Guideline for Assessment and Management of Patients At-Risk for Suicide									
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement				
2013	Not specified	Literature Review	Ratings not	Yes.	No.	TREATMENT FOR OPIOID DEPENDENCE				
			associated with opioid section (but used for other sections).			M8. Use of Methadone and Naloxone to Reduce Death from Opioid Overdose  1. Methadone substitution therapy should be considered in opiate dependent patients to reduce the risk of death by overdose (see VA/DoD clinical practice guideline for management of SUD External Web site Policy).				
				<u> 7023&amp;search=(%22nalt</u>	rexone%22+OR+%22buprend	orphine%22+OR+%22methadone%22). Many of these guidelines were based upon a				
cons	ensus process informe	d by the literature review	WS.							

					1	ons: Management of Benzodiazepines in MAT
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
2013	Not specified	Literature Review	Not rated.	Yes.	Yes. Generic statement that CM can be incorporated and in case of non-compliance, consider providing increased intensity of psychosocial treatment.	<ul> <li>CNS depressant use is not an absolute contraindication for either methadone or buprenorphine, but is a reason for caution because of potential respiratory depression. Serious overdose and death may occur if MAT is administered in conjunction with benzodiazepines, sedatives, tranquilizers, antidepressants, or alcohol.</li> <li>People who use benzodiazepines, even if used as a part of long-term therapy, should be considered at-risk for adverse drug reactions including overdose and death.</li> <li>Many people presenting to services have an extensive history of multiple substance dependence and all substance abuse, including benzodiazepines, should be actively addressed in treatment. MAT should not generally be discontinued for persistent benzodiazepine abuse, but requires the implementation of risk-management strategies.</li> <li>Clinicians should ensure that every step of decision making is clearly documented.</li> <li>Clinicians would benefit from the development of a toolkit about the management of benzodiazepines in methadone treatment that includes videos and written materials for individuals in MAT.</li> <li>In case of non-compliance, consider providing increased intensity of psychosocial treatment.</li> <li>See original guidelines for more specific guidelines covering:</li> <li>Assessment for MAT Addressing benzodiazepine use MAT for patients with concurrent benzodiazepine use Non-compliance with treatment agreement Risk-management/Impairment assessment Special circumstances</li> </ul>
ı. Full	uniqueline toung at http	://www.ccbh.com/pdfs/pr	oviders/nealthcholces/t	Desidiactice/DD_dUIGelli	nes ior penzodiazeninės noti	Many of these guidelines were based upon a consensus process informed by the

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	TABLE A	.11. BAP Reco		•		delines for the Pharmacological Management on and Co-morbidity
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
2012	Not specified, but	Literature Review	Categories of	Yes. Also includes	YesGeneric	TREATMENT FOR OPIOID DEPENDENCE
	inferred as several		evidence for causal relationships and treatment:	diamorphine and lofexide, which are not FDA-approved.	recommendation.	Recommendations: opioid maintenance treatment for opioid dependence  Methadone maintenance treatment
			la: Evidence from meta-analysis of randomised			MMT is an appropriate treatment option for opioid-dependent patients. It is effective in reducing heroin use, injecting, and sharing of injecting equipment (A).
			controlled trials. <b>Ib</b> : Evidence from at least 1			MMT is more effective at doses in the range 60-120mg than at lower doses. Following safe induction of methadone treatment (see Department of Health Guidelines), consideration should be given to higher maintenance doses (A).
			randomised controlled trial.			Buprenorphine maintenance treatment
			IIa: Evidence from at least 1			BMT is an appropriate treatment option for opioid-dependent patients. It is effective in reducing heroin use (A).
			controlled study without randomization.			Buprenorphine should be prescribed at doses of 8mg or higher when used for maintenance treatment (B), and preferably at doses over 12mg (D).
			IIb: Evidence from at least 1 other			Where concerns over diversion are paramount, buprenorphine-naloxone combinations may be preferred (B).
			type of quasi- experimental			Choice of methadone or BMT
			study.  III: Evidence from		Both methadone and buprenorphine are effective treatments. Opioid-dependent patients should be offered either medication, guided by patient choice and safety considerations. (A).	
			non-experimental descriptive studies, such as			Additional therapies
			comparative studies, correlation studies and case-			MMT or BMT should be provided in conjunction with psychosocial interventions such as regular counselling ( <b>B</b> ).
			control studies.			Injectable opioid maintenance treatments
			IV: Evidence from expert committee reports or opinions			Highly supervised injectable diamorphine maintenance treatment should be considered for patients who have failed to respond to optimised MMT or BMT (B).
			and/or clinical experience of respected authorities.			We do not recommend injectable methadone treatment at present, although further studies are warranted (C).

				TABLE	A.11 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
			Proposed categories of evidence for observational relationships:  I: Evidence from large representative population samples.  II: Evidence from small, well-designed, but not necessarily representative samples.  III: Evidence from non-representative samples.  IV: Evidence from expert committee reports or opinions and/or clinical experience of respected authorities.  Strength of recommendation:  A: Directly based on category I evidence.  B: Directly based on category II evidence or extrapolated recommendation from category I			Recommendations: management of withdrawal from opioid drugs  There is a robust evidence base for 3 approaches to opioid detoxification: methadone at tapered doses, buprenorphine, or an α2 adrenergic agonist (usually lofexidine) (A).  The choice of agent will depend on what treatment patients are already receiving, for example methadone or buprenorphine and individual preference. However, if short duration of treatment is desirable, or in patients with mild or uncertain dependence, α2 adrenergic agonists may be preferable (A).  SROM is not recommended for opioid detoxification (B).  UROD is not recommended (A).  Pharmacological management of withdrawal should be supported by psychosocial treatment (A).  Recommendations: naltrexone for treatment of opioid dependence  Oral naltrexone treatment should be considered for formerly opioid-dependent people who are highly motivated to remain abstinent (D).  Recommendations: younger people  There is limited evidence on treatment of SUDs in younger people on which to base recommendations to guide specific pharmacological approaches. However, it is important that pharmacotherapy be considered, particularly in alcohol, opioid or nicotine dependence, and ideally by a specialist multidisciplinary service.  Pharmacological treatment should follow the evidence base for the general adult population with appropriate dose adjustments for age-related pharmacokinetic and pharmacodynamic changes (C).  Younger people with harmful substance use, abuse or dependence should have full routine health screens with identification and treatment of psychiatric or physical health problems (S).  There should be a lower threshold for admission for inpatient assessment and treatment, for example for assisted alcohol withdrawal, opioid stabilisation in younger people (D).

				TABLE	A.11 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
			C: Directly based			Recommendations: opioids and pregnancy
			on category III			
			evidence or			Methadone and buprenorphine (not buprenorphine-naloxone) maintenance treatment
			extrapolated			improves maternal and foetal outcomes, and substitution treatment should be offered
			recommendation			to pregnant opioid-dependent women ( <b>B</b> ).
			from category I or			
			II evidence.			The choice of medication should be based on individual need and preference
						following full assessment, and the dose of methadone prescribed should be that which
			<b>D</b> : Directly based			maintains clinical stability (C).
			on category IV			D
			evidence or			Buprenorphine may be associated with less NAS ( <b>B</b> ).
			extrapolated			
			recommendation			Detoxification should be avoided in the first trimester, is preferred in the second and
			from category I, II			only with caution in third trimester (S).
			or III evidence.			
			C. Ctandard of			See original guidelines for guidelines on opioid treatment for patients with
			S: Standard of			CODs, and opioid treatment for older people.
4 - "			care.		<u> </u>	
1. Full	guideline found at <a href="http:/">http:/</a>	<u>//www.ncbi.nlm.nih.gov/</u>	<u>pubmed/22628390</u> . Ma	iny of these guidelines i	were based upon a consensu	is process informed by the literature reviews.

	TABLE A.12.	Substance Mis	use and Alcoh	ol Use Disord	ers: Evidence-Bas	ed Geriatric Nursing Protocols for Best Practice
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
2008, revised 2012	Office-based practice, state licensed clinics	Literature Review	Level I: Systematic reviews (integrative/meta- analyses/clinical practice guidelines based on systematic reviews).  Level II: Single experimental study (RCTs).  Level III: Quasi- experimental studies.  Level IV: Non- experimental studies.  Level V: Care report/program evaluation/narrative literature reviews.  Level VI: Opinions of respected authorities/ consensus panels.	Yes.	YesGeneric recommendation; relapse prevention section for all types of substance abuse recommends group psychotherapy using CBT.	TREATMENT FOR OPIOID DEPENDENCE Heroin or opioid dependence  Older long-term opioid users may continue use, relapse, and seek treatment. Methadone or buprenorphine are current pharmacological treatment options, effective in conjunction with self-help programs and/or psychosocial interventions. Treatment with methadone, a synthetic narcotic agonist, suppresses withdrawal symptoms and drug cravings associated with opioid dependence but requires daily dosing of 60mg, minimum. It is dispensed only in state licensed clinics. Buprenorphine (Subutex or Suboxone), recently approved for use in office practice by trained physicians, is an opioid partial agonist-antagonist. Alone and in combination with naloxone (Suboxone), it can prevent withdrawal when someone ceases use of an opioid drug and then be used for long-term treatment. Naloxone is an opioid antagonist used to reverse depressant symptoms in opiate overdose and at different dosages to treat dependence (CSAT, 2004 [Level VI]).  Close collaboration with the prescriber is required because these drugs should not be abruptly terminated or used with antidepressants and interact negatively with many prescription medications.  Naltrexone, a long-acting opioid antagonist, blocks opioid effects and is most effective with those who are no longer opioid dependent but are at high risk for relapse (Srisurapanont & Jarusuraisin, 2005 [Level III]).  Treatment and relapse prevention  • Monitor pharmacologic treatment such as naltrexone as short-term treatment for alcohol dependence. The benefits of this treatment are dependent on adherence and psychosocial treatment should accompany its use (WHO, 2000 [Level II]). Methadone or buprenorphine should be used for long-term treatment opioid dependence.  • Group psychotherapy in limited studies using a cognitive behavioral approach has produced good outcomes with older adults (Payne & Marcus, 2008 [Level III]).  • Refer to community-based groups such as AA, NA, Al-Anon groups, and encourage attendance.  • Educate family and patient r

	TABLE A.12 (continued)							
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement		
						Learn cognitive strategies to avoid negative moods.     Make lifestyle changes to reduce stress, improve the quality of life, and increase pleasure.     Learn cognitive and behavioral activities to cope with cravings and urges to use.     Encourage development or expansion of patient's social support system.		
						See original guidelines for full guidelines.		
1. Full	guideline found at http://	/www.guideline.gov/con	tent.aspx?id=43939&se	earch=(%22naltrexone%	622+OR+%22buprenorphine	%22+OR+%22methadone%22). Many of these guidelines were based upon a		

consensus process informed by the literature reviews.

TABLE A.13. Guidelines for Improving Entry Into and Retention in Care and Antiretroviral Adherence for Persons with HIV:  Evidence-Based Recommendations from an International Association of Physicians in AIDS Care Panel								
Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement			
t specified	Literature Review	Quality of the Body	Yes.	No.	TREATMENT FOR OPIOID DEPENDENCE			
nt specified	Literature Review	Quality of the Body of Evidence  Excellent (I): RCT evidence without important limitations. Overwhelming evidence from observational studies.  High (II): RCT evidence with important limitations. Strong evidence from observational studies.  Medium (III): RCT evidence with important limitations. Strong evidence from observational studies.  Medium (III): RCT evidence with critical limitations. Observational study evidence without important limitations.  Low (IV): Observational study evidence with important or critical limitations.  Strength of Recommendations  Strong (A): Almost all patients should receive the	Yes.	No.	TREATMENT FOR OPIOID DEPENDENCE  Substance Use Disorders  Individuals with alcohol and other SUDs are at increased risk for poor retention in care, poor adherence, and virologic failure. Several adherence strategies not recommended for general clinic populations are effective among those with SUDs.  Recommendation 27: Offering buprenorphine or methadone to opioid-dependent patients is recommended (II A).  Recommendation 29: Integration of DAART into MMT for opioid-dependent patients is recommended (II B).			
С	Eviderare Setting	Evidence-Based Ro Guideline Source of Information <sup>1</sup>	Guideline Source of Information¹  Specified  Literature Review  Literature Review  Literature Review  Coverwhelming evidence from observational studies.  High (II): RCT evidence with important limitations. Strong evidence from observational studies.  Medium (III): RCT evidence with important limitations. Strong evidence with critical limitations. Observational studies.  Low (IV): Observational study evidence with important limitations.  Low (IV): Observational study evidence with important limitations.  Strength of Recommendations  Strong (A): Almost all patients	Evidence-Based Recommendations from an Inference of Information In	Evidence-Based Recommendations from an International Associater Setting    Guideline Source of Information¹    Specified    Literature Review    Cuality of the Body of Evidence    Excellent (I): RCT evidence without important limitations.    Overwhelming evidence from observational studies.    High (II): RCT evidence with important limitations.    Medium (III): RCT evidence with critical limitations.    Observational studies.    Medium (III): RCT evidence with critical limitations.    Low (IV): Observational study evidence with important limitations.    Low (IV): Observational study evidence with important or critical limitations.    Strong (A): Almost all patients should receive the recommended    Strong (A): Almost all patients should receive the recommended			

	TABLE A.13. Guidelines for Improving Entry Into and Retention in Care and Antiretroviral Adherence for Persons with HIV:  Evidence-Based Recommendations from an International Association of Physicians in AIDS Care Panel								
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement			
			Moderate (B): Most patients should receive the recommended course of action. However, other choices may be appropriate for some patients.						
			Optional (C): There may be consideration for this recommendation on the basis of individual patient circumstances. Not recommended routinely.			(22+0P+%22methodone%22) Many of those quidelines were based upon a			

<sup>1.</sup> Full guideline found at <a href="http://www.guideline.gov/content.aspx?id=36947&search=(%22naltrexone%22+OR+%22buprenorphine%22+OR+%22methadone%22">http://www.guideline.gov/content.aspx?id=36947&search=(%22naltrexone%22+OR+%22buprenorphine%22+OR+%22methadone%22</a>). Many of these guidelines were based upon a consensus process informed by the literature reviews.

		Bupr			or Addiction and oid Dependence,	Mental Health: Clinical Practice Guideline
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
2011	Ambulatory- primary care setting, specialized addiction treatment setting	Literature Review	Levels of Evidence  I: Evidence from randomized, controlled trial(s).  II-1: Evidence from controlled trial(s) without randomization.  II-2: Evidence from cohort or case-control analytic studies, preferably from more than 1 centre or research group.  II-3: Evidence from comparisons between times or places with or without the intervention; dramatic results in uncontrolled experiments could be included here.  III: Opinions of respected authorities, based on clinical experience; descriptive studies or reports of expert committees.	Yes.	No.	Selecting Buprenorphine-Naloxone Maintenance Therapy  1. Once a patient is diagnosed with opioid dependence and is deemed appropriate for opioid agonist treatment, prescribers are encouraged to consider prescribing either buprenorphine-naloxone or methadone in order to increase retention in treatment and decrease opioid misuse. (Level I, Grade A)  Clinical Assessment  2. Buprenorphine-naloxone maintenance treatment can be prescribed to patients in either a primary care setting or in a specialized addiction treatment setting. (Level I, Grade A)  3. Prior to initiating maintenance opioid agonist treatment the patient should meet the diagnostic criteria for opioid dependence. (Level III, Grade A)  4. The decision to initiate opioid agonist therapy with either buprenorphine-naloxone or methadone maintenance should be guided by the individual clinical circumstances and the patient's preferences. (Level III, Grade I)  Initiation, Maintenance, and Discontinuation of Buprenorphine-Naloxone Maintenance Treatment  5. A physician should have a structured approach, to initiating buprenorphine-naloxone maintenance treatment in order to stabilize a patient at their maintenance dose as rapidly as possible while at the same time avoiding over-sedation or precipitated withdrawal. (Level III, Grade A)  6. Prior to initiation of buprenorphine-naloxone treatment, the patient must provide informed consent and there must be physician documentation that the patient has been informed of the physical dependence on the medication and possible long-term nature of the maintenance treatment. (Level III, Grade A)  7. Once a stable maintenance dose is achieved, physicians can consider non-daily dosing of buprenorphine-naloxone with respect to retention in treatment and reduction in illicit drug use. (Level II, Grade A)

				TABLE	A.14 (continued	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
			Grades of Recommendation  A: There is good evidence to recommend the action.  B: There is fair evidence to recommend the action.  C: The existing evidence is conflicting and does not allow making a recommendation for or against the use of the action; however, other factors may influence decision making.  D: There is fair evidence to recommend against the action.  E: There is good evidence to recommend against the action.  I: There is insufficient evidence (in quantity and/or quality) to make a recommendation; however, other factors may influence decision			8. When monitoring a patient on buprenorphine-naloxone maintenance, the physician should adopt a patient-centered urine drug testing strategy that maximizes clinical utility while avoiding testing without indication. (Level III, Grade I)  9. In making decisions regarding the provision of take-home doses of buprenorphine-naloxone, providers should use a clinical risk stratification strategy that aims to support patient autonomy while at the same time respecting patient and public safety. (Level III, Grade A)  Overdose, Mortality, and Other Adverse Effects  10. Policymakers should be aware that in countries where buprenorphine is equally available as methadone, buprenorphine has a lower attributable death rate than methadone. (Level II-3, Grade A)  11. Limited public funding is currently the major barrier to accessibility of buprenorphine-naloxone maintenance treatment in Ontario. The guideline authors recommend that policymakers remedy this barrier. (Level III, Grade B)  Clinicians should be aware that there is little in the medical literature to guide them in terms of which opioid maintenance agent to prescribe an individual opioid-dependent patient. In making this decision, the prescriber and patient should consider the following, which is based on clinical experience.  12. Buprenorphine-naloxone may be preferred over methadone to treat opioid dependence in the following patient populations:  a. When methadone is absolutely or relatively contraindicated, such as:  i. Presence of, history of or increased risk of prolonged QT interval. (Level I, Grade A)  ii. History of significant side effects on methadone such as:  i. Sexual side effects on methadone. (Level III-2, Grade B)  ii. Severe sedation or constipation with methadone. (Level III, Grade C)  c. Increased risk of toxicity from a full mu-opioid agonist:  i. If suspect a lower tolerance to opioids. (Level III, Grade B)  ii. If concurrent heavy or unstable use of sedating drugs/medication. (Level II-3, Grade B)  iii. If elderly. (Level III, Grade B)

Year Care Setting Guideline Source of Information Statement Grade and Rating Scale Medications Treatment  TABLE A.14 (continued)  Statement Grade and Rating Scale Medications Treatment	
of Information Definition Medications Treatment	Guideline Statement
Definitions of Levels of Evidence and Grades of Recommendations of the Canadian Task Force on Preventive Health Care. Available from the CMAJ Web site External Web site Policy.  13 po a. na b. ha c. (Lu d. e. inc. f. F. ab sici	Briefer history (i.e., less than 1 year) of opioid misuse. (Level III, Grade C) Social supports. (Level III, Grade C) ii. Adolescents and young adults. (Level III, Grade B)  B. Past history of successful stabilization with buprenorphine-naloxone. (Level III, Grade I)  Patient choice and access. In particular patients residing in geographic areas where nethadone is not available in a timely manner, or when challenging pharmacy access makes the possibility of alternate-day dosing of buprenorphine-naloxone desirable.  Level III, Grade B)  B. Methadone may be preferred over buprenorphine-naloxone in the following patient populations:  B. Pregnancy (specifically avoiding the naloxone component in the buprenorphine-naloxone combination product). (Level III, Grade A)  C. Clinical situations where opioid withdrawal during induction is particularly nazardous (i.e., cardiovascular instability). (Level III, Grade B)  B. Prior inability to stabilize on buprenorphine-naloxone maintenance treatment.  Level III, Grade B)  B. History of abusing buprenorphine-naloxone via injection. (Level III, Grade A)  B. Patient side effects with or allergy to buprenorphine-naloxone or to excipients including acesulfame. (Level III, Grade A)  B. Patients experiencing dry mouth of severity that would interfere with dissolution and absorption of sublingual buprenorphine-naloxone tablets (dry mouth may be due to indeed effects of concurrent medications, chemotherapy, or conditions causing dry mouth, e.g., Sjogren's syndrome). (Level III, Grade A)  B. Patient choice and access, in particular patients with limited financial resources that make reliable long-term use of buprenorphine-naloxone uncertain. (Level III, Grade B)

			TA	BLE A.15. Sub	stance Use in Pr	egnancy
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
2011	Not specified, but	Literature Review	I: Evidence obtained	Yes.	No.	SCREENING
	likely outpatient		from at least 1 properly RCT.			Identification of Substance-related Disorders in Pregnancy Screening and Assessment/Role of Toxicology Testing
			II-1: Evidence from			Screening and Assessment/Note of Toxicology Testing
			well-designed controlled trials without			All pregnant women and women of childbearing age should be screened periodically for alcohol, tobacco, and prescription and illicit drug use. (III-A)
			randomization.			2. When testing for substance use is clinically indicated, urine drug screening is the preferred method. (II-2A) Informed consent should be obtained from the woman
			II-2: Evidence from well-designed cohort			before maternal drug toxicology testing is ordered. (III-B)
			(prospective or retrospective) or case-control studies, preferably from more			3. Policies and legal requirements with respect to drug testing of newborns may vary by jurisdiction, and caregivers should be familiar with the regulations in their region. (III-A)
			than 1 centre or research group.			Components of Office Management
			II-3: Evidence obtained from			<ol> <li>Health care providers should employ a flexible approach to the care of women who have substance use problems, and they should encourage the use of all available community resources. (II-2B)</li> </ol>
			comparisons between times or places with or without the			5. Women should be counselled about the risks of periconception, antepartum, and post-partum drug use. (III-B)
			intervention.			TREATMENT FOR OPIOID DEPENDENCE
			Dramatic results in uncontrolled			Opioid Dependence/Opioids for CNCP
			experiments (such as the results of treatment with penicillin in the			7. MMT should be standard of care for opioid-dependent women during pregnancy. (II-IA) Other slow-release opioid preparations may be considered if methadone is not available. (II-2B)
			1940s) could also be included in this category.			8. Opioid detoxification should be reserved for selected women because of the high risk of relapse to opioids. (II-2B)
			III: Opinions of respected			See original guidelines for full guidelines including effects of dependence on neonates and breastfeeding considerations.
			authorities, based on clinical experience,			
			descriptive studies,			
			or reports of expert committees.			

TABLE A.15 (continued)						
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
			*Adapted from the Evaluation of Evidence criteria described in the Canadian Task Force on Preventive Health Care.			
			Classification of Recommendations†			
			A. There is good evidence to recommend the clinical preventive action.			
			B. There is fair evidence to recommend the clinical preventive action.			
			C. The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision making.			
			D. There is fair evidence to recommend against the clinical preventive action.			
			E. There is good evidence to recommend against the clinical preventive action.			

	TABLE A.15 (continued)								
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement			
			L. There is						
			insufficient evidence						
			(in quantity or						
			quality) to make a						
			recommendation;						
			however, other						
			factors may influence						
			decision making.						
1. Full	guideline found at http:/	//www.guideline.gov/coi	ntent.aspx?id=33136&sea	rch=(%22naltrexone%2	22+OR+%22buprenorphine%	522+OR+%22methadone%22)#Section420. Many of these guidelines were based			
	a consensus process					•			

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	TABLE A	A.16. Colorado	Division of Wo	orkers' Compe	nsation: Chronic	Pain Disorder Medical Treatment Guidelines
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
2011	Outpatient, licensed methadone and buprenorphine clinics, inpatient	Literature Review	Not rated.	YesFor those medications that were FDA-approved at the time of the guideline's publication.	YesGeneric recommendation.	OPIOID/CHEMICAL TREATMENT PROGRAMS  Chemical dependency, which for worker compensation issues will usually be related to opioids, anxiolytics, or hypnotics as prescribed for the original workers compensation injury, should be treated with specific programs providing medical and psychological assessment, treatment planning and individual as well group counseling and education.  They may be inpatient or outpatient programs, depending upon the level of intensity of services required. Formal treatment programs are appropriate for patients who have more intense (e.g., use extraordinarily excessive doses of prescription drugs to which they have developed tolerance) or multiple drug abuse issues (e.g., benzodiazepines and/or alcohol) and those with complex medical conditions or psychiatric issues drug misuse. A medical physician with appropriate training preferably board certified in addiction medicine, should provide the initial evaluation and oversee the program. Full primary assessment should include behavioral health assessment; medical history; physical examination; mental status; current level of functioning; employment history; legal history; history of abuse, violence, and risk taking behavior; education level; use of alcohol, tobacco and other drugs; and social support system.  Addiction counselors, and other trained health care providers as needed, are involved in the program. Peer and group support is an integral part of the program and families are encouraged to attend. There should be good communication between the program and other external services, external health care providers, Al-Anon, AA and pain medicine providers. Drug screening is performed as appropriate for the individual, minimally initially and at least weekly during the initial detoxification and intensive initial treatment.
						Clear withdrawal procedures are delineated for voluntary, against medical advice, and involuntary withdrawal. Withdrawal programs must have a clear treatment plan and include description of symptoms of medical and emotional distress, significant signs of opicid withdrawal, and actions taken. All programs should have clear direction on how to deal with violence in order to assure safety for all participants. Transition and discharge should be carefully planned with full communication to outside resources. Duration of inpatient programs is usually 4 weeks while outpatient programs may take 12 weeks.  Drug detoxification may be performed on an outpatient or inpatient basis. Detoxification is unlikely to succeed in isolation when not followed by prolonged chemical dependency treatment. Isolated detoxification is usually doomed to failure with very high recidivism rates.  Neither UROD nor rapid-detoxification are recommended due to possible respiratory depression and death and the lack of evidence for long range treatment success.

				TABLE	A.16 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
						TREATMENT FOR OPIOID DEPENDENCE
						Abstinence models are preferred by most chemical dependency treatment programs but are problematic for those chronic pain patients who may require the continued use of opioid analgesics. Methadone, buprenorphine, or buprenorphine-naloxone are usually the first-line agents for treating such patients; however, continued use in an outpatient setting of methadone for opioid dependency requires dispensing by a licensed methadone clinic and buprenorphine, for the same purpose, by a physician possessing a special DEA license. As of the time of this guideline writing, some formulations of buprenorphine-naloxone have been FDA-approved for the treatment of opioid dependence. It is strongly recommended that the use of either drug for the purpose of treating chronic pain be limited to physicians with additional training. In the case of methadone, there are increasing numbers of inadvertent deaths due to misuse, including prescribing errors. In the case of buprenorphine, its use as an analgesic is not currently FDA-approved and conversion to this drug from other opioids is difficult. It should never be a first-line analgesic for chronic pain due to high cost and the presence of other opioids that may be more effective for moderate-to-severe chronic pain.
						DETOXIFICATION  Tapaging explaids an an outpatient basis requires a highly metivated nations and
						Tapering opioids on an outpatient basis requires a highly motivated patient and diligent treatment team and may be accomplished by decreasing the current dose 10%/day or week. Tapering should be accompanied by addiction counseling. Failing a trial of tapering a patient should be sent to a formal addiction program. When the dose has reached one-third of the original dose, the taper should proceed at half or less of the initial rate. Doses should be held or possibly increased if severe withdrawal symptoms, pain, or reduced treatment failure otherwise occurs. This method is tedious, time consuming and more likely to fail than more rapid and formalized treatment programs.  Refer to the original guideline document for time to produce effect, frequency,
						and optimum/maximum duration of programs.
1. Full	guideline can be found	at http://www.guideline.	gov/content.aspx?id=38	3441&search=(%22nalt	rexone%22+OR+%22bupren	orphine%22+OR+%22methadone%22). Many of these guidelines were based upon a

1. Full guideline can be found at <a href="http://www.guideline.gov/content.aspx?id=36441&search=(%22naltrexone%22+OR+%22buprenorphine%22+OR+%22methadone%22]">http://www.guideline.gov/content.aspx?id=36441&search=(%22naltrexone%22+OR+%22buprenorphine%22+OR+%22methadone%22]</a>. Many of these guidelines were based upon consensus process informed by the literature reviews.

		TABLE A			the Biological Trea , Part 2: Opioid De	atment of Substance Use and ependence
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
2011	Outpatient, inpatient	Literature Review	A. Full Evidence From Controlled Studies is based on:  2 or more double- blind, parallel- group, RCTs showing superiority to placebo (or in the case of psychotherapy studies, superiority to a "psychological placebo" in a study with adequate blinding). AND 1 or more positive RCT showing superiority to or equivalent efficacy to established comparator treatment in a 3- arm study with a placebo control or in a well-powered non-inferiority trial (only required if such a standard treatment exists).	Yes. Also includes heroin-assisted treatment, lofexide and clonidine, which are not FDA-approved.	The following options are mentioned, with a stated variation in the strength of the evidence in support of the options: CM, CBT, family therapy, relapse prevention, self-help groups. MMT can be enhanced when combined with CM, whereas there is no indication that CM increases the efficacy of BMT.	Recommendation: Methadone is the standard medication for the treatment of opioid dependence (RG1). Its efficacy can be enhanced when combined with CM (RG1).  Injectable methadone has occasionally been used in the treatment of opioid dependence (Hartnoll et al. 1980; Strang et al. 2010), but the results are disappointing (Strang et al. 2000, 2010). This form will, therefore, not be discussed further in these practice guidelines.  Recommendation: There is compelling evidence for the efficacy of heroin-assisted treatment in treatment refractory, opioid-dependent patients (3). Based on data from Switzerland (Uchternhagen 2010) and the Netherlands (Blanken et al. 2010), it appears that heroin-assisted treatment can be implemented routinely in medical settings. Further study of this treatment is needed. Despite ethical concerns among both scientists and the lay public over heroin substitution, such treatment is routine in some countries.  Recommendation: Buprenorphine and buprenorphine-naloxone are standard medications for the treatment of opioid dependence (1). Whether the combination of buprenorphine and naloxone has advantages over buprenorphine alone requires empirical validation. There are no indications that adding CM to BMT enhances its effectiveness (1).  Recommendation: Oral naltrexone is not a first-line treatment for opioid dependence (1). However, oral naltrexone might be effective in a small subgroup of highly motivated and well-integrated patients (3). Retention in naltrexone treatment is usually poor.  DETOXIFICATION  Recommendation: Methadone is a standard and safe medication for opioid detoxification (1).  Recommendation: Deprenorphine is a standard and safe medication for opioid detoxification (Kleber et al. 2007; NICE 2007) (RG1).

			TABLE	A.17 (continued)	
Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
		In the case of existing negative studies (studies showing non-superiority to placebo or inferiority to comparator treatment), these must be outweighed by at least 2 additional positive studies or a meta-analysis of all available studies showing superiority to placebo and non-inferiority to an established comparator treatment.  Studies must fulfil established methodological standards. The decision is based on the primary efficacy measure.  B. Limited Positive Evidence From Controlled Studies is based on:  1 or more RCTs showing superiority to placebo (or in			Rapid-detoxification using naltrexone in combination with clonidine  Recommendation: There is no convincing evidence for the use of the combination of opioid antagonists plus clonidine under heavy sedation. Given the lack of evidence for a substantial advantage of this approach, the associated risks and costs do not appear to be justified.  Pregnancy:  Recommendation: During pregnancy, detoxification should be avoided, especially in the first trimester (RG4). Methadone and buprenorphine are effective and safe in the treatment of opioid-dependent pregnant women.  Use of multiple substances by opioid-dependent individuals  Recommendation: Increasing the dosage of methadone or buprenorphine, particularly in conjunction with CM, are generally effective in the treatment of cocaine use by opioid dependent individuals (RG4).  Excerpted table:  Table II. Categories of evidence (CE) and grade of recommendation (RG) for pharmacological treatments in opioid dependence.  Medication and CE RG Typical recommended daily dose for adults  Abuse and dependence  Methadone A 1 40-100mg  Buprenorphine-naloxone A 1 4-16mg  Buprenorphine-naloxone A 1 4-16mg  Naltrexone B 3 50mg  Heroin B 3 200-600mg  Withdrawal  Methadone A 1 40-100mg initial  Buprenorphine-naloxone A + 4-16mg initial  Buprenorphine-naloxone A + 4-16mg initial  Buprenorphine-naloxone A + 4-16mg initial  Buprenorphine-naloxone C 4 1.6-3.2mg  Naltrexone under general anesthesia D 5
	Care Setting	Care Setting	and Rating Scale Definition  In the case of existing negative studies (studies showing non-superiority to placebo or inferiority to comparator treatment), these must be outweighed by at least 2 additional positive studies or a meta-analysis of all available studies showing superiority to placebo and non-inferiority to an established comparator treatment.  Studies must fulfil established methodological standards. The decision is based on the primary efficacy measure.  B. Limited Positive Evidence From Controlled Studies is based on:  1 or more RCTs showing superiority to placebo (or in	Guideline Source of Information¹  Statement Grade and Rating Scale Definition  In the case of existing negative studies (studies showing non-superiority to placebo or inferiority to comparator treatment), these must be outweighed by at least 2 additional positive studies or a meta-analysis of all available studies showing superiority to placebo and non-inferiority to an established comparator treatment.  Studies must fulfil established methodological standards. The decision is based on the primary efficacy measure.  B. Limited Positive Evidence From Controlled Studies is based on:  1 or more RCTs showing superiority to placebo (or in	Care Setting    In Maring Scale Definition    In the case of existing negative studies (studies showing non-superiority to placebo or inferiority to comparator treatment), these must be outweighed by at least 2 additional positive studies showing superiority to placebo and non-inferiority to placebo and non-inferiority to an established comparator treatment.  Studies must fulfil established methodological standards. The decision is based on the primary efficacy measure.  B. Limited Positive Evidence From Controlled Studies is based on:  1 or more RCTs showing superiority

				TABLE	A.17 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
			A randomized controlled comparison with a standard treatment without placebo control with a sample size sufficient for a non-inferiority trial. AND In the case of existing negative studies (studies showing non-superiority to placebo or inferiority to comparator treatment), these must be outweighed by at least 1 additional positive study or a meta-analysis of all available studies showing superiority to placebo or at least 1 more randomized controlled comparison showing non-inferiority to an established comparator treatment.  C. Evidence from Uncontrolled Studies or Case Reports/Expert Opinion  C1. Uncontrolled studies is based			
j			on:			

				TABLE	A.17 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
			1 or more positive naturalistic open studies (with a minimum of 5 evaluable patients). OR A comparison with a reference drug with a sample size insufficient for a non-inferiority trial. AND No existing negative controlled studies.  C2. Case reports is based on: 1 or more positive case reports AND No existing negative controlled studies.  C3. Based on the opinion of experts in the field or clinical experience.  D. Inconsistent results:  Positive RCTs are outweighed by an approximately equal number of negative studies.  E. Negative			
			E. Negative evidence:			

	TABLE A.17 (continued)									
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement				
			The majority of RCTs or exploratory studies show non-superiority to placebo (or in the case of psychotherapy studies, non-superiority to a "psychological placebo") or inferiority to comparator treatment.							
			F. Lack of evidence Adequate studies proving efficacy or non-efficacy are lacking.							
			Recommendation Grade (RG)							
			Based on:  1. Category A evidence and good risk-benefit ratio.							
			Category A     evidence and     moderate risk- benefit ratio.							
			3. Category B evidence.							
			4. Category C evidence.							
1. Full q			5. Category D evidence.			onsensus process informed by the literature reviews.				

		TABLE A.18	8. NOUGG: Can	adian Guidelin	e for Safe and Eff	ective Use of Opioids for CNCP
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
2010	Not specified	Literature	Canadian	Yes.	No.	TREATMENT FOR OPIOID DEPENDENCE
		Review	Guideline			Cluster 5: Managing Opioid Misuse and Addiction in CNCP Patients
			Recommendation			5
			Grading			For patients with CNCP who are addicted to opioids, 3 treatment options
			Out de A			should be considered: methadone or buprenorphine treatment ( <b>Grade A</b> ),
			Grade A:			structured opioid therapy ( <b>Grade B</b> ), or abstinence-based treatment
			Recommendations			( <b>Grade C</b> ). Consultation or shared care, where available, can assist in selecting and implementing the best treatment option ( <b>Grade C</b> ).
			are supported by evidence from			selecting and implementing the best treatment option ( <b>Grade C</b> ).
			RCTs.			Relevant section excerpted above. See original guidelines for full
			NOTS.			guidelines.
			Grade B:			
			Recommendations			
			are supported by:			
			Evidence from			
			controlled trial(s)			
			without			
			randomization.			
			OR			
			Evidence from			
			cohort or case-			
			control analytic			
			studies, preferably			
			from more than 1 centre or research			
			group.  OR			
			Evidence from			
			comparisons			
			between times or			
			places with or			
			without the			
			intervention;			
			dramatic results in			
			uncontrolled			
			experiments could			
			be included here.			

	TABLE A.18 (continued)									
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement				
			Grade C:							
			Recommendations							
			are supported by							
			consensus opinion							
			of the National							
			Advisory Panel.							
1. Full	guideline can be fou	nd at http://www.guio	deline.gov/content.aspx	id=35111&search=</td <td>(%22naltrexone%22+OR-</td> <td>+%22buprenorphine%22+OR+%22methadone%22). Many of these</td>	(%22naltrexone%22+OR-	+%22buprenorphine%22+OR+%22methadone%22). Many of these				
guid	lelines were based u	pon a consensus pro	cess informed by the li	iterature reviews.		, ·				

	TABLE A.19. New York State Department of Health: Preconception Care for HIV-Infected Women									
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement				
2010	Not specified; several settings inferred	Literature Review	Rating information provided, but not connected to footnote.	Yes.	No.	b. For opioid-dependent pregnant women, MMT is effective therapy, does not adversely affect fetal or post-natal development, and is preferred to detoxification.  (Above is a footnote of a table).				
4 5 "				1 (2/ 22 1/	0/00 00 0/00/	ornhine%22+0R+%22methadone%22) Many of these guidelines were hased upon a				

<sup>1.</sup> Full guideline can be found at http://www.guideline.gov/content.aspx?id=24033&search=(%22naltrexone%22+OR+%22buprenorphine%22+OR+%22methadone%22). Many of these guidelines were based upon a consensus process informed by the literature reviews.

		TABI	LE A.20. VDH/A	ADAP OVHA: \	/ermont Buprenor	phine Practice Guidelines
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
2010	Office-based	Other (collaborative effort of VDH, ADAP, OVHA and local treatment providers)	Not rated.	Yes.	YesSuggested: CBT, Motivation Enhancement Therapy, Dialectical Behavioral Therapy.	Excerpts:  Psychosocial Treatment-Related:  To qualify for a [DATA 2000] waiver, the physician must have the capacity to refer patients for appropriate counseling and other services that might be needed in conjunction with buprenorphine treatment. These services include the following:  Different levels of chemical dependency treatment services Psychiatric consultation Consultation for medical co-morbidities 12 Step program  Physicians should expect that clinicians to whom they refer their buprenorphine treated patients will have been trained in evidence-based therapies such as CBT, Motivation Enhancement Therapy, Dialectical Behavioral Therapy, etc.  Buprenorphine:  The following 2 available buprenorphine medications are both dissolved sublingually: Subutex is a mono-therapy containing only buprenorphine. It is available from a pharmaceutical house in small supply to be kept in physicians' offices. It may be used for induction but is not necessary for this.  2. Suboxone is a combination therapy, containing both buprenorphine and naloxone. Naloxone has been added to avoid diversion and IV abuse. Suboxone is the recommended preparation for induction, maintenance, and, if necessary, supervised withdrawal (detoxification).  To minimize diversion of buprenorphine, especially the mono-therapy product, it is recommended that Subutex only be used during the management of pregnant, opioid dependent women or in the extremely rare occurrence of allergy or intolerance to Suboxone (not just because the patient does not like the taste of Suboxone).  Treatment Settings:  Office-Based Practice Care may be provided by a solo practitioner or a group practice with the required training and ability to provide clinical evaluation, buprenorphine induction, maintenance and follow-up. The practitioner or group also must be able to provide consultation and referrals as needed with Primary Care Providers and medical specialists. Some practitioners may be able to provide all services on their own (e.g., an addictions psychiatrist with bu

				TABLE	A.20 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
						OTPs may provide Subutex or Suboxone following the same regulations that exist for methadone treatment (42 CFR Part 8: Code of Federal Regulations, Title 42: Public Health, Part 8Certification of OTPs, http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr;sid=d5f2d13f11085410f289dd08209805f4;rgn=div5;view=text;node=42% 3A1.0.1.1.9;idno=42;cc=ecfr), including a take-home schedule in which buprenorphine is dispensed from the window without giving a prescription. Due to the long-acting nature of buprenorphine, multiple day dosing can occur 2-3 times per week. Buprenorphine is part of the OTP's DEA registration, not an individual physician's; consequently, physicians working in OTPs do not have to seek a waiver or complete the 8 hour training. In addition, these programs are exempt from the 30 patient limit.
						Screening/Intake:
						Initial screening for opioid addiction should consist of a combination of interviews, objective screening instruments and laboratory evaluations (see Appendices B-I and B-II for examples of screening and assessment tools that may help determine how appropriate a patient is for office-based treatment), and include the following:
						Medical history with attention paid to liver and cardiac status and medications.  Psychiatric history with attention to current compliance with medications.
						Substance abuse history and treatment history to identify whether patient was ever on buprenorphine and to insure patient is not currently on methadone but meets criteria for Opiate Dependence (see Appendix A, DSM-IV Diagnosis of Opiate Dependence). If a patient reports they have been using buprenorphine obtained on the street, and even provides the dose they have been taking, they still should go through the induction process to determine the appropriate clinical dose.
						Social, work, and family circumstances history.
						Physical exam, mental status exam.
						Lab screening for ALT, AST, hepatitis B and C, HIV, gonorrhea, chlamydia, syphilis, TB test. Urine screen (witnessed) with attention to opiates, including methadone and buprenorphine, and benzodiazepines.
						If urine is negative for opiates (which may occur with synthetic opiates), evidence of IV puncture marks on the skin and evidence of withdrawal symptoms, such as runny eyes, sniffling, yawning, tremor, sweating, gooseflesh, vomiting, abdominal cramps, muscle aches, pupil dilation. The CINA Scale for withdrawal symptoms can be very useful (see Appendix D).

	TABLE A.20 (continued)										
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement					
						In some cases, dependence may be diagnosed through the use of 1cc of naloxone (Narcan) (0.4mg/ml) injected subcutaneously followed by observing the patient for up to 30 minutes for evidence of precipitated withdrawal. Naltrexone (ReVia) would not be used due to the protracted withdrawal syndrome it causes.  Sometimes a patient previously detoxed from opiates will present for treatment due to high risk of returning to opiate use. Examples include individuals recently released from prison. Physicians are encouraged to consult with a substance abuse counselor or addiction specialist in these cases.  11. Women using illicit opioids may experience menstrual cycle irregularity and infertility. Unplanned pregnancy can occur as women recover and improve their health status. As opioid agonist therapy is initiated, the potential for pregnancy should be addressed and a plan for contraception developed. If pregnancy is desired, women should receive a prescription for prenatal vitamins (for additional folic acid).  Possible Indications of Less Appropriate Candidacy. Certain factors may suggest a patient is LESS likely to be an appropriate candidate for office-based buprenorphine treatment (see Appendices B-I and B-II for criteria and guidelines for assessing candidacy). Some factors to consider include the following:  Dependence on high doses of benzodiazepines, alcohol, or other CNS depressants Significant psychiatric co-morbidity Active or chronic suicidal or homicidal ideation or attempts Multiple previous treatments and relapses Non-response to buprenorphine in the past High level of physical dependence (risk for severe withdrawal) High relapse risk Pregnancy Current medical conditions that could complicate treatment Poor support systems Patient needs cannot be addressed with existing office-based resources  **TREATMENT FOR OPIOID DEPENDENCE**  II. Induction  Induction onto buprenorphine is considered to be an ambulatory procedure not requiring an inpatient admission unless there are medical complications or other exten					

				TABLE	A.20 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
						Begin induction early in the week.
						Plan on 3-5 days for stable dosing.
						Patient's last reported use should have been at least 6 hours prior to induction.
						MAKE SURE THE PATIENT IS NOT ON METHADONE as buprenorphine may cause an acute withdrawal syndrome; if patient is on methadone, see below protocol for long-acting opiates.
						Day 1: Give the patient a prescription for #2 2mg Suboxone tablets.
						Patient takes the prescription to the pharmacy and returns to the office with the medication.
						Patient takes the tablet and lets it dissolve under the tongue for 5 minutes with no talking, drinking, or swallowing.
						Target buprenorphine dose range should be 12-16mg/day, with a recommended maximum of 16mg daily.
						If more than 8mg are needed, gradually increase the dose in 2mg increments over the next several days.
						The patient's condition before dosing time is 1 of the best ways to assess adequacy of the dose. (Refer to Appendix E: COWS, for assessing withdrawal symptoms before the first dose is given and throughout the Induction period.
						Guidelines for patients NOT physically dependent on opioids (e.g., coming out of incarceration or otherwise high risk for relapse):
						First dose: 2mg sublingual buprenorphine.  Monitor for 2+ hours and consider 2mg incremental dosage increases over the next several days.
						Note: See original guidelines for specific guidelines for treating patients dependent on short-acting opioids and long-acting opioids.
						III. Stabilization
						Patient should receive daily dose until stabilized.
						An option is to shift to alternate-day dosing, by increasing the amount on the dosing day by the amount not received on the intervening days (see #5 below).
						Urine screens should be done once a week.

				TABLE	A.20 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
		of Information <sup>1</sup>		Medications	Treatment	Non-attendance for counseling for more than 2 consecutive sessions should trigger an automatic call from the counselor. The physician should schedule an office visit with the patient to make sure the patient understands that failure to follow through with counseling jeopardizes treatment and puts them outside of "good standing."  Write 7 days' worth of medication at a time for 2 months.  IV. Maintenance and Follow-Up  Once patient has remained compliant with counseling and physician visits, has not had any mishaps with the Suboxone, and feels ready to do so, extend the prescriptions to 14 days for the next 2 months.  A patient may choose to take Suboxone every 2-3 days. The dose is doubled or tripled, depending on the time frame, and taken all at once. This is very effective in controlled settings, such as dispensing by a family member or clinic, but may be done for patient preference only.  After a period of time that varies with each patient but should reflect compliance with treatment, a prescription for 30 days may be written. Pill counts may be a useful monitoring tool at this point.  Urine drug testing is now available for determining the presence of the buprenorphine metabolite and this may be used as a clinical tool to encourage success in treatment, as well as a precautionary measure for avoiding diversion.  Note: See original guidelines for guidelines on tapering patients off of buprenorphine.  DETOXIFICATION  VI. Detoxification  Rapid-detox: 3 days or less.  Low doses of buprenorphine given 2-3 times daily.  More effective in suppressing withdrawal than clonidine.  Long-term efficacy not well documented.  Not recommended due to poor outcomes and should only be done when there is a compelling reason for patient to be detoxed quickly (e.g., out of country travel, imminent incarceration).  Moderate detox: 30 days or less.  Raise dose daily over 4 days to equal opiates taken, then decrease by 2mg every 1-2
						days until weaned.  Better tolerated than clonidine. Few studies of buprenorphine for this time period.

	TABLE A.20 (continued)									
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement				
						Long detox: more than 30 days.  Raise dose daily over 4 days to equal opiates taken, then reduce by 2mg weekly until weaned.  Not well studied but some evidence suggests this approach is more efficacious than				
4 5 11					1: 5 : 0:1: 5	briefer ones, especially if naltrexone is started after an appropriate wash out period.				
, 1. Full (	guideline can be found :	at <u>http://www.healthverr</u>	<u>mont.gov/adap/treatmer</u>	<u>nt/documents/Buprenor</u>	phinePracticeGuidelinesFINA	L_U1-15-2U1U.pdf.				

	TABLE A.21. Commonwealth of Australia: National Guidelines for MAT for Opioid										
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement					
2014	Generalist settings (general practice and hospital, clinic or community settings not specialized in treatment of alcohol and other drug problems)	of Information Literature Review	***** Body of evidence can be trusted to guide practice  **** Body of evidence can be trusted to guide practice in most situations  *** Body of evidence provides some support for recommendation(s) but care should be taken in its application  * Body of evidence is weak and recommendations must be applied with caution  (C) Recommendations based on a consensus of clinical experience.  (S) Recommendations reflecting a standard of care that should be routine in competent clinical	Yes. Also clonidine, which is not FDA-approved.	YesCognitive and behavioral approaches and CM can increase effectiveness of MAT. Financial management/advice and participation in self-help groups also encouraged.	ASSESSMENT EXCERPT  Co-existing health and psychosocial conditions are likely to influence the preferred treatment approach, setting and broad (holistic) treatment plan, including the need for specialist advice or referral (\$).  The clinician should assess general health and well-being, targeted within the context of the patient's substance use. Opioid and other substance use is commonly associated with a range of:  Physical conditions (e.g., chronic non-malignant pain, liver, cardiovascular, injecting related infections, endocrine).  Psychiatric conditions (e.g., anxiety, depression, cognition).  Social problems (e.g., unemployment, housing, financial, relationships).  High-risk behaviours (e.g., overdose, self-harm, child protection and domestic violence).  Treatment Planning Excerpt:  As in other areas of chronic disease management, addiction treatment planning should:  Be a continuous process.  Involve the patient and reflect the patient's circumstances and case complexity.  Be based on coordinated care across service providers to address multiple domains.  Be documented so as to be meaningful to the patient, their carers and other service providers (\$).  All types of available treatment for opioid dependence should be considered in consultation with the patient, taking into account the patient's circumstances and treatment preferences, and be based upon the evidence of effectiveness and safety of available options (\$).  The principles of informed consent should be observed in selecting and referring patients to treatment services (\$).  A stepped care approach to treatment delivery suggests using less restrictive treatment approaches for those with low severity dependence (e.g., detoxification,					
			routine in			A stepped care approach to treatment delivery suggests using less restrictive					

				TABLE A	A.21 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
			Definition  ◆ is used to indicate areas where caution is required and specialist advice or referral is recommended.  Note: symbols used are different from original guideline's symbols (e.g., asterisks instead of stars).			Certain medical and psychiatric conditions (e.g., chronic pain, psychotic disorders, acute medical conditions such as infective endocarditis, HIV) can be destabilized during detoxification and attempts at sustaining an opioid-free lifestyle; such patients are often better directed to opioid substitution treatment.  Women who are opioid-dependent and pregnant should usually be directed to opioid substitution treatment due to the risk of antenatal complications associated with detoxification, and high rates of relapse to heroin or other opioid use with other treatment approaches.  People with a preference for abstinence-based interventions who are well supported and well motivated are more likely to respond to counselling with or without naltrexone.  People with poor living skills.  DETOXIFICATION EXCERPTS  Detoxification in opioid dependence should always be considered as part of a structured treatment approach (C).  Settings for Withdrawal Excerpt:  Management of withdrawal may occur in a range of settings:  Hospitals, particularly when drug users have been admitted for other reasons.  Residential services, which provide a safe, supportive environment for withdrawal management, but a lower level of medical care than hospitals.  Ambulatory (outpatient and/or home-based services) for those individuals with stable social settings and without significant medical or psychiatric complications or dependence on other drugs.  Selection of setting and approach to detoxification should take into account the goal of the care episode, the purpose of detoxification and timescale (S).  Intensive inpatient care is appropriate with:  Unstable medical or psychiatric condition.  Polydrug dependence.  History of medical or psychiatric conditions, or uncertain past drug use indicate a need for close monitoring.  Supported residential care, such as a community withdrawal unit, is appropriate with:
						<ul> <li>Unsupportive home environment, such as with other drug users, or without anyone reliable to supervise and support the patient.</li> <li>Repeated failure at outpatient withdrawal.</li> </ul>

				TABLE	A.21 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
Year	Care Setting		and Rating Scale			Psychosocial Support Excerpt:  Psychosocial support during the withdrawal episode should be aimed specifically at helping the patient through problems associated with withdrawal and in facilitating post-withdrawal links.  Patient Information Excerpt:  Patients need information regarding:  • The risk of overdose should they relapse after withdrawal as well as approaches to prevent and manage overdose.  • The nature and duration of withdrawal symptoms.  • Strategies for coping with symptoms and cravings.  • Strategies to manage high-risk situations.  • The role of medication.  Medication Approaches for Withdrawal Excerpt:  Two distinct medication approaches are recommended for the management of opioid withdrawal:  • Abrupt cessation of opioid use and symptom amelioration using non-opioid drugs (usually benzodiazepines, NSAIDs, antiemetics, clonidine, antispasmodic drugs (such as hyoscinebutylbromide) for relief of symptoms.  • Short-course (usually less than 1 month) of reducing doses of buprenorphine.  Both of these approaches are well supported by evidence, but the use of buprenorphine to manage withdrawal is associated with significantly better amelioration of withdrawal than clonidine and supplementary medications (****). It is the most flexible approach in that it supports cessation of medication with minimal rebound withdrawal symptoms while also enabling transfer to naltrexone for relapse prevention treatment, or to substitution treatment if the detoxification attempt is not successful.  The appropriate starting dose of buprenorphine and duration of withdrawal treatment will vary according to the clinical presentation of each individual. In general, higher doses and longer duration of treatment would be preferred in outpatient settings where the risk of unsanctioned opioid use is greater.
						The first dose of buprenorphine should be administered once mild withdrawal is apparent to avoid the risk of precipitated withdrawal.

	TABLE A.21 (continued)										
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement					
						There is research evidence for the use of reducing doses of methadone for the management of opioid withdrawal, but the duration of tapered methadone withdrawal interventions tend to be greater than a month, blurning the line between withdrawal management and substitution treatment. While research evidence directly comparing methadone and buprenorphine for the management of opioid withdrawal remains limited, the flexibility of buprenorphine provides advantages in a withdrawal context.  Detoxification can also be achieved using opioid antagonists (naltrexone and/or naloxone), also known as antagonist-induced withdrawal or rapid-detoxification. This approach should only be considered as a means of facilitating induction of naltrexone to support relapse prevention treatment. Antagonist-induced withdrawal with minimal sedation is feasible, but the evidence base is weak (**). Specialist referral is recommended. Antagonist-induced withdrawal should only be provided in facilities that have the capacity to retain people as inpatients in the event of severe withdrawal, and only following approval by that facility's drug review committee or other formal approval mechanism. Patients should be properly informed, and consent obtained, which includes information that the use of naltrexone is an off-label indication.  TREATMENT FOR OPIOID DEPENDENCE EXCERPTS  Choice of Medication Excerpt:  A substantial body of research evidence supports a conclusion that both methadone and buprenorphine are safe and effective in the treatment of opioid dependence (*****). The choice between methadone or buprenorphine for opioid substitution treatment should be made in consultation with the patient, and informed by the patient's preference and goals. However, there are factors that indicate particular directions, as summarized below.  It is easier to transition in and out of treatment with buprenorphine compared to methadone. This is both an advantage in terms of greater patient flexibility, and a disadvantage with lower rates of retention in					

	TABLE A.21 (continued)										
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement					
						Some patients report that methadone has greater impact upon cognition than buprenorphine, with stronger sedation and opioid-like subjective effects (*). This can be a therapeutic advantage for some patients with concurrent psychological distress. In contrast, many patients describe greater "clarity of thought" with buprenorphine—an advantage for patients requiring good cognitive function (e.g., those employed, caring for children, studying, driving, elderly patients with other conditions affecting cognition, and patients taking other sedative medications).  Methadone has greater sedating effects and is more commonly associated with overdose than buprenorphine, particularly in the context of:  (a) The first 2 weeks of treatment as tolerance increases (***).  (b) In combination with other sedatives (alcohol, benzodiazepines) (*).  (c) Use by individuals for whom the medication was not prescribed—in particular children and other opioid-naïve individuals (****). Consequently buprenorphine should be the preferred medication where there is limited opportunity for monitoring or supervision of dosing.  Induction of substitution treatment with buprenorphine is usually safer and easier with maintenance doses reached more quickly than is the case with methadone (***). However, precipitated withdrawal can be an issue if buprenorphine is commenced too soon after the last use of a full opioid agonist, and this can be a barrier for some patients commencing and engaging in treatment (**).  Induction Excerpt:  The goal of the first month of treatment is to safely achieve an adequate dose of medication, stabilise the patient's opioid use, and to address co-existing conditions (C).  Key objectives of the induction dose regimen are:  Reduction of withdrawal symptoms.  Reduction of cravings.  Reduced unsanctioned opioid and other drug use.  Patient satisfaction and engagement in treatment.  The differing pharmacological properties of methadone and buprenorphine mean that induction with methadone necessitates commencing at a low do					
						Key principles:					

				TABLE A	A.21 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
						1. Methadone is sedating and can cause overdose in too high doses, particularly in those with low opioid tolerance, and in combination with other sedatives, or in those with altered pharmacokinetics (e.g., due to hepatic failure, drug interactions).  2. The elimination half-life of methadone is typically in the range 24-48 hours, but extremes either side of this range have been recorded. Methadone accumulates in the plasma during induction, with achievement of steady state equilibrium on a dose after approximately 3-5 half-lives (4-7 days). Patients should be told to expect increasing opioid effects after each dose during this time.  3. Methadone has a delayed onset of action—with peak effects achieved 2-4 hours after dosing. Patients should be cautious in using other drugs (e.g., benzodiazepines, alcohol) during initiation of methadone treatment. Patients should be assessed 2-3 hours after a dose to observe the peak effects of methadone (assessing for intoxication), and 24 hours after a dose to assess the extent to which methadone dose is preventing withdrawal.  (a) Recommended regimen for outpatients with unsanctioned use of opioids (excerpt):  • The opioids involved are likely to include heroin, and injected morphine, and codeine.  • All doses of methadone should be supervised, where possible, and a clinician (doctor, nurse, pharmacist) should review the patient daily during the first week of treatment, corresponding to the greatest risk period for methadone-related overdose. The review provides an opportunity to assess intoxication (e.g., sedation, constricted pupils) or withdrawal symptoms, side effects, other substance use and the patient's general well-being.  • Commence with 20-30mg daily. Lower doses (e.g., 20mg or less) are suited to those with low or uncertain levels of opioid dependence, with high-risk polydrug use (alcohol, benzodiazepines) or with severe other medical complications. Higher doses (30-40mg) should be considered with caution if clinically indicated, at the discretion of the prescrib

				TABLE A	A.21 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
		of information.	Definition	Medications	Heatment	<ul> <li>The dose should be gradually increased in order to achieve cessation (or marked reduction) in unsanctioned opioid use, and alleviation of cravings and opioid withdrawal features between doses, whilst minimising methadone side effects. Daily methadone doses above 80mg will also markedly reduce the effects of any ongoing heroin or other opioid use.</li> <li>Consider specialist advice or referral in the following circumstances ◆:         <ul> <li>Patients with an unclear level of opioid tolerance, high-risk polydrug use, concomitant physical conditions or use of other medications that may affect the metabolism of methadone.</li> <li>Patients seeking higher and more rapid dose increases (inpatient settings with close monitoring may also be helpful).</li> <li>Patients who have difficulty stabilising on a dose of methadone due to continued substance use, side effects or other complications.</li> </ul> </li> <li>When deciding on induction of methadone, take account of pharmacy availability for supervision of dosing and monitoring of response. If 7-day pharmacy services are not available, the commencement of treatment should be timed so that induction is well underway before the first day of unsupervised dosing.</li> <li>Buprenorphine Excerpt:</li> <li>Key principles:         <ul> <li>1. Patients choosing buprenorphine should be commenced on the combination preparation (buprenorphine-naloxone) unless pregnant or breastfeeding or with a proven allergy to naloxone. This is an abuse deterrent strategy as buprenorphinenaloxone combination preparations are less likely to be injected than mono preparations containing only buprenorphine (**). Furthermore, it is easier to supervise the dosing of the film preparation, compared to tablets, of buprenorphine-naloxone.</li> <li>2. As a partial agonist, buprenorphine is a safer opioid than methadone with regard to the potential for over-sedation, respiratory depression and overdose.</li></ul></li></ul>

				TABLE /	A.21 (continued	)
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
						<ul> <li>4. The general principle for safe induction is that the first dose of buprenorphine should be delayed until there is incipient withdrawal (***) as assessed by a suitably trained clinician or measured by a validated scale or scales that assess both objective signs and subjective symptoms (e.g., the COWS).</li> <li>(a) Recommended induction regimen for outpatients using heroin and/or short-acting pharmaceutical opioids.</li> <li>Initial doses should be supervised, and a clinician (doctor, nurse, pharmacist) should review the patient daily during the first few days of treatment while the dose is stabilised. The review provides an opportunity to assess intoxication (e.g., sedation, constricted pupils) or withdrawal symptoms, side effects, other substance use and the patient's general well-being.</li> <li>Defer the first dose of buprenorphine until the patient is experiencing mild to moderate withdrawal (anxiety, abdominal or joint pain, dilated pupils, sweating). The use of a validated rating scale such as COWS can be helpful: - For the patient with mild withdrawal (subjective symptoms but no signs of opioid withdrawal that would produce a score less than 8 with the COWS), provide an initial dose of 4mg, with the possibility of a subsequent dose of 4mg after 1-2 hours ('split dosing' reduces the risk of precipitated withdrawal) For the patient with moderate or severe withdrawal at the time of the first dose, an initial dose of 8mg is appropriate Lower doses (e.g., 2-4mg total on day 1) are suited to those with low or uncertain levels of opioid dependence, with high-risk polydrug use (alcohol, benzodiazepines) or with other severe medical complications. Seek specialist advice if concerned (C). ◆</li> <li>Delivering Safe and Effective Agonist Maintenance Treatment Excerpt:</li> <li>Patient input to treatment decisions, including determination of dosing levels, promotes a good therapeutic relationship by enhancing patient trust and self-responsibility. Doses should be tailored to each patient, adjusting</li></ul>
						Side effectsmany opioid side effects subside in the first 2-4 weeks of treatment, but some are persistent and may require dose adjustment (seek specialist advice if uncertain).  Continued drug useincreasing doses of methadone or buprenorphine is often an effective response to unsanctioned opioid use, but has a limited role in addressing use of other drugs (e.g., alcohol, cannabis, benzodiazepines, stimulants).
						Patient report of dose adequacy and treatment goals.

				TABLE	A.21 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
			Definition 1			Methadone Excerpt:  Adjust doses by 5-10mg at a time, as needed, with at least 3 days between each dose adjustment.  Methadone in doses of 60mg/day or greater is more effective than lower doses in terms of retention in treatment, reduction in unsanctioned opioid use and associated high-risk behaviours (****).  Most patients require methadone doses in the range 60-120mg/day to achieve stabilisation and this should be regarded as an appropriate range for maintenance doses. A small proportion of patients may require higher (e.g., up to 150mg/day) or lower (e.g., 30-40mg/day) doses to achieve their treatment goals. Doses above 150mg/day are generally associated with little additional benefit and increase the risk of dose-related adverse events (C). Specialist referral is recommended for patients seeking methadone doses greater than 150mg/day (C) for an investigation of the reasons for the high dose requirement. ◆ There may also be jurisdictional requirements for approval of doses greater than 120mg/day.  Buprenorphine Excerpt:  Adjust doses by 2-8mg at a time as needed. Evidence indicates that buprenorphine doses of 8-16mg are superior to lower doses in terms of retention in treatment, reduction in unsanctioned opioid use, and associated high-risk behaviours (****).  Most patients require daily buprenorphine doses in the range 12 -24mg to achieve stabilisation, although some patients require higher (e.g., up to 32mg/day) or lower (4-8mg/day) doses to achieve their treatment goals. Doses greater than 16mg are associated with increased duration of action, with little or no increase in the degree of opioid effect. The maximum possible dose of 32mg is a regulatory and manufacturer's limit (R). Higher doses may be associated with dose-related adverse events; specialist consultation is recommended for patients seeking doses greater than 32mg. ◆  The characteristics of buprenorphine allow a wide range of dosing regimens, from several times daily to once every 2-3 days. The main reasons for considering reduced frequency d

				TABLE A	A.21 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
						RELAPSE PREVENTION
						Naltrexone Excerpt:
						The evidence on the effectiveness of naltrexone maintenance treatment is limited by low rates of retention in studies, and the small number of comparable studies. Current evidence indicates no significant difference in treatment retention or abstinence for people treated with naltrexone, with or without adjunctive psychosocial therapy, compared to placebo or psychosocial therapy alone (**).
						The best approach to initiation of naltrexone maintenance treatment is to manage withdrawal from opioids with small doses of buprenorphine before commencing naltrexone.
						Introduce naltrexone with caution if there is any uncertainty about time of last opioid use (C). An interval of 5 days between last buprenorphine and first naltrexone is recommended for generalist settings. If heroin was the last opioid used, an interval of 7 days is recommended, and 10-14 days if methadone was the last opioid used. If a faster transition is desired, seek specialist advice or referral. ◆
						Urine drug screening is of little use during naltrexone induction. The best approach is to advise the patient that the first dose of naltrexone may precipitate withdrawal if opioids have been used recently. If there is a risk of precipitated withdrawal due to uncertain recent opioid use, seek specialist advice (C).
						Commence naltrexone at 25mg/day for 3 days, then increase to 50mg/day if tolerated (C). Note that the onset of withdrawal triggered by naltrexone can be delayed following buprenorphine treatment.
						Psychosocial Support:
						Psychosocial support is an integral component of MAT.
						People who are opioid dependent often have complex issues—social, housing, legal, employment, mental health, etc. The first aim of treatment is stabilization—it is best to delay interventions for relapse prevention and structural behavioural therapies until immediate needs have been addressed.
						Psychosocial interventions delivered as one-on-one and group sessionsincluding cognitive and behavioural approaches and CM techniquescan add to the effectiveness of MAT. Psychosocial services should be made available to all patients, although those who do not take up the offer should not be denied effective pharmacological treatment.
						Psychosocial support should be tailored to the individual and should include issues such as financial management and advice ( <b>C</b> ). Psychosocial support also encompasses the promotion of treatment compliance.

				TABLE	A.21 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
						Participation in self-help groups (e.g., NA, SMART Recovery) should be recommended to patients, but attendance should not be mandatory ( <b>C</b> ). The effectiveness of self-help groups is related to participation, not just attendance, and mandatory attendance can be counterproductive.
						Adolescents:
						Treatment of adolescents (generally those aged less than 18), should take into account a broader health and welfare context. The emphasis should be on psychosocial responses, family intervention approaches, vocational issues, and harm reduction, particularly around prevention of sexually transmitted diseases and blood-borne viruses. Nonetheless pharmacotherapy may also be an important component of treatment for some young people (C).
						Pharmacotherapy should only be used after careful assessment of risks and benefits, and in the context of a comprehensive treatment plan embracing various psychosocial approaches ( <b>C</b> ). The legal and regulatory requirements of the relevant jurisdiction should be checked before prescribing methadone or buprenorphine to a patient less than 18 years of age.
						If pharmacotherapy is used, buprenorphine may be preferred over methadone because of easier cessation. Doses may need to be adjusted from those used for adults.
						Depending on their drug use history and social circumstances, adolescents may stabilise quickly on substitution treatment enabling cessation of pharmacotherapy to be considered more quickly than would be the case with adult s ( <b>C</b> ). However, as with adults, adolescent patients should be monitored for signs of destabilisation and substitution treatment reinstated if necessary.
4 5 "						See original guidelines for much more information.  DREE00E8CA257CD1001E0E5D/\$File/National Guidelines 2014.pdf. Many of these

<sup>1.</sup> Full guideline can be found at <a href="http://www.nationaldrugstrategy.gov.au/internet/drugstrategy/Publishing.nsf/content/AD14DA97D8EE00E8CA257CD1001E0E5D/\$File/National\_Guidelines\_2014.pdf">Guidelines\_2014.pdf</a>. Many of these guidelines were based upon a consensus process informed by the literature reviews.

## APPENDIX B. MEDICATION-ASSISTED TREATMENT FOR ALCOHOL USE CLINICAL GUIDELINES: VERBATIUM EXCERPTS FROM RELEVANT GUIDELINE SECTIONS

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Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
2015	Not specified	Consensus	Not rated.	Yes.	YesGeneric recommendation.	Assessment
						The following steps are recommended for initiating treatment with any of the medications approved for the management of moderate or severe alcohol use disorder or the prevention of relapse to alcohol use:[1,2,7]
						Educate the patient about MAT and the specific medication being recommended.
						Obtain informed consent for MAT.
						Complete a medical, psychiatric, and substance use history, including history of CVD diabetes, thyroid disease, seizure disorder, CNS impairment, and kidney or liver disease.
						Determine which prescription and OTC medications the patient is taking, including herbal preparations.
						Perform a physical examination, baseline liver and kidney function tests, urine toxicology screen, and (in women) a pregnancy test.
						Assess the patient for allergies to the proposed medication and to other medications
						For women, assess reproductive status, including current pregnancy or plans to become pregnant or to breastfeed.
						TREATMENT FOR ALCOHOL DEPENDENCE
						Initiating Treatment with Disulfiram
						Steps in initiating treatment with disulfiram are as follows:[2,55,56]
						Wait until the patient has abstained from alcohol for at least 12 hours and/or until the breath or blood alcohol level is zero.
						Perform an electrocardiogram if clinically indicated (e.g., in a patient with a history of heart disease).
						Confirm the absence of allergy to disulfiram.
						Perform the following tests to confirm abstinence and determine baselines after stabilization:
						a. Breath or blood alcohol tests, if clinically indicated to confirm abstinence

				TABLE	B.1 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
						b. Liver function tests: alanine aminotransferase, aspartate aminotransferase, GGT, alkaline phosphatase, lactate dehydrogenase, bilirubin, total protein, albumin, prothrombin time  c. Complete blood count and routine chemistries, if clinically indicated  d. Kidney function tests: routine blood urea nitrogen, creatinine  Initiating Treatment with Naltrexone  Naltrexone has not been shown to be effective in patients who are drinking at treatment initiation.  The clinician should consider how best to induct a prospective patient into treatment with extended-release injectable naltrexone.  Advise all patients being treated for alcohol use disorder that it is imperative to notify health care providers of any recent use of opioids or any history of opioid use disorder before starting extended-release injectable naltrexone, to avoid precipitation of opioid withdrawal. A urine drug screen should be conducted to verify abstinence before beginning induction. [80] If patients are to be treated for both alcohol and opioid SUD, they should be off all opioids, including prescription opioid analgesics, for a minimum of 7-10 days before starting naltrexone. [81] Patients transitioning from opioid agonist therapy to extended-release injectable naltrexone may be vulnerable to precipitation of withdrawal symptoms for as long as 2 weeks. Ensure that patients understand that withdrawal precipitated by administration of an opioid antagonist is different from the experience of spontaneous withdrawal that occurs with discontinuation of opioids in a dependent individual. Withdrawal precipitated by an opioid antagonist may be severe enough to require hospitalization.  When discontinuing naltrexone for patients with a history of co-occurring opioid use disorder, advice on opioid overdose prevention should be provided. After a period of abstinence from opioids, tolerance is greatly reduced. This means a previously tolerated amount of opioid could result in opioid overdose. Patients discontinuing opioid antagonist therapy in order to rece

				TABLE	B.1 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
						<b>Dosing and Administration</b> . For appropriate candidates, the recommended dose of extended-release injectable naltrexone is 380mg, delivered intramuscularly approximately every 30 days, alternating buttocks for each subsequent injection. See original guidelines for more information.
						Initiating Treatment with Acamprosate
						Acamprosate typically is initiated 5 days after the cessation of alcohol use. The drug typically reaches full effectiveness in 5-8 days.[2,75,76]
						Acamprosate therapy should be continued even if a patient relapses to alcohol use.[1]
						Psychosocial Treatments. Psychosocial treatments can enhance adherence to the treatment plan, including use of prescribed medications, and thus improve treatment outcomes. Conversely, to the extent that they reduce craving and help patients maintain abstinence, medications may help patients be more receptive to psychosocial interventions.[2,28]
						Almost all studies of medications for the treatment of alcohol use disorder have included some type of counseling, and it is recommended that all patients for whom these medications are prescribed receive at least brief counseling. Evidence is accumulating that weekly or biweekly brief (i.e., 15-20 minutes) counseling sessions combined with use of a medication is an effective treatment for many patients in early recovery. [2,7,9] This counseling typically focuses on encouraging abstinence, adherence to the medication regimen, and participation in mutual-help groups.
						Although psychiatrists may be able to deliver psychosocial therapies on-site, most clinicians need to refer patients for individual or group therapy.
						Treating Adolescents and Young Adults
						Empirical validation of the value of MAT in adolescents is lacking. Moreover, none of the available medications is approved by the FDA for use in people younger than age 18. Therefore, younger adolescents in need of treatment should be referred to a clinician or program specializing in adolescent addiction.[1,33]
						However, in older adolescents and young adults, the limitations of available psychosocial interventions for youth and the demonstrated effectiveness of pharmacologic interventions in adults suggest that it may be reasonable to consider pharmacologic treatments for patients in this age group.[34,35]

	TABLE B.1 (continued)								
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement			
						There are no specific safety contraindications for older adolescents/young adults for the medications discussed here, and available information supports the safe and judicious use of medications in this population.[36] This is particularly true of older adolescents and young adults who have severe alcohol use disorder, as well as those who have not achieved success with psychosocial interventions alone and those who exhibit more adult patterns of moderate and severe alcohol use disorder.[37]  See original guidelines for guidelines on withdrawal, special populations, monitoring and many more topics.			
1. Full	guideline can be found a	at http://store.samhsa.g	ov/shin/content/SMA15	-4907/SMA15-4907.pd	<ol> <li>Text footnotes are from original</li> </ol>	ginal guideline.			

	TABLE B.2. NICE: Technology Appraisal Guidance of Nalmefene for Reducing Alcohol Consumption									
	in People with Alcohol Dependence									
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement				
2014	Not specified	Committee review of a literature review and results from 3 RCTs. The committee functioned in a manner similar to NQF measure review committees.	Not provided.	No. Nalmefene is approved for use in Europe. The FDA has not approved its use in treating people with alcohol dependence.	YesGeneric recommendation.	Nalmefene is recommended within its marketing authorisation, as an option for reducing alcohol consumption, for people with alcohol dependence:  Who have a high drinking risk level (defined as alcohol consumption of more than 60g/day for men and more than 40g/day for women, according to the WHO's drinking risk levels) without physical withdrawal symptoms.  Who do not require immediate detoxification.  The marketing authorisation states that nalmefene should:  Only be prescribed in conjunction with continuous psychosocial support focused on treatment adherence and reducing alcohol consumption.  Be initiated only in patients who continue to have a high drinking risk level 2 weeks after initial assessment.				
1. Full <u>g</u>	guideline can be found	at https://www.nice.org.	.uk/guidance/ta325/chaj	oter/1-Guidance.						

ır	ement Grade	r the Identification	ideilles for the			
	Rating Scale Definition PDA-Approved Psychosocial Guideline Statement Guideline Statement	ade FDA-Approved Medications	Statement Grade and Rating Scale Definition	Guideline Source of Information <sup>1</sup>	Care Setting	Year
	mmendations very low ty of evidence.  Benzodiazepines are a FDA- pregnancy perganary or  an quality: ner research is  including: the research is  including: the research is  th	situations.  Benzodiazepines are a FDA- pregnancy category D drug, meaning "there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks."  ch is the time that t	Generally strong recommendations with very low quality of evidence.  GRADE Working Group Grades of Evidence  High quality: Further research is very unlikely to change confidence in the estimate of effect.  Moderate quality: Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.  Low quality: Further research is very likely to have an important impact on confidence in the estimate of effect and may change the estimate of effect and is likely to change the estimate.  Very low quality: The GDG is very uncertain about the estimate.  Strength of Recommendation	Literature Review	Inpatient	2014
	benefits may warrant use of the drug in pregnant women despite potential risks."  Equal attention should be paid to the hand treatment adjusted accordingly.  The exceptions to this recommendation which are covered by Recommendation of evidence of the effectiveness of the evidence of harm to the fetus of ongoing both mother and fetus of ceasing alcolosupervision strongly outweighs any positive to not denote in the nate of effect is likely to nave mortant attention should be paid to the hand treatment adjusted accordingly.  The exceptions to this recommendation which are covered by Recommendation of evidence of the effectiveness of the evidence of harm to the fetus of ongoing both mother and fetus of ceasing alcolosupervision strongly outweighs any positive to not denote in the nate of effect is likely to nave more than the nate of effect is likely to nave nave nave nave nave nave nave nave	be is benefits may warrant use of the drug in pregnant women despite potential risks."  the is the table to the drug in pregnant women despite potential risks."	Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.  Low quality: Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate.  Very low quality: The GDG is very uncertain about the estimate.  Strength of			

				TABLE	B.3 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
			Strong: The GDG was confident that the quality of the evidence of effect, combined with certainty about the values, preferences, benefits and feasibility, made this a recommendation that should be done in most circumstances and settings.  Conditional: There was less certainty about the quality of the evidence and values, preferences, benefits and feasibility of this recommendation. Thus, there may be circumstances or settings in which it			Alcohol withdrawal can be a severe and even life-threatening condition, provoking seizures and delirium. Evidence from non-pregnant populations has demonstrated the effectiveness of long-acting benzodiazepines for preventing seizures and delirium in alcohol withdrawal. Given the severity of alcohol withdrawal, and the lack of significant harm from short-term benzodiazepine use, and the evidence supporting the use of benzodiazepines in the management of alcohol withdrawal in the general population, the GDG decided that this recommendation should be strong despite the low quality of evidence in pregnant women.  Recommendation 10  Given that the safety and efficacy of medications for the treatment of alcohol dependence has not been established in pregnancy, an individual risk-benefit analysis should be conducted for each woman. (Strength of recommendation: Conditional; Quality of evidence: Very low)  Remarks  Pregnant patients with alcohol dependence should be offered psychosocial interventions.  The recommendation was considered conditional given the complete lack of research on this issue.  See alcohol table for mutually relevant guidelines and original guidelines for full guidelines.
			settings in which it should not apply.			promises (/ 22 , OD , s/, 22 methodops (/ 22). Many of these guidelines were based upon a

<sup>1.</sup> Full guideline can be found at <a href="http://www.guideline.gov/content.aspx?id=48894&search=(%22naltrexone%22+OR+%22buprenorphine%22+OR+%22methadone%22">http://www.guideline.gov/content.aspx?id=48894&search=(%22naltrexone%22+OR+%22buprenorphine%22+OR+%22methadone%22</a>). Many of these guidelines were based upon a consensus process informed by the literature reviews.

TABLE B.4. BAP Recommendations: Updated Evidence-Based Guidelines for the Pharmacological Management of Substance Abuse, Harmful Use, Addiction and Co-morbidity									
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement			
2012	Inpatient, ambulatory	Literature Review	Statement grade varies based upon the specific guidance. See the "Guideline Statement" column for individual grades.  Categories of evidence for causal relationships and treatment:  la: Evidence from meta-analysis of randomised controlled trials.  lb: Evidence from at least 1 randomised controlled trial.  lla: Evidence from at least 1 controlled study without randomization.  lib: Evidence from at least 1 controlled study without randomization.	Yes. It also includes, carbamazepine, and clomethiazole, which are not FDA-approved.	Yes, it is indirectly suggested in the "evidence section" preceding the guidelines and notes that all pharmacotherapies for treatment for alcohol discussion have been studied in combination with psychosocial treatment and medical treatment alone is not recommended.	DETOXIFICATION Treatment Regimens  Benzodiazepines are efficacious in reducing signs and symptoms of withdrawal (A); fixed-dose regimens are recommended for routine use with symptom-triggered dosing reserved for use only with adequate monitoring (D).  Carbamazepine has also been shown to be equally efficacious to benzodiazepines (A).  Clomethiazole is reserved for inpatient settings only after due consideration of its safety (A).  TREATMENT FOR ALCOHOL DEPENDENCE Recommendations: preventing relapse, maintaining abstinence  Acamprosate can be used to improve abstinence rates (A). It should be continued if the person starts drinking, since there is evidence that acamprosate reduces alcohol consumption (A), at least for a period to assess whether there is overall patient benefit attributable to acamprosate.  Naltrexone can be used to reduce risk of lapse becoming a relapse, but there is less evidence to support its use in maintaining abstinence (A). Naltrexone may therefore be a better choice if someone is "sampling" alcohol regularly but wishes to be abstinent.  For acamprosate and naltrexone there is no consistent evidence to suggest which types of patient will respond, and relapse prevention medication should be offered to/considered for everyone who is alcohol-dependent wanting to be abstinent (A).  Disulfiram is effective if intake is witnessed. Disulfiram can be offered as a treatment option for patients who intend to maintain abstinence, and for whom there are no contraindications (B).  Baclofen should be considered if a patient wants to be abstinent, has high levels of anxiety and has not benefited from or is unable to take acamprosate, naltrexone or			

TABLE B.4 (continued)										
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement				
			III: Evidence from non-experimental descriptive studies, such as comparative studies, correlation studies and case-control studies.  IV: Evidence from expert committee reports or opinions and/or clinical experience of respected authorities.  Proposed categories of evidence for observational relationships:  I: Evidence from large representative population samples.  II: Evidence from small, well-designed, but not necessarily representative samples.  III: Evidence from non-representative surveys, case reports.			Recommendations: alcohol and pregnancy  Women and men are advised not to drink alcohol when trying to conceive (S).  Pregnant women with symptomatic withdrawal should be offered medical cover for their detoxification, ideally as an inpatient (D).  Starting relapse prevention medication should be avoided, although if already successfully established on relapse prevention medication, patients' needs should be assessed on a case-by-case analysis (D).  See original guidelines for full guidelines. See opioid table for guidelines for adolescents.				

				TABLE	B.4 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
			IV: Evidence from			
			expert committee			
			reports or opinions			
			and/or clinical			
			experience of respected			
			authorities.			
			authorities.			
			Strength of			
			recommendation			
			A: Directly based			
			on category I			
			evidence.			
			D. Directly based			
			B: Directly based on category II			
			evidence or			
			extrapolated			
			recommendation			
			from category I			
			evidence.			
			C: Directly based			
			on category III			
			evidence or			
			extrapolated			
			recommendation			
			from category I or			
			II evidence.			
			D: Directly based			
			on category IV			
			evidence or			
			extrapolated			
			recommendation			
			from category I, II			
			or III evidence.			
			S: Standard of			
			care.			
1. Full ç	juideline can be found	at http://www.ncbi.nlm.i	nih.gov/pubmed/226283	90. Many of these guide	elines were based upon a co	onsensus process informed by the literature reviews.

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TABLE B.	5. Substance Misu	ise and Alcoho	I Use Disorder	s: Evidence-Based	d Geriatric Nursing Protocols for Best Practices
Year Care Settin	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
2008, Revised 2012 Not specified	Literature Review	Statement grade varies based upon the specific guidance. See the "Guideline Statement" column for individual grades.  Level I: Systematic reviews (integrative/ meta-analyses/ clinical practice guidelines based on systematic reviews).  Level II: Single experimental study (RCTs).  Level III: Quasi-experimental studies.  Level IV: Non-experimental studies.  Level V: Care report/program evaluation/narrative literature reviews.  Level VI: Opinions of respected authorities/ consensus panels.	Yes.	YesRecommended, group psychotherapy-CBT promising in older adults.	Parameters of Assessment  Screening for alcohol, tobacco, and other drug use is recommended for all community-dwelling and hospitalized older adults. It is essential that the nurse: State the purpose of questions about substances used and link them to health and safety. Be empathic and non-judgmental; avoid stigmatic terms such as alcoholic. Ask the questions when the patient is alcohol-free and drug-free. Inquire re: patient's understanding of the question (Aalto, Pekuri, & Seppä, 2003 [Level III]).  Assessment and screening tools:  The QF Index (Khavari & Farber, 1978 [Level VI]): Review all classes of drugs: alcohol, nicotine, illicit drugs, prescription drugs, OTC drugs, and vitamin supplements, for each drug used. Record the types of drugs, including types of beverages; Frequency: the number of occasions on which the drug is consumed (daily, weekly, monthly); Amount of drug consumed on each occasion during the last 30 days. The psychological function, what the drugs does for the individual, is also important to identify. The QF Index tool should be part of the intake nursing history. The "brown bag" approach is also useful. Ask the patient to bring all drugs and supplements he or she uses in a brown bag to the interview.  SMAST-G: Highly valid and reliable, this is a 10-item tool that can be used in all settings. Three minutes for administration. This instrument is derived from the MAST-G with a sensitivity of 93.6% and positive predictive value of 87.2% (Blow et al., 1992 [Level III]).  AUDIT: This 10-item questionnaire has good validity in ethnically mixed groups and scores classify alcohol use as hazardous, harmful, or dependent. Administration: 2 minutes. Sensitivity scores range 0.74-0.84% and specificity around 0.90% in mixed age and ethnic groups (Allen et al., 1997 [Level III]). This instrument is highly effective for use with older adults (Roberts, Marshall, & MacDonald, 2005 [Level III]). Its derivative, the AUDIT-C, is composed of 3 questions that have proved equally valid in detecting an alcoho

				TABLE I	B.5 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
						<ul> <li>Assess vital signs and determine respiratory, cardiac, or neurological depression.</li> <li>Assess for existing medical conditions, including depression.</li> <li>Arrange for emergency room or hospitalization treatment as necessary.</li> <li>Obtain urine for toxicology, if possible.</li> <li>Assess for delirium that can be confused with intoxication and withdrawal in the older adult.</li> <li>At-risk drinking is regular consumption of alcohol in excess of 1 drink per day for 7 days a week or more than 3 drinks on any 1 occasion.</li> <li>Assess for readiness to change behavior using stages of change model (Prochaska &amp; Di Clemente, 1992 [Level II]).</li> <li>Is drinker concerned about amount or consequences of the drinking? Has she or he contemplated cutting down?</li> <li>Does she or he have a plan for cutting down or stopping consumption?</li> <li>Has she or he previously stopped but then resumed risky drinking?</li> <li>Personalized feedback and on "at-risk drinking" results in a reduction in at-risk drinking among older primary care patients.</li> <li>DETOXIFICATION</li> <li>Treatment of acute alcohol withdrawal syndrome (guidelines are modified for other CNS depressant drugs such as barbiturates, heroin, sedative-hypnotics):</li> <li>Assess for risk factors: (a) previous episodes of detoxification; (b) recent heavy drinking; (c) medical co-morbidities including liver disease, pneumonia, and anemia; and (d) previous history of seizures or delirium (Wetterling et al., 2006 [Level III]).</li> <li>Assess for extreme CNS stimulation and a minor withdrawal syndrome evidenced in tremors, disorientation, tachycardia, irritability, anxiety, insomnia, and moderate diaphoresis. When these signs are not detected, life-threatening situations for older adults often result. Whithdrawal, occurring 24-72 hours after the last drink, can progress to seizures, hallucinosis, withdrawal delirium, extreme hypertension, and profuse diarrhea 4-8 hours and for up t</li></ul>

				TABLE	B.5 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
4 Full o	uideline oon he found o	t bite //www.guideling.c	ov/content conv2id=42	2208 soorsh- (9/ 22) silter	ovene <sup>2/</sup> 22 i OD i 9/ 22 burgene	Reported sleep disturbance, anxiety, depression, problems with attention and concentration (acute care):  Assess for neuropsychiatric conditions using the mental status exam, Geriatric Depression Scale, or Hamilton Anxiety Scale.  Obtain sleep history because drugs disrupt sleep patterns in older persons.  Assess intake of all drugs, including alcohol, OTC, prescription, herbal and food supplements, and nicotine. Use "brown bag" strategy.  If positive for alcohol use, assess for last time of use and amount used.  Assess for alcohol or sedative drug withdrawal as indicated.  TREATMENT FOR ALCOHOL DEPENDENCE  Treatment and relapse prevention  Monitor pharmacologic treatment such as naltrexone as short-term treatment for alcohol dependence. The benefits of this treatment are dependent on adherence and psychosocial treatment should accompany its use (WHO, 2000 [Level I]).  See guidelines related to psychosocial treatment in opioid table.

<sup>1.</sup> Full guideline can be found at <a href="https://www.guideline.gov/content.aspx?id=43939&search=(%22naltrexone%22+OR+%22buprenorphine%22+OR+%22methadone%22">https://www.guideline.gov/content.aspx?id=43939&search=(%22naltrexone%22+OR+%22buprenorphine%22+OR+%22methadone%22)</a>. Many of these guidelines were based upon a consensus process informed by the literature reviews.

	TABLE B.6. NICE: Alcohol-Use Disorders Diagnosis, Assessment and Management of Harmful Drinking and Alcohol Dependence										
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement					
2011	Outpatient, inpatient, residential	Literature Review and informal consensus	Not provided. Ratings of the individual studies can be found on the NICE Web site.	Yes; it also includes carbamazepine, and clomethiazole, which are not FDA-approved.	YesRecommend individual psychological intervention (CBTs, behavioral therapies or social network and environment-based therapies) or behavioural couples therapy with MAT.	ASSESSMENT EXCERPTS  Brief Triage Assessment  1.2.2.5 All adults who misuse alcohol who are referred to specialist alcohol services should have a brief triage assessment to assess:  • The pattern and severity of the alcohol misuse (using AUDIT) and severity of dependence (using SADQ).  • The need for urgent treatment including assisted withdrawal.  • Any associated risks to self or others.  • The presence of any co-morbidities or other factors that may need further specialist assessment or intervention.  Agree the initial treatment plan, taking into account the service user's preferences and outcomes of any previous treatment.  Comprehensive Assessment  1.2.2.6 Consider a comprehensive assessment for all adults referred to specialist alcohol services who score more than 15 on the AUDIT. A comprehensive assessment should assess multiple areas of need, be structured in a clinical interview, use relevant and validated clinical tools (see 1.2.1.4), and cover the following areas:  Alcohol use, including:  • Consumption: historical and recent patterns of drinking (using, for example, a retrospective drinking diary), and if possible, additional information (for example, from a family member or carer).  • Dependence (using, for example, SADQ or LDQ).  • Alcohol-related problems (using, for example, APQ).  • Other drug misuse, including OTC medication.  • Physical health problems.  • Cognitive function (using, for example, the MMSE).  • Readiness and belief in ability to change.  1.2.2.7 Assess co-morbid mental health problems as part of any comprehensive assessment, and throughout care for the alcohol misuse, because many co-morbid problems (though not all) will improve with treatment for alcohol misuse. Use the assessment of co-morbid mental health problems to inform the development of the overall care plan.					

				TABLE	B.6 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
						1.2.2.8 For service users whose co-morbid mental health problems do not significantly improve after abstinence from alcohol (typically after 3-4 weeks), consider providing or referring for specific treatment (see the relevant NICE guideline for the particular disorder).
						1.2.2.9 Consider measuring breath alcohol as part of the management of assisted withdrawal. However, breath alcohol should not usually be measured for routine assessment and monitoring in alcohol treatment programmes.
						1.2.2.10 Consider blood tests to help identify physical health needs, but do not use blood tests routinely for the identification and diagnosis of alcohol use disorders.
						1.2.2.11 Consider brief measures of cognitive functioning (for example, MMSE) to help with treatment planning. Formal measures of cognitive functioning should usually only be performed if impairment persists after a period of abstinence or a significant reduction in alcohol intake.
						1.3.2 Care coordination and case management
						Care coordination is the routine coordination by any staff involved in the care and treatment of a person who misuses alcohol. Case management is a more intensive process concerned with delivering all aspects of care, including assessment, treatment, monitoring and follow-up.
						1.3.2.1 Care coordination should be part of the routine care of all service users in specialist alcohol services and should:
						<ul> <li>Be provided throughout the whole period of care, including aftercare.</li> <li>Be delivered by appropriately trained and competent staff working in specialist alcohol services.</li> <li>Include the coordination of assessment, interventions and monitoring of progress, and coordination with other agencies.</li> </ul>
						1.3.2.2 Consider case management to increase engagement in treatment for people who have moderate-to-severe alcohol dependence and who are considered at risk of dropping out of treatment or who have a previous history of poor engagement. If case management is provided it should be throughout the whole period of care, including aftercare.
						1.3.2.3 Case management should be delivered in the context of Tier 3 interventions by staff who take responsibility for the overall coordination of care and should include:
						<ul> <li>A comprehensive assessment of needs.</li> <li>Development of an individualised care plan in collaboration with the service user and relevant others (including families and carers and other staff involved in the service user's care).</li> </ul>

				TABLE	B.6 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
						<ul> <li>Coordination of the care plan to deliver a seamless multiagency and integrated care pathway and maximisation of engagement, including the use of motivational interviewing approaches.</li> <li>Monitoring of the impact of interventions and revision of the care plan when necessary.</li> <li>1.3.3 Interventions for harmful drinking and mild alcohol dependence</li> <li>1.3.3.1 For harmful drinkers and people with mild alcohol dependence, offer a psychological intervention (such as cognitive behavioural therapies, behavioural therapies or social network and environment-based therapies) focused specifically on alcohol-related cognitions, behaviour, problems and social networks.</li> <li>1.3.3.2 For harmful drinkers and people with mild alcohol dependence who have a regular partner who is willing to participate in treatment, offer behavioural couples therapy.</li> <li>For harmful drinkers and people with mild alcohol dependence who have not responded to psychological interventions alone, or who have specifically requested a pharmacological intervention, consider offering acamprosate[6] or oral naltrexone[7] in combination with an individual psychological intervention (cognitive behavioural therapies, behavioural therapies or social network and environment-based therapies) or behavioural couples therapy (see Section 1.3.6 for pharmacological interventions).</li> <li>Delivering psychological interventions</li> <li>1.3.3.3 Cognitive behavioural therapies focused on alcohol-related problems should usually consist of 1 60-minute session per week for 12 weeks.</li> <li>1.3.3.5 Social network and environment-based therapies focused on alcohol-related problems should usually consist of 8 50-minute sessions over 12 weeks.</li> <li>1.3.3.6 Behavioural couples therapy should be focused on alcohol-related problems and their impact on relationships. It should aim for abstinence, or a level of drinking pre-determined and agreed by the therapiest and the service user to be reasonable and safe. It should usually consist of 1</li></ul>
						responded to psychological interventions alone, or who have specifically pharmacological intervention, consider offering acamprosate[6] or oral na combination with an individual psychological intervention (cognitive behar therapies, behavioural therapies or social network and environment-base or behavioural couples therapy (see Section 1.3.6 for pharmacological in Delivering psychological interventions  1.3.3.3 Cognitive behavioural therapies focused on alcohol-related proble usually consist of 1 60-minute session per week for 12 weeks.  1.3.3.4 Behavioural therapies focused on alcohol-related problems should consist of 1 60-minute session per week for 12 weeks.  1.3.3.5 Social network and environment-based therapies focused on alcohol-related problems should usually consist of 8 50-minute sessions over 12 weeks.  1.3.3.6 Behavioural couples therapy should be focused on alcohol-related and their impact on relationships. It should aim for abstinence, or a level pre-determined and agreed by the therapist and the service user to be re and safe. It should usually consist of 1 60-minute session per week for 12 1.3.4 Assessment and interventions for assisted alcohol withdrawal

	TABLE B.6 (continued)									
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement				
						<ul> <li>1.3.4.1 For service users who typically drink over 15 units of alcohol per day and/or who score 20 or more on the AUDIT, consider offering:</li> <li>An assessment for and delivery of a community-based assisted withdrawal.</li> <li>Assessment and management in specialist alcohol services if there are safety concerns (see 1.3.4.5) about a community-based assisted withdrawal.</li> <li>1.3.4.2 Service users who need assisted withdrawal should usually be offered a community-based programme, which should vary in intensity according to the severity of the dependence, available social support and the presence of co-morbidities.</li> <li>For people with mild to moderate dependence, offer an outpatient-based assisted withdrawal programme in which contact between staff and the service user averages 2-4 meetings per week over the first week.</li> <li>For people with mild to moderate dependence and complex needs[8], or severe dependence, offer an intensive community programme following assisted withdrawal in which the service user may attend a day programme lasting 4-7 days per week over a 3-week period.</li> <li>1.3.4.3 Outpatient-based community assisted withdrawal programmes should consist of a drug regimen (see 1.3.5) and psychosocial support including motivational interviewing (see 1.3.1.1).</li> <li>1.3.4.4 Intensive community programmes following assisted withdrawal should consist of a drug regimen (see 1.3.6), group treatments, psychoeducational interventions, help to attend self-help groups, family and carer support and involvement, and case management (see 1.3.2.2).</li> <li>1.3.4.5 Consider inpatient or residential assisted withdrawal if a service user meets 1 or more of the following criteria. They:</li> <li>Drink over 30 units of alcohol per day.</li> <li>Have a score of more than 30 on the SADQ.</li> <li>Have a history of epilepsy, or experience of withdrawal-related seizures or DTs during previous assisted withdrawal programmes.</li> <li>Need concurrent withdrawal from alcohol and benzodiazepines.</li></ul>				

				TABLE	B.6 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
						DETOXIFICATION
						1.3.5 Drug regimens for assisted withdrawal
						1.3.5.1 When conducting community-based assisted withdrawal programmes, use fixed-dose medication regimens[9].
						1.3.5.2 Fixed-dose or symptom-triggered medication regimens[10] can be used in assisted withdrawal programmes in inpatient or residential settings. If a symptom-triggered regimen is used, all staff should be competent in monitoring symptoms effectively and the unit should have sufficient resources to allow them to do so frequently and safely.
						1.3.5.3 Prescribe and administer medication for assisted withdrawal within a standard clinical protocol. The preferred medication for assisted withdrawal is a benzodiazepine (chlordiazepoxide or diazepam).
						1.3.5.4 In a fixed-dose regimen, titrate the initial dose of medication to the severity of alcohol dependence and/or regular daily level of alcohol consumption. In severe alcohol dependence higher doses will be required to adequately control withdrawal and should be prescribed according to the SPC. Make sure there is adequate supervision if high doses are administered. Gradually reduce the dose of the benzodiazepine over 7-10 days to avoid alcohol withdrawal recurring.
						1.3.5.5 When managing alcohol withdrawal in the community, avoid giving people who misuse alcohol large quantities of medication to take home to prevent overdose or diversion[11]. Prescribe for installment dispensing, with no more than 2 days' medication supplied at any time.
						1.3.5.6 In a community-based assisted withdrawal programme, monitor the service user every other day during assisted withdrawal. A family member or carer should preferably oversee the administration of medication. Adjust the dose if severe withdrawal symptoms or over-sedation occur.
						1.3.5.7 Do not offer clomethiazole for community-based assisted withdrawal because of the risk of overdose and misuse.
						1.3.5.8 For service users having assisted withdrawal, particularly those who are more severely alcohol-dependent or those undergoing a symptom-triggered regimen, consider using a formal measure of withdrawal symptoms such as the CIWA-Ar.
						1.3.5.9 Be aware that benzodiazepine doses may need to be reduced for children and young people[12], older people, and people with liver impairment (see 1.3.5.10).

				TABLE	B.6 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
		OI IIIOIIIIAIOII	Definition	medications	Treatment	1.3.5.10 If benzodiazepines are used for people with liver impairment, consider 1 requiring limited liver metabolism (for example, lorazepam); start with a reduced dose and monitor liver function carefully. Avoid using benzodiazepines for people with severe liver impairment.  1.3.5.11 When managing withdrawal from co-existing benzodiazepine and alcohol dependence increase the dose of benzodiazepine medication used for withdrawal. Calculate the initial daily dose based on the requirements for alcohol withdrawal plus the equivalent regularly used daily dose of benzodiazepine[13]. This is best managed with 1 benzodiazepine (chlordiazepoxide or diazepam) rather than multiple benzodiazepines. Inpatient withdrawal regimens should last for 2-3 weeks or longer, depending on the severity of co-existing benzodiazepine dependence. When withdrawal is managed in the community, and/or where there is a high level of benzodiazepine dependence, the regimen should last for longer than 3 weeks, tailored to the service user's symptoms and discomfort.  1.3.5.12 For managing unplanned acute alcohol withdrawal and complications including DTs and withdrawal-related seizures, refer to NICE clinical guideline 100.  TREATMENT FOR ALCOHOL DEPENDENCE  1.3.6 Interventions for moderate and severe alcohol dependence, consider offering acamprosate or oral naltrexone[7] in combination with an individual psychological intervention (cognitive behavioural therapies, behavioural therapies or social network and environment-based therapies) focused specifically on alcohol misuse (see Section 1.3.3).  1.3.6.2 After a successful withdrawal for people with moderate and severe alcohol dependence, consider offering acamprosate or oral naltrexone[7] in combination with behavioural couples therapy to service users who have a regular partner and whose partner is willing to participate in treatment (see Section 1.3.3).  1.3.6.3 After a successful withdrawal for people with moderate and severe alcohol dependence, consider offering disulfiram[14] in combinatio
						Delivering pharmacological interventions

			TABLE	B.6 (continued)	
Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
					1.3.6.4 Before starting treatment with acamprosate, oral naltrexone or disulfiram, conduct a comprehensive medical assessment (baseline urea and electrolytes and liver function tests including GGT). In particular, consider any contraindications or cautions (see the SPC), and discuss these with the service user.  Acamprosate  1.3.6.5 If using acamprosate, start treatment as soon as possible after assisted withdrawal. Usually prescribe at a dose of 1998mg (666mg 3 times a day) unless the service user weighs less than 60kg, and then a maximum of 1332mg should be prescribed per day. Acamprosate should:  • Usually be prescribed for up to 6 months, or longer for those benefiting from the drug who want to continue with it[15].  • Be stopped if drinking persists 4-6 weeks after starting the drug.  1.3.6.6 Service users taking acamprosate should stay under supervision, at least monthly, for 6 months, and at reduced but regular intervals if the drug is continued after 6 months. Do not use blood tests routinely, but consider them to monitor for recovery of liver function and as a motivational aid for service users to show improvement.  Naltrexone  1.3.6.7 If using oral naltrexone[7], start treatment after assisted withdrawal. Start prescribing at a dose of 25mg/day and aim for a maintenance dose of 50mg/day. Draw the service user's attention to the information card that is issued with oral naltrexone about its impact on opioid-based analgesics. Oral naltrexone should:  • Usually be prescribed for up to 6 months, or longer for those benefiting from the drug who want to continue with it.  • Be stopped if drinking persists 4-6 weeks after starting the drug.  1.3.6.8 Service users taking oral naltrexone[7] should stay under supervision, at least monthly, for 6 months, and at reduced but regular intervals if the drug is continued after 6 months. Do not use blood tests routinely, but consider them for older people, for people with obesity, for monitoring recovery of liver function and as a motivational aid for service users to
	Care Setting	Cara Satting	Care Setting Guideline Source and Rating Scale	Care Setting Guideline Source and Rating Scale FDA-Approved and Rating Scale Medications	Care Setting Suite and Rating Scale Modications Treatment

				TABLE	B.6 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
			Definition			<ul> <li>1.3.6.9 If using disulfiram, start treatment at least 24 hours after the last alcoholic drink consumed. Usually prescribe at a dose of 200mg/day. For service users who continue to drink, if a dose of 200mg (taken regularly for at least 1 week) does not cause a sufficiently unpleasant reaction to deter drinking, consider increasing the dose in consultation with the service user.</li> <li>1.3.6.10 Before starting treatment with disulfiram, test liver function, urea and electrolytes to assess for liver or renal impairment. Check the SPC for warnings and contraindications in pregnancy and in the following conditions: a history of severe mental illness, stroke, heart disease or hypertension.</li> <li>1.3.6.11 Make sure that service users taking disulfiram:</li> <li>Stay under supervision, at least every 2 weeks for the first 2 months, then monthly for the following 4 months.</li> <li>If possible, have a family member or carer, who is properly informed about the use of disulfiram, oversee the administration of the drug.</li> <li>Are medically monitored at least every 6 months after the initial 6 months of treatment and monitoring.</li> <li>1.3.6.12 Warn service users taking disulfiram, and their families and carers, about:</li> <li>The interaction between disulfiram and alcohol (which may also be found in food, perfume, aerosol sprays and so on), the symptoms of which may include flushing, nausea, palpitations and, more seriously, arrhythmias, hypotension and collapse.</li> <li>The rapid and unpredictable onset of the rare complication of hepatotoxicity; advise service users that if they feel unwell or develop a fever or jaundice that they should stop taking disulfiram and seek urgent medical attention.</li> <li>Drugs not to be routinely used for the treatment of alcohol misuse</li> <li>1.3.6.13 Do not use antidepressants (including SSRIs) routinely for the treatment of alcohol misuse alone.</li> <li>1.3.6.15 Benzodiazepines should only be used for managing alcohol withdrawal and not as ongoing treatment for</li></ul>
						psychological, educational or social consequences, in children and young people aged 10-17 years, conduct an initial brief assessment to assess:

				TABLE	B.6 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
						<ul> <li>The duration and severity of the alcohol misuse (the standard adult threshold on the AUDIT for referral and intervention should be lowered for young people aged 10-16 years because of the more harmful effects of a given level of alcohol consumption in this population).</li> <li>Any associated health and social problems.</li> <li>The potential need for assisted withdrawal.</li> <li>1.3.7.2 Refer all children and young people aged 10-15 years to a specialist CAMHS for a comprehensive assessment of their needs, if their alcohol misuse is associated with physical, psychological, educational and social problems and/or co-morbid drug misuse.</li> <li>1.3.7.3 When considering referral to CAMHS for young people aged 16-17 years who misuse alcohol, use the same referral criteria as for adults (see Section 1.2.2).</li> <li>1.3.7.4 A comprehensive assessment for children and young people (supported if possible by additional information from a parent or carer) should assess multiple areas of need, be structured around a clinical interview using a validated clinical tool (such as the ADI or the T-ASI), and cover the following areas:</li> <li>Consumption, dependence features and patterns of drinking.</li> <li>Co-morbid substance misuse (consumption and dependence features) and associated problems.</li> <li>Mental and physical health problems.</li> <li>Peer relationships and social and family functioning.</li> <li>Developmental and cognitive needs, and educational attainment and attendance.</li> <li>History of abuse and trauma.</li> <li>Risk to self and others.</li> <li>Readiness to change and belief in the ability to change.</li> <li>Obtaining consent to treatment.</li> <li>Developing a care plan and risk-management plan.</li> <li>Assisted withdrawal in children and young people aged 10-17 years who need assisted withdrawal.</li> <li>1.3.7.5 Base assisted withdrawal for children and young people aged 10-17 years on the recommendations for adults (see 1.3.5) and in NICE clinical guideline 100.</li> <li>Consult the SP</li></ul>

				TABLE	B.6 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
Year	Care Setting		and Rating Scale	FDA-Approved	Psychosocial	1.3.7.7 For all children and young people aged 10-17 years who misuse alcohol, the goal of treatment should usually be abstinence in the first instance.  1.3.7.8 For children and young people aged 10-17 years who misuse alcohol offer:  Individual cognitive behavioural therapy for those with limited co-morbidities and good social support.  Multicomponent programmes (such as multidimensional family therapy, brief strategic family therapy, functional family therapy or multisystemic therapy) for those with significant co-morbidities and/or limited social support.  1.3.7.9 After a careful review of the risks and benefits, specialists may consider offering acamprosate[15] or oral naltrexone[7] in combination with cognitive behavioural therapy to young people aged 16-17 years who have not engaged with or benefited from a multicomponent treatment programme.  Delivering psychological and psychosocial interventions for children and young people  1.3.7.10 Multidimensional family therapy should usually consist of 12-15 family-focused structured treatment sessions over 12 weeks. There should be a strong emphasis on care coordination and, if necessary, crisis management. As well as family sessions, individual interventions may be provided for both the child or young person and the parents. The intervention should aim to improve:  Alcohol and drug misuse.  The child or young person's educational and social behavior.  Parental well-being and parenting skills.  Relationships with the wider social system.  1.3.7.11 Brief strategic family therapy should usually consist of fortnightly meetings over 3 months. It should focus on:  Engaging and supporting the family.  Using the support of the wider social and educational system.  Identifying maladaptive family interactions.  Promoting new and more adaptive family interactions.
						<ul> <li>Engaging and motivating the family in treatment (enhancing perception that change is possible, positive reframing and establishing a positive alliance).</li> <li>Problem-solving and behaviour change through parent training and communication training.</li> </ul>

				TABLE	B.6 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
						Promoting generalisation of change in specific behaviours to broader contexts, both within the family and the community (such as schools).
						1.3.7.13 Multisystemic therapy should be provided over 3-6 months by a dedicated member of staff with a low caseload (typically 3-6 cases). It should:
						<ul> <li>Focus specifically on problem-solving approaches with the family.</li> <li>Use the resources of peer groups, schools and the wider community.</li> </ul>
						1.3.8 Interventions for conditions co-morbid with alcohol misuse
						1.3.8.1 For people who misuse alcohol and have co-morbid depression or anxiety disorders, treat the alcohol misuse first as this may lead to significant improvement in the depression and anxiety. If depression or anxiety continues after 3-4 weeks of abstinence from alcohol, assess the depression or anxiety and consider referral and treatment in line with the relevant NICE guideline for the particular disorder[17].
						1.3.8.2 Refer people who misuse alcohol and have a significant co-morbid mental health disorder, and those assessed to be at high risk of suicide, to a psychiatrist to make sure that effective assessment, treatment and risk-management plans are in place.
						1.3.8.3 For the treatment of co-morbid mental health disorders refer to the relevant NICE guideline for the particular disorder, and:
						<ul> <li>For alcohol misuse co-morbid with opioid misuse actively treat both conditions; take into account the increased risk of mortality with taking alcohol and opioids together[18].</li> </ul>
						For alcohol misuse co-morbid with stimulant, cannabis[19] or benzodiazepine misuse actively treat both conditions.
						Service users who have been dependent on alcohol will need to be abstinent, or have very significantly reduced their drinking, to benefit from psychological interventions for co-morbid mental health disorders.
						1.3.8.4 For co-morbid alcohol and nicotine dependence, encourage service users to stop smoking and refer to 'Brief interventions and referral for smoking cessation in primary care and other settings' (NICE public health guidance 1).
						See original guidelines for full guidelines, including more guidelines on assessment.

		TABLE	B.7. Medical	Services Com	mission, British C	Columbia: Problem Drinking
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
2011	Ambulatory	Literature Review	Not rated.	Yes.	YesGeneric recommendation (addiction counseling).	See original guidelines for screening and assessment guidelines.  Problem Drinking Part 2Brief Intervention  Note: If a patient is being seen for another problem, it may be necessary for screening to be done at the first appointment and intervention done at a follow-up appointment.  Selected interventions should be based on the assessment completed during the screening (see "Problem Drinking Part 1Screening and Assessment" recommendations above). Although alcohol misuse is a spectrum disorder, positive screens will fall into 1 of 3 categories indicated above (at-risk drinking, alcohol abuse, alcohol dependence).  Practitioners may wish to use the "Brief Intervention Follow-up Note" provided with the guideline.  Intervention for Alcohol Abuse (See also the "Brief Intervention for At-Risk Drinking [No Abuse or Dependence]" algorithm in the original guideline document.)  Physicians are advised to take the following steps when conducting an intervention:  1. State your conclusion and recommendation clearly:  * "I believe that you have an alcohol use disorder. I strongly recommend that you stop drinking and I'm willing to help."  * Relate to the patient's concerns and medical findings if present.  2. Negotiate a goal and develop a plan:  * Abstaining is the safest course for most patients with alcohol use disorders.  * Patients who have milder forms of abuse or dependence and are unwilling to abstain may be successful at cutting down.  3. Consider referring to external or community resources:  * Alcohol and drug counselor, addiction medicine physician.  * Community groups such as AA.  * See CHARD.  For abuse: If patient will not abstain, advise cutting down to established drinking limits. Provide follow-up and support.
'n						Intervention for Alcohol Dependence

			TABLE	B.7 (continued)	
Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
					For dependence, complete the following in addition to steps 1-3 above:  4. For patients who have dependence: •Monitor for withdrawal—15-20% of alcohol-dependent drinkers require inpatient withdrawal. Refer to "Problem Drinking Part 3-Office-Based Management of Alcohol Withdrawal and Prescribing Medications for Alcohol Dependence" below.  5. Prescribing Medications for Alcohol Dependence Medication, in conjunction with psychosocial interventions, can play a valuable part in the management of alcohol dependence. See "Problem Drinking Part 3-Office-Based Management of Alcohol Withdrawal and Prescribing Medications for Alcohol Dependence" below for more information on prescribing medications.  6. Arrange follow-up appointments, including medication management support if needed. See "Problem Drinking Part 3Office-Based Management of Alcohol Withdrawal and Prescribing Medications for Alcohol Dependence" below. To support behaviour change, consider seeing patient at least once every 14 days in initial period.  For dependence: Advise abstinence with medication support.  Follow-up and Support (see the "Follow-up and Support" algorithm in the original guideline document).  REMINDER: Document alcohol use and review goals at each visit (use the "Brief Intervention Follow-up Note" in the original guideline document). If the patient is receiving a medication for alcohol dependence, medication management support should be provided.  Prescribing Medications for Alcohol Dependence  Three medications are currently available:  • Naltrexone*: Blocks euphoria associated with alcohol use. Contraindicated in patients taking opiates.  • Acamprosate*: Reduces chronic withdrawal symptoms.  • Disulfiram: Adversive agent, causes nausea, vomiting, dysphoria with alcohol use and requires abstinence and counseling before initiation. Disulfiram should be used with caution.  *Not covered, product(s) are under review.
	Care Setting	Caro Sotting	Care Setting Guideline Source and Rating Scale	Care Setting Guideline Source Statement Grade and Rating Scale FDA-Approved	Care Setting Guideline Source and Rating Scale FDA-Approved Psychosocial And Rating Scale Medications Treatment

				TABLE	B.7 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
						Consider pharmacotherapy for all patients with alcohol dependency. Patients who fail to respond to psychosocial approaches and/or addiction counselling are particularly strong candidates. The above medications can be used immediately following withdrawal or any time thereafter; however, these medications should be used in conjunction with addiction counselling and other psychosocial supports.  Must Patients Agree to Abstain?  No matter which alcohol dependence medication is used, patients who have a goal of abstinence, or who can abstain even for a few days prior to starting the medication, are likely to have better outcomes. Still, it is best to determine individual goals with each patient. Some patients may not be willing to endorse abstinence as a goal, especially at first. However, abstinence remains the optimal outcome.  A patient's willingness to abstain has important implications for the choice of medication. For example, a study of oral naltrexone demonstrated a modest reduction in the risk of heavy drinking in people with mild dependence who chose to cut down rather than abstain. Acamprosate is approved for use in patients who are abstinent at the start of treatment. Total abstinence is needed with disulfiram. Disulfiram is contraindicated in patients who continue to drink, because a disulfiram-alcohol reaction occurs with any alcohol intake.  Which of the Medications Should Be Prescribed? (See Appendix A: "Prescription Medication Table for Alcohol Dependence" in Part 3 of the original guideline document.)  Which medication to use will depend on clinical judgment and patient preference. Each has a different mechanism of action. Some patients may respond better to 1 type of medication than another.  Naltrexone  Naltrexone works by blocking the euphoria associated with alcohol use. Its use is contraindicated in patients taking opiates. Oral naltrexone is associated with lower percentage drinking days, fewer drinks per drinking day, and longer times to relapse. It is most effective in patients with strong

	TABLE B.7 (continued)							
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement		
						Acamprosate  Acamprosate works by reducing chronic withdrawal symptoms. Acamprosate increases the proportion of dependent drinkers who maintain abstinence for several weeks to months, a result demonstrated in multiple European studies and confirmed by a meta-analysis of 17 clinical trials. However, this has not been demonstrated in patients who have not undergone detoxification and not achieved alcohol abstinence prior to beginning treatment. Acamprosate should be initiated as soon as possible after detoxification and the recommended duration of treatment is 1 year. There is currently insufficient evidence to suggest that acamprosate has a therapeutic advantage over naltrexone.  Disulfiram  Disulfiram is an adversive agent that causes nausea, vomiting, and dysphoria with alcohol use. Abstinence and counselling are required before initiation of treatment with disulfiram Data on the effectiveness of disulfiram in alcohol use disorders is mixed. Disulfiram has been shown to have modest effects on maintaining abstinence from alcohol, particularly if it is administered under supervision. It is most effective when given in a monitored fashion, such as in a clinic or by a spouse. Thus the utility and effectiveness of disulfiram may be considered limited because compliance is generally poor when patients are given it to take at their own discretion. Disulfiram may be considered for those patients that can achieve initial abstinence, are committed to maintaining abstinence, can understand the consequences of drinking alcohol while on disulfiram, and can receive adequate ongoing supervision. It may also be used episodically for high-risk situations, such as social occasions where alcohol is present. Daily uninterrupted disulfiram therapy should be continued until full patient recovery, which may require months to years.  How Long Should Medications Be Maintained?  The risk for relapse to alcohol dependence is very high in the first 6-12 months after initiating abstinence and gradually diminishes over several years. There		

				TABLE	B.7 (continued)	
Year	Care Setting	Guideline Source of Information <sup>1</sup>	Statement Grade and Rating Scale Definition	FDA-Approved Medications	Psychosocial Treatment	Guideline Statement
Year	Care Setting				•	Is There Any Benefit to Combining Medications?  There is no evidence that combining any of the medications to treat alcohol dependence improves outcomes over using any 1 medication alone.  Should Patients Receiving Medications Also Receive Specialized Alcohol Counselling or a Referral to Mutual-Help Groups?  Offering the full range of effective treatments will maximize patient choice and outcomes, since no single approach is universally successful or appealing to patients. Medications for alcohol dependence, professional counselling, and mutual-help groups are part of a comprehensive approach. These approaches share the same goal while addressing different aspects of alcohol dependence: neurobiological, psychological, and social. The medications are not prone to abuse, so they do not pose a conflict with other support strategies that emphasize abstinence. Using medications to treat patients does not interfere with counselling or other abstinence-based programs such as AA.  Almost all studies of medications for alcohol dependence have included some type of counselling, and it is recommended that all patients taking these medications receive at least brief medical counselling. In a recent large trial, the combination of oral
						naltrexone and brief medical counselling sessions delivered by a nurse or physician was effective without additional behavioral treatment by a specialist. Patients were also encouraged to attend mutual support groups to increase social encouragement for abstinence.

<sup>1.</sup> Full guideline can be found at <a href="http://www.guideline.gov/content.aspx?id=38894&search=(%22naltrexone%22+OR+%22buprenorphine%22+OR+%22methadone%22">http://www.guideline.gov/content.aspx?id=38894&search=(%22naltrexone%22+OR+%22buprenorphine%22+OR+%22methadone%22</a>). Many of these guidelines were based upon a consensus process informed by the literature reviews.

# APPENDIX C. ALCOHOL USE: MEDICATION-ASSISTED TREATMENT AND OTHER RELATED MEASURES

	TABLE C.1. AI	cohol Use: MAT and Other Related	Measures		
Measure	Denominator	Numerator	Setting	Data Source	Developer/Steward
EFFECTIVE CLINICAL CARE (Medic					
Pharmacotherapy for alcohol dependence (a) offered, (b) filled, (c) refused, or (d) contraindicated.	Patients with:  a) Alcohol dependence with a new treatment episode.  b) Alcohol dependence in a new treatment episode and a co-morbid mental health diagnosis (major depressive disorder, bipolar disorder, Schizophrenia, PTSD).	Patients from the denominator who were:  a) Offered a prescription for naltrexone, Antabuse (disulfiram) or acamprosate but did not fill within 30 days on or after the start of the new treatment episode.  OR b) Offered a prescription and filled within 30 days of the start of the new treatment episode.  OR c) Offered a prescription for naltrexone, Antabuse (disulfiram) or acamprosate but refused medication within 30 days on or after the start of the new treatment episode.  OR d) Found to have documentation that prescription is contraindicated within 30 days on or after start of new treatment episode.  OR e) Found to have no documentation of offer or refusal and no record of prescription being filled.	Unspecified.	Administrative/Medical records.	VHA
Proportion of adults with moderate or severe alcohol dependence completing a successful medically assisted withdrawal who receive relapse prevention medication.	The number of adults with moderate or severe alcohol dependence completing a successful medically assisted withdrawal.	The number of adults in the denominator receiving relapse prevention medication.	Ambulatory and inpatient specialty settings.	Unspecified.	National Institute for Health and Care Excellence
EFFECTIVE CLINICAL CARE (Psych	nosocial Treatments)				
Proportion of adults accessing specialist services for alcohol misuse who receive evidence-based psychological interventions in accordance with NICE clinical guideline 115 (http://guidance.nice.org.uk/CG115)	The number of adults accessing specialist services for alcohol misuse.	The number of adults in the denominator receiving evidence-based psychological interventions in accordance with NICE clinical guideline 115.	Ambulatory and inpatient specialty settings.	Unspecified.	National Institute for Health and Care Excellence
EFFECTIVE CLINICAL CARE (Scree	ning and Treatment Counseling)				
NQF #2152 Preventive Care and Screening: Unhealthy Alcohol Use: Screening and Brief Counseling	All patients aged 18 years and older who were seen twice for any visits or who had at least 1 preventive care visit during the 2-year measurement period.	Patients who were screened at least once within the last 24 months for unhealthy alcohol use using a systematic screening method AND who received brief counseling if identified as an unhealthy alcohol user.	Ambulatory.	Electronic Clinical Data.	American Medical Association convened Physician Consortium for Performance Improvement

		TABLE C.1 (continued)			
Measure	Denominator	Numerator	Setting	Data Source	Developer/Steward
		Definitions:  Systematic screening methodFor purposes of this measure, 1 of the following systematic methods to assess unhealthy alcohol use must be utilized.  Systematic screening methods and thresholds for defining unhealthy alcohol use include:  AUDIT Screening Instrument (score >= 8)  AUDIT-C Screening Instrument (score >=4 for men; score >=3 for women)  Single Question ScreeningHow many times in the past year have you had 5 (for men) or 4 (for women and all adults older than 65 y) or more drinks in a day? (response >=2)			
NOF #1661	The number of hospitalized inpatients 18	Brief counselingBrief counseling for unhealthy alcohol use refers to 1 or more counseling sessions, a minimum of 5-15 minutes, which may include: feedback on alcohol use and harms; identification of high-risk situations for drinking and coping strategies; increased motivation and the development of a personal plan to reduce drinking.  The number of patients who were screened for	Inpatient.	Electronic Clinical	TJC
SUB-1 Alcohol Use Screening	years of age and older.	alcohol use using a validated screening questionnaire for unhealthy drinking within the first 3 days of admission.		Data/paper-based medical records.	
NQF #1663 SUB-2 Alcohol Use Brief Intervention Provided or Offered and SUB-2a Alcohol Use Brief Intervention	The number of hospitalized inpatients 18 years of age and older who screen positive for unhealthy alcohol use or an alcohol use disorder (alcohol abuse or alcohol dependence).	SUB-2: The number of patients who received or refused a brief intervention.  SUB-2a: The number of patients who received a brief intervention.	Inpatient.	Electronic Clinical Data/paper-based medical records.	TJC
NQF #1664 SUB-3 Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and SUB-3a Alcohol and Other Drug Use Disorder Treatment at Discharge	The number of hospitalized inpatients 18 years of age and older identified with an alcohol or drug use disorder	SUB-3: The number of patients who received or refused at discharge a prescription for medication for treatment of alcohol or drug use disorder OR received or refused a referral for addictions treatment.  SUB-3a: The number of patients who received a prescription at discharge for medication for treatment of alcohol or drug use disorder OR a referral for addictions treatment.	Inpatient.	Electronic Clinical Data/paper-based medical records.	TJC

Icohol dependence.	Denominator  All patients aged 18 years and older with a diagnosis of current alcohol	Numerator Patients who were counseled regarding psychosocial	Setting	Data Source	Developer/Steward
Icohol dependence.		Patients who were counseled regarding psychosocial			
	dependence.	AND pharmacologic treatment options for alcohol dependence within the 12 month reporting period.	Unspecified.	Administrative/electronic clinical data.	APA; Physician Consortium for Performance Improvement
FFECTIVE CLINICAL CARE (Brief Int	tervention)				
ehavioral health: percent of atients screened for alcohol hisuse with AUDIT-C who meet or exceed a threshold score of 5 who	Patients screened for alcohol misuse with AUDIT-C who meet or exceed a threshold score of 5 and who were not seen in a VA specialty SUD program in the prior 90 days.	Patients screened for alcohol misuse with AUDIT-C who meet or exceed a threshold score of 5 who were not seen in a SUD addiction program in the prior 90 days and have brief alcohol counseling documented in the medical record within 14 days of the positive screen.	Ambulatory, Inpatient.	Administrative/paper- based medical records.	VHA
isits for patients with alcohol abuse r dependence.	This indicator is evaluated for the following populations:  1. All SUD patients with alcohol abuse or dependence within the study period.  2. All SUD patients with alcohol abuse or dependence in a new treatment episode.	Numerator for 1: Proportion of patients that have medical records documenting:  (a) Provider advice to drink less or abstain from alcohol and feedback was provided about risks of alcohol use to health condition or to general health during the study period.  OR  (b) Completed referral to specialty mental health during the study period.  OR  (c) Already in specialty care.  OR  (d) All other patients  Numerator for 2: Proportion of patients that have medical records documenting:  (e) Within 30 days of the new treatment episode; provider advice to drink less or abstain from alcohol and feedback was provided about risks of alcohol use to health condition or to general health.  OR  (f) Within 30 days of the new treatment episode; completed referral to specialty mental health.  OR  (g) Started the new treatment episode in specialty care.  OR  (h) All other patients.	Ambulatory.	Administrative/paper-based medical records.	VHA

### APPENDIX D. SUBSTANCE USE: MEDICATION-ASSISTED TREATMENT AND OTHER RELATED MEASURES

	TABLE D.1. Sub	stance Use: MAT and Other Relate	d Measures		
Measure	Denominator	Numerator	Setting	Data Source	Developer/Steward
<b>EFFECTIVE CLINICAL CAI</b>	RE				
NQF #2597 Percentage of patients aged 18 years and older who were screened at least once within the last 24 months for tobacco use, unhealthy alcohol use, non-medical prescription drug use, and illicit drug use AND who received an intervention for all positive screening results.	All patients aged 18 years and older who were seen twice for any visits or who had at least 1 preventive care visit during the 12 month measurement period.	Patients who received the following substance use screenings at least once within the last 24 months AND who received an intervention for all positive screening results:  Tobacco use component Patients who were screened for tobacco use at least once within the last 24 months AND who received tobacco cessation intervention if identified as a tobacco user.  Unhealthy alcohol use component.  Patients who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.  Drug use component (non-medical prescription drug use and illicit drug use).  Patients who were screened for non-medical prescription drug use and illicit drug use at least once within the last 24 months using a systematic screening method AND who received brief counseling if identified as a non-medical prescription drug user or illicit drug user.	Multiple, including ambulatory.	Electronic clinical data.	ASAM
Assessment for Substance Abuse Problems of Psychiatric Patients.	Total number of patients in a plan who received psychiatric evaluations within a specified period of time.	Number of patients in the denominator whose medical record indicates explicit evidence of assessment of current and/or past SUDs.	Multiple, including ambulatory	Administrative/Paper	APA
SUDs: percentage of patients aged 18 years and older with a diagnosis of current substance abuse or dependence who were screened for depression within the 12 month reporting period.	All patients aged 18 years and older with a diagnosis of current substance abuse or dependence.	Patients who were screened for depression within the 12 month reporting period.	Multiple, including ambulatory	Administrative/Paper- based medical records	APA

		TABLE D.1 (continued)			
Measure	Denominator	Numerator	Setting	Data Source	Developer/Steward
Assessment of SUD, and trauma and patient strengths completed.	All psychiatric inpatient discharges with at least a 72 hour stay.	Patients whose records include documentation of initial assessment completed:	Inpatient.	Administrative/paper- based medical records.	VHA
		Within 72 hours of admission:     Presence/absence of co-occurring SUD in past 12 months.     Presence/absence of history of psychological trauma and contribution of trauma to current presentation.			
Assessment of recent substance usetype, quantity and frequency.	Patients in a new treatment episode.	Assessment of patient strengths.  Patients in the denominator who have an assessment of recent substance abuse, including type, quantity, and frequency, within the first 30 days of the new treatment episode.	Likely multiple.	Administrative/paper- based medical records.	VHA
Substance Abuse Detection.	All enrollees in a health plan over a 12-month period x 1000.	Those enrollees who received an alcohol or drug- related diagnosis or received at least 1 substance abuse related plan service during the same period.	Multiple Ambulatory, hospital.	Administrative/paper- based medical records.	Washington Circle Group
Proportion of patients with SUD diagnosis that received evidence-based CM or Contingency Contracting.	Patients with SUD diagnosis who have at least 1 psychotherapy visit in the study period.	Patients from the denominator who received:  a) Any evidence-based CM or Contingency Contracting in the study period.  b) The number of CM or Contingency Contracting visits received in the study period by the same provider in (a).	Unclear Ambulatory and possibly inpatient.	Administrative/paper- based medical records.	VHA
Proportion of patients with SUD diagnosis that received evidence-based cognitive behavioral RPT by the first provider of RPT.	Patients with SUD diagnosis who have at least 1 psychotherapy visit in the study period.	Patients from the denominator who received:  a) Any evidence-based cognitive behavioral RPT in the study period.  b) The number of RPT visits received in the year following the first RPT encounter by the same provider in (a).	Unclear Ambulatory and possibly inpatient.	Administrative/paper- based medical records.	VHA
Early discharge rates from residential care for SUD.	SUD-related inpatient admissions during the study period for patients with cohort diagnosis of SUD.	a) Inpatient admission in the denominator where patient was discharged from residential care for SUD within 1 week of admission.      b) Total length-of-stay in days per related inpatient admission for patients in the denominator discharged from residential care for SUD.	Inpatient, residential.	Administrative.	VHA
Program Completion for Chemical Dependency Treatment.	Total number of clients who were discharged from a chemical dependency rehabilitation program during a specified period.	Number of clients in the denominator who completed the program (i.e., their reason for discharge was "all or most treatment goals met" on PAS-45, Item 18).	Rehabilitation program.	Other.	New York State Office of Alcoholism and Substance Abuse Services

		TABLE D.1 (continued)			
Measure	Denominator	Numerator	Setting	Data Source	Developer/Steward
Completion of Treatment for Substance Abuse.	All patients discharged from a state- funded substance abuse treatment program during a specified interval, excluding those who have been reassessed as inappropriate for the program, discharged due to loss of program funding, or died.	Patients from the denominator whose records contain a discharge note indicating they met at least 75% of:  (1) Their planned duration of stay (documented on the treatment plan).  (2) The behavioral objectives identified in their treatment plan.	State-funded substance abuse treatment program.	Paper-based medical records.	Texas Commission on Alcohol and Drug Abuse
Completion of Treatment for Substance Abuse (Child/Adolescents).	All patients under 18 years of age discharged from a state-funded substance abuse treatment program during a specified interval, excluding those who have been reassessed as inappropriate for the program, discharged due to loss of program funding, or died.	Patients from the denominator whose records contain a discharge note indicating they met at least 75% of:  (1) Their planned duration of stay (documented on the treatment plan).  (2) The behavioral objectives identified in their treatment plan.	State-funded substance abuse treatment program.	Paper-based medical records.	Texas Commission on Alcohol and Drug Abuse
1-Week Retention Rate for Chemical Dependency Treatment.	Total number of clients discharged from an inpatient chemical dependency program during a specified period.	Number of clients in the denominator who EITHER completed the program (i.e., their reason for discharge was "all or most treatment goals met" on PAS-45, Item 18) or had a length-of-stay in the program of 1 week or longer at time of discharge.	Multiple, including ambulatory.	Administrative/paper- based medical records.	New York State Office of Alcoholism and Substance Abuse Services
1-Month Retention Rate for Chemical Dependency Treatment.	Total number of clients discharged from an outpatient or residential chemical dependency treatment program during a specified period.	Number of clients in the denominator who EITHER completed the program (i.e., their reason for discharge was "all or most treatment goals met" on PAS-45, Item 18) or had a length-of-stay in the program of 1 month or longer at time of discharge.	Multiple, including ambulatory.	Administrative/paper- based medical records.	New York State Office of Alcoholism and Substance Abuse Services
60-Day Continuation of Substance Abuse Treatment.	All plan members who are admitted to an inpatient, intensive outpatient, or alternative intensive setting for a primary diagnosis of substance abuse and have at least 1 claims-based encounter during a specified time period. [Patients with nicotine and caffeine disorders are excluded.]	Patients in the denominator who remain in treatment after more than 60 days but less than 90 days following admission.	Multiple, including ambulatory.	Administrative.	New York State Office of Alcoholism and Substance Abuse Services
3-Month Retention Rate for Chemical Dependency Treatment.	Total number of clients discharged from an outpatient or residential chemical dependency treatment program during a specified period who EITHER completed the program or had a length-of-stay of 1 month or longer.	Number of clients in the denominator who EITHER completed the program [i.e., their reason for discharge was "all or most treatment goals met" on PAS-45, Item 18] or had a length-of-stay in the program of 3 months or longer at time of discharge.	Multiple, including ambulatory.	Administrative/paper- based medical records.	New York State Office of Alcoholism and Substance Abuse Services

		TABLE D.1 (continued)			
Measure	Denominator	Numerator	Setting	Data Source	Developer/Steward
1-Year Retention Rate for Chemical Dependency Treatment.	Total number of clients who were discharged from an outpatient or residential chemical dependency treatment program who EITHER completed the program or had a length-of-stay of 1 month or longer during a specified period.	Number of clients in the denominator who EITHER completed the program [i.e., their reason for discharge was "all or most treatment goals met" on PAS-45, Item 18] or had a length-of-stay in the program of 1 year or longer at time of discharge.	Multiple, including ambulatory.	Administrative/paper- based medical records.	New York State Office of Alcoholism and Substance Abuse Services
Mental health: percent of patients beginning a new episode of treatment for SUD who maintain continuous treatment involvement for at least 90 days after qualifying date.	Number of Veterans beginning specialty treatment for SUD.	Number of Veterans beginning specialty treatment for SUD who maintain continuous treatment involvement for at least 90 days as demonstrated by at least 2 days with visits every 30 days for a total of 90 days in any of the outpatient specialty SUD clinics.	Multiple, including ambulatory.	Administrative/paper- based medical records.	VHA
Substance Abuse Maintenance Treatment.	The number of patients 18 and older in a health plan discharged from inpatient or outpatient treatment with primary or secondary diagnosis of an alcohol or drug disorder.	The subset of patients from the denominator who report receiving specific services and/or monitoring by the plan to promote and sustain positive treatment outcomes post-discharge.	Multiple, including ambulatory.	Administrative/patient survey.	Washington Circle Group
COMMUNICATION AND C	ARE COORDINATION				
For selected SUD patients, mean time to initiation of appropriate follow-up SUD treatment.	Patients with an SUD diagnosis in a new treatment episode.	For those in the denominator:  a) Patients with any follow-up in the 90 days following the start of the new treatment episode.  b) For those patients with follow-up within 90 days, number of days until first outpatient follow-up visit.	Multiple, including ambulatory.	Not specified.	VHA
Proportion of patients with COD and severe functional impairment that receive integrated substance abuse and mental health treatment.	a) Patients, with a COD and who have GAF score ≤40, who had at least 2 diagnosis-related visits during the study period.  b) Patients, with a COD and who have GAF score >40, who had at least 2 diagnosis-related visits during the study period.  c) Patients, with a COD and who have no reported GAF, who had at least 2 diagnosis-related visits during the study period.	Patients from the denominator who received treatment for both their mental health and SUD during the study period from:  a) 1 clinic team or clinician cross-trained in both mental health and SUD issues (e.g., IDDT) OR b) Separate clinic teams that are well coordinated (e.g., notes indicated active communication or knowledge that separate clinics were working with patient).  OR c) Separate clinic teams not well coordinated (e.g., no communication between the 2 clinic teams or only a referral).  OR d) Only received treatment for 1 condition.	Likely multiple.	Administrative/paper-based medical records.	VHA

		TABLE D.1 (continued)			
Measure	Denominator	Numerator	Setting	Data Source	Developer/Steward
Referral to Post-Detoxification Services.	All patients discharged from a state- funded substance abuse treatment program.	Patients from the denominator whose records contain documentation of completed detoxification and a referral or transfer to a less intensive level of treatment.	State-funded substance abuse treatment program; likely inpatient.	Paper-based medical records.	Texas Commission on Alcohol and Drug Abuse
Outpatient Visit within 3 Days of Discharge (Substance Abuse).	All inpatients discharged with a diagnosis of substance abuse during a 1 year period who remained in the community for at least 30 days following discharge.	Those patients from the denominator who had 1 or more outpatient visits for a primary or secondary diagnosis of substance abuse within 3 days of their index discharge.	Multiple, including ambulatory.	Administrative.	VAPalo Alto Health Care System
14-Day Follow-up after Initiating Substance-related Treatment.	The number of patients enrolled in a health plan during a specified interval who receive a service-related diagnosis of an alcohol or drug disorder.	The subset of patients in the denominator who receive any additional alcohol or drug treatment services within 14 days of "index" diagnosis.	Multiple, including ambulatory.	Administrative/paper- based medical records.	Washington Circle Group
Substance Abuse Treatment Following Detoxification.	The number of patients 18 and older enrolled in a health plan who were diagnosed with a substance abuse or dependence disorder and discharged from detoxification treatment within a defined time period.	The number of patients in the denominator who entered alcohol or drug treatment services within 14 days following discharge from detoxification treatment.	Multiple, including ambulatory.	Administrative/paper- based medical records.	Washington Circle Group
NQF #2605 Follow-up after Discharge from the Emergency Department for Mental Health or AOD Dependence.	Patients who were treated and discharged from an emergency department with a primary diagnosis of mental health or AOD dependence on or between January 1 and December 1 of the measurement year.	Rate 1: An outpatient visit, intensive outpatient encounter or partial hospitalization with any provider with a primary diagnosis of AOD dependence within 7 days after emergency department discharge.  Rate 2: An outpatient visit, intensive outpatient encounter or partial hospitalization with any provider with a primary diagnosis of AOD dependence within 30 days after emergency department discharge.	Multiple, including ambulatory.	Administrative claims.	NCQA
Attendance at First Post-Discharge Appointment.	All patients discharged from an inpatient setting with a primary psychiatric or substance abuse disorder diagnosis who are scheduled for a follow-up outpatient appointment during a 1 month period.	Patients from the denominator who attended their scheduled appointment.	Multiple, including ambulatory.	Administrative.	None provided. The measure was found in the Center for Quality Assessment and Improvement in Mental Health's measures inventory.
Follow-up Attended within 30 Days of Discharge (Psychiatric/Substance Abuse).	All patients discharged from an inpatient facility with a primary diagnosis of a psychiatric or SUD during the first 6 months of a specified year.	Patients in the denominator who attend an outpatient visit within 30 calendar days of discharge.	Multiple, including ambulatory	Administrative	Leslie et al., 2000. (No further information was provided.) The measure was found in the Center for Quality Assessment and Improvement in Mental Health's measures inventory.

		TABLE D.1 (continued)			
Measure	Denominator	Numerator	Setting	Data Source	Developer/Steward
Ambulatory Follow-up Attended within 30 Days of Discharge (Substance Abuse).	The number of hospital discharges to a setting other than another inpatient facility (e.g., outpatient, partial or residential program) occurring during a specified period of time for plan members with a primary or secondary diagnosis indicating a substance-related disorder and who remain continuously enrolled in the plan for 30 days after discharge.	The number of discharges in the denominator that are followed by an ambulatory substance abuse assessment or therapeutic encounter within 30 days of hospital discharge.	Multiple, including ambulatory.	Administrative.	VHA
Outpatient Follow-up After First Substance Abuse Visit.	The number of patients 18 and older enrolled in a health plan who receive a service-related diagnosis of a SUD.	Patients from the denominator who receive:  (i) 1.  OR  (ii) 3 plan-provided alcohol or drug treatment services within 30 days following the index service.	Multiple, including ambulatory.	Administrative/paper- based medical records.	Washington Circle Group
Multiple Outpatient Visits after Substance-Related Hospitalization.	All inpatients treated in substance abuse units during the FY who remained in the community for at least 30 days following their index discharge.	Those patients from the denominator who had 2 or more outpatient mental health visits within 30 days of discharge.	Multiple, including ambulatory.	Administrative.	VHA
Intensity of Aftercare within 180 Days of Discharge (Psychiatric/Substance Abuse).	All patients admitted to a hospital and discharged with a primary diagnosis of a psychiatric or SUD during the first 6 months of a specified year.	The number of outpatient visits attended by patients from the denominator during the first 180 days following inpatient discharge.	Multiple, including ambulatory.	Administrative.	Leslie et al., 2000. (No further information was provided.) The measure was found in the Center for Quality Assessment and Improvement in Mental Health's measures inventory.
Follow-up Attended within 180 Days of Discharge (Psychiatric/Substance Abuse).	All patients discharged from an inpatient setting with a primary diagnosis of a psychiatric or SUD during the first 6 months of a specified year.	Patients in the denominator who attend an outpatient visit within 180 calendar days of discharge.	Multiple, including ambulatory.	Administrative.	Leslie et al., 2000. (No further information was provided.) The measure was found in the Center for Quality Assessment and Improvement in Mental Health's measures inventory.
Continuity of Care for Dual Diagnoses.	The number of inpatients discharged with diagnoses for both psychiatric and substance-related disorders.	Those patients in the denominator who receive at least 4 psychiatric and 4 substance abuse outpatient visits within the 12-month period following discharge.	Multiple, including ambulatory.	Administrative.	VHA

		TABLE D.1 (continued)			
Measure	Denominator	Numerator	Setting	Data Source	Developer/Steward
Care Planning for Dual Diagnosis.	The number of individuals participating in a case management program who are dually diagnosed with a mental disorder and a substance abuse disorder during a 6-month period.	Those individuals from the denominator for whom a case manager has documented a plan of care that addresses the consumer's need for treatment of both conditions.	Multiple, including ambulatory.	Administrative/paper- based medical records.	None provided. The measure was found in the Center for Quality Assessment and Improvement in Mental Health's measures inventory
Case Management for Dual Diagnosis.	The number of dually diagnosed individuals enrolled in a health plan and participating in mental health case management services who respond to a biannual consumer survey at a specified point in time.	The number of participants from the denominator who report that their mental health case manager assisted them to obtain substance abuse treatment.	Multiple, including ambulatory.	Administrative/patient survey.	Tennessee Department of Mental Health and Mental Retardation
7-Day Hospital Readmission Rate (Psychiatric or Substance Abuse).	The number of inpatients discharged from an acute mental health or substance abuse facility within a 90-day period.	The number of patients in the denominator who were readmitted to the same type of facility (substance abuse or mental illness) within 7 days of discharge.	Inpatient.	Administrative/paper-based medical records.	None provided.
14-Day Readmission Rate (Psychiatric or Substance Abuse).	All patients admitted to a hospital and discharged with a primary diagnosis of a psychiatric or SUD during the first 6 months of a specified year.	Patients in the denominator who are readmitted to a hospital within 14 calendar days following the index discharge.	Inpatient.	Administrative.	Leslie et al., 2000. (No further information was provided. The measure was found in the Center for Quality Assessment and Improvement in Mental Health's measures inventory.)
180-Day Readmission Rate (Psychiatric or Substance Abuse).	All patients admitted to a hospital and discharged with a primary diagnosis of a psychiatric or SUD during the first 6 months of a specified year.	Patients in the denominator who are readmitted to a hospital within 180 calendar days following the index discharge.	Inpatient.	Administrative.	Leslie et al., 2000. (No further information was provided. The measure was found in the Center for Quality Assessment and Improvement in Mental Health's measures inventory.)
Readmission Rates for Chemical Dependency. (This measure has been retired by the NCQA and is not part of the current HEDIS measure set.)	All plan members hospitalized with a primary diagnosis of a substance abuse related disorder in a specified year.	Those members from the denominator who are readmitted for related care of chemical dependency:  a) Within 1 year of discharge (count 1 readmission per member).  OR b) Within 90 days of discharge.	Inpatient.	Administrative.	NCQA

	TABLE D.1 (continued)						
Measure	Denominator	Numerator	Setting	Data Source	Developer/Steward		
Continuation after Substance-Related Treatment Initiation.	All members of a health plan who have an outpatient visit for a primary diagnosis of a SUD during a specified period.	Those members in the denominator who within 30 days of diagnosis utilize:  i) 3 substance abuse specialty outpatient visits, consecutive inpatient days, or consecutive residential days.  ii) 3 general medical outpatient visits for a primary diagnosis of substance abuse disorder.	Ambulatory.	Administrative/paper- based medical records.	Washington Circle Group		
		iii) 3 visits consisting of either specialty substance abuse treatment or general medical treatment.					
COMMUNITY, POPULATION	N, AND PUBLIC HEALTH	·					
Proportion of selected SUD patients who engage in timely treatment for alcohol and other drug dependence.	All patients with an SUD diagnosis in a new treatment episode.	Those members in the denominator who within 30 days of the start of a new treatment episode have engaged with SUD treatment.	Multiple, including ambulatory.	Not specified.	VHA		
Access to Substance Abuse Treatment (Adults).	Estimate (based on survey of random-digit dialing sample of households) of state residents aged 18 and older who report having alcohol or drug-related problems (abuse or dependence as defined by DSM-IV criteria) who are medically indigent (annual household income <\$10,000; receiving Medicaid or other public assistance; and have no medical insurance) and who desire substance-related treatment at a specified point in time.	Number of residents (based on unduplicated count of client billings) from the denominator who have received services from a substance abuse treatment program funded by the state substance abuse agency.	Multiple, including ambulatory (restricted to state-funded services).	Patient survey.	Texas Commission on Alcohol and Drug Abuse		
Access to Substance Abuse Treatment (Children).	The estimate (based on 2 public school- based prevalence surveys) of state residents 12-17 years of age who report having alcohol or drug-related problems (abuse or dependence as defined by certain problem-related survey questions) who are medically indigent (based on census, 200% federal poverty level) and who desire substance-related treatment at a specified point in time.	Number of residents (based on unduplicated count of client billings) from the denominator who have received services from a substance abuse treatment program funded by the state substance abuse agency.	Multiple, including ambulatory (restricted to state-funded services).	Patient survey.	Texas Commission on Alcohol and Drug Abuse		

	TABLE D.1 (continued)						
Measure	Denominator	Numerator	Setting	Data Source	Developer/Steward		
Proportion of patients with COD in a new treatment episode for COD with an administrative discharge.	Patients with a new treatment episode for a COD.	a) Proportion of patients with an administrative discharge on or after the start of the new treatment episode. b) Patients with an administrative discharge within 90 days of the start of a new treatment episode. c) Patients with an administrative discharge more than 90 days of the start of a new treatment episode. d) Patients with no documentation of an administrative discharge. e) For descriptive purposes, note reasons for discharge.	Unclear, we infer it includes inpatient and possibly ambulatory.	Administrative/paper-based medical records.	VHA		
Homeless: percent of eligible homeless Veterans with an intake interview who receive timely mental health or SUD specialty services.	Number of Veterans identified by intake interview as homeless or at imminent risk of homelessness who are eligible for VHA health care and indicate an interest in receiving VA psychiatric or substance abuse services.	Number of Veterans in the denominator who receive timely* mental health or SUD specialty care.  *Timely care is defined as applicable inpatient, residential, or outpatient care occurring within the period of 30 days prior to and extending to 60 days after the index date. Refer to the original measure documentation for additional details.	Multiple, including ambulatory.	Administrative/paper- based medical records, ambulatory, inpatient, residential, substance use treatment programs.	VHA		
Identification of alcohol and other drug services: summary of the number and percentage of members with an AOD claim who received the following chemical dependency services during the measurement year: any service, inpatient, intensive outpatient or partial hospitalization, and outpatient or emergency department.	For commercial, Medicaid, and Medicare product lines, all member months during the measurement year for members with the chemical dependency benefit, stratified by age and sex.	Members who received inpatient, intensive outpatient, partial hospitalization, outpatient and emergency department chemical dependency services (see the related "Numerator Inclusions/Exclusions" field).	Multiple, including ambulatory.	Administrative, EHR, paper-based medical records (health plan).	NCQA		
Chemical Dependency Utilization- Percent of Members Receiving Inpatient, Day/Night Care and Ambulatory Services.	The number of members receiving chemical dependency services during the measurement year.	The number of members receiving services in the following categories: any chemical dependency services; day/night chemical dependency services; ambulatory chemical dependency services. Reported by age and sex.	Multiple, including ambulatory.	Administrative.	NCQA		

		TABLE D.1 (continued)			
Measure	Denominator	Numerator	Setting	Data Source	Developer/Steward
Identification of alcohol and other drug services: summary of the number and percentage of members with an AOD claim who received the following chemical dependency services during the measurement year: any service, inpatient, intensive outpatient or partial hospitalization, and outpatient or emergency department.	For commercial, Medicaid, and Medicare product lines, all member months during the measurement year for members with the chemical dependency benefit, stratified by age and sex.	Members who received inpatient, intensive outpatient, partial hospitalization, outpatient and emergency department chemical dependency services (see the related "Numerator Inclusions/Exclusions" field).	Multiple, including ambulatory.	Administrative, EHR, paper-based medical records.	NCQA
CARE COORDINATION					
NQF #0004 IET.	Patients age 13 years of age and older who were diagnosed with a new episode of AOD dependency during the first 10½ months of the measurement year (e.g., January 1-November 15).	Initiation of AOD Dependence Treatment:  Initiation of AOD treatment through an inpatient admission, outpatient visit, intensive outpatient encounter or partial hospitalization within 14 days of diagnosis.  Engagement of AOD Treatment:  Initiation of AOD treatment and 2 or more inpatient admissions, outpatient visits, intensive outpatient encounters or partial hospitalizations with any AOD diagnosis within 30 days after the date of the Initiation encounter (inclusive).	Multiple, including ambulatory.	Administrative clinical data, electronic health/medical record, paper-based medical record.	NCQA
Patients diagnosed with SUD in primary care were given a referral to specialty SUD care.	Patients with SUD diagnosis.	(1) Patients from the denominator who were already in Specialty SUD care.  OR (2) Patients from the denominator not already in Specialty SUD care who were offered a referral to Specialty SUD care and who:  a) Refused referral to Specialty SUD care.  b) Did not complete a referral to Specialty SUD care.  c) Completed at least 1 visit to Specialty SUD care.	Multiple.	Administrative/paper- based medical records.	VHA
	R CENTERED EXPERIENCE OU				
Substance Abuse Education in Primary Care.	All enrollees of a health plan age 18 and older who had a primary care visit and responded to an enrollee survey within a specified time period.	The total number of patients in the denominator who report that they were advised or given information about alcohol and/or drug abuse by the primary care provider.	Multiple, including ambulatory.	Patient survey.	Washington Circle Group

		TABLE D.1 (continued)			
Measure	Denominator	Numerator	Setting	Data Source	Developer/Steward
Mental health/substance abuse: mean of patients' change scores on the "Substance Abuse" subscale of the BASIS-24® survey.	Adult patients 18 years of age and older who completed a BASIS-24® survey at the beginning of psychiatric and/or substance abuse treatment and at another point in the treatment process.*  *Note: Completion of the second survey may be at discharge/termination or at another follow-up point during the episode of care.	The mean of patients' change scores on the "Substance Abuse" subscale of the BASIS-24® survey.	Multiple, including ambulatory.	Administrative/patient survey.	McLean Hospital, Department of Mental Health Services Evaluation- Hospital/Medical Center (Eisen, Susan V., Ph.D.)
Proportion of patients abstinent from drugs OR alcohol in the 30 days prior to their last visit for outpatient specialty care treatment.	Patients with SUD diagnosis in specialty mental health care.	Patients from the denominator who were abstinent from drugs OR alcohol in the 30 days prior to their last visit for outpatient specialty care treatment during the study period.	Ambulatory.	Administrative/paper- based medical records.	VHA
Family Involvement in Substance Abuse Treatment.	The total number of members 18 and older enrolled in a health plan who report using AOD treatment services.	The number of respondents from the denominator who report that their family members and/or significant other received preventive interventions.	Likely multiple.	Patient survey.	Washington Circle Group
HIV ambulatory care satisfaction: percentage of HIV-positive adult patients who reported how often their plan covered alcohol and drug use treatment as much as they needed.	HIV-positive adult patients 18 years of age and older continuously enrolled in a Medicaid managed care plan in the last 12 months and completed the survey.	The number of patients who indicated "All of the time," "Most times," "Sometimes," "Rarely," "Never," or "Does Not Apply" to the item, "My plan covered alcohol and drug use treatment as much as I needed."	Multiple.	Patient survey.	New York State Department of Health AIDS Institute
HIV ambulatory care satisfaction: percentage of HIV-positive adult patients who reported whether their substance use counselors explained to them in a way they could understand how their substance use treatment (for example, methadone) and their HIV medications might interact.	HIV-positive adult patients 18 years of age and older engaged in a substance use treatment program who completed the survey.	The number of patients who indicated "Strongly Disagree," "Disagree," "Agree," "Strongly Agree," or "Does Not Apply" to the item, "My substance use counselors explained to me in a way I could understand how my substance use treatment (for example, methadone) and my HIV medications might interact."	Multiple.	Patient survey.	New York State Department of Health AIDS Institute

## DEVELOPMENT AND TESTING OF BEHAVIORAL HEALTH QUALITY MEASURES

### **Reports Available**

Development of Quality Measures for Inpatient Psychiatric Facilities: Final Report

HTML <a href="https://aspe.hhs.gov/basic-report/development-quality-measures-inpatient-">https://aspe.hhs.gov/basic-report/development-quality-measures-inpatient-</a>

psychiatric-facilities-final-report

PDF https://aspe.hhs.gov/pdf-report/development-quality-measures-inpatient-

psychiatric-facilities-final-report

Review of Medication-Assisted Treatment Guidelines and Measures for Opioid and Alcohol Use

HTML https://aspe.hhs.gov/report/review-medication-assisted-treatment-

guidelines-and-measures-opioid-and-alcohol-use

PDF https://aspe.hhs.gov/pdf-report/review-medication-assisted-treatment-

guidelines-and-measures-opioid-and-alcohol-use

Strategies for Measuring the Quality of Psychotherapy: A White Paper to Inform Measure Development and Implementation

HTML <a href="https://aspe.hhs.gov/report/strategies-measuring-quality-psychotherapy-">https://aspe.hhs.gov/report/strategies-measuring-quality-psychotherapy-</a>

white-paper-inform-measure-development-and-implementation

PDF https://aspe.hhs.gov/pdf-report/strategies-measuring-quality-

psychotherapy-white-paper-inform-measure-development-and-

<u>implementation</u>

To obtain a printed copy of this report, send the full report title and your mailing information to:

U.S. Department of Health and Human Services Office of Disability, Aging and Long-Term Care Policy Room 424E, H.H. Humphrey Building 200 Independence Avenue, S.W. Washington, D.C. 20201

FAX: 202-401-7733

Email: webmaster.DALTCP@hhs.gov

NOTE: All requests must be in writing.

#### **RETURN TO:**

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Assistant Secretary for Planning and Evaluation (ASPE) Home <a href="http://aspe.hhs.gov">http://aspe.hhs.gov</a>

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