The ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use

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Professor of Psychiatry, Perelman School of Medicine
ASAM State of the Art Course in Addiction Medicine
6 October 2016
The ASAM State of the Art Course
6 October 2016
Kyle Kampman M.D.

Disclosure Information

Indivior – Grant support, Consultant
Alkermes – Grant Support
Opiant -Grant Support, Consultant
Braeburn – Grant Support
Why this Guideline?

- Medications for opioid use disorder underused
- Most physicians have little training in the use of medications for opioid use disorder
- Although guidelines exist for specific medications none include all approved medications.
- Few guidelines include guidance for special populations such as adolescents, pain patients, pregnant patients, prisoners and probationers
Overview of the Process

- RAND/UCLA Appropriateness Method (RAM)
  - Combines scientific evidence and clinical knowledge to determine the appropriateness of a set of clinical procedures
- Appropriate for this guideline for 2 reasons
  - Few trials compare the approved medications
  - Varying levels of evidence for the individual medications
- 5 step process
RAM Process Step 1

- Literature search
- Review of existing guidelines
- Psychosocial treatment literature review
RAM Process Step 2

- Identification of Hypothetical Statements and Appropriateness Rating
  - 245 hypothetical statements created
  - Evaluated by the Guideline Committee
    - Rated for appropriateness
    - Discussed at Guideline Committee meeting
  - Second literature search conducted
  - Outline created
RAM Process Step 3

- **Comparative Analysis, Review and Necessity Rating**
  - Committee rated hypotheticals for necessity
  - Final draft outline created
RAM Process Step 4

- **Drafting the National Practice Guideline**
  - The initial draft was prepared and sent to the
    - Guideline Committee for review.
  - Committee met and discussed the draft document
  - Revised draft was prepared for external review
RAM Process Step 5

- **External Review**
  - Document was made available for public comment
  - Document sent to invited reviewers
  - Results of review discussed with QIC

- **Final document prepared**
Guideline Committee

- Sandra Comer, PhD
- Chinazo Cunningham, MD, MS
- Marc J. Fishman, MD, FASAM
- Adam Gordon, MD, MPH, FASAM
- Kyle Kampman, MD, Chair
- Daniel Langleben, MD
- Ben Nordstrom, MD, PhD
- David Oslin, MD
- George Woody, MD
- Tricia Wright, MD, MS
- Stephen Wyatt, DO
ASAM Quality Improvement Council

- John Femino, MD, FASAM
- Margaret Jarvis, MD, FASAM, Chair
- Margaret Kotz, DO, FASAM
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- Robert J. Roose, MD, MPH 22
- Alexis Geier-Horan, ASAM Staff
- Beth Haynes, ASAM Staff
TRI Technical Team

- Kyle Kampman, MD
- David Festinger, PhD
- Keli McLoyd, JD
- Amanda Abraham, PhD
- Karen Dugosh, PhD
- Abigail Woodworth, MS
- Brittany Seymour, BA
Overview of the Guideline

- Part 1  Assessment and Diagnosis of Opioid Use Disorder
- Part 2  Treatment Options
- Part 3  Opioid Withdrawal
- Part 4  Methadone
- Part 5  Buprenorphine
- Part 6  Naltrexone
- Part 7  Psychosocial Treatment
Overview of the Guideline

- Part 8  Pregnant women
- Part 9  Individuals with Pain
- Part 10  Adolescents
- Part 11  Individuals with co-occurring psychiatric disorders
- Part 12  Individuals in the criminal justice population
- Part 13  Naloxone for the treatment of opioid overdose
- Part 14  Areas for further research
Updates / Clarifications

- **Part 1 Assessment and Diagnosis**
  - Physical exam and psychiatric evaluation as part of the complete exam

- **Part 2 Withdrawal Management**
  - Nonnarcotic medications for withdrawal management

- **Part 4 Methadone**
  - Methadone dosing
Updates / Clarifications

♦ Part 5 Buprenorphine
  ♦ Induction techniques
  ♦ Probuphine approved
    ♦ Probuphine
      ♦ Long acting implantable buprenorphine
      ♦ Approved for maintenance treatment of opioid dependence in patients who have achieved and sustained prolonged clinical stability on low-to-moderate doses of a transmucosal buprenorphine-containing product (i.e., doses of no more than 8 mg per day of Subutex or Suboxone sublingual tablet or generic equivalent).
Updates / Clarifications

- Probuphine cont’d
  - Two phase three trials in newly abstinent opioid dependent patients showed probuphine reduced illicit opioid use
  - Probuphine not inferior to sublingual buprenorphine in maintaining abstinence in stable patients
    - Responders: 96% Probupine vs. 88% buprenorphine
      - Complete abstinence: 80% Probuphine vs. 67% buprenorphine
Updates / Clarifications

- Part 7 Psychosocial counseling
  - The need for psychosocial counseling along with medications

- Part 12 Individuals in the Criminal Justice System
  - New data for extended release injectable naltrexone
    - Multicenter trial involving 308 offenders
    - 24 weeks treatment, randomized to XR naltrexone or placebo
    - XR naltrexone treated subjects vs. placebo-treated subjects:
      1. longer time to relapse 10.5 weeks vs. 5.0 weeks
      2. lower rate of relapse 43% vs. 64%
      3. higher rate opiate neg urine samples 74% vs. 56%

Lee et al., N Engl J Med 374;13 1232-42.
Discussion

- The Guideline is a unique and clinically useful document
- It was developed using a validated method
- It will need to be updated as new data becomes available
HHS Opioid Initiative
The ASAM State of the Art Course
October 6, 2016
Disclosure Information

CAPT Jennifer Fan, PharmD, JD

No Disclosures
Behavioral Health is Essential To Health

Prevention Works

Treatment is Effective

People Recover
The Future of Prevention: Addressing the Prescription Drug Abuse and the Opioid/Heroin Epidemic in our Country

CAPT Jennifer Fan, PharmD, JD
Special Assistant to the Director
SAMHSA’s Center for Substance Abuse Prevention

Integrating Primary and Behavioral Health Care Through the Lens of Prevention
July 14, 2016
New Orleans, Louisiana
The Growing Drug Overdose Epidemic

2014

New York Times – NYtimes.com
Opioids

oxycodone

hydrocodone

heroin

SAMHSA
Prescription Opioids and Heroin: Public Health Challenge

In 2014, 1.9 million people had a prescription opioid use disorder and nearly 600,000 had a heroin use disorder. The national data on overdose deaths are startling: in 2014, there were 28,647 overdose deaths involving prescription opioid medications and/or heroin.

That is equivalent to an average of one death every 18 minutes.
Past Month Nonmedical Use of Pain Relievers among People Aged 12 or Older, by Age Group: 2002-2014

+ Difference between this estimate and the 2014 estimate is statistically significant at the .05 level.
Past Month Heroin Use among People Aged 12 or Older, by Age Group: 2002-2014

+ Difference between this estimate and the 2014 estimate is statistically significant at the .05 level.
Numbers of Past Year Initiates of Selected Substances among People Aged 12 or Older: 2014

- Marijuana: 2,568,000 (2.6 Million)
- Pain Relievers: 1,425,000 (1.4 Million)
- Tranquilizers: 1,133,000 (1.1 Million)
- Cocaine: 766,000
- Stimulants: 690,000
- Ecstasy: 676,000
- LSD: 586,000
- Inhalants: 512,000
- Heroin: 212,000
- Methamphetamines: 183,000
- Sedatives: 173,000
- Alcohol: 4,655,000 (4.7 Million)
- Cigarettes: 2,164,000 (2.2 Million)
- Smokeless Tobacco: 1,016,000 (1.0 Million)
Perceived Great Risk from Substance Use among People Aged 12 or Older: 2014
Perceived Great Risk from Trying Heroin Once or Twice among People Aged 12 or Older, by Age Group: 2002-2014

+ Difference between this estimate and the 2014 estimate is statistically significant at the .05 level.
Source Where Pain Relievers Were Obtained for Most Recent Nonmedical Use among Past Year Users Aged 12 or Older: 2012-2013

Note: The percentages do not add to 100% due to rounding.

1The Other category includes the sources "Wrote Fake Prescription," "Stole from Doctor’s Office/Doctor’s Fridge," and "Some Other Way."
Moving Toward Integration: Prevention Across the Lifespan

Interventions by Developmental Phase

Prior to Conception → Prenatal → Infancy → Early Childhood → Childhood → Early Adolescence → Adolescence → Young Adulthood

- Pregnancy Prevention
- Prenatal care
- Home visiting
- Early childhood interventions
- Parenting skills training
- Social and behavioral skills training
- Classroom-based curriculum to prevent substance abuse, aggressive behavior, or risky sex
- Prevention of depression
- Prevention of schizophrenia
- Prevention focused on specific family adversities (bereavement, divorce, parental psychopathology, parental substance use, parental in carceration)
- Community interventions
- Policy

FIGURE II-1 Interventions and their targeted developmental stages.

Moving Toward Integration: Continuum of Care

Prevention
  - Universal
  - Selective
  - Indicated

Treatment
  - Case Identification
  - Standard Treatment for Known Disorders
  - Compliance with Long-term Treatment (Goal: Reduction in Relapse and Recurrence)
  - After-care (including Rehabilitation)

Recovery

Promotion
  - Promotion

Course in Addiction Medicine
Four Pillars:

1. Education
2. Tracking and Monitoring
3. Proper Medication Disposal
4. Enforcement
HHS Strategy to Address Opioid Epidemic

1. Improve prescriber practices.
2. Increase naloxone use.
3. Expand MAT access.
Prescription Drug Policy Academies

- Department of Health and Human Services (HHS)
- SAMHSA/ASTHO
- CDC/NGA
SAMHSA’s Prescription Drug Abuse Policy Academy in Partnership with ASTHO
Turn the Tide – Rx
www.TurnTheTideRx.org/join

THE OPIOID EPIDEMIC IN NUMBERS

Since 1999, there has been a

300%

increase in the sales of opioid
prescriptions – without an
overall change in reported pain

SOURCE: CDC
SAMHSA’s Strategic Initiatives

1. Prevention of Substance Abuse and Mental Illness
2. Trauma and Justice
3. Recovery Support
4. Health Care and Health Systems Integration
5. Health Information Technology
6. Workforce Development
Strategic Initiative #1 - Prevention of Substance Abuse and Mental Illness

1.1  Promote emotional health and wellness, prevent or delay the onset of and complications from substance abuse and mental illness, and identify and respond to emerging behavioral health issues.

1.2  Prevent and reduce underage drinking and young adult problem drinking.

1.3  Prevent and reduce attempted suicides and deaths by suicide among populations at high risk.

1.4  Prevent and reduce prescription drug and illicit opioid misuse and abuse.
SAMHSA’s Rx Drug/Opioid Abuse Efforts

- Prescriber Education
- PCSS-Opioids and PCSS-MAT
- Screening, Brief Intervention, and Referral to Treatment – SBIRT
- SAMHSA/CDC Prescription Drug Abuse Prevention Campaign
- Not Worth the Risk, Even If It’s Legal (pamphlet series)
- Federal Drug-Free Workplace Program
- Prescription Drug Monitoring Program (grants and pilots)

- Opioid Overdose Prevention Toolkit
- Drug Free Communities
- Substance Abuse Block Grant
- Partnerships for Success grants
- SPF Rx grants (new)
- PDO grants (new)
- MAT-PDOA
- Buprenorphine Rule
- Treatment Drug Courts
- PPW
Safe and Effective Opioid Prescribing for Chronic Pain

Excessive or inappropriate use of opiates in the treatment of pain is a major national problem in the delivery of healthcare. Opioids are both underprescribed and overprescribed. Prescribing clinicians need training in effective communication skills as well as an understanding of when and how to prescribe opioids.

In addition to the specialists who frequently prescribe opioids (pain specialists, orthopedists, rheumatologists), primary care clinicians have increasingly taken on the burden of managing pain effectively. Safe and Effective Opioid Prescribing for Chronic Pain offers clinicians necessary education in how to work with their patients who are living with chronic pain – how to define chronic pain, how to manage its treatment, the tools available to assess pain and the risk involved in prescribing opioids, and how to discontinue treatment if necessary.

SAMHSA Funded Free Courses
Providers Clinical Support System for Opioid Therapies (PCSS – O)
Screening, Brief Intervention, and Referral to Treatment (SBIRT)

SBIRT is a comprehensive, integrated, public health approach to the delivery of early intervention and treatment services for persons with substance use disorders, as well as those who are at risk of developing these disorders. Primary care centers, hospital emergency rooms, trauma centers, and other community settings provide opportunities for early intervention with at-risk substance users before more severe consequences occur.

- Screening quickly assesses the severity of substance use and identifies the appropriate level of treatment.
- Brief intervention focuses on increasing insight and awareness regarding substance use and motivation toward behavioral change.
- Referral to treatment provides those identified as needing more extensive treatment with access to specialty care.
Prescription Drug Monitoring Programs (PDMPs)

- Many states established PDMPs to reduce prescription drug abuse and diversion.
- Statewide electronic databases:
  - Collect prescription records for all outpatient controlled substance prescriptions dispensed in the state
  - Distribute patient health information from the database to individuals authorized under state law.
Prescription Drug Monitoring Programs

Depending on state law:
- Prescribers
- Pharmacists
- Pharmacies
- Law Enforcement
- Licensing Boards
- Patients
- Others (delegate accounts allow nurses, licensed social workers to access)
Federal Drug-Free Workplace Program

- The biggest prevention program in the nation.
- Certifies drug testing labs for federal programs.
- Sets drug testing standards for the workplace.
- Prevention of Prescription Drugs in the Workplace (PAW)
Opioid Overdose Prevention Toolkit

SAMHSA
Opioid Overdose Prevention TOOLKIT:
- Facts for Community Members
- Five Essential Steps for First Responders
- Information for Prescribers
- Safety Advice for Patients & Family Members
- Recovering From Opioid Overdose

SAMHSA
Grants

- Strategic Prevention Framework Partnerships for Success State and Tribal Initiative Grants (SPF-PFS)
- Strategic Prevention Framework for Prescription Drugs (SPF Rx)
- Grants to Prevent Prescription Drug/Opioid Overdose-Related Deaths (PDO)
- Joint Drug Court Solicitation to Enhance Services, Coordination, and Treatment
Grants

- Grants to Expand Substance Abuse Treatment Capacity in Adult Treatment Drug Courts and Adult Tribal Healing to Wellness Courts (Treatment Drug Courts)
- Targeted Capacity Expansion: Medication Assisted Treatment - Prescription Drug and Opioid Addiction (MAT-PDOA)
- Services Grant Program for Residential Treatment for Pregnant and Postpartum Women (PPW)
Other HHS Federal Agency Responses

- Centers for Disease Control and Prevention (CDC)
- Health Resources and Services Administration (HRSA)
- U.S. Food and Drug Administration (FDA)
- National Institute on Drug Abuse (NIDA)
- Others
Further Questions?

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Guidelines on Treating Substance Use Disorders During Pregnancy

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Sidney Kimmel Medical College at Thomas Jefferson University
Karol.Kaltenbach@jefferson.edu
STATE OF THE ART THE ASAM Course in Addiction Medicine
October 6, 2016 | Washington, DC

Disclosure Information

Karol Kaltenbach, PhD

No Disclosures
Overview

Discussing methadone and buprenorphine, labeled by the US Food and Drug Administration (FDA) as Category C for use in pregnancy for the treatment of maternal opioid dependence: “Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.”

Pregnant women with opioid use disorders can be effectively treated with methadone or buprenorphine. Both these medications should not be considered “off-label” use in the treatment of pregnant patients with opioid use disorder (Jones et al., Am J Obstet Gynecol, 2014).
Educational Objectives:

At the conclusion of this session, participants should be able to:

Summarize main international and national guidance points regarding how to identify, assess and treat women for substance use disorders during the perinatal period.
Acknowledgements

- WHO Guideline Funding: The project was funded by the Government of the United States of America (U.S. Department of State, Bureau for International Narcotics and Law Enforcement Affairs) through the United Nations Office on Drugs and Crime, and the Government of the Kingdom of Norway.

- The National Institute of Drug Abuse (NIDA), USA, and the National Institute of Alcohol Abuse and Alcoholism (NIAAA), USA, supported some evidence reviews and attendance of participants at the initial scoping meeting held in Washington DC, USA.


- The members of the project’s Guideline Development Group were: Sawitri Assanangkornchai, Guilherme Borges, Grace Chang, Anju Dhawan Dutta, Elizabeth Elliott, Katherine Everett-Murphy, Gabriele Fischer, Erikson Furtado, Hendree Jones, Fareed A. Minhas, Alice Ordean, Gabrielle Katrine Welle-Strand.

Clinical Guideline USA: Center for Substance Abuse Treatment (CSAT), Substance Abuse and Mental Health Services Administration (SAMHSA), U.S. Department of Health and Human Services (HHS) by JBS International, Inc. (JBS), under contract number HHSS283200700003I/HHSS28342007T. Melinda Campopiano von Klimo, MD, Medical Officer, Division of Pharmacologic Therapies (DPT), CSAT, SAMHSA, HHS, served as the primary medical advisor; Susan Hayashi; Joseph Perpich; Anne Leopold; Krystyna Isaacs; Federal Steering Committee (FSC) representing 14 federal agencies, Expert Panel and Scientific Advisors.
Outline

- WHO Background
- WHO Process
- WHO Recommendations
- WHO Impact
- Update on USA Guidance
Background

- Substance use disorders (SUD) during pregnancy exist in every nation, yet accepted guidance for providers and women is lacking.
- 2010 a pre-consensus meeting and survey (N=22 countries from 6 continents).
- Over 90% agreement on many of the principles of treating pregnant women for SUD.
- These data provided the critical momentum needed to develop international guidance.
Objectives and Scope

- Provide evidence-based technical advice to health-care providers:
  - identifying and managing substance use and substance use disorders in pregnant women
  - apply the scientific principles of a public health approach in their own countries
- Enable pregnant women to make health decisions about alcohol and other substance use in the context of pregnancy and breastfeeding

Objectives and Scope

Guidelines focus on 6 areas:

1. Screening and Brief Intervention
2. Psychosocial Interventions
3. Detoxification
4. Dependence Management
5. Infant feeding
6. Management of Infant Withdrawal
Process

Form
• WHO established a Guideline Development Group (GDG)
• Teleconferences and virtual meetings, two face-to-face meetings

Review
• Reviewed evidence for the harms of different patterns of alcohol and drug use in pregnancy
  • Scope and areas of evidence retrieval agreed upon

Develop
• Evidence retrieved was presented and final recommendations were formulated

Review
• Recommendations were then reviewed by an External Review Group (ERG)

Approval
• GDG offered final approval, using online discussions and a teleconference
<table>
<thead>
<tr>
<th>Underlying methodology</th>
<th>Quality rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomized trials; or, double-upgraded observational studies.</td>
<td>High</td>
</tr>
<tr>
<td>Downgraded randomized trials; or, upgraded observational studies.</td>
<td>Moderate</td>
</tr>
<tr>
<td>Double-downgraded randomized trials; or, observational studies.</td>
<td>Low</td>
</tr>
<tr>
<td>Triple-downgraded randomized trials; or, downgraded observational studies; or, case series/case reports.</td>
<td>Very low</td>
</tr>
</tbody>
</table>
Evidence Search and Retrieval

<table>
<thead>
<tr>
<th>Database</th>
<th>Number of records</th>
</tr>
</thead>
<tbody>
<tr>
<td>PubMed</td>
<td>1479</td>
</tr>
<tr>
<td>EmBase</td>
<td>3614</td>
</tr>
<tr>
<td>CENTRAL</td>
<td>84</td>
</tr>
<tr>
<td>PsychInfo</td>
<td>512</td>
</tr>
<tr>
<td>CINAHL</td>
<td>754</td>
</tr>
<tr>
<td>TOTAL</td>
<td>6443</td>
</tr>
<tr>
<td>Deduplicated</td>
<td>5632</td>
</tr>
</tbody>
</table>
Evidence Search and Retrieval

Figure 1: Screening of records from the literature search to eligible articles

- Screened: 5632
- Full text obtained: 172
- Eligible articles: 93
Recommendations

A set of agreed upon principles guided the recommendations

- **Strength of the recommendation** was set as either:
  - ‘strong’: meaning that 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
  - or
  - ‘conditional’: meaning 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 the recommendation should not apply
# Recommendations

Identification and Management of Substance Use and Substance Use Disorders in Pregnancy

<table>
<thead>
<tr>
<th>No.</th>
<th>Recommendation</th>
<th>Strength of recommendation</th>
<th>Quality of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>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.</td>
<td>Strong</td>
<td>Low</td>
</tr>
<tr>
<td>2</td>
<td>Health-care providers should offer a brief intervention to all pregnant women using alcohol or drugs.</td>
<td>Strong</td>
<td>Low</td>
</tr>
</tbody>
</table>
Recommendations

Identification and Management of Substance Use and Substance Use Disorders in Pregnancy

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<tr>
<td>3</td>
<td>Health-care providers managing pregnant or postpartum women with alcohol or other substance use disorders should offer comprehensive assessment², and individualized care³.</td>
<td>Conditional</td>
<td>Very low</td>
</tr>
</tbody>
</table>

¹ The concept of “substance use disorders” includes dependence syndrome and harmful use of psychoactive substances such as alcohol, cannabis, amphetamine type stimulants (ATS), cocaine, benzodiazepines, etc.

² A comprehensive assessment of women using alcohol or drugs in pregnancy and the postpartum period include assessment of patterns of substance use, medical or psychiatric co-morbidity, family context and social problems.

³ Individual care planning involves selecting appropriate psychosocial and pharmacological interventions based on a comprehensive assessment.
## Recommendations

### Identification and Management of Substance Use and Substance Use Disorders in Pregnancy

<table>
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<tr>
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<tr>
<td>4</td>
<td>Health-care providers should at the earliest opportunity advise pregnant women dependent on alcohol or drugs to cease their alcohol or drug use and offer, or refer to, detoxification services under medical supervision where necessary and applicable.⁴</td>
<td>Strong</td>
<td>Very low</td>
</tr>
<tr>
<td>5</td>
<td>Pregnant women dependent on opioids should be encouraged to use opioid maintenance treatment⁵ whenever available rather than to attempt opioid detoxification.</td>
<td>Strong</td>
<td>Very low</td>
</tr>
</tbody>
</table>

⁴ Pregnant women dependent on alcohol or drugs who agree to undergo detoxification should be offered the supported withdrawal from substance use in an inpatient or hospital facility, if medically indicated; equal attention should be paid to the health of mother and fetus and treatment adjusted accordingly.

⁵ Methadone maintenance treatment or buprenorphine maintenance treatment.
# Recommendations

Identification and Management of Substance Use and Substance Use Disorders in Pregnancy

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<tr>
<td>6</td>
<td>Pregnant women with benzodiazepine dependence should undergo a gradual(^{6}) dose reduction, using long-acting benzodiazepines.</td>
<td>Strong</td>
<td>Very low</td>
</tr>
<tr>
<td>7</td>
<td>Pregnant women who develop withdrawal symptoms following the cessation of alcohol consumption should be managed with the short-term use of a long-acting benzodiazepine.(^{7})</td>
<td>Strong</td>
<td>Very low</td>
</tr>
<tr>
<td>8</td>
<td>In withdrawal management for pregnant women with stimulant dependence, psychopharmacological medications may be useful to assist with symptoms of psychiatric disorders but are not routinely required.</td>
<td>Strong</td>
<td>Very low</td>
</tr>
</tbody>
</table>

\(^{6}\) For as short a time as is medically feasible.

\(^{7}\) Management of alcohol withdrawal usually includes administration of thiamine.

## Recommendations

Identification and Management of Substance Use and Substance Use Disorders in Pregnancy

<table>
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<tr>
<td>9</td>
<td>Pharmacotherapy is not recommended for routine treatment of dependence on amphetamine-type stimulants, cannabis, cocaine, or volatile agents in pregnant patients.</td>
<td>Conditional</td>
<td>Very low</td>
</tr>
<tr>
<td>10</td>
<td>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.</td>
<td>Conditional</td>
<td>Very low</td>
</tr>
<tr>
<td>11</td>
<td>Pregnant patients with opioid dependence should be advised to continue or commence opioid maintenance therapy with either methadone or buprenorphine.</td>
<td>Strong</td>
<td>Very low</td>
</tr>
</tbody>
</table>
# Recommendations

## Identification and Management of Substance Use and Substance Use Disorders in Pregnancy

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<tbody>
<tr>
<td>12</td>
<td>A. Mothers with substance use disorders should be encouraged to breastfeed unless the risks clearly outweigh the benefits.</td>
<td>Conditional</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>B. Breastfeeding women using alcohol or drugs should be advised and supported to cease alcohol or drug use; however, substance use is not necessarily a contraindication to breastfeeding.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Skin-to-skin contact is important regardless of feeding choice and needs to be actively encouraged for the mother with a substance use disorder who is able to respond to her baby's needs.</td>
<td>Strong</td>
<td>Low</td>
</tr>
<tr>
<td>14</td>
<td>Mothers who are stable on opioid maintenance treatment with either methadone or buprenorphine should be encouraged to breastfeed unless the risks clearly outweigh the benefits.</td>
<td>Strong</td>
<td>Low</td>
</tr>
</tbody>
</table>
## Recommendations

### Identification and Management of Substance Use and Substance Use Disorders in Pregnancy

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<tbody>
<tr>
<td><strong>Management of infants exposed to alcohol and other psychoactive substances</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Health-care facilities providing obstetric care should have a protocol in place for identifying, assessing, monitoring and intervening, using non-pharmacological and pharmacological methods, for neonates prenatally exposed to opioids.</td>
<td>Strong</td>
<td>Very low</td>
</tr>
<tr>
<td>16</td>
<td>An opioid should be used as initial treatment for an infant with neonatal opioid withdrawal syndrome if required.</td>
<td>Strong</td>
<td>Very low</td>
</tr>
<tr>
<td>17</td>
<td>If an infant has signs of a neonatal withdrawal syndrome due to withdrawal from sedatives or alcohol, or the substance the infant was exposed to is unknown, then phenobarbital may be a preferable initial treatment option.</td>
<td>Conditional</td>
<td>Very low</td>
</tr>
<tr>
<td>18</td>
<td>All infants born to women with alcohol use disorders should be assessed for signs of fetal alcohol syndrome.</td>
<td>Conditional</td>
<td>Very low</td>
</tr>
</tbody>
</table>

Impact in the USA

State and Federal governments have referred to these guidelines when addressing opioid use disorders during pregnancy and prenatal exposure to opioids.

Guidance updated from most influential practice organizations:
- American Congress of Obstetricians and Gynecologists
- American Society of Addiction Medicine
- American Academy of Addiction Psychiatry
- Academy of Breastfeeding Medicine
Goal: SAMHSA set out to provide concrete recommendations for clinicians for providing care to pregnant and parenting women with opioid use disorder and their children, including recommendations for how to treat prenatal opioid use and neonatal abstinence syndrome (NAS).
Summary

- Background
- Process
- Recommendations
- Moving Forward
Questions and Answers