Guidelines and Research for Provision of Medication-Assisted Treatment for Adolescents in Office-Based Settings

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Topic

Lamprey Health Care, located in Nashua, New Hampshire, currently provides medication-assisted treatment (MAT) to persons ages 18 and older and would like to expand MAT services using buprenorphine and naltrexone (marketed under the trade name Vivitrol) to adolescents ages 16 and 17 in office-based settings. This would be a new service area for Lamprey Health Care, and they have requested information on policies and guidelines for this special population.

Background

Treatment for opioid use disorder in adolescents presents unique medical, legal, and ethical issues. Confidentiality is a key concern for adolescents seeking treatment and should be considered in treatment planning. However, providers may need to make decisions based on best medical judgment to address imminent danger. Opioid agonists (methadone and buprenorphine) and antagonists (naltrexone) may be considered for treatment, but efficacy studies have largely been conducted in adults and limited data are available for adolescents. Buprenorphine is approved by the U.S. Food and Drug Administration (FDA) for patients ages 16 and older. Methadone is approved for patients ages 18 and older to improve outcomes and prevent adverse effects of untreated opioid use disorder (OUD). FDA regulations allow for younger patients with a documented history of at least two prior unsuccessful withdrawal management attempts to receive buprenorphine treatment with consent from parents or guardians. Naltrexone has been approved for patients ages 18 and older but the safety, efficacy, and pharmacokinetics of extended-release injectable naltrexone have not been established in the adolescent population. The FDA does not recommend naltrexone for anyone younger than 18 years of age. However, naltrexone is prescribed off-label to treat OUD in patients younger than 18 (as evidenced by the Banta-Green and Cooley article and the New York State Clinical Practice Standards for Adolescent Programs cited in this document). Banta-Green and Cooley speak to this discrepancy when they point out that FDA approval means a medication is safe and has efficacy in a controlled clinical environment. However, adolescents with OUD in need of MAT are not living in controlled environments. Naltrexone may be safe and effective in treating adolescents, even though it is not approved by the FDA.

Brief Overview of MAT Drugs

Methadone has the largest evidence base and has been in use the longest of all the medications used to treat OUD. Methadone is a full opioid agonist, meaning that it activates the opioid receptors in the brain, reducing cravings and withdrawal symptoms. For the first several years of their treatment, patients must report to a federally supervised methadone clinic daily to receive doses that are taken onsite.

Buprenorphine has been used to treat OUD for two decades, and there is strong evidence for its effectiveness. Buprenorphine is a partial opioid agonist, meaning it partially activates the brain's opioid receptors. It is often combined with naloxone to help prevent diversion or abuse. (Naloxone is an opioid antagonist; its presence prevents the high that opioid agonists can produce.)

Naltrexone, in long-acting injectable form, has been used since 2010 to treat OUD. Because it is relatively new, naltrexone has the smallest evidence base of the MAT drugs. Naltrexone is an opioid antagonist, meaning that it prevents opioids from activating the brain's opioid receptors. People taking naltrexone will not experience an

opioid high and will not easily overdose. Once patients stop taking naltrexone, they are at increased risk of overdose for at least 7–10 days.

Methodology

NHTAC conducted an online review of state and federal policies and guidelines on MAT. The review also included the latest research on treating youth ages 16 and 17 using buprenorphine and naltrexone in office-based settings.

About This Technical Assistance (TA) Product

The New Hampshire Technical Assistance Center, operated by Growth Partners, is funded by the New Hampshire Bureau of Drug and Alcohol Services (BDAS) to provide a wide range of TA services to support the state's alcohol and other drug continuum of care. If you would like more information about this document or to request TA, please visit us at www.nhtac.org.

NATIONAL AND STATE GUIDANCE

Substance Abuse and Mental Health Services Administration. (2015). Federal Guidelines for Opioid Treatment Programs. HHS Publication No. (SMA) PEP15-FEDGUIDEOTP.

The 2015 Federal Guidelines for Opioid Treatment Programs (OTP) serve as a guide to accrediting organizations for developing accreditation standards. The guidelines also provide OTPs with information on how programs can achieve and maintain compliance with federal regulations. The Guidelines reflect the obligation of OTPs to deliver care consistent with patient-centered, integrated, and recovery-oriented standards of substance use disorder (SUD) treatment. SAMHSA defines youth as ranging in age from 13 to 18. Guidance specific to youth includes ensuring that providers use developmentally appropriate treatment and evidence-based psychosocial support, such as family involvement, where appropriate. Screenings and assessments should be tailored to youth to ensure MAT is the most appropriate treatment. The guidelines also include detailed information on the components of an individual record ranging from an initial assessment report to a closing summary, including reasons for discharge and any referrals.

New Hampshire Department of Health and Human Services, Bureau of Drug and Alcohol Services. (2018). Guidance Document on Best Practices: Key Components for Delivering Community-Based Medication Assisted Treatment for Opioid Use Disorders in New Hampshire, Second Edition.

The New Hampshire Department of Health and Human Services (DHHS) and BDAS convened a panel of practitioners from health care, behavioral health, specialty SUD treatment services, and the state's Medical Society to review existing MAT models in New Hampshire and other states. The panel was tasked with identifying key components and best practices for developing recommendations and resources for initiating and expanding MAT capacity to serve more patients with OUD. The goals of this effort were to:

- Increase the number of waivered buprenorphine prescribers.[1]
- Increase office-based access to MAT programs through multiple settings, including primary care, offices and clinics, and specialty MAT programs.
- Increase awareness of, and access to, extended-release injectable naltrexone and other medications by prescription.
- Include a focus on medications such as buprenorphine and naltrexone that may be prescribed in an office-based setting, unlike methadone, which per federal regulation must be dispensed at certified opioid treatment programs.

English, A. (2019). Adolescent & Young Adults Health Care in New Hampshire: A Guide to Understanding Consent & Confidentiality Laws. Adolescent & Young Adult Health National Resource Center and Center for Adolescent Health & the Law.

This guide provides information to healthcare providers on the legal consent requirements and confidentiality protections for adolescents and young adults in New Hampshire. New Hampshire has several laws either

[1] The federal Omnibus Spending Bill signed at the end of 2022 included the Mainstreaming Addiction Treatment Act, which removed the Drug Enforcement Agency's waiver requirement, making it possible for any prescribing provider (e.g., nurse practitioners, physician assistants, and physicians) to write prescriptions for buprenorphine (https://www.pewtrusts.org/en/research-and-analysis/articles/2022/12/30/president-signs-bipartisan-measure-to-improve-addiction-treatment).

allowing minors to receive certain services without prior parental consent or authorizing them to consent for specific healthcare services, including some preventive services. In particular, these laws cover emergency care, STI care, HIV testing, treatment for drug dependency or problems related to drug use, and community mental health services.

The ASAM National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update
The American Society of Addiction Medicine (ASAM) has developed the National Practice Guideline for the Treatment of Opioid Use Disorder, an update to the 2015 ASAM guideline for MAT for OUD. The Guideline provides evidence-based information for treating OUD. The Guideline primarily covers FDA-approved medications for the treatment of OUD and the prevention of opioid overdose-related deaths. For example, ASAM has updated its guidance regarding adolescents to include the importance of psychosocial treatment. Psychosocial treatment is recommended for adolescents with OUD. Providers should carefully consider the risk–benefit balance of pharmacological treatment without concurrent psychosocial treatment and discuss with patients and their parent or guardian as appropriate. A patient's decision to decline psychosocial treatment or the absence of available psychosocial treatment should not preclude or delay pharmacological treatment of OUD with appropriate medication management. Motivational interviewing or enhancement can be used to encourage patients to engage in psychosocial treatment services appropriate for addressing their individual needs.

American Academy of Pediatrics Committee on Substance Use and Prevention. (2016). Medication-Assisted Treatment of Adolescents with Opioid Use Disorders. *Pediatrics,* 138(3): e20161893.
The American Academy of Pediatrics (AAP) advocates for increasing resources for MAT for opioid addiction in adolescents and young adults, including increasing resources for MAT in primary care and access to SUD counseling. AAP recommends that pediatricians offer MAT to their patients or refer them to other providers for this service, and supports further research on appropriate SUD treatment in adolescents and young adults, including prevention, behavioral interventions, and medication treatment.

RESEARCH

Bagley, S. et al. (2022). An Exploration of Young Adults With Opioid Use Disorder and How Their Perceptions of Family Members' Beliefs Affects Medication Treatment. *Journal of Addiction Medicine,* 16: 689–694.
This study investigated how young adults with OUD perceived their families' beliefs about OUD and MAT, and how those beliefs influenced their own treatment decisions. The study used a qualitative approach and involved 20 young adults receiving care from an urban safety net hospital in Massachusetts. Results showed that families' history of SUD and treatment, as well as negative or stigmatizing views of MAT, had an impact on how young adults perceived their own OUD and treatment. Family acceptance was found to be important, but young adults sometimes kept their treatment decisions from their families. The findings suggest that improving engagement and retention of young adults with OUD may require targeting the beliefs of family members.

Subramaniam, G., & Levy, S. (2022). Treatment of Opioid-Dependent Adolescents and Young Adults Using Sublingual Buprenorphine. Providers Clinical Support System Guidance.
The buprenorphine-naloxone combination (marketed under the trade name Suboxone) is an effective treatment for opioid-dependent adolescents and young adults, according to studies reviewed by the authors. Adolescents

with opioid dependence benefit from comprehensive treatment that includes both buprenorphine-naloxone and behavioral therapy tailored to their individual needs. Before starting MAT, the diagnosis of opioid dependence must be confirmed through a thorough substance use history, medical and mental health evaluation, and laboratory tests. Next, authors recommend establishing a set of expectations for patients beginning MAT (i.e., medication compliance, participation in psychosocial treatments, risk of concurrent alcohol and/or benzodiazepine abuse/dependence). Current research suggests that continued buprenorphine-naloxone for at least 12 weeks significantly improves outcomes. Parental/guardian involvement is also recommended, whenever possible. Additionally, parental consent may be required prior to starting medication. If psychosocial support is not available onsite, referrals should be made to ensure the client develops relapse prevention skills. Screening for co-occurring psychiatric disorders is also important and should be addressed simultaneously. Finally, it is important to address concomitant social issues that may likely hinder progress of treatment, such as unstable housing, conflict and/or substance use within the family home, academic disengagement, employment issues, and legal problems. Buprenorphine-naloxone maintenance has been shown to increase treatment retention, reduce opioid use, and decrease HIV risk behaviors among opioid-dependent youth.

Bagley, S., et al. (2021). Receipt of Medications for Opioid Use Disorder Among Youth Engaged in Primary Care: Data from 6 Health Systems. ***Addiction Science & Clinical Practice,*** **16(46). https://doi.org/10.1186/s13722-021-00249-3**

This study aimed to describe the prevalence of OUD and the use of MAT for OUD among youth engaged in primary care. The study analyzed data from electronic health records and insurance claims of 303,262 youth ages 16–25 in six health systems across six states. Results showed that 0.7% of the youth (2,131) had a documented OUD diagnosis, with higher prevalence in older age groups. Half of the youth with OUD had depression or anxiety and one-third had co-occurring SUDs. The receipt of medication for OUD was low, with the lowest rate (14%) among those ages 16–17 and the highest (39%) among those ages 22–25. The study highlights the need for increased MAT for OUD and integration of treatment for other substance use and mental health disorders among youth in primary care.

Stull, S.W., McKnight, E.R., & Bonny, A.E. (2020). Patient and Clinician Perspectives on Adolescent Opioid Use Disorder Treatment During a Pandemic: One Step Back, but Two Forward? ***JMIR Pediatrics and Parenting,*** **3(2): e23463. doi: 10.2196/23463+**

This 2020 study highlights the challenges faced by adolescents and young adults (AYAs) with OUD during the COVID-19 pandemic. The authors present the perspective of a person in OUD recovery and two clinicians supporting AYAs with OUD and discuss the implications of changes in treatment from in-person to online clinical care, telehealth, and peer support. The authors suggest that the increased use of telehealth and mobile technologies by OUD patients may help counter barriers to treatment access during the pandemic and offer insights for improving AYA OUD treatment in the long term.

Banta-Green, C., & Cooley, L. (2018). The Role of Medications in the Treatment of Adolescents and Young Adults with Opioid Use Disorder. Alcohol and Drug Abuse Institute. University of Washington.

Current research supports the use of buprenorphine and methadone for the treatment of OUD in young adults (18–24) and adolescents (under 18). The AAP recommends MAT for adolescents with OUD. As of 2018, there had

been few studies focusing specifically on MAT for OUD in young adults. This may explain why, despite expert recommendations, only a limited number of young adults and adolescents receive MAT for OUD. (Only 2.4 percent of adolescents in treatment for heroin received MAT; only 0.4 percent of adolescents in treatment for prescription opioids received MAT.) A double-blind, placebo-controlled study showed that a longer buprenorphine-naloxone taper resulted in higher retention in treatment and lower opioid use among patients ages 16–24. Another study found that a 12-week buprenorphine-naloxone treatment reduced drug use and injection and resulted in higher treatment retention among patients ages 15–21. The evidence base for using naltrexone to treat OUD in adolescents is even more scant. A chart review of 16 patients ages 16–20 receiving naltrexone found it to be a feasible treatment option.

Other benefits of MAT may include reducing injection-related HIV risk behaviors and reducing the likelihood of transitioning to injection. Detoxification is often necessary but not sufficient for the treatment of OUD, and relapse prevention medications are often necessary. The treatment of adolescents and young adults with OUD is a complex issue that faces several barriers, including the recognition of the need for treatment, capacity to deliver medication for OUD (MOUD), limited data on MOUD effectiveness, and limited access to treatment. Other factors include the complexity of MOUD, polydrug use, and financial and family situations. A protocol for treating youth with OUD is needed, as well as more school-based education and counseling, comprehensive long-term treatment, and strategies to address the stigma associated with OUD. Effective solutions include more integrated care, interdisciplinary teams, training for counselors, and connecting pediatricians to youth treatment agencies.

Borodovsky, J., et al. (2018). Buprenorphine Treatment for Adolescents and Young Adults with Opioid Use Disorders: A Narrative Review. *Journal of Addiction Medicine*, 12(3): 170–183.

The objective of this narrative review was to summarize studies that evaluated the use of buprenorphine and buprenorphine-naloxone in treating adolescents and young adults with OUD. The results suggest that OUD in youth should be treated as a chronic condition and buprenorphine should be used in combination with other treatments. However, further study is needed to determine the best practices for optimizing treatment outcomes for these young people. Further research is needed to develop practical and scalable treatment methods for adolescents. The present data show little age-related differences in OUD and response to buprenorphine, but youth are a difficult population to recruit and retain in treatment. The authors recommend that future studies focus on developmentally appropriate buprenorphine treatment engagement strategies, such as flexible medication prescribing, administration durations, and treatment settings. They note the importance of evaluating different psychosocial therapies in conjunction with buprenorphine. New medications such as long-acting buprenorphine implants and extended-release naltrexone should also be evaluated. Methadone is another potential treatment, but it is difficult for minors to access due to stricter federal regulations. Addressing the treatment gap for OUD in youth is critical for early intervention and preventing escalation of problematic opioid use.

Woody, G.E., et al. (2008). Extended vs. Short-Term Buprenorphine-Naloxone for Treatment of Opioid–Addicted Youth: A Randomized Trial. *JAMA*, 300(17): 2003–2011.

A clinical trial was conducted to evaluate the efficacy of 12-week buprenorphine-naloxone therapy compared to a 14-day detoxification treatment for opioid-addicted youth (15–21 years old), with 152 patients randomly assigned to either 12 weeks of buprenorphine-naloxone therapy or detoxification. The study found that patients

in the 12-week buprenorphine-naloxone group had lower positive opioid urine test results at the conclusion of the study and higher treatment retention rates compared to the detox group. Additionally, they reported less opioid use, less injecting, and less addiction treatment outside of study parameters. The authors note that further research is needed to assess the long-term effects of buprenorphine therapy for young individuals with opioid dependence.

State Examples

Massachusetts Practice Guidance: Medication for Opioid Use Disorders Among Adolescents and Young Adults (2019).

This guidance for behavioral health service providers was specifically developed with an emphasis on youth ages 16 to 24 with identified OUD. The document describes the essential elements of effective MAT and provides detailed guidance on how best to deliver the most effective treatment to adolescents and young adults with OUD. It stresses the importance of care coordination with other providers, such as community-based pediatricians, family physicians, and office-based opioid treatment programs and treatment centers to increase MAT access and service capacity. The guidance includes key aspects of caring for youth and young adults:

- Developmentally appropriate MAT care models that include behavioral health services (e.g., cognitive behavioral therapy, family- and community-centric approaches)
- Training of prescribers, clinicians, and support staff in the developmentally appropriate services that are rooted in motivational interviewing and cognitive behavioral approaches
- Convenient locations with flexible meeting times and days for counseling sessions
- Contingency management should be used where appropriate to incentivize youth and young adults to engage and stay in treatment
- Organizational leadership must be committed to the integration of MAT, whether directly or through coordinated care
- Management and supervisory staff with support from leadership, must be able to address stigma and cultural differences and facilitate training of staff, board members, and clients/patients
- Medication for addiction treatment does not violate a drug-free policy, and individuals utilizing medications should not be excluded from programs, support groups, sober homes, or other licensed treatment or recovery services

New York State Clinical Practice Standards for Adolescent Programs (CPS-AP), Office of Addiction Services and Supports (2021).

The New York State Office of Addiction Services and Supports (OASAS) developed practice standards containing broad goals to help providers deliver high-quality, evidenced-based treatment services to adolescents with SUD. OASAS standards acknowledge there are significant gaps in the research on treating OUD in adolescents with MAT but state buprenorphine is indicated for the treatment of patients with OUD ages 16 and older, and extended release naltrexone injection is indicated for patients ages 18 and older. The standards note off-label use of both medications with younger populations is allowable and may be necessary.

The standards suggest that MAT for adolescents with OUD is much safer and leads to better outcomes than treatment without medication or no treatment at all. Treatment decisions should be made in collaboration with

clients and their families based on available treatment options, medication side effects, risks (including the risks of foregoing medication), benefits, and requirements of various medication options (route of administration, setting, frequency of visits, etc.). The standards note that although all medications can have side effects, there is no suggestion that any of these medications have any additional specific age-related risks or safety concerns for the target population of adolescents and youth.

Washington State Opioid Use Disorder Diagnosis and Treatment Guideline. (2023). Kaiser Permanente: Interim Update.

The Kaiser Foundation Health Plan of Washington developed guidelines to assist patients and providers in choosing appropriate health care for special clinical populations, including adolescents (ages 13 through 17). The purpose of this guideline is to:

- Create reliable pathways to OUD treatment from all points of entry into the health system, so there is "no wrong door" for patients wanting to access OUD treatment and no patient abandonment.
- Decrease the difficulty of making accurate OUD diagnoses, particularly in patients who are prescribed opioids.
- Increase awareness of the multiple effective medication treatment options for OUD.
- Create a harm reduction pathway for patients who are not ready to stop their opioid use (e.g., needle exchange, naloxone, monitoring).
- Provide a clear process for reducing the return to use.
- Increase understanding of OUD as a chronic disease and decrease the stigma that prevents people from seeking help.