ASAM COVID-19 TASK FORCE RECOMMENDATIONS

CARING FOR PATIENTS DURING THE COVID-19 PANDEMIC

Access to Buprenorphine in Office-Based Settings

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ACCESS TO BUPRENORPHINE IN OFFICE-BASED SETTINGS

A guide for addiction treatment clinicians and programs working to treat patients with substance use disorders safely and effectively during the COVID-19 pandemic[1].

For additional recommendations for the Ongoing Management of the Continuum of Addiction Care during COVID-19, please click here.

CONTENT DISCLAIMER

This Clinical Guidance ("Guidance") is provided for informational and educational purposes only. It is intended to provide practical clinical guidance to addiction medicine physicians and others caring for individuals with substance use disorders during the COVID-19 pandemic as it unfolds. Adherence to any recommendations included in this Guidance will not ensure successful treatment in every situation. Furthermore, the recommendations contained in this Guidance should not be interpreted as setting a standard of care or be deemed inclusive of all proper methods of care nor exclusive of other methods of care reasonably directed to obtaining the same results.

The ultimate judgment regarding the propriety of any specific therapy must be made by the physician and the patient in light of all the circumstances presented by the individual patient, and the known variability and biological behavior of the medical condition.

This Guidance and its conclusions and recommendations reflect the best available information at the time the Guidance was prepared. The results of future studies may require revisions to the recommendations in this Guidance to reflect new data.

ASAM does not warrant the accuracy or completeness of the Guidance and assumes no responsibility for any injury or damage to persons or property arising out of or related to any use of this Guidance or for any errors or omissions.

Purpose of the document

Buprenorphine is a life-sustaining medication. Abrupt discontinuation can lead to withdrawal as well as return to pretreatment substance use, overdose, and overdose death. The anxiety and stress associated with the COVID-19 pandemic, and the societal response to it, is exacerbating symptoms of opioid use disorder for many people. In addition, ongoing changes to the drug supply has increased the need for treatment. Every effort should be made to ensure that patients currently taking buprenorphine have timely access to refills of this medication and that any new patients in need of treatment for opioid use disorder can initiate treatment in a timely manner.

[1]This resource was developed by a Task Force appointed by ASAM's Executive Council. To enable more rapid development and dissem-ination it was not developed through ASAM's normal process for clinical guidance development that is overseen by the ASAM Quality Improvement Council.

These materials seek to provide guidance to ambulatory addiction treatment clinicians, including those working in primary care, and in addiction treatment programs as they strive to ensure that patients continue to have safe, appropriate access to buprenorphine[1] during the COVID-19 pandemic.

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1. Leveraging Telehealth

Clinicians and programs should take steps to minimize in-person interactions throughout the COVID-19 crisis. Telehealth is an important tool for maintaining access to treatment while minimizing the risk of transmission of COVID-19. This section is intended to provide guidance to clinicians and programs in developing policies and practices to leverage telehealth to provide buprenorphine[1] treatment. See ASAM's Supporting Access to Telehealth for Addiction Services Guidance, which provides an overview of federal and state policy changes to enable telehealth during the COVID-19 crisis.

Despite the availability of telehealth, it is also important to recognize that not everyone may have access to these resources. Clinicians and programs do well to implement protocols and procedures to ensure continued treatment with buprenorphine for patients who may not have access to telehealth services.

Recommendation

Telehealth or telephonic visits should be used whenever possible and appropriate to provide buprenorphine treatment to patients.

Historically, an in-person medical evaluation was required prior to initiating a controlled substance prescription. However, federal policymakers have enabled exceptions during this public health emergency (which was initially declared on January 21, 2020) that allow for the prescription of buprenorphine via telehealth.

In addition, as of March 15, 2020, sanctions and penalties have been temporarily waived for healthcare clinicians who do not comply with certain provisions of the HIPAA Privacy Rule. This waiver may enable the use of non-

[2]Throughout this document, the term 'buprenorphine' will be used to refer to any formulation of buprenorphine including those containing both buprenorphine and naloxone.

HIPAA compliant telehealth applications that are widely available, such as FaceTime or Skype. (See Supporting Access to Telehealth for Addiction Services Guidance)

Telehealth communication conducted using an audio-visual, real-time, two-way interactive communication system is preferred but telephone-based visits should also be considered. For example, some patients may not have the technical capabilities available for video visits but have access to a phone.

For stable patients, the risk of in-person visits is likely to outweigh the benefits. Patients who are unstable, or patients that do not have reliable access to a telephone (e.g. unhoused patients) may still benefit from in-person visits. Clinicians and programs should consider infection mitigation strategies for in person visits. See Infection Control and Mitigation Strategies in Outpatient Settings.

Please note that at the time of this writing, the exception to the need for an in-person evaluation does NOT apply to the provision of methadone for opioid use disorder. That is, methadone for opioid use disorder still must be initiated only after an in-person medical evaluation has taken place.

Clinicians should carefully assess whether an in-person physical exam would change the management of a given patient. For patients maintained on buprenorphine, monitoring for signs of intoxication is recommended. This assessment can be accomplished with visual inspection alone, and partially and sufficiently evaluated through an audio-only platform as well (e.g., slurred speech might suggest use of alcohol or other opioids, while pressured speech might suggest stimulant use).

For patients seeking to initiate buprenorphine, assessment of opioid withdrawal can typically be accomplished through visual inspection alone, for signs such as yawning, pupillary dilation, lacrimation, rhinorrhea, and restlessness. While an accurate COWS score may sometimes require palpation for subtle tremor or piloerection, the benefit of obtaining a COWS score with perfect accuracy is unlikely to outweigh the risk of COVID-19 exposure. Home versions of the COWS scale or the Subjective Opioid Withdrawal Scale (SOWS) can be self-administered by the patient. At-home initiation of buprenorphine (formerly called home "induction") does not require a perfectly accurate COWS assessment and has demonstrated feasibility and safety relative to office-based buprenorphine starts. Clinicians can carefully instruct patients on at-home initiation and provide anticipatory guidance for the management of precipitated withdrawal, should it occur.

Resources

- AMA Quick Guide to Telehealth in Practice: https://www.ama-assn.org/practice-management/digital/ama-quick-guide-telehealth-practice
- American Psychiatric Association: Telepsychiatry and COVID-19: https://www.psychiatry.org/psychiatrists/practice/telepsychiatry/blog/apa-resources-on-telepsychiatry-and-covid-19
- CMS General Provider Toolkit: https://www.cms.gov/files/document/general-telehealth-toolkit.pdf
- National Consortium of Telehealth Resource Centers: https://www.telehealthresourcecenter.org/
- National Council Resources for COVID-19: https://www.thenationalcouncil.org/covid19/

2. Prescriptions and Refills

Providing refills as clinically appropriate without requiring in-person visits is another strategy for reducing risk of exposure to COVID-19. Given the safety profile of buprenorphine and the uncommon occurrence of severe adverse events like fatal overdoses with its use, the benefits of providing refills is greater than the risk.[3] This section is intended to provide guidance to clinicians and programs in developing policies and practices regarding buprenorphine refills.

The Centers for Disease Control recommends that individuals maintain a 2-week supply of prescription medications as part of a "household plan of action in case of illness in the household or disruption of daily activities" due to COVID-19. Physical distancing, including avoiding non-essential travel, and universal use of face coverings, are keys to reducing the spread of COVID-19.

Clinicians can help their patients adhere to these guidelines by e-prescribing the longest possible safe duration of medications. In addition, clinicians should preferentially utilize pharmacies that offer home delivery, curbside or drive-through capabilities or other reduced or no contact delivery options. SAMHSA and the DEA have released guidance to facilitate e-prescribing of controlled substances, including buprenorphine without an in-person medical evaluation during this public health emergency. The DEA also issued an Exception to Separate Registration Requirements Across State Lines. This exception applies to the prescription of controlled substances via telehealth. Subject to the conditions of the DEA letter's temporary exception, DEA-registered practitioners may prescribe controlled substances to patients via telehealth in states in which they are not registered with the DEA. See ASAM's Supporting Access to Telehealth for Addiction Services Guidance for more information.

Buprenorphine prescribers typically provide 1-4-week prescriptions for sublingual buprenorphine/naloxone formulations for their patients with opioid use disorder. As prescribers respond to recommendations for decreased in-person, face-to-face visits and other COVID-19 guidance, ASAM recommends a thoughtful approach to changing buprenorphine prescribing to ensure three goals:

1) Expand outpatient access to buprenorphine with the aim of reducing strain on emergency departments and hospitals
2) Protect patients' safety
3) Minimize unintended exposures to buprenorphine, especially of children and pets

Recommendation

Provide buprenorphine refills to stable patients, without requiring in-person visits or drug testing. Patients who are unstable may benefit from having less medication on hand and more frequent contact with clinicians (e.g. remote or in-person visits). However, for stable patients, the benefits of buprenorphine refills are likely to outweigh the risks of buprenorphine refills.

[3] Paone D, Tuazon E, Stajic M, et al. Buprenorphine infrequently found in fatal overdose in New York City. Drug Alcohol Depend. 2015;155:298–301. doi:10.1016/j.drugalcdep.2015.08.007

Clinicians may be concerned about the possibility of diversion if they provide patients with buprenorphine refills. While diversion happens, relative to other opioid agonists, diversion of buprenorphine is much lower.[4] In addition, diversion often occurs for the purpose of self-treating opioid withdrawal rather than achieving euphoria.[5] Appropriately setting expectations for medication safety, including shorter prescriptions should the patient have difficulty maintaining medication safety, should be in place and clearly communicated to patients.

Policies or practices to consider

Considerations for clinicians when deciding upon durations of buprenorphine prescriptions for the treatment of opioid use disorder include:

1) Does the patient fall into a high-risk group for severe COVID-19 illness either due to age or underlying health conditions as outlined by the CDC? Coming to clinics and pharmacies more often increases their risk for COVID-19 infection and ensuing risks to clinicians and the public.

2) Is the patient under quarantine or isolation, either due to symptoms concerning for COVID-19 disease, confirmed COVID-19 positive, or after contact with someone testing positive for COVID-19 or awaiting test results? Access to clinic and pharmacies may be impacted. Patients need access to medication continuity to support recommended quarantine or isolation.

3) What capability does the patient have for safely and securely storing different quantities of sublingual buprenorphine/naloxone formulations? Without access to safe storage, less medication may be preferable either in the form of shorter total prescription duration or shorter individual refill quantities.

4) Who has potential access to medications in the home, including children, pets, or neighbors? While buprenorphine is associated with relatively less respiratory depression risk compared with methadone, opioid-naïve individuals, especially children, can be harmed from unexpected exposure. Clinicians should co-prescribe or assure naloxone is in the home. If naloxone access is limited, prioritize patients in households with children and adolescents or others who would poorly tolerate reductions in respiratory function.

5) How stable is the patient's opioid use disorder and/or other substance use disorders, if present? Less medication and more frequent monitoring by telehealth or audio-only check in may be preferable for patients at higher risk of overdose due to co-occurring alcohol or sedative/hypnotic misuse.

Resources

- Provision of Telehealth While Providing MAT (May 2018)

https://www.samhsa.gov/sites/default/files/programs_campaigns/medication_assisted/telemedicine-dea-guidance.pdf

[4] Cicero TJ, Surratt HL, Inciardi J. Use and misuse of buprenorphine in the management of opioid addiction. J Opioid Manag. 2007;3(6):302–308. doi:10.5055/jom.2007.0018

[5] Fox AD, Chamberlain D, Sohler NL, Frost T, Cunningham CO. Illicit buprenorphine use, interest in and access to buprenorphine treatment among syringe exchange participants. J Subst Abuse Treat. 2015 Jan;48(1):112-6. PMC4250323

- DEA Information on Telehealth

https://www.samhsa.gov/sites/default/files/programs_campaigns/medication_assisted/dea-information-telehealth.pdf

- FAQs: Provision of Methadone and Buprenorphine for the Treatment of OUD in the COVID-19 Emergency

https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf

- DEA Policy: Exception to Separate Registration Requirements Across State Lines

https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-018)(DEA067)%20DEA%20state%20reciprocity%20(final)(Signed).pdf

3.Psychosocial Treatment

ASAM's National Practice Guideline for the Treatment of Opioid Use Disorder recommends that "a patient's decision to decline psychosocial treatment or the absence of available psychosocial treatment should not preclude or delay pharmacotherapy, with appropriate medication management."[6] This guidance is even more applicable right now when patients may need to be under self-quarantine or have other risk factors that lead them to want to minimize external interactions.

While some patients are likely to benefit from psychosocial counseling depending on their specific conditions and scenarios, five randomized trials found that enhanced psychosocial counseling provided no additional benefit compared to typical medical management that occurs during routine office-based visits for many patients[7] .

This section provides guidance to clinicians and programs in developing policies and practices regarding psychosocial treatment during the COVID-19 crisis.

Recommendation

Psychosocial counseling should not be required as part of buprenorphine treatment. However, for some, maintaining access to psychosocial treatments during a time of increased anxiety and stress such as the COVID pandemic may be important for preventing substance use and minimizing other mental health risks.

Individual therapy, when needed, may be continued through telehealth when possible. Guided group therapy with a licensed therapist (e.g. "Seeking Safety") may also be continued when possible through telehealth. Some patients may also benefit from virtual support groups (See Promoting Support Group Attendance Guidance).

Policies or practices to consider

- Do not require patients to participate in counseling – virtual or in-person – in order to access medication. This is a generally recommended practice and particularly important during the COVID-19 pandemic.
- Consider which therapies are possible to convert to a virtual platform.

[6] https://www.asam.org/Quality-Science/quality/2020-national-practice-guideline

[7] https://pubmed.ncbi.nlm.nih.gov/22065255/ ; https://www.nejm.org/doi/full/10.1056/nejmoa055255 ; https://pubmed.ncbi.nlm.nih.gov/24656054/ ; https://pubmed.ncbi.nlm.nih.gov/22348921/ ; https://pubmed.ncbi.nlm.nih.gov/22938914/.

- Limit physical, in-person groups to no more than 10 individuals, in a larger room where physical distancing of 6 feet between individuals is possible. All participants in such groups, including facilitators, should wear face coverings at all times.

Resources

ASAM's National Practice Guideline for the Treatment of Opioid Use Disorder

"Taking Care of Your Behavioral Health" https://www.samhsa.gov/sites/default/files/tips-social-distancing-quarantine-isolation-031620.pdf

Updated definition of "close contact" by the CDC: https://www.cdc.gov/coronavirus/2019-ncov/php/contact-tracing/contact-tracing-plan/appendix.html#contact

4. Ensuring Adequate Supply of Buprenorphine

Buprenorphine is a life-sustaining medication. Abrupt discontinuation can lead to a return to pretreatment substance use, overdose, and overdose death. Every effort should be made to ensure that all patients have timely access to this medication.

Recommendation

Clinicians and programs should take steps to ensure that all patients currently taking buprenorphine for addiction treatment have continued access to this medication. Clinicians should consider how each patient will obtain their medications if they are under quarantine/isolation or otherwise unable to leave their home.

Policies or practices to consider

- Consider longer duration prescriptions as safe and appropriate to minimize community exposure retrieving prescriptions from pharmacies.
- Consider appropriateness of mail-order pharmacies, as covered by insurance.
- Consider assigning a staff member to routinely follow up with patients to ensure they are able to obtain their refill on time.

Resources

- SAMHSA's information page for Buprenorphine: https://www.samhsa.gov/medication-assisted-treatment/medications-counseling-related-conditions/buprenorphin

5. Harm Reduction, Including Naloxone Distribution

The current COVID-19 crisis has put patients at greater risk for harms related to substance use. The anxiety and stress associated with this pandemic, as well as the social isolation, is exacerbating addiction and mental health related symptoms. In addition, physical distancing and other restrictions may make it more difficult for individuals who use drugs to access safe injection supplies. The restrictions on travel, especially at U.S. border crossings, impact the illicit drug supply.

To minimize the harms associated with these circumstances, clinicians and programs should consider implementation of additional harm reduction strategies.

Recommendation

Ensure patients have access to naloxone. Naloxone is a life-saving medication in the event of an overdose and needs to remain easily accessible to persons who are at risk of an overdose themselves or of witnessing an overdose by someone else. First responders' availability to respond to an overdose may be diminished due to other acute needs. As a result, prescribing or distributing additional doses of naloxone is warranted.

Educate patients about the potential risks during this crisis:

- Persons who may have difficulty accessing opioids for a period of time due to quarantine status as individuals or as a community, may have decreased tolerance upon access to drug supply. Public service announcements reinforcing the importance of test injections should be considered.
- Highlight the importance of having naloxone on hand.
- Provide information on safer drug use practices.

Policies or practices to consider

- Partner with pharmacies in your community to ensure they have naloxone on hand so patient prescriptions can be filled.
- Partner with community naloxone distribution programs to keep naloxone available to distribute to patients and community members.

6. Considerations for High Risk Patients

According to the CDC individuals who are at higher risk for severe illness from COVID-19 include:

- People aged 65 and older
- People with chronic health conditions including
    - Serious heart conditions
    - Lung disease or moderate to severe asthma
    - Immunocompromised or on immune suppressing drugs
    - Severe obesity (BMI ≥40) or diabetes.

Over 8000 pregnancies affected by COVID-19 have been reported. Symptoms of COVID-19 occur at the same rate in pregnant people and non-pregnant women. Pregnant people with COVID-19 report more underlying disease such as diabetes, chronic lung disease, and cardiovascular disease. If COVID-19 symptoms occur, pregnant people might be at an increased risk for severe illness from COVID-19 compared to non-pregnant people. Additionally, there may be an increased risk of adverse pregnancy outcomes, such as preterm birth, among pregnant people with COVID-19. The increased risk is especially true for pregnant people of Hispanic and Black background. Hospitalization is more common in pregnant people with COVID-19 symptoms, but it is not known if this is due to infection symptoms, pregnancy complications, or a lower threshold for admission. Severe disease due to COVID-19 is more common in pregnant people, with increased rate of ICU admission (5-fold) and mechanical ventilation (4-fold). Pregnant people do not have an increased risk of death from COVID-19.

This guidance is focused on helping clinicians and programs to establish recommendations for continuing to offer high risk patients appropriate care while minimizing their risk for exposure to COVID-19.

Recommendation

High risk patients should continue to have access to appropriate addiction treatment, which should include some capacity for face-to-face treatment. However, every effort should be made to minimize in-person interactions. Telehealth services should be used whenever possible (see Supporting Access to Telehealth for Addiction Services Guidance).

Policies or practices to consider

- Consider risk stratifying patients further based on level of individual risk, stage of infection, ability to access telehealth services and recent history of non-prescribed substance use.
- Consider extending prescriptions beyond usual practice to allow for fewer in-person healthcare touches including at pharmacies where additional exposure may occur.

Resources

https://www.cdc.gov/coronavirus/2019-ncov/specific-groups/people-at-higher-risk.html

https://www.samhsa.gov/sites/default/files/medicare-telemedicine-health-care-fact-sheet.pdf