TIP 63

MEDICATIONS FOR OPIOID USE DISORDER

Executive Summary

For Healthcare and Addiction Professionals, Policymakers, Patients, and Families

The Executive Summary of this **Treatment Improvement Protocol** provides an overview on the use of the three Food and Drug Administration-approved medications used to treat opioid use disorder—methadone, naltrexone, and buprenorphine—and the other strategies and services needed to support recovery.

TIP Navigation

Contents

Foreword

The Substance Abuse and Mental Health Services Administration (SAMHSA) is the U.S. Department of Health and Human Services agency that leads public health efforts to advance the behavioral health of the nation. SAMHSA's mission is to reduce the impact of substance abuse and mental illness on America's communities.

The Treatment Improvement Protocol (TIP) series fulfills SAMHSA's mission by providing science-based best-practice guidance to the behavioral health field. TIPs reflect careful consideration of all relevant clinical and health service research, demonstrated experience, and implementation requirements. Select nonfederal clinical researchers, service providers, program administrators, and patient advocates comprising each TIP's consensus panel discuss these factors, offering input on the TIP's specific topic in their areas of expertise to reach consensus on best practices. Field reviewers then assess draft content.

The talent, dedication, and hard work that TIP panelists and reviewers bring to this highly participatory process have helped bridge the gap between the promise of research and the needs of practicing clinicians and administrators to serve, in the most scientifically sound and effective ways, people in need of behavioral health services. We are grateful to all who have joined with us to contribute to advances in the behavioral health field.

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Executive Summary

The goal of treatment for opioid addiction or opioid use disorder (OUD) is remission of the disorder leading to lasting recovery. Recovery is a process of change through which individuals improve their health and wellness, live self-directed lives, and strive to reach their full potential.[1] This Treatment Improvement Protocol (TIP) reviews the use of the three Food and Drug Administration (FDA)-approved medications used to treat OUD—methadone, naltrexone, and buprenorphine—and the other strategies and services needed to support recovery for people with OUD.

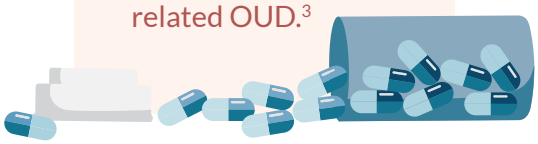
Introduction

Our nation faces a crisis of overdose deaths from opioids, including heroin, illicit fentanyl, and prescription opioids. These deaths represent a mere fraction of the total number of Americans harmed by opioid misuse and addiction. Many Americans now suffer daily from a chronic medical illness called "opioid addiction" or OUD (see the Glossary in Part 5 of this TIP for definitions). Healthcare professionals, treatment providers, and policymakers have a responsibility to expand access to evidence-based, effective care for people with OUD.

Estimated cost of the **OPIOID EPIDEMIC** was **$504 BILLION** in 2015.[2]

An expert panel developed the TIP's content based on a review of the literature and on their extensive experience in the field of addiction treatment. Other professionals also generously contributed their time and commitment to this project.

An estimated **1.8M AMERICANS** have OUD related to opioid painkillers; **626K** have heroin-related OUD.[3]



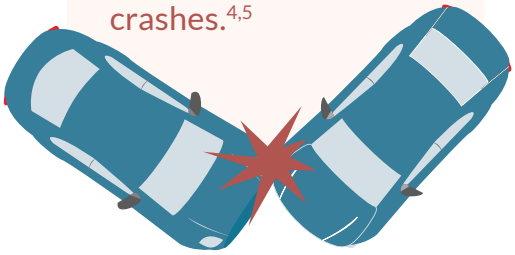
The TIP is divided into parts so that readers can easily find the material they need. Part 1 is a general introduction to providing medications for OUD and issues related to providing that treatment. Some readers may prefer to go directly to those parts most relevant to their areas of interest, but everyone is encouraged to read Part 1 to establish a shared understanding of key facts and issues covered in detail in this TIP.

Following is a summary of the TIP's overall main points and brief summaries of each of the five TIP parts.

Overall Key Messages

Addiction is a chronic, treatable illness. Opioid addiction, which generally corresponds with moderate to severe forms of OUD, often requires continuing care for effective treatment rather than an episodic, acute-care treatment approach.

Opioid overdose caused **42,249 DEATHS** nationwide in 2016—this exceeded the # caused by motor vehicle crashes.[4,5]



General principles of good care for chronic diseases can guide OUD treatment. Approaching OUD as a chronic illness can help providers deliver care that helps patients stabilize, achieve remission of symptoms, and establish and maintain recovery.

Patient-centered care empowers patients with information that helps them make better treatment decisions with the healthcare professionals involved in their care. Patients should receive information from their healthcare team that will help them understand OUD and the options for treating it, including treatment with FDA-approved medication.

Patients with OUD should have access to mental health services as needed, medical care, and addiction counseling, as well as recovery support services, to supplement treatment with medication.

The words you use to describe OUD and an individual with OUD are powerful. The TIP defines, uses, and encourages providers to adopt terminology that will not reinforce prejudice, negative attitudes, or discrimination.

There is no "one size fits all" approach to OUD treatment. Many people with OUD benefit from treatment with medication for varying lengths of time, including lifelong treatment. Ongoing outpatient medication treatment for OUD is linked to better retention and outcomes than treatment without medication. Even so, some people stop using opioids on their own; others recover through support groups or specialty treatment with or without medication.

The science demonstrating the effectiveness of medication for OUD is strong. For example, methadone, extended-release injectable naltrexone (XR-NTX), and buprenorphine were each found to be more effective in reducing illicit opioid use than no medication in randomized clinical trials, which are the gold standard for demonstrating efficacy in clinical medicine.[6,7,8,9,10] Methadone and buprenorphine treatment have also been associated with reduced risk of overdose death.[11,12,13,14,15]

This doesn't mean that remission and recovery occur only through medication. Some people achieve remission without OUD medication, just as some people can manage type 2 diabetes with exercise and diet alone. But just as it is inadvisable to deny people with diabetes the medication they need to help manage their illness, it is also not sound medical practice to deny people with OUD access to FDA-approved medications for their illness.

Medication for OUD should be successfully integrated with outpatient and residential treatment. Some patients may benefit from different levels of care at different points in their lives, such as outpatient counseling, intensive outpatient treatment, inpatient treatment, or long-term therapeutic communities. Patients treated in these settings should have access to OUD medications.

2.1 MILLION people in the U.S., ages 12 and older, had OUD involving **PRESCRIPTION OPIOIDS, HEROIN,** or both in 2016.[16]

Patients treated with medications for OUD can benefit from individualized psychosocial supports. These can be offered by patients' healthcare providers in the form of medication management and supportive counseling and/or by other providers offering adjunctive addiction counseling, recovery coaching, mental health services, and other services that may be needed by particular patients.

Expanding access to OUD medications is an important public health strategy.[17] The gap between the number of people needing opioid addiction treatment and the capacity to treat them with OUD medication is substantial. In 2012, the gap was estimated at nearly 1 million people, with about 80 percent of opioid treatment programs (OTPs) nationally operating at 80 percent capacity or greater.[18]

Improving access to treatment with OUD medications is crucial to closing the wide gap between treatment need and treatment availability, given the strong evidence of effectiveness for such treatments.[19]

Data indicate that medications for OUD are cost effective and cost beneficial.[20,21]

OPIOID-RELATED
EMERGENCY DEPARTMENT
visits nearly doubled from 2005–2014.[22]

Content Overview

The TIP is divided into parts to make the material more accessible according to the reader's interests.

Part 1: Introduction to Medications for Opioid Use Disorder Treatment

This part lays the groundwork for understanding treatment concepts discussed later in this TIP. The intended audience includes:

- Healthcare professionals (physicians, nurse practitioners, physician assistants, and nurses).
- Professionals who offer addiction counseling or mental health services.
- Peer support specialists.
- People needing treatment and their families.
- People in remission or recovery and their families.
- Hospital administrators.
- Policymakers.

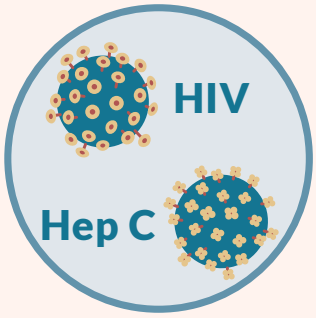
In Part 1, readers will learn that:

- Increasing opioid overdose deaths, illicit opioid use, and prescription opioid misuse constitute a public health crisis.
- OUD medications reduce illicit opioid use, retain people in treatment, and reduce risk of opioid overdose death better than treatment with placebo or no medication.
- Only physicians, nurse practitioners, and physician assistants can prescribe buprenorphine for OUD. They must get a federal waiver to do so.
- Only federally certified, accredited OTPs can dispense methadone to treat OUD. OTPs can administer and dispense buprenorphine without a federal waiver.
- Any prescriber can offer naltrexone.
- OUD medication can be taken on a short- or long-term basis, including as part of medically supervised withdrawal and as maintenance treatment.
- Patients taking medication for OUD are considered to be in recovery.
- Several barriers contribute to the underuse of medication for OUD.

Part 2: Addressing Opioid Use Disorder in General Medical Settings

This part offers guidance on OUD screening, assessment, treatment, and referral. Part 2 is for healthcare professionals working in general medical settings with patients who have or are at risk for OUD.

OPIOID ADDICTION is linked with significant **MORBIDITY** and **MORTALITY** related to HIV and hepatitis C.[23]



In Part 2, readers will learn that:

- All healthcare practices should screen for alcohol, tobacco, and other substance misuse (including opioid misuse).
- Validated screening tools, symptom surveys, and other resources are readily available; this part lists many of them.
- When patients screen positive for risk of harm from substance use, practitioners should assess them using tools that determine whether substance use meets diagnostic criteria for a substance use disorder (SUD).
- Thorough assessment should address patients' medical, social, SUD, and family histories.
- Laboratory tests can inform treatment planning.
- Practitioners should develop treatment plans or referral strategies (if onsite SUD treatment is unavailable) for patients who need SUD treatment.

Part 3: Pharmacotherapy for Opioid Use Disorder

This part offers information and tools for healthcare professionals who prescribe, administer, or dispense OUD medications or treat other illnesses in patients who take these medications. It provides guidance on the use of buprenorphine, methadone, and naltrexone by healthcare professionals in:

- General medical settings, including hospitals.
- Office-based opioid treatment settings.
- Specialty addiction treatment programs, including OTPs.

In Part 3, readers will learn that:

- OUD medications are safe and effective when used appropriately.
- OUD medications can help patients reduce or stop illicit opioid use and improve their health and functioning.
- Pharmacotherapy should be considered for all patients with OUD. Opioid pharmacotherapies should be reserved for those with moderate-to-severe OUD with physical dependence.
- Patients with OUD should be informed of the risks and benefits of pharmacotherapy, treatment without medication, and no treatment.
- Patients should be advised on where and how to get treatment with OUD medication.

OPIOID-RELATED inpatient hospital stays **INCREASED 64%** nationally from 2005–2014.[24]

- Doses and schedules of pharmacotherapy must be individualized.

Part 4: Partnering Addiction Treatment Counselors With Clients and Healthcare Professionals

This part recommends ways that addiction treatment counselors can collaborate with healthcare professionals to support client-centered, trauma-informed OUD treatment and recovery. It also serves as a quick guide to medications that can treat OUD and presents strategies for clear communication with prescribers, creation of supportive environments for clients who take OUD medication, and ways to address other common counseling concerns when working with this population.

In Part 4, readers will learn that:

- Many patients taking OUD medication benefit from counseling as part of treatment.
- Counselors play the same role for clients with OUD who take medication as for clients with any other SUD.
- Counselors help clients recover by addressing the challenges and consequences of addiction.
- OUD is often a chronic illness requiring ongoing communication among patients and providers to ensure that patients fully benefit from both pharmacotherapy and psychosocial treatment and support.
- OUD medications are safe and effective when prescribed and taken appropriately.
- Medication is integral to recovery for many people with OUD. Medication usually produces better treatment outcomes than outpatient treatment without medication.
- Supportive counseling environments for clients who take OUD medication can promote treatment and help build recovery capital.

Part 5: Resources Related to Medications for Opioid Use Disorder

This part has a glossary and audience-segmented resource lists to help medical and behavioral health service providers better understand how to use OUD medications with their patients and to help patients better understand how OUD medications work. It is for all interested readers.

In Part 5, readers will learn that:

- Practice guidelines and decision-making tools can help healthcare professionals with OUD screening, assessment, diagnosis, treatment planning, and referral.
- Patient- and family-oriented resources provide information about opioid addiction in general; the role of medication, behavioral and supportive services, and mutual-help groups in the treatment of OUD; how-tos for identifying recovery support services; and how-tos for locating medical and behavioral health service providers who specialize in treating OUD or other SUDs.

Notes

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Expert Panelists

Each Treatment Improvement Protocol's (TIP's) expert panel is a group of primarily nonfederal addiction-focused clinical, research, administrative, and recovery support experts with deep knowledge of the TIP's topic. With the Substance Abuse and Mental Health Services Administration's (SAMHSA's) Knowledge Application Program (KAP) team, they develop each TIP via a consensus-driven, collaborative process that blends evidence-based, best, and promising practices with the panel's expertise and combined wealth of experience.

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This TIP's scientific reviewers are among the foremost experts on the three medications discussed in this TIP to treat opioid use disorder. Their role in the collaborative TIP development process was to help the KAP team include current, accurate, and comprehensive information and instructions about the use of each of these medications.

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Field reviewers represent each TIP's intended target audiences. They work in addiction, mental health, primary care, and adjacent fields. Their direct front-line experience related to the TIP's topic allows them to provide valuable input on a TIP's relevance, utility, accuracy, and accessibility.

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Disclaimer

The views, opinions, and content expressed herein are the views of the consensus panel members and do not necessarily reflect the official position of SAMHSA or HHS. No official support of or endorsement by SAMHSA or HHS for these opinions or for the instruments or resources described is intended or should be inferred. The guidelines presented should not be considered substitutes for individualized client care and treatment decisions.

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