Initiation of MAT for Opioid Use Disorder in the Hospitalized Patient and ER Setting: Promoting Best Outcomes in the Wake of an Opioid Crisis
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Learning Objectives

By participating in this webinar, participants will be able to:

• Describe the factors contributing to rising morbidity and mortality with the opioid epidemic and the burden of the epidemic on emergency rooms (ER) and hospitals.
• Understand the setting where agonist medication assisted treatment (MAT) can be used to treat opioid use disorder (OUD) and the federal laws and regulations for MAT medications prescribing.
• Summarize the exceptions to federal laws that allow medications to be provided to patients in the emergency department and in hospitalized patients.
• Analyze ER and hospital-based initiatives to treat opioid use disorder in cooperation with community substance use treatment settings.
• Describe one model for initiation of buprenorphine in an ER setting with continuation of MAT in a community partner setting.
Scope of the Problem

• 90 Americans die of an opioid overdose daily
• In 2016, overdose deaths exceeded 59,000 -- the largest annual increase ever recorded in the United States
• Opioids thus have become the leading cause of death among Americans under age 50, and two-thirds of the deaths involve a prescription opioid

CDC.GOV
Overview of the Problem

• 2.1 million people in the U.S., ages 12 and older, had opioid use disorder (OUD) involving prescription opioids, heroin, or both in 2016

• Opioid-related emergency department (ED) visits nearly doubled from 2005 to 2014

• Opioid-related inpatient hospital stays increased 64% nationally from 2005 to 2014

• Opioid addiction is linked with high rates of illegal activity and incarceration.

CDC.GOV
Important Longitudinal Study: Outlook Not Good for Opioid Use Disorder

- 581 males with OUD, mean age 25.4, followed for 33 years (Hser, et. al., 2001)
National Institute on Drug Abuse (NIDA) Statistics

U.S.: Drug- and Alcohol-Related Intoxication Deaths

More than 72,000 Americans died from drug overdoses in 2017.

Peak car crash deaths (1972)
Peak H.I.V. deaths (1995)
Peak gun deaths (1993)
Centers for Disease Control (CDC)
Statistics

Drugs Involved in U.S. Overdose Deaths, 1999 to 2017

- Synthetic Opioids other than Methadone, 29,406
- Heroin, 15,958
- Natural and semi-synthetic opioids, 14,958
- Cocaine, 14,556
- Methamphetamine, 10,721
- Methadone, 3,295
NIDA Stats

National Overdose Deaths
Number of Deaths Involving Cocaine in Combination with Non-Methadone Opioid Synthetics

Source: National Center for Health Statistics, CDC Wonder
Our ERs and Hospitals are Overburdened with the Epidemic (AHRQ.GOV)
State to State the Numbers Speak for Themselves (AHRQ.GOV)
The Disease of Addiction

• ADDICTION IS Disease that is TREATABLE!!!

• The medications approved for treating opioid use disorder are 40 to 60% effective per evidence based studies in preventing opioid use for 1 to 2 years (Phillips, JK et al., 2017)
Nora Volkow

• “A key driver of the overdose epidemic is underlying substance use disorder. Consequently, expanding access to addiction treatment services is an essential component of a comprehensive response.” (Volkow, Nora D. et al, 2014)
OUD is Chronic Illness

• “Drug dependence generally has been treated as if it were an acute illness. Review results suggest that long term care strategies of medication management and continued monitoring produce lasting benefits. Drug dependence should be insured, treated and evaluated like other chronic illnesses.” (McClellan, AT et al., 2000)
Introduction to TIP 63, Medications for OUD

• Reviews the three FDA-approved medications used to treat OUD — methadone, naltrexone, and buprenorphine — along with strategies and services to support recovery for people with OUD

• OUD medications are more effective than treatment with placebo or no medication in:
  • Reducing illicit opioid use
  • Retaining people in treatment

• OUD medication can be taken on a short- or long-term basis, including as part of medically supervised withdrawal or maintenance treatment
Buprenorphine

- On WHO’s list of essential medications
- DATA 2000 – applies only to buprenorphine formulations FDA – approved for OUD treatment
  - Physicians, nurse practitioners and physician assistants
  - 6-month implant (Probuphine®): additional training required per FDA REMS for ordering and inserting/removing, not dispensed directly to patient
  - Monthly injection (Sublocad®): special certification required pursuant to FDA-approved REMS, not dispensed directly to patient
Duration of Treatment

• Continued medication treatment associated with better outcomes compared to medically supervised withdrawal

• Expert TIP panel:
  • “...supports maintaining patients on medication for years, decades and even a lifetime if patients are benefiting.”
  • Does not recommend medically supervised short-term withdrawal alone because of high rates of return to illicit opioid use
  • Recommends discontinuing dose reductions and allowing for dose increases if patient destabilizing, prompt re-entry to treatment, encouraging psychosocial adjuncts
Pharmacology

• Review of buprenorphine pharmacology
• High affinity, partial opioid agonist, improved safety profile vs. full agonists
• Wide individual variability in pharmacokinetics:
  • Peak plasma concentrations after a first dose of transmucosal (TM) product occur between 40 min-3.5 hours after dosing (Elkader et al., 2005)
  • Long and variable elimination half-life from 24-69 hours (Kuhlman et al., 1998)
  • TM products: long half-life and partial agonist properties allow for less than daily dosing (e.g., doubling the daily dose once stable and giving on alternate days, 12 mg daily = 24 mg every other day; Marsh et al., 2005)
New Transmucosal Formulations

• New transmucosal (TM) formulations with improved bioavailability
  • Ex: Zubsolv 5.7/1.4, Bunavail 4.2/0.7, Suboxone film 8/2, generic 8/2 Suboxone tablets all with bioequivalent buprenorphine exposures compared to 8/2 mg Suboxone tablet (that is no longer available)

• Goals of dosing of all TM formulations:
  • Eliminate withdrawal
  • Reduce or eliminate opioid craving.
  • Provide effective blockade when there is illicit opioids use (patient reports diminished positive effects from the use of illicit opioid)
  • Be well-tolerated
Review of Transmucosal Dosing

• Induction: In-office or at home. Home induction can be safe and effective (Gunderson et al, 2010; Lee et al., 2014)

• Individualize dosing –several factors to consider including level of physical dependence
  - For those with current physical dependence, initiate when in withdrawal with an initial 2-4 mg dose of bup/nx. FDA label recommends a maximum dose of 8 mg on day 1 and 16 mg on Day 2. Remember some patients stabilize on lower doses. Scant data to support more than 24 mg daily
  - For those not currently physically dependent, initiate at lower doses (e.g., 1 mg with slow incremental increases, holding for sedation; Vocci et al. 2015)
New Long-Acting Formulations

- 6-month implant: approved in 2016 for clinically stable patients on buprenorphine (bup)/naloxone (nx) <8 mg / day for at least 90 days

- Monthly injection: recently approved for moderate-severe OUD after initiation with TM bup/nx with at least 7 days of dose adjustment
New Long Acting Formulations: Implant

- 6 month subdermal implants:
  - Dose is 4 implants (each containing 80 mg buprenorphine), inserted in upper arm
  - Peak plasma concentration 12 hours after insertion
  - Removed & replaced after 6 months, wound care check within 1 week of implant and removal, office visits at least monthly to assess continued stability
  - Consider TM supplementation if destabilize –17.9% required in Phase 3 RCT but low dose (2/0.5) and for short periods (Rosenthal et al. 2016)
New Long Acting Formulations: Implant cont...

- In a non-inferiority trial, improved abstinence rates compared to SL bup/nx (Rosenthal et al., 2016)
- Approved for two rounds of implants
- Serious adverse events: uncommon but possible including migration and nerve damage, potential for extraction and misuse. USE ONLY IN STABLE PATIENTS
- Limited data in pregnancy
New Long Acting Formulations: Injection

• Monthly subcutaneous abdominal injection:
  • Refrigerate, keep at room temperature for at least 15 minutes prior to injection
  • Dose: Months one and two 300 mg, month 3 and thereafter 100 mg (may increase if clinically indicated)
  • Do NOT rub or massage or let belts/waistbands rub against
  • Obtain baseline liver function tests (LFTs) and monitor monthly, particularly with 300 mg dose
• Most common side effects were: nausea, vomiting, headache, constipation, increased LFTs, tiredness, injection site itching and pain. Uncommon: need for surgical removal of injection

• Limited data in pregnancy. Contains excipient, N-Methyl-2pyrrolindone, that has reported adverse fetal effects in animal studies
Regulatory Considerations

• Waiver for physicians:
  • 30, 100, 275 patients.
  • Additional proactive reporting requirements for medical doctors (MDs) with approval to treat 275 patients.
  • Requires on-call service and documented diversion control plan.

• Waiver for nurse practitioners (NPs) and physician assistants (PAs):
  • 30 and 100 patients.
  • 24 hours of training.

• Unique requirements for new long-acting formulations.
Efficacy of MAT and Relapse Rates
Bottom Line!

• In both controlled and retrospective studies, the success rate for most medications is between 40 and 60% (one or two years, Connery 2015)

• When patients come off the medications, they relapse (Weiss 2011, Fiellin 2014)

• Relapse may be associated with an increased chance of overdose and death (Kakko 2003)
Ball 1988: Reduction in IVDU with Methadone

**FIGURE 1.** Effect of Methadone Maintenance Treatment on IV Use for 388 Male Methadone Patients in Six Programs

- **Percent IV Users**
  - 100%
  - 81.4%
  - 63.3%
  - 41.7%
  - 28.9%

- **Mean Time in Treatment:** 45 Months

- **Pre-Admission Period**

- **Last Addiction Period**

- **Admission**

- **In-Treatment Period**

- **Interview**
Ball 1988: Reduction in IVDU with Methadone

FIGURE 1. Effect of Methadone Maintenance Treatment on IV Use for 388 Male Methadone Patients in Six Programs

- 100% at admission
- 81.4% at last addiction period
- 63.3% at admission
- 41.7% in the 3rd year
- 28.9% at interview

Mean time in treatment: 45 months
FIGURE 1. Two-year retention and duration of treatment among patients receiving buprenorphine/naloxone maintenance in primary care.
Vivitrol® (injectable naltrexone) for opioid dependence:
Addiction Tx in Russia

Krupitsky et al; Lancet 2011; 377: 1506-13
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3160743/
No XRNTX: Abstinence 40%  
(Kruptisky et al., 2011)
XRNTX: Abstinence 50% (Kruptisky et al., 2011)
Ball 1988: Resumption of IVDU After Tapering Off Methadone
Ball 1988: Resumption of IVDU After Tapering Off Methadone
40 heroin addicts were started on buprenorphine/naloxone.

20 were “detoxed” off and offered counseling.

20 were kept on buprenorphine/naloxone and offered counseling.

A year later.......
Medical Withdrawal vs Maintenance

- N=20
- Both groups received counseling
- High mortality rate in detox group (20%, n=4)

Kakko et al., Lancet; 361:662-668, Feb 22 2003
Medical Withdrawal vs Maintenance

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Kakko et al., Lancet; 361:662-668, Feb 22 2003
Luty 2003: Opioid Detoxification During Pregnancy

- 101 women underwent detox during pregnancy
- 40 successfully detoxed
- No adverse fetal effects documented
- BUT: only 1 of 101 abstinent at delivery!
Luty 2003: Opioid Detox During Pregnancy

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Can You Taper off Buprenorphine Without Relapse?

Adjunctive Counseling During Brief and Extended Buprenorphine-Naloxone Treatment for Prescription Opioid Dependence

A 2-Phase Randomized Controlled Trial

Roger D. Weiss, MD; Jennifer Sharpe Potter, PhD; David A. Fiellin, MD; Marilyn Byrne, MSW; Hilary S. Connery, MD, PhD; William Dickinson, DO; John Gardin, PhD; Margaret L. Griffin, PhD; Marc N. Gourevitch, MD, MPH; Deborah L. Haller, PhD; Albert L. Hasson, MSW; Zhen Huang, MS; Petra Jacobs, MD; Andrzej S. Kosinski, PhD; Robert Lindblad, MD; Elinore F. McCance-Katz, MD; Scott E. Provost, MSW; Jeffrey Selzer, MD; Eugene C. Somoza, MD, PhD; Susan C. Sonne, PharmD; Walter Ling, MD
Can You Taper off Buprenorphine Without Relapse?

- 654 patients enroll on buprenorphine for 2 weeks.
- 50% stay abstinent.
- They are tapered off and over 90% relapse.
- 360 remain, they go back on buprenorphine for 12 weeks,
- 50% stay abstinent.
- They taper off and 90+% relapse.
- Moral of the story: medications work as long as you take them.

Weiss, 2011
Long-term Outcomes from the National Drug Abuse Treatment Clinical Trials Network Prescription Opioid Addiction Treatment Study

Roger D. Weiss, Jennifer Sharpe Potter, Margaret L. Griffin, Scott E. Provost, Garrett D. Fitzmaurice, Katherine A. McDermott, Emily N. Srisarajivakul, Dorian R. Dodd, Jessica A. Dreifuss, R. Kathryn McHugh, and Kathleen M. Carroll

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eDepartment of Psychiatry, Yale University School of Medicine, 333 Cedar Street, New Haven, CT 06510, USA
Outcomes?

• About half were reached by phone
• No urine drug screens were done; interviews only
• 32% were abstinent without M.A.T.
• 29% were abstinent WITH M.A.T.
• 8% were using while on M.A.T.
• 31% were using without M.A.T.
• Conclusion: M.A.T. was twice as successful
Other Concerns about Buprenorphine

- It can be abused
  - (mostly for withdrawal; Kenney 2017)
- It is unsafe when combined with sedatives & alcohol.
- Adding naloxone (Suboxone/Zubsolv) doesn’t help (Cohier 2014)
- It is an opioid.
- Relapse rates after detox exceed 90%. (Weiss, 2011)
“Opioid use prevention effects weaned after treatment discontinuation”: Lee 2017 NEJM

Figure 2. Kaplan–Meier Curves for Relapse-free Survival.
Conclusions

• “MAT” is effective at decreasing opioid use.
• Stopping MAT will usually result in relapse & potentially increased chance of death. (Sordo, 2017)
• Why would you expect otherwise?
• Methadone is better at keeping you in treatment. Buprenorphine has a superior safety profile. (Mattick 2014)
• Vivitrol® (injectable naltrexone) is effective at reducing opioid use. (Kruptisky 2011); it doesn’t work when you don’t take it (Lee 2016)
Emergency Department–Initiated Buprenorphine/Naloxone Treatment for Opioid Dependence (D’Onofrio, et. al., 2015)

ED indicates emergency department; MINI, Mini-International Neuropsychiatric Interview

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Miscellaneous reasons (e.g., unable to consent, non-English speaking, pregnant, deceased, isolation, age <18 years, police custody).

Miscellaneous reasons (e.g., isolation, sexual assault, deceased).
Emergency Department–Initiated Buprenorphine/Naloxone Treatment for Opioid Dependence (D’Onofrio, et. al., 2015)

- Eighty-nine of 114 patients (78%; 95% CI, 70%-85%) in the buprenorphine group were engaged in treatment at significantly higher rates than the 38 of 102 patients (37%; 95% CI, 28%-47%) in the referral group or 50 of 111 patients (45%; 95% CI, 36%-54%) in the brief intervention group ($P < .001$).
Don’t Miss the Opportunity

• Psychiatric emergency rooms and ERs are often the initial point of care for patients with OUD
• Community physicians should be aware of the resources available to refer their patients to
• Buprenorphine is a potentially life-saving medication for a deadly illness
Warm-Handoffs

- Process of communication with patient and the family in the primary care setting and connecting the patient to the behavioral health setting.
- Ensure that the patient in the ER is screened and assessed upon admission.
- Once the patient is stabilized, educate the individual and the family/friends on substance abuse treatment options.
  - Use of brief pamphlets/brochures to explain purpose of warm-handoff and need for treatment following discharge from ER.
  - Provide Narcan (naloxone) kits for the family/friends to take home in case of future overdose.
- Help with transport and admission to treatment.
- Continue to track the patient through initiation of treatment in the community.

Use of Peers in Warm-Handoffs

• Have the patient met by a Certified Recovery Peer Specialist in hospital after ER admission.

• Peer will provide support and educate the patient and the family in conjunction with hospital staff to “meet them where they’re at”.
  – Helps acceptance of treatment as the best next step to address opioid use disorder, recovery, and prevention of future overdose.
  – Continue to check on and communicate with patient through early stages of treatment in the community.

(Lackawanna Opioid Coalition 2017; Agency for Healthcare Research and Quality, 2017; Vimont, 2016)
Maintenance Medications for OUD

- FDA Approved – Methadone (Methadose; Dolophine)
- Buprenorphine (Suboxone; Suboxone Film; Subutex; Bunavail; Zubsolv; Sublocade) –
- Naltrexone (Trexan; Vivitrol)
Early Attempts to Treat OUD

• “I received a note from her when she had used this. She was much encouraged and had ordered two pounds more... I saw her recently when she assured me that she had no desire for morphine.”

Dr. W.H. Bentley
Detroit Therapeutic Gazette, 1880
(about a woman for whom he had prescribed one pound of cocaine for morphine addiction)
The Harrison Narcotics Act (1914)
Early Recognition of Addiction as a Disease

“The shallow pretense that drug addiction is “a disease” which the specialist must be allowed to “treat,” which pretended treatment consists of supplying victims with the drug has caused their physical and moral debauchery...”

American Medical Association
Report of the Committee of the Narcotic Drug Situation, 1920
Review of Medications
Dole and Nyswander

A Medical Treatment for Diacetylmorphine (Heroin) Addiction
A Clinical Trial With Methadone Hydrochloride

Vincent P. Dole, MD, and Marie Nyswander, MD

A group of 22 patients, previously addicted to diacetylmorphine (heroin), have been stabilized with methadone hydrochloride. This medication appears to have two useful effects: (1) relief of narcotic hunger, and (2) induction of sufficient tolerance to block the euphoric effect of an average illegal dose of diacetylmorphine. With this medication, and a comprehensive program of rehabilitation, patients have shown marked improvement; they have returned to school, obtained jobs, and have become reabsorbed with their families. Medical and psychiatric tests have disclosed no signs of toxicity, apart from conversion. This treatment requires careful medical supervision and many social services. In our opinion, both the medication and the supporting program are essential.

The question of "maintenance treatment" of addicts is one that is often argued but seldom clearly defined. If this procedure is conceived as no more than an unsupervised distribution of narcotic drugs to addicts for self-administration of doses and at times of their choosing, then few physicians would accept it as proper medical practice. An uncontrolled supply of drugs would trap confirmed addicts in a closed world of drug taking, and tend to spread addiction. This procedure certainly would not qualify as "maintenance" in a medical sense. Uncontrolled distribution is mentioned here only to reject it, and to emphasize the distinction between distribution and medical prescription. The question at issue in the present study was whether a narcotic medicine, prescribed by physicians as part of a treatment program, could help in the return of addict patients to normal living.

No definitive study of medical maintenance has yet been reported. The Council on Mental Health of the American Medical Association, after a thorough review of evidence available in 1957, concluded that "The advisability of establishing clinics or some equivalent system to dispense opiates to addicts cannot be settled on the basis of objective facts. Any position taken is necessarily based in part on opinion, and on this question opinions are divided." With respect to previous trials of maintenance treatment, the Council found that "Assessment of the operation of the narcotic dispensation between 1919 and 1923 is difficult because of the paucity of published material. Much of the small amount of data that is available is not sufficiently objective to be of great value in formulating any clear-cut opinion of the purpose of the clinic, the way in which it operated, or the results attained." No new studies bearing on the question of maintenance treatment have appeared in the eight years since this report was published. Meanwhile, various medical and legal committees have called for additional research.

See also page 875.

The present study, conducted under the auspices of the departments of health and hospitals, New York city, has yielded encouraging results; patients who before treatment appeared hopelessly addicted are now engaged in useful occupations and are not using diacetylmorphine (heroin). As measured by social performance, these patients have ceased to be addicts. It must be emphasized that this paper is only a progress report, based on treatment of 22 patients for periods of 1 to 15 months. Such limited study obviously does not establish a new treatment for general application. The results, however, appear sufficiently promising to justify further study of the procedure on a large scale.

Procedure
The patients admitted to the program to date were men, aged 19 to 37, "mainline" diacetylmorphine users for several years with history of failures...
Opioids and the Law

- Narcotic Addict Treatment Act (1974)
- Comprehensive Addiction & Recovery Act (CARA)(2016)
Comprehensive Drug Abuse Prevention and Control Act of 1970

• “Controlled Substances Act”
• Effectively replaced all previous laws dealing with “narcotic”/dangerous drugs
• Established a commission on marijuana and substance use disorders.
• Divided drugs into 5 “schedules”
Comprehensive Drug Abuse Prevention and Control Act of 1970

• Generally, there are 2 requirements that a practitioner must meet if they wish to “administer or dispense directly ... a narcotic drug listed in any schedule to a narcotic dependent person for the purpose of maintenance or detoxification treatment . .”

  1. Practitioner must be separately registered with the DEA as a narcotic treatment program.

  2. Practitioner must be in compliance with DEA regulations, including those for treatment qualifications, security, records, and unsupervised use of the drugs – 2 exceptions
Relief of Acute Withdrawal Exception

• The “3-day rule” provides an exception to the CSA.
• Title 21 C.F.R.§ 1306.07
• allows a physician to “administer (but not prescribe) narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. However, the prescriber may not administer more than one day’s medication at one time and such treatment may not last for more than 3 days; no renewals or extensions of that period are permitted.”

• Applies in out-patient and Emergency Department settings
The “adjunct rule” provides an exception to the CSA.
• Title 21 C.F.R. § 1306.07
• allows “a physician or authorized hospital staff to administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.”
• Unclear if this applies in the Emergency Department setting
• Generally does not apply in sub-acute hospital setting
Narcotic Addict Treatment Act (1974)

• Primarily spells out requirements for methadone programs
• Added a provision for “Use of narcotic drugs in hospitals”:
  – “For hospitalized patients, the use of a narcotic drug for narcotic addict treatment may be administered or dispensed only for detoxification treatment. If a narcotic drug is administered for treatment of narcotic dependence for more than 180 days, the procedure is no longer considered detoxification but is, rather, considered maintenance treatment. ..This does not preclude the maintenance treatment of a patient who is hospitalized for treatment of medical conditions other than addiction and who requires temporary maintenance treatment during critical period of his or her stay or whose enrollment in a program which has approval for maintenance treatment using narcotic drugs has been verified.”
Narcotic Addict Treatment Act (1974)

• Any hospital which already has received approval under this paragraph may serve as a temporary narcotic treatment program when an approved treatment program has been terminated and there is no other facility immediately available in the area to provide narcotic drug treatment for the patients.
Drug Abuse Treatment Act Of 2000

Section 3502 of The Children’s Health Act of 2000 Schedule III, IV, and V medications* (Buprenorphine) approved for detoxification and maintenance

Allows:
- physicians to prescribe (in office-based setting) & pharmacists to dispense “narcotics”, specifically buprenorphine, to treat opioid addiction

*does not apply to methadone or other opioids that are Schedule II
Comprehensive Addiction & Recovery Act (CARA) 2016

Allows:
Nurse practitioners and physicians assistants to prescribe buprenorphine (requires extra training)

Allows certified addiction specialists to treat 275 patients at a time (with extra reporting requirements)
Current Treatment Gap Along Opioid Use Disorder Cascade of Care (Health Affairs Blog, 2017)
Community Treatment Center Model

• Patient Presents to Tampa General Hospital with Overdose – Narcan Rescue, assessment and Dx of OUD
• First Dose of BUP delivered in ER at 8 mg (administered with ER Provider with X-Number)
• Patient with Warm-Handoff to DACCO, comes into Assessment and Referral next day
• Patient seen in MAT evaluation for consideration of OBOT or OTP BUP
Community Treatment Center Model

• Patient admitted to TGH for Medical Co-Morbidity
• Dx with OUD and in opioid withdrawal
• Patient consults DACCO physician and initiates MTD after education. Patient initially induced with MTD at 30 mg daily and DACCO provider and Hospital service cooperate with induction, patient discharged in 1 week and presents to DACCO next day for admission to OATS, our OTP.
References


References


- CDC.GOV

References

References

• TIP 63: Medications for Opioid Use Disorder from SAMHSA


References


References


References


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