**Linda Hurley, CODAC Behavioral Healthcare, Inc.**

1. Many of the proposals to address the opioid epidemic call for expanded access to medication assisted treatment (MAT). What is MAT? Is there data on its effectiveness? Why is access to it limited at present? Finally, are there any downsides or risks to MAT?

Medication Assisted Treatment (MAT) for opioid dependence is the practice of using both medication and behavioral health interventions/treatments to assist individuals in becoming free of dependence on, or addiction to, prescription pain medication, heroin and other opioids. Medication Assisted Treatment (MAT) references the three (3) federally-approved medications for the treatment of opioid dependence – methadone, buprenorphine (commonly known as Suboxone), and naltrexone (commonly known as Vivitrol). The key word here is "assisted." As providers we have often found that our communities view medications, including those used to treat opioid addiction, as a "magic bullet" capable of "curing" a disease. And, while medication is a crucial element of MAT (see below), it is not usually effective on its own. Best practice emphasizes the importance of addressing the complexity of, yes, the biological, but also psychological, spiritual and social components of the disease. Although it is certainly less expensive—and simpler—to treat only the biological component, this approach has not proven successful in supporting and sustaining long-term recovery in the treatment of opioid dependence.

**Methadone,** a synthetic opioid that has been used in the US for maintenance since the 1960's, is considered the "gold standard" for treating opioid dependence. **Naltrexone,** approved by the FDA in 2006**,** is a medication used to support recovery once abstinence is achieved, and has proved effective with only a relatively small percentage of individuals. More recently, **buprenorphine** was developed, approved by the FDA in 2002**,** and is available through OTPs, and frequently accessed through approved primary care physicians. The efficacy of all three of these medications is fully potentialized when they are used concurrently with behavioral health (mental health) interventions as part of MAT.

The National Institute of Drug Addiction (NIDA) published their *Four Principles of Drug Addiction Treatment*: "Effective treatment tends to multiple needs of the individual, not just his or her drug abuse. To be effective, treatment must address the individual's drug abuse and any associated medical, psychological, social, vocational and legal problems. It is also important that treatment be appropriate for the individual's age, gender, ethnicity, and culture." Once again: a comprehensive approach, utilizing a combination of supervised medication along with clinical and behavioral interventions, provides the safest, most effective, long-term outcomes in the treatment of this complex disease.

**Methadone** has been utilized since the 1960s in the treatment opioid dependence. It has been widely studied and heavily regulated. (There is a list of the literature supporting the efficacy of methadone treatment following the response to these questions.)* When used in proper doses, under supervised care, methadone does not create euphoria, sedation or an analgesic effect, but ***does*** relieve cravings for other opioids and mitigates withdrawal symptoms.

Part of the success of methadone treatment lies in the mandated, comprehensive and competent care provided in the OTP setting. Due to federal and state regulation, as well as SAMHSA/CSAT required accreditation standards, most OTPs offer care that reflects the NIDA principles. The longer an individual is maintained in an

OTP, the lower the risk of HIV/Aids, Hepatitis C, other drug use, overdose, incarceration, medical costs, child protective and other social service cost, and the higher the rate of employment, training, intact families, healthy infants and measured perceptions of well-being.

An individual participating in an OTP setting will begin by receiving daily methadone medication, daily interaction with nursing staff, individual and group counseling, and recovery support services. Many programs also offer psychiatric or mental health treatment and access to medical services. Family involvement is encouraged. Over time, when the treatment is successful for an individual, they may receive medication to take home, requiring less time at the program and more time to develop aspects of their recovery environment, e.g., employment or stable housing.

Methadone is often referred to as a "replacement" therapy because it replaces all other opioids in the brain. Where heroin or a prescription opioid may fill a neural receptor, methadone will replace and block other opioids from activating that receptor. Methadone is categorized as a full agonist for this reason. The medically effective dosage of methadone will provide an individual with freedom from painful and debilitating withdrawal symptoms, while not inducing a high or euphoria. This allows time for building recovery in all the areas described above. Some individuals will require months of medication, others may utilize the medication for a lifetime. Addiction is a chronic, recurring disease of the brain that often results in permanent brain change. Medication regimes are adapted to the individuals needs along this continuum.

Access issues vary from state to state, dependent upon state regulation and geography. In Rhode Island, access is not an issue at all. There are no wait lists, admissions are within 24-48 hours and multiple OTP locations result in strong geographic penetration. A suggestion would be to support this access model across all states. Nevertheless, the significant rise in numbers of individuals seeking treatment in the last two years has put considerable strain on providers. If Rhode Island is to be able to continue to meet demand, both physical (number and size of facilities) and capacity (professional workforce) will have to be increased moving forward.

Downsides/Risks

1. Overdose when not take as prescribed or taken with other CNS depressants
2. Diversion risks as a patient receives their medication to take at home
3. Contraindicated with other central nervous system depressants (potentiation) resulting in lethal outcomes

**Naltrexone** is the only approved medication for opioid addiction that is not a controlled substance. It works by blocking the euphoric and sedative effects of opioids such as heroin, morphine, and codeine. So if a person who is abstinent (in recovery) and using naltrexone relapses and uses the "problem" drug, the naltrexone will prevent the feeling of getting high. However, unlike methadone, naltrexone does not eliminate cravings or withdrawal symptoms. Because naltrexone must be taken orally, on a daily basis, a patient whose cravings become overwhelming can easily satisfy those cravings by skipping a dose before resuming problem opioid use. Cravings are strong motivators for relapse and naltrexone, therefore, is generally most successful with individuals who are highly motivated to remain abstinent and who have a structured support system in place to help them resist cravings. There is no abuse and diversion potential with naltrexone.

Although the usefulness of oral naltrexone in opioid dependence has been demonstrated to be limited, extended-release injections of naltrexone, administered once per month, have proven somewhat more effective. It works differently in the body than buprenorphine and methadone, which activate opioid receptors in the body that suppress cravings. It is important to keep in mind that: "as with any other medication intended for the treatment of addiction, naltrexone was never intended to be used alone without other conventional accepted modalities for treatment." For patients receiving monthly injections, there is no way to require or monitor compliance with clinical and other behavioral health interventions.

Downsides/Risks:

1. Patients utilizing naltrexone may have reduced tolerance to opioids and may be unaware of their potential sensitivity to the same, or lower, doses of opioids that they used to take. If patients who are treated with naltrexone relapse after a period of abstinence, it is possible that the dosage of opioid that was previously used may have life-threatening consequences, including respiratory arrest and circulatory collapse; overdose.
2. People using naltrexone should not use any other opioids or illicit drugs; drink alcohol; or take sedatives, tranquilizers, or other drugs.
3. Patients receiving naltrexone must choose to administer the medication either daily or monthly. It is very easy to simply not take their medication when faced with cravings.

**Buprenorphine** is categorized as a partial agonist, whereas methadone, like heroin, is a full agonist. This simply refers to the medications ability to fill a receptor and its relative tenacity in continuing to fill it. It is by their action in blocking opioid receptors that opioids achieve their analgesic (pain-killing), as well as their addictive, effects.

Methadone, as a full agonist, continues to produce effects on the receptors until either all receptors are fully activated or the maximum effect of the medication is reached.

Buprenorphine, as a partial agonist, does not activate receptors to the same extent as methadone. Its effects increase until reaching a plateau. Buprenorphine reaches its ceiling effect at a moderate dose, which means that its effects do not increase after that point, even with increases in dosage, resulting in less risk for overdose. This is an important benefit to the utilization of buprenorphine.

Like all opioids, buprenorphine can cause respiratory depression and euphoria, but its maximal effects are less than those of a full agonist. The benefits, from an overdose perspective, of the ceiling effect constitute the safety profile of buprenorphine—a lower risk of abuse, addiction, and side effects than with full agonists.

For people who are not addicted to, or dependent on opioids, the effects of partial (buprenorphine) and full (methadone) agonists are indistinguishable. However, at a certain point, the increasing effects of partial agonists reach maximum levels. For this reason, people who are dependent on high doses of opioids are better suited to treatment with a full agonist, such as methadone.* Buprenorphine is proven to be best suited for those who are physiologically naïve, newer to their addiction, and/or have a high degree of existing psycho-social supports.

An individual receiving buprenorphine medication in a PCP office will be assessed by the physician and prescribed the medication. Often the patient will be asked to remain in the office for an hour to 3 hours to make sure that the patient does not experience any adverse responses. They then receive prescriptions for 7 to 30 days and possible referrals for counseling and toxicology. There is no consistent state or federal accountability structure in place to assure that even the referrals for additional services are made, not to mention whether the services themselves are utilized.

Downsides /Risks:

1. Although buprenorphine has less potential for overdose, it, has a serious potential for drug-drug interactions. It must be used cautiously with other medications, in particular sedatives, opioid antagonists like naltrexone, and opioid agonists. Benzodiazepine and buprenorphine are a particularly lethal combination.*

2. Non-prescribed buprenorphine can be used for its psychotropic effect, or high. There is a continued growth in the market for illicit buprenorphine. Due to less stringent regulation (compared to

methadone), non-prescribed buprenorphine use is present and continues to increase in our communities.*

3. Because the prescription of buprenorphine does not require, by regulation, accompanying counseling and recovery support, many who access care find it unsuccessful. Counseling, relapse prevention, family counseling, diagnostic toxicology and other components of a SAMHSA, DEA approved OTP are not required in the primary care practice site. It is important that, as we move forward, the utilization of buprenorphine is supported by psychosocial and recovery supports. *

4. Diversion risks due to prescribed medications in the community

5. There is no consistent state or federal accountability structure in place to assure that referrals for additional services are made, not to mention whether the services themselves are accessed. As established, best practice for all forms of opioid-related MAT includes medication and clinical interventions; yet, current regulations for buprenorphine do not have a mechanism in place to monitor doctor compliance with best practice or patient access/follow-through with the clinical component. By comparison, methadone facilities are mandated to provide the clinical component and accreditation renewal is tied to compliance with clinical requirements.

6. Although buprenorphine is perfect for the patients who fit a specific medical profile, for many others the plateau effect of the medication, and the potential for forgoing crucial clinical support, can result in a patient receiving a lower level of care than their disease requires.

7. Limited access to the medication: a.) it is expensive b). physicians have not enthusiastically embraced the practice resulting in insufficient numbers of prescribers c.) the limit of 30/100 patients per physician license is seen by many as a barrier to access.

These are all potent, effective medications and there are risks just as with other medications. These risks can be mitigated, however, through comprehensive patient education, and treatment including but not limited to; counseling, medical oversight and supervision, toxicology screening, referral to specialty care when indicated and a full continuum of recovery support. Including all of the above represents a model that is safe, replicable and fully capable of effectively addressing this epidemic.

**Linda Hurley, CODAC Behavioral Healthcare, Inc.**

**Q: What sort of tools are available to providers of MAT to help their patients receive much needed counseling to accompany the medication assisted treatment?**

A comprehensive MAT recognizes the value of a well-integrated treatment and recovery support system including a well-trained and skillful team of counselors, therapists, and clinicians with access to the tools they need to understand this disorder and meet the complex demands of patients under their care.

"Tools" necessary to assure that patients receive much needed comprehensive and competent counseling are both external and internal and include, but are not limited to the following:

**A. Research and Publications**

Decades of information available in the rich, world-wide history of research on MAT and the best-practice and evidence-based models for treatment and recovery that have been derived from this research.

The research on MAT, particularly as it relates to the use of methadone, is extensive. Much of this research began in the late 1960s and continues today. While the preponderance of research, data, and opinion relates to the use of methadone, the more recent inclusion of buprenorphine-based products and injectable naltrexone has added to the body of evidence that MAT is a most effective way of treating opioid dependence – a chronic and relapsing disease/disorder of brain chemistry.

Along with world-wide research, and its conclusions, studies by the National Institute on Drug Abuse (NIDA) and publications made available by the Substance Abuse and Mental Health Services Administration (SAMHSA) have provided much by way of understanding the complexity of this disease as well as evolving treatment and recovery strategies.

SAMHSA's "Treatment Improvement Protocols (TIPs)", "Treatment Assistance Publications (TAPs)", "Knowledge Application Programs (KAP)", and "Quick Guides for Clinicians" are but a few publications that are rooted in the information and conclusions provided by this rich and extensive research and serve as tools for clinical competence.

**B. Regulatory, accreditation, certification, and other external standards**

Notwithstanding the MAT provider commitment to clinical/counseling competency, the knowledge "tools" provided by the above-referenced research and other documentation, are complemented and supported by specifically designed federal, state, and accreditation standards,

regulations, and licensing requirements that define and articulate treatment and recovery standards.

These include, but are not limited to clinical and cultural competence, clinical supervision, on-going training and continuing education, counselor certification, co-occurring disorders, the value and applicability of toxicology screening, interface with the criminal justice system, housing, education, health and wellness, recovery systems, and access to the most relevant and current, best practice and evidence-based information.

However, it is important to note that the above requirements and obligations are universal and standard of practice and care for all federally-credentialed narcotic/opioid treatment (methadone) programs – they are not optional. They assure a consistent and accountable system of care within states and across the country.

By contrast, there are no similar requirements, regulations, standards, or mandates for patients receiving MAT as associated with DATA 2000, Vivitrol, or other office-based practices. Likewise, there is no evidence or accountability model to assess or assure that these "tools" are utilized in these practices or that patients have the opportunity to benefit from same.

**C. On-going training and supervision; mentoring; and continuing education**

Clinical competence is a function of provider commitment to assure that counselors have access to information through on-going training and continuing education and are adequately supervised and mentored in their professional growth. Historical, recent, and current research provides a valuable underpinning for the guidance and development of sound, evidence-based medical, clinical, and counseling practices necessary to sustain a comprehensive array of treatment and recovery support services indicated to treat this disease.

By design, by commitment, and by an understanding of the complexity of this disease, the nation's certified OTPs help their patients receive counseling and recovery support and continued quality improvement through the combined use of the tools afforded and available through research, medical, clinical competency, and best/evidence-based practice.

Again, there is no evidence or accountability model to assess or assure that these "tools" are utilized in "non-methadone" treatment settings.

Medication Assisted Treatment (MAT) references the three (3) federally-approved medications for the treatment of opioid dependence – methadone, buprenorphine (commonly known as Suboxone®), and naltrexone (commonly known as Vivitrol®).

It is important to note that by definition MAT includes the term "assisted" which suggests that medication is only one of many tools indicative of, and necessary for a comprehensive treatment and recovery system.

Opioid Treatment Programs (OTPs) are the only addiction treatment entities authorized to use methadone for the treatment of opioid dependence. They fall under the regulatory jurisdiction of SAMHSA and the DEA as well as State Opioid Treatment Authorities (SOTAs) and may also use buprenorphine and naltrexone, however, the most frequently used is methadone. The requirements and obligations are universal and standard of practice and care for all federally-credentialed OTPs – they are not optional. They assure a consistent and accountable system of care within states and across the country.

Title XXXV, Section 3502 of the Children's Health Act of 2000, (DATA2000) permits physicians who meet certain qualifications to treat opioid addiction with Schedule III, IV, and V narcotic medications that have been specifically approved by the Food and Drug Administration for that indication. Such medications may be prescribed and dispensed by waived physicians in treatment settings other than the traditional Opioid Treatment Program "(methadone clinic)" setting. There are no regulatory requirements for these physicians other than completing a one-time eight (8) hour course.

Both methadone and buprenorphine are oral medications.

While relatively new in its current formulation, Vivitrol® (injectable naltrexone) can be provided by OTPs, and DATA 2000 physicians. Physicians using Vivitrol® must receive special training related to the injection.

**Summary**

Medication Assisted Treatment (MAT) recognizes that opioid dependence is a complex disorder often combining addiction and dependence with other medical illnesses and psychosocial/behavioral health disorders. A comprehensive MAT program has been demonstrated to be an effective means to treat this disorder.

None of the three federally-approved medications were ever intended to be used alone but to be part of a comprehensive and well-designed treatment and recovery plan. These medications should not be regarded as any type of "cure" but, simply one of the tools which, when used in combination with a comprehensive and multidisciplinary array of treatment and recovery support (inpatient and outpatient drug rehabilitation, counseling, and NA/AA meetings) can improve the patients' chances for a successful recovery. It has been established that a "well-equipped", skilled, and competent clinical workforce with access to information, training and education - in combination with the right medication - offers patients the greatest opportunity for sustained recovery and wellness.

**Sample Publications:**

TIP 39: Substance Abuse Treatment and Family Therapy
TIP 42: Substance Abuse Treatment for Persons With Co-Occurring Disorders
TIP 43: Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs
TIP 44: Substance Abuse Treatment for Adults in the Criminal Justice System
TIP 48: Managing Depressive Symptoms in Substance Abuse Clients During Early Recovery
TIP 51: Substance Abuse Treatment: Addressing the Specific Needs of Women
TIP 52: Clinical Supervision and Professional Development of the Substance Abuse Counselor
TIP 59: Improving Cultural Competence

American Society of Addiction Medicine (ASAM) - National Practice Guidelines for the Use of Medications in the Treatment of Addiction Involving Opioid Use

Opioid Treatment Accreditation Standards – Commission on Accreditation of Rehabilitation Facilities (CARF)

Written Responses to Follow-up Questions:
**Senate Committee on the Judiciary Hearing - January 27, 2016**
**"Attacking America's Epidemic of Heroin and Prescription Drug Abuse"**

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**Suggested Reading:** SAMHSA's Treatment Improvement Protocols (TIP) Series, including:


**TIP 1:** Substance Abuse and Mental Health Services Administration. *State Methadone Treatment Guidelines.* Treatment Improvement Protocol (TIP) Series, No.1. HHS Publication No. (SMA) 93-1991. 1993

**TIP 42**: Substance Abuse and Mental Health Services Administration. *Substance Abuse Treatment for Persons With Co-Occurring Disorders.* Treatment Improvement Protocol (TIP) Series, No. 42. HHS Publication No. (SMA) 133992. 2005.

**TIP 43:** Substance Abuse and Mental Health Services Administration. *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*. Treatment Improvement Protocol (TIP) Series, No. 43. HHS Publication No. **(**SMA) 12-4214. 2008

**TIP 44:** Substance Abuse and Mental Health Services Administration *Substance Abuse Treatment for Adults in the Criminal Justice System.* Treatment Improvement Protocol (TIP) Series, No.44. HHS Publication No. (SMA) 13-4056. 2005

**TIP 51:** Substance Abuse and Mental Health Services Administration. *Substance Abuse Treatment: Addressing the Specific Needs of Women.* .Treatment Improvement Protocol (TIP) Series, No.52. HHS Publication No. (SMA) 15-4426. 2015