Reclarifying important terminology

Now more than ever, the United States is experiencing a pressing need to address the opioid epidemic. Before discussing this and outlining what can and should be done to help people with opioid addiction, a clarification of terms is necessary. In talking about what is happening with opioids, the popular press and social media channels use many buzzwords, one of which is “opioid epidemic” itself. There are several facets to classifying this as an “epidemic” that are important to address: 1) the number of people who use heroin and/or fentanyl has dramatically increased over the last few years; 2) people’s misuse of prescription opioids like hydrocodone (Vicodin) and oxycodone (OxyContin) has also greatly increased; 3) more people than ever are becoming addicted to opioids; and 4) an alarming number of people are dying from opioid overdoses (Center for Behavioral Health Statistics and Quality, 2015; Rudd et al., 2016). The increasing trend in opioid overdose deaths is depicted in Figure 1.

These aspects of the epidemic have led a number of health care organizations and health-related government agencies to focus on two key areas: how to prevent misuse of opioids in the first place, and how to effectively treat opioid addiction once it occurs. The federal government is addressing these areas with some clear tactics, including the recently-formed Commission on Combatting Drug Addiction and the Opioid Crisis as well as the allocation of billions of dollars to fight the epidemic over the next few years. The 21st Century Cures Act, signed into law by former president Barack Obama in late 2016, gave the Substance Abuse and Mental Health Services Administration (SAMHSA) hundreds of millions of dollars over the next two years to allocate via state-targeted response (STR) grants. As I write this paper, single state agencies (typically departments of human services) are figuring out how to award these funds to organizations that want to address the epidemic.

SAMHSA’s announcement of the Cures funding focuses on many activities, one of which is medication-assisted treatment (MAT) for the treatment of opioid use disorders (OUD). MAT has become another buzzword, and a great deal of confusion exists about what the approach actually entails. The components of the term are perfectly descriptive and intentional. The “medication” part refers to the use of three FDA-approved medications to treat OUD: buprenorphine, naltrexone and methadone. The medications differ in terms of their effect on the brain and the challenges they address. An important piece that is not widely understood is that medications are only part of a MAT approach. In true medication-assisted treatment, the medications are “assisting” other components of treatment. These
components include a variety of psychosocial approaches that address the non-biological aspects of OUD, including a person’s behavior, emotions, thought processes, and interactions within social environments (The PEW Charitable Trusts, 2016; SAMHSA, 2016a).

These are important points to keep in mind, because it is easy to confuse the use of medications with MAT itself. A recent blog on an alcohol/drug treatment center website discusses the advantages and disadvantages of MAT, yet nearly all of the content focuses on methadone and Suboxone. The author briefly mentions the importance of counseling in a single sentence and describes it apart from medications, stating “medication-assisted treatment does not address emotional or traumatic issues that may have led to substance abuse” (http://www.pathwaysfl.org/blog/pros-and-cons-of-medication-assisted-treatment). Similarly, another treatment center blog on MAT only refers to the use of Suboxone and methadone, and doesn’t mention any psychosocial approaches (http://www.thewellrecoverycenter.com/advantages-and-disadvantages-of-suboxone-and-methadone-for-treating-opioid-addiction/). The use of evidence-based psychosocial approaches alongside the medications (i.e., in concert with them) is often not acknowledged. Given the significance of MAT and the fact that it is becoming part of the national dialogue and strategy around how to address opioid addiction, it is important to understand and communicate about the approach accurately.

The psychosocial aspects of MAT

The psychosocial therapies included as part of a MAT approach to OUD differ, depending on the needs of the client, their challenges and clinical severity, and the type of provider administering the services (e.g., an addiction treatment provider vs. a primary care doctor). To increase the benefit that patients receive from these approaches, they should be evidence-based. The term “evidence-based” is another widely misunderstood term. An evidence-based practice refers to a practice that has been heavily studied by researchers in well-designed scientific studies. These studies should be structured in such a way that the effect of the practice of interest (e.g., cognitive-behavioral therapy) can be clearly measured, typically by comparing a group of patients who receive the intervention with a group who do not receive it. When an intervention has been found to positively impact patients across a number of studies involving different patient groups, it qualifies as evidence-based.

Table 1 provides a brief overview of some commonly used evidence-based approaches for the treatment of substance use disorders. These therapies range from a focus on the patient’s motivation to change their substance use behaviors, to helping them see inaccuracies in how they process information about their environment, to increasing their understanding of spirituality and stressing the importance of Twelve Step meeting attendance as supporting recovery. Any of these approaches can be included in MAT for the treatment of OUD.

### Commonly-used psychosocial evidence-based practices for treatment of substance abuse disorders

<table>
<thead>
<tr>
<th>Approach</th>
<th>Clinical focus</th>
<th>Settings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cognitive-behavioral therapy (CBT)</td>
<td>Teaching the client to anticipate problems/risks to relapse and how to address them; recognizing distorted thinking processes and how to correct them; enhancing self-control through coping strategies</td>
<td>Addiction treatment programs (residential/inpatient and IOP); mental health programs/providers</td>
</tr>
<tr>
<td>Motivational enhancement therapy (MET)</td>
<td>Addressing barriers in the client’s motivation to change maladaptive behaviors; eliciting rapid and internally motivated change; focusing on empathic communication</td>
<td>Addiction treatment programs (residential/inpatient and IOP); mental health programs/providers</td>
</tr>
<tr>
<td>Twelve Step Facilitation (TSF)</td>
<td>Promoting abstinence through facilitating client engagement with Twelve Step fellowship groups like AA and NA; teaching the concepts of acceptance, surrender to a Higher Power and the importance of helping others</td>
<td>Addiction treatment programs</td>
</tr>
<tr>
<td>Community Reinforcement</td>
<td>Eliminating positive reinforcement for using drugs and increasing positive reinforcement for abstinence; teaching new coping behaviors for high-risk situations; focusing on involving significant others in the recovery process</td>
<td>Addiction treatment programs</td>
</tr>
<tr>
<td>Contingency management</td>
<td>Grounded in learning theory, involving applying nondrug-related reinforcers to increase abstinence</td>
<td>Addiction treatment programs (residential/inpatient and IOP); mental health programs/providers; primary care settings</td>
</tr>
</tbody>
</table>

NOTE: Information compiled from National Institute on Drug Abuse, 2012; McHugh et al., 2010; Miller et al., 1999
Efficacy of MAT for OUD

Rather than discuss the efficacy of MAT in general for helping individuals with OUD, which has been well-established (The PEW Charitable Trusts, 2016; U.S. Dept. of Health and Human Services, 2016), in this section I address the issue of whether the psychosocial treatment aspect of MAT is important. As more physicians in primary care settings are trained in prescribing buprenorphine for patients, office-based opioid treatment (OBOT) is increasing (LaBelle et al., 2016). The approach typically used by physicians in this setting is called medication management, which focuses on prescribing information and educating the patient about the drug, its effects, the importance of compliance, and similar issues (Weiss et al., 2011; Fiellin et al., 2013). Ideally, these sessions also include a brief counseling component, but it is unclear to what extent this happens at each medication visit. In some cases, it seems unlikely that these counseling sessions are occurring, given that physicians report increasing pressures to see more patients and spend less time with them per visit (Rabin, 2014; Dugosh et al. 2016). What is clear is that the counseling sessions conducted via medication management in primary care settings are different than sessions conducted by mental health professionals in both length and content (Weiss et al., 2010).

The evidence that opioid agonist medications like buprenorphine help people with opioid use problems is also quite solid at this point. Study findings converge on the conclusion that these medications are effective in controlling cravings, easing withdrawal and reducing opioid use (American Society of Addiction Medicine, 2013). There is also some evidence that the psychosocial aspects of MAT are important, but the research is somewhat mixed: some studies have found that psychosocial treatments increase positive outcomes above and beyond meds alone, whereas some have found no differences. In a recent review of this topic, Dugosh et al. (2016) summarize the results of three literature reviews and 27 empirical studies. Among 14 studies examining methadone maintenance, 12 (86%) showed better outcomes for patients who received a psychosocial intervention along with methadone as compared to methadone alone. Psychosocial therapies included cognitive-behavioral therapy (CBT), contingency management and general supportive counseling. Patient outcomes were measured by treatment retention, opioid use and medication compliance.

Of eight studies involving buprenorphine, three (38%) showed an incremental effect of the psychosocial intervention (therapies included CBT, community reinforcement and family training, and intensive role induction). These findings are not as strong as for methadone maintenance, in that over half of the studies found no effect of psychotherapy beyond the medications. Details of some studies are shown in Table 2. A closer inspection of study methodologies reveals some interesting patterns. First, nearly all of these studies were conducted on patients presenting to primary care settings. Second, certain patients were excluded from participating based on clinical severity, including suicide risk, active dependence on alcohol and/or sedatives, poor physical health, past trauma and mental health issues like depressive disorders (Fiellin et al., 2013; Weiss et al., 2011; Moore et al., 2012). The

<table>
<thead>
<tr>
<th>Authors</th>
<th>Type of participants and setting</th>
<th>Study design</th>
<th>Psychosocial intervention</th>
<th>Main findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weiss et al., 2011</td>
<td>Prescription opioid dependence; primary care (10 sites in the U.S.)</td>
<td>med management (meds only) vs. enhanced med mgmt. (meds + counseling)</td>
<td>General opioid dependence counseling</td>
<td>no differences in opioid use</td>
</tr>
<tr>
<td>Ling et al., 2013</td>
<td>Opioid dependence; recruited via ads and word of mouth from the Los Angeles area</td>
<td>med management (meds only) vs. CBT vs. contingency mgmt. vs. CBT + contingency mgmt.</td>
<td>CBT and contingency management</td>
<td>no differences in opioid use</td>
</tr>
<tr>
<td>Fiellin et al., 2006</td>
<td>Opioid dependence (heroin and prescription); primary care</td>
<td>med management with weekly dispensing (meds only) vs. three times per week dispensing (meds only) + CBT</td>
<td>General opioid dependence counseling</td>
<td>no differences in opioid use</td>
</tr>
<tr>
<td>Fiellen et al., 2013</td>
<td>Opioid dependence (heroin and prescription); primary care</td>
<td>med management (meds only) vs. meds mgmt. (meds only) + CBT</td>
<td>CBT</td>
<td>no differences in opioid use</td>
</tr>
<tr>
<td>Moore et al., 2012</td>
<td>Opioid dependence (heroin and prescription); primary care</td>
<td>med management with weekly dispensing (meds only) vs. med management with three times per week supervised meds dispensing + CBT</td>
<td>CBT</td>
<td>no differences in opioid use; # of CBT sessions attended significantly associated with improved outcomes/abstinence</td>
</tr>
</tbody>
</table>
characteristics of participants in these studies are not realistic in most clinical settings, where people with multiple problems and co-morbidities are seeking care (Hsier et al., 2017). To the extent that patients higher in clinical severity are most likely to benefit from psychosocial approaches, the relatively low patient acuity in these studies might help explain why the psychosocial therapies did not have an effect beyond the medications.

Another way to make sense of the null buprenorphine study findings pertains to how well the intervention was delivered and how engaged the patient was in the therapeutic process. Regarding delivery, the therapist or practitioner administering the intervention needs to follow the treatment protocol consistently across patients and across sessions. This is called fidelity of implementation. Regarding engagement, in order for patients to get the most benefit from the intervention, they need to show up to all sessions over the course of treatment (Joe et al., 1999; Ledgerwood et al., 2008). If either or both of these things don’t happen, one could expect to find little to no impact of psychosocial therapy on outcomes. Weiss et al. (2011) pointed out that in the prescription opioid addiction treatment study (POATS), patients in the medication plus counseling group were much more likely to miss counseling appointments than medication appointments. Fiellin et al. (2013) also reported low CBT session attendance, where patients attended an average of 6.7 of 12 sessions (56% of the time). Patients in the CBT condition were also significantly more likely to miss their medication sessions than medication-only patients. This is not surprising, given that attendance at CBT sessions was optional in the study. These findings illustrate why treatment adherence and engagement are so important for patients with OUD. If adherence had been higher in the CBT groups, CBT might have had more of an impact on outcomes. Notably, in a study using similar methodology, Moore et al. (2012) reported that the greater the number of CBT sessions people attended, the more likely they were to achieve abstinence from opioids.

Clearly, more research is needed to determine which combination of MAT medications (especially buprenorphine) and psychosocial therapies work best for which types of patients. It is possible that patients lower in clinical severity may fare well with medication management, and counseling is not going to create much more difference on outcomes. In contrast, patients with higher clinical severity are likely to benefit from medication and counseling (i.e., medication-assisted treatment), particularly intensive counseling using an evidence-based model. This is consistent with what we know about the treatment of substance abuse disorders (SUD) overall (SAMHSA, 2016b). Future studies need to recruit clinically severe samples of patients with OUD from a variety of care settings, and examine how different components of MAT impact outcomes.

The Hazelden Betty Ford Foundation’s Comprehensive Opioid Response with the Twelve Steps™ (COR-12)

Many discussions of MAT for OUD assume that the use of opioid agonists like methadone and buprenorphine is separate from formal addiction treatment, particularly programs that stress the importance of abstinence. For example, a piece aired last year on NPR’s All Things Considered talked about inpatient addiction treatment as one alternative, and the use of opioid agonists like buprenorphine as another. The two types of treatment are discussed as separate approaches instead of one integrated approach. Michael Botticelli, director of National Drug Control Policy at the time, is quoted as saying: “I’ve seen people with opioid-use disorders go through inpatient treatment without medications time and time again, without ever being offered alternatives.” The piece also points out that despite what science is telling us, many people “stand by the so-called abstinence route—recovery without the use of medications.” (http://www.npr.org/sections/health-shots/2016/05/17/478387232/treating-opioid-addiction-with-a-drug-raises-hope-and-controversy).

In early 2013, the Hazelden Betty Ford Foundation acknowledged an urgent need to be doing more for patients with opioid addiction. Patients admitted to the Foundation’s programs reported extensive past treatment histories, had a large degree of clinical severity in addition to their opioid use, and were leaving treatment prematurely. Most critically, some were overdosing and dying. In response to this, and based on a strong belief that anti-addiction medications have a place in abstinence-based treatment, a cross-disciplinary team of Hazelden Betty Ford staff designed and implemented a MAT model for patients with OUD. The core elements of this model, called Comprehensive Opioid Response with the Twelve Steps (COR-12), are: 1) the use of buprenorphine-naloxone or naltrexone (where appropriate); 2) Twelve Step-based treatment; 3) individual and group counseling sessions; and 4) the use of evidence-based practices in counseling sessions, such as motivational interviewing and CBT. Regarding group counseling, a core part of the program is the use of opioid support groups both during and after treatment. These groups focus on issues and challenges specific to recovering from OUD, including the experiences related to taking buprenorphine or naltrexone as part of treatment and recovery.

Importantly, buprenorphine-naloxone is used with some patients beyond detoxification from opioids. Patients are maintained on buprenorphine not only as part of treatment, but as part of ongoing recovery. In this sense, COR-12 is really a model of medication-assisted recovery (MAR). Because OUD and other SUD are chronic illnesses that need to be managed over the long term (Dennis & Scott, 2007; McLellan et al., 2000), providing patients with a number of different ways to recover from these disorders after a formal treatment episode is important. Recovery from SUD is a long-term process, and the basis of Hazelden Betty Ford Foundation’s COR-12 model is to help patients achieve recovery from OUD with all of the means available to effectively treat these disorders. The use of medications, both during treatment and as a way to support long-term recovery, is a key component of this approach. The Foundation views patients who take buprenorphine in this way as being abstinent and in recovery, just as patients in recovery from SUD would be considered in recovery if they were taking prescription opioids as prescribed by their doctor to treat pain after a major surgery. Each patient’s recovery trajectory will be different, and some patients may need to take...
buprenorphine over an extended period of time. The overall goal is to get the patient well and on a path to long-term recovery with any clinical means that are beneficial for that patient.

**Stage 1 of bringing OUD services to providers is called Discovery.** In this stage the Foundation works with organizational leaders to understand their system’s current environment, identify which evidence-based practices for treating OUD they want to implement, identify funding opportunities or other means of financial support, and evaluate the system’s current ability to deliver these services. This information is collected by Foundation staff through an organizational readiness assessment. The results of this assessment are analyzed and reported to senior leadership along with recommendations for how to address gaps in the organization’s current ability to implement services.

Stage 2 is called Visioning. The Foundation works with leaders to create a formal plan for moving forward with MAT implementation and socializing that plan (including assigning accountability) within the organization. As part of this work, Foundation staff members conduct onsite training with executive leaders and other key clinical leaders of the client organization. Training provides the knowledge, skills and tools to successfully design and implement a plan for treating OUD within a system, including how to foster a culture of evidence-based practice and how to form effective alliances with other local providers.

Stage 3 is called Implementation and involves putting the plan created in the Visioning stage into action. A key offering in this stage is onsite training for clinicians, doctors and other frontline staff who are directly delivering services to patients. Training focuses on building knowledge and skills for successful administration of MAT, including management of medications and the use of evidence-based psychosocial therapies.

The final stage of the model is called Sustaining. Once implementation of OUD services is complete, it is necessary to measure the extent to which implementation was successful. Because implementation of services is a complex undertaking, there will be challenges and obstacles to overcome. What providers do not want to do is move forward with the plan and just assume that implementation was a success. This approach often leads to poor outcomes (McGovern et al., 2013). To help with this, several months after implementation, the Foundation’s subject matter experts conduct a fidelity of implementation assessment. This assessment measures how effectively the program elements have been implemented at two care providers. Over the last several months, the Foundation has been working with a number of health care systems across the country to help implement MAT for OUD, thereby increasing patient access to services at the community level. Figure 3 (next page) gives an overview of the stage-based model for MAT implementation and the Foundation’s service offerings associated with each stage. Importantly, the approach is based on implementation science, which involves using research, measurement and data analysis to guide implementation of clinical practices (McGovern et al., 2013).

The Hazelden Betty Ford Foundation is bringing MAT for OUD to other providers

In response to the increasing national need to implement and expand services for people with OUD, Hazelden Publishing has created a model for bringing COR-12 services to other health care providers. Over the last several months, the Foundation has been working with a number of health care systems across the country to help implement MAT for OUD, thereby increasing patient access to services at the community level. Figure 3 (next page) gives an overview of the stage-based model for MAT implementation and the Foundation’s service offerings associated with each stage. Importantly, the approach is based on implementation science, which involves using research, measurement and data analysis to guide implementation of clinical practices (McGovern et al., 2013).

Stage 1 of bringing OUD services to providers is called Discovery. In this stage the Foundation works with organizational leaders to understand their system’s current environment, identify which evidence-based practices for treating OUD they want to implement, identify funding opportunities or other means of financial support, and evaluate the system’s current ability to deliver these services. This information is collected by Foundation staff through an organizational readiness assessment. The results of this assessment are analyzed and reported to senior leadership along with recommendations for how to address gaps in the organization’s current ability to implement services.

Stage 2 is called Visioning. The Foundation works with leaders to create a formal plan for moving forward with MAT implementation and socializing that plan (including assigning accountability) within the organization. As part of this work, Foundation staff members conduct onsite training with executive leaders and other key clinical leaders of the client organization. Training provides the knowledge, skills and tools to successfully design and implement a plan for treating OUD within a system, including how to foster a culture of evidence-based practice and how to form effective alliances with other local providers.

Stage 3 is called Implementation and involves putting the plan created in the Visioning stage into action. A key offering in this stage is onsite training for clinicians, doctors and other frontline staff who are directly delivering services to patients. Training focuses on building knowledge and skills for successful administration of MAT, including management of medications and the use of evidence-based psychosocial therapies.

The final stage of the model is called Sustaining. Once implementation of OUD services is complete, it is necessary to measure the extent to which implementation was successful. Because implementation of services is a complex undertaking, there will be challenges and obstacles to overcome. What providers do not want to do is move forward with the plan and just assume that implementation was a success. This approach often leads to poor outcomes (McGovern et al., 2013). To help with this, several months after implementation, the Foundation’s subject matter experts conduct a fidelity of implementation assessment. This assessment measures how effectively the program elements have been implemented at two
levels: the individual staff members who deliver services, and the organization as a whole. Issues with implementation are identified, and a plan to address them is created and delivered to organizational leaders. This stage also involves ongoing consultation with the Foundation as needed, including addressing needs for additional training, monitoring and guidance.

An important aspect of this model is that the approach and offerings are tailored to an individual organization or health care system, because systems differ in the number and types of patients they serve, current staffing models for delivery of services (including types of roles and bandwidth), organizational infrastructure, strategic priorities and funding streams. For example, a federally qualified health center that is not providing any psychosocial services for addiction treatment will have different needs than a community mental health clinic already offering robust, evidence-based services. The model is designed to be comprehensive yet flexible.

The importance of care coordination and an integrated service model

Many organizations wanting to implement a full model of MAT will likely not have all of the elements necessary to deliver services. For example, consider again a community-based mental health organization that provides both medications and psychosocial therapy for patients with opioid addiction. Patients with very high clinical severity may need to be referred to inpatient addiction treatment programs. For this process to work well, the mental health organization needs to have relationships with local treatment providers and work with them to design procedures for ensuring that patients get placed into the appropriate level of care. Another example would be a primary care clinic that is administering medications but does not have trained counselors in-house to deliver psychosocial therapies. In that case, a patient needing these services would have to get them from another provider. In addition, an organization providing services for an OUD may need to transition the patient to other providers in the community for ongoing support once the patient has completed treatment. A great deal of evidence indicates that to maintain gains made in treatment, many patients with SUD need ongoing care over the long term, particularly for managing challenging issues like a co-occurring mental health disorder (NIDA, 2013).

Few patients with substance use disorders seek out treatment on their own, and those who recognize their need for treatment face a lot of obstacles in accessing care. These include the ability to pay, the stigma associated with having substance use problems and not knowing how to access services (Rapp et al., 2006). When people with OUD do seek care, it tends to be in general health care settings like primary care and non-specialized hospitals and clinics.
arsenal of skills in delivering evidence-based practices for OUD, the level is vital: the practitioner and/or therapist should have an approach, and a key component of this approach is having a large portfolio of services to offer patients. Ideally, these services would be available in the communities of people with SUD, and these individuals would have access to all services. This is also where clinical practice at the individual practitioner level is vital: the practitioner and/or therapist should have an arsenal of skills in delivering evidence-based practices for OUD, so that they can utilize different approaches with each patient as necessary. For example, a patient who is experiencing a great deal of cognitive distortion may benefit from CBT, a person experiencing a lack of motivation to change and/or a lack of recognition in not achieving their goals may benefit from MET, and a patient struggling with staying abstinent may benefit from relapse prevention. Patients receive quality care when a provider’s staff members are competent in these practices or the provider is connected in a formal way with organizations that offer this expertise.

The following list summarizes the main points of this paper. It is recommended that providers keep these in mind as they explore ways to strengthen their offerings for the treatment of OUD:

- True medication-assisted treatment is a combination of addiction-specific medications and evidence-based psychosocial therapies.
- Many MAT studies showing no effect of psychotherapies on OUD outcomes have reported two things: a relatively low degree of clinical severity in OUD patients, and a lack of full patient engagement with services, particularly the psychosocial components.
- Future studies of the impact of medications vs. psychosocial therapies on OUD should focus on a variety of different patient populations receiving treatment in a variety of settings.
- Hazelden Betty Ford has designed and implemented a MAT model called COR-12 with OUD patients. This model uses buprenorphine-naloxone and naltrexone within abstinence-based Twelve Step treatment.
- Hazelden Publishing has created a multi-stage model for bringing MAT to other providers in need of evidence-based OUD services.
- Effective care coordination within a community is vital for effective treatment of OUD.
- The processes of implementing MAT and determining its impact should be data-driven. This means having formal processes within an organization for accurate measurement and reporting of results, and strategies for ensuring that results continuously inform service delivery.

For further information on Hazelden’s medication-assisted treatment implementation offerings, or to request an initial consultation, please contact:

Jennifer Fox
COR-12 Outreach Manager, Hazelden Publishing
jfox@hazeldenbettyford.org
651-213-4689
References


