

MODULE 12 REFERRAL FOR MEDICATION

Table Of Contents

TABLE OF CONTENTS	II
MODULE 12: REFERRAL FOR MEDICATION	1
BACKGROUND	1
INTRODUCTION.....	2
EXPLORE CLIENT’S PREVIOUS EXPERIENCES	2
ELICIT BELIEFS ABOUT THE ACCEPTABILITY AND EFFICACY OF ADDICTION MEDICINE	3
ADDRESS NEGATIVE PERCEPTIONS	4
“Medication is not doing anything that can’t be achieved through counseling and AA attendance”	4
“Medication is going to harm my liver, I need to give it a rest.”	4
“Medication is a crutch; I need to be completely drug free for true recovery.”	4
“Some medications are addictive. Taking medication is just trading one bad habit for another.”	5
PROVIDE EDUCATION ABOUT THE AVAILABLE OPTIONS FOR TREATMENT	6
ELICIT CLIENT’S THOUGHTS ABOUT TRYING MEDICATION.....	6
SUMMARIZE SESSION	7
COMPLETE AGENCY SPECIFIC TASKS	7
REVIEW HOME ASSIGNMENT	7
END SESSION	7
 APPENDIX A: SESSION MATERIALS	 8
MODULE 12 SESSION CHECKLIST.....	9
 APPENDIX B: BACKGROUND INFORMATION	 10
<i>Disulfiram</i>	11
<i>Oral Naltrexone (Revia™)</i>	11
<i>Acamprosate (Campral™)</i>	12
<i>Depot Naltrexone (Vivitrol™)</i>	12
MEDICATIONS APPROVED FOR TREATING OPIOID DEPENDENCE.....	13
<i>Methadone</i>	13
<i>Buprenorphine</i>	13
Buprenorphine alone (<i>Subutex™</i>).....	14
Buprenorphine + Naloxone (<i>Subutex™</i>).....	14
<i>Naltrexone (Revia™)</i>	14
ABOUT OFF-LABEL TREATMENT OPTIONS.....	16

Module 12: Referral for Medication

The objectives of this module are to: 1) discuss client's thoughts and beliefs about medication as an adjunct to counseling, 2) educate the client about medications that can be prescribed for treatment of substance use disorders, and 3) follow-up with referral for a medication evaluation as needed.

====|| Module Outline ||=====

Target Discussion Points

- Introduction
- Set the agenda
- Explore the client's previous experiences with addiction medicine
- Elicit beliefs about the acceptability and efficacy of addiction medicine
- Address negative perceptions
- Provide education about the available options for treatment
- Elicit client's thoughts about trying medication
- Facilitate a referral as needed
- Summarize session
- Conduct agency-specific tasks
- Preview next session
- Review home assignment
- End Session

Background

Research over the past two decades has greatly increased our understanding of the neurochemical mechanisms that are altered by prolonged substance use, contributing to a movement towards treating addiction as a disease, in part, of the brain (Leshner, 2003). These advances have contributed to the effort to develop and test medications that can be used to treat substance use disorders, and the availability of FDA approved medications has grown. Despite the advances, many substance use disorders are not routinely treated with medication (e.g., cocaine dependence) as there have been no medications with sufficient safety and efficacy to earn FDA approval. For the substance use disorders for which there are approved medications (alcohol dependence, opioid dependence, nicotine dependence), there is a disparity in the commercial promotion and prescribing practices for these medicines. Nicotine replacement therapies and other smoking cessation medication have been the most widely promoted and used within the United States. Medications to treat alcohol and opioid dependence are less well known among both

patients seeking care and health care providers. Particularly for alcohol dependence, some patients may simply be unaware that there are FDA approved medications to treat the disorder. The goal of this module is to provide a framework that can be used to educate clients about the options for addiction medicine and facilitate a referral for medication evaluation as appropriate. In treatment settings that do not have a standard of care that includes evaluation for medication, this module may be more pertinent as many patients in these settings may not be aware of the options for treatment.

Introduction

Depending upon the context of when this module is used and how the discussion begins, the introduction to this topic may vary. For instance, if a client has some awareness of medication that may augment counseling and is actively seeking additional information, then the counselor may not need to provide any extensive introduction to the topic. In circumstances in which the client has little or no knowledge of medications that augment counseling, then a more detailed introduction may be needed to begin to explore this option.

“We have talked about some of the things we can work on together to help you cut back on your drinking. One of the options that we haven’t yet considered is for you to take one of the medications that have been approved for treating alcohol problems. There are no “silver bullets” out there that will make this easy, but we do have some good medicines that help people who are motivated to make some changes in their drinking. If you would like to take some time today, we can talk about what some of these options are and consider if this is something you want to pursue.”

“One of the things you have been interested in is learning more about the options for taking medication that will help you cut back on your drinking. Would it be OK if we took some time today to talk about this?”

Set the Agenda

“I would like to begin by getting a better understanding of what you already know about options for medication. I can fill you in on some additional details, and try to answer questions you might have about these medications. My goal is to provide you with information about options and let you make a choice as to whether or not this is something you want to pursue. If it is, I will make a recommendation for somebody you can see who would be qualified to evaluate you for these medications.”

Explore client’s previous experiences

A good place to begin assessing the client’s knowledge is to ask about previous experience with addiction medication.

“Have ever taken any medication that was prescribed to treat your alcohol problems?”

IF THE CLIENT HAS NOT HAD ANY PREVIOUS EXPERIENCE, SKIP TO “NO PREVIOUS EXPERIENCE.”

If the client has some previous experience with addiction medicine, the counselor may take some time exploring the treatment episode(s) and understanding the client’s perceptions about the medication(s).

“Do you think the medication was helpful?”

“Did you ever feel uncomfortable taking medication to treat your _____ use?”

“How long were you taking medication and what led you to stopping the medication?”

Elicit beliefs about the acceptability and efficacy of addiction medicine

As the client describes their experience with addiction medicine it is important to recognize any negative perceptions about medication. It may be possible to address some of the negative perceptions by providing accurate information to the client. For example, some clients may have had an adverse reaction when taking disulfiram while drinking and believe that all addiction medications cause similar unpleasant side effects. Other negative perceptions may be less amenable to change. For example, some clients may have taken addiction medication and received little therapeutic benefit.

Some clients may have strong positive or negative beliefs about medication to treat addiction; other may be indifferent or not even aware that there are medications that can be helpful. The goal of this discussion is to understand the client’s thoughts about medication before providing any education about the options.

For patient’s that have previously used addiction medicine and have had a positive experience, it is still important to talk about the experience. Encouraging the client to describe their success with medication may help to bolster their commitment to trying this as an adjunct to counseling.

“You found naltrexone to be helpful – tell me more about that”

“In what ways did taking _____ help you?”

“How did you feel when you were taking _____?”

“How would taking this medication help you today?”

No Previous experience

For clients who have not had any previous experience with addiction medicine, there may still be an overall negative perception based on others’ experience with addiction medicine. It is important to assess and address negative perceptions that may preclude the client from considering a medication evaluation.

Address negative perceptions

There are many common reasons why patients express reluctance to taking medications, including potential side effects, cost, the burden of taking pills each day, denial about the condition, and the influence of others. More so than other medical conditions, however, there may be a greater reluctance to taking medications for addiction because of negative perceptions of addiction medicine. When clients are reluctant to consider medications, it may be helpful to explore the client's views about medication in addiction treatment. Begin by asking open-ended questions and use reflective listening to fully understand the client's concerns before attempting to address negative perceptions. Some common negative perceptions include:

“Medication is not doing anything that can't be achieved through counseling and AA attendance”

Clients sometimes question whether there is any added benefit or advantage to taking medication in addition to, or in place of, other types of treatment. Counseling approaches to treating addiction vary in efficacy – some work very well and others do not work as well. The evidence suggests, however, that medication combined with counseling is more effective than counseling alone for opioid, alcohol, and nicotine dependence. While counseling and AA are both effective for some people without the aid of medication, the addition of medication may address the biological factors that promote substance use and improve the chances of successful outcomes.

Watch Demonstration Video

“Medication is going to harm my liver, I need to give it a rest.”

Some medications used to treat addiction can adversely impact the health of the liver, but these medications would not be routinely prescribed to patients with significant impairment in liver function. The potential harm to the liver that is caused by medications is less than the harm to the liver caused by uncontrolled drinking for most patients. When patients do show evidence of impaired liver function due to medication, dosage reduction or discontinuation is usually effective in reversing these effects.

Watch Demonstration Video

“Medication is a crutch; I need to be completely drug free for true recovery.”

Abstinence from other drugs of abuse is important to maintaining abstinence from the drug of choice. Being 100% drug free is an appealing goal for most people who have suffered through some chronic disease. Many people would choose to recover from disease without the aid of medicine if there was a clear chance of success.

Addiction can be seen as a disease of the brain with measurable changes that have a direct impact on one's ability to function without substances. Like any other disorder with a biological basis, addiction can be treated with medication. Medication may have the greatest impact in early phases of recovery when clients are most vulnerable to relapse. A short period of combined counseling and medication may be all that is needed to establish the stability needed for drug free recovery.

Watch Demonstration Video

“Some medications are addictive. Taking medication is just trading one bad habit for another.”

None of the medications approved for the treatment of alcohol dependence are physically addictive. Concerns about the addictive potential of medication are warranted for clients who are considering replacement therapies like methadone or buprenorphine. While these medications are physically addictive, they are not generally used as a first line of treatment. It is usually after repeated attempts to quit over a significant period of time that replacement therapies are considered. Although these therapies may in fact be trading one addiction for another, the harm associated with unsuccessful treatment outcomes may exceed the harm of taking a medication which is physically addictive.

Replacement therapies for opioid/opiate dependence have a proven track record for reducing harmful consequences of opiate dependence, including health problems, overdose, HIV infection, and crime. Replacement therapies are also associated with an increase in quality of life and an increased chance of achieving complete abstinence in the future.

Watch Demonstration Video

Helping clients to resolve their ambivalence about taking medications for addiction treatment may take time within treatment. Rushing clients into a decision may elicit some resistance or result in the clients committing themselves to something they do not want to pursue. If negative perceptions cannot be resolved, the Clinician may choose to leave the topic alone or discuss the topic at a later time.

“It sounds like you have some concerns about using medication in this treatment and perhaps now is not the right time to consider this any further. Would it be OK with you if we revisited this later on?”

Some clients may benefit from hearing more about the treatment options as a means to resolve ambivalence about medication.

“I know that you are unsure right now as to whether or not medication is something you want to pursue. I would like to give you more information about what options are available as this may help you to decide. Would it be OK if I told you about some of the medications?”

Provide education about the available options for treatment

Prior to providing information to the client about potential treatment options, the Clinician should take time to enhance his or her own knowledge about the FDA approved medications for treating substance use. Appendix A is included as a basic guide to the FDA approved medications for treating substance use disorders. Additional information can be found online at www.nida.nih.gov/ or www.niaaa.nih.gov.

The discussion of treatment options is intended to correct any misconceptions about medications that are available and educate the client about medications that were previously unknown to them. Example dialogue for discussing options for treating alcohol dependence follows:

“It sounds like you have a good idea about how disulfiram works and that’s not something you want to try again. I can tell you about some other medications that may be helpful if you would like”

“One of the medicines that the FDA has approved for alcohol problems is called naltrexone – it’s sold under the trade name Revia. Have you heard of this medication?”

“Naltrexone is a medication that is intended to reduce the pleasure or reward associated with drinking. There are many different reasons why people enjoy alcohol but one reason is because of the way alcohol enhances feelings of pleasure. Naltrexone is a medication that blocks some of the pleasure or reward that people feel when they drink. It doesn’t keep people from being intoxicated or make people sick when they drink, but it does make the effects of alcohol feel a little less compelling. When people take this medication and they start drinking, they tend to drink less and they tend to drink for a fewer number of days. The current evidence suggests that naltrexone is more effective than the other medications that are approved for treating alcohol problems. Do you have any questions about this medicine?”

Elicit client’s thoughts about trying medication

The goal of this session is not to convince or encourage clients to take medication but to provide clients with accurate information and encourage them to make their own choice. While it may be true that some clients would likely be better able to change with the aid of medication, the Clinician should try to avoid engaging in a tug-of-war with the client over whether they should seek a medication referral. Consistent with the principles of motivational interviewing, the Clinician should allow the client to verbalize their own reasons for wanting to consider medication.

“We have been talking about some of the options that are available to you – I’m wondering what your thoughts are right now about adding medication to your plan?”

“What are the advantages and disadvantages of giving this a try?”

If the client appears to be hesitant or expresses some reluctance to consider a medication evaluation the Clinician may want to allow the client time to think and revisit the question later.

“This is not something that you need to decide on right away, these medications will be available at any time if you decide that it is something you want to pursue. It sounds like you are not so sure that this is what you want right now. Would it be OK if we revisit this later on?”

Follow-up with the client

After a plan is made it is the Clinician’s role to facilitate the referral. This referral process may be handled differently in different settings depending upon local resources and agency policy. The important aspects of this phase is facilitating the first contact, following up with the client to make sure that the plan has been successful, and troubleshooting when the plan has not been successful.

Summarize session

The Clinician should provide a closing summary of the session highlighting major accomplishments made during the session, reviewing any commitments the client has made to thinking about or pursuing a medication referral and recognizing the client’s efforts.

Complete agency specific tasks

Complete any agency-specific paperwork with the client as needed.

Preview next session

Provide a brief preview of what will be covered in the next session.

Review home assignment

The client will have a home assignment to complete, such as a task related to making an appointment or weighing options. The Clinician will follow-up in the next session to see if the client has completed the task.

End session

“I think we have made some good progress in today’s session. Do you have any other questions, concerns or thoughts before we end today?”

**APPENDIX A
REFERRAL FOR
MEDICATION
SESSION MATERIALS**

Module 12 Session Checklist

Referral for medication

PREPARATIONS	✓
Session checklist	
Agency-specific paperwork	
GETTING STARTED	
Check-in	
Review of previous session	
Set the agenda	
ELICIT CLIENT'S VIEW	
Explore Previous experience with addiction medicine	
Elicit beliefs about efficacy and acceptability	
Discuss Negative perceptions	
PROVIDE EDUCATION	
Provide education about the available options for treatment	
ELICIT A RESPONSE	
Elicit client's thoughts about trying medication	
Facilitate referral as appropriate	
COMPLETION OF AGENCY-SPECIFIC TASKS	
WRAP UP	
Summarize session	
Preview coming sessions	
Assign home exercise	

APPENDIX B BACKGROUND INFORMATION

Medications approved for treating Alcohol Dependence

Within the United States, four medications have been approved by the FDA for the treatment of alcohol dependence. These medications are Disulfiram, oral Naltrexone, Acamprosate, and injectable Naltrexone. Other medications are used to treat alcohol dependence through off-labeled prescribing practices.

Disulfiram

Disulfiram is the oldest of the approved medications for alcohol dependence in the United States and is the only approved medication that is sensitizing agent. Disulfiram interferes with the body's ability to metabolize alcohol, resulting in toxic concentrations of acetaldehyde in the blood. This byproduct is a toxin in large concentrations that causes a range of intense and unpleasant sensations, including flushing, sweating, nausea, vomiting, headache, heart palpitations and difficult breathing. This adverse reaction serves as the primary deterrent to drinking.

After consuming alcohol, a patient taking disulfiram can expect to experience an adverse reaction lasting on average 30 minutes. The intensity and duration of this reaction is related to both the dosing level of disulfiram and the amount of alcohol consumed. In extreme cases, this aversive reaction can last for up to three hours. This reaction can also become life-threatening if more serious symptoms emerge, including respiratory depression, cardiac arrhythmias, or cardiac failure. These life-threatening reactions are very rare.

Although the use of disulfiram has been widespread and there are many positive findings for the efficacy of disulfiram, recent meta-analyses of methodologically rigorous studies have provided less compelling data about the efficacy of disulfiram. Disulfiram appears to be most effective when used in combination with psychotherapy that focuses on medication adherence. Among the therapies that show improved outcomes when combined with disulfiram are behavioral couple's therapy and the community reinforcement approach.

Oral Naltrexone (Revia™)

Naltrexone is an opioid receptor antagonist that was approved by the FDA for alcohol dependence in 1995. Naltrexone dampens the perceived reward or pleasure of drinking by disrupting the transmission of dopamine, one of the primary neurotransmitters involved in the perception of pleasure. Naltrexone interferes with the dopamine transmission and diminishes the perceived reinforcing effects of alcohol. The dampening of alcohol-related pleasure is believed to be one of the mechanisms contributing to the efficacy of Naltrexone. Naltrexone has been found to help people reduce the number of drinking days each month and reduce the number of drinks consumed per drinking day. The combination of psychological treatment with Naltrexone improves the outcomes for patients taking Naltrexone. The efficacy of Naltrexone is dependent upon good compliance with dosing.

Acamprosate (Campral™)

Acamprosate is an anti-craving medication approved by the FDA for alcohol dependence in 2004. Acamprosate is believed to reduce the physiological aspects of craving. The mechanism by which acamprosate is helpful to problem drinkers is not fully understood, but one of the leading hypotheses is that acamprosate decreases the hyper-excitability of a neurotransmitter that is associated with withdrawal. Acamprosate is thought to alleviate cravings for people in early sobriety by normalizing this neurotransmitter function.

Clinical trials conducted in European countries provide compelling evidence for the efficacy of Acamprosate. Acamprosate has been shown to increase the length of continuous abstinence from alcohol in these trials and improve retention in treatment for patients who had achieved seven-to-ten days of abstinence before beginning the medication. Results from studies in the United States, however, have been less compelling. In the largest placebo controlled trial in the U.S., Acamprosate was found to be no better than placebo.

Depot Naltrexone (Vivitrol™)

In 2006 the FDA approved another formulation of Naltrexone for the treatment of alcohol dependence which is designed to overcome problems with medication compliance. This injectable form of Naltrexone provides an extended release that allows for once-monthly dosing. As with oral Naltrexone, sustained release Naltrexone is believed to reduce drinking by providing some blockage of the dopamine transmission and dampening the pleasurable effects of alcohol. The use of a monthly dosing with extended release naltrexone has some significant advantages over daily dosing with oral naltrexone. The monthly dosing schedule reduces noncompliance due to both forgetfulness and fluctuations in motivation. Monthly dosing also provides greater stability in maintenance of a therapeutic dose. Similar to the findings of oral naltrexone, extended release naltrexone has been found to reduce the number of drinking days each month and decrease the number of heavy drinking days each month.

Medications approved for treating Opioid Dependence

Within the United States, three medications have been approved by the food and drug administration for the treatment of opioid dependence. These medications are Methadone, Naltrexonem, and Buprenorphine. Buprenorphine is approved in two separate formulations either with or without Naloxone as a counter-measure to misuse.

Methadone

Methadone was introduced in the United States as a narcotic analgesic. Methadone is a full agonist at the mu opioid receptors. The binding of methadone at these receptor sites provides relief from craving and withdrawal symptoms without causing significant intoxication or euphoria. Repeated administration of methadone causes a high cross-tolerance to other opioids that bind at the mu opioid receptor. This high tolerance results in a diminished effect if opiate drugs are used by patients maintained on methadone.

Although methadone is a narcotic, the slow rate of absorption achieved by oral administration minimizes the potential for euphoric effects and abuse. The half-life of methadone is long, relative to heroin and other opiate drugs. For example, the short half-life of heroin results in a need to administer the drug three-to-four times per day, whereas the long half-life of methadone requires only once daily administration. Daily dosing is required for people maintained on methadone due to the risk of withdrawal when time between dosing exceeds 36 hours. A synthetic opioid similar to methadone but longer acting was withdrawn from the U.S. markets due to adverse cardiac effects.

Methadone maintenance is one of the most widely studied treatments in the addiction literature. Methadone maintenance has clear therapeutic effects on not just the target drug use behavior but also other outcomes related to quality of life. Methadone maintenance is associated with a reduction in use of illicit opioids, a decrease in the rates of HIV transmission, a reduction in infection associated with needle use, and a reduction in crime. The savings in healthcare and legal costs associated with methadone maintenance treatment have been well documented.

Buprenorphine

Buprenorphine is a synthetic opioid which is a partial agonist at the mu opioid receptor. At this receptor, full agonists like heroin and morphine produce feelings of pleasure, euphoria and sedation. Buprenorphine activates the mu opioid receptors to a lesser degree than full agonists, providing relief from cravings and withdrawal without producing intoxication and euphoria. Because buprenorphine has a higher affinity for the mu opioid receptors than full agonist opioid drugs like heroin, buprenorphine will displace full agonists, limiting the intoxicating effects of illicit opioids taken by patients maintained on buprenorphine. Buprenorphine is marketed alone under the trade name Subutex and in combination with a drug Naloxone under the trade name Suboxone.

Buprenorphine alone (Subutex™)

Buprenorphine alone is used for the treatment of opioid withdrawal and dependence. Buprenorphine is an effective agent for the management of opioid withdrawal symptoms. Although buprenorphine is a narcotic, its action as a partial agonist at the mu opioid receptor lessens the potential for abuse that full agonist may have. With increasing doses, the level of activation of the mu opioid receptor is limited because buprenorphine is a partial agonist. Buprenorphine is an effective substitution therapy for opioid dependence, but it not often used in the US due to the possibility of diversion or misuse. The most common use of subutex in the US is for pregnant women who are opioid dependent as subutex is believed to be safer for them than suboxone.

Buprenorphine + Naloxone (Suboxone™)

Suboxone is a combination therapy of buprenorphine and naloxone which has been approved by the FDA for treating opioid dependence. Because of the potential for misuse of buprenorphine alone, naloxone has been combined with buprenorphine to reduce this abuse liability. Naloxone is a powerful opioid antagonist that has a very high affinity for the mu opioid receptor which will displace other opioids for binding. Using a low dose of naloxone and a sublingual route of administration, this medication minimal impact on binding of buprenorphine at the mu opioid receptor. If Subutex were to be crushed and injected however, the antagonist action of naloxone would be 10- 20 times greater, precipitating abrupt withdrawal and providing blockade against the binding of opioids at the mu opioid receptor site. With this formulation, buprenorphine can be used with greater safety than methadone as a substitution therapy that patients can take home and self-administer daily.

The outcome data for Buprenorphine has provided compelling evidence for its efficacy as a substitution therapy. Because Suboxone can be given as a take-home medication without significant risk of abuse, maintenance therapy with Suboxone does not require daily visits to a clinic for dose administration. This model of care may greatly increase the availability and acceptability of substitution therapy in the U.S.

Naltrexone (Revia™)

Naltrexone is a mu opioid receptor antagonist approved by the FDA for the treatment of opioid dependence. Naltrexone will bind to the mu opioid receptors displacing any partial or full agonist opioids that are present. Naltrexone also prevents any further binding of full or partial agonists. When given to a patient who is using opioids, Naltrexone will precipitate an abrupt withdrawal syndrome as naltrexone provides no activation of the mu opioid receptor. This blockade of the opioid receptors disrupts the potential for rewarding or euphoric effects if opioids were to be used after taking Naltrexone.

Naltrexone is associated with a reduction in opioid use for patients who maintain good medication compliance. The rates of treatment dropout are greater for naltrexone than substitution therapies. There are several potential reasons for non-compliance with naltrexone including the following. Naltrexone has no reinforcing properties when taken, providing less incentive for medication compliance than substitution therapies which do

provide relief from craving and withdrawal. Because naltrexone is non-addictive, patients do not experience withdrawal symptoms when they stop the medication abruptly. Additionally, patients require complete detoxification before starting naltrexone. Despite these potential problems with compliance, there are groups for whom naltrexone may be a good choice for treating opioid dependence. Patients with high motivation and significant coping resources are most likely to benefit from this medication.

About off-label treatment options

Within the United States, medications are approved by the FDA for treatment of specific disorders, but prescribing physicians have the authority to use medications for disorders other than for what the medication was intended. This prescribing practice, known as “off-label use,” allows prescribing physicians to use medications to treat dependence on substance use disorders for which there are no approved medicines. For example, there is some evidence that certain classes of antidepressants have some benefit for depressed cocaine users who are trying to cut back or quit using. Although there is no approved medication for treating cocaine dependence, some physicians may try using medications off-label which have some therapeutic promise.

Physicians may also use medications off-label because of some perceived benefit over the medications that are approved by the FDA to treat a specific disorder. For example, there are several well-controlled studies which show that the anti-seizure medication topiramate is effective as an agent for treating alcohol dependence. Some physicians may choose to use this medication to treat alcohol dependence for patients who do not have a good response from the approved medications for alcohol or for other reasons including tolerability. Although the therapeutic value of medications taken off-label is less certain than for medications taken for disorders as approved by the FDA, off-label prescribing may provide some benefit to clients for whom an approved medication is not available.