

**Medical Management  
Treatment Manual:  
A Clinical Guide for  
Researchers and Clinicians  
Providing Pharmacotherapy for  
Alcohol Dependence  
(Generic Version; 2010 edition)**

by  
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This manual is an adaptation of:  
**Medical Management Treatment Manual: A Clinical Research Guide  
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# Message to the Users of this Medical Management (MM) Manual from the Editors

## Background

This “Generic Version” of the Medical Management (MM) manual is an adaptation of an earlier manual constructed specifically for use by medical providers in the COMBINE multisite clinical trial<sup>1,2,3,4</sup>. The Generic Version was prepared in 2009 and finalized in 2010 by Dr. Helen Pettinati, who was the originator (first author) of the 2004 Medical Management COMBINE manual, and, Dr. Margaret Mattson, an NIAAA collaborator in the COMBINE study. This adaptation consists of removing specific references to the COMBINE trial, such as instructions related to the two medications tested, naltrexone and acamprosate, completion of COMBINE-specific case report forms, and other operational features unique to the COMBINE study. This adaptation was done to facilitate the use of Medical Management when treating alcohol use disorders in clinical pharmacotherapy research trials and in practice-based clinical settings.

Users should note that the original philosophy of the COMBINE study’s Medical Management intervention is unchanged in the Generic Version: i.e., abstinence as the treatment goal, number of sessions, use of forms and charts to assist the practitioner in delivering the sessions, etc. (MM checklists have been streamlined since the Combine study.) We consider this Generic Version of the Medical Management manual (2010 edition) suitable for use in other pharmacologic studies of alcohol use disorders, and by practitioners who choose to use a structured approach to managing patients receiving pharmacotherapy for an alcohol use disorder.

## Caveats

We realize that other studies may have different goals or time constraints, and users may wish to further customize this Medical Management manual to meet their needs. The editors offer advice in this regard.

### ***Do you plan to change or adapt this manual?***

First, consider carefully the implications of altering underlying premises of the Medical Management intervention, such as changing the goal to one of reduction or moderation of drinking. This Medical Management manual follows the long-established belief that for the alcohol-dependent drinker, a goal of abstinence is the safest path to recovery.

The advice throughout the sessions in the Medical Management manual recommends abstinence, while providing positive reinforcement for any improvements reported.

We recognize that individual patients may not wish to completely stop drinking, and researchers may wish to evaluate outcomes of drinking reduction. Indeed, some patients may succeed in reducing their drinking to less harmful levels without complete cessation, but as yet there is no definitive guidance available to predict which patients are candidates for this approach. However, keep in mind that it may not be in the best interest of alcohol-dependent patients to initiate treatment with a goal of controlled reduction, given that their disorder is one of uncontrolled drinking and reduction has evidently not been successful for them in the past. For the most part, patients in trials are presenting with a desire for treatment and almost always have numerous social, physical and other problems associated with out-of-control drinking.

Therefore, if the medical clinician chooses to replace the stated goal of abstinence with a stated goal of reduction, the fabric of Medical Management as a tested approach is no longer in play. The investigator should consider the applicability of Medical Management and ramifications of alteration of the fundamental goal of abstinence. In such cases, a careful review of this manual would be necessary to address how the therapist dialogue needs to change and the implications of a different goal for relapses and slips, and perhaps adherence to the medication regimen.

### ***Importance of Version Control and Front Material***

The second caveat involves the straightforward need to maintain clear lines of separation between the various versions of the manual that may emerge as users adapt it for their studies. If the user makes changes of any type, NIAAA requests that the title page of the manual distributed to the trial staff or others prominently identify the document as a different version of the Medical Management Manual: Generic Version (2010 edition), clearly noting on the cover page that the document has been **Modified for the [name of your study] trial on [date.]** Such an annotation will avoid confusion in the future when modified versions of the manual arising from other studies are circulated and cited in the literature. Also, if a modified version is produced, we request that **pages 2, 3, 4 and 5 (“Message to the Users of this MM Manual from the Editors” and “Acknowledgements”)** always be included in the document so that citation of original sources and proper authorship credits are retained.

Users should also be aware that the concept of Medical Management has been used to date in two other documents. First, the Medical Clinician’s Guide<sup>5</sup>, developed and published by NIAAA, incorporated selected elements of Medical Management in a practical and brief protocol suitable for use by practice-based medical clinicians who prescribe medications, such as naltrexone, acamprosate and topiramate, to treat patients with an

alcohol use disorder. The Medical Clinician's Guide is consistent with the original Medical Management philosophy, although abbreviated and simplified for use by medical practitioners in private practice and clinics.

Second, interested researchers have recently revised the Medical Management Manual to reflect a particular emphasis of their studies, such as non-abstinent goals. Such versions are the product of the individual researcher's efforts and have not been evaluated by NIAAA. Given the adaptations and modifications the original Medical Management concept has undergone, users are urged to cite the NIAAA/NIH reference for Medical Management when reporting their studies.

The editors are pleased to offer this tool to the alcohol research and treatment communities; and welcome any suggestions from users.

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<sup>1</sup> Anton et al for the Combine Study Research Group. (2006) Combined pharmacotherapies and behavioral interventions for alcohol dependence - The COMBINE Study: A randomized controlled trial. **JAMA**, 295, 2003-2017.

<sup>2</sup> COMBINE Study Research Group. (2003) Testing combined pharmacotherapies and behavioral interventions in alcohol dependence: Rational and methods. **Alcohol Clin Exp Res**, 27, 1107-1122.

<sup>3</sup> Complete information on the COMBINE Study and COMBINE Study Research Group is available on the COMBINE website at <http://www.csc.unc.edu/combine>

<sup>4</sup> COMBINE fue financiado por el Instituto Nacional sobre el Abuso de Alcohol y Alcoholismo, NIH, DHHS

<sup>5</sup> "Helping Patients Who Drink Too Much: A Clinician's Guide", National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, (updated 2005). [www.niaaa.nih.gov/guide](http://www.niaaa.nih.gov/guide)

# Acknowledgements

The citation for the original Medical Management (MM) manual used in the COMBINE multisite clinical trial is:

- Pettinati, H.M.; Weiss, RD.; Miller, W.R; Donovan, D.; Ernst, D.B.; and Rounsaville, B.J. (2004) *Medical Management Treatment Manual: A Clinical Research Guide for Medically Trained Clinicians Providing Pharmacotherapy as Part of the Treatment for Alcohol Dependence. COMBINE Monograph Series, Series Ed., M.E. Mattson, Volume 2.* DHHS Publication No. (NIH) 04-5289. Bethesda, MD: NIAAA.

Medical Management (MM), as used in COMBINE, was constructed with permission, from pre-existing manuals that included some form of medical management. Those manuals are:

- Carroll, K.M., and O'Malley, S. (1996). *Adherence Enhancement: A Manual for the Psychopharmacotherapy of Alcohol Dependence.* Unpublished treatment manual, Yale University.
- Fleming, M.; Zweben, A; Barrett, D.; and Manwell, L. (1997). *Brief Motivational Enhancement Therapy Conducting BMET in a Combined Psychosocial and Pharmacotherapy Clinical Trial.* Unpublished treatment manual, University of Wisconsin.
- Mason, B.J., and Goodman, A.M. (1997). *Brief Intervention and Medication Adherence Procedures Therapist's Manual.* <http://www.alcohol-free.com>.
- Volpicelli, J.R; Pettinati, H.M.; McLellan, A.T.; and O'Brien, C.P. (2001). *Combining Medication and Psychosocial Treatments for Addictions: The BRENDA Approach.* New York: Guilford Press.

The COMBINE Medical Management (MM) authors, with the assistance of Kelly Tobin Murray (University of North Carolina, COMBINE Coordinating Center), rewrote and edited sections of these source manuals to provide a focused, cohesive set of guidelines for medical clinicians to follow in delivering MM treatment. Amy Schuhl, Carla Nappi (both from University of Pennsylvania), and Judith Arroyo, Ph.D. (University of New Mexico) also assisted that effort, and MM clinicians from the COMBINE study generously provided feedback on all aspects of MM treatment and use of the manual. Margaret E. Mattson, Ph.D. (NIAAA/NIH) is the editor of the COMBINE Monograph Series. For the Generic version (2010 edition), we are grateful for the editorial assistance of Ann M. Bradley and Megan Ryan (both from NIAAA/NIH), William Dundon, Ph.D., Gail Kaempf, CRNP, and Laura Sorensen (all from University of Pennsylvania).

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# 1. Introduction to Medical Management (MM)

## Rationale for Medical Management (MM) Treatment

This manual is a standardized guide for delivering MM treatment to persons with alcohol dependence. In keeping with the national trend toward integrating the treatment of alcohol disorders into medical practice, MM treatment was designed to be used in conjunction with prescribed medication and to be easily implemented by medically-trained practitioners in nonspecialty settings, as well as specialty settings. MM is also a suitable behavioral platform for clinical trials evaluating new medications to treat alcohol use disorders.

Nonadherence with medication regimens is a common problem both in clinical practice and in research, regardless of the disorder being treated. One focus of MM treatment is to assist medical clinicians in providing education, support, and strategies that help to ensure that alcohol dependent patients are medication-adherent, i.e., take medications as prescribed. As a medical practitioner, it is important that you familiarize yourself with the common reasons why patients skip doses or stop taking their medications (see Chapter 4). This understanding will assist you in monitoring and promoting medication adherence, and in helping patients to overcome obstacles to adherence.

## MM Treatment Overview

The goal of the MM intervention is to facilitate the patient's recovery from alcohol dependence. You can help your patients by:

- providing patients with strategies for taking their medication and staying in treatment.
- providing educational materials about alcohol dependence and pharmacotherapy.
- supporting patient efforts to change drinking habits.
- making direct recommendations for changing drinking behaviors.

Follow your patients throughout treatment, providing expert assessment, support, and direct advice for their efforts to achieve recovery from alcohol dependence. When talking with your patients, appeal to their common sense and reasoning ability, especially in relation to the overall goal of preserving or restoring health. In expressing concern for your patients, it is important to be nonjudgmental. Also be friendly, supportive, and optimistic about

recovery. Acknowledge and praise any accomplishments or steps taken towards recovery.

The MM Initial Session occurs after your patient has been evaluated and lasts 40 to 60 minutes. In this session, you will:

- review results from the intake evaluation and address any medical concerns.
- explain the diagnosis, demonstrate how it applies to the patient, discuss the patient's prognosis, and recommend abstinence.
- identify patient's goals, i.e., what patient wants to accomplish with treatment.
- provide a rationale for taking medication, explain how this medication is nonaddicting, and different from disulfiram (Antabuse), and from medications that are used for detoxification.
- provide information about the prescribed medication and review the directions for dosing. Explain blister card packaging, if used.
- provide a rationale for discussing medication adherence and develop an individualized Medication Adherence Plan.
- discuss mutual-support group participation and offer print materials about alcohol dependence, medication treatment for alcohol dependence, and mutual-support groups.
- summarize what was covered in the MM Initial Session, address patient questions and concerns, and conclude the session.

In follow-up sessions, you will:

- perform a medical check of the patient's general functioning.
- take a reading of the blood alcohol concentration (BAC).
- take the patient's vital signs, and weigh the patient.
- ask about medication side effects and concurrent medications.
- perform a brief assessment of the patient's drinking.
- perform a brief assessment of the patient's medication adherence.
- based on patient's drinking and pill taking behaviors, make recommendations for the patient to follow until the next session.

Follow-up sessions typically last 15 to 25 minutes, although they may be as long as 30 minutes depending on the patient's medical status, recovery progress, and medication adherence between sessions.

This manual contains Medical Management Clinician Tools (*Appendix*) to use in the initial and follow-up sessions.

## **MM Treatment in a Research Context**

When using MM in a research study, it is important to avoid certain pitfalls.

### ***Extra-MM Therapeutic Strategies***

Many professional therapies, including confrontational sessions, skills-training approaches, client-centered counseling, and family therapy, use techniques and strategies that extend beyond the scope of MM treatment. Although these methods may complement MM treatment in a clinical setting, they are not part of the specific MM intervention. Including them in a research context may skew the trial results.

### ***Nonabstinent Goals***

Encourage your patients to be abstinent, if possible, throughout MM treatment. To this end, do not tell patients to "expect slips; they are a natural part of recovery" or "some reduction in the amount that you are drinking is an acceptable goal." However, when patients do drink during treatment, avoid expressing disapproval or disappointment. Praise all improvements and steps toward recovery. If a patient does slip, reassure him/her that slips happen and do not signal that s/he will not attain recovery.

## **MM Materials**

*Appendix: Tools for MM Clinician* contains forms (MMC #1- MMC #9) to use in delivering MM treatment, including MM Clinician adherence checklists to use at each MM session. MMC stands for Medical Management Clinician, and is the preferred term for the health professional that delivers MM.

## **2. Medical Management (MM) Initial Session (40 to 60 minutes)**

### **MM Initial Session Overview**

Gather and review documents you will need for the MM Initial Session by referring to the relevant MMC forms in the *Appendix*, starting with Advance Preparation for MM Initial Session (*MMC #1, Appendix*). You will cover six topics with the patient in the MM Initial Session:

1. Review results from the intake evaluation: MM Clinician Report (*MMC #3, Appendix*) supports this activity; and address any medical concerns.
2. Explain the diagnosis and demonstrate how it applies to the patient; Discuss the patient's prognosis, and recommend abstinence; Discuss patient's goals for treatment.
3. Provide a rationale for using medication to treat alcohol dependence. Discuss specific information on the medication that will be prescribed, and how this medication is non-addicting, and differs from disulfiram (Antabuse) and from medications for detoxification.
4. Provide a rationale for medication adherence and develop an individualized Medication Adherence Plan.
5. Provide additional support. Discuss mutual-support group participation and offer print materials about alcohol dependence, medication treatment for alcohol dependence, and mutual-support groups.
6. Summarize what was covered in the MM Initial Session, address patient questions and concerns, and conclude session.

### **Guidelines for MM Initial Session Topics**

#### ***Topic 1. Review results from the intake evaluation and address any medical concerns***

You will meet with the patient for the first time after s/he has undergone the intake evaluation and, in the context of a research trial, randomization to treatment. Introduce yourself, describe your role in the treatment plan, and explain how frequently you expect to see the patient over the course of treatment. In research trials, distinguish your role as primary clinician versus research staff that may be collecting outcome data, and explain what communications will occur among research and clinical staff.

If blood alcohol concentration (BAC), vital signs, and weight have not been recorded, take these measures. Record the results. If the patient registers a positive breathalyzer reading, you or another clinician will explain that the MM Initial Session must be postponed until the patient can provide a negative reading. *(Note: Some settings may permit patients with positive BACs to continue the session if the BAC reading is extremely low).* If the reading is above the legal limit, make arrangements to have the patient escorted from the facility to another unit capable of retaining him/her or contact a family member who can transport the patient home. Observe the same procedures at each MM treatment follow-up session.

The MM Initial Session will go more smoothly if you have assembled and systematically reviewed results from the patient's intake evaluation beforehand. Before seeing the patient, as you review the evaluation results, record information from the measures listed below on the MM Clinician Report (*MMC #3, Appendix*):

- blood pressure, laboratory results (blood and urine), and medical problems identified on the physical exam.
- quantity/frequency of drinking in recent weeks (*Timeline Follow back [TLFB] or a similar measure of alcohol consumption*).
- self-report of alcohol-related problems (*Drinker Inventory of Consequences [DrInC], MMC #1a*) or a similar measure of alcohol consequences).
- symptoms of alcohol dependence (obtained from a diagnostic interview).

*(Note: The narrowly-focused MM treatment report differs from more broadly-focused reports such as that for Motivational Enhancement Therapy.)*

Review results from the intake evaluation by progressing from the patient's medical status to his/her lifetime and current drinking behavior.

**Review medical information.** Provide the patient with information from the MM Clinician Report (*MMC #3, Appendix*) in the same manner that you deliver results from any laboratory report. Tailor the discussion to the patient's specific situation and knowledge level. *(Note: Although the MMC Clinician Report form does not encompass all indications of alcohol use disorder, the included topics are especially useful in motivating patients to accept treatment.)*

The example below suggests language for discussing a medical test result.

**CLINICIAN:**

*Let's begin today by reviewing your physical health and then move on to talk about your drinking. First, let's review the results of your blood and urine tests.*

*When we review the medical status of patients who are drinking heavily, we pay particular attention to blood tests because some of them tell us how your liver is working. Your liver is extremely important to your health. It is involved in producing energy, and it filters and neutralizes impurities and poisons in your bloodstream.*

*Alcohol damages the liver by causing inflammation. In some cases, permanent scars, called cirrhosis, can form. Prior to cirrhosis, physical changes in the liver caused by drinking begin as a leakage of chemicals called enzymes into the blood. When this happens, we see abnormally high values on these blood tests.*

*Your laboratory results showed the following (show patient the results).*

**If test results are within normal ranges:**

*Your liver function tests show no significant elevations yet. Although normal results on these tests do not guarantee that your liver is functioning normally, this is a positive sign that, with treatment, you may be able to change your heavy alcohol drinking habits before you do any permanent damage to your body. A healthy liver also will help you to make a quicker, more complete recovery.*

**If test results are abnormal:**

*This/these elevated value(s) in the abnormal range probably reflect unhealthy changes in your body resulting from the excessive use of alcohol and/or other drugs. It is possible that you can improve your medical status and return the value(s) to the normal range if you stop drinking. The longer that you continue to drink, however, the more difficult it will be to reverse physical damage.*

**Review drinking consequences and practices.** When reviewing the patient's drinking information, focus primarily on drinking-related consequences (medical, interpersonal, etc), than on the patient's reported quantity and frequency of drinking. Because of individual differences in physical and other factors, some people can drink heavily with few consequences whereas others experience serious adverse consequences despite drinking less. A focus on drinking-related consequences helps to avoid fruitless debates with the patient about safe drinking levels.

Review the responses on the DrInC (MMC #1a, Appendix) in advance and select up to three items that the patient has endorsed for the MM Clinician Report (MMC #3, Appendix). Note that some people will report only a single adverse consequence from drinking, but the consequence may be quite serious (e.g., liver disease, DUI arrest).

**CLINICIAN:**

*I see that you drink heavily when you drink and that you have experienced several consequences that are related to having a serious problem with alcohol, such as driving after drinking and doing impulsive things that you later regret. Taken together, these events are warning signs that drinking for you is destructive to your health and/or wellbeing.*

*People who drink as much as you do at one time have what we call high tolerance for alcohol. This is a warning sign, because it means that, when you have a high blood alcohol level, you may not feel drunk, sick, or sleepy--any of which would lead a less tolerant drinker to stop drinking for the night. For this reason, you are more likely to continue to drink, wind up in risky situations, and experience or cause harm or others.*

***Topic 2. Explain the diagnosis and demonstrate how it applies to the patient. Discuss the patient's prognosis, and recommend abstinence; Determine with the patient his/her goals for treatment***

Inform the patient that, according to the diagnostic assessment, s/he has [supply number of symptoms of alcohol dependence]. Review with the patient each of the symptoms reported.

Provide basic information about what is currently known about alcohol use disorders. Emphasize that, unless the patient stops drinking, the problems s/he has already experienced will continue and new problems (e.g., hypertension, cancer, heart disease, brain disease, decreased life expectancy) may occur.

Tell the patient that, although any reduction in the amount of his/her drinking will help, the only way to be sure that alcohol will not cause further damage is to stop drinking altogether.

The example below suggests language for discussing the patient's diagnosis and recommending abstinence.

**CLINICIAN:**

*Let's look at the facts. The results of your evaluation point to a clear diagnosis of alcohol dependence. Here is the list of your symptoms: you have a history of excessive drinking, likely coupled with alcohol-related problems; you have made previous unsuccessful attempts to cut down or quit drinking; and you drink more than you intend to drink on a regular basis.*

*Therefore, I strongly suggest that you stop drinking altogether. Let me explain. Given your current condition, I cannot guarantee you that there is a level of drinking that will cause you no harm. Consistent heavy drinking puts you at risk for physical harm and negative social consequences. If your goal is only to "cut down" your amount of drinking, there is a good probability that you will return to heavy drinking. If you continue to drink, your dependence is likely to worsen and will become even harder to stop.*

*That's why abstinence is the safest choice for you. If you stop drinking, you can be sure that you won't have any new problems related to drinking. After some time of no drinking, your ability to think, complete tasks, get along with others, and even resolve problems related to past drinking all are likely to improve. When you are abstinent, you may discover things about yourself that you have forgotten.*

If it is apparent that the patient is unwilling or unable to commit to abstinence, suggest trying a brief period of abstinence. Possible advantages of undertaking a brief period of abstinence could also generate greater support of family and friends, rebuilding relationships, improved functioning, greater energy, and increasing the level of confidence about a changing the drinking behavior. The example below suggests language to introduce this subject.

**CLINICIAN:**

*If you are thinking that lifelong abstinence is too difficult a goal to commit to right now, you could try a brief period of abstinence of, say, a month, to find out what it's like to live without alcohol. Would you be willing to try this? You also may suggest additional reasons for abstinence, e.g., experiencing a change, building confidence, pleasing a spouse or other family members.*

### ***Topic 3. Provide information about and the rationale for using medication***

Begin by asking the patient what s/he knows already about the medication that will be prescribed. Correct any misinformation and misunderstanding. Tell the patient the purpose of the medication, that it is non-addicting, and distinguish it from medications used during detoxification. In a research trial, some of this information may have been covered during the Informed Consent process. However, it bears repeating during the initial MM session to ensure that the patient remembers the information.

**In particular, distinguish the medication from disulfiram (Antabuse), an aversive medication that produces unpleasant symptoms if the patient drinks alcohol.**

Review with the patient any other medications that the patient is taking, including all medications reported during the medical exam and any that were started between that exam and the MM Initial Session. Determine whether the patient is experiencing any adverse event(s) or has somatic complaints prior to starting medication.

Review with the patient information about the medication to be prescribed in the current treatment, focusing on:

- efficacy
- proposed mechanism of action
- potential side effects
- dosing

Inform the patient that side effects do not occur in all patients with this medication. If side effects should occur, they are usually temporary and ultimately manageable; patients should not expect that any side effect will be a permanent occurrence with the medication. Tell the patient that some side effects (e.g., headache, gastrointestinal problems or whatever side effects are applicable to the medication involved) may occur and are manageable with over-the-counter remedies.

To address persistent or more severe side effects, the medical clinician may decide to prescribe a reduced or different daily dosage. Advise the patient to contact you between sessions if s/he is concerned about any symptoms, medication-related or not.

Show the patient the medication in its container and review the dosing regimen, storage of the medication, and medication return. Tell the patient what to do if s/he misses a dose, loses medication, or runs out of medication before returning for the next session. Review the procedures to follow in case of an emergency. Be sure to allow time to address any

patient questions about the medication and/or dosage instructions. Write down any specifics you think the patient may forget, or any instructions that may be confusing. If blister card packaging is used, be sure that the patient understands which pills to take, how to remove pills from the card, and the importance of returning all blister cards, whether empty or containing pills.

Research studies involving medication should give the patient an emergency card to carry with them at all times. This card is designed to inform medical personnel if the patient seeks medical treatment elsewhere. The card states that the patient is/may be taking the prescribed medication and includes space for the dates that treatment began and will end, the name of the medical clinician, and a 24-hour emergency telephone contact number.

Emphasize that it may take time for the medication to be effective.

Remind the patient that some people will feel the medication's effectiveness more slowly than others and that it is important to continue taking the medication as prescribed and trying to maintain abstinence.

Encourage adherence by telling the patient that the medication is thought to increase the ability to achieve and maintain abstinence by improving his/her ability to resist drinking.

#### ***Topic 4. Provide a rationale for medication adherence and develop an individualized Medication Adherence Plan***

##### ***Provide the patient with the rationale for medication adherence.***

It is vital that your patient take the medication as you prescribe it so that you can evaluate its effectiveness and how well it is tolerated. Explain to the patient that consistently taking the medication as prescribed is important for personal well being and an important contribution to the study.

Educating your patient about the nature of alcohol dependence and the nature of the medication, including the time course of medication effects, also can help to foster adherence.

If you spend your time addressing medication adherence at this MM Initial session, and you ask about it at each of the MM follow-up

sessions, you will convey to the patient the importance of consistently taking their medication. If it is important to you, it will be important to your patient!

The example below suggests language for discussing the expected time course of medication effects.

**CLINICIAN:**

*For you to get the benefit of any medication prescribed to support your treatment goal of abstinence, you must take the medication consistently and as prescribed. It can take several days to achieve a steady therapeutic level in your blood. And, once you have the right amount of medication in your blood, it can still take some time for the medication to have its full effect on helping you to change your drinking behaviors.*

*This medication is not like aspirin, which you take only when you think that you need it. This medication can help you to maintain abstinence only if you take it consistently everyday, as you would insulin or a blood pressure medicine.*

**Develop a patient-tailored Medication Adherence Plan.** Follow the format outlined in the Medication Adherence Plan (see MMC #4 in Appendix) to design a concrete plan for regularly taking medication and to minimize the number of missed doses.

**Examine patient's history of medication-taking practices.** It is useful to initiate a dialogue by starting with an open-ended question about medication adherence. You might ask your patient about the past times when he/she has had trouble taking medication. At the same time, you can ask about prior successes in taking prescribed medication. This allows you the opportunity to identify medication adherence issues that may not be already specified in the manual. This initial dialogue is followed by asking:

- have you ever been asked to take, or have you ever taken any pills on a daily basis?
- have you ever been asked to take, or have you ever taken more than one pill at a time on a daily basis?
- have you ever been asked to take, or have you ever taken pills at the same time each day for 3 months or more?
- have you ever been asked to take, or have you ever taken pills from a blister card?
- do you typically carry your pills with you?
- have you ever been asked to take prescribed medications until all pills were gone?

Determine from the patient's answers if s/he has had sufficient experience to take a new medication as it will be prescribed.

If you find that the patient has been successful in remembering to take pills daily, ask about the strategies s/he found useful for this

task. If possible, use already-established pill-taking strategies in formulating the Medication Adherence Plan (*MMC #4, Appendix*).

If you find that the patient has not had experience taking medication on a regular basis or takes medications inconsistently, skipping doses, or quitting medication early, discuss some of the common reasons for medication nonadherence, such as the patient:

- forgets to take/misplaces medication.
- reports troublesome side effects.
- believes s/he is taking placebo.
- has misconceptions about what the medication will do or not do (expects instant change).
- is uneasy about taking medication (has never liked taking pills).
- is convinced by Alcoholic Anonymous (AA) group members to stop medication.
- sometimes simply wants to drink or "get high".
- refuses to accept a diagnosis of alcohol dependence.
- disagrees that s/he has a disorder sufficiently serious to warrant medication, believes s/he is "cured."

See Chapter 4 for techniques for dealing with each of these reasons for medication nonadherence.

**Select pill-taking strategies.** If your patient has been successful in taking pills in the past, solicit strategies s/he used to maintain adherence, and write them on the Medication Adherence Plan (*MMC #4, Appendix*). If your patient has never had a successful routine for pill-taking, assist him/her in tailoring an individualized plan for taking the medication as prescribed. Prompt the patient to think of ideas, or suggest that the patient:

place notes or other reminders in prominent places, such as a bedside table or bathroom mirror.

- use an alarm feature on a watch or cell phone that rings when it is time to take medication.
- involve others to witness pill-taking or administer the pill.
- take morning medication when brushing teeth or with morning coffee or vitamins.  
take medication during a favorite television program that occurs about the same time of day as medication dose.

Enter relevant suggestions on the Medication Adherence Plan. Explain that you will routinely review the plan's success plan at the beginning of each session. Tell the patient to bring the blister card(s) to each session because you will use pill counts of the returned blister card(s) to verify his/her medication adherence.

Be sure to tell the patient that if his/her plan proves unsuccessful at any time, you will help revise the plan to one with which s/he feels more comfortable.

***Topic 5. Provide additional support. Discuss mutual-support group participation and offer print materials about alcohol dependence, medications, and mutual-support groups***

***Discuss mutual-support group participation.*** Describe mutual support groups, such as AA and SMART Recovery, as a way to support an alcohol-free lifestyle that many people with alcohol dependence seek. Mutual-support groups allow the patient to quickly acquire a network of friends who have found ways to live their lives without alcohol. Mention that the medication treatment is time-limited and that many patients find that the importance of mutual support groups increases when they stop taking the medication.

Let the patient know that s/he is not required to attend a mutual-support group to participate in MM treatment. Tell him/her, in addition, that it is important for you to keep track of whether or not s/he does attend mutual-support group meetings, so that you will ask about it from time to time. Unless the patient is adamantly opposed, provide a list of telephone numbers, times, and locations of meetings of local groups (see Help Group Information for the Patient, *MMC #7, Appendix*). Choose a specific meeting or general location from the list and suggest that the patient try it out and later report about the experience.

The official position of AA is that members should take prescribed medications in good faith. Nonetheless, individual AA members may discourage any use of medication to stop drinking. Prepare the patient to cope with some mutual-support group members' objections to the use of medications.

The examples below suggest language to discuss aspects of AA that your patient may find problematic.

If the patient is reluctant to attend a meeting for the first time:

***CLINICIAN:***

*Participating in a mutual-support group is an excellent way to meet people who don't drink. There are also people there who have been through what you are about to go through and may be able to help you with the hardest parts in ways that you can't imagine at this time. Would you be willing to try just one meeting before our next session? Next time we can talk about what you thought of it.*

If the patient has attended a meeting and was uncomfortable

**CLINICIAN:**

*I know that you are saying that your experiences in the past with AA meetings have been disappointing. Who makes up the group really matters, and not all groups are alike. It is likely that you will need to try out several groups before finding one that feels right- --much as you would look for a new restaurant. Would you be willing to let me suggest a group for you to start with? Try the group out and tell me at our next session what you did or did not like about it. Sometimes talking out the problem can help to pinpoint the type of group you might feel more comfortable*

If the patient is concerned about AA members' disapproval of medications:

**CLINICIAN:**

*Some members of mutual-support groups believe that it isn't possible to get over an addiction while taking a pill. If you choose to reveal at a meeting that you are taking medication, you may run into a member who objects and tries to discourage you or other members from taking medication. It is important to remember, however, that the medication that you are taking as part of your treatment is just one tool that you use in your efforts not to drink. Medications have been shown to help others stop drinking and remain abstinent. In addition, the prescribed medication is not addictive, and the official policy of AA is supportive of people taking nonaddicting medications prescribed by a doctor.*

**Offer print materials.** The National Institute on Alcohol Abuse and Alcoholism ([www.niaaa.nih.gov/publications](http://www.niaaa.nih.gov/publications)) and other agencies offer educational publications about alcohol dependence and medication treatment for alcohol dependence at no charge. MM clinicians may offer these materials or suggest that patients obtain them independently.

***Topic 6. Summarize what was covered in the MM Initial Session, address patient questions and concerns, and conclude session***

To conclude the MM Initial Session,

- summarize the diagnosis and recommendation for abstinence.
- summarize the dosage regimen that the patient will follow.
- remind the patient to bring the blister card to the next session.
- ask about remaining questions or concerns.
- schedule the next session and tell the patient if contact might occur before the next session.

### **3. Medical Management (MM) Follow-up Sessions (15 to 25 minutes)**

#### **Overview**

At each MM follow-up session, make the following three assessments (in any sequence):

1. Perform a brief check of the patient's medical status, including general functioning, BAC, vital signs, weight, concurrent medications, laboratory data (when applicable), and medication side effects.
2. Check the patient's medication adherence.
3. Check the patient's drinking status.

Based on whether or not the patient has been medication adherent, and whether or not the patient continues to drink, make recommendations for the upcoming weeks.

Subsequent sections of this chapter provide details about the assessments.

The length of the session depends on the patient's progress, adherence with prescribed medication, and side effects. Most sessions will range from 15 to 25 minutes, but they may be as long as 30 minutes.

#### **Brief Assessment -- Medical Status and Medication Safety Check (5 minutes)**

In each follow-up session,

- take the patient's BAC, vital signs, and weight if this was not done immediately preceding the session. Record the results.
- ask the patient if s/he has experienced any medication side effects or adverse events.
- review any previous adverse effects to see if the patient continues to experience any of these effects.
- inquire if s/he has taken any concurrent medications. Record any medications the patient is taking in addition to the target pharmacotherapy, including over-the-counter medications and herbal supplements.
- if the patient has had laboratory tests performed, review the results with him/her; reinforce the concept that improvements in drinking and/or laboratory data are linked with the patient's decision to remain abstinent or drink less.
- If the patient is female and of childbearing potential, inquire about regular use of birth control and her menstrual cycle.

- Ask the patient whether s/he has any questions or concerns about the pharmacotherapy.

If a research patient describes a serious adverse event, complete the *Serious Adverse Event Report*. Process the reporting of such events according to the Sponsor's instructions and U.S. Food and Drug Administration (FDA) guidelines and, as necessary, Institutional Review Board (IRB) guidelines.

## **Brief Assessment -- Medication Adherence Check (5 minutes)**

The use of blister cards in clinical trials provides a built-in mechanism for straightforward pill counts. If the patient brought the blister card to the session, inspect it for any evidence of missed pills. Even if there are no pills in the card, inquire whether s/he took all medication following the prescribed schedule, because an empty blister card does not necessarily indicate adherence. If the patient did not take the medication as instructed, you may need to address nonadherence during the session.

In clinical practice where blister packaging is not typically used, ascertainment of patient adherence to the medication regimen needs to be obtained by tactful questioning of the patient and probing as necessary.

If the patient took the medication as prescribed, praise him/her for adhering to the treatment regimen. If s/he skipped any doses, inquire about the reasons. Most patients say that they skipped a dose because they forgot to take the medication. Although this is true for some patients who are unaccustomed to taking medication, other patients may say this because it is the easiest answer to give. If the patient tells you that s/he "forgot" at other sessions, probe further into the circumstances (see Chapter 4. Managing Treatment Adherence, for common reasons for not taking pills).

Try to determine why nonadherent patients skipped dose(s) so that you can provide helpful advice for future adherence. For example, if a patient tells you that s/he didn't take the medication because s/he was drinking, determine whether the patient skipped the medication and then drank, or drank first and then missed the dose. If the latter, determine whether the patient drank and then forgot to take the medication, or decided to skip a dose after drinking because s/he didn't want to mix alcohol and the medication. Point out that, regardless of the specifics, the patient's drinking was related to missing doses.

## Brief Assessment -- Drinking Status Check

Ask the patient about his/her drinking status, as well as about illegal drug use and attendance at mutual-support groups, since the last session.

Allow for some open-ended discussion of the patient's current concerns about drinking or the medication. Reward any positive steps the patient has made toward achieving recovery. Continue to provide the patient with optimism that s/he can recover.

The examples that follow suggest questions to ask about different aspects of the patient's drinking status.

### **CLINICIAN:**

*How have you been since our last session?  
What was difficult? What went well?*

*Did you have any problems taking your medication as we discussed?*

#### **If the patient reports problems with taking the medication...**

*What are the circumstances? Were any of the problems related to times when you were drinking? Let's find another way to remember to take your medication. If we find the right strategies, learning to take your medication can be an easier goal to attain than learning to reduce or stop your drinking.*

#### **If the patient reports no problems with taking the medication...**

*Congratulations on successfully taking your medication. You are demonstrating your determination to change. You are making great progress toward your recovery!*

*How well were you able to stay with your specified goal for abstinence or reducing your drinking?*

#### **If the patient is still drinking...**

*What were the circumstances? Remember, change occurs in small steps; keep trying, don't get discouraged.*

#### **If the patient continued with abstinence...**

*Congratulations for staying away from alcohol. You are demonstrating your determination to change. You are making great progress toward your recovery!*

#### **Finish the session with positive, supportive statements such as,**

*"It sounds as if things are going well. Let's keep working together on this!" OR "Keep up the good work!"*

Ensure that the patient's self-report accurately reflects the information on the Medical Management Communication Form (*MMC #8, Appendix*). The Medical Management Communication Form is filled out at each patient session. It is meant to ensure that drinking and medication adherence data collected at the patient's visit by research staff are consistent with the drinking and medication status reported by the patient to the medical clinician. By using the MM communication form to relay the number of drinking days, heavy drinking days, and percent medication adherence approximately reported to the research staff and, independently, to the MM clinician while the patient is still in the clinic, discrepancies can be clarified immediately.

## **Troubleshooting Outcomes, Making Recommendations (5-10 minutes)**

Results from the brief assessments described in this chapter dictate how you should spend the remaining session time.

At each session, patients will have achieved one of four possible outcomes: the patient is not drinking and is medication-adherent, the patient is drinking but is medication-adherent, the patient is not drinking but is medication-nonadherent, or the patient is drinking and is medication-nonadherent. The scenarios that follow describe ways to manage each outcome. Form *MMC #5a in Appendix* provides a quick-reference tool for addressing each of these outcomes.

***Outcome 1. The patient is not drinking and is medication adherent.*** Many patients will take the medication faithfully and discontinue drinking. Some will be adherent early in treatment, others will become adherent at midtreatment, and some will not achieve adherence until treatment is almost completed. Whenever the patient achieves adherence:

- reinforce the patient's ability to follow advice and stick to the plan. Discuss how most patients have trouble achieving abstinence and being medication adherent. Ask the patient to tell you specifically how s/he did so well.
- address the common, incorrect belief that s/he can put aside the Medication Adherence Plan constructed during the MM Initial Session as soon as s/he feels successful in treatment. Focus on the fact that, if the patient completes treatment as prescribed, recovery is more likely to continue following treatment. Explain that, even when recovery has been progressing well for some time, these sessions serve as "booster shots" or a form of insurance that successful response to treatment can continue beyond treatment.

- review the benefits of abstinence in general terms (e.g., improved health, fewer drinking-related problems) and the benefits of medication treatment.
- conclude the session with positive, supportive statements such as, “It sounds as if things are going well. Keep up the good work!”

**Outcome 2. The patient is drinking but is medication adherent.** This is one of the most difficult situations encountered in MM treatment. It can occur early in the course of treatment, at mid-treatment, or at the end. If your patient is in this situation in early treatment, encourage him/her by saying that the medication may not yet be working fully. Patients who start drinking later in treatment may be encouraged to attend mutual support groups such as AA and SMART Recovery. Although some patients may have initially informed you that they have no intention of attending such meetings, they now may be willing to do so. You can help them overcome a fear of groups or previous negative experiences by suggesting alternative options (e.g., attending a small or same-sex AA meeting, attending SMART Recovery instead of AA).

In addition, the clinician may choose to:

- be supportive that the patient took the medication as prescribed, but remind him/her that medication takes time to work.
- praise any small steps the patient has made toward achieving abstinence. Reassure your patient that recovery is a gradual process and that an occasional return to drinking sometimes occurs.
- review the benefits of abstinence (e.g., improved health, fewer drinking-related problems) and the benefits of medication treatment. Encourage the patient to give abstinence a chance. Tell the patient that beginning abstinence typically is the most difficult time but that maintaining abstinence usually becomes easier over time.
- review ways the patient can reduce drinking.
- review benefits of support group meetings.

**Outcome 3. The patient is not drinking but is medication nonadherent.** Some patients will discontinue drinking but report difficulties in routinely taking the medication. This can occur early in treatment, at mid-treatment, or at the end. When this occurs:

- congratulate the patient for not drinking.
- review the benefits of abstinence (e.g., improved health, fewer drinking-related problems) and the benefits of medication treatment.
- probe further why the patient is not taking medication regularly and address problems, such as side effects, that you can help the patient to resolve.

- tell the patient that taking the medication may significantly improve his/her chances for sustained improvement.
- revise and reconstruct the patient's Medication Adherence Plan.

***Outcome 4. The patient is drinking and is medication-nonadherent.***

Patients who continue drinking frequently will report difficulty in routinely taking the medication. This can occur early in treatment, at mid-treatment, or at the end of treatment. When this occurs:

- review the benefits of abstinence (e.g., improved health, social functioning, quality of life, and fewer drinking-related problems).
- praise any small steps that patient made toward achieving abstinence. Reassure your patient that recovery is a gradual process and that occasional "slips" or returning to risky drinking sometimes occurs.
- review the benefits of medication treatment.
- Probe why the patient is not taking medication regularly and address problems, such as side effects, that you can help the patient to resolve.
- encourage the patient to give the treatment a chance. Explain that although it is very difficult to give up drinking, it is a lot easier to routinely take medication as prescribed.
- tell the patient that taking the medication may significantly improve his/her chances for sustained improvement.
- reconstruct the Medication Adherence Plan with the patient and add new ways to circumvent obstacles to medication adherence.

If your review reveals that the patient is no longer motivated to stop or reduce drinking:

- remind the patient of the specific reasons that s/he originally sought treatment as discussed in the MM Initial Session (see MM Clinician Report; *MMC #3, Appendix*).
- review the information gathered prior to the MM Initial Session about consequences of the patient's recent drinking behavior.
- repeat points made in the Mm Initial Session about the general benefits of abstinence.
- review the benefits of attending as many mutual-help group meetings as possible to maintain abstinence. If the patient had negative experiences previously, suggest alternative options (e.g., attending a small or same-sex AA meeting, attending SMART Recovery instead of AA).

In addition, you may be required to consider the following, and managing these will somewhat depend upon the clinical and/or research protocols' guidelines.

***Social service referrals.*** During the course of treatment, patients may report a problem such as loss of a place to live, unemployment, or lack of health care. When such situations arise, make referrals to the appropriate social service agencies as you would in your clinical practice.

***Emergency crisis intervention.*** If a patient reports life crises and requests your assistance on more than two occasions, it is probable that the patient's needs require greater attention than that provided in MM treatment. Use your clinical judgment to determine the action warranted, including referral to more intensive treatment. If at any time you feel that the immediate welfare and safety of the patient or another person is in jeopardy (e.g., impending relapse, the patient is acutely suicidal or violent), intervene immediately and appropriately for the protection of those involved.

***Psychosocial issues.*** If the patient raises psychosocial issues at MM treatment sessions, encourage him/her to attend mutual-help meetings or see/consider seeing a therapist. If the patient already attends mutual-help meetings, suggest that s/he increase the number of meetings s/he attends and/or seek additional support from e.g., family, friends, a minister, or another source.

***A need for additional treatment.*** Use MM treatment strategies, such as suggesting mutual-help attendance, to address ancillary (e.g., marital, parenting) problems that arise during treatment. If your patient requests additional professional help, advise him/her that achieving and maintaining abstinence may resolve or reduce ancillary problems. Tell him/her that you will review these ancillary matters again at the end of MM treatment. If the patient is struggling with problems beyond the scope of the MM treatment, refer him/her to other professional treatment(s). This can help to provide the necessary foundation to support ongoing abstinence. Address clinical deterioration immediately by referring the patient to a more intensive, structured treatment program.

***Post-treatment planning.*** Once you have effectively involved the patient in the treatment and s/he has experienced several productive sessions, you and the patient should initiate planning for the end of the trial. Well before the last session, plan with the patient how s/he will establish a long-term plan.

## 4. Managing Treatment Adherence

This chapter details strategies that can be used to foster treatment adherence, including strategies to address medication nonadherence and strategies to address session non-attendance.

### Strategies to Address Medication Nonadherence

The Medication Adherence Plan (*MMC #4, Appendix*) lists common reasons for medication nonadherence, ranging from subjects that are easily discussed with your patient to subjects that are more difficult (*note: reasons are not ranked according to frequency of occurrence or influence on adherence*). Suggested strategies to address each reason for not taking medication are also provided.

#### ***Forgets to take or loses medication packet and/or individual pills.***

Even people with life-threatening diseases forget to take their medications. It is not unusual for people to be distracted by other things in their lives and either forget to take a dose of medication or forget whether they have taken it already. There are ways to combat forgetfulness, but do not assume that patients will develop such strategies on their own. Once you have established that your patient is actually forgetting and not intentionally avoiding the task, suggest ways to incorporate the treatment medication into an existing routine. For example:

- place notes or other reminders in prominent places, such as a bedside table or bathroom mirror.
- wear an alarm watch that rings when it is time to take medication.
- involve others to witness pill-taking or administer the pill.
- take morning medication when a medication when brushing teeth or with morning coffee or vitamins.
- take medication during a favorite television program that occurs about the same time of day as medication dose.

If the patient loses or misplaces a dose, instruct him/her to take a pill from the extra medication doses, if provided on the blister card. If the patient loses an entire blister card but has additional medication cards available, instruct him/her to start with the appropriate day and time of day using the next numbered medication card. If the patient has no more blister cards, inform him/her to call you or your staff immediately.

**Worries about side effects.** Although it is logical to assume that the most common reason people stop taking medication is because of side effects, in fact, patients who report side effects are not more likely than others to drop out of treatment. Properly explaining side effects, so that the patient has confidence in your ability to manage them, can greatly improve adherence.

Many patients believe that the only way to stop unpleasant side effects is to stop taking the medication altogether. Inform your patients in advance that other remedies are possible that might not involve having to stop taking the medication. Let the patient know that you would be glad to discuss these, as long as you are fully informed.

Try the following steps; inform the patient that:

1. most people taking the particular medication(s) experience no side effects.
2. most side effects are transient and with proper management are likely to likely disappear.
3. if s/he keeps you informed about side effects and the level of discomfort, you will adjust the dosage, either temporarily or for the duration of the trial.

Remember that, for some patients, it may be important to determine whether reported side effects are actually linked to the medication or are caused by other factors in the patients' lives. For example, many patients who have just quit drinking will experience anxiety or sleep or mood disturbances, but they may believe that these discomforts are medication-related. If you review the patient's overall situation, you may help him/her to find alternative explanations and continue with medication rather than discontinue.

Discuss with your patients the severity and annoyance level of the side effects experienced. One patient may describe as unbearable the same side effect that another finds bothersome. Talk through the pros and cons of continuing the medication. Ask the patient to weigh the impact of the side effects against the impact of a potential relapse. As always, avoid accusations or giving the impression that you want the patient to continue the medication at any cost. Through other means, you may assist the patient to find reasons to continue treatment, when appropriate.

**Believes s/he is taking placebo.** In a placebo-controlled clinical trial, if a patient is concerned that s/he is taking a placebo rather than the active medication, it is probable that s/he will stop taking the pills. If the patient thinks that s/he is taking a placebo, explore why and address the reasons in the same session or you may lose the patient. Typically, the patient will relate his/her perception to the fact that s/he is still drinking or dramatically craving alcohol. It is

important to emphasize that the medication's effects usually require time to develop and in some patients take more time than others.

Whether or not the patient is reporting side effects, s/he may be wondering whether s/he is taking placebo or active medication. If the patient has not reported side effects, be sure to say that the absence of side effects does not mean that s/he is taking a placebo. Explain that many patients taking the prescribed medication report no side effects at all. Restate that it is important to keep taking the medication as prescribed and to continue trying to achieve full recovery.

***Has misinformation about the medication.*** Medication nonadherence also can occur when patients have mistaken beliefs about what the medication is supposed to do. For example, people starting on antidepressants may quickly decide that the pills are worthless if they haven't been educated to the fact that it will take 10 days or more to begin to see improvements in mood.

Sometimes it is difficult for patients to know if a medication is having a therapeutic effect, particularly if the patient does not detect any medication side effects and "feels nothing" when s/he takes the medication. To combat this, inform patients that they may not know when the medication has taken effect, but over time, they will see a change in their drinking behaviors. Patients with alcohol dependence are particularly prone to want instant medication results; warn them that the prescribed medication may or may not produce instant results, depending upon individual response. Discuss expectations thoroughly so that you can correct mistaken ideas about what the medication will and will not do.

***Has never liked taking pills.*** Some patients are nonadherent because they are not comfortable taking any medication, even aspirin. Try to address this type of concern proactively by reiterating why the medication may be helpful in achieving recovery from alcohol dependence. Encourage the patient to ask you any questions s/he might have that are still unanswered. Some patients may feel uneasy about taking medication because they are influenced by the views held by members of a mutual-support group they attend. In this case, give the patient the pamphlet, *The AA Member--Medications and Other Drugs* and refer the patient to the statement that no AA member "plays doctor." Explore with the patient the possibility of his/her participating in and attending specific groups in which members are more tolerant of appropriate use of medication. Reassure the patient about the safety and nonaddicting properties of the prescribed medication.

***Desires to drink or "get high".*** Many patients will stop taking their medication for a day or a weekend when they want to drink or "get high." Some patients do this because they have found that, when they drink alcohol after taking the medication, the pleasant feeling is reduced or absent. Other patients may not wish to mix alcohol and pills and may resolve the situation by not taking the medication. Regardless of whether your patient fits into one of those two categories, it is important to directly address medication nonadherence, taking a nonjudgmental, and common sense approach to helping the patient resolve the problem.

***Disagrees about having an alcohol disorder or feels that s/he no longer needs medication.*** Many patients refuse to accept the fact that they have a chronic illness or that their condition is sufficiently serious to require medication. Patients may not always express this attitude; it is often something that they think to themselves because they deny the severity of their condition. This may result in medication nonadherence. To address this issue, provide the patient with all the information about his/her condition and its treatment. If the patient expresses doubt that his/her condition is serious enough to warrant medication, gently but continually remind the patient of his /her presenting symptoms and of the past consequences of his/her alcohol misuse. Emphasize that having an alcohol dependence problem is not the patient's fault, but also stress that s/he has the responsibility to receive treatment and properly follow treatment instructions. Discuss the use of medication as an "aid" rather than a sign of the severity of the problem. After all, most people want to receive state-of-the-art treatment for even a minor problem if they have the option.

Patients who experience a successful recovery, even those who fully comply in the initial phases of treatment, may later decide to stop taking their medication because they believe that the problem has been resolved and does not require further "chemical" assistance. They may make this decision on their own, without consulting a medical clinician and without knowledge of why continuing a medication may be necessary. If your patient has decided prematurely that s/he is "cured," educating him/her about the treatment regimen is the most helpful technique. Explain that feeling ready to stop treatment before it has time to work is common with all illnesses (e.g., antibiotics for a bacterial infection). Stress that making the decision to stop medication should be done as a collaborative effort between him/her and you, the medical clinician.

***Takes medication at nonprescribed times and in "catch-up" doses.*** If your patient wants to "make up" medication doses s/he missed as the result of forgetfulness, lack of organization, and another reason, support his/her willingness to adhere to the regimen but inform him/her that taking the medication at other than the sched-

uled times could cause problems. Review the Medication Adherence Plan and develop new strategies to help the patient remember to take the prescribed doses if needed.

## Strategies to Address Session Non-Attendance

The strategies that follow may be used to address the most common reasons for non-attendance at treatment sessions.

**Missed appointments.** Irregular attendance is typical of patients with alcohol dependence. When pharmacotherapy is part of the primary treatment, a patient who misses office visits also can miss one or more weeks of medication. This can be much more serious than missing one or two days of medication, and you should address it proactively.

You should proactively contact the patient as soon as possible,

- clarify the reasons for the missed appointment.
- affirm the patient and reinforce his/her commitment in attending the last session.
- express your eagerness to see the patient again.
- briefly mention concerns about patient's disorder and running out of medication.
- express your optimism about the patient's prospects for change.
- reschedule the missed appointment.

If the patient offers no reasonable explanation (e.g., illness, transportation breakdown) for missing an appointment, explore with him/her whether non-attendance may reflect:

- uncertainty about whether treatment is needed (e.g., the patient may state, "I don't really have that much of a problem").
- failure to accept the alcohol dependence diagnosis.
- frustration or anger about pressure to participate in treatment (especially if the patient has been coerced by others into entering the program).

Indicate that it is not surprising, particularly in the beginning phase of treatment, for people to express their reluctance (or frustration, anger, or another emotion) by tardiness or failure to keep appointments. Encouraging the patient to voice these concerns directly may help to reduce his/her future missed appointments.

Affirm the patient for being willing to discuss concerns. Then summarize what you have discussed, adding your own optimism about the prospects for positive change. Obtain a recommitment to treatment and reschedule the appointment.

**Inactive status.** Especially in a research study, the fixed duration of the intervention phase requires attendance at all (or almost all) clinic visits in order to ensure maximal exposure to the planned treatment. When a patient misses consecutive scheduled sessions or has not been to a session in a month (whichever comes first), and you have not been able to contact him/her, consider sending a formal note to the patient acknowledging his/her apparent decision not to attend or resume MM treatment sessions and/or take medication. Your note should encourage the patient to return to MM treatment and/or resume medication at a later time if desired. Urge the patient to have a final evaluation to return unused medication and have a physical exam as a safety check. It is important for safety purposes to have documentation that every attempt was made to conduct a final evaluation on any patient who prematurely discontinues pharmacotherapy.

**Patients dissatisfied with treatment.** Patients may report thinking that their treatment is not going to help or may indicate that they want a different treatment. Under these circumstances, you should reinforce them for honestly expressing their feelings (e.g., "I'm glad you expressed your concerns to me right away"). You should also confirm, if asked, that patients have the right to

- quit treatment at any time.
- seek help elsewhere.
- decide to work on the problem independently.

In any event, you should attempt to further explore the patient's feelings (e.g., "Whatever you decide is up to you, but it might be helpful for us to talk about why you're concerned").

**When concerns arise during the first session.** If your patient expresses these concerns at the first session, s/he is probably worried about a suggested approach that s/he has not yet tried. It is appropriate to reassure the patient that you will offer all the help that you can. You cannot guarantee that any particular treatment will work, but you can encourage the patient to give it a good try for the planned period and see what happens. Add that, should the problem continue or worsen, you will discuss other possible approaches and options.

**When concerns arise after two or three sessions.** If a patient expresses reservations after two or three sessions, explore whether there have been new developments in his/her life. Ask, for example,

- have new problems occurred?
  - related or not to drinking? -- related or not to the medication?
- is there input or pressure from someone else for a change in approach or for discontinuation of treatment?
- are you aware now of problems that you ignored in the past?
- did the Medication Adherence Plan fail?
  - was it properly implemented? -- did you try it long enough?

## 5. Medical Attention (MA)

Some patients receiving MM will be unable to continue taking medication(s) after starting them. The most common reasons for this are intolerable side effects and a medical or psychiatric contraindication, such as an elevated liver function test or pregnancy.

In addition, patients may at some time during treatment temporarily discontinue pharmacotherapy for various reasons, but with the goal of restarting medication at some later time during treatment.

Medical attention (MA) is an intervention that has been derived from MM for patients who want to continue seeing their MM clinician but are not able to take the medication. Medical attention consists of medical monitoring (e.g., checking on general functioning, obtaining a BAC, vital signs, weight, and adverse events report), and a discussion of drinking according to MM principles.

The sections that follow describe the process of administering MA within MM treatment context.

### MA Treatment Overview

The goal of MA is to promote recovery from alcohol dependence by encouraging patients to continue with their MM clinician sessions, supporting patients' efforts to stop drinking, and making recommendations for changing drinking behaviors. MA treatment should be delivered by a medical professional who will follow the patient throughout the treatment. Your role as the medical clinician is to provide expert assessment, support, and direct advice to patients in their efforts to achieve recovery from alcohol dependence. When talking with the patient, appeal to reason and common sense, particularly in relation to the overall goal of preserving or restoring health. It is important in expressing concern for the patient to be nonjudgmental. Always be friendly, supportive, and optimistic about recovery.

MA sessions include a medical check on BAC, vital signs, and weight; a review of health status; a brief assessment of drinking; review of attendance at mutual-support recovery groups; and recommendations for the patient to follow until the next session.

### Frequency of MA Sessions

MA sessions can be held as frequently as MM sessions. MA sessions typically last about 15 minutes, although they may be as brief as 10 or as long as 20 minutes, depending on each patient's medical status and progress in treatment.

## **MA Treatment in a Research Context**

### ***Extra-MA Therapeutic Strategies***

Many professional therapies utilize techniques and strategies that extend beyond the scope of MA treatment. Among them are confrontation, skills-training approaches, client-centered counseling, and family therapy. Although these methods may complement MA treatment in a clinical setting, they are not part of the specific MA intervention. Most medical staff do not have training to deliver these methods and they should not be applied in a research context.

### ***Nonabstinent Goals***

Encourage patients to be abstinent throughout treatment, if possible. To this end, do not tell patients to "expect slips; they are a natural part of recovery" or "some reduction in the amount that you are drinking is an acceptable goal." However, when patients do drink during treatment, avoid expressing disapproval or disappointment. Praise any improvements and steps toward achieving recovery. If a patient does slip, reassure him/her that slips sometimes happen and do not signal that recovery is unattainable.

## **Brief Assessment: Medical Status and Drinking Status Checks (10 minutes)**

Ask the patient about his/her general functioning, and record the patient's BAC, vital signs, and weight. Ask the patient about his/her drinking status since the last session. Allow for some open-ended discussion so that the patient can tell you his/her current concerns about drinking. Reward any positive steps s/he has made toward achieving recovery. Be optimistic that the patient can recover.

In a research study, ensure that the patient's drinking self-report accurately reflects the information on the Medical Management Communication Form (*MMC #8, Appendix*). The Medical Management Communication Form is filled out at each patient visit. It is meant to ensure that drinking data collected at the patient's visit by research staff are consistent with the drinking status reported by the patient to the medical clinician. By using the MM communication form to relay the number of drinking days and heavy drinking days approximately reported to the research staff and, independently, to the MM clinician while the patient is still in the clinic, discrepancies can be clarified immediately.

Before determining the content of the discussion for the rest of the session, ask the patient any other questions that will provide you with

information you feel you need, including whether or not s/he has been attending mutual-support groups.

Below are questions to ask during the status review:

**CLINICIAN:**

*How have you been?*

*What was difficult?*

*What went well?*

*Were you able to keep from drinking?*

**If the patient drank**

*What were the circumstances?*

*Remember that change occurs in small steps; keep trying, don't get discouraged.*

*How great was your desire to drink?*

**If the patient drank and found that desire to drink was greatly diminished**

*Reductions in your desire to drink may be the first sign of change for you.*

**If the patient had a strong desire to drink but did not do so**

*Congratulations on not drinking, even though you really wanted to.*

*You have taken an important step toward your recovery!*

**If the patient remained abstinent**

*Congratulations on staying abstinent! You are demonstrating your determination to change and are making great progress toward recovery!*

## **Review Attendance at Mutual-Support Group Meetings**

Ask the patient if s/he has been attending mutual-support group meetings. If the patient has gone to meetings, reinforce the importance of this action. If s/he has not gone, provide encouragement to do so.

## Recommendations/Troubleshooting (5 to 10 minutes)

Because the patient is not taking medication, the recommendations and troubleshooting focus should be on drinking status.

***The patient is not drinking.*** Many patients will attend their MA appointments faithfully and discontinue drinking. Some will do so early in treatment, others will do so at mid-treatment, and some will not reach this point until treatment is almost over. When the patient has achieved this outcome:

- reinforce the patient's ability to follow advice and stick to the plan. Discuss how most patients have trouble initially achieving and maintaining abstinence. Inquire about how, specifically, s/he was able to do so well.
- review with the patient that, when things are going well, it is important to remember that adherence with treatment also means continuing to attend his/her MA sessions and continuing to make the scheduled sessions until the end of treatment. Address the common but incorrect belief that the patient can abandon the plan constructed at his/her MM Initial Session as soon as s/he feels successful in treatment. Focus on the fact that completing treatment as prescribed may better ensure recovery after treatment is over. Explain to the patient that, even when things have been going well for some period of time, continued MA sessions serve as "booster shots" or insurance to help his/her successful adherence and response to treatment continue beyond the end of treatment.
- review the benefits of abstinence (e.g., improved health, fewer drinking-related problems).
- encourage and reinforce attendance at mutual-support group meetings between appointments.
- offer additional support. End the session positively (e.g., "It sounds as if things are going well. Keep up the good work!").

If the patient has not been attending MA sessions, probe further as to why s/he missed appointments and suggest that continuing to come to the MA sessions regularly may help sustain recovery.

***The patient continues to drink.*** Patients who continue to drink during treatment need to revisit their reasons for coming to treatment and their treatment goals. This can occur early in treatment, at mid-treatment, or at the end of treatment. Encouraging patients to attend mutual-support groups such as AA or SMART Recovery is the first-line response in this situation. Although some patients will inform you early on that they have

no intention of attending these meetings because of fear or previous negative experiences, encourage them to try these groups. Offer potential solutions to patient concerns (e.g., attending a small or same-sex group, attending SMART Recovery instead of AA).

Strategies to help patients stop drinking include:

- remind the patient of the specific reasons that s/he originally sought treatment as discussed in the MM Initial Session (see MM Clinician Report; *MMC #3, Appendix*).
- review the information gathered prior to the MM Initial Session about consequences of the patient's recent drinking behavior.
- review the benefits of abstinence (e.g., improved health, social functioning, quality of life, and fewer drinking-related problems).
- praise any small steps that patient has made toward achieving abstinence. Reassure your patient that recovery is a gradual process and that occasional "slips" or returning to risky drinking sometimes occurs.
- encourage the patient to give abstinence a chance. Tell him/her that beginning abstinence is the most difficult time but that if s/he can get the process started, it should become easier over time.
- revisit attendance at support groups.

## **Coexisting Medical/Psychiatric Problems**

In all cases, evaluate coexisting medical/psychiatric conditions and, if clinically appropriate, refer the patient to the appropriate practitioner (e.g., an internist or psychiatrist) for further evaluation and perhaps treatment of that condition. If the severity of the patient's medical condition warrants, schedule more frequent sessions than ordinarily recommended by the MA protocol.

## **Appendix - Tools for MM Clinician (MMC)**

To be kept in Patient File.

- **MMC #1 –Advance Preparation for MM Initial Session**
- **MMC #1a – Drinker Inventory of Consequences (DrInC)<sup>1</sup>**
- **MMC #2 – Medical Management Checklist (Initial Session)**
- **MMC #3 – Medical Management (MM) Clinician Report**
- **MMC #4 – Medication Adherence Plan**
- **MMC #5 – Medical Management Checklist (Follow-Up Session)**
- **MMC #5a – MM Follow-up Session Dialogue Flowchart  
(from NIAAA Clinician’s Guide)**
- **MMC #6 – Medical Attention Checklist (Follow-Up)**
- **MMC #7 – Help Group Information for the Patient**
- **MMC #8 - Medical Management Communication Form**
- **MMC #9 – Example of Study Fact Sheet for MM Clinician**

<sup>1</sup> Miller, W.R., Tonigan, J.S. & Longabaugh, R. (1995). *The Drinker Inventory of Consequences (DrInC): An Instrument for Assessing Adverse Consequences of Alcohol Abuse*. Project MATCH Monograph Series, Vol. 4. DHHS Publication No. 95-3911. Rockville, MD: National Institute on Alcohol Abuse and Alcoholism.

Patient ID # \_\_\_\_\_

Session # \_\_\_\_\_

MMC NAME \_\_\_\_\_

Date \_\_\_\_\_

## Advance Preparations for MM Initial Session

Gather and Review information that was already collected from the patient and will be needed for the MM Clinician Report Form for the MM Initial Session (See MMC #3)

	<b>Medical Information:</b> Double-check lab report, and record any other drinking-related medical symptoms as noted on physical examination or lab reports.
	<b>Alcohol Use:</b> Record the number of drinking days per week and average number of drinks per drinking day from the Timeline Followback method or a similar drinking collection method.
	<b>Consequences of Drinking:</b> Record one to three negative consequences acknowledged by the patient. Select items from the DrInC (MMC #1a) or a similar drinking consequence collection method with the highest score or impact to discuss as examples of drinking-related problems.
	<b>Diagnostic Information:</b> Review symptoms of alcohol dependence from diagnostic evaluation.

Prepare Other Items Needed for the MM Initial Session (optional examples listed below)

	<b>1. Vital Signs</b>
	<b>2. BAC</b>
	<b>3. Prior and Concomitant Medications Form</b>
	<b>4. Adverse Events Log</b>
	<b>5. Serious Adverse Event Form</b>
	<b>6. Medication Adherence Plan</b>
	<b>7. Medical Management Session Attendance Calendar</b>
	<b>8. Self-Help Group Information</b>
	<b>9. Other Treatment Services Utilization</b>

Patient ID # \_\_\_\_\_

Session # \_\_\_\_\_

MMC NAME \_\_\_\_\_

Date \_\_\_\_\_

## Drinker Inventory of Consequences

Instructions: Here are a number of events that drinkers sometimes experience. Read each one carefully, and indicate how often each one has happened to you IN THE LAST THREE MONTHS by selecting the appropriate number (0= Never, 1= Once or a few times, etc.). If an item does not apply to you, select zero (0).

In the LAST 3 MONTHS about how often has this happened to you? Circle one answer:	Never	Once or a few times	Once or twice a week	Daily or almost daily
1. I have had a hangover or felt bad after drinking.	0	1	2	3
2. I have felt bad about myself because of my drinking.	0	1	2	3
3. I have missed days of work or school because of my drinking.	0	1	2	3
4. My family or friends have worried or complained about my drinking.	0	1	2	3
5. I have enjoyed the taste of beer, wine, or liquor.	0	1	2	3
6. The quality of my work has suffered because of my drinking.	0	1	2	3
7. My ability to be a good parent has been harmed by my drinking.	0	1	2	3
8. After drinking, I have had trouble with sleeping, staying asleep, or nightmares.	0	1	2	3
9. I have driven a motor vehicle after having three or more drinks.	0	1	2	3
10. My drinking has caused me to use other drugs more.	0	1	2	3
11. I have been sick and vomited after drinking.	0	1	2	3
12. I have been unhappy because of my drinking.	0	1	2	3
13. Because of my drinking, I have not eaten properly.	0	1	2	3
14. I have failed to do what is expected of me because of my drinking.	0	1	2	3
15. Drinking has helped me to relax.	0	1	2	3

Patient ID # \_\_\_\_\_

Session # \_\_\_\_\_

MMC NAME \_\_\_\_\_

Date \_\_\_\_\_

In the LAST 3 MONTHS, about how often has this happened to you? Circle one answer:	Never	Once or a few times	Once or twice a week	Daily or almost daily
16. While drinking I have said or done embarrassing things.	0	1	2	3
17. When drinking, my personality has changed for the worse.	0	1	2	3
18. I have taken foolish risks when I have been drinking.	0	1	2	3
19. I have gotten into trouble because of drinking.	0	1	2	3
20. While drinking or using drugs, I have said harsh or cruel things to someone.	0	1	2	3
21. When drinking, I have done impulsive things that I regretted later.	0	1	2	3
22. I have gotten into a physical fight while drinking.	0	1	2	3
Now answer these questions about things that may have happened to you.				
In the LAST 3 MONTHS, about how much has this happened to you? Circle one answer:	Not at All	A Little	Some-what	Very Much
23. My physical health has been harmed by my drinking	0	1	2	3
24. Drinking has helped me to have a more positive outlook on life.	0	1	2	3
25. I have had money problems because of my drinking.	0	1	2	3
26. My marriage or love relationship has been harmed by my drinking.	0	1	2	3
27. I have smoked tobacco more when I am drinking.	0	1	2	3
28. My physical appearance has been harmed by my drinking.	0	1	2	3
29. My family has been hurt by my drinking.	0	1	2	3
30. A friendship or close relationship has been damaged by my drinking.	0	1	2	3
31. I have been overweight because of my drinking.	0	1	2	3

Patient ID # \_\_\_\_\_

Session # \_\_\_\_\_

MMC NAME \_\_\_\_\_

Date \_\_\_\_\_

In the LAST 3 MONTHS, about how much has this happened to you? Circle one answer:	Not at All	A Little	Some-what	Very Much
32. I have lost interest in activities and hobbies because of my drinking.	0	1	2	3
33. When drinking, my social life has been more enjoyable.	0	1	2	3
34. My spiritual or moral life has been harmed by my drinking.	0	1	2	3
35. Because of my drinking, I have not had the kind of life that I want.	0	1	2	3
36. My drinking has gotten in the way of my growth as a person.	0	1	2	3
37. My drinking has damaged my social life, popularity, or reputation.	0	1	2	3
38. I have spent too much or lost a lot of money because of my drinking.	0	1	2	3
39. My drinking has damaged my social life, popularity, or reputation.	0	1	2	3
40. I have spent too much or lost a lot of money because of my drinking.	0	1	2	3
Now please indicate whether these things have happened to you in the last 3 months.				
Has this happened to you in the LAST 3 MONTHS? Circle one answer.	No	Almost	Yes, Once	Yes, More than Once
41. I have been arrested for driving under the influence of alcohol.	0	1	2	3
42. I have had trouble with the law (other than driving while intoxicated) because of my drinking.	0	1	2	3
43. I have lost a marriage or a close love relationship because of my drinking.	0	1	2	3
44. I have been suspended/fired from or left a job or school because of my drinking.	0	1	2	3
45. I drank alcohol normally, without any problems.	0	1	2	3
46. I have lost a friend because of my drinking.	0	1	2	3
47. I have had an accident while drinking or intoxicated.	0	1	2	3
48. While drinking or intoxicated, I have been physically hurt, injured, or burned.	0	1	2	3
49. While drinking or intoxicated, I have injured someone else.	0	1	2	3
50. I have broken things while drinking or intoxicated.	0	1	2	3

Patient ID # \_\_\_\_\_

Session # \_\_\_\_\_

MMC NAME \_\_\_\_\_

Date \_\_\_\_\_

## Medical Management Checklist (Initial Session)

Session start time: \_\_\_\_\_ (hr:min a.m./p.m.)

**Completed?\***

- |  | Yes | No |
|--|-----|----|
| 1. <b><u>Structuring statement:</u></b> Describe MMC's role, # & length of MM sessions   | Yes | No |
| 2. Present to patient his/her medical status   | Yes | No |
| <i>Vitals -- BAC _____ T _____ P _____ B/P _____ / _____ Wt _____ lbs</i>  | Yes | No |
| <i>Ask about current medications &amp; pre-existing somatic complaints</i>   | Yes | No |
| <i>Review with patient:</i>  | Yes | No |
| <i>Lab results -- AST _____ ALT _____ GGT _____ MCV _____</i>  |     |    |
| <i>Other abnormal results:</i>   |     |    |
| <i>Other medical problems from alcohol use:</i>  |     |    |
| 3. Briefly explain to patient how alcohol affects the liver & other organs   | Yes | No |
| 4. Present to patient his/her drinking pattern and hazardous alcohol use   | Yes | No |
| 5. Present to patient each DSM alcohol dependence symptom that s/he has  | Yes | No |
| 6. Ask patient for two (2) goals for treatment:  | Yes | No |
| a.   |     |    |
| b.   |     |    |
| 7. Summarize patient's medical probs, drinking level, dependence dx  | Yes | No |
| 8. Recommend abstinence to patient; discuss its possibility  | Yes | No |
| 9. Present patient reasons for taking medication / describe study med/<br>dosing schedule/ possible side effects/ importance of adherence/<br>returning pills/ emergency procedures. | Yes | No |
| Also, remember to distinguish med from disulfiram & detox meds   | Yes | No |
| 10. Recommend support groups as an aid to change   | Yes | No |
| 11. Schedule/verify next session   | Yes | No |

Session end time: \_\_\_\_\_ (hr:min a.m./p.m.)

\*Circle "Yes" or "No" to indicate whether the line item has been completed.

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Patient ID # \_\_\_\_\_

Session # \_\_\_\_\_

MMC NAME \_\_\_\_\_

Date \_\_\_\_\_

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## Medical Management (MM) Clinician's Report

### I. Medical Information

A. The most recent record of your blood pressure was: \_\_\_\_/\_\_\_\_

B. Your liver enzymes and bilirubin are at the following levels (from laboratory reports\*):

		<u>Female</u>	<u>Male</u>
AST (SGOT): _____	Normal Range	____ IU/L	____ IU/L
ALT (SGPT): _____	Normal Range	____ IU/L	____ IU/L
GGT (GGTP): _____	Ranges	____ IU/L	____ IU/L
Bilirubin: _____	Normal Range	____ MG/DL	____ MG/DL

\*Don't forget to explain the significance of enzyme/bilirubin elevation, if applicable.

C. Other abnormal lab values: (from Clinical laboratory form)

a). \_\_\_\_\_ c). \_\_\_\_\_

b). \_\_\_\_\_ d). \_\_\_\_\_

D. You have the following drinking – related medical symptom(s)/condition(s): (from Clinical Chart)

a). \_\_\_\_\_ c). \_\_\_\_\_

b). \_\_\_\_\_ d). \_\_\_\_\_

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Patient ID # \_\_\_\_\_

Session # \_\_\_\_\_

MMC NAME \_\_\_\_\_

Date \_\_\_\_\_

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## Medical Management (MM) Clinician's Report (continued)

### II. **Alcohol Use** (Fill in blanks from TLFB or other drinking measure)

On average, you drink \_\_\_\_\_ days/week.

On average, you drink \_\_\_\_\_ drinks per drinking occasion.

Notes:

### III. **Consequences of Drinking**

*(Note: From DrInC (See MMC#1a). Discuss up to 3 items to which the patient responded "yes")*

1.

2.

3.

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Patient ID # \_\_\_\_\_

Session # \_\_\_\_\_

MMC NAME \_\_\_\_\_

Date \_\_\_\_\_

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## Medical Management (MM) Clinician's Report (continued)

### IV. Diagnostic Information

You have the following symptoms of alcohol dependence:  
[Check below "yes" or "no" for each symptom from Dx Interview.]

- |   |     |    |
|---|-----|----|
| a) When you start drinking, you end up drinking more, or longer than you planned.                                   | Yes | No |
| b) You have tried to, or wanted to, cut down or stop drinking alcohol.  | Yes | No |
| c) You have spent a lot of time drinking or being hung over.  | Yes | No |
| d) You have given up important social, occupational, or recreational activities because of alcohol use.             | Yes | No |
| e) You have continued to drink even though alcohol has caused, or made worse psychological or physical problems.    | Yes | No |
| f) You have an increased tolerance to alcohol.  | Yes | No |
| g) You have experienced withdrawal symptoms when you cut down or stopped drinking.                                  | Yes | No |
| h) Your Dx Interview says you meet criteria for alcohol dependence. (At least three symptoms must be checked "YES") | Yes | No |

Notes:

### V. Patient Treatment Goals:

Patient ID # \_\_\_\_\_

Session # \_\_\_\_\_

MMC NAME \_\_\_\_\_

Date \_\_\_\_\_

## Medication Adherence Plan

### I. Examine Patient's History of Medication/Vitamin-Taking Practices

#### A. Determine Patient's Experience with Pill-Taking

*For each item below, check a "Yes" or "No" response (Y/N). If "Y", indicate in the next column if patient was successful (Y/N) at taking the pills under the conditions specified. If the patient has not had the opportunity to experience such an event, check (N/A).*

		Patient Response	Was Patient Successful
1.	Have you ever been asked to take or have you ever taken any pills on a daily basis?	Y N	Y N N/A
2.	Have you ever been asked to take or have you ever taken more than one pill at the same time on a daily basis?	Y N	Y N N/A
3.	Have you ever been asked to take or have you ever taken pills at the same time each day for 3 months or more?	Y N	Y N N/A
4.	Have you ever been asked to take or have you ever taken pills from a blister card?	Y N	Y N N/A
5.	Do you typically carry pills on or with you?	Y N	Y N N/A
6.	Have you ever been asked to take prescribed medications until all pills were gone?	Y N	Y N N/A

Notes:

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Patient ID # \_\_\_\_\_

Session # \_\_\_\_\_

MMC NAME \_\_\_\_\_

Date \_\_\_\_\_

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## Medication Adherence Plan (continued)

### B. Review Common Reasons for Pill Nonadherence (optional – to be used when appropriate per patient; however, suggested use is with all patients at MM Initial Session)

Ask patient, "Might any of the following common situations be problems for you when taking medication?" (Circle number next to any that apply)

- |   |   |
|---|---|
| 1. Forgets to take or loses medications   | 6. Desires to drink or "get high"               |
| 2. Worries about side effects   | 7. Tires of taking pills every day              |
| 3. Believes he/she is taking placebo  | 8. Disagrees about having an alcohol disorder   |
| 4. Has misinformation about medications (e.g., expects instant changes in drinking) | 9. Feels like he/she no longer needs medication |
| 5. Has never liked taking pills – even aspirin                                      |   |

***Tell patient, "If any of these situations occur, please talk to me about it."***

Notes:

### C. Discuss Successful Pill-Taking Strategies

List any pill-taking strategies that the patient uses/has used and were successful. If the patient has no prior pill-taking experience, have him/her think of strategies for remembering to take pills and list them here:

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Patient ID # \_\_\_\_\_

Session # \_\_\_\_\_

MMC NAME \_\_\_\_\_

Date \_\_\_\_\_

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## Medication Adherence Plan (continued)

### D. Summary and Recommendations

Based on patient responses to above Medication Adherence questions, check number below that best applies to this patient:

- \_\_\_ 1. Experienced and successful with daily pill-taking. May not need a new plan.
- \_\_\_ 2. Experienced but has NOT been successful with daily pill-taking. Requires a comprehensive plan with continual re-evaluation.
- \_\_\_ 3. No experience with daily pill-taking. Requires a basic plan for pill-taking.

### VI. Personalized Medication Adherence Plan

Record date: _____ / _____ / 20____ Note: This plan can be revised as needed. Month Day Year
---

Patient ID # \_\_\_\_\_

Session # \_\_\_\_\_

MMC NAME \_\_\_\_\_

Date \_\_\_\_\_

**Medical Management Checklist (Follow-Up)**

Session start time: \_\_\_\_\_ (hr:min a.m./p.m.) **Completed?\***

1. Opening statement -- “how have you been?” Yes No

2. Evaluate patient’s medical status with patient Yes No

Vitals-- BAC \_\_\_\_ T \_\_\_\_ P \_\_\_\_ B/P \_\_\_\_/\_\_\_\_ Wt \_\_\_\_ lbs Yes No

Problems, adverse events: Yes No

New current medications: Yes No

Update: Yes No

Lab results-- AST \_\_\_\_ ALT \_\_\_\_ GGT \_\_\_\_ MCV \_\_\_\_

Other abnormal results:

Other medical problems from alcohol use:

3. Ask patient about drinking to determine patient’s drinking status Yes No

4. Ask patient if the prescribed medication was taken as directed Yes No

5. Determine patient’s status (answers to #3 & 4 above) (circle only one): Yes No

Abstinent/Adherent

Non-Abstinent/Adherent

Abstinent/Non-Adherent

Non-Abstinent/Non-Adherent

6. Provide direct advice based on patient’s status (1 of 4 dialogues) Yes No

7. Patient change since in treatment? (circle only one) Yes No

Improved No/ Minimal Change Worse

8. Ask patient about/ encourage support group attendance Yes No

9. Remind patient how medication works & promote continued use Yes No

10. Encourage/praise patient’s efforts Yes No

11. Schedule/verify next session Yes No

Session end time: \_\_\_\_\_ (hr:min a.m./p.m.)

\*Circle “Yes” or “No” to indicate whether the line item has been completed.

Patient ID # \_\_\_\_\_

Session # \_\_\_\_\_

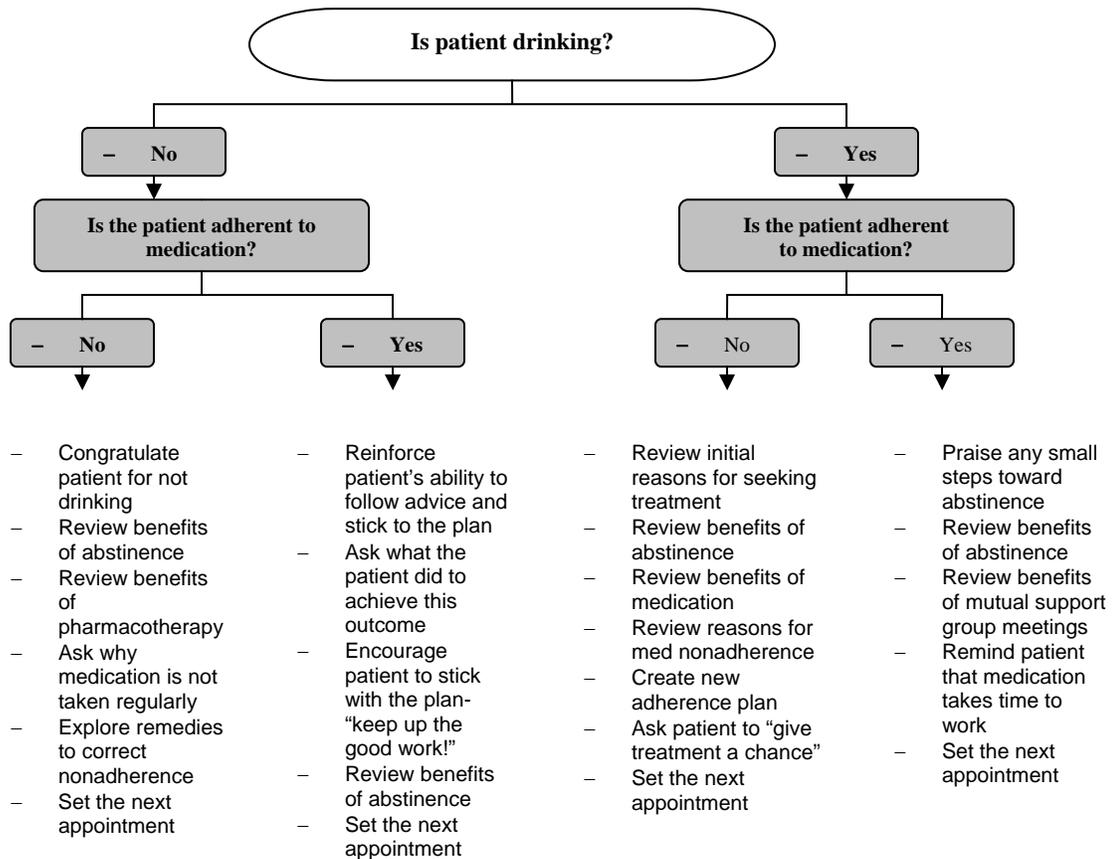
MMC NAME \_\_\_\_\_

Date \_\_\_\_\_

**MM Follow-up Session Dialogue Flowchart**

(Adapted from "Helping Patients Who Drink Too Much: A Clinician's Guide", National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, (updated 2005), p. 22; www.niaaa.nih.gov/guide)

**Put checks in the boxes re: dialogue that occurred for MM session**



Other recommendations (e.g. side effects management, new adherence plan): \_\_\_\_\_

Follow-up:      -Continue the current treatment plan  
                   -Change the treatment plan as follows: \_\_\_\_\_

                  -Refer for medical evaluation

Next appointment date: \_\_\_\_\_



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Patient ID # \_\_\_\_\_

Session # \_\_\_\_\_

MMC NAME \_\_\_\_\_

Date \_\_\_\_\_

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## Medical Management Information for the Patient

\*\*\*\*\*Clinician, please list information on local mutual help groups, such as, AA and secular support groups

Patient ID # \_\_\_\_\_

Session # \_\_\_\_\_

MMC Name \_\_\_\_\_

Date \_\_\_\_\_

*The purpose of this form is to provide a reporting mechanism that can be rapidly circulated each "day-of-session" among the research-treatment team about the patient's drinking and pill-taking behaviors, thus, preventing a patient from reporting differently among staff.*

### Medical Management Communication Form

Time period includes: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ to \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
last day TLFB collected day prior to session

#### ALCOHOL USE:

Has patient been drinking since last session? yes no

***If yes***, how many days drinking? \_\_\_\_\_ / \_\_\_\_\_ # days heavy drinking? \_\_\_\_\_  
# days drinking / total # days since last session

#### MEDICATION ADHERENCE:

Did patient *report* taking all pills as prescribed? yes no

***If no, or if there are unresolved discrepancies between the patient's report and blister card***, please explain here:

What was the adherence rate? \_\_\_\_\_ / \_\_\_\_\_ = \_\_\_\_\_ % adherence  
# pills taken / total # pills prescribed since last session

Signature of RA: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

#### MM CLINICIAN:

Does patient's report agree with information on this form? yes no

***If no***, please speak with the patient about it and notify the RA that they should talk with the patient in order to correct the misinformation.

Signature of MM Reviewer: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

## **EXAMPLE of: Study Fact Sheet for MM Clinician**

**NOTE: Research staff should prepare a fact sheet for the MM clinician similar to the sample below that summarizes the main features of the study**

### **Study Title**

**[Name of investigated product]** for the treatment of alcohol dependence

### **Study Purpose**

The primary objective of this study is to assess the efficacy of **[Name of investigated product]** in reducing the weekly percentage of days of heavy drinking (5 or more drinks per drinking day for men, 4 or more drinks for women) in alcohol dependent subjects who frequently consume more than 10 drinks per drinking day for men and 8 for women. Secondary objectives assess other measures of the effects of **[Name of investigated product]** on reduction of alcohol use as well as effects on psychological assessments during Study Days 15 through 77 and safety throughout the study in this very heavy drinking population as compared to placebo.

### **Study Duration**

Subjects are scheduled to receive MM for a total of 9 sessions beginning at the randomization visit. The final in-clinic visit will occur during week 13. Subjects who discontinue study treatment prematurely should be brought back a final evaluation, at the time of treatment discontinuation and at week 13.

### **MM Session Schedule**

There are nine sessions total: Weeks 1, 2, 3, 4, 6, 8, 10, 12, and 13. Two additional in-clinic visits are permitted if 1) the subject has concerns either about the medication or his/her drinking and wishes to be seen at a time other than the next scheduled in-clinic visit, or 2) the subject has been absent from the study for 2 or more weeks and wishes to resume regular participation before the next scheduled visit.

### **Medication Packaging**

Configuration of tablets for blister packaging will be identical for each day. Each day will consist of 5 blisters with four blisters containing a 50 mg tablet and one blister containing a 200 mg tablet. Each blister pack will contain a 10-day supply.

## Timing of Doses

Study medication is taken at bedtime. Each day's dose is taken at one time.

## Procedure for Dispensing Medication

1. A medical professional will dispense medication at MM sessions.
2. Each blister pack will contain a 10-day supply of **[Name of investigated product]** or identical matching placebo
3. Dose titration: The dose will be titrated up over the first 2 weeks after randomization up to a target dose of 400mg as tolerated. Study med is taken once daily **at bedtime**. An additional week of titration is permitted at the medical clinician's discretion. Caution subjects about performing activities that require alertness (i.e. driving a car) until certain that study medication does not affect them adversely.
4. Maintenance: Day 15 through 77: up to 400mg as tolerated (dose must be minimally 50mg /day to be considered on maintenance dose). Each day will consist of 5 blisters with four blisters containing 50mg/placebo and one blister containing 200mg/placebo tablet.
5. Dose taper: Day 78 through 84: dose taper is at a schedule determined by the investigator and occurs over the last 7 days. In the case of a drug related AE, the medical clinician will evaluate the subject to determine whether the investigational product should be discontinued immediately or tapered prior to discontinuation.
6. Dose adjustments: Maximum dose tolerated is determined by the medical clinician with 50mg per day as the lowest acceptable maintenance dose.

## Missed Dose

Instruct subject to take the study medication at the last dose he/she was taking before stopping. If one dose is missed, instruct the subject to wait until bedtime to take the dose and not to double up doses. If study medication hasn't been taken for 7 or more days, reinstitute study medication using a schedule deemed appropriate to the clinical situation and the subject's prior response (may require re-titration). If a subject hasn't taken study medication for 4 or more weeks, complete laboratory retesting is required.

## Emergency Cards

A wallet card identifying the subject as participating in the study will be given. This card lists contraindicated medications. The card will provide the name and 24-hour phone number of the site investigator to be contacted in the event of an emergency. The card will instruct the non-study medical clinician rendering emergency care to contact the study medical clinician and inform him/her about the care.

## Procedure for Handling Side Effects

1. Listen to subject complaints seriously.
2. Rule out any serious concomitant medical disorders.
3. Rule out serious drug-related adverse experiences.
4. Ask the patient if he/she has recently used alcohol or other drugs. Rule out alcohol or drug abuse as contributors to presenting complaints. Ascertain what strategies the subject has used to manage the presenting symptom(s) and the degree of relief obtained, if any.
5. Reassure the patient that some of the adverse medication experiences tend to be transient and that you will work with them to maintain their safety and comfort.

## Procedure for Handling Adverse Events

Note: Advise subjects that orthostatic hypotension is more likely to occur during the initial 3-5 days of dose titration; this may also be the case with drowsiness.

1. Headaches: subject should take medication of choice for headaches, i.e. ASA, ibuprofen
2. Daytime drowsiness, sleepiness: inform subject that this usually resolves within a few days. Give usual precautions about operating machinery or driving. If it persists, consult with medical clinician about decreasing study medication dose or prolonging titration. Bedtime drowsiness may actually help common alcohol-induced insomnia.
3. Dizziness, syncope: discuss with study medical clinician about decreasing study medication dose; may consider increasing dose again after several days.
4. Orthostatic hypotension: discuss with study medical clinician; return to previous dose of study medication; lengthen time of titration
5. Dry mouth: use hard candy, increase non-alcoholic fluids
6. Constipation: discuss foods to increase fiber, increase water intake, possible use of Milk of Magnesia
7. Dyspepsia: suggest the use of Pepto-Bismol
8. Seizure: discuss with study medical clinician
9. Symptoms of infection (i.e., fever, pharyngitis): perform a CBC and WBC differential count.
10. Agranulocytosis: if the absolute neutrophil count (ANC) is  $<1.5 \times 10^9/L$ , repeat test as soon as possible. If the repeated ANC remains below this level, the subject will be instructed to discontinue the study medication. Weekly CBC and differentials will continue until counts recover.

## Situations Requiring Medication Discontinuation

1. Pregnancy.
2. Contraindicated medications: if this occurs while taking study medication, the subject will stop taking study medication. Medications for pain are allowed without discontinuation.
3. Elevated liver enzymes: ALT/AST >3X normal will have the lab repeated within 1-2 weeks. If repeated lab is still >3X normal, the study medication will be stopped. If the repeat values is <3X normal but still elevated, the subject should be monitored using clinical judgment.
4. Elevated bilirubin: subjects whose bilirubin is 2 or more times normal.
5. Elevated blood glucose: if 2 hour + fasting blood glucose is >120 mg/dL, repeat  $\geq 8$  hour fasting blood glucose test. If the glucose level on repeat test is >100 mg/dL, the subject has either impaired glucose tolerance or presumed diabetes. Subjects in either category will be discontinued from receiving study medication and will be referred to their treating medical clinician for further evaluation.
6. Elevated triglycerides: subjects whose  $\geq 2$  hour fasting blood triglyceride level is >400 mg/dL will have a repeat  $\geq 8$  hour fasting triglyceride analysis. If repeated result is >350 mg/dL, the subject may be at increased risk for pancreatitis and will be discontinued from study medication. The subject will be referred to his/her treating medical clinician for further evaluation.
7. Dyskinesia or neuroleptic malignant syndrome.
8. Repeated absolute neutrophil count (ANC) is  $<1.5 \times 10^9/L$ .
9. Physical illness: subjects will be removed from study medication if they have a disabling condition that precludes them from taking the study medication.
10. Any AE, which in the opinion of the investigator mandates the discontinuation of study medication.

## Situations Requiring Discontinuation from All Study Treatment

These subjects will be discontinued from both the study medication and MM and referred to an appropriate level of care. They will still remain a part of the research sample and will be followed and assessed regularly.

1. Clinical deterioration: subjects whose alcohol problem worsens, and, in the opinion of the site medical staff, require a more intense level of care than provided in the study.
2. Psychiatric crises: acute psychosis, suicidal or homicidal ideation, hospitalization for psychiatric symptoms.

3. Absence from the protocol due to confinement in a controlled environment (i.e. hospital or jail): if less than 2 weeks, the subject can resume full participation in the trial. Before resuming medication, the subject should be assessed by the study medical clinician for appropriateness. If a subject is in a controlled environment for >2 weeks, resumption of participation is at the discretion of the investigator.

## **Procedure for Adding Concurrent Medications**

1. Medication for headache (i.e., ASA) is allowed.
2. Subjects should be regularly reminded to report any concurrent medications they are taking, including over-the-counter preparations, vitamins, and herbal supplements.
3. Subjects must have permission from site PI to take prescription or over the counter medication.
4. Subjects should check with the PI before taking any new medication that is prescribed.

## **Non- Allowed Concomitant Medications, etc.**

Oral antifungals: ketoconazole, itraconazole, fluconazole

Macrolides: erythromycin, clarithromycin, etc.

Hydantoin anticonvulsants: phenytoin, mephenytoin, ethosuximide

Antihypertensives: beta blockers, alpha adrenergic agents, & calcium channel blockers

Sedating antihistamines: diphenhydramine, hydroxyzine

Hypnotics

Antipsychotics

Psychomotor stimulants

Anti-anxiety agents (except for trial prescribed benzodiazepines for the management of alcohol withdrawal)

Naltrexone

Acamprosate

Topiramate

Disulfiram

Grapefruit products

St. John's wort

## **Procedure for Managing Subjects Who Request Treatment Outside of the Study**

The medical clinician should follow the steps below for problematic subjects:

1. Employ MM strategies, such as suggesting the subject attend more AA/support meetings.
2. Subjects requesting additional formal help for non-crisis psychiatric matters (marital problems, work issues) should be encouraged to postpone such activity until their study participation is concluded. Attendance at self-help support groups is encouraged. Remind subjects that it is common for ancillary problems such as marital or parenting issues to arise during the course of treatment; such problems

- might eventually be resolved or reduced if he/she maintains abstinence. Review these matters at the end of the subject's treatment but focus primarily on MM-related concerns (i.e., medication non-adherence, side effects, and support for abstinence).
3. The PI should be involved if clinical deterioration is an issue.
  4. If the subject is struggling with concrete problems such as housing, unemployment, or financial matters, refer for help.

### **Preparing for the Final MM Session**

As soon as the MM clinician feels he/she has engaged the subject in the treatment and has had several productive visits, the MM clinician needs to begin to anticipate, with the subject, what will occur at the end of the research treatment period. Before the final visit, the MM clinician should discuss with the subject what type of treatment, if any, the subject may want to pursue following completion of the research treatment trial. The MM clinician should inform the subject that he/she can not continue treatment with the MM clinician after the scheduled treatment ends. The MM clinician should ask the subject about his/her thoughts about continuing treatment or not and use best clinical judgment in discussing this issue and in recommending future treatment. The MM clinician should consider the subject's current clinical condition and wishes when making this recommendation.