

Monitoring Center Procedures

Table of Contents

E.1. Medical Management (MM).....	E-3
Certification.....	E-3
Purpose	
Pre-certification	
On-site Training and Preparation	
Cases Used for Certification	
Role-play Scenarios	
Provisional Certification	
Criteria for Provisional Certification on Initial Session	
Criteria for Provisional Certification of Follow Up Sessions	
Monitoring.....	E-6
Purpose	
Session Record Form data	
Selection of Sessions	
Coding Procedures	
Likert Scale of Coding Scores	
Subscale Standards	
Informative	
Direction	
Authoritativeness	
Warmth	
Protocol	
(Avoiding) Non-protocol	
Overall	
Adherence Checklists	
Tape Issues	
Feedback	
Red-Line Warning	
Red-Line	
Coder's Checklist for Initial Visit	
Coder's Checklist for Follow Up Visit	
Tape Management.....	E-16
Purpose	
Recording of Sessions	
Quality check of recordings requested by Monitoring Center	
Proper Labeling of Tapes	
Tape Requests	
Proper Packaging and Shipping Information	
Tape Maintenance	
Blank Tape Request	

E.2. Combined Behavioral Intervention (CBI).....	E-19
Certification.....	E-19
Purpose	
Pre-certification	
On-site Training and Preparation	
Pre-Screening	
Cases Used for Certification	
Practice, non-research participants	
Role-play Scenarios	
Provisional Certification	
Monitoring.....	E-22
Purpose	
Session Record Form data	
Selection of Sessions	
Coding Procedures	
Likert Scale of Coding Scores	
Subscale Standards	
Non-specific/Interpersonal	
Direction	
Empathy	
Motivational Interviewing Style	
Protocol	
Overall	
Client Subscale Standards	
Affect	
Cooperation	
Interactive Element	
Adherence Checklists	
Tape Issues	
Feedback	
Red-Line Warning	
Red-Line	
Tape Management.....	E-28
Purpose	
Recording of Sessions	
Quality check of recordings requested by Monitoring Center	
Proper Labeling of Tapes	
Tape Request	
Proper Packaging and Shipping Information:	
Tape Maintenance	
Blank Tape Request	

E.1. Medical Management (MM)

Certification

It is important to have at least two staff per site trained to conduct MM sessions at all times. Even if one staff will be providing the MM intervention only as backup, this person must be trained and certified. Before clinicians may see randomized participants in the main trial, they will be certified by the Monitoring Center. A minimum of two post-training cases per therapist will be required for certification. An MM clinician will be certified when the Training Coordinator determines that he or she is adhering to treatment procedures as described in the MM clinician manual. Additional practice cases may be required prior to certification.

Purpose

Before clinicians may see randomized participants in the main trial, they must demonstrate they are able to conduct sessions in accordance with the MM or CBI manual and COMBINE protocol.

Pre-certification

The site must notify the Monitoring Center about the MM practitioner candidate before certification begins. The site along with the Monitoring Center will establish a time line in which certification process will take place. The Monitoring Center will send a copy of the “Information for potential MM Practitioner” to the candidate. The candidate must read and sign this form and it must be returned to the Monitoring Center before any feedback will be sent. The Monitoring Center will request that the CC send a therapist assessment packet to the candidate. The completion of this is optional. Once completed, the packet should be sent to the Monitoring Center.

On-site Training and Preparation

Prior to the taping of sessions to be used for certification, the MM practitioner candidate should have studied the protocol (either Main Trial or Pilot 3 as appropriate), the Clinician Report Forms (CRFs) relating to each MM session, the MM manual, and reviewed the MM videotapes. The candidate should become familiar with the site specific procedures associated with the MM condition such as how to get the CRF and other paperwork necessary for the initial session, who is responsible for taking vital signs, who is responsible for the pill count form, etc. In addition, the candidate is encouraged to complete several practice sessions prior to taping.

Cases Used for Certification

For certification, the MM practitioner candidate must be evaluated on two full cases. A full case includes an initial session and four follow ups representing all forms of clinical presentations (e.g., abstinent/compliant; abstinent/non-compliant; non-abstinent/compliant; non-abstinent/non-compliant).

Role-play Scenarios

Candidates may be certified with Pilot 3, Cell 10 participants. If these participants are not available, candidates may be certified through role-play scenarios. The Monitoring Center will send the role-play scenarios to the site upon notification that a candidate is seeking certification. Candidates seeking certification with role played scenarios exclusively will be asked to submit 5 tapes each for 2 “pseudo patients”. Each role-play scenario will include an initial session along with all four possible clinical presentations, e.g., abstinent/compliant; abstinent/non-compliant; non-abstinent/compliant; non-abstinent/non-compliant. The MM practitioner candidate should be made to take the same level of responsibility for insuring all the necessary materials are available for the role-play session as s/he would do if this were a real patient. To be certified, a candidate must receive an overall rating of 5 (on a scale of 1 – 7) on all submitted sessions.

MM practitioner candidates should not be informed in advance of the content of the role-plays. It is appropriate to indicate that their sessions with the person playing the role of an MM patient will be audio taped. For cross-site consistency and fairness, the role-plays should be conducted as described here.

To complete and audiotape the MM role-plays the site will need audiotape recorder with microphone(s) sufficiently sensitive to record both voices clearly. The set up should be tested in advance. The site will also need a minimum of one, and for candidates who will be certified based on only role plays, two different “speakers” who will interact with the candidates. If possible, the two speakers should be of opposite gender (one male, one female) and be unknown to the candidate.

The basic steps to follow are:

1. Identify the two speakers who will participate in the role-plays. These should preferably be the same speakers in the same role for each candidate at your CRU. Give the role-play instructions to the speakers who will be playing the role of the patient with sufficient time for them to review and become familiar with the materials.
2. Try a brief practice run with the speakers to (1) make sure that the tape recorder makes a clear tape and (2) increase the credibility of their portrayal of the patient. This practice can be as simple as having the PC or other identified staff member ask the speaker if they have any questions or concerns about their role-play to having the speaker practice one or more of the scenarios. However, the MM practitioner candidate should not partake in any practicing that the speaker does because the candidate should have no knowledge about the scenario.

3. Audiotape the MM candidate conducting the required scenario(s) with the speaker(s). Label each audiotape and with the staff ID #, the first name of the pseudo patient, and the type of session.
4. The initial session and all four follow up scenarios may be recorded at the same time. This might take 2 – 3 hours depending on the length of the sessions and allowing for breaks. It is not required (or recommended) that both role-plays or all relevant sessions be recorded on the same day.
5. Send completed MM tapes and materials to:

Denise Ernst, MA
COMBINE, UNM CASAA
2650 Yale SE
Albuquerque, NM 87106
6. Tapes will be reviewed in the order in which they are received. However, priority will be given to certification tapes over main trial tapes. Feedback will be sent via e-mail.

Provisional Certification

A provisional certification is possible in extreme and emergency situations to insure that all sites have at least one MM therapist able to accept patients when the site is approved to recruit Main Trail patients. It is up to the Monitoring Center to determine if provisional certification is granted and for what types of sessions it has been granted for. After provisional certification has been granted, the MM practitioner must still complete the requirements outlined in Medical Management Certification to be fully certified. Partial provisional certification may be granted in cases where the MM practitioner is unable to demonstrate acceptable competence in either only initial sessions or only in follow up sessions. In this case, the MM practitioner may be provisionally certified for the type in which they do demonstrate acceptable competence (i.e., for either only initial sessions or only follow-up sessions). Provisional certification may also be granted in situations where the site is seeing patients and there is no MM practitioner certified at the site. In order for provisional certification to be granted, the Monitoring Center must have received tapes for the MM practitioner, and the MM practitioner must have been through a majority of the site's training. The sessions in which the MM practitioner has been recorded for may be either Pilot 3, Cell 10 patients or role-play scenarios. If an MM practitioner has been granted provisional certification, a timeline and a plan must be established by the Monitoring Center in agreement with the practitioner to complete full certification. The Monitoring Center will maintain a list of all certified staff.

Criteria for Provisional Certification on Initial Session

Provisional certification may be granted for only initial sessions. In order to be provisionally certified for initial sessions the MM practitioner must have passed with a rating of 5 or greater on two initial sessions.

Criteria for Provisional Certification of Follow Up Sessions

Provisional certification may be granted for only follow up sessions. In order to be provisionally certified for follow up sessions the MM practitioner must have passed with a rating of 5 or greater on all types of clinical presentations (e.g., abstinent/compliant; abstinent/non-compliant; non-abstinent/compliant; non-abstinent/non-compliant).

Monitoring

Purpose

Ongoing performance monitoring of the COMBINE interventions (both CBI and MM) serves two purposes. First, the process is designed to identify and correct any drift from trial standards determined for each intervention. The process also provides documentation of the fidelity of the interventions such that adherence and discriminability of protocols can be demonstrated in scientific peer review.

Session Record Form data

There is an ongoing review and rating of selected sessions for each certified practitioner after certification. All sessions are audio-taped, and details of the sessions are recorded on the Session Record Form (SRF). SRFs are entered at each site. The data from the SRFs are retrieved regularly by the Coordinating Center+, and the compiled data from all sites is sent to the Monitoring Center monthly. The data from SRFs are used by the Monitoring Center to identify sessions to be requested for monitoring. The completion and entry of the SRFs must be kept up-to-date by the sites for current and timely feedback.

Selection of Sessions

Overall, the Monitoring Center will request one tape for every two MM cases. Tapes will be selected so that all types of clinical presentations (abstinent/compliant, non-abstinent/compliant, abstinent/non-compliant, non-abstinent/non-compliant) at all times of treatment (initial session, follow-up weeks) will be monitored. There may be additional sessions requested from a practitioner's first cases following certification or if there is some concern or question about performance. The Monitoring Center will chose all sessions to be monitored and will also chose replacements for any sessions not available.

Coding Procedures

All ratings are based on a 7-point Likert scale. Ratings are based primarily on the practitioner's own behavior during the session. A single grade is assigned to every subscale, and every subscale is graded. Ratings are given in whole numbers. The coder should record notes on the performance of the practitioner

during the session. At the end of the session, these notes are compiled to help the coder determine a global rating for the subscale. The practitioner begins the session with a rating of 6 on each item. This rating will change in accordance to the notes made regarding each item. The notes regarding the practitioner's performance may be in half points or in whole points, however, the global rating must be in whole numbers. In the notes, if only a half point has been added or subtracted, round to the whole number one. However, if 1.5, 2.5, 3.5, etc. have been added or subtracted round to the lowest whole number. For example, a 1.5 rounds to 1, 2.5 rounds to 2. So, only the first half rounds up, any following halves round down. For any digression made by the practitioner, only detract from one area. For example, if in the initial session the SAFTEE is done after the first dose of medication is delivered, the coder should detract from direction only and not from protocol too.

Likert Scale of Coding Scores

- 1 = Absence of this characteristic
- 2 = Some ability to convey this characteristic
- 3 = Inconsistent evidence of this characteristic but evidence that therapist is attempting to achieve
- 4 = Some need for improvement on this characteristic
- 5 = Acceptable level of this characteristic; therapists may have one or two scores at this level, indicating differences in personality and emphasis in therapeutic approach.
- 6 = Moderate to high levels of this characteristic
- 7 = High levels of this characteristic: top 10% of therapists

Subscale Standards

Informative

Score 6 (Pass): Practitioner communicates information to the participant appropriately and effectively. The information is provided in a way so that it is clear, concise and understandable to the participant. . This includes information about the participant's clinical feedback; the study; action, dosing, and side effects of the medication; self-help organizations.

Score 4 (Marginal Fail): Practitioner fails to provide clear and appropriate information on parts of the treatment elements, or the practitioner provides inaccurate or misleading or irrelevant information.

Score 2 (Fail): Practitioner fails to provide clear and appropriate information for the whole treatment session, or the practitioner provides a great deal of inaccurate, misleading or irrelevant information.

Direction

Score 6 (Pass): Practitioner maintains appropriate control of the session and follows the recommended sequencing. The practitioner provides appropriate structure, moves smoothly through treatment procedures and brings the participant back on task when conversation drifts away to

tangential subjects. The direction of the session moves in a cohesive flow that is logical and builds a case for the treatment.

Score 4 (Marginal Fail): Practitioner does not maintain a consistent structure throughout the session that is in accordance with the adherence checklist. The direction of the session may be disjointed, illogical and hard for the participant to follow. In other instances, the participant may determine the topics of discussion and the practitioner experiences difficulty in returning to the appropriate topic.

Score 2 (Fail): The segments of the intervention are provided in a scattered fashion and the session is severely lacking in cohesion. The participant determines the topics of discussion, and the practitioner follows along wherever the participant goes instead of bringing the participant back to structured agenda.

Authoritativeness

Score 6 (Pass): Practitioner high on authoritativeness give the participant the impression that they have expert advice and suggestions for recovery. They convey confidence in their competence to effectively provide treatment to the participant. The practitioner acts in a professional manner and appears as an expert in the field.

Score 4 (Marginal Fail): Practitioner is lacking in confidence in delivering the treatment elements. The practitioner is only weakly affirmative in his/her suggestions and the treatment, therefore, lacks in impact on the participant.

Score 2 (Fail): Practitioner is unable to convey to the participant confidence in effectively offering treatment. They fail to communicate to the participant "I have expertise in this area and can help you". The practitioner is not affirmative in his/her suggestions to the participant, and the practitioner is, therefore, ineffectual in offering the treatment to the participant.

Warmth

Score 6 (Pass): Practitioner is perceived as warm, friendly, engaged, compassionate, helpful, and concerned.

Score 4 (Marginal Fail): Practitioner presents an impression of being cool, aloof, detached, or unfriendly, showing little overt evidence of helpful concern and compassion during sections of the session or to a moderate degree during the entire session.

Score 2 (Fail): Practitioner presents an impression of being cold, distant, detached, or unfriendly, showing little overt evidence of helpful concern and compassion through the majority of the session or to a severe degree during sections. The practitioner may also appear condescending or judgmental toward the participant.

Protocol

This is the extent to which the practitioner is delivering treatment procedures as prescribed in the MM manual. (The extent to which things *other* than the protocol are also being delivered is covered next). Be particularly careful not to detract from protocol and from some other area for the same digression made by the practitioner. For example, if the practitioner forgets to do a section of the adherence checklist, this detracts from protocol only and not from direction.

In assigning a grade to the protocol performance, the coder is to rely on the completion of all steps outlined in the MM manual. The content of the session should correspond to the procedures in the manual for the initial session and the presenting profile at follow up sessions. These elements include appropriate sequencing of material, clear adherence to the treatment procedures described for this portion of MM, and appropriate use of procedures, forms, and materials. As the practitioner deviates from these elements, the score will be lowered from the starting score of a six. For the majority of cases, the practitioner will be graded based on his/her completion of elements listed in the adherence checklist. However, the score will also reflect sessions that run excessively long or short in time.

(Avoiding) Non-protocol

This is the extent to which the practitioner is delivering appropriate treatment procedures other than those prescribed in the MM manual.

Score 6 (Pass): Practitioner delivers only procedures prescribed in the MM manual.

Score 4 (Marginal Fail): Practitioner delivers treatment procedures not included in the MM manual during sections of the session. Non-protocol procedures may or may not be inconsistent with the overall approach of MM. For example, working of a particular AA "step" in the session, while consistent with MM advice to use self-help, is not part of the MM protocol. The non-protocol score may be lowered as a result of excessive interruption of the session (phone calls, knocks on the door, etc.) or counseling the participant.

Score 2 (Fail): Practitioner delivers treatment procedures not included in the MM manual for large sections of the session.

Overall

The Overall rating summarizes the practitioner's overall skillfulness in this session. It will ordinarily be close to the arithmetic average of the 6 practitioner scales. Participant ratings are not considered in this overall scale score.

MM Coder Adherence Checklists

The Adherence Checklists are used by the practitioner in conducting the sessions and by the Monitoring Center in grading the sessions. The coder adherence checklists attached give the grade weighting connected to each

element of the checklist. The weight described is the maximum that would be added or subtracted from that element. However, the total weight may not be given by the coder on any single element. The overall grade given for a subscale will be determined in part by the weightings of each item and by the judgment of the coder.

Tape Issues

Any problems observed with the tape are to be listed in the feedback form under 'tape issues'. These issues may include mislabeling of the tape, poor quality of the tape, or other issues.

Feedback

The audiotapes of the sessions chosen for monitoring will be listened to and coded by trained coders at the Monitoring Center. The sessions are coded according to standardized procedures (see section B.2.2.3). The coding sheets are then reviewed by the MM Monitoring Coordinator for consistency. If there is any question about the ratings by the Coordinator or if the coder requests, the session is coded by a second coder. The Coordinator sends the coding results to the PC or the site's designee at each site.

If the rating for any dimension falls below criterion (5 on the 7-point Likert Scale), the Monitoring Center will provide written feedback about the session. Additionally, the Coordinator may choose to send written feedback about performance when several sessions have been reviewed in a short period of time. It is the Monitoring Center's policy to review tapes in the order received unless there is a specific reason that other tapes take priority. It is also the policy to monitor more recent sessions first in order that the feedback may be more relevant.

Red-Line Warning

A red-line warning will be issued by the Monitoring Center as a preliminary step prior to red-lining. This warning triggers an intensification of monitoring both recent and new sessions. Priority is given to monitoring these sessions so a determination can be made expeditiously as to whether to proceed to red-lining. The Monitoring Center will request specific tapes to review, and role-play sessions may also be required. In the interim, the MM practitioner may continue to see COMBINE participants, including new participants.

Red-Line

If adherence to protocol drops below the criterion level (average of 5 on a 7-point Likert Scale), a MM practitioner may be red-lined (decertified) by the MM Monitoring Coordinator. The PI and all staff designated to receive feedback at the site will be immediately notified, and a remedial plan will be created and implemented. The MM practitioner is prohibited from beginning new cases until adherence returns to an acceptable level. Session monitoring will increase during this period. Improved adherence may be demonstrated with cases that were

already in treatment at the time of the decertification, or with additional practice cases that will not be included in the main trial data. The MM Monitoring Coordinator must recertify the MM practitioner as consistently adhering to the MM protocol (ratings of 5 or higher) before he or she may see new research participants.

Coder's Checklist for Initial Visit

Weights of Items on Coder's Adherence Checklist for Initial Visit

Participant ID _____ Follow up week _____

Practitioner ID _____ Date _____

Initial MM Visit

When grading, only detract or add to one subscale score for any one event. For example, if an item on the checklist is omitted, subtract from protocol only and not from direction too.

- _____ Introduce yourself and your role, check vitals, give overview and timeline of intervention
1 point maximum.
- _____ Conduct baseline SAFTEE (reference last 90 days)
1 point maximum.
- _____ Complete Concurrent Medication Form (reference last 30 days)
1 point maximum.
- _____ Complete Menstrual Calendar (indicate NA if not appropriate)
1 point maximum.
- _____ Provide Feedback from CRF (Vital Signs, lab results, drinking related symptoms, drinking pattern and consequences, dependence criteria)
2 points maximum.
- _____ Provide Information (importance of the liver and how it works, effects of alcohol, diagnostic information, reasons for abstinence)
2 points maximum.
- _____ Give professional opinion about severity of the problem
1/2 point maximum.
- _____ Recommend abstinence
1 point maximum.
- _____ Ask participant for commitment to abstinence (if participant is unwilling to commit to long-term abstinence, restate the rationale for and seek agreement to abstinence for duration of study)
1 point maximum.

- _____ Explain purpose and function of medications, and provide Medication Information Sheets
1 point maximum.

- _____ Discuss likelihood of side effects and give Patient Instructions for Managing Side Effects
1 point maximum.

- _____ Explain proper medication use (extra doses, 2 hrs between doses, don't crush, can take with food, morning dose always first) and give first dose (allow 20 minutes for observation)
2 points maximum.

- _____ Give Medical Emergency Cards and explain emergency procedures
1 point maximum.

- _____ Provide rationale for and complete Medication Compliance Plan
1 point maximum.

- _____ Briefly review diagnosis, recommendation, and plan
½ point maximum.

- _____ Encourage AA/support group attendance, give list of local meetings
1 point maximum.

- _____ Schedule next visit and discuss 3-day phone call (prepare Day 3 Phone Contact Form)
1 point maximum.

- _____ Complete MM Treatment Coordination Checklist (if appropriate) and Session Record Form

Coder's Checklist for Follow Up Visit

Weights of Items on Coder's Adherence Checklist for Follow Up Visits

Participant ID _____ Follow up week _____

Practitioner ID _____ Date _____

Follow Up MM Visit

When grading, only detract or add to one subscale score for any one event. For example, if an item on the checklist is omitted, subtract from protocol only and not from direction too.

_____ Review Vital Signs and BAC with participant
1/2 point maximum.

_____ Conduct brief assessment of drinking, medication compliance, and general function
1 point maximum.

_____ Complete Concurrent Medication Form
1 point maximum.

_____ Conduct SAFTEE (reference time since last visit) (complete Serious Adverse Event Report, Inactive Status Form, or Active Status Form as needed)
1 point maximum.

_____ Complete Menstrual Calendar (indicate NA if not appropriate)
1 point maximum.

_____ Review new lab results if appropriate; compare with earlier results
1 point maximum.

_____ Check blistercard for missed doses or trouble with medication compliance (complete Medication (Non) Compliance Checklist if indicated)
1 point maximum.

_____ Reinforce and praise progress
1 point maximum.

Session Type: *1 point maximum.*

__1.Abstinent/medication compliant __ 2.Non-abstinent/medication compliant

__3.Abstinent/non medication compliant __4.Non-abstinent/non-medication compliant

Options for review and problem solving; Opportunities for praise and reinforcement

2 points maximum.

- _____ Benefits of abstinence
- _____ Participant's reasons for seeking treatment (from original CRF)
- _____ How the medications work
- _____ Importance of medication compliance
- _____ Suggestions of strategies for abstaining from alcohol
- _____ Suggestions for improving medication compliance

Wrap-up

- _____ Inquire about and encourage AA/support group attendance
1 point maximum.
- _____ Provide support; complete MM Treatment Coordination Checklist, Session Record Form, and MM Follow-up Coordination Checklist (session 12 only)
1 point maximum.

Tape Management

Purpose

The purpose of providing tape management instructions is to help ensure the Sites are able to effectively record sessions, label tapes, and ship tapes. Effective tape management helps maintain quality in tape monitoring.

Recording of Sessions

All Medical Management sessions should be recorded. Prior to actually recording, the Site should test the placement of the recorder within the room of the session to make sure the voices of the MM practitioner and the participant can be heard. The Site should try and limit the amount of background noise heard on the tape (e.g., do not place the recorder next to a heating vent where the fan noises will be recorded as well and might interfere with the audibility of the voices). Other noises that can occasionally make parts of the session inaudible are telephones, cellular phones, pagers and computer noises. Each session recording should start with the practitioner clearly stating his/her MM practitioner ID number, the participant's ID number (in case of role player session, the first name of the pseudo participant. i.e., Gina or Martin), the date, and the week number. Practitioners are also advised to check the quality of recording before the session starts (see below- Quality Check of Recording). The practitioner should avoid pausing the tape during the session. If the tape has to be paused, the reason for the interruption should be stated on the recording.

Quality check of recordings requested by Monitoring Center

The Monitoring Center will send each Site a request for tapes of specific sessions to be monitored. Before tapes are copied and sent to the Monitoring Center, the Site is to check the tapes to ensure that they are of sufficient quality to be coded. Coders must be able to hear and understand both the practitioner and the participant. The Site may record multiple sessions on a tape but only the session requested by the Monitoring Center is to be copied and sent. In case of poor recording, the tape is not to be sent to the Monitoring Center. If the tape is of poor quality, indicate on the MM Tape Request Form (this goes back to the Monitoring Center) that the tape is not available (see below- Proper Packaging and Shipping Information). It is the policy of the Monitoring Center to try to do what they can to hear the tapes. However, if the quality is poor and the coder is having to strain to hear the session, the Site will be notified and the session will not be coded until a good quality audible tape is provided. The original session tapes are kept at the Site. Only copies of the requested sessions are sent to the Monitoring Center.

Proper Labeling of Tapes

Tapes must be properly labeled before they are sent to the Monitoring Center. All tapes and their covers should be labeled with the following information:

1. MM practitioner ID number (i.e., not the name or abbreviation)

2. Participant ID number (in case of role player session, the first name of the pseudo participant. i.e., Gina or Martin)
3. Date of session (i.e., MM/DD/YY)
4. Session week number (i.e., 00 through 16)
5. Session type (i.e., 1 through 7, Initial = 1, Abstinent & Compliant = 2, Non-Abstinent & Compliant = 3, Abstinent & Non-Compliant = 4, Non-Abstinent & Non-Compliant = 5, Medical Attention = 6, Uncertified Practitioner (conducting the session) = 7)

An example of label:

Practitioner ID: 444 Participant ID: 0444444
Session week: 04 Session's date: 04/04/04
Session type: 4

Tape Requests

Tape requests are e-mailed and faxed to the Site project coordinator (PC), unless the Site has identified someone else to receive it. The Monitoring Center will update this information (i.e., tape request receiver) annually. If changes at a particular Site are made between the updates, the Site is to notify the Monitoring Center of those changes.

Proper Packaging and Shipping Information

A copy of the MM Tape Request Form must accompany the package of tapes (i.e., appendix A2). The form provides space to indicate the disposition of all session tapes requested. Please take extra precaution in packaging of the tapes to prevent breakage or other types of damage caused by delivery.

Send completed MM tapes and materials to:

MM monitoring coordinator
Denise Ernst, MA
Nariman Arfai
COMBINE, UNM CASAA
2650 Yale SE
Albuquerque, NM 87106

The Monitoring Center will send acknowledgment to the Site of the receipt of the tapes.

Tape Maintenance

All tapes sent to the Monitoring Center are kept for 12 months. The tapes are then destroyed.

E.2. Combined Behavioral Intervention (CBI)

Certification

It is important to have at least two staff per site trained to conduct CBI sessions at all times. Even if one staff member will be providing the CBI intervention only as backup, this person must be trained and certified. Before clinicians may see randomized participants in the main trial, they will be certified by the Monitoring Center. A pre-screening interview must be passed, and competence with the protocol on a minimum of two post-training cases per therapist will be required for certification. A CBI clinician will be certified when the Training Coordinator determines that he or she is adhering to treatment procedures as described in the CBI manual. Additional practice cases may be required prior to certification.

Purpose

Before clinicians may see randomized participants in the main trial, they must demonstrate they are able to conduct sessions in accordance with the MM or CBI manual and COMBINE protocol.

Pre-certification

The site must notify the Monitoring Center about the CBI practitioner candidate before certification begins. The site along with the Monitoring Center will establish a time line in which the certification process will take place. The site must ensure the CBI practitioner candidate has been through the site's training procedures. This training should include (but not be limited to) having the candidate read the CBI manual and COMBINE protocol, watch CBI session training video tapes, Motivational Interviewing video tapes and have practiced appropriate procedures used during a study session. The CBI practitioner candidate should have read and completed the packet entitled "Information for potential CBI practitioner".

On-site Training and preparation

Prior to certification, the CBI practitioner candidate should have studied the COMBINE protocol (either Main Trial or Pilot 3 as appropriate), the Clinician Report Forms (CRFs) relating to the CBI sessions (PRF, IPI, AASE, DED, What I Want from Treatment, Client Services Request Form), the CBI manual, reviewed the CBI session training videotapes and the Motivational Interviewing videotapes. The candidate should become familiar with the site specific procedures associated with the CBI condition such as client assignment, how to get the materials necessary for the sessions, and how to interact with the MM practitioner.

Pre-Screening

All new potential CBI practitioners must submit two pre-screening interviews to the Monitoring Center in order to be approved for training. The Monitoring Center reviews the pre-screening interviews and either approves the potential CBI

practitioner to go forward with training, or requests further pre-screening interviews. The potential CBI practitioner has two opportunities to pass the pre-screening interview.

Cases Used for Certification

CBI practitioner candidates will be expected to participate in one of two types of certification procedures. The candidate can either see practice patients or conduct role-play sessions. A combination of these two types of participants may also be used. For certification, the CBI practitioner candidate must be evaluated on two full cases. A full case includes Phase 1 (Session 1-MET and Session 2 – PFR), SSO orientation and involvement, Phase 2 (Functional Analysis and Treatment Plan) and Phase 3 (three modules – recommending ASSN, MOOD, MUTU and SARC). Pull-out procedures should be used as appropriate. Certification audiotapes must be sent to the Monitoring Center as they are completed with session record forms and therapist session checklists. The Monitoring Center must be notified of what participants are being used in the certification process (i.e., if the participants are practice clients or role-plays).

Practice, non-research participants

If the informed consent at the CBI practitioner candidate's site allows it, certification may be done with practice clients. Sessions with such clients are conducted as if the client were a Main Trial research participant. The same procedures apply (Phase 1, Phase 2, Phase 3 and Phase 4 within 20 sessions or 16 weeks whichever comes first). No follow up research or therapy sessions will be conducted on such practice clients. Certification will be based on the potential CBI practitioner's performance on phases 1, 2, and 3. To be certified, a candidate must receive an overall rating of 5 (on a scale of 1 – 7) for all of the sessions, and should receive ratings of 5 on protocol scores.

Role-play Scenarios

Candidates seeking certification with role played scenarios exclusively will be asked to submit audiotapes of Phases 1, 2, and 3 for two "pseudo" patients. The CBI practitioner candidate will be evaluated on two role-play scenarios which include Phase 1 (Session 1-MET and Session 2-PFR), SSO orientation and involvement, Phase 2 (Functional Analysis and Treatment Plan) and Phase 3 (three modules – recommending ASSN, MOOD, MUTU and SARC). Pull-out procedures should be used as appropriate. The CBI practitioner candidate should be made to take the same level of responsibility for insuring all the necessary materials are available for the role-play session as s/he would do if this were a real patient. To be certified, a candidate must receive an overall and protocol rating of 5 (on a scale of 1 – 7) on all submitted sessions.

CBI practitioner candidates should not be informed in advance of the content of the role-plays. It is appropriate to indicate that their sessions with the person playing the role of a CBI patient will be audio taped. For cross-site

consistency and fairness, the role-plays should be conducted as described here.

To complete and audiotape the CBI role-plays the site will need audiotape recorder with microphone(s) sufficiently sensitive to record both voices clearly. The set up should be tested in advance. The site will need a minimum of two different “clients” who will interact with the candidates. If possible, the two speakers should be of opposite gender (one male, one female) and be unknown to the candidate.

The basic steps to follow are:

1. Identify the two speakers who will participate in the role-plays. These should preferably be the same speakers in the same role for each candidate at your CRU. Give the role-play instructions to the speakers who will be playing the role of the patient with sufficient time for them to review and become familiar with the materials. (Role play materials are available from the Monitoring Center).
2. Try a brief practice run with the speakers to (1) make sure that the tape recorder makes a clear tape and (2) increase the credibility of their portrayal of the patient. This practice can be as simple as having the PC or other identified staff member ask the speaker if they have any questions or concerns about their role-play to having the speaker practice one or more of the scenarios. However, the CBI practitioner candidate should not partake in any practicing that the speaker does because the candidate should have no knowledge about the scenario.
3. Audiotape the CBI candidate conducting the required scenario(s) with the speaker(s). The CBI candidate should complete any paperwork associated with the session such as the session record form, and required CRFs, and submit them along with the audiotape. Label each audiotape and accompanying material with the staff ID #, the first name of the pseudo patient, date of session and the type of session.
4. All sessions (Phase 1 – Phase 3) may be recorded at the same time (on different tapes). This might take 6-7 hours depending on the length of the sessions and allowing for breaks. It is not required (or recommended) that both role-plays or all relevant sessions be recorded on the same day.
5. Send completed CBI tapes and materials to:

Lisa T. Arciniega, Ph.D.
COMBINE, UNM CASAA
2650 Yale SE
Albuquerque, NM 87106

6. Tapes will be reviewed in the order in which they are received. However, certification tapes are given priority status. Feedback will be sent via e-mail.

Provisional Certification

Provisional certification is possible in extreme and emergency situations to insure that all sites have at least one CBI therapist able to accept patients when the site is approved to recruit Main Trail patients. It is up to the Monitoring Center to determine if provisional certification is granted. After provisional certification has been granted, the CBI practitioner must still complete the requirements outlined in Combined Behavioral Intervention Certification to be fully certified. In order for provisional certification to be granted, the Monitoring Center must have received tapes for the CBI practitioner, and the CBI practitioner must have displayed competence in the majority of the certification tapes.

Monitoring

Purpose

Ongoing performance monitoring of the COMBINE interventions (both CBI and MM) serves two purposes. First, the process is designed to identify and correct any drift from trial standards determined for each intervention. The process also provides documentation of the fidelity of the interventions such that adherence and discriminability of protocols can be demonstrated in scientific peer review.

Session Record Form data

There is an ongoing review and rating of selected sessions for each certified practitioner after certification. All sessions are audio-taped, and details of the sessions are recorded on the Session Record Form (SRF). SRFs are entered at each site. The data from the SRFs are retrieved regularly by the Coordinating Center and the compiled data from all sites is sent to the Monitoring Center on a monthly basis. The data from SRFs are used by the Monitoring Center to identify sessions to be requested for monitoring. The completion and entry of the SRFs must be kept up-to-date by the sites for current and timely feedback.

Selection of Sessions

Overall, the Monitoring Center will request one tape for every CBI case. Tapes will be selected so that all types of clinical presentations (Phase 1, Phase 2, Phase 3 and Phase 4) will be monitored. There may be additional sessions requested from a practitioner's first cases following certification or if there is some concern or question about performance. The Monitoring Center will chose all sessions to be monitored and will also chose replacements for any sessions not available.

Coding Procedures

All ratings are based on a 7-point Likert scale. Ratings are given for both the practitioner and the client's behavior. A single number is assigned to every subscale, and every subscale is rated. Ratings are given in whole numbers. The

coder should record notes on the performance of the practitioner during the session. At the end of the session, these notes are compiled to help the coder determine a global rating for the subscale. The practitioner begins the session with a rating of 5 on each item. This rating will change in accordance to the notes made regarding each item.

Likert Scale of Coding Scores

- 1 = Absence of this characteristic
- 2 = Some ability to convey this characteristic
- 3 = Inconsistent evidence of this characteristic but evidence that therapist is attempting to achieve
- 4 = Some need for improvement on this characteristic
- 5 = Acceptable level of this characteristic; therapists may have one or two scores at this level, indicating differences in personality and emphasis in therapeutic approach.
- 6 = Moderate to high levels of this characteristic
- 7 = High levels of this characteristic: top 10% of therapists

Subscale Standards

Nonspecific/Interpersonal Factors

Nonspecific factors include acceptance, egalitarianism and warmth. Each of these dimensions must be high for therapists to receive a high score on this element.

Acceptance: Therapists high on acceptance should communicate acceptance and respect of the client. This acceptance is person-focused (unconditional positive regard) and should not be confused with acceptance/approval of the person's behavior. Therapists at the low end of the acceptance scale may be perceived as harsh, judgmental, disrespectful or condescending.

Egalitarianism: Therapists high on egalitarianism emphasize by their words and manner the client's personal autonomy, choice and responsibility. They may offer their expertise when asked, or after obtaining the client's permission to inform or advise.

Warmth: Therapists high in warmth are perceived as friendly, engaged, compassionate, helpful, caring and concerned. Therapists at the low end of this scale present an image of being cold, distant, detached or unfriendly. They show little evidence of helpful concern and compassion.

Direction

This element encompasses the therapist's ability to move the conversation toward a desirable goal. Sometimes this goal will encompass protocol material; at other times it will reflect the therapist's movement toward building discrepancy or eliciting a self-motivational statement.

High: Therapists high on direction maintain appropriate control of the therapy session and keep it moving along. Even within periods of

reflecting, there is a direction to the therapist's reflections. The therapist provides appropriate structure with opening statements and moves smoothly through the treatment procedures, brings the client back on task when conversation drifts away to tangential subjects.

Low: Therapists low on direction provide little structure for the session. The client determines the topics of discussion, and the therapists follows wherever the client goes instead of bringing the client back to the structured agenda.

Empathy

The focus here is on the extent to which the therapist understands the client's perspective, and not on warmth, acceptance, genuineness, or identification with the client.

High: Therapists high on this scale are able to attain and communicate an accurate understanding of the client's perceptions, situation, meaning, feelings through high-quality reflective listening. Their manner shows an active interest in and an effort to understand the client's perspective, and their responses actively express an attentive understanding of the client's perspective and experience. They probe to understand more fully, and reflect their understanding back to the client.

Low: Therapists at the low end of this scale show little interest in or appreciation of the client's perspective, little overt understanding or reflection of what the client is experiencing. They evidence little effort at seeking a deeper understanding of the client's perspective. Therapists low in empathy may ask many questions to gain factual information or pursue their agenda, but do not seek to understand the client's own perspective.

Motivational Interviewing style

This is an overall, global rating of the extent to which the therapist manifests the fundamental spirit of motivational interviewing. It should not be regarded as merely an average of the other scales, but rather the coder's judgment of the extent to which the therapist manifests the overall therapeutic style of MI, evidencing a grasp of the "music" and not just the words.

High: Therapists high on this scale manifest a directive, client-centered style of facilitating, coaching and negotiating. Reflections are frequent and complex. The therapist honors and values the client's perspective. There is a naturalness, comfort and loving or artistic quality to the therapist's style. The therapist is attuned to the client and actively "mines" for the client's motivation.

Low: Therapists low on this scale show a lack of the balanced directive, client-centered style, erring on the side of passivity or over control (or both). On the passivity side, the therapist is inattentive to significant client material, and may seem indifferent, isolated, ignoring, preoccupied or detached. On the over controlling side, the therapist may communicate distrust, disrespect, disregard, or simply the pursuit of the therapist's own

agenda without sufficiently involving the client. A critical component of motivational interviewing is the skill of reflective listening, which should be coded in this element.

Within the COMBINE protocol, motivational interviewing style is especially important in Phase I, but should be evident in treatment planning and module completion as well. Therapists should be skillful in implementing the basic procedures of motivational interviewing for Phase I and should remain true to the spirit of MI in Phase II and III. Ambivalence on the part of the client should elicit MI interventions from the therapist at any stage.

Protocol

This element is meant to indicate how well the therapist is adhering to the CBI manual.

High: Therapists high on this scale deliver treatment procedures as described in the CBI therapist manual. They are familiar with the sequencing of the material and exhibit clear adherence to the treatment. They are often able to “fit” the client’s concerns into the module at hand and are good at integrating the client’s examples and experiences to the modules being taught. Therapists high on protocol use the pullouts and optional segments of the manual appropriately. They do not offer treatments other than those in the CBI manual and do not spend substantial time discussing non-protocol related material.

Low: Therapists low on protocol are not delivering the treatments from the CBI manual appropriately. They may be omitting required procedures, using optional procedures when they are not necessary or improperly sequencing the procedures. They may be confused by the details of the procedures (for example the change of reference groups in the PFR) or they may spend too much time discussing non-protocol material. In the worst case, they may be offering treatments, which are not specified in the CBI manual.

Overall

The Overall rating summarizes the practitioner’s overall skillfulness in this session. It will ordinarily be close to the arithmetic average of the 5 practitioner scales. Participant ratings are not considered in this overall scale score.

Client Subscale Standards

Elements that focus on the client’s behavior during the session are also coded. Because client’s behavior often changes markedly over the course of the session, these are not meant to be averages across the entire session (as with therapist elements), but rather reflect the client’s “high point” – a period (more than momentary) that reflects the client’s highest level of the characteristic during the session. Scores should be given from a seven-point

scale, where one indicates the absence of the characteristic, four indicates an average level, and seven indicates a very high level of the characteristic.

Affect

This element is intended to reflect how much and how intensely the client expresses emotion during the session. All emotion is coded, both negative and positive. Both verbal expressions of emotion as well as non-verbal are coded.

High: Clients high on affect show clear emotion during (but not necessarily throughout) the session. The emotion may include anger, happiness, sadness, fear or love.

Low: Clients at the low end of the scale express little or no emotion throughout the session.

Cooperation

High: Clients high on this scale are generally “going with” the therapist during the session. They respond to requests, cooperate with the therapist’s efforts and show little resistance. Clients who are acquiescent are generally high in cooperation.

Low: Clients at the low end of this scale appear generally unfriendly and uncooperative with the therapist’s direction throughout the session, with a sense of detachment (passive resistance) or opposition (active resistance).

Interaction Element

This is a rating for the collaboration between the therapist and client. It is intended to convey how the therapist and client work together, especially with regard to sharing power. As with therapist ratings, this element is based on the entire interview or sample, which might include longer periods of favorable collaboration mixed with bits of struggle.

High: Interactions high on this scale might be called “dancing” and have the quality of partners or companions or collaborative consultation. The therapist moves with the client’s efforts; negotiating, encouraging; collaborating and empowering. There is a quality of synergy, of the therapist and client moving together.

Low: Interactions low on this scale might be called “wrestling” and have the feeling of an uncooperative, competitive or adversarial struggle for power. The therapist and client appear to struggle against each other. Wrestling, however, does not require that the client “fight back.” In response to a wrestling therapist, the client may just acquiesce and be “pinned”.

Adherence Checklists

The Adherence Checklists are used by the practitioner in conducting the sessions and by the Monitoring Center in grading the sessions on Protocol score.

Tape Issues

Any problems observed with the tape are to be listed in the feedback form under 'tape issues'. These issues may include mislabeling of the tape, poor quality of the tape, or other issues.

Feedback

The audiotapes of the sessions chosen for monitoring will be listened to and coded by trained coders at the Monitoring Center. The sessions are coded according to standardized procedures (see section **B.2.3.3**). The coding sheets are then reviewed by the CBI Monitoring Coordinator for consistency. If there is any question about the ratings by the Coordinator or if the coder requests, the session is coded by a second coder. The Coordinator sends the coding results to the PC or the site's designee at each site.

If the rating for any dimension falls below criterion (5 on the 7-point Likert Scale), the Monitoring Center will provide written feedback about the session. Additionally, the Coordinator may choose to send written feedback about performance when several sessions have been reviewed in a short period of time.

It is the Monitoring Center's policy to review tapes in the order received unless there is a specific reason that other tapes take priority (certification or red line warning). It is also the policy to monitor more recent sessions first in order that the feedback may be more relevant.

Red-Line Warning

A red-line warning will be issued by the Monitoring Center as a preliminary step prior to red-lining. This warning triggers an intensification of monitoring both recent and new sessions. Priority is given to monitoring these sessions so a determination can be made expeditiously as to whether to proceed to red-lining. The Monitoring Center will request specific tapes to review, and role-play sessions may also be required. In the interim, the CBI practitioner may continue to see COMBINE participants, including new participants.

Red-Line

If adherence to protocol drops below the criterion level (average of 5 on a 7-point Likert Scale), a CBI practitioner may be red-lined (decertified) by the CBI Monitoring Coordinator. The PI and all staff designated to receive feedback at the site will be immediately notified, and a remedial plan will be created and implemented. The CBI practitioner is prohibited from beginning new cases until adherence returns to an acceptable level. Session monitoring will increase during this period. Improved adherence may be demonstrated with cases that were already in treatment at the time of the decertification, or with additional practice cases that will not be included in the main trial data. The CBI Monitoring Coordinator must recertify the CBI practitioner as consistently adhering to the

MM protocol (ratings of 5 or higher) before he or she may see new research participants.

Tape Management

Purpose

The purpose of providing tape management instructions is to help ensure the Sites are able to effectively record sessions, label tapes, and ship tapes. Effective tape management helps maintain quality in tape monitoring.

Recording of Sessions

All Combined Behavioral Intervention (CBI) sessions should be audiotape recorded. Prior to actually recording, the Site should test the placement of the recorder within the room of the session to make sure the voices of the CBI practitioner and the participant can be heard. The Site should try and limit the amount of background noise heard on the tape (e.g., do not place the recorder next to a heating vent where the fan noises will be recorded as well and might interfere with the audibility of the voices). Other noises that can occasionally make parts of the session inaudible are telephones, cellular phones, pagers and computer noises. Each session recording should start with the practitioner clearly stating his/her CBI practitioner ID number, the participant's ID number (in case of role player session, the first name of the pseudo participant. i.e., Gina or Martin), the session number and the date. The practitioner should avoid pausing the tape during the session. If the tape has to be paused, the reason for the interruption should be stated on the recording.

Quality check of recordings requested by Monitoring Center

The Monitoring Center will send each Site a request for tapes of specific sessions to be monitored. Before tapes are copied and sent to the Monitoring Center, the Site is to check the tapes to ensure that they are of sufficient quality to be coded. Coders must be able to hear and understand both the practitioner and the participant. There should be no more than one session on each tape. In case of poor recording, the tape is not to be sent to the Monitoring Center. If the tape is of poor quality, indicate on the CBI Tape Request Form (this goes back to the Monitoring Center) that the tape is not available (see below- Proper Packaging and Shipping Information). It is the policy of the Monitoring Center to try to do what they can to hear the tapes. However, if the quality is poor and the coder is having to strain to hear the session, the Site will be notified and the session will not be coded until a good quality audible tape is provided. The original session tapes are kept at the Site. Only copies of the requested sessions are sent to the Monitoring Center.

Proper Labeling of Tapes

Tapes must be properly labeled before they are sent to the Monitoring Center. All tapes and their covers should be labeled with the following information:

1. CBI therapist ID number (i.e. not the name or abbreviation)
2. Site abbreviation
3. Therapy type (CBI)
4. Participant ID number (in case of role play session, the first name of the pseudo participant. i.e., Gina or Martin)
5. Date of session (i.e., MM/DD/YY)
6. Session number (01-20)

An example of a label:

Client ID: 2235	Session #: 2
Therapist ID: 409	Date: 1-2-02
COMBINE - ABQ - CBI	

Recording of each session should begin by therapists clearly indicating the above information and each label should be matched to that specific session.

Tape Request

Tape requests are e-mailed and faxed to the Site project coordinator (PC), unless the Site has identified someone else to receive it. The Monitoring Center will update this information (i.e., tape request receiver) annually. If changes at a particular Site are made between the updates, the Site is to notify the Monitoring Center of those changes.

Proper Packaging and Shipping Information:

A copy of the CBI Tape Request Form must accompany the package of tapes (i.e., appendix A3). The form provides space to indicate the disposition of all session tapes requested. Please take extra precaution in packaging of the tapes to prevent breakage or other types of damage caused by delivery.

Send completed CBI tapes and materials to:

CBI monitoring coordinator
Lisa T. Arciniega, PhD
COMBINE, UNM CASAA
2650 Yale SE
Albuquerque, NM 87106

Tape Maintenance

All audiotapes received at the Monitoring Center are kept for a period of 12 months and then destroyed.

