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Compliance Enhancement: A Manual for the Psychopharmacotherapy of Drug Abuse and Dependence

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Like the other manuals and training materials in this series, *Compliance Enhancement (CE)* is intended to facilitate broader use in research and clinical settings of scientifically validated treatments for drug dependence, that is, treatments that have been demonstrated to be effective in randomized clinical trials. However, unlike the other manuals in this series, *Compliance Enhancement* is aimed chiefly at clinical researchers evaluating pharmacotherapies or psychotherapy-pharmacotherapy combinations in clinical trials with substance abusers.

In pharmacotherapy trials, *Compliance Enhancement* is one of several treatments that may be used to provide a standardized psychosocial *platform* against which to evaluate the efficacy of the study medications. Provision of a standardized psychosocial treatment to all patients participating in clinical trials is becoming a virtual requirement of pharmacotherapy research (Carroll, 1997). This has occurred because failure to provide a common, effective psychosocial treatment in the context of a pharmacotherapy trial is likely to increase *noise* or variability associated with different patients receiving different levels or types of psychosocial treatment, reduce statistical power, increase protocol deviation in the form of attrition and non-compliance with study medication, and raise ethical concerns (e.g., in cases where no psychosocial treatment is provided to patients receiving placebo or medications of unknown efficacy). Because it emphasizes medication compliance, retention, and abstinence but specifically prohibits several unique *active ingredients* of many alternate psychosocial treatments for substance use disorders (e.g., Cognitive Behavioral Therapy (CBT), Contingency Management (CM), Twelve Step Facilitation (TSF)), it is seen as a low-intensity relatively inexpensive treatment and thus may be a good choice when study populations are comparatively stable.

In studies of psychotherapy-pharmacotherapy combinations, *Compliance Enhancement* may be used as a lower-intensity, *minimal* comparison treatment for active psychotherapies. Because it invokes a pharmacotherapy rationale and provides *common* elements of psychotherapy such as empathy, education, a convincing rationale, and a supportive patient-clinician relationship, it provides a rigorous control condition against which to evaluate the *active ingredients* of comparison psychotherapies. For example, in our study of disulfiram and psychotherapy for cocaine-alcohol dependent patients, we found that two *active* psychotherapies (CBT and TSF) in combination with disulfiram were more effective than CE plus disulfiram; however, some analyses also indicated that that CE and disulfiram was more effective than the two psychotherapies delivered without disulfiram. Furthermore, because it is comparatively low in intensity, *Compliance Enhancement* is often used in studies aimed at identifying the optimal or minimal level of psychosocial support needed for effective delivery of pharmacotherapies.

HOW HAS COMPLIANCE ENHANCEMENT BEEN USED?

This version of *Compliance Enhancement* has been used in a range of pharmacotherapy and psychotherapy-pharmacotherapy combination trials. This includes our recent study of disulfiram and psychotherapy for individuals dependent on cocaine and alcohol (Carroll et al., 1997; Carroll, Nich, Ball, et al., in press), and a large multisite study sponsored by Pfizer of sertraline for depressed alcohol-dependent patients, from which this version was adapted.

WHO MAY DELIVER CE?

Although based on Fawcett and colleague's manual for Clinical Management (1987), which was developed for use by experienced psychiatrists who were delivering antidepressant pharmacotherapy in a multisite trial of treatments for depression (Elkin et al., 1985), we have modified *Compliance Enhancement* to be used by a broader range of clinicians in clinical trials of pharmacotherapy. That is, with *sufficient physician back-up* as well as training and supervision, *Compliance Enhancement* may be used by qualified nurses, psychologists, social workers, and counselors. That is, when a study protocol allows for medication monitoring and dose adjustments to be made during brief, infrequent visits by the trial physician (e.g., beginning of the trial and as needed thereafter), *Compliance Enhancement* may be delivered by nurses and non-medical personnel as a low intensity approach aimed at fostering retention, compliance, and abstinence. Here, the role of non-medical personnel is to monitor the patient's compliance, increase the patient's motivation to be compliant with medication and to become or remain abstinent, and to explore and implement strategies to improve compliance and outcome. Here, the patients' specific questions about dose changes, dose scheduling, side effects, drug interactions and so forth should always be referred to the study physician. In studies where *Compliance Enhancement* is delivered by physicians or other licensed medical personnel, issues of dose changes, dose scheduling, side effects and interactions can be handled within the session and as the protocol allows.

THE *GENERIC* NATURE OF THIS MANUAL

This manual describes interventions and provides *general guidelines* for implementing CE with a range of study populations and medications and is therefore in a sense *generic*. However, in order to apply *Compliance Enhancement* in a specific protocol and with a specific medication, it is necessary that the investigator develop a supplement to this manual to provide clear guidance to clinicians regarding:

- The nature of the study and its goals
- The study medication, its rationale for use with the study population, its expected benefits and side effects
- Guidelines for dosing and dose adjustments
- The timing of patient meetings with the study physician and other medical personnel for monitoring of clinical response, symptoms and side effects (e.g., bloodwork, physical examinations) vis a vis CE sessions
- The length of treatment, the timing and maximum number of CE sessions
- Other modifications of the CE protocol as needed.

PATIENT-THERAPIST RELATIONSHIP

In CE, as in all psychosocial treatments, the patient-therapist relationship is at the core of treatment and a positive working alliance is the foundation of treatment. Even though sessions are brief and focussed on compliance, this is essentially a supportive treatment and the therapist should recognize that the quality of the relationship is of the utmost importance and a major *active ingredient* of CE.

Moreover, if the relationship with the CE therapist and the rest of the study/treatment staff is positive, compliance and retention are more likely. Thus, the CE therapist should strive to promote the therapeutic relationship throughout the treatment through empathic listening, providing support and encouragement,

displaying genuine concern for the patient and his/her welfare, responding to patient concerns and addressing disagreements when they occur, and providing needed clarifications and explanations throughout treatment.

CE therapists should avoid those interventions that are likely to elicit resistance. These include aggressive confrontation of denial, questioning, interrupting the patient, arguing with the patient and so on. The therapist must be responsive to patient concerns and complaints while maintaining control of the sessions through providing a consistent structure for the sessions (Fawcett et al., 1985).

Therapist behaviors that avoid resistance, such as reflective listening, reframing patients' concerns, are encouraged. These and other interventions foster greater retention and compliance with study medication (e.g., support, encouragement, and a positive relationship between the patient and the study staff) are often undervalued, and are sometimes seen as necessary but inert. However, Lambert and Bergin (1994) and others have argued that *non-specific* is not the same as *inert*. Factors such as the patient-therapist relationship have been shown to have consistent and robust effect sizes, often larger than the discernible effect of *active ingredients* of different psychotherapies (Carroll et al., 1997; Horvath & Symonds, 1991).

A NOTE ON BALANCING ADHERENCE AND ADDRESSING THE NEEDS OF THE PATIENT

There is an important distinction between adherence and competence, that is, the degree to which the therapist follows the guidelines laid out in the therapy manual, and therapist competence, which refers to the therapist's level of skill in delivering that treatment (Carroll & Nuro, 1997). Several investigators have noted that a therapist's adherence and competence are not necessarily closely related (Carroll, Nich, Sifrey, et al., in press; Shaw & Dobson, 1988; Waltz, Addis, Koerner, & Jacobson, 1993). That is, a therapist can follow a treatment manual virtually word-for-word and not deliver that treatment competently or skillfully (e.g., with an appropriate level of flexibility and understanding of a particular patient, using appropriate timing and language). In some cases extremely high adherence (e.g., a wooden, mechanistic rote repetition of material in the manual) may be indicative of very low competence in a therapist. High adherence and low skillfulness may also occur in cases where a therapist delivers a technique perfectly, but at an inappropriate time that is insensitive to the needs of a particular patient. Conversely, there may be cases of high skillfulness and low competence, for example where a therapist empathetically responds to the patient and provides incisive interpretations at the precise moment they are most likely to be helpful, but rarely touches on material described in the manual (Carroll & Nuro, 1997).

Achieving a high level of adherence to the CE manual and fostering a positive therapeutic alliance should be seen as complementary, not contradictory, processes. Because CE is a supportive treatment that seeks to foster retention in treatment, compliance with medication, and abstinence, all of which are heavily dependent on a positive relationship, the specific CE interventions discussed below are intended specifically to cultivate a good working relationship and build patient motivation for treatment and compliance.

CAVEAT

This manual, like the others in this series, provides guidance on how to implement specific techniques and is aimed at experienced clinicians who have mastered basic psychotherapeutic techniques with substance using populations. It should be used only with training and appropriate levels of ongoing supervision. This manual may not be applicable to all patient types nor compatible with all clinical programs, pharmacotherapies or treatment approaches. The manual should be viewed as a supplement to, but not a replacement for, careful assessment of each patient, appropriate case formulation, ongoing monitoring of clinical status, and clinical judgement.

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Contents

1. General Description of Compliance Enhancement

Description

This manual describes Compliance Enhancement (CE), a standardized psychosocial treatment for therapists treating drug dependent patients in pharmacotherapy trials. The goal of the treatment is to provide high quality supportive treatment to all individuals participating in the trial, as well as to reduce variability in therapist delivery of psychosocial interventions. Compliance Enhancement is intended for patients in short-term, ambulatory pharmacotherapy trials, and can be delivered by clinicians with or without medical degrees. It is also a potential model for physicians conducting brief medication management in clinical settings, but its efficacy in non-research clinical settings has not been evaluated.

Therapist Goals

The therapist has three principal goals:

1. Foster patient compliance with study medication
2. Enhance patient retention throughout the trial
3. Maximize abstinence from psychoactive drugs.

To achieve the first goal, principal therapist strategies include close monitoring of compliance and an array of compliance-enhancing interventions. To achieve the second and third goals, the therapist promotes a positive, supportive therapeutic relationship and seeks to enhance the patient's motivation to participate fully in treatment during the entire study period and to make some efforts on his/her own to become and remain abstinent from psychoactive substance use. Because of the brief focused nature of the treatment and the brevity of the sessions (25 to 30 minutes), therapists should refrain from interventions associated with other formalized therapies (e.g., cognitive-behavioral, interpersonal, behavioral).

In this treatment, therapists should strive to obtain a balance between emphasis on compliance with the study medication and identification and support of patient efforts to become abstinent. That is, the therapist should discourage a patient stance of overreliance on the medication, or viewing the medication as a *magic bullet* that will solve all his/her problems with little effort on his/her part. **The medication should be conceived as an important tool that is likely to enhance the patient's own efforts to become and remain abstinent.**

Treatment Format

Treatment is generally delivered in weekly sessions over 12-24 weeks. In some

cases (e.g., with stable or compliant populations), sessions may be spaced less frequently (e.g., weeks 1, 2, 3, 4, 6, 8, 12, 16, 24). Sessions typically last approximately 25-30 minutes and will be structured, focused on patient compliance and current functioning. One family education session and up to two emergency sessions are typically permitted in most protocols and guidelines for the conduct of these are specified later in this manual.

CE should be delivered in *individual* sessions which should last no longer than 25-30 minutes and follow a common structured format. Sessions should begin with inquiry as to the patient's functioning since the last visit, followed by more detailed inquiry as to the patient's:

1. substance use since the last session
2. psychiatric symptoms since the last session (if appropriate)
3. medication compliance, response, and any medication-related problems since the last session.

Finally, sessions typically end by the therapist encouraging abstinence and attendance at self-help groups (e.g., NA/CA/AA), and eliciting the patient's plans for the period before the next scheduled session.

Treatment Goals

The principal goal of this treatment is abstinence from psychoactive substances. The means by which this goal will be reached includes, primarily, the study medication. Encouraging patient compliance with study medication is thus a principal focus of the therapist's interventions.

Rationale for Focus on Compliance

Non-compliance with medication is a common problem in pharmacologic research, particularly with substance abusers (O'Malley & Carroll, 1996). Non-compliance raises profound problems from both clinical and research perspectives (Carroll, 1996). Clinically, compliance is important because compliant patients generally have better outcomes than non-compliant patients (Coronary Drug Project Research Group, 1980; Horwitz & Horwitz, 1993; Horwitz, Viscoli, Berkman, et al., 1990; Startup & Edmonds, 1994; Fuller et al., 1986; Volpicelli et al., 1997). The strong relationship between compliance and outcome holds even when placebo treatments are being evaluated (Horwitz & Horwitz, 1993). This suggests that compliant behavior may tap important beneficial processes other than active ingredients of the treatment itself, such as the instillation of hope, self-efficacy, and enhanced health-promoting behaviors. In addition, non-compliance often leads to need for additional services (clinic visits, hospital admissions, emergency room visits), need for increased provider time and thereby reduced access of other patients to needed services, increases health care costs, and increases the risk of complications and even patient death (Bond & Hussar, 1991; Cowen et al., 1981; Macharia et al., 1992).

From a research perspective, non-compliance is problematic because it reduces

statistical power to detect treatment effects, leads to the need for larger sample sizes, increases sample bias, undermines internal validity, and is associated with a host of other methodological and statistical concerns (see Freedman, 1990; Lackin & Foulkes, 1986; Lavori 1992; Lee, Ellenberg, Hirtz & Nelson, 1991). In clinical trials, differential compliance across treatments leads to *compliance bias* (Feinstein, 1979), where differences in outcomes between treatments may be due to differences in level of compliance across treatments rather than effects of the treatments themselves.

Comorbidity

In many instances, CE has been used with patients with comorbid psychiatric symptoms (e.g. evaluating the effects of antidepressants on depressed substance abusers). In these cases, the goals of treatment expand to include monitoring and reduction of psychiatric symptoms as well. Depending on the specific medication, various hypotheses may be provided to the patient.

> Example:
> T: "The medication is intended to help you reduce your substance use, not your depression. However, we have reason to think that reducing your substance use will also help your depression."
>
> T: "The medication is intended to help your attention deficit disorder. However, it is possible your ADHD has played a role in your continuing to use cocaine. Thus, we think the medication may help with both, but you should remember that this, or any medication, is unlikely to be a magic bullet. It will be important for you to make some efforts of your own to reduce your use."

2. Therapist Behaviors Prescribed and Proscribed

Essential Required Interventions

To clarify the range of therapist interventions that are consistent with this approach, the following is a list of interventions which define, or characterize, this treatment and thus are essential or required interventions. **These should be delivered to all patients during the course of treatment and should be present in most CE sessions.**

Category 1

COMPLIANCE MONITORING AND ENHANCEMENT

- Assess medication compliance since last session
- Praise medication compliance
- Use a problem-solving strategy for non-compliance
- Address patient concerns about medication
- Relate patient's clinical improvement to compliance OR lack of improvement to non-compliance
- Inquire as to patient's previous experience with medication

Category 2

CLINICAL MANAGEMENT AND MOTIVATION BUILDING

- Establish history/characterize episode of drug use
- Establish history/characterize psychiatric episode
- Assess drug use since last session
- Assess psychiatric symptoms since last session (if appropriate)
- Assessment of general functioning
- Link drug use/abstinence to psychiatric symptoms (if appropriate)
- Review, set, or monitor patient goals for treatment
- Discuss abstinence as a treatment goal
- Provide optimistic reassurance
- Explore costs of continued drug use
- Encourage involvement in self-help groups (e.g., Narcotics Anonymous (NA), Alcoholics Anonymous (AA), Cocaine Anonymous (CA)

Recommended Interventions and Activities

The following therapist interventions and activities are recommended within CE. These should be used, as appropriate, for most patients, but are **not required to be delivered to all patients or to be present in every session**:

Make a specific referral to a self-help group

Trouble-shoot self-help concerns and resistance

Discuss medication compliance in the context of self-help attendance

Discuss level of family support

Educate family members regarding study/treatment protocol, the nature of the study medication and expected benefits, answer family questions regarding patient's participation in protocol

Proscribed Interventions

The following are proscribed interventions, that is, those which are uniquely associated with other therapies and **should be avoided**, particularly in protocols that compare CE to other psychosocial interventions.

Cognitive-behavioral interventions for substance use (e.g., skill training, role playing, exploring cognitions, self-monitoring of substance use, functional analysis of relapse episodes)

Cognitive-behavioral interventions for psychiatric issues when there is a comorbid disorder

Interpersonal or psychodynamic interventions (e.g., exploring conflicts about relationships)

Family or relationship therapy (e.g., specific training in effective communication styles, paradoxical or structural interventions)

Twelve-step or disease model interventions (e.g., confrontation of denial, invoking of specific Steps)

Sessions should be structured so that the treatment is highly supportive but distinct from formal psychotherapy. Even though sessions are brief and thus extensive interventions by the therapist are effectively precluded, it is important that CE therapists not engage in behaviors which are characteristic of organized systems of psychotherapy. In CE, therapists encourage patients to come up with their own strategies to become or remain abstinent (e.g., "What do you think you could do about that….", "What have you done in that situation in the past?"), but do not suggest specific strategies or interventions (e.g., "something you could have tried there is….", "I wonder what you were telling yourself when….", "…I think this is a pattern established by your family….").

A good rule of thumb is that any ideas or strategies that arise from the patient can and should be encouraged by the therapist, but the therapist should not supply or suggest specific strategies to the patient.

3. Description of CE Interventions

Category 1: Compliance-enhancing Interventions

a. Previous Experience with Medication

Before providing a rationale for the study treatment, the CE therapist should ask about the patient's prior history with pharmacotherapy for substance abuse and/or any psychiatric disorder or condition, including the patient's view of why it was prescribed, whether is was helpful, under what conditions pharmacotherapy was terminated, and, importantly, whether the patient took the medication as prescribed.

Previous non-compliance should alert the CE therapist to the need to establish the patient's view of why s/he did not comply previously, and to attempt to address those issues proactively.

> Example:
> T: "You mentioned earlier that you had been prescribed medication X a few years ago. What was your experience with it?"
>
> P: "I didn't like it, what do you want to know?"
>
> T: "Well, what you didn't like about it, but also your understanding of why it was prescribed, how much you took, how long you took it, and why you stopped."

b. Concerns about Medication

During all sessions, the therapist should listen carefully for any patient concerns, misunderstandings, or prejudices about taking medication, and address these rapidly and assertively. This may include patient misconceptions about expected medication effects, time to effect, side effects, dosing, and interactions with drugs and alcohol. The CE therapist should provide clarification in clear, understandable terms, frequently checking back with the patient. For complex medical questions or those which indicate the patient's desire to change the medication schedule or dosing, the patient should be referred immediately to the Principal Investigator, and/or the study psychiatrist.

> Example:
> T: "It sounds like your concern is that by taking medication it is just replacing one drug with another, so you are still not drug free. We have found that medication X is particularly helpful with craving and it is not addictive. As a result, it can help you to get and stay clean without

creating another addiction or interfering with your life the way that drug X has."

It should be emphasized to the patient that the treatment is based on specific therapeutic effects of the medication. The therapist should check frequently for the accuracy of the patient's understanding of the effects of the medication and reiterate the rationale for the prescribing of the medication as necessary.

It is important to convey how long it may take for therapeutic effects of the medication to emerge, as this may vary depending on the medication being prescribed for the patient. **Variations in the emergence of medication effects provides an opportunity for the CE therapist to emphasize that the patient should not expect to benefit from an entirely passive stance regarding treatment.** Rather, the patient should be strongly encouraged to take steps on their own to reduce drug use. This also sets the stage for referral to self-help meetings.

The concept of variation in the emergence of therapeutic effects, depending on the specific medication being used, can be helpful when the patient becomes discouraged or expresses the fear that s/he is receiving placebo. *The CE therapist should assume, throughout any study treatment, that the patient is on active study medication and behave likewise (e.g., attributing any reasonably positive change in target symptoms to the medication).* In addition, with many medications patients do not experience any side effects and thus the absence of side effects is not an indicator that the patient has been assigned to a placebo condition.

c. Assess Medication Compliance Since Last Session

Close, consistent, and careful monitoring of compliance is one of the most effective strategies for enhancing patient compliance with medications. Thus, a major portion of each session should be devoted to evaluating medication compliance and working through any difficulties with compliance that might arise.

In general, until the patient's compliance pattern is clearly established, CE therapists should, at each meeting, inquire about medication compliance, day by day, since the last session. This should include inquiry as to when the patient takes the medication, how the patient takes the medication, and thorough discussion of any deviation from the prescribed dose and schedule.

Example:
T: "From what you've been telling me, for the last week you have been taking your medication at different times during the day, when you remember it and sometimes that means you might not have the medication with you. By the time you get home you are tired and it doesn't occur to you to take it. It might be helpful to set a regular time to take the medication, in the morning for example, when you know you will be home and the medication will be available. What do you think? See how this week goes and we will review it next session."

Fawcett (1985) has noted that compliance and retention are most difficult to achieve early and late in treatment: early if the patient is not receiving obvious benefit, and later if the patient, after obtaining a partial or full therapeutic response, does not appreciate the need to continue treatment. Thus, CE therapists should be particularly attentive to compliance and motivation issues during early and later sessions.

d. Praise Medication Compliance

The CE therapist should convey confidence in the study medication and that the medication is likely to be of benefit to the patient and his/her current concerns. The CE therapist should be strongly on the side of compliance and praise patients' compliance enthusiastically and genuinely.

> Example:
> T: "I see you took your medication every day since our last meeting. That's really great. I know had your doubts about whether the medication would work for you, and I'm glad you were willing to give it a try. Have you noticed any positive changes you think might to due to the medication?"

e. Relate Clinical Improvement to Compliance *OR* Lack of Improvement to Non-compliance

A crucial role of the CE therapist is to establish and stress the connection between medication compliance and improvement. The therapist should make explicit causal links between the patient's compliance and improvement in drug use, psychiatric symptoms (if appropriate), and other appropriate target symptoms. Conversely, the CE therapist might tie a patient's poorer compliance to failure to improve.

> Example:
> T: "Since you've been taking the medication, I can see a lot of positive changes in your life…you've stopped using drugs and you say you've been feeling a lot better. I think the changes reflect that the medication is helping you. What do you think?"
>
> T: "I know you're feeling discouraged about how you've been feeling, but since we have begun to work together, you've also told me you haven't been taking the medication every day. As I've discussed, I don't think you'll notice a real change until you take the medication more consistently. How about giving it a try?"

For a patient who continues to use drugs, the therapist may also point out that medication blood levels may be effected by continued drug use. Thus, the more the patient strives to become and remain abstinent, the more likely it is the medication will work more effectively and more rapidly.

f. Use a Problem Solving Strategy for Non-compliance

In cases where the patient is not compliant with medication, the CE therapist should take a practical, objective approach, seeking to help the patient clarify reasons or obstacles to compliance and generating practical solutions. For example, patients may report difficulty remembering to take the medication. Practical strategies to *cue* the patient to take the medication (e.g., notes on the bathroom mirror, taking medication in relation to a regular mealtime, etc.) should be generated in such cases, and then followed up on in the next session. Whenever possible, the patient should be encouraged to develop his/her own solution. The therapist's role is thus to facilitate or further develop the patient's strategies.

> Example:
> T: "You say that some days you just forget to take the medication. As we look at each day you missed, it was on days you weren't working. Where do you keep your medication and when do you usually take it? You might want to think about how you could remind yourself to take the medication on your days off. Do you have any ideas about that?"

Some patients may have misconceptions about expected medication effects, potential adverse effects, and so on. These should be addressed clearly by the therapist, and if necessary, followed up by a referral to the prescribing psychiatrist. Similarly, if a patient indicates s/he has experienced family objections to the medication, a family session should be scheduled to clarify and address these concerns.

Category 2: Clinical Management and Motivation Building

a. Establish Drug History/ Characterize Episode of Drug Use

In early sessions, the CE therapist should devote considerable time to obtaining a clear history of past substance use, with particular emphasis on the current episode and the symptoms or problems that prompted the patient to seek treatment at this time. The CE therapist should also be particularly sensitive to the likelihood that the patient has already spent a great deal of time responding to detailed inquiry about his/her history as part of the pretreatment assessment process and should indicate their awareness of the results of the pretreatment assessment battery.

> Example:
> T: "I know you talked about your drug history as part of the intake process. I have seen a brief summary of your assessments, so I won't ask you to repeat everything to me. However, it is important and helpful for me to ask about your drug history, so I have a sense of it from you directly, not just on paper. This will also give you a chance to elaborate on anything you may want to address in our work together and help me get to know you."

Inquiry concerning past history of drug use should include at least the following:

- Family history of substance use
- Patient's first use of substances
- Patient's first regular use of substances
- First problematic use of substances
- Treatment history

The CE therapist should also obtain a detailed description of any extended periods of abstinence, how they began, when they occurred, and how the patient felt and functioned during this period.

Regarding the current episode, the CE therapist should make an open-ended inquiry as to how the present episode began, any major events that coincided with the increase in substance use, how substance use has affected the patient's family and social interactions, work, health, or other important spheres, and any other concerns the patient may have about his/her substance use. The CE therapist should obtain a detailed picture of the patient's current level of substance use, craving for substances, and usual substance using pattern, in order to obtain a baseline against which change can me measure as treatment unfolds.

b. Establish History/ Characterize Psychiatric Symptoms

The CE therapist should also devote some time to obtaining a clear psychiatric history, with particular emphasis on the current symptoms and how they may relate to substance use. This would include the temporal relationship between substance use and psychiatric symptoms, whether these symptoms exist during periods of extended abstinence, and symptoms experienced during periods of increase or decrease in substance use.

> Example:
> T: "From what you are telling me, when you become anxious you smoke pot to help calm yourself down. Does it help? Does the anxiety decrease immediately or does it take some time? Sometimes people feel more relaxed at first, but if they smoke heavily or if the marijuana is particularly potent, they become even more anxious and at times paranoid. Does this happen to you? What was your anxiety like during the time you were abstinent for 3 months? If the anxiety persisted, how did you manage it without smoking pot?"

c. Assess Substance Use Since Last Session

Early in all sessions, the therapist should conduct detailed inquiry as to the patient's substance use since the last session. Until complete abstinence is firmly established, this should include *day-to-day* assessment of any substance use, when it occurred, what precipitated it, what and how much the patient used, and how the episode terminated.

Abstinence, and the patient's efforts to become or remain abstinent, should be

noted and praised. As most patients experience a substantial drop in substance use at the beginning of treatment, the therapist may capitalize on this by framing this as an indicator of the patient's motivation to change and/or result of the medication.

> Example:
> T: "You have been clean for three weeks. That's terrific. At the beginning of treatment you weren't sure you could do it. This time you seem really motivated to stay clean. You are taking the medication as prescribed, which is helping with your symptoms. Another thing I've noticed is that you're looking at lifestyle changes you need to make to remain abstinent."

d. Assess Psychiatric Symptoms Since Last Session (if appropriate)

The early part of each session should also include review of current status of psychiatric symptoms, as well as any change in level of symptoms since the last session. As with review of substance use, review of psychiatric symptomatology should be as concrete as possible.

> Example:
> T: "Last time we met you were having trouble concentrating at work and feeling depressed. How are you feeling today? You were also forcing yourself to eat. Has your appetite improved? How are you sleeping? Have you been less short-tempered with other people? Did you get out to see your friends as you had planned?… It sounds like some of your symptoms have improved, though you are still not so sure things will get better. The longer you are abstinent from drugs and compliant with the medication, the better you will feel."

e. Assessment of General Functioning

In addition to an assessment of substance use and any psychiatric symptoms the CE therapist should leave each session with a clear understanding of the patient's current functioning in important spheres such as work, health, and family/social activities. Often, the patient will spontaneously describe his/her recent experiences and current concerns in response to open-ended inquiry by the therapist ("How has it been going for you since we last saw each other?"); however, if the patient does not volunteer this information, the therapist should make specific inquiries and cover the major domains until a clear pattern is established.

f. Link Substance Use/Abstinence to Psychiatric Symptoms (if appropriate)

Wherever appropriate, psychiatric symptoms and changes in these symptoms should be linked to substance use. For example, improvement of symptoms might be linked to a sustained abstinence; conversely, an increase in symptoms for a patient who has only recently become abstinent might be interpreted in terms of withdrawal symptomatology.

Fairly early in treatment, the relationship between psychiatric symptoms and

substance use should be outlined by the therapist. Although the specific nature of this relationship may vary depending on the specific type of substance use and psychiatric disorders in question, key points to cover generally include:

- Substance use and psychiatric symptoms very often co-occur
- The nature of the relationship is complicated and not always well understood. Some types of substance use can *cause* psychiatric symptoms (e.g., depression in chronic cocaine users or alcoholics). Some individuals use substances in an attempt to reduce symptoms associated with a psychiatric disorder (e.g., abuse of benzodiazepenes in an individual with an anxiety disorder, abuse of cocaine in a depressed patient)
- Reduction in substance use WILL make it easier to assess and treat psychiatric symptoms
- Reductions in substance use MAY bring about improvement in psychiatric symptoms
- Whether the medication is intended to affect substance use, psychiatric symptoms, or both

g. Review, Set, or Monitor Patient Goals for Treatment

Patients seeking psychopharmacological treatment for substance abuse typically have as treatment goals the reduction of substance use and psychiatric symptoms (if appropriate). It is possible, however, to identify and target a few other, concrete problems, but these must be fairly limited, given the brevity and scope of CE and most study protocols.

These secondary goals should be consistent with and related to the general goal of abstinence from substances. Appropriate secondary goals might include spending more time with family, establishing more regular sleep pattern, and so on. Once these are identified, the therapist should ask the patient to generate a strategy to reach these goals, and progress in reaching these goals should be monitored during each session.

> Example:
> T: "One of the main things you have identified as a problem is how bored you are since you stopped associating with your friends who use. What did you enjoy doing before you used drugs? Do you have any interests? You seem to be a sociable person. Can you think of places you could go or people you could see where you would not be exposed to drugs?"

More complex problems (e.g., serious marital dissatisfaction, severe anxiety) should be noted, but not made a focus of this treatment. The therapist might suggest that it would be most effective to reassess, and possibly, seek treatment for such problems after a sustained period of abstinence (e.g., after completing this study).

> Example:
> T: "It sounds like you're very concerned about your marriage right now and whether or not your wife might ask you to leave the house.

Marriage problems are pretty common among people who have a substance abuse problem, though, and I wonder if things might not start to improve with her if you stay clean over an extended period of time. What we could do in the next week is to ask Mary to come in for one of our sessions. We could use that time to describe the treatment to her, as well as your goals around abstinence, and how the treatment and the medication might help you reach these goals, because getting involved with this treatment is a clear indicator of your willingness to make changes in your substance use, this might help her feel more encouraged. What do you think?"

T: "Marriage problems are pretty common when someone is dealing with psychiatric symptoms. When people experience difficult symptoms they often withdraw from the relationship and family members can feel discouraged and rejected. Often when the psychological symptoms improve with medication, things go better at home."

h. Discuss Abstinence as a Treatment Goal

The goal of this treatment is abstinence from alcohol and other psychoactive substances. The CE therapist should make this goal explicit, express confidence that the patient can, with the help of the medication and participation in treatment, attain this goal. Also, the therapist should provide a clear rationale for the benefits of abstinence.

The CE therapist should recognize, however, that many patients entering the treatment are ambivalent about renouncing substances altogether, and should allow for some exploration of this ambivalence, in effect, giving substances their due. The CE therapist should explore past periods of abstinence and how the patient felt during these periods, as well as feeling out what the patient imagines life might be like without using substances.

Example:
T: "Last week you said you thought that a significant part of your using drugs was an attempt to deal with uncomfortable emotions. So it's understandable that you have mixed feelings about the idea of giving up drugs altogether. You have had periods of abstinence in the past. How did you deal with your emotions then? What do imagine your life will be like now if you become abstinent?"

i. Provide Optimistic Reassurance

The CE therapist should assume and convey that, as long as the patient remains in treatment and takes the medication, s/he can and will derive benefit and progress toward treatment goals. The CE therapist should always assume the patient is receiving the active study medication and therefore adopt a tone of optimism and confidence about the medication.

Example:
T: "I know it's been difficult coming off drug X. Let me reassure you that by coming to sessions, taking the medication as prescribed, and staying

clean, with each day you will feel better than the last. When you are feeling better, both physically and emotionally, you will be more available to deal with your goals at work and at home."

j. Encourage Patient Efforts and Use of Personal Resources

As CE is intended to be a supportive, brief treatment, therapists should refrain from providing directive interventions characteristic of organized systems of psychotherapy. It is a treatment, however, that recognizes that, first, to effect enduring change, the patient must make some efforts outside of sessions to reduce substance use in addition to taking the medication. Second, CE treatment assumes that the majority of patients are capable of determining what it is they need to do to effect such changes.

For the majority of patients, the support they receive from the therapist, coupled with medication expectations and effects, will be sufficient. However, in patients who express the desire for more structured intervention, therapists should use the following strategies:

First, refer to the pharmacotherapy rationale (e.g., "It sounds like right now you are experiencing a great deal of craving for 'X' substance and that's making it difficult for you to resist temptations. However, if you take the medication as prescribed and as the medication starts to take effect, you will experience a marked reduction in craving and that will help you deal with those temptations to use substances.")

Second, refer the situation back to the patient. That is, while the medication can do much to ameliorate some target symptoms, the attainment of abstinence requires some changes on the part of the patient as well; however, there are wide variations between individuals with respect to successful strategies for attaining abstinence. Thus, to some extent "the patient must find his own way"; this is exemplified by therapist statements such as, "We discussed that previously you have been able to be abstinent for as long as two months. How did you do it? Do you think that would work now?"

Third, direct advice-giving, within certain limits, is permissible. While some advice-giving may be necessary to maintain the therapeutic alliance, CE is based on a pharmacotherapy rationale and any interventions which resemble active, directive psychotherapies are to be avoided.

k. Explore Costs of Continued Substance Use

An important strategy to build and shore up motivation is to explore what the patient has to gain or lose by continued substance use. This intervention will be most powerful and persuasive when it is the patient, rather than the therapist, that articulates concerns about substance use, abstinence, and reasons for change.

Therapists should thus seek to elicit self-motivational statements (statements directly from the patient that express their own concerns about substance use) (Miller et al., 1992; Miller & Rollnick, 1991). Strategies to elicit self-motivational statements include, first, asking open-ended questions about the patient's concerns.

Examples (from Miller et al., 1992):

"What worries you about your substance use?"

"What makes you think that perhaps you need to make a change in your substance use?"

"From what you've told me, it doesn't seem like you're that concerned about your substance use. Is that all you're worried about?"

NOTE: Position on Self-help Programs

Depending on the study protocol, a decision should be made regarding the protocol's position on supporting/encouraging the patient's involvement in self-help groups (e.g., Alcoholics Anonymous, Cocaine Anonymous, Narcotics Anonymous). At times it may be important to encourage a patient to go to meetings, and at other times that might introduce complicated confounds in the study. In this manual, we present a middle of the road position, gently encouraging patients that self-help groups may be an important source of support for the patient, but not requiring him/her to do so.

l. Encourage 12-Step/Self-help Involvement

This treatment is seen as consistent with and complementary to involvement in 12-Step (Narcotics Anonymous, Alcoholics Anonymous, Cocaine Anonymous) or other self-help groups. Encouragement of self-help attendance should be conveyed as a means of helping the patient become and maintain abstinence during the treatment and to perpetuate gains made during treatment after treatment ends.

Referral to self-help groups (e.g., NA/CA/AA) should be made early in treatment (first or second session). This referral should include:

1. A clear rationale for attending meetings (e.g., NA/CA/AA meetings are an excellent source of support in the patient's efforts to become and remain clean and sober, they don't cost any money and they are widely available
2. Inquiry as to whether the patient has attended 12-Step groups in the past and his/her reaction to that experience
3. Whether the patient is willing to attend NA/CA/AA meetings
4. Referral to a specific meeting at a specific time and place in the local area. Therapists should have a schedule of appropriate 12-Step meetings and locations in their areas to distribute to patients

The CE therapist should be familiar enough with self-help meetings to address

patient misconceptions about NA/AA/CA and to provide reasons why involvement in 12-Step groups might be of particular benefit to the patient.

> Example:
> T: "I've heard you say several times how hard it is for you to think of things to do that don't involve using. Going to 12-Step meetings is an excellent way of meeting people who don't use substances, and who have dealt with exactly this problem in the past. Would you be willing to go to one meeting before our next session? We can talk next time about what you thought about it."

CE therapists should recall, however, that attendance at self-help meetings is encouraged, but not required as part of participation in this treatment. If a patient has had a negative experience with 12-Step or other self-help groups, and is unwilling to attend, therapists should not risk the therapeutic alliance or patient's commitment to the treatment by too aggressively pressing for 12-Step meeting attendance.

It is permissible for patients to attend self-help groups other than NA/AA/CA, including Rational Recovery.

m. Coping with 12-Step Members' Objections to Medications

The CE therapist should also prepare the patient to cope with some 12-Step groups objections to the treatment medications. While there are an increasing number of meetings where members distinguish the benefits of non-addicting, prescribed psychotropic medications from dependence-producing medications (in fact, there are now "Dual Diagnosis Anonymous" meetings available in many cities), and accept members who are on medications, this may not be so in all areas. CE therapists should make special efforts to locate meetings and refer patients to them.

Therapists may also prepare patients for such objections by (1) clarifying the difference between the use of prescribed medication which is intended to help the patient become abstinent and use of psychoactive medication as a 'substitute' for other substances, and (2) clarify the 12-Step position regarding medications and other drugs, possibly distributing the AA pamphlet, The AA Member-Medications and Other Drugs: A Report from a Group of Physicians in AA. This pamphlet clarifies that no 12-Step member should play doctor, and that failure to comply with a prescribed medication may be harmful to the individual.

> Example:
> T: "If you choose to reveal at a meeting that you're taking a medication, you may run into a member who objects to this. Some 12-Step members believe that one can't get over an addiction by taking a pill, and discourage other members from taking a medication. It's important to remember, however, that the treatment medication is not addicting and that it is a medication that is intended to treat your symptoms and help you get and stay clean and sober. Remember that the medication is a tool you can use in your efforts to not use."

Contrasts between CE and Other Treatments

The following table highlights the differences between CE and other treatments as to how different situations are handled and what types of interventions are used in the treatments.

Table 3.1
Contrasts Between CE and Other Treatments

	Twelve Step Facilitation (TSF)	Cognitive-Behavioral (CBT)
Goals of Treatment	Encourage patient to accept the diagnosis of addiction and understand addiction as a progressive, fatal disease. Facilitate patient's integration into AA/CA/NA.	Help patient master coping behavior as effective alternative to drug use. Increase patient's self-efficacy.
Approach	Medical/disease oriented	Behavioral
Agent of Change	Treatment Fellowship/Higher Power	Treatment Mastery of skills
Labelling	Labelling patient as *addict* is encouraged, as this label provides the framework for the treatment. Acceptance of the diagnosis is necessary, it determines a set of symptoms (e.g., lack of control, denial) and the steps required for recovery.	Labelling discouraged; drug abuse/dependence is conceived as overlearned behavior that can be broken down into a finite set of discrete problem situations and behaviors.
Control	Emphasis on loss of control. Patient cannot control drug use; as s/he has the disease, addiction, which s/he is powerless to control. Patient can control whether s/he has the next run, whether or not s/he uses CA/AA, whether or not patient harbors the idea that s/he can control drug use.	Emphasis on self-control. Patient makes decisions regarding drug use over which s/he has control. Patient can learn to understand and better control the decision-making process. Patient can exert self-control by choosing to engage in alternative behaviors.
Responsibility	Patient responsible for own sobriety, by *working* the 12 Step program.	Patient responsible for own behavior. Emphasis on enhancing self-efficacy through skills training.
Conception of Craving	Because of disease processes, patient's body will crave cocaine periodically. First use will trigger craving.	Craving as conditioned response. Craving can be coped with and reduced through stimulus control, urge control, etc.

Motivational Enhancement (MET)	Interpersonal Therapy (IPT)
Maximize patient's motivation and commitment to change his/her drug use.	Help patient develop more productive strategies for dealing with social and interpersonal problems associated with drug use.
Motivational Patient Readiness for change	Brief dynamic Treatment Acquisition of alternate strategies for meeting interpersonal needs
Labelling is strongly discouraged; alternative conceptions of drug use are accepted/encouraged.	Labelling strongly discouraged; drug use seen as highly individualized and related to interpersonal context.
Emphasis on choice. Patient has full control over decision to alter drug use.	Emphasis on self-control and the function that drug use serves for the patient. Symptom of drug use seen as a method of controlling environment and others to get needs met.
Patient responsible for own choices. Emphasis on autonomy, self-efficacy.	Patient responsible for own behavior. Exploration of own role in interpersonal relationships.
Patient free to develop and capable of developing strategies for dealing with craving on his/her own.	Signal of unresolved interpersonal problem. Patient should begin to translate what triggered craving into underlying interpersonal problem.

Table 3.1 (cont.)

Contrasts Between CE and Other Treatments

	Twelve Step Facilitation (TSF)	Cognitive-Behavioral (CBT)
Strategies Addressing Ambivalence and Motivation	Remember last run. Addiction is a disease that motivates denial, educate patient re *sinister* aspects of disease. Current problems attributed to disease.	Positive/negative consequences of decisions to use or stay abstinent. Instill belief that effective coping will provide alternatives to drug use.
Patient's Response to Substance Use	External, uniform approach. Use CA/AA social network (call sponsor, go to a meeting). Remember slogans (eschews alternative strategies, because of denial). "Do not think you can control the consequences of use."	Individualized approach. Develop and use individualized set of coping strategies (challenge cognitions, problem-solve, etc.). Examine antecedents, behaviors, and consequences. "You can learn skills to avoid lapses and prevent lapses from becoming relapse."
Coping Behaviors	CA/AA fellowship/network constitute a ready-made set of strategies and the one preferred solution.	Individualized set of strategies, generalizeable problem-solving approach. Specific training in drug refusal skills, urge control, altering cognitions, emergency planning, etc.
Cognitions	Generally interpreted as evidence of denial, e.g., "stinking thinking".	Identified, examined, and challenged; encourage alternative perceptions/cognitions.
Handling Resistance	Confrontation of denial, exhortation of acceptance of addiction.	Application of problem-solving. Reinforcement of even minimal positive steps.
Role of Spouse/S.O. in Treatment	Reduce enabling, facilitate detaching, seek support through AlAnon.	Reinforce positive behavior change.
Phone Calls/crises	Refer patient to CA sponsor. "Use the fellowship".	Encourage patient to implement coping and problem-solving strategies.
Level of Structure	Highly directive and structured	Moderately directive and structured

Motivational Enhancement (MET)	Interpersonal Therapy (IPT)
Acknowledge validity of patient feelings, elicit self-motivational statements. Empathic listening, primacy of patient's choice. FRAME.	Challenge positive view of drug effects and emphasize deleterious effects by enumerating cost repeatedly. Emphasize authentic gratification patient will experience from improved interpersonal functioning.
Internal, individualized approach. Reviews progress, reviews/evaluates initial plan, renews motivation and commitment.	Explore interpersonal consequences of drug use and what needs were being met by using. Call attention to discrepancy between patient's goals and drug use.
"It's up to you whether you use or not."	"You feel more sociable when you're high, yet your cocaine use has alienated your family. What about that?"
Patient free to develop own coping strategies. Development of strategies encouraged, but not provided by therapist.	Patient free to develop own coping strategies. Development of strategies is encouraged, but not provided by therapist. Encouragements to use social supports instead of drugs.
Accepted as valid, met with exploration and reflection.	Exploration of effects of distorted thinking on interpersonal relationships is critical.
Reflection, empathy, reframing. Patient actively avoids evoking resistance.	Explored and interpreted in interpersonal context. Limited exploration of transference.
Facilitate patient's motivation to change drug use behavior.	Explore ways of providing support to patient. Exploration of relationship vis-a-vis drug use.
Meets patient's concerns with reflection.	Reinforce use of interpersonal contact instead of drugs in times of crisis. Encourage use of social supports.
Patient structured	Moderately directive and loosely structured

4. Guidelines for the Course of Treatment

The Initial Session

The first session may last up to one hour. The goals of this session are to establish a positive relationship with the patient, explore the patient's history and goals for treatment, provide a basis for and rationale for the medication, and build the patient's motivation to engage in treatment.

In most research studies, in preparation for the first session, therapists will receive a brief summary of the patient's history from the study staff, but will not have access to patient pretreatment assessments. Similarly, the therapists will not have access to any of the patient's research assessments throughout the treatment.

Target Symptoms

In the first session, much of the hour should be devoted to establishing clearly defined target symptoms for focus in the treatment. In establishing target symptoms, the CE therapist should attend to both drug use and psychiatric symptoms (if appropriate). Thorough review of target symptoms will lead off and provide a principal focus for all subsequent sessions. Moreover, establishment of target symptoms will provide a basis for treatment with the medication and thus set the stage for compliance monitoring.

Medication History

Following clarification of the target symptoms, the CE therapist should also establish the patient's past history of treatment with psychiatric medications, response, and duration of therapy. The CE therapist should also provide a rationale for the medication, in terms readily understandable to the patient, that corresponds closely with the patient's target symptoms and thus provides the basis of the patient's motivation to comply with treatment (relief from target problems).

> Example:
> T: "You've been telling me about your fairly long history of drug use, which you feel has caused quite a few problems for you. These are the problems we'll be working on over the next 10 weeks. It seems to me that your choosing to enter this treatment is an excellent plan for you, as the medication that's being prescribed, is likely to be very helpful with these problems and help you remain abstinent over time. I think you'll notice that you'll start feeling much better. In order for this to occur, however, it is very important that you take your medication as prescribed. The dose of the medication will be based on your response to it."

Foster Motivation

Another important goal of the first session is to foster the patient's motivation to stay in treatment and comply with the medication. To accomplish this goal, the CE therapist should engage in interventions that have been shown to build motivation to change addictive behaviors (Miller, Benefield & Tonigan, 1993). These include conducting open-ended inquiry about what the patient stands to lose or gain by continued drug use, and addressing the patient's ambivalence about stopping drug use.

The patient should be instructed that future visits will last 25-30 minutes and will be devoted to reviewing that patient's progress as well as discussing his or her concerns.

Subsequent Sessions

A consistent, structured format should be used for all other sessions, with each session organized as follows:

First 10-15 min: Assessment of Functioning

The beginning of each session should focus on detailed review of using, any psychiatric issues, general functioning and other target problems since the last session. This part of the session should also allow some open-ended discussion of the patient's current concerns.

Second 5-15 min: Compliance

Medication compliance, response, and any medication-related problems or concerns should be reviewed in detail.

Final 10 min: Motivation Building and Commitment

The therapist should use the final portion of the session to reconfirm/bolster the patient's motivation for abstinence, to encourage 12-Step meeting attendance, and review the patient's plans for the time between sessions.

Family Session

In the service of preventing attrition or providing reassurance, ONE brief family session can be offered in the course of treatment. The family member may be a spouse or significant other, a parent, a sibling, or a member of the patient's household. 12-Step program sponsors should not attend this session.

This session should follow the same parameters as the rest of the visits (e.g., no longer than 25-30 minutes, following a CE model). Content of the sessions should be limited to:

1. Providing information about medication and the treatment protocol
2. Answering family member's questions about the patient's treatment
3. Provision of support and encouragement.

Family sessions are intended to increase the level of family support, particularly during the period before a medication response is achieved.

When talking with the patient about a family session, the CE therapist should clarify the limited goals of the session and plan for the session with the patient (what topics can be reasonably covered, *clarifying that the session will not be family therapy*).

Because family meetings in CE are intended to be informative and supportive, interventions closely associated with family therapy per se should be avoided (e.g., paradoxical or structural interventions, communication skills training). In general, these sessions should be organized to be congruent with CE goals, that is, explore strategies the family may implement to help the patient be compliant with medication and reduce substance use. CE therapists should not provide or suggest particular strategies, but it is permissible for the therapist to endorse an idea a family member or patient comes up with on their own as a strategy for family support (e.g., having a family member to monitor compliance, asking for a particular type of support). Family members requesting additional family intervention should be encouraged to wait until the CE treatment ends. A referral may be provided by the study staff. Family members may be encouraged to attend Nar-Anon and/or Al-Anon meetings, which are 12-Step groups for family members of persons with substance abuse problems.

Termination

As in any treatment, patients are likely to become attached to the CE therapist and apprehensive about the end of treatment as the final session approaches. Sometimes in study protocols, patients who have shown a therapeutic response will be eligible to enter a continuation study, where sessions with the therapist would be less frequent. If the patient has not shown a therapeutic response final CE sessions should be directed at determining an appropriate treatment plan and/or referral, depending on the specific protocol.

Regardless of the patient's disposition, as the end of treatment approaches, the therapist should ask about the patient's reactions to the end of the study, and the loss of the relationship with the therapist, and discontinuation of medication. Review and recognition of progress towards the patient's goals should also be emphasized. In most cases, continued 12-Step meeting attendance should be encouraged as a strategy to maintain gains the patient has made during treatment and to maintain commitment to abstinence. The therapist and patient should work together to address any concerns that arise and develop a plan for the patient to remain abstinent, or in some cases, seek further treatment, once the CE protocol is completed.

5. Troubleshooting: Strategies for Dealing with Common Clinical Problems

Therapist Response to Missed Sessions

First, the therapist should recognize that many patients miss sessions because (a) they used drugs and are simply too embarrassed to admit their "failure" to the therapist, or (b) they are ambivalent about complete abstinence from drugs. Careful inquiry by the therapist will reveal which of these situations is the case. If the patient misses sessions because of fear of admitting failure, the therapist should reiterate that occasional slips are relatively frequent occurrences, and often signal a need to raise the dose of their medication and to redouble other efforts to become abstinent.

If the patient misses sessions because of continuous psychiatric symptoms and discouragement about their lack of response to treatment, the therapist should suggest that this may signal a need to raise the dose of the medication and the patient should be encouraged to come back in to treatment. The therapist should assure the patient that if they keep coming in, taking medications as prescribed, and trying their best, they will get better. If they drop out, they are much more likely to relapse.

Therapist Response to Slips and Relapses

The patient relapses, continues to use episodically and says: "I messed up", "I'm a failure", "This isn't working".

First, commend the patient on his/her honesty. Convey the idea that occasional relapses are normal occurrences in the course of treatment, and do not mean that the medication is not working or that the patient is a failure, (e.g., "I've frequently found that some patients on medication slip after several weeks of abstinence. It's actually a pretty common occurrence and nothing to feel ashamed about. You were abstinent for about three weeks before that slip. I'd expect you to be abstinent for at least twice that long now. What are some things you can do to remain abstinent that long?").

Second, continued substance use should be met with stronger encouragement to become more deeply involved in 12-Step programs. These recommendations should be as concrete as possible: if the patient is already attending meetings, the CE therapist might recommend he/she double the number of meetings attended per week. If the patient is not attending meetings, a clear commitment to attend them should be made (e.g., "Changing drug use is difficult, and you can't expect the medication to work all by itself, without some efforts on your part. Think about how many hours per week you've spent using. That's about how many hours you need to put, each week, into not using").

Finally, some *limited* inquiry into why the slip occurred may be appropriate. If

the patient mentions psychiatric symptoms, repeat the rationale for psychiatric medication. If the slip occurred because of clear external factors ("it's because of problems with my wife"), the therapist should feel free to listen and offer support, but add a statement such as, "Problems with your wife are somewhat out of the scope of the problems we are trying to work on here; however, as you feel better and our use of substances decreases, your wife will see that you're really making an effort to change, and you may find that the situation with her improves. If, after we've given the medications an adequate trial, you're still having problems with your wife, we can consider referring you to couples treatment after you finish this treatment."

Patient Concerns about Placebo

"It's not working", "I know I'm on placebo".

First, the therapist should repeat the pharmacotherapy rationale; reinforcing the concept of gradual, progressive change. The therapist may draw on his/her experience and state that with some patients, "it simply takes longer, but if the medication is to work, you must stay on the prescribed dosage and keep trying".

Second, review target symptoms/side effects. Question the patient's assumption that s/he is on placebo; point out any evidence that the patient is not on placebo. ("Well, you say you're on placebo because you still are experiencing distressing symptoms, and you haven't stopped using completely…. However, when you started treatment, you seemed to be much more symptomatic and you were using every day. Although you're not completely abstinent, I think that's pretty substantial progress. I think this may be evidence that the medication is beginning to work").

Third, encourage the patient to make further change in his/her behavior as outlined above. If the patient is not already doing so, strong encouragement to attend 12-Step meetings, or encouragement to deepen involvement (e.g., attending more meetings, getting a sponsor) may be useful.

Clinical Deterioration

A clinical issue of great importance is the identification and referral of patients who either do not respond to the treatment or whose clinical status deteriorates during the trial. If the patient has shown no improvement or begins to deteriorate after a reasonable therapeutic trial of medication and CE, the therapist should alert the Principal Investigator, and follow the study clinical deterioration protocol which, in most cases, involves terminating the study treatment and referring the patient to a more intensive level of care. The Principal Investigator will evaluate whether continuation in the study protocol would be detrimental to the patient, and determine whether the patient should be withdrawn from the study. If medication and CE is determined inappropriate treatment, appropriate referral arrangements should be made for the patient.

6. Therapist Selection, Training, and Supervision

Therapist Characteristics and Training Requirements

In the research studies which have evaluated this approach, CE has been implemented primarily by psychiatrists with substantial experience in and commitment to psychopharmacotherapy as a therapeutic intervention for treating a broad range of substance abusers. These therapists were selected to reduce the likelihood of therapist effects on treatment outcomes by utilizing a comparatively homogeneous group. Furthermore, because therapist training/piloting period for these clinical trials is comparatively brief, it was important to select therapists who already had a high level of expertise and experience in pharmacotherapy and medical management of substance abusers, and thus could easily learn CE and achieve levels of adherence and competence rapidly.

However, a much broader range of therapists have, with appropriate training and supervision, implemented Compliance Enhancement effectively. However, because this manual, like most others, focuses on specific CE techniques and does not cover basic clinical skills, we would recommend certain minimal requirements for clinicians:

- A master's degree or equivalent in psychology, counseling, social work or a related field.
- At least 3 years experience working with a substance abuse population.
- Some familiarity with and commitment to a psychopharmacotherapy approach.

Personal characteristics of therapists that are associated with improved outcome in CE have not been an explicit focus of our research to date. However, we assume the attributes identified by Luborsky and colleagues (1985) as associated with better patient outcome would apply to this treatment as well, including personal adjustment, interest in helping the patient, ability to foster a positive working alliance, and high empathy and warmth.

Therapist Training

Just as reading a textbook on surgery could not be expected to produce a qualified surgeon, mere review of this manual would be inadequate for a therapist to apply this manual in clinical practice or research. Appropriate therapist training for CE for substance dependence requires completion of a didactic seminar and at least one closely supervised training case.

Didactic Seminar

The didactic seminar usually lasts 2 days or more, depending on the experience

level of the therapists. The seminar includes a review of the rationale for Compliance Enhancement and a review of the manual. Videotaped examples of therapists implementing the treatment are reviewed, and therapists participate in several role-play and practice exercises. There is discussion of case examples, and rehearsing of strategies for difficult or challenging cases.

Supervised Training Cases

The supervised training cases provide an opportunity for the therapist to practice this approach and to learn to adapt their usual approach to conform more closely to manual guidelines. The number of training cases varies, of course, according to the experience and skill level of the therapist. Generally, we find that more experienced therapists require only one or two training cases to achieve high levels of competence, which is consistent with experience from the NIMH Treatment of Depression Collaborative Research Program (Rounsaville et al., 1986; Weissman et al., 1982). Less experienced therapists generally require two to four supervised cases.

For supervision of training cases, each session is audiotaped, or preferably, videotaped and forwarded to the supervisor. The supervisor reviews each session, completes a rating form (described below) evaluating the therapist's adherence and competence in implementing the treatment session, and provides one hour of individual supervision to the therapist. Supervision sessions are structured around the supervisor's ratings of adherence and competence, with the supervisor noting areas in which the therapist delivered the treatment effectively, as well as areas in need of improvement.

Rating and Assessment of Therapist Adherence and Competence

To have a concrete basis on which to evaluate therapist implementation of CE, both therapists and supervisors complete parallel adherence rating forms after each session conducted or viewed. The rating forms are provided in the appendix. These consist of Likert-type items covering a range of key CE interventions (supporting compliance with medication and treatment sessions). We have found that these instruments, (a) have acceptable levels of interrater reliability, and (b) and successfully distinguish between CE and other therapies commonly used in substance abuse treatment (Carroll, Nich, Sifrey, et al., in press).

CE Therapist Checklist

The therapist version of the form, called the CE Therapist Checklist (Appendix 6.1), asks the therapist to rate what CE strategies and interventions were implemented in a given session, and how frequently the intervention was used. The CE Therapist Checklist has a variety of purposes. First, it is intended to remind the therapist, at each session, of the key ingredients of CE. Second, the CE Therapist Checklist is intended to foster a greater adherence to the manual through self-monitoring of adherence. Third, it can organize and provide the basis for supervision, as the therapist can more readily note and explore with the supervisor the strategies and interventions s/he has trouble implementing

with a given patient. Fourth, in our research studies, completion of the CE Therapist Checklist facilitates process research by generating a useful record of which interventions were or were not delivered to each patient in a given session. Thus, for example we can construct a session-by-session map of the order, intensity of CE interventions introduced to a range of patients.

CE Therapist Adherence/ Competence Rating Form

The supervisor version of the form, called the CE Therapist Adherence/ Competence Rating Form (Appendix 6.2) differs from the therapist version by adding a skillfulness rating for each item. Thus for each intervention, both quantity and quality are rated. The CE Therapist Adherence/Competence Rating Form is an essential part of training, as it provides structured feedback to the therapist and forms the basis of supervision. It also provides a method of determining whether a therapist in training is ready to be certified to deliver the treatment in the clinical trial or protocol. When used with ongoing supervision, it enables the supervisor to monitor and correct therapist drift in implementation of the treatment. Finally, for therapists who have difficulty adhering to manual guidelines but who maintain that their implementation is adequate, pointing out discrepancies between the supervisor-generated CE Therapist Adherence/Competence Rating Form and the therapist-generated CE Therapist Checklist is often a useful strategy for enhancing adherence and helping the therapist understand areas in need of improvement.

For both versions of the scale, it is important to note that not all items on the rating forms are expected to be covered, or covered at a high level, during all sessions. However, the essential CE items (identified on page 4) should be present at least at a moderate level in the majority of sessions. A copy of the rating manual and rater's guidelines that accompanies this form is available through the Psychotherapy Development Center. It is also described in Carroll, Nich, Sifrey, et al., (in press).

Certification of Therapists

Therapists are certified, or approved to implement the treatment at lower levels of supervision, when the supervisor determines that the therapist has completed an adequate number of training cases successfully. For certification we generally require that for the most recent case, the therapist is given an adherence score of a 3 or more on several key CE items, and no skill rating below a 4 (adequate) on any item delivered. Due to the importance of CE being delivered as a treatment that does not overlap with other formalized psychotherapies, it is important that the therapist clearly differentiates his/her technical interventions from other comparison treatments in the particular protocol.

After certification, therapist adherence is monitored closely using the CE Therapist Adherence/Competence Rating Form on a portion of the therapist's ongoing cases. When therapist drift occurs, (the therapist strays from adequate fidelity to the manual), supervisors increase the frequency of supervision until the therapist's performance returns to acceptable levels.

Ongoing Supervision

We require ongoing supervision for all therapists delivering CE. However, the level and intensity of ongoing supervision reflects the experience and skill of the therapists, as well as the time available for supervision. The minimum acceptable level of ongoing supervision for an experienced therapist is monthly; weekly supervision is recommended for less experienced therapists. In addition, supervisors typically review and evaluate using the CE Therapist Adherence/Competence Rating Form, based on 1-2 randomly selected sessions per patient. Supervision sessions themselves should include a general review of the therapists current cases, discussion of any problems in implementing CE, review of recent ratings from the supervisor, and at least one of every two supervision sessions should include review of a recent session videotape.

Guidelines for Ongoing Supervision

In general, supervision is most effective when conducted at a consistent place, date, and time; the goals of supervision are clear and both participant's roles are defined; the procedures that will be used for evaluation of the therapists are clarified; and feedback to the therapist is based on session tapes and is focused and concrete ("When you explored X's last slip, I thought you could have facilitated his/her developing some strategies to avoid slips in the future. For example, relate the slip to possible non-compliance with medication. It is always important to encourage the patient to generate their own ideas to become and maintain abstinence.") (Witte & Wilber, 1997).

Common Problems Encountered in Supervision

FAILURE TO BALANCE MANUAL-SPECIFIED INTERVENTIONS AND PATIENT NEEDS AND CONCERNS. As noted earlier, the structure of CE sessions is intended to foster compliance with medication, abstinence, and attendance to treatment sessions. CE is a supportive therapy designed to meet the needs of each individual patient. Novice therapists, particularly those with less experience in treating substance abusers and the need to maintain a higher level of structure than that to which they may be accustomed, often tend to let sessions become unfocused, without clear goals (retention, abstinence, and compliance with medication). Therapists sometimes allow themselves to become overwhelmed by the constant substance-use related crises presented by a patient and fail to focus on CE treatment goals. Falling into a crisis driven approach tends to increase, rather than decrease, patient anxiety and undermine self-efficacy. On the other hand, maintaining a relatively consistent session routine and balancing the patient driven discussion of current concerns and encouraging patients to develop strategies of their own, helps them to avoid and/or manage crises effectively.

Conversely, some therapists become overly fixed and inflexible in their adherence to the manual. Some therapists, anxious to *get it right*, present the material in the manual more or less verbatim to patients. This overly wooden approach necessarily fails to adapt the teaching of the training material to the particular needs and readiness of particular patients. CE is a supportive treatment, designed to be delivered in a way that

facilitates the patient's ability to develop strategies to become and remain abstinent, and to be compliant with sessions and medication. Motivating patients who are ambivalent and/or resistant to treatment can be a delicate process. In CE, as in other therapies, the therapeutic relationship is instrumental in achieving treatment goals. Therefore, it is important to remind therapists that the manual is merely a blueprint, or set of guidelines for treatment, to be used to provide a clear set of goals and overall structure to the treatment, but manuals are by no means scripts for treatment. The treatment should be fresh, dynamic and individualized to the particular patient's concerns. Patients should never be aware that the therapist is following a manual.

ABANDONING THE MANUAL WITH DIFFICULT PATIENTS. Many patients present with a range of complex and severe comorbid problems. Again, some therapists become overwhelmed by concurrent problems and drift from use of the manual in an attempt to address all the patient's problems. In such cases, the therapist often takes a less, rather than the more structured approach needed by the patient. Generally, if the patient is sufficiently stable for outpatient therapy, we have found that the CE manual, which provides guidelines for a structured approach to treatment, prioritizing of current problems, offering limited case management, and focusing primarily on achieving initial abstinence and medication compliance, is adequate to contain even fairly disturbed patients.

TENDENCY TO DRIFT FROM DELIVERING CE AS A SUPPORTIVE TREATMENT WHERE THE *ACTIVE INGREDIENT* IS THE QUALITY OF THE THERAPEUTIC RELATIONSHIP. In CE formal technical interventions are not used, as in other psychotherapies (e.g., CBT, MET, IPT). Rather, the quality of the therapeutic relationship and the therapist's sensitivity to the non-specific aspects of treatment (e.g., reflective listening, empathy, attention to non-verbal cues) are critical. For CE to be effective, the therapist must support the patient's efforts whenever possible and be attuned to the therapeutic relationship at all times. It is the quality of this support that fosters compliance, abstinence and retention. In addition, when CE is delivered within its scope and done well, it serves as an effective treatment that is consistent with standard practice in delivering pharmacotherapy for drug abuse.

USING TECHNICAL INTERVENTIONS FROM OTHER FORMAL PSYCHOTHERAPIES. Many times experienced therapists draw from other formal psychotherapies, using specific techniques to address patient concerns. This is done with good intention and with interest in helping the patient, but serves to blur the differentiation between CE and other psychotherapies. When in doubt, focus on the therapeutic relationship and help the patient identify strategies that will help him/her accomplish treatment goals (compliance, retention and abstinence).

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Appendix

CE Therapist Checklist

STUDY: ___ PATIENT ID: ___ ___ ___ ___ DATE: ___ ___ /___ ___ /___ ___

SITE: ___ ___ ___ THERAPIST ID: ___ ___ WEEK: ___ ___ SESSION: ___ ___

PLEASE COMPLETE THE FOLLOWING BASED ON THIS SESSION WITH THE PATIENT. DO NOT COMPLETE IF THIS WAS AN EMERGENCY SESSION OR IF THE SESSION WAS TRUNCATED DUE TO PATIENT DRUG USE.

---

1. To what extent did you **ASSESS THE PATIENT'S SUBSTANCE USE** since the last session?

   1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
   Not at all Somewhat Considerably Extensively

2. To what extent did you discuss or address the patient's **CURRENT COMMITMENT TO ABSTINENCE**?

   1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
   Not at all Somewhat Considerably Extensively

3. To what extent did you discuss, review, or reformulate the patient's **GOALS FOR TREATMENT**?

   1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
   Not at all Somewhat Considerably Extensively

4. **BIOCHEMICAL RATIONALE FOR DRUG USE:** To what extent did you present a rationale which suggested that drug use or craving may be related to changes in neurotransmitter levels or post-synaptic adaptation associated with chronic drug abuse?

   1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
   Not at all Somewhat Considerably Extensively

5. **PHARMACOTHERAPY RATIONALE:** To what extent did you provide a rationale which emphasized the importance of reversing neuroadaptation to drug use via medication? **UPDATE BASED ON MEDICATION USED.**

   1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
   Not at all Somewhat Considerably Extensively

6. **CONCERNS ABOUT MEDICATION:** To what extent did you assess the patient's concerns about taking medication **AND** address those concerns?

   1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
   Not at all Somewhat Considerably Extensively

7. **MEDICATION EFFECTS EXPECTED:** To what extent did you discuss the specific symptom relief (e.g., reduced craving, gradual reduction in amount and frequency of use) and the temporal course of that relief that the patient might anticipate as a consequence of taking the study medication?

   1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
   Not at all Somewhat Considerably Extensively

8. **GENERALIZED IMPROVEMENT FROM MEDICATION:** To what extent did you convey the idea that the pharmacotherapy whould lead to positive changes in other areas of his/her life (in addition to reducing drug use and craving)?

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Not at all Somewhat Considerably Extensively

9. **RELATING CHANGE TO MEDICATION:** To what extent did you relate positive change to the study medication the patient was receiving **OR** discuss the patient's lack of response or slowness to respond to the study medication?

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Not at all Somewhat Considerably Extensively

10. **OPTIMISTIC REASSURANCE:** To what extent did you attempt to reassure the patient that the problems s/he encountered (e.g., initial non-response, side effects) would eventually subside if the patient adhered to the medication regimen**.**

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Not at all Somewhat Considerably Extensively

11. **MEDICATION DOSAGE:** To what extent did you discuss the medication dosage that was prescribed?

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Not at all Somewhat Considerably Extensively

12. **MEDICATION SCHEDULE:** To what extent did you discuss or adjust the patient's schedule for taking the medication?

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Not at all Somewhat Considerably Extensively

13. **MEDICATION COMPLIANCE:** To what extent did you discuss the patient's compliance/non-compliance with the prescribed medication regimen?

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Not at all Somewhat Considerably Extensively

14. **OCCURRENCE OF SIDE EFFECTS:** To what extent did you inquire about the occurrence of side effects?

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Not at all Somewhat Considerably Extensively

15. **HANDLING OF SIDE EFFECTS:** To what extent did you discuss procedures for handling medication side effects, either those which have already occurred **OR** those which might occur?

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Not at all Somewhat Considerably Extensively

CE Therapist Adherence/Competence Rating Form

RATER: ___ THERAPIST ID: ___ ___ ___ SITE: ___ ___ ___ PATIENT ID: ___ ___ ___

WEEK: ___ ___ SESSION: ___ ___

SESSION DATE: ___ ___ /___ ___ /___ ___ DATE RATED: ___ ___ /___ ___ /___ ___

Category 1: Compliance Monitoring and Enhancement

1. **ASSESS COMPLIANCE:** To what extent did the therapist *assess medication compliance since the last session*?

   1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
   Not at all Somewhat Considerably Extensively

   QUALITY OF INTERVENTION:

   1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
   Poor Adequate Good Excellent

2. **PRAISE COMPLIANCE:** To what extent did the therapist *praise medication compliance*?

   1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
   Not at all Somewhat Considerably Extensively

   QUALITY OF INTERVENTION:

   1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
   Poor Adequate Good Excellent

3. **PROBLEM-SOLVE NONCOMPLIANCE:** To what extent did the therapist *use a problem-solving strategy for non-compliance*?

   1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
   Not at all Somewhat Considerably Extensively

   QUALITY OF INTERVENTION:

   1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
   Poor Adequate Good Excellent

4. **ASSESS PATIENT CONCERNS:** To what extent did the therapist *address the patient's concerns about medication*?

   1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
   Not at all Somewhat Considerably Extensively

   QUALITY OF INTERVENTION:

   1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
   Poor Adequate Good Excellent

5. **RELATE CHANGE TO COMPLIANCE:** To what extent did the therapist *relate the patient's clinical improvement to compliance **OR** lack of improvement to non-compliance*?

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Not at all Somewhat Considerably Extensively

QUALITY OF INTERVENTION:

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Poor Adequate Good Excellent

6. **MEDICATION HISTORY:** To what extent did the therapist *inquire as to the patient's experience with medication*?

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Not at all Somewhat Considerably Extensively

QUALITY OF INTERVENTION:

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Poor Adequate Good Excellent

Category 2: Clinical Management and Motivation Building

7. **DRUG HISTORY:** To what extent did the therapist *establish a history of or characterize the patient's current episode of drug use*?

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Not at all Somewhat Considerably Extensively

QUALITY OF INTERVENTION:

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Poor Adequate Good Excellent

8. **PSYCHIATRIC HISTORY:** To what extent did the therapist *establish a history of or characterize the patient's current episode of psychiatric symptoms/problems*?

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Not at all Somewhat Considerably Extensively

QUALITY OF INTERVENTION:

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Poor Adequate Good Excellent

9. **ASSESS DRUG USE:** To what extent did the therapist *assess the patient's drug use since the last session*?

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Not at all Somewhat Considerably Extensively

QUALITY OF INTERVENTION:

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Poor Adequate Good Excellent

10. **ASSESS PSYCHIATRIC SYMPTOMS:** To what extent did the therapist *assess psychiatric symptoms since the last session*?

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Not at all Somewhat Considerably Extensively

QUALITY OF INTERVENTION:

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Poor Adequate Good Excellent

11. **ASSESS GENERAL FUNCTIONING:** To what extent did the therapist *assess the patient's general functioning since the last session*?

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Not at all Somewhat Considerably Extensively

QUALITY OF INTERVENTION:

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Poor Adequate Good Excellent

12. **LINK DRUG USE AND PSYCHIATRIC SYMPTOMS:** To what extent did the therapist *link the patient's drug use or abstinence to psychiatric symptoms*?

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Not at all Somewhat Considerably Extensively

QUALITY OF INTERVENTION:

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Poor Adequate Good Excellent

13. **GOAL SETTING:** To what extent did the therapist *review, set, or monitor patient goals for treatment*?

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Not at all Somewhat Considerably Extensively

QUALITY OF INTERVENTION:

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Poor Adequate Good Excellent

14. **ABSTINENCE AS TREATMENT GOAL:** To what extent did the therapist *discuss abstinence as a treatment goal*?

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Not at all Somewhat Considerably Extensively

QUALITY OF INTERVENTION:

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Poor Adequate Good Excellent

15. **OPTIMISTIC REASSURANCE:** To what extent did the therapist *provide optimistic reassurance*?

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Not at all Somewhat Considerably Extensively

QUALITY OF INTERVENTION:

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Poor Adequate Good Excellent

16. **SELF-EFFICACY:** To what extent did the therapist *encourage patient efforts and use of personal resources*?

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Not at all Somewhat Considerably Extensively

QUALITY OF INTERVENTION:

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Poor Adequate Good Excellent

17. **COSTS OF DRUG USE:** To what extent did the therapist *explore the costs of continued drug use*?

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Not at all Somewhat Considerably Extensively

QUALITY OF INTERVENTION:

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Poor Adequate Good Excellent

18. **ENCOURAGE SELF-HELP:** To what extent did the therapist *encourage NA/CA/AA/self-help involvement*?

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Not at all Somewhat Considerably Extensively

QUALITY OF INTERVENTION:

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Poor Adequate Good Excellent

Category 3: Recommended Interventions

19. **SPECIFIC REFERRAL TO NA/CA/AA:** To what extent did the therapist *make a specific referral to a self-help group*?

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Not at all Somewhat Considerably Extensively

QUALITY OF INTERVENTION:

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Poor Adequate Good Excellent

20. **PROBLEM-SOLVE RESISTANCE TO NA/CA/AA:** To what extent did the therapist *problem-solve any self-help concerns and resistance*?

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Not at all Somewhat Considerably Extensively

QUALITY OF INTERVENTION:

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Poor Adequate Good Excellent

21. **MEDICATION AND SELF-HELP:** To what extent did the therapist *discuss medication compliance in the context of self-help attendance*?

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Not at all Somewhat Considerably Extensively

QUALITY OF INTERVENTION:

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Poor Adequate Good Excellent

22. **FAMILY SUPPORT:** To what extent did the therapist *discuss the level of the patient's family support for treatment or abstinence*?

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Not at all Somewhat Considerably Extensively

QUALITY OF INTERVENTION:

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Poor Adequate Good Excellent

23. **EDUCATE FAMILY MEMBERS ABOUT STUDY/TREATMENT:** To what extent did the therapist *educate the patient's family member regarding the study/treatment protocol, the nature of the study/treatment, or address other concerns expressed by the family members about the study/treatment protocol*?

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Not at all Somewhat Considerably Extensively

QUALITY OF INTERVENTION:

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Poor Adequate Good Excellent

24. **EDUCATE FAMILY MEMBERS ABOUT MEDICATION:** To what extent did the therapist *address family concerns or questions about the medication and expected benefits, answer family questions*?

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Not at all Somewhat Considerably Extensively

QUALITY OF INTERVENTION:

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Poor Adequate Good Excellent

Category 4: Proscribed Interventions

25. **CBT/DRUGS:** To what extent did the therapist *engage in cognitive-behavioral interventions for substance use (e.g., skill training, role playing exploring cognitions, self-monitoring of substance use, functional analysis of relapse episodes)*?

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Not at all Somewhat Considerably Extensively

QUALITY OF INTERVENTION:

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Poor Adequate Good Excellent

26. **CBT/PSYCHIATRIC SYMPTOMS:** To what extent did the therapist *engage in cognitive-behavioral interventions for psychiatric symptoms (e.g., self-monitoring of symptoms, explain ABC theory of cognition, confront psychogenic cognitions)*?

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Not at all Somewhat Considerably Extensively

QUALITY OF INTERVENTION:

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Poor Adequate Good Excellent

27. **PSYCHODYNAMIC INTERVENTIONS:** To what extent did the therapist *engage in interpersonal or psychodynamic interventions (e.g., exploring conflicts about important relationships, make transference interpretations)*?

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Not at all Somewhat Considerably Extensively

QUALITY OF INTERVENTION:

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Poor Adequate Good Excellent

28. **FAMILY THERAPY:** To what extent did the therapist *engage in family or relationship therapy*?

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Not at all Somewhat Considerably Extensively

QUALITY OF INTERVENTION:

1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7
Poor Adequate Good Excellent