

Chapter 9: Cost Effectiveness Study

9.1 Study Objectives

The purpose of the Cost Effectiveness (CE) study is to examine the cost and cost-effectiveness of the combined behavioral and pharmacological interventions included in the main COMBINE trial. The specific research questions are:

- What are the 12-month and 36-month costs of COMBINE therapies?
- How do the costs and effectiveness of the monotherapies in COMBINE compare to each other at the 12-month and 36-month follow-ups?
- How do the costs and effectiveness of the COMBINE monotherapies compare to the combination therapies at the 12- and 36-month follow-ups?

9.2 Participant Eligibility

Study subjects for the cost-effectiveness study are recruited from the COMBINE main trial. All sites participating in the main trial, with the exception of Miami and Texas have agreed to participate in the cost-effectiveness study. All subjects recruited into the main trial at participating sites are eligible to participate in the economic study. There are no exclusions restrictions for the economic study beyond those of the main COMBINE trial. Subjects that have signed the COMBINE informed consent are asked to sign the cost-effectiveness study informed consent.

9.3 Informed Consent

Each site may use its discretion as to the most appropriate COMBINE visit in which to consent subjects for the CE study. Each subject receives an explanation of the cost-effectiveness study protocol, its risks, and potential benefits by a study staff member. Following resolution of any questions, subjects who appear to understand the nature of the study and consent are asked to sign the CE study consent form. If for some reason, a face to face encounter is not possible in obtaining the informed consent, complete details of the study is explained over the phone and the participant is asked to fax or mail in the signed consent. However, this protocol is site specific and the site should consult its IRB before obtaining any telephone consents.

The informed consent form requires two signatures – one agreeing to transfer the participant's main trial data for the economic study and the other agreeing to participate in 20

additional months of follow-up interviews. If a patient refuses to participate in additional follow-up, effort must be made to at least obtain consent to transfer main trial data. After the consent is obtained, a complete copy of the informed consent form is given to each subject.

9.4 Data Collection and Management

9.4.1 Schedule of Data Collection

The cost-effectiveness study entails 5 additional follow-up interview visits at weeks 88, 105, 122, 139 and 156. These interviews consist of the Form 90 Follow-up (FED), the Concurrent Medication Form (COM), and the World Health Organization's Quality of Life form (WHO). Some sites may choose to add the SF-12 (SFA). No other instruments are administered as a part of the CE study protocol. No physical examination is conducted and no blood or urine specimen is collected. For detailed information on administering the FED, COM, WHO or SF-12, please refer to the COMBINE Manual of Operations, Chapter 6.

9.4.2 Data Collection Setting

Each interview is intended to take place face to face. A breathalyzer test is conducted at the beginning of each session. If BAC > 0.05, the interview is re-scheduled. In the event that the participant is unwilling or unable to meet the interviewer at the treatment setting, the interview may be conducted over the phone. Data for all the forms listed in the section above can be collected over the phone. If the participant is unwilling to complete the entire Form 90 follow-up, the shorter telephone version of the Form 90 (FAQ) should be administered. The forms may also be mailed to the participant along with a self-addressed stamped envelope. In these instances, the breathalyzer test cannot be administered. It is up to the interviewer to look for signs of intoxication during the phone conversation such as slurred speech etc. If the interviewer feels that the participant is not fully alert, the interview is rescheduled. For all form-90 interviews completed over the phone, the BAC is entered as missing in the DMS.

9.4.3 Data Entry and Data Management

The procedure for CE study data collection, data entry into the Data Management System (DMS) and the transfer of data to the Coordinating Center remains the same as in the COMBINE trial. For more details, please refer to the COMBINE Manual of Operations, Chapter 7.

9.5 Incentives

When assessments are completed, the participant is thanked for his/ her participation, paid \$50, and his/ her next visit is scheduled. A participant who completes all the CE follow-ups at weeks 88, 105, 122, 139 and 156 receives \$250.

9.6 Active/ Inactive Status

The Cost Effectiveness Study Status form (CES) must be completed if a patient is designated inactive for the CE study (if he/ she is 3 months overdue for a follow-up visit), or becomes re-engaged and is active again. The completed form should be entered into the Data Management System.

9.7 Contact Information

For questions related to protocol, data collection and data management, please contact the UNC Coordinating Center:

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