6. Chapter 6: Psychosocial Measurement

6.1 Introduction and Overview

The primary objective of ENRICHD is to reduce mortality and recurrent MI by ameliorating depression and increasing social support in post-MI patients. Thus, evaluation of the effects of the psychosocial intervention on the presence and severity of depression, and on degree and type of social support, are major secondary objectives of ENRICHD. Other secondary goals are the evaluation of the effects of the intervention on health-related quality of life (HQL) and on other psychosocial factors, such as perceived stress and self-efficacy. This chapter describes the procedures to be used to measure the psychosocial endpoints in ENRICHD at three separate timepoints: at screening/baseline, at the 6-month follow-up, and at the 18-month follow-up.

6.2 Schedule of assessment

Chapter 2 of this manual provides a flow chart depicting the screening and recruitment process to be used in ENRICHD. As shown in the chart, patients’ initial psychosocial eligibility for ENRICHD is determined in hospital via administration of the DISH Part A and ENRICHD Social Support Instrument (ESSI). While self-administration may be the most common mode of assessment, often these instruments may need to be administered by an interviewer. If patients meet DSM-IV criteria for major or minor depression, or are determined to have low social support via their scores on the ESSI (see Chapter 2 for details on how to determine psychosocial eligibility using these instruments), they are administered a battery of psychosocial measures, preferably while still in-hospital, and then randomized to either psychosocial treatment or usual care. The psychosocial measures administered at baseline, along with the BDI, ESSI and DISH Part B, are administered again at 6 months post-randomization, and a subset of these measures are administered at 18 months post-randomization. The following table outlines the specific psychosocial measures used in ENRICHD, their schedule of administration, and other relevant descriptive information.
### 6.3 Table:

The table below summarizes the revised schedule for collection of Psychosocial Data:

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Content</th>
<th>Baseline</th>
<th>6</th>
<th>12</th>
<th>18</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modified DIS + Hamilton (DISH)</td>
<td>Depression</td>
<td>A¹</td>
<td>A</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Beck Depression Inventory (BDI)</td>
<td>Depression</td>
<td>A</td>
<td>A</td>
<td>A</td>
<td>A</td>
</tr>
<tr>
<td>ENRICHD Social Support Instrument (ESSI)</td>
<td>Social Support</td>
<td>A</td>
<td>A</td>
<td>A</td>
<td>A</td>
</tr>
<tr>
<td>Longitudinal Course Chart (LCS) (Derived from the DISH)</td>
<td>A</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ISEL subscale</td>
<td>Tangible Support</td>
<td>S (400)</td>
<td>S (400)</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Perceived Social Support Scale (PSSS)</td>
<td>Social Support</td>
<td>A</td>
<td>A</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Social Network Questionnaire (SNQ)</td>
<td>Social Networks</td>
<td>S (800)</td>
<td>S (800)</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>MOS SF36 (HQL)</td>
<td>Health Quality of Life</td>
<td>-</td>
<td>S (800)</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Life Satisfaction (LSS)</td>
<td>Life Satisfaction and Meaning</td>
<td>-</td>
<td>S (800)</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Perceived Stress Scale (PSS)</td>
<td>Perceived Stress</td>
<td>S (400)</td>
<td>S (400)</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Self-Efficacy (SEM)</td>
<td>ENRICHD Intervention</td>
<td>S (400)</td>
<td>S (400)</td>
<td>-</td>
<td></td>
</tr>
</tbody>
</table>

¹A: all participants  
S: subsample of participants (first 400/800 randomized)  
-: not collected
6.4 Mode of assessment

The DISH is the only psychosocial measure used in ENRICHD that is always interview-administered. The other psychosocial measures are intended to be self-administered by patients, but can be interview-administered when the need arises. Section 6.11. of this chapter provides guidelines for determining when instruments should be interview versus self-administered, and the Forms Appendix provides instructions for transforming each self-administered measure into an interview.

6.5 Location of assessment

6.5.1 Screening

The measures administered during screening and baseline are intended to be administered in-hospital. In cases where eligibility is not completely determined prior to discharge, the screening instruments can be administered via telephone (see Chapter 3 for details).

6.5.2 Baseline

Although it is intended that the baseline assessment take place in-hospital, this will prove unfeasible for some patients. When the baseline assessment is not conducted in-hospital, patients should be scheduled for assessment prior to discharge where possible, or telephoned as soon as possible after discharge and scheduled for a baseline visit. If it does not take place in hospital, the baseline visit can take place in a clinic or other setting (e.g., research offices), or in the patient's home, if necessary.

6.5.3 Follow-up

Follow-up visits will typically take place in the hospital or clinic (scheduling of these visits may be done to coincide with the patients' regular hospital or clinic visit, where possible). If it is impossible for the patient to travel to the hospital or clinic for a follow-up visit, home visits can be scheduled.

6.6 Screening

Following determination of medical eligibility, the patient is approached in hospital by the Case Coordinator or other ENRICHD staff member and administered the DISH Part A and ESSI.

6.6.1 Beck Depression Inventory (BDI)

The 21-item BDI is used in ENRICHD to evaluate baseline status and outcomes, and to assess progress during treatment and to monitor patients for relapse (use of the BDI to assess treatment progress and relapse is described in Chapter 10). The BDI is intended to be a self-administered instrument, with each item consisting of four answers without a question. This format makes it difficult to administer as an interview; however, a standard list of questions have been developed so that the BDI can be administered orally by telephone or in person to patients who require that it be interview-administered (e.g., those with poor vision, poor reading ability, etc.). Details on interview administration of psychosocial measures appear in Section 6.11, and instructions on transforming the BDI into an interview appears in the Forms Appendix.
Each item on the BDI is rated on a 0-3 scale. To score the BDI, the items are added so that the total ranges from 0 to 63. (Item #19 (weight loss) is an exception to this rule: if the patient endorses item 19a (dieting to lose weight), Item 19 counts as a zero regardless of how the patient responded to it.)

6.6.2 ENRICHD Social Support Instrument (ESSI)

The ESSI is a 7-item scale which primarily measures functional social support and, in particular, emotional support. It was developed using individual items from previous studies of post-MI and CAD patients that have been shown to predict cardiac events and death. The ESSI is used as a screening tool to determine patients' eligibility for ENRICHD based on low social support, and to assess changes in patients' social support following treatment (at 6 and 18 months post-randomization).

The ESSI is administered with the DISH Part A during hospitalization as the first screening measure to determine patient eligibility. Patients who score 2 or lower on at least two items of the ENRICHD Social Support Instrument (excluding item 4) or (b) a score of 3 or less on two or more items, excluding items #4 and 7 (help with chores and marital status) and a total score of 18 or less on items 1, 2, 3, 5 and 6 within 14 days of the onset of acute myocardial infarction are considered to meet the psychosocial eligibility criteria for ENRICHD based on low social support, and should be scheduled for a baseline assessment session, preferably while still in hospital. The ESSI is designed to be self-administered; however, should there be a need for it to be administered orally, the Forms Appendix provides procedures to be used to administer the ESSI as an interview.

6.6.3 DSM-IV Depression Interview and Structured Hamilton (DISH)

The DISH is a structured psychodiagnostic interview that was developed specifically for ENRICHD. It is based on the modified versions of the National Institute of Mental Health Diagnostic Interview Schedule (DIS) that have been used in some of the most important studies of depression in post-MI and other cardiac populations, and on a structured version of the Hamilton Rating Scale for Depression (HAM-D) that was developed by Dr. Janet Williams. The DISH was developed to eliminate the redundancy between certain items on the modified DIS and the HAM-D in order to make the interview more time efficient and less burdensome for the patients and interviewers.

The DISH is used to (1) diagnose current major and minor depressive episodes and dysthymia according to the American Psychiatric Association's DSM-IV criteria; (2) characterize the pattern and duration of depressive symptoms, both in absolute terms and in relation to the MI and other stressors; (3) measure the severity of the depressive disorder on the Hamilton Scale; and (4) document the patient's psychiatric history, including prior episodes of depression, other psychopathology, and previous treatment for depression or other psychiatric disorders. The Hamilton scale is almost universally used in clinical trials of treatments for depression and will also serve important clinical purposes in this trial (e.g., to determine whether the patient may need concurrent antidepressant therapy). The DISH requires about 20 minutes to administer to the average nondepressed patient, and between 30 and 45 minutes for most depressed patients.
The DISH Part B is administered to patients who are determined to meet DSM-IV criteria for either major or minor depression or dysthymia using the DISH Part A are considered eligible for participation in ENRICHD, and should be scheduled for baseline assessment and randomization (see Chapter 3 for further details concerning the DISH and use of depression criteria for enrollment in ENRICHD).

The DISH is also used to assess depression at 6 months post-randomization. In most respects, the interview is conducted the same way at each of these timepoints, but there are a few exceptions to this rule. For example, when the DISH is being used to determine patient eligibility, the interviewer will know after asking the first 6 questions whether the patient has lost interest in his/her favorite activities or whether he or she has been feeling dysphoric (sad) most of the time lately. If neither of these symptoms are present, the patient cannot meet the DSM-IV criteria for major or minor depression, and therefore, the interview can be abbreviated.

At this point, only if the patient has received a score of 2 or lower on at least two items of the ENRICHD Social Support Instrument (excluding item 4) or (b) a score of 3 or less on two or more items, excluding items #4 and 7 (help with chores and marital status) and a total score of 18 or less on items 1, 2, 3, 5 and 6 on the ESSI will he or she be eligible for participation in ENRICHD.

The Psychiatric History section of the DISH should only be administered during screening/baseline, and not at subsequent timepoints. The opposite is true for the Longitudinal Course Chart, since it is to be administered only at follow-up and not at screening/baseline.

The DISH is called a "structured" interview because it requires every interviewer in the project to ask the same set of questions in the same order. Previous research has shown that structured interviews are much more reliable, thorough, and accurate than unstructured, open-ended clinical interviews. However, clinical interviews that are too rigidly structured can be insensitive to the unique and unexpected responses of individual patients. Consequently, although the DISH is designed to be a structured interview, it is designed to be as flexible as possible.

Problems can arise when structured clinical interviews are conducted in an excessively rigid, rote, or detached manner. These approaches can cause the interviewer to miss important information and to irritate or alienate the patient. When administering a structured clinical interview like the DISH, the questions must be asked in a sensitive manner, and the interviewer should aim to sound like he or she is conversing with and truly interested in the patient as a unique individual, rather than merely reading aloud from a script, or rushing through the interview as fast as possible just to get it over with. Furthermore, the interviewer must listen carefully to -- and think carefully about -- the patient’s responses, and try to clarify the ones that are vague, confusing or contradictory, or that suggest the patient did not fully understand the question. Consequently, although the DISH is a structured interview, interviewers often have to improvise when asking clarifying questions on the DISH.

This more flexible approach to interviewing is different than the approach to be taken when the self-administered questionnaires used in ENRICHD need to be interview-administered. In the case of the
DISH, a clinical interview, flexibility and improvising to better clarify patients' answers are important parts of conducting the interview. In the case of the other psychosocial measures, which are intended to be administered as self-administered items but may need to be transformed into interviews when patients have literacy or visual problems, questions should be asked in a more standardized, neutral way to ensure objectivity and eliminate bias. Because the procedures used for administering the DISH are somewhat complex and involve judgment and flexibility on the part of the interviewer, guidelines for administering the DISH are described in detail in the Forms Appendix (General Instructions for the DISH) and (Interview Techniques to be used in Administration of the DISH). Guidelines for transforming the other psychosocial measures into interviews, when needed, appear in Section -- and in the Forms Appendix for each measure.

6.6.4 Short Blessed Test (SBT)

The SBT is a short mental status test that should be administered during screening when the Case Coordinator or ENRICHD staff member has sufficient reason to believe that the patient may be too cognitively impaired to participate in ENRICHD. Guidelines for when to administer the SBT and how to score this test are given in the Forms Appendix.

6.7 Baseline

If the patient is determined to be eligible to participate in ENRICHD, a baseline assessment should be scheduled while the patient is hospitalized or as soon as possible after discharge. The psychosocial measures to be administered during the baseline visit include the following:

6.7.1 Perceived Social Support Scale (PSSS)

This measure is a 12-item scale incorporating subscales which measure the degree of perceived support the patient receives from family, friends and significant others.

6.7.2 New Haven EPESE Social Network Questionnaire (SNQ)

The EPESE SNQ will be used to measure the structure of the patients' social networks. This 19-item questionnaire covers size, frequency of visual and non-visual contact, geographic proximity of close relatives and friends, marital status and religious and group membership.

6.7.3 Selected items from the Interpersonal Support Evaluation List (ISEL)

Ten items selected from the ISEL measure tangible support, or the extent to which the patient has someone in his or her life to call on for help with practical, financial and other tangible assistance, when needed.

6.7.4 Perceived Stress Scale (PSS)

The PSS is a 10-item scale that measures the degree to which situations in patients' lives are perceived as stressful (unpredictable, uncontrollable, overwhelming).
6.7.5 Self-efficacy Measure (SEM)

Self-efficacy refers to the confidence in one's ability to behave in such a way as to produce a desirable outcome (Bandura, 1977). The SEM is a 10-item scale developed to reflect the intervention's expected effects on patients' self-efficacy related to the targets of depression and social support.

These measures appear in self-administered form, with guidelines for administering the measures as interviews in the Forms Appendix.

6.8 Follow-up

Six-months following randomization patients should be contacted by the Case Coordinator or other ENRICHD staff member and scheduled for a 6-month follow-up visit. This visit will include assessment of medical status (see Chapter 5 for details on medical aspects of this visit), and administration of the psychosocial measures used in screening (ESSI, DISH) and those administered at the baseline visit (BDI, PSSS). The PSS, and SEM and SNQ, are administered only on a subsample of patients (the first 400/800 patients randomized to ENRICHD). The 10-item ISEL is administered only on a subsample of patients -- the first 400 patients randomized to ENRICHD. In addition to these measures the six-month follow-up will include the LOL, LSS, and selected items from the MOS SF-36 (HQL), also administered to subsample of patients.

6.8.1 Selected Medical Outcome Study Short-Form 36 items (MOS SF-36)

The MOS SF-36 is a generic, standardized survey instrument for the assessment of health-related quality of life (HQL). Selected subscales from the SF-36 to be used in ENRICHD include the physical functioning, role limitations and social functioning subscales; individual items from the SF-36 assess health perceptions, pain and aspects of emotional functioning not captured in the depression measures, such as vitality.

6.8.2 Life Satisfaction Scale (LSS)

The LSS is an 8-item scale measuring satisfaction with life and meaning in life which was derived from studies of long-term survivors of AIDS, and includes items from Ironson's Purpose in Life measure and Neugarten's Life Satisfaction measure, administered to a subsample of randomized patients.

6.8.3 Ladder of Life (LOL)

The LOL, developed by Cantril (1965) uses a 1-10 scale ladder technique to assess patients' overall satisfaction with their lives now, their satisfaction with their lives in the past, and their perceptions of how satisfied they will be in the future.

Eighteen-months following randomization, patients will be scheduled for another follow-up medical and psychosocial assessment; however, the psychosocial measures administered at this visit involve a subset of the measures administered earlier: the BDI, ESSI, and MOS SF-36 items.
6.8.4 Procedures to maximize blindness of interviewers

As a rule, the procedures for administering the psychosocial measures at follow-up are identical to those used at the baseline assessment. However, in order to minimize possible bias on the part of the interviewer, it is important that the assessor who does the psychosocial assessment at follow-up is kept blind to the randomization status of the study participant and to whether they were depressed or not at entry into the trial (i.e., the assessor should not know whether the study participant was in the intervention or usual care group, nor their original depression diagnosis). (In the case of the DISH, there are certain exceptions to this rule, which are discussed in the following section on "Special procedures for BDI and DISH as follow-up measures.")

To maximize blindness of interviewers to the patient's treatment assignment at follow-up psychosocial assessment, the following procedures are recommended:

1. Randomization is done by a person different that the one who will be doing follow-up assessments;
2. Randomization group assignment is not communicated to the follow-up assessor;
3. Follow-up assessment may not be done by the therapist or other individual who has knowledge of treatment assignment;
4. An ENRICHD staff person (NOT the person doing follow-up assessments) should ideally contact the patient prior to follow-up to schedule the follow-up visits. This person should instruct the patient at that time: "DO NOT SAY ANYTHING TO THE INTERVIEWER/ASSESSOR ABOUT WHETHER YOU ARE ASSIGNED TO THE THERAPY PART OF THIS STUDY OR THE USUAL CARE PART."
5. Participants should be reminded at the start of the assessment session not to divulge which part of the study (treatment versus usual care) they are in.
6. Assessors should note whether the participant gave them any information indicating which group they were assigned to on the evaluation form.

6.8.5 Procedures when suicidal features are present

When the BDI and the DISH are administered as follow-up measures, the interviewer may determine that suicidal features are present. If so, the assessment, classification and notification procedures discussed in Chapter 2 and Chapter 8 are to be followed. In addition, if the patient is in the treatment arm of the study, his/her therapist and if applicable, the study psychiatrist should be notified (since the interviewer will ideally be blinded to treatment assignment, the Principal Investigator or another individual at the clinical site who has broad oversight and access to treatment assignment should provide follow-up information to the therapist/psychiatrist).
6.8.6 Procedures for using the DISH at follow-up

When the DISH is administered as part of the 6-month follow-up assessment, the interviewer should be blinded to treatment assignment, and to whether or not the patient was depressed when he or she was recruited to participate (see section on blinding of interviewer, above). However, this only applies to the Current Depression Symptoms portion of the DISH through Item 49. During the remaining portion of the interview, you will have to be unblinded in order to complete Item #48, the History and Course Chart, and the Diagnostic Summary Form. In order to complete the Longitudinal Course Chart and Diagnostic Summary Form, you will have to be unblinded to the patient’s status at baseline and to what has happened to him/her between then and now.

When preparing to conduct a follow-up interview, you should be given a photocopy of the Diagnostic Summary Form (DSF) from the previous interview (i.e., the screening interview DSF if preparing for the 6-month interview; and the 6-month interview DSF if preparing for the 18-month interview.) This should be given to you in a sealed envelope so that you will be able to remain blinded to the patient’s previous assessment until you reach Item #48 on the Longitudinal Course Chart, which concerns the patient’s diagnosis from the previous interview. Open the envelope and record the previous diagnosis when you reach Item #48.

The principal objective of the 6-month DISH interviews is to determine the patient’s current diagnosis and the current severity of depression. In order to arrive at the current diagnosis, you have to know what the patient’s diagnosis was at baseline, and you have to try, under admittedly difficult circumstances, to determine the course of the patient's depressive disorder (if he or she was indeed depressed) since the previous assessments.

A simple example is that you cannot determine whether the patient meets the criteria for major depression in full remission (code #9 on the Diagnostic Summary Form) unless you know that the patient had major depression to begin with, and that the patient has been free of depressive symptoms for at least two months. To make this example a little more complicated, it is possible for a patient to have had only minor depression at baseline, but to have deteriorated over the next few months such that he or she developed major depression. In this case, you would know from reviewing the baseline findings that the patient had minor depression at baseline, and you would know from interviewing the patient about current symptoms that he or she doesn’t have any, but you would not know what happened during the months in between.

Unfortunately, you cannot ask the therapist to tell you what happened during these months for patients in the Treatment arm, and there is no therapist to ask in any case for patients in the Usual Care arm. The patient is your only source of information, and you will have to try to retrospectively reconstruct the interim course of the patient's depressive disorder (if one was present). There is no specific structure to follow for this portion of the interview, since you will have to adapt your questions to fit the individual patient.
It is unlikely that you will be able to specify the interim course of the disorder to a high degree of accuracy, even in the best of cases. In some cases, it will be very difficult to obtain a very clear picture of the course. In the more difficult cases, you are simply expected to make a reasonable attempt to document the course, and to discontinue whenever you reach the point at which further efforts on your part are unlikely to yield any useful information.

One other difficulty you may encounter in administering the DISH during follow-up is that the Hamilton scale was designed to measure the severity of depression in depressed patients. Some of the patients you will be assessing will not have had a depressive disorder at baseline, and others will have depressive disorders that are in full remission. In these cases, it is important to bear in mind that the Hamilton items are about depression and associated psychopathology, not about anything else. For example, at least two Hamilton items ask about gastrointestinal distress. One is meant to determine whether the patient doesn't feel like eating; the other is meant to determine whether he or she is feeling nervous. Neither item is designed to detect GI disorders or other GI symptoms that have nothing to do with depression.

6.9 Procedures for Administration of Psychosocial Measures (other than the DISH)

With the exception of the DISH, all of the psychosocial measures described in this chapter are intended to be used as self-administered questionnaires. In some instances, as discussed below, these measures may be need to be administered via interview. Regardless of whether they are self-administered or interview-administered, the procedures to be used in administering standardized psychosocial instruments such as those outlined in Table 1 (except for the DISH) are very different than the procedures to be used with the DISH, which is a clinical interview. This section outlines the specific procedures to be used for all psychosocial measurement other than DISH administration.

6.9.1 Demeanor and Manner of administration

As with administration of the DISH, administration of all other psychosocial measures requires establishment of a positive rapport with the patient. It is important that the Case Coordinator or other ENRICHD staff member maintain a professional and friendly manner at every contact with the patient. However, unlike the DISH, which depends upon the interviewer's flexibility and ability to improvise in order to clarify patient responses, a critical aspect of the ENRICHD staff members' demeanor when administering the psychosocial measures is neutrality and objectivity, and assessors should never improvise when clarifying questions or probing for responses. This more neutral, standardized manner helps ensure that the ENRICHD staff member's presence does not influence the patient's perception of or response to a question. For example, when introducing the questionnaire or answering questions, the assessor should be careful to avoid any statements that could influence the patient's responses.

The assessor should also convey a sense of impartiality, and should be gracious and adaptable to all patients regardless of whether or not their dress, appearance, style of speech or personal preferences are consistent with the interviewer's values and preferences. The patient should be confident in the
interviewer and feel that his or her responses are important. The demeanor of the assessor should be casual, yet professional. This requires a thorough familiarity with the questionnaire and procedures prior to administering the first questionnaire to a patient.

Finally, the assessor should be pleasant and friendly, with a sympathetic and understanding attitude. The respondent should be made to feel that there are no correct answers, that what he or she thinks is really what counts, and that his/her opinion can never be wrong. However, the interviewer should avoid long explanations of the study and should not invent or improvise explanations of the study or of specific questions. He or she should use the standard responses and introductory material provided below. Similarly, the assessor should never try to justify or defend what he or she is doing; should not try to explain procedures or question wording; should never suggest an answer; never agree or disagree with an answer; and should never interpret the meaning of a question. If the patient does not understand a question, just repeat the question slowly, exactly as written.

6.9.2 Introducing the Self-Administered items

The following script should be used verbatim when introducing the self-administered items:

"WE WOULD LIKE TO BETTER UNDERSTAND HOW YOU FEEL AND HOW OTHER PERSONS IN THIS STUDY FEEL AND HOW YOU ARE DOING. TO HELP US BETTER UNDERSTAND THESE THINGS ABOUT YOU, PLEASE COMPLETE THIS QUESTIONNAIRE ABOUT YOUR HEALTH AND HEALTH-RELATED INFORMATION.

WE WOULD LIKE YOU TO FILL OUT THE QUESTIONNAIRE. BE SURE TO READ THE INSTRUCTIONS CAREFULLY. REMEMBER, THIS IS NOT A TEST AND THERE ARE NO RIGHT OR WRONG ANSWERS. CHOOSE THE RESPONSE THAT BEST REPRESENTS THE WAY YOU FEEL. YOUR RESPONSES TO THESE QUESTIONS ARE COMPLETELY CONFIDENTIAL -- YOU ARE IDENTIFIED ONLY BY A CODE NUMBER, NOT YOUR NAME. I WILL BRIEFLY LOOK OVER THE QUESTIONNAIRE WHEN YOU ARE DONE JUST TO MAKE SURE THAT ALL THE ITEMS HAVE BEEN COMPLETED.

YOU SHOULD ANSWER THESE QUESTIONS BY YOURSELF. SPOUSES, OR OTHER FAMILY MEMBERS, OR VISITORS, SHOULD NOT ASSIST YOU IN COMPLETING THE QUESTIONNAIRE.

PLEASE FILL OUT THE QUESTIONNAIRE NOW. I WILL BE NEARBY IN CASE YOU WANT TO ASK ME ANY QUESTIONS. RETURN THE QUESTIONNAIRE TO ME WHEN YOU HAVE COMPLETED IT.

6.9.3 Administering and Completing the Self-administered items

Provide a firm writing surface such as a clipboard or table top. Provide a pencil.
If administration is in the hospital or in the home, special attention should be paid to maintaining the privacy of the participant to the extent possible. If feasible, administration should be in a private setting or room. If administration is in a clinic or office setting, or in the hospital, if the patient is mobile and capable of filling out the questionnaire in a private area of the hospital rather than his or her room, you should assist the patient in finding a comfortable, quiet place to complete the questionnaire. If this place is not in the immediate clinic area, it is important that you take responsibility in making sure the patient is returned to familiar surroundings once the questionnaire is completed. If the patient is completing the questionnaire while waiting for a procedure or the doctor, it is your responsibility to monitor the time for the patient or assist in making arrangements for a short delay. The patient should not have to be worrying about a missed appointment while they are completing the questionnaire.

The patient should complete the questionnaire without the help of a spouse or friend, and you should discourage others from staying with the patient while they are completing the questionnaire. This may not always be possible, however, you should reinforce the value of the patient's response.

The assessor should make it clear to the patient that he or she is easily available if the patient has any difficulty with the questions. The assessor should stay in the room while the first page or so of the questionnaire is being filled out, and should say something like: "I'll wait with you while you get started to be sure it is clear to you what is being done." When the subject finishes the first page, the assessor should indicate how he or she can be located should any questions arise. It is advisable for the assessor to periodically check back in with the patient while he or she is taking the questionnaire to ensure there are no problems or questions.

6.9.4 Respondent questions and problems

The assessor should be very familiar with all questions and their meaning. In response to requests for clarification, re-read the question exactly as it appears, stressing by your voice intonation references to time, place, and question intent -- for facts or feelings. Do not ad-lib an explanation of the question. It is important to stay with the literal expression of the questions since this is the best way to assure standardization of psychosocial assessment across centers.

Always take the blame for problems with the questionnaire. If the respondent complains of particular wording or redundancy or length of the questionnaire, say you don't know why it was done as it was, but it is important for the respondent to answer as best they can.

Appendix 6-A to this chapter contains a list of answers to common questions and problems you may encounter. Should you encounter difficulties with questionnaire wording or procedures that you have serious concerns about or cannot otherwise resolve yourself, check with your Principal Investigator or another person on-site who is responsible for supervising the study, or with a Coordinating Center or Project Office representative.
6.9.5 Closing and Review of questionnaire

When the patient returns the questionnaire, the assessor should ask the patient if any of the questions were not clear. Then the assessor should check over the questionnaire for completeness of responses. Among the things to note: Are the answers clearly marked? Are any answers left out or double-marked? Is there a systematic response bias (i.e., patient responds yes to everything)? This review should be done immediately while the patient is in the room so any problems can be addressed right away. If the questionnaire is not complete, ask the respondent whether he/she had any difficulty completing it. Where the patient had difficulty with an item, use the methods described below to clarify the question or probe for a response. If the patient indicates the omission was purposeful, simply record this on the Evaluation form and continue reviewing the questionnaire (it is within the patient's right to decline to answer any particular question). If the incomplete answer or omission was not purposeful (e.g., an inadvertently missed page or item), ask the patient if he or she would complete the unanswered questions. If there are ambiguous responses, such as double markings or unclear erasures, ask for clarification.

Finally, thank the respondent using the following exit script:

THANK YOU FOR TAKING THE TIME TO COMPLETE THIS SURVEY. IT IS POSSIBLE YOU WILL BE ASKED TO COMPLETE THE QUESTIONNAIRE AGAIN AT A LATER DATE.

Complete the "Reviewer Evaluation Form" (form to be developed) following each psychosocial assessment, taking care to note whether the questionnaire was self- or interview administered, noting any difficulties the patient had with the questionnaire or other irregularities (e.g., lack of privacy/spouse present, interruptions to questionnaire administration).

6.10 Interview administration of psychosocial measures

While the self-administered questionnaire is designed for ease of administration, for a variety of reasons you can anticipate that a number of respondents will have difficulty completing this task by themselves. Approximately 6% of the American population (with a range of from 2 - 13% across individual states) is formally considered functionally illiterate, having completed fewer than four years of schooling. This rate is probably a gross underestimate of individuals who are likely to have difficulty in completing our self-administered questionnaire because of problems in reading fluency and comprehension. In addition, a number of respondents will have vision problems or difficulty in writing responses. We do not want to lose these respondents, and it is important to provide them the opportunity to get our help in completing the questionnaire.

It is important to provide the opportunity for help in a positive manner, taking care not to convey any negative judgment or feelings. When handing the questionnaire to the respondent, the assessor should say to the respondent "we have found that some people prefer to have the questions read to them. Would you like me to read these questions to you, or would you prefer to fill out the questionnaire yourself?" If the patient is not sure, you might suggest he or she take a minute to look over the
questions to help decide what they prefer. You should be aware of any indications that patients might have trouble reading the questions, such as: less than an eighth grade education; trouble with the informed consent; trouble with seeing the words clearly; a puzzled look or very slow progress on the first page of the questionnaire. Some of the problems you may encounter that would encourage interview-administration of the forms include: vision problems (lighting, patient forgot glasses, or does not have their glasses in the hospital), hearing problems, paralysis, tremor, numbness or insensitivity in their fingers, inability to write legibly, or trouble sustaining the attention needed for the task.

Another potential difficulty which may interfere with self-administration is pain and fatigue. Having more than one session may be necessary. Keeping on track may reduce overall time. Finding small windows of opportunity (when they are not in pain or fatigue) may also be helpful.

If you identify any of the above signs of low literacy, visual or other difficulties filling out the questionnaire, or if the patient indicates he or she prefers to have the questionnaire read, an interview format should be used instead of the self-administered format. All of the self-administered questionnaires can be turned into interviews, if needed. The Forms Appendix contains specific instructions for administering each psychosocial measure as an interview. In addition, the following general guidelines for using an interview format with the self-administered questionnaires should be followed (these guidelines are relevant for all psychosocial measures EXCEPT THE DISH):

1. The questions should be read verbatim, not improvised or changed in any way.

2. The interviewer should provide neither verbal nor non-verbal responses that can influence the patient's responses. For example, an assessor should not show surprise, pleasure or disapproval to any answer. Even apparently innocuous behaviors like nodding, smiling or sighing will influence the patient's responses to questions. The interviewer's role in administering the psychosocial measures other than the DISH is to obtain as unbiased and uninfluenced a response to the questions as possible.

3. Although it is essential that the questions be read verbatim, the interviewer should not sound like an automaton. The interviewer should be thoroughly familiar with the measures, and know the questions so well that it never sounds as if he or she is reading them formally. The interviewer should use a natural, conversational style, but at the same time, he or she should "stay on track" and politely, but firmly, lead the patient through the questionnaire.

4. Never add to or subtract words from a question. Read the question exactly as written, and as evenly as possible, without giving unusual inflection to any particular words -- do not give emphasis to any one part of the question or to any response alternative.

5. Never change the sequence of questions -- read them in the exact order written -- and never try to ask questions from memory.
(6) Do not rush the patient -- let him or her understand the question fully, and don't show impatience. Do not record a "don't know" answer too quickly -- people may say "I don't know" when stalling for time to arrange their thoughts. The phrase merely may be an introduction to a meaningful answer, so give the patient a little time to think.

(7) Never patronize patients who do not speak English fluently, and never react to answers or do anything that suggests to the patient that an answer is right or wrong.

(8) Never let another person answer for the patient.

6.11 Probing for Responses

The psychosocial measures used in ENRICHD (with the exception of the DISH) have been designed to minimize open-ended responses. However, even with closed-response categories, probing is sometimes required. Probing is a critical technique to master as it is an easy place to fall prey to directing responses or altering the meaning of a question. Thus, probes must be as uniform as possible within and across centers.

If the patient provides an inappropriate response to a question (e.g. uses the wrong response category), repeat the question and the response categories. For example, if the interviewer asks a question that requires a patient to provide his or her degree of agreement and instead, the patient says "that's true," the interviewer responds "would you say you strongly agree, agree, etc."

If a patient provides an ambiguous response to a question, then the interviewer must obtain a clarification without directing the response. The following can be used:

⇒ (1) pausing -- sometimes just waiting expectantly, or giving the respondent time to think may be helpful;

⇒ (2) rereading the question focuses the respondent on the questionnaire task, especially if there is distraction or possible misunderstanding. Say "I'm going to reread the question," then reread the question exactly as written, do not paraphrase.

⇒ (3) when necessary, you may ask for more information in a neutral way: "can you tell me more?"

⇒ (4) stress generality -- "usually," "mainly," "overall," which answer comes closest?

⇒ (5) stress subjectivity -- "your opinion," "your best estimation," "your recollection."

⇒ (6) when zeroing in, keep it neutral (e.g., "can you remember who?" not "was it your son?") -- don't suggest any specific response.
### Table 1. ENRICHD Data Collection Schedule, Revised March 1998

<table>
<thead>
<tr>
<th>Psychosocial Measures</th>
<th>Baseline</th>
<th>3 mo</th>
<th>6 mo</th>
<th>9 mo</th>
<th>12 mo</th>
<th>18 mo</th>
<th>24 mo</th>
<th>30 mo</th>
<th>36 mo</th>
<th>42 mo</th>
<th>48 mo</th>
<th>54 mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrichd Social Support Instrument (ESSI)</td>
<td>All</td>
<td>All</td>
<td>All</td>
<td>All</td>
<td>All</td>
<td>All</td>
<td>All</td>
<td>All</td>
<td>All</td>
<td>All</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beck Depression Inventory (BDI)</td>
<td>All</td>
<td>All</td>
<td>All</td>
<td>All</td>
<td>All</td>
<td>All</td>
<td>All</td>
<td>All</td>
<td>All</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depression Interview and Structured Hamilton (DISH)</td>
<td>All</td>
<td>All</td>
<td>All</td>
<td>All</td>
<td>All</td>
<td>All</td>
<td>All</td>
<td>All</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Longitudinal Course Chart (LCS)</td>
<td>All</td>
<td>All</td>
<td>All</td>
<td>All</td>
<td>All</td>
<td>All</td>
<td>All</td>
<td>All</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perceived Social Support Scale (PSSS)</td>
<td>All</td>
<td>All</td>
<td>All</td>
<td>All</td>
<td>All</td>
<td>All</td>
<td>All</td>
<td>All</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health Quality of Life (HQL)</td>
<td></td>
<td></td>
<td></td>
<td>800</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ladder of life (LOL)</td>
<td></td>
<td></td>
<td></td>
<td>800</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Life Satisfaction Scale (LSS)</td>
<td></td>
<td></td>
<td></td>
<td>800</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social Network Questionnaire (SNQ)</td>
<td></td>
<td></td>
<td></td>
<td>800</td>
<td>800</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perceived Stress Scale (PSS)</td>
<td></td>
<td></td>
<td></td>
<td>400</td>
<td>400</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Self-efficacy Scale (SEM)</td>
<td></td>
<td></td>
<td></td>
<td>400</td>
<td>400</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interpersonal Support Evaluation List (ISEL)</td>
<td></td>
<td></td>
<td></td>
<td>400</td>
<td>400</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Telephone contact: identification of potential events, contact information update</td>
<td></td>
<td></td>
<td></td>
<td>400</td>
<td>400</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Screened: all patients screened  
All: All randomized patients  
400/800: First 400/800 patients randomized