

MODIFICATION OF DIET IN RENAL DISEASE STUDY

Manual of Operations

Volume 1, Chapter 8

The Behavioral Science Chapter

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	<u>CHAPTER 8 TABLE OF CONTENTS</u>	<u>PAGE</u>
Section 8.1	Introduction.....	1.8.1
Section 8.2	The Quality of Well Being Test.....	1.8.1
Section 8.3	The SCL-90 Test and Patient Check List.....	1.8.3
Section 8.4	Patient Information.....	1.8.4

MODIFICATION OF DIET IN RENAL DISEASE STUDY

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Behavioral Science Material

8.1 Introduction

To assess the effectiveness of diet in the management of renal insufficiency, it is essential to know the effect of the renal disease and the diet on the patients' general well-being and activity. It is also important to detect psychological distress having an effect on compliance with the protocol. In order to accomplish this, two general types of behavioral assessment will be performed in MDRD Phase III, the Quality of Well Being Test (QWB) and the SCL-90 Test.

8.2 The Quality of Well Being Test (Form #27)

The QWB is a quantitative measure of the degree to which patients' activities are limited by renal disease or its treatment, including diet. This measure should allow calculation of cost-utility analyses. The QWB interview is an available, tested instrument which will allow adequate data collection when administered once during Baseline, each 6 months during Follow-Up, and at the time of conclusion or drop-out of each patient. A trained interviewer can conduct the interview by telephone in about 15 minutes. These data will be used in Study outcome analyses. A detailed protocol for the use of this instrument in the MDRD Study is provided separately by Dr. Robert Kaplan. The functions of the MDRD QWB Center are provided in the QWB Center's internal Manual of Operations.

GENERAL DESCRIPTION OF THE QUALITY OF WELL BEING (QWB)

The Quality of Well-being (QWB) scale is a general quality of life measure that is used for the quantification of health related quality of life and for policy analysis. The QWB combines preference-weighted measures of symptoms and functioning to provide a numerical expression of Well-being that ranges from zero (0) for death to one (1.0) for asymptomatic optimum functioning. A structured questionnaire is used to obtain information for the calculation of the QWB. One advantage of the QWB is that it is a component of a General Health Policy Model

that integrates many diverse health system inputs, such as dollar savings, discount rates, morbidity, mortality, consumer preferences for health states and duration of problem. This allows the risks and benefits of the program to be expressed in terms of an integrated unit called the well-year. Different health care options can then be compared according to their cost to produce a well-year unit.

Instruction for the QWB

a. Interviewing Procedure

Interviews for the QWB will be conducted according to the Manual, "Function Status Profile and Quality of Well-being Scale" by J.W. Bush and J.P. Anderson (11/21/85 revision).

b. Quality Control

The MDRD interviewers (on the Data Coordinating Center Staff) will be trained for the standardized administration of the interview. The training requires attendance of two training sessions and the administration of sample interviews under supervision. The performance of interviewers will be reviewed by a QWB assessment lab supervisor at least once each six months. A random selection of 10% of the interviews will be reviewed.

c. Interval of Administration

The QWB will be administered every six months, at B3, F6, F12, etc. The interviews will be conducted over the telephone, with the Data Coordinating Center interviewer calling the patient at a time established by the Clinical Center Personnel.

d. Clinical Center Procedure

1. The physician and team will advise the patient that an interviewer will contact them.
2. Each Clinical Center will provide the interviewer at the Data Coordinating Center with a list of patient names, ID's phone numbers and times that would be appropriate to contact the patient.
3. The interviewer will call the patient and either conduct the interview or schedule the interview for a specific time.
4. Materials (Symptom Flash Cards) will be distributed to the patient by the MDRD Clinical Center staff.

5. Interviews should be conducted within plus or minus one month of the target date. If the patient is ill or in a hospital on the target date, the interview should be conducted if possible. For severely ill patients, an appropriate proxy respondent should be interviewed. If a proxy is interviewed instead of the patient, this will be noted on the form.

e. Data Management

1. The Data Coordinating Center will review, code, and score the questionnaires.
2. Raw data and QWB scores will be entered into the Data Coordinating Center database for permanent storage and for incorporation into the data base.

f. Analysis

The QWB laboratory will work with the Data Coordinating Center on plans for analysis and interpretation of the QWB results.

8.3 The SCL-90 Test (Form #28) and Patient Check List (Form #26)

- a. The MDRD Study requires check-lists more specifically related to symptoms of renal disease, diet, malnutrition and psychological stress, to collect information so that:
 1. Distressed patients at risk for non-compliance, drop-out or psychiatric illness may be identified and appropriate action taken.
 2. Differences in symptoms between Study groups may be noted as the Study progresses.
- b. The objectives will be realized through the SCL-90 administered each 4 months, (B3, F-4, F8, F12, etc.) supplemented by the MDRD Patient Symptom Check List administered monthly starting with the B0 visit. These will be self-administered near the beginning of the visit and reviewed by the study physician during the visit.
- c. The SCL-90 is designed to aid the clinician in the detection of psychological distress which could lead to poor compliance or withdrawal of the patient from the Study. Study personnel must familiarize themselves with the questionnaire and its administration. The QWB Center will train the MDRD Study Coordinators how to present the questionnaire to the patient.

- d. The questionnaire is self-administered by the patient at a time close to the beginning of the visit. Patients should be encouraged to view the test as their opportunity to say how they feel, independently of questions asked by the clinician.
- e. Responses marked #2 ("moderately") or above should be directly reviewed by the clinician with the patient. This review should be documented, and the documentation should be placed in the patient's MDRD file.
- f. These check lists will assist, but should not replace, the traditional history-taking and concerned interview of the patient by the physician. This interview must include attention to symptoms of renal failure, the burden of the diet protocol, the psychological status of the patient and any specific needs that may impair continued participation.

8.4 Patient Information

The following information will be given to each patient on an information sheet.

INFORMATION CONCERNING THE SOCIAL AND PSYCHOLOGICAL QUESTIONS IN THE MDRD STUDY

- a. It is important to know whether the diet helps maintain kidney function but it is also important to know how well people are feeling while following their diet programs. From time to time in the MDRD Study you will be asked about how you feel, and how much limitation you may have in your daily activities. Sometimes these questions will be asked during a telephone interview. These questions will help us be aware of your general health and well-being.
- b. The purpose of the questions is to help in deciding whether the diet treatments are worthwhile.
- c. Several specific means are used to accomplish these purposes:
 - 1. Each month a symptom form is filled out. This asks questions about symptoms relating particularly to kidney disease, and takes about five minutes to complete.

2. Each four months, the SCL-90 form is filled out with questions relating particularly to psychological symptoms and the stress of illness. This takes about 15 minutes to complete.
3. Each 6 months during the Study (and at the beginning and end of your participation in it) a telephone interview will be performed. This will take place at home at a convenient time for you and will take about 15 minutes. It will ask to what degree your kidney condition or your diet or your participation in the Study limit your ability to live your normal life.
4. We would like you to answer all the questions in these forms and interviews, but if a particular question is bothersome for you, you may skip it. If you ever are feeling particularly anxious or frustrated or sad, please take the opportunity to bring it up with the Study personnel.