Manual of Operations

Volume I, Chapter 10

Key Entry

August 1988

MDRD Manual of Operations

Volume 1, Chapter 10

The Key Entry Chapter

TABLE OF CONTENTS

SECTION		PAGE
10.1	Introduction and Responsibilities.	10.1
10.2	Procedures	10.2

Chapter 10

THE KEY ENTRY CHAPTER

Section 10.1 Introduction and Responsibilities

At each clinical center, a key entry person or a secretary/key entry clerk will be interviewed and hired. Previous computer experience is suggested for this position but is not necessary. All key entry persons must be certified at the Data Coordinating Center in the areas of 1) Forms Completion, 2) Data Entry, 3) Data Transmission, 4) Error Correction, and 5) Electronic Mail (as described in Chapter 2). Two years into the study, key entry persons will be re-certified at the Data Coordinating Center. Any replacement key entry person must be centrally trained and certified. In the absence of the key entry person, the Study Coordinator will serve as a back-up. If the dietitian or MDRD Technician is certified in Data Entry, Data Transmission, and Error Correction (as described in Chapter 2), that person may also serve as a back-up.

Certification can be accomplished in two ways: by attendance at the overall week-long certification session prior to enrollment of the Phase III patients (for all initial Key Entry Persons) or by a two-day certification visit to the Data Coordinating Center (for new personnel required when original personnel leave). During Phase III, two-day certification sessions to train replacement personnel will be held no more frequently than quarterly. All key entry persons serve as back-ups for study coordinators and will fill in during times in which one study coordinator has left and a second has not yet been certified.

The overall responsibilities of the key entry person include the timely and accurate entry and transmission of all data collected at the Clinical Center, entering and transmitting the responses to query reports, and other duties essential for maintaining the integrity and confidentiality of the Modification of Diet in Renal Disease (MDRD) Study data. At each center, one person must assume overall responsibility for the electronic mail system. It is recommended that the key entry person do this.

Section 10.2 Procedures

Each day, study forms will be collected and completed by the Study Coordinator, the study physicians, the dietitians, and/or the MDRD Technicians. Using Datalex Entrypoint-90 software (Chapter 5, Section 4 of this manual), the key entry person should enter and verify those forms that are complete and ready for entry. Forms should be entered and transmitted to the Data Coordinating Center (DCC) once a day or at least once every other day, depending on the number of data forms completed that day. Occasionally the frequency of data entry and data transmission will depend on the discretion of the study coordinator and/or the key entry person.

Once all data are entered by the key entry person (or Study Coordinator), data are ready to be transmitted to the DCC using the Crosstalk automatic transmission routine (Chapter 5, Section 5). These data will be sent in the middle of the night via Crosstalk. If for any reason data transmission problems occurred, the data transmission report will document these errors. Every day, the key entry person should thoroughly inspect this report to check for any discrepancies. If there are any problems that cannot be solved at the Clinical Center, the Data Coordinating Center should be notified as soon as

possible. Additional steps in the entry and transmission routine allow the key entry person to automatically back-up copies of the transmitted data (Chapter 5, Section 5). These steps are essential for a number of reasons. First, should information not get transmitted due to an error, there would be less work for the key entry person to re-transmit this data and second, all data must be backed up should the hard copy forms for any reason be lost or damaged.

Occasionally the data may be rejected by the MDRD database due to a discrepancy or inconsistency. When this occurs a query report is generated at the DCC and mailed electronically to the Clinical Center. The Study Coordinator and the key entry person work in conjunction with one another to clarify, correct, and respond to the query as soon as possible. Two working days should be an adequate length of time to accomplish this task. Once the study coordinator reads and clarifies or corrects the information, the key entry person responds following the query system procedure documented in Chapter 5, Section 7.

The process of completing, entering, and transmitting data collection forms accurately and error free is crucial to attaining the goals of the MDRD Study.

Since communication between all members of this multidisciplinary team is routine and vital, the electronic mail system provides a simple, quick, and effective means of contacting those individuals who can best offer information or solutions to specific questions, problems, and situations. At least once everyday the mail should be accessed, read, and printed (Chapter 5, Section 8) by a designated person and distributed to the person the message is intended for. Filing paper copies of these mail messages is recommended for reference.

Replying to and forwarding mail messages can occur at any given time. Chapter 5, Section 8 contains more details regarding this and other electronic mail features that will be encountered. The person who assumes primary responsibility for the mail system must make sure that the mail is read daily in his or her absence. A back-up mail reader should be assigned.

Modification of Diet in Renal Disease Study

Manual of Operations

Volume I, Chapter 11

SAFETY ISSUES AND MONITORING OF HYPERTENSIVE PATIENTS IN THE MDRD STUDY

REVISED MAY 1990

MDRD Clinical Center Manual of Operations
Chapter 11
Safety Issues and Monitoring of Hypertensive Patients
in the MDRD Study

CONTENTS PAGE

1. Introduction.....1.11.1
2. Responsibility for BP Management.....1.11.1
3. Documentation of Blood Pressure Control.....1.11.2
   3.1 Blood Pressure Documentation.....1.11.2
   3.2 Sodium Intake.....1.11.3
   3.3 Symptom Documentation.....1.11.3
   3.4 Patient Own Assessment.....1.11.3
   3.5 Action Items.....1.11.3
4. Intervention.....1.11.3
5. Data Assembly, Output and Reporting.....1.11.5

Section 1 INTRODUCTION:

Control of hypertension in patients participating in the MDRD is accepted as co-equal in importance to dietary intervention. The purpose of this chapter is to codify and formalize the rationale and procedures for blood pressure monitoring, intervention and documentation as outlined in the Protocol (Section 8, and on pages 27.1 - 27.16), and in the Administrative Manual (Volume III, Chapters 9 and 10), in order to assist Clinical Center Staff to achieve assigned BP targets in individual patients, and to provide for study-wide safety monitoring of the blood pressure intervention.

Section 2 RESPONSIBILITY FOR BP MANAGEMENT:

MDRD Study physicians have the primary responsibility for initiating and/or modifying the blood pressure regimen, to achieve the desired MAP, and wherever possible and appropriate, in consultation with study participants' primary physician. However, when starting or changing medication, counseling about medication use, side-effects, etc. may be delegated to a registered nurse who operates according to the Protocol under the physician's supervision. Designated members of the Clinical Center team are responsible for blood pressure data collection, and for maintaining records and flow charts.

(Note: While this "Doctors and Nurses Chapter" deals with the control of hypertension, it does not imply any limitation on the myriad other duties of these professionals.)

Section 3 DOCUMENTATION OF BLOOD PRESSURE CONTROL.

All patients will have a dedicated record system on hypertension. This record will contain the following:

3. Summary of Data to be obtained during Follow-Up

3.1 Blood Pressure Documentation: (See Protocol Section 8.3)

(1) **MDRD Office:** Each time the blood pressure is taken according to protocol the level is documented on Form 46. This is the official blood pressure on which decisions about therapy are based in order to achieve each patient's assigned blood pressure target.

Other methods of measurement:

(2) **24 hour Ambulatory Blood Pressures Monitoring:** Whereas this may reflect the blood pressure level throughout the day, this one-day monitoring is also unlikely to reflect the true blood pressure level of the patient throughout a longer interval. Furthermore, it is a relatively inconvenient, uncomfortable and expensive method of blood pressure assessment. It may be used in approved ancillary studies.

(3) **Home Blood Pressure Monitoring:** When measured, using calibrated instruments, on a regular schedule by patients after appropriate training, home blood pressures more comprehensively reflect the patients' true blood pressure "exposure." Although this method has not been used in prior, large-scale controlled clinical studies it does reflect contemporary, "state-of-the-art"

clinical management technique. This method may also have a positive effect on compliance to antihypertensive regimens, and achievement of blood pressure goals. However, because of suspected, inherent relative imprecision of this method, these pressures will not be used to modify therapy, but to maintain alertness in those patients whose blood pressures approximate or exceed their assigned blood pressure goals, or whose pressures trend upward and approach their assigned goal. Patients will be requested to bring their measurement devices to the Clinical Center for retraining and recalibration ever 3-6 months.

3.2 Sodium Intake (excretion, mg/d) and Weight Changes

Data can be retrieved from other flow sheets.

3.3 Symptom Documentation:

All symptoms relating to hypertension and management regimen, such as, side effects from medications, should be clearly identified. (See Form 52)

3.4 Patient Own Assessment (See Form 52)

Patients' assessment of their blood pressure management should also be documented.

3.5 Action Items:

Action items relative to blood pressure are processed as specified in the Protocol and elsewhere in this Manual of Operations.

Section 4 INTERVENTION

Forms 23, 46, and 52. Protocol Sections 8, 13.3,3(5-8)

1. Treatment Regimen Documentation

Reasons for change in the management program will be recorded on Form 52. New medications, including dosage, and any increment in the existing ones will be recorded on the drug list for each visit.

2. Intervention Strategy:

The following protocol items using MDRD office blood pressures are again emphasized:

a) New pharmacological interventions will be reviewed and employed in each case (Protocol, p 27.4).

b) If MAP is less than target BP without medication and without side effects the management regimen should not be altered.

c) If MAP is less than target on medication, no changes in antihypertensive agents are necessary, but consideration may be given to reduction in medication, to allow BP to rise toward, but not exceed target.

d) If MAP is less than target and patient has side effects from medications, ACE inhibitors or Calcium channel blockers with or without duretics may be substituted, as appropriate. Consideration may be given to reducing or discontinuing dosage of the offending medication, and the BP allowed to rise to, but not exceed, target.

e) If MAP is at or above target and without side effects, dosages of current medications should be increased, or ACE inhibitors or calcium channel blockers with or without duretics should be added as appropriate.

f) If MAP is at or above target and patient is experiencing side effects from medication, ACE inhibitors, then calcium channel blockers should be added (with or without duretics) as first new drugs in the step care approach and dosage of the offending medication reduced or discontinued.

Section 5 DATA ASSEMBLY, OUTPUT AND REPORTING

This is the responsibility of the Data Coordinating Center. Data output is as follows:

1. To Clinical Centers: new flow sheets concerning BP management that assembles all of the above data for each patient, merged as necessary from several parts of the database.

2. To PCC, CMC: Information packets (blinded), for action items.

3. To EMC: Unblinded tabulations of group data, or individual data. The report may include the following items as determined by the EMC Safety Subcommittee:

- o MAPs at all visits (B0 to date)
- o Reasons or factors responsible for out-of-range MAP's
- o Adverse effects from the BP regimen
- o Number of patients that reach BP action items
- o Drug categories for control of BP and corresponding MAP's
- o Recent changes made in the BP drug profile