MDRD Clinical Center Manual of Operations

Chapter 1

Dietitian's Chapter

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Section 1

Overview of Nutrition Intervention in the MDRD Study

1.1 Introduction

This chapter has been prepared by the MDRD Nutrition Coordinating Center (NCC) at the University of Pittsburgh. Some portions, particularly patient educational materials, have been developed collaboratively with nutrition personnel in the clinical centers. We are indebted to these dietitians for their help, not only for materials development, but also for their input on forms and report formatting. In addition, assistance with the Computerized Diet Design Tool has been invaluable. This overview will summarize the responsibilities of the NCC and our approach to nutrition intervention programming.

1.2 Major Responsibilities of the NCC

The major responsibilities of the NCC are to:

1. Design the protocol for nutrition assessment, intervention, and follow-up.

2. Design and/or select and refine measures for estimating compliance in individual participants as well as in the randomized study groups.

3. Develop the appropriate materials for assessment, intervention, follow-up, compliance monitoring, training, certification, and intervention evaluation. These materials include forms, educational materials for patients, an Intervention Manual for MDRD Dietitians, as well as a guidelines for dietary data collection (Section 6, Manual of Operations).

4. Design and implement appropriate training for clinical center personnel involved with nutrition assessment procedures, including the collection of anthropometric measures and dietary data, and for the implementation of nutrition intervention and follow-up activities.

5. Analyze dietary data and design analyses to provide maximum feedback to clinical centers on compliance patterns within randomized groups.

6. Assist in the development of procedures for monitoring nutritional adequacy.

7. Develop a system of regular communication with nutrition interventionists in each center.

8. Serve as a resource to clinical centers for nutrition information, dietary assessment methodology, and intervention and compliance monitoring approaches.

9. Develop and distribute motivational materials for patients, such as newsletters, birthday cards, diplomas, etc.

1.3 Fundamentals of Nutrition Intervention

In designing the nutrition protocol and intervention program certain fundamental principles must be considered. The first is that the primary objective of any nutrition intervention is behavior change and the maintenance of these changes. The second fundamental principle is that the intervention should be designed to promote high levels of compliance and the maintenance of these levels. Therefore, the design of intervention for any dietary condition should recognize the controlling influences on behavior and the conditions necessary to effect change.

Behavior is controlled by antecedent and consequent influences (Caggiula, Milas, and Wing, 1987)[1]. Antecedent influences relate to conditions and situational influences which prompt behavior such as environmental cues (sight, smell, and proximity of food), advertising, social modelling (other people eating a food), or simply the habit of eating certain foods with other foods. Consequent influences are what a person actually experiences as a result of engaging in the eating behavior. They include immediate and long-term effects. Immediate effects are usually related to the taste and pleasure of eating the food while the long-term effects may be related to health. While antecedent influences may cause someone to try a behavior once or twice, the long-term adoption is determined by the physical, social, economic, or emotional consequences. A successful intervention will help the patient eliminate or change as many of the antecedent influences as possible and help them concentrate on the positive, reinforcing long-term consequences. If one analyzes the consequent influences of a low protein diet it appears that adherence will produce more immediate negative than positive consequences, a fact that creates a significant obstacle to change. The example on the following page illustrates this point:

	DESIRED	UNDESIRED
IMMEDIATE	I feel that I am taking care of my health	Food tastes different Preparation takes too much time Others around me are eating things I like Others view me as different or "sick"
DELAYED	I feel better on the low protein diet I can avoid dialysis or serious kidney disease	Shopping is more time consuming and difficult I have fewer choices in restaurants More time is needed for food preparation Parties and social occasions are a problem Some new foods cost more

The intervention program designed for the MDRD study must attempt to remove or reduce specific immediate negative consequences while introducing competing positive ones and providing the skills to produce new positive behaviors.

The critical question is how to maximize the conditions for positive behavior change. While there are different models (Becker, Maiman, et al., 1977[2]; Agras, 1978[3]; Benfari, 1981[4]), there is general agreement that the necessary conditions include motivation for change and an awareness in the patient as to why this change is necessary. These conditions can be met during the baseline period with careful patient selection and information provided by the physician and other study personnel regarding the value of study participation to maximize future health. Motivation and awareness are critical components, but after they have been satisfied, the quality of intervention is the determinant of compliance.

Intervention activities should provide for knowledge acquisition and more importantly for skills development by patients. The skills to be mastered are on several levels. Nutrition-related skills are in the area of food selection, purchasing, and preparation. These skills are supported by behavioral strategies of self-monitoring and pre-planning. Intervention design should also provide social support and minimize patient burden associated with compliance. One way to accomplish this goal is to provide low protein food products for patients, which is one feature of the MDRD nutrition intervention program.

1.4 Intervention Strategies

The intervention program in MDRD is implemented during two phases, the baseline period and the follow-up period. During baseline, which includes four visits, the prospective MDRD patient is oriented to the study, has his or her nutritional status assessed, practices study procedures such as urine collection and recording of food intake, begins to discriminate foods based on their protein content, and learns to tailor protein intake to conform to the **Baseline Diet Prescription.** Following randomization the dietitian translates the **Study Diet Prescription** into a personalized eating pattern based on knowledge of the patient's usual pattern as obtained during the baseline.

The study diet eating pattern is introduced to the patient at Follow-Up Visit 1 (FU 1) using seven-day menu plans. Strategies are developed in a step-wise progressive approach to enhance adherence to selected components of the eating pattern. As successive levels of compliance are reached by the patient, additional units/modules are introduced and the process is continued until optimal levels of compliance are reached. This intensive intervention phase continues over the next five visits, FU 1A, 2, 2A, 3, and 4. By waiting until FU 5 to complete the first formal compliance assessment, the dietitian has the advantage of the previous four months of intervention sessions to bring the patient closer to goal. While the intent of the intervention program will be to have all patients at goal protein intake by FU 5, a proportion of them will need additional intervention to reach goal, particularly on Diet K which is very low in protein. Intervention materials for use after FU 5 and for the remaining months of the study will focus on improving compliance, maintaining motivation, and in establishing plans to prevent relapse. For patients who have successfully reached goal at FU 5, the emphasis will be placed on strategies to maintain compliance. A general outline of intervention appears below; materials to support these areas are part of the Intervention Manual.

The initial focus of the NCC has been to develop strategies to enhance patient participation during the baseline phase, including the development and refinement of forms to support assessment of the patients' usual food intake and development of the baseline diet. In addition a major activity has been the development of the MDRD nutrient data base. These areas of concentration will provide a sound foundation upon which to develop the components of the intensive intervention and compliance assessment phase which will be expanded and intensified post randomization. Two training sessions for dietitians will occur in the first six months of the study. The first one will concentrate on baseline procedures; the second will emphasize follow-up activities. Subsequent training will occur on a yearly basis.

It should be noted that the MDRD intervention program has been designed to intervene primarily on dietary protein with additional emphasis on phosphorus. Modification of other nutrients such as sodium or fat may be necessary in some patients in order to improve overall health and/or support other study goals. In order to achieve the highest level of compliance to all target nutrients, the **Study Diet Prescription** can be adjusted to incorporate these additional requirements. Should it become necessary during follow-up to incorporate modifications of additional nutrients for intervention, great care must be taken to do this without compromising compliance to protein and phosphorus.

1.4.1 Intervention Activities During the First Year

Intervention activities in Year 1 are planned according to the following outline. The general topics are similar for each randomization diet (M, L, or K) but the specific materials developed for each may differ.

Visit	Topic/Theme
Baseline period	Identifying low and high protein foods by self-monitoring
FU 1	Orientation to dietary assignment Goal setting and initial strategy development
FU 1A	Low protein shopping tips
FU 2	Starting early with low protein breakfasts
FU 2A	New approaches to lunch
FU 3	Different dinners

FU 4	Low protein snacking
FU 5	Compliance assessment visit
FU 6	Dressing up low protein meals for entertaining
FU 7	Eating out in social situations
FU 8	Relapse prevention
FU 9	Compliance assessment visit
FU 10	Fine tuning your protein intake
FU 11	Improving social support
FU 12	New recipe and product update
FU 13	Compliance assessment visit

Because most of these sessions should focus on counseling, data collection activities have been minimized. Intervention will initially be delivered through individual counseling; however, group sessions should be considered, particularly in Years 2-4 of Follow-up. Group sessions are particularly important because social support is one factor that has been linked to successful maintenance of weight loss in weight control programs[5]. The development of a buddy system for patients also serves the same purpose. Social support outside of the family may be particularly appropriate for patients in this study since the family members may feel overburdened by the difficulties related to the low protein eating patterns.

[1] Caggiula, A.W., Milas, N.C., and Wing, R.R. Optimal Nutritional Therapy in the Treatment of Hypertension. Biblthca Cardiol, No. 41:6-21, 1987.

[2] Becker, M.H., Maiman, L.A., Kirscht, J.P., et al. The Health Belief Model and Prediction of Dietary Compliance: A field Experiment. Journal of Health and Soc Behav, 18:348-366, 1977.

[3] Agras, W.S., The Behavior Therapies: Underlying principles and procedures, in "Behavior Modification: Principles and Clinical Applications" (W.S. Agras, Ed.). Little, Brown, Boston, 1978.

[4] Benfari, R.C. The Multiple Risk Factor Intervention Trial (MRFIT). III. The Model for Intervention. Prev Med, 10:426-442, 1981.

[5] Brownell, Kelly D. and Jeffery, Robert W. Improving Long-term Weight Loss: Pushing the Limits of Treatment. Behavior Therapy 18, 353-374, 1987.

Section 2

Qualifications, Environment and Communication

2.1 Qualifications

The MDRD dietitian should be a Registered Dietitian with a Master's degree and several years of clinical experience, preferably with renal patients. Professional experience should include: the calculation of renal diets, the interpretation and implementation of biochemical findings, an understanding of renal physiology and rationale for dietary intervention, menu planning, group and individual counseling experience, the use of behavioral intervention strategies, and an interest in incorporating computer-assisted design techniques into the counseling interview. Previous clinical trial experience is highly desirable as is familiarity with both pharmological and nonpharmological treatment of hypertension. Good interpersonal skills are critical for establishing and maintaining quality relationships with the patient as well as the study team. Because of the complexity of the low protein eating pattern, skills necessary for developing an individualized eating pattern for the patient are critical. A background in statistics and data analysis is also useful. Because the MDRD study has a responsibility to produce a high rate of compliance to the various eating patterns and supplements, experience in compliance assessment would be advantageous.

2.2 Environment

The atmosphere of the clinical setting as well as the attitudes of the staff work together to provide an environment that is comfortable and nonintimidating to the MDRD patients. Attention to patient privacy, confidentiality, and to a quiet counseling space where the physician, dietitian or entire study team can meet with the patient and his/her family is optimal.

Each dietitian should have a private counseling space free of telephone interruptions. It is desirable that the computer be accessible in order to provide the patient with immediate feedback about his/her diet. A private place should also be available where the patient can undress and where the dietitian can perform anthropometry. A nearby file cabinet or closet is necessary in order to store dietary data collection props, low protein products, forms, patient gowns, and anthropometry equipment. Access to a refrigerator-freezer or microwave oven would simplify or make it possible for the dietitian to prepare or store food products for the patients to taste.

2.3 Communication

Communication is enhanced when a regularly scheduled staff meeting occurs. It is important that all members of the study team make this meeting a priority.

A well-developed staff organization chart can be a useful tool to detail the exact responsibilities of each staff person and to formalize the person to whom each individual is responsible.

The physical layout of the clinic facility should allow for ease of access to the study team. The space for photocopying and data entry should be separate from the clinical area.

In addition to the above situation related to staff interactions, it is necessary to establish a regular case-conference time where staff can meet to discuss issues related to patient care. At this time a care plan of a patient can be presented and through staff brainstorming activities, creative new strategies to enhance patient care or study participation can be developed.

Section 3

Certification of Clinical Center Dietitians

3.1 Introduction

Certification is a procedure used in clinical trials to ensure that research quality is maintained for data known to have considerable collection variability. This measurement variability can result in unreliable and invalid data. MDRD clinical center dietitians will be certified in two data collection areas by the MDRD Nutrition Coordinating Center: anthropometry and dietary data documentation.

Certification for research quality data consists of both skills development and maintenance components. After initial training for specific data collection procedures, skills maintenance is supported through on-going data monitoring, periodic direct monitoring of data collection procedures, and periodic re-certification. The MDRD-NCC's certification procedures include an initial certification consisting of didactic and experiential pre-training, training and post-training activities. On-going monitoring is comprised of direct monitoring during yearly site visits and indirect monitoring through analysis of data submitted for processing. Certification maintenance is achieved through periodic re-certification. Re-certification for documentation of dietary intake data is done five times yearly through successful completion of four sets of documentation exercises and yearly re-certification at NCC's dietitians' trainings. Anthropometrics re-certification is done twice yearly: once during yearly site visits and again at yearly dietitians' trainings.

3.2 Anthropometry

The requirements for certification for dietitians who attend the first formal NCC Training Program in October/November 1988 differ from requirements for those who replace certified dietitians after January 1989.

3.2.1 Certification Requirements Prior to Initiation of Phase III

The requirements for certification are:

1. Prior to training, read Section 3, "Anthropometrics", in the Training Manual for MDRD Dietitians.

2. Attend a four-hour lecture/demonstration conducted by the NCC anthropometry consultant during the training program.

3. Participate in a four-hour "hands-on" session. Each dietitian will take weight, stature, skinfolds (biceps, triceps, and subscapular), and arm circumference measures on five volunteers during the training program. Technique will be discussed and observed by the consultant.

4. Calibrate anthropometric equipment at the clinical center, as instructed during training and in the Training Manual, recording results in the Calibration Log and forwarding these to the NCC by the defined deadline.

5. Perform measurements (weight, stature, skinfolds, arm circumference) on at least two volunteers weekly. Measurements will be taken by two dietitians sequentially for the purposes of: a) practicing technique and b) providing data on inter- and intra-observer reliability. Data are to be recorded and forwarded monthly to the NCC from December 1988 through March 1989. The consultant will review, monitor, and analyze the data.

6. Attend a four-hour session at the second NCC training program. Anthropometric measurements on five volunteers will be taken and recorded, with observation and approval of technique by the consultant.

3.2.2 <u>Certification of Dietitians Who Replace Certified Dietitians or Who are Added to a Clinical Center</u>

If the dietitian's date of hire coincides with an annual NCC Training Program that he/she is able to attend, the requirements for certification are:

1. Prior to training, read Chapter 1, Section 7 in the Manual of Operations (Anthropometrics).

2. Observe measurement of patients by certified dietitians at the clinical center.

3. View the NCC videotape on anthropometrics (a four-hour lecture/demonstration by the NCC anthropometry consultant).

4. Observe a four-hour "hands on" session during the training program. Measurement of weight, stature, skinfolds (biceps, triceps, subscapular), and arm circumference will be taken by the consultant and certified dietitians during this session. Technique and particular aspects to observe will be discussed with the trainee by the consultant.

5. Attend a two-hour intensive training session during which the dietitian will take all measures while being observed and instructed by the consultant.

6. Calibrate anthropometric equipment at the clinical center, as instructed during training and in the Manual of Operations, Chapter 1, recording results in the Calibration Log and forwarding these to the NCC.

7. Perform measurements on two volunteers/patients per day for two weeks post-training. The measures will also be collected, on the same patient, by a certified dietitian. Results will be recorded and forwarded to the consultant for monitoring and review.

<u>If the dietitian is not able to attend an annual NCC Training Program, the requirements for certification are</u>:

1. Read Chapter 1, Section 7 in the Manual of Operations (Anthropometrics).

2. Observe measurement of patients by a certified dietitian at the clinical center.

3. View the NCC videotape on anthropometrics (a four-hour lecture/demonstration by the NCC anthropometry consultant).

4. Attend a mini training program conducted at the NCC in Pittsburgh by the consultant and NCC staff. This session will include demonstration of technique by the consultant and measurement of several volunteers by the dietitian with observation by the consultant.

5. Calibrate anthropometric equipment at the clinical center, as instructed during training and in the Manual of Operations, Chapter 1, recording results in the Calibration Log and forwarding these to the NCC.

6. Perform measurements on two volunteers or patients per day for two weeks post-training. The measures will also be collected, on the same volunteer or patient, by a certified dietitian. Results will be recorded and forwarded to the consultant for monitoring and review.

3.2.3 <u>Maintenance of Certification in Anthropometry</u>

Following initial certification, the dietitian will maintain certification in anthropometry by:

1. Continued application of procedures and techniques during the study.

2. Attendance at the annual NCC training program where a four-hour "hands on" review session will be conducted by the consultant and/or NCC staff.

3. Maintenance of calibration of all equipment as specified in the Manual of Operations, Chapter 1, Section 7.

4. Completion of quality control procedures as outlined in the Manual of Operations, Chapter 1, Section 7.

A prolonged absence of the dietitian from the study will be evaluated by the Nutrition Coordinating Center for consideration of the necessity for re-certification. At the annual visit to each clinical center by the NCC anthropometry trainer and/or the consultant, procedures and technique will be reviewed and observed to insure standard methods among the centers.

3.3 Dietary Data Documentation

Certification requirements for dietitians are the same regardless of when they enter the MDRD Study.

3.3.1 Certification Requirements

1. Prior to training, read Sections 4 and 5 of the Training Manual for MDRD Dietitians and/or Chapter 1, Sections 5 and 6 of the Manual of Operations.

2. Complete the pretraining exercise and requirements listed in the following sections of the Training Manual for MDRD Dietitians:
   1.1.3 Nutrient Data Base (Section 1)
   1.1.4 Dietary Data Documentation (Section 1)

3. Attend the four-hour NCC training session on Dietary Data Collection.

4. Complete the post-training exercises listed in the following "After Training" sections of the Training Manual for MDRD Dietitians:
   1.3.3 Nutrient Data Base (Before 2/1/89 for those trained 11/88, and within two weeks after training for those trained after 11/88.)

   1.3.4 Dietary Data Collection (Two weeks after training session.)

5. Complete the Dietary Data Documentation Exercise that consists of nine days of food records. The NCC will review the exercise for completeness and accuracy according to the following standard: no more than three significant details of documentation should be missing or incorrect per food record day.

   If a training documenter does not successfully complete this exercise, he/she will be given a second and final set of three food records to complete. This exercise is due at the NCC within six weeks of training.

3.3.2 Maintenance of Certification in Dietary Data Documentation

Following initial certification, the dietitian will maintain certification by:

1. Completing dietary data documentation exercises distributed four times per year. These exercises are due one month after they have been distributed.

   For successful completion of these exercises, the documenter must meet this standard: no more than three significant details of documentation should be missing or incorrect per food record day.

2. Attendance at the annual NCC training program session on Dietary Data Documentation.

A prolonged absence of the certified dietitian from the study will be evaluated by the NCC for consideration of the necessity for re-certification.

Section 4

Nutrient Composition of Diets[a]

	Moderate Protein Diet (M)	Low Protein Diet (L)	Very Low Protein (Keto acid) Diet (K)
Total Protein (g/kg/day)[b]	1.30	0.575	0.28
High Biological Value Protein (g/kg/day)	No upper or lower limit[c]	≥0.35	No upper or lower limit
Low Biologic Value Protein (g/kg/day)	No upper or lower limit[c]	≥0.25	No upper or lower limit
Energy (kcal/kg/day)	Adequate to maintain or promote standard weight[a]		
Calcium (mg/day)[f]	1450 - 1550	1450 - 1550	1450 - 1550
Phosphorus (mg/kg/day)	16 - 20	5 - 10	4 - 9
Magnesium (mg/day)	≥300 - 350[d]	≥300 - 350[d]	≥300 - 350[d]
Sodium (mg/day)	≥1200[j]	≥1200[j]	≥1200[j]
Potassium (mEq/day)	50 - 150	50 - 150	50 - 150
Iron (mg/day)	≥10 - 18[e]	≥10 - 18[e]	≥10 - 18[e]
Zinc (mg/day)[f]	15 - 20	15 - 20	15 - 20
Vitamin A (IU/day)[g]	5000	5000	5000
Vitamin D (ug/day)[h]	5.0 - 7.5[i]	5.0 - 7.5[i]	5.0 - 7.5[i]

[a] See text for further discussion of nutrient composition of diet.

[b] Add one gram of high quality protein for each gram of daily urine protein loss during Baseline up to a maximum of eight grams.

[c] The patient can eat any combination of high and low biological value protein as long as 1) total protein intake remains at the prescribed level, and 2) the dietitian indicates that the patient ingests the minimum recommended safe intake of essential amino acids.

[d] ≥350 mg/day for males; ≥300 mg/day for females.

[e] ≥10 mg/day for males and nonmenstruating females; ≥18 mg/day for menstruating females.

[f] Including supplements.

[g] The average of Vitamin A intake from foods should be at least 5000 IU/day but this will not be a requirement of the dietary prescription. If the average of Vitamin A intake is less than 3300 IU/day, a supplement of 5000 IU/day of Vitamin A will be given; otherwise, no Vitamin A supplement will be administered to the patient.

[h] Given as cholecalciferol or ergocalciferol.

[i] 5.0 ug/day for men and women ages 23 to 74 years old; 7.5 ug/day for men and women ages 19 to 22 years old.

[j] Level ad[illegible]ted to <2000 mg/day as non-pharmacologic therapy [illegible] hypertension.

Section 5

Nutrient Data Base

5.1 Features of the MDRD Nutrient Data Base (As of 8/1/88 prior to pilot testing)

5.1.1 Items

The MDRD nutrient data base has been developed using as a foundation Version 4 of the University of Pittsburgh Dietary Data Center's nutrient data base. The MDRD data base includes approximately 3700 items expressed in both household units and on a gram weight basis.

The MDRD data base includes four types of items: 1) elemental foods, 2) mixed foods, including recipes, 3) vitamin/mineral supplements, and 4) medications.

The data base includes sodium-modified, calorie-modified, and protein-modified items.

The data base items have been derived from the following sources:

1. 1991 items from the USDA Nutrient Data Base for Standard Reference (Release 6, 1987) data tape.

2. 1210 items from the USDA Nutrient Data Base for Individual Food Intake Surveys (Release 2, 1985) data tape.

3. 256 items from the Primary Nutrient Data Set for USDA Nationwide Food Consumption Surveys (PDS, Release 1, 1985) data tape.

4. 140 brand-name manufactured items not available from USDA data.

5. 16 MDRD nutrient supplements and 39 brand-name low-protein products.

6. 21 fish items from the printed copy of USDA Agricultural Handbook 8-15.

5.1.2 Nutrient Values

Nutrient values are from the above sources as well as from USDA provisional tables, refereed scientific journals,

The MDRD data base includes these 22 nutrients: protein, total fat, total carbohydrate, crude fiber, food energy (kilocalories), alcohol, calcium, iron, magnesium, phosphorus, potassium, sodium, zinc, vitamin A (IU), ascorbic acid, thiamin, riboflavin, niacin, cholesterol, total saturated fat, total monounsaturated fat, and total polyunsaturated fat.

A code is also included which identifies foods containing protein of high biological value.

Nutrient values have been imputed if possible when no published or analytic data are available. Imputed values are based on calculations from a similar food, other nutrients in the same food, a different form of the same food, an ingredient list or recipe.

Missing nutrient values appear as blanks.

The recipe calculation program for the MDRD data base applies USDA yield factors to the nutrient values for each recipe ingredient.

Nutrient values for many standard recipe items on the data base are from USDA sources (particularly the Nutrient Data Base for Individual Food Intake Surveys, Release 2).

5.1.3 Data Base Development

To build the MDRD data base, the NCC at the University of Pittsburgh has consulted the Case Western NCC for information on the types of food items typically consumed by the study population, including specific protein-modified products, nutrient supplements, medications, and so on.

Version 4 of the University of Pittsburgh Dietary Data Center's nutrient data base was then modified to fill the needs of MDRD data entry and analysis. The modification of Pittsburgh's Version 4 has included the standard updating procedures (see Prepare for Update under Maintenance, Update, Verification, and Release) as well as the following steps as of September 1, 1988:

1. deleted:
   - 186 items (pertinent only to other studies, off the market, or replaced with new items)

2. added:
   - 337 items from Release 2 (many are chicken items which have more usable portion sizes than the items in Version 4)
   - 17 items from Release 6

- 55 items unique to MDRD (16 supplements, 39 low-protein products)

- 21 fish items from the printed copy of USDA Agricultural Handbook 8-15 (this USDA handbook will not be on data tape until Release 7)

- 15 manufactured items

Added 1014 nutrient values for the unique MDRD items, the fish items, and the manufactured items. Nutrient values for the new Release 2 and Release 6 items are from USDA data tapes.

3. updated Version 4 nutrient values for manufactured items:
   - 266 values were missing on Version 4

   - 287 values were on Version 4 but were updated (of the total 553, we imputed 143 values (using USDA values for similar items); 410 values were from manufacturers)

4. updated nutrient values for Release 5 items on Version 4 using Release 6 values

5. designated as high biological value:
   - 266 added items

   - 1273 items from Version 4

6. assigned food group codes to:
   - 445 added items

   - 3345 items from Version 4

7. changed 19 brief descriptions for Version 4 items

8. assigned an entry range for 1423 items (223 added items, 1200 Version 4 items). Entry people must verify entry if amount entered is outside of this range. The entry range is based on the 5th and 95th percentiles of quantity consumed per eating occasion from 1977-78 Nationwide Food Consumption Survey (NFCS) data (3-day) in Foods Commonly Eaten by Individuals (Home Economics Research Report Number 44).

During pilot testing, nutrient values for the MDRD data base will be verified (see Verify Update in Maintenance, Update, Verification, and Release).

5.1.4 Data Base Maintenance, Update, Verification, and Release

The MDRD data base will be maintained as described below. Other than the addition of a minimum number of specific items necessary for entry, no updates will be made to the MDRD version without a joint decision between the NCC and other responsibility centers. For all additions and changes, a rationale and documentation will be provided.

Meanwhile, a separate version of the data base will be updated, verified, and released according to the schedule below.

A decision will be made at the end of the trial regarding which subset of the records for MDRD will be recalculated using the most current version of the data base.

Schedule		Task
		Maintain Data Base
daily	1.	Answer questions regarding entry problems and judgment calls.
1x/week	2.	Maintain entry guidelines and all data flow logs.
6x/year	3.	Review Problem Item Report (see section on Quality Control) and written documentation for accuracy and consistency in solutions to problem items.
		Prepare for Update
1x/month	4.	Scan grocery store shelves for new products and new manufacturers. List foods to be added to data base and send for nutrient information.
2x/year	5.	Search USDA sources and refereed scientific journals for food composition information.
2x/year	6.	For brand-name manufactured items, send for updated nutrient information.
2x/year	7.	Review Problem Item Report (see Quality Control) for items not on the data base that have been encountered on food records.
		Update
1x/year	8.	Update nutrient values with analytic or imputed values using latest USDA releases and other sources.

1x/year	9.	Add new foods to and delete outdated foods from the data base.

Verify Update

1x/year	10.	For any updated items, total calories from protein, carbohydrate minus crude fiber, fat, and alcohol. Compare this with calorie values. Verify items for which difference between calculated calories and calorie value is greater than or equal to 12 percent and greater than or equal to 40 calories.
1x/year	11.	For any updated items, compare nutrients per 100 grams as calculated from one portion (E) to nutrients as calculated from another portion (F). Verify items for which difference is greater than 15 percent of the USRDA.
1x/year	12.	For studies using food groups, sort items by food groups and compare nutrients within groups. Verify out-of-range values for study-specific nutrients.
1x/year	13.	Perform all software calculations on a test set of food records for each new version of the data base. Compare with the calculations from the previous version. Verify all differences.

Release Update

1x/year	14.	Report imputed or missing values as percent of total number of nutrient values.
1x/year	15.	Report updated values and date updated.
1x/year	16.	Report foods or nutrients added to the data base and date.
1x/year	17.	Report source of items and nutrients as percent of data base.
1x/year	18.	Report foods deleted, date, and rationale.

5.2 How to Read the MDRD Nutrient Data Base Printout

For each item on MDRD data base, the printout includes the following (the numbers circled on this example are identified below):

```
(A) 5118001  BAGEL: WHITE: WITH SALT: (INCL. WATER, FLAVORED.: EGG, BIALY BAGELS)
(1)          (2) E  1SMALL MINI(2IN DIA):26.00 (3)
             (4) F        1 MED (3" DIA):55.00 (5)                    (6) BAGELS
```

A. Item #
Each data base item has a unique item number of up to 9 digits.

1. Levels
Each data base item is described in full in up to nine description segments called "levels" (separated by semicolons). The first is the "Main" level, and this is the broadest level of description (such as "Milk"). An entry person types in this level first to enter a food.

The second level is a more specific level of description than the Main level (such as "Cow" or "Goat"). After the entry person types in "Milk", each unique Level 2 for which the Main level equals "Milk" appears in a list on the computer screen. The entry person chooses one.

Each level of description becomes more and more specific. After the entry person chooses one of the levels from a list on the screen, each unique level of the next degree of specificity appears in a new list on the computer screen, and the entry person chooses one. This continues until the complete description of an item has been chosen.

2. E Amount Desc
Each data base item is expressed in one or two common portion sizes called E or F.

3. E Gram Value
This is the gram weight for the E Portion.

4. F Amount Desc
The second of two common portion sizes. Some items do not have an F Portion.

5. F Gram Value
The gram weight for the F Portion.

6. Item Description
Each data base item has a 20-character brief description which appears on reports. The brief description must include enough information to distinguish the item from every other item in the data base, so many abbreviations are used.

5.3 Fast Foods on the MDRD Nutrient Data Base

ARBY'S:

Beef and Cheese
Chicken Breast Sandwich
Chocolate Shake
Ham and Cheese
Jamocha Shake
Junior Roast Beef
Roast Beef
Super Roast Beef
Turkey Deluxe
Vanilla Shake

BURGER KING:

Chicken Specialty Sandwich
Chocolate Shake
Double Beef Whopper w/Cheese
French Fries: regular/large
Vanilla Shake
Whaler Sandwich
Whopper
Whopper Jr.
Whopper Jr. w/Cheese

DOMINO'S PIZZA:

Plain Pizza w/cheese
Pizza w/pepperoni and cheese

HARDEE'S:

Hamburger
Roast Beef Sandwich
1/4 Pound Cheeseburger

JACK-IN-THE-BOX:

Bonus-Jack Hamburger
Cheeseburger
Hamburger
Hamburger Deluxe
Jumbo-Jack Hamburger
Jumbo-Jack Hamburger w/Cheese
Regular Taco

MCDONALD'S:

Apple Pie
Big Mac
Biscuit w/Bacon/Egg and Cheese
Biscuit w/Sausage
Biscuit w/Sausage and Egg
Cheeseburger
Chicken McNuggets
Chicken Sandwich
Chocolate Shake
Egg McMuffin
English Muffin, buttered
Fish Fillet
French Fries/regular
Hamburger
Hash Browns
Hot Fudge Sundae
McDLT
Quarter Pounder w/Cheese and wo/Cheese
Sausage
Scrambled Eggs

RAX:	Beef/Bacon/Cheddar Sandwich Chicken Sandwich French Fries/regular Philly Beef-N-Cheese Roast Beef Turkey Bacon Club
ROY ROGERS:	Cheeseburger Hamburger

WENDY'S:	Baked Potatoes:
	  Bacon-N-Cheese
	  Broccoli-N-Cheese
	  Cheese
	  Chili-N-Cheese
	  Sour Cream-N-Chives
	Chili
	French Fries
	Frosty
	Single w/Cheese and wo/Cheese
	Double w/Cheese and wo/Cheese
	Triple w/Cheese and wo/Cheese

5.4 Low Protein Products on the MDRD Nutrient Data Base

Baking Mixes
Kingsmill:
. Unimix
Dietary Specialties:
. Baking mix (dp)
. Baking mix (Wel-Plan)

Bread
Dietary Specialties:
. Low protein (dp)
. Low protein brown bread
. Rusks (Aproten)
Med Diet:
. Rice Starch bread

Cookies
Dietary Specialties:
. Wafers, vanilla or chocolate, cream filled (Wel-Plan)
. Sweet (Wel-Plan)
. Chocolate, cream filled (Wel-Plan)
. Chocolate chip (dp)
. Butterscotch chip (dp)
Ener-g:
. Chocolate sandwich
Kingsmill:
. Chocolate chip
. Cinnamon
. Orange
. Sugar cookie
Med Diet:
. Wafers, vanilla cream filled (Aglutella)

Crackers
Dietary Specialties:
. Low protein (Wel-Plan)

Egg Replacer
Kingsmill:
. Egg replacer

Gelatin
Dietary Specialties (all Prono):
. Cherry
. Lime
. Orange
. Strawberry
Kingsmill:
. All flavors (strawberry, cherry, or orange)

Milk Substitute
Med Diet:
. Low protein milk from mix

Pasta

Dietary Specialties:

Wel-Plan:

- Macaroni
- Spaghetti
- Spaghetti Rings

Aproten:

- Anellini
- Ditalini
- Ragatini
- Tagliatelle

Ener-g (all wheat free, gluten free, Aglutella):

- Macaroni
- Spaghetti
- Spaghetti Rings
- Tagliatelle

Starch

Kingsmill:

- Wheat starch

Dietary Specialties:

- Wheat starch

5.5 Nutrient Supplements on the MDRD Nutrient Data Base

Calcium:
- Biocal 250 Chewable
- Biocal 500
- Cal-sup tablets
- Caltrate 600
- Os-Cal 500
- Tums, Extra Strength
- Tums, Regular

Ketoacids (tablet and 2.8 gram packet)

Iron:
- Fumurate
- Sulfate

Polycose Liquid
Polycose Powder
Magnesium
Moducal
Multivite Tablets
Vitamin A

5.6 A Mock-up of the MDRD Nutrient Summary Report

(For your reference)

Day 1 Page 1

ID: 156901
NAME CODE: BGIL

3-DAY FOOD RECORD
VISIT TYPE: B
VISIT NUMBER: 3.0

CLINICAL CENTER: 15
DIETITIAN: 15D01

DAY 1
DATE: 06/10/89

SQ #	M	L	FOOD NAME	QUAN	PORTION SIZE	GM WT	PROT (GM)	PR QL	CALOR KCAL	PHOS (MG)
1	B	H	Fruity Pebbles	1.3	3/4 ounce box	27.7	XX.X		XXXXX	XXXXX
2	L	A	Bev. Cola Type	1.0	1 fl. oz.	30.8	XX.X		XXXXX	XXXXX
3	D	H	Turk.dark meat only, Rstd	0.6	1 cup (5 oz.)	84.0	XX.X	HI	XXXXX	XXXXX
4	S	H	Pretzels	1.0	1 pretzel, dutch type	16.0	XX.X		XXXXX	XXXXX
5	S	A	Banana, Raw	1.0	1 med. 8-3/4" long	114.0	XX.X		XXXXX	XXXXX
					Total from Food Day 1		XX.X	XX	XXXX	XXXXX
					Total from Supplement Day 1		XX.X	XX	XXXX	XXXXX
					Total from Food and Supplement Day 1		XX.X	XX	XXXX	XXXXX

* Missing Value

MDRD STUDY
NUTRIENT SUMMARY TABLE

ID: 156901
NAME CODE: BGIL

3-DAY FOOD RECORD
VISIT TYPE: B
VISIT NUMBER: 3.0

CLINICAL CENTER: 15
DIETITIAN: 15D01

NUTRIENT AVERAGES

Nutrient	Unit	Daily Average From: Food	Supplement	Total	Percent of Calories	Percent RDA From Total	Percent Protein HI QL
Protein	GRAM	XXXXX.X	XXXXX.X	XXXXX.X	XXX		
High Quality Protein	GRAM	XXXXX.X	XXXXX.X	XXXXX.X			XXX
Calories	KCAL	XXXXX.X	XXXXX.X	XXXXX.X			
Phosphorus	MG	XXXXX.X	XXXXX.X	XXXXX.X			
Sodium	MG	XXXXX.X	XXXXX.X	XXXXX.X			
Potassium	MG	XXXXX.X	XXXXX.X	XXXXX.X			
Carbohydrate	GRAM	XXXXX.X	XXXXX.X	XXXXX.X	XXX		
Total Fat	GRAM	XXXXX.X	XXXXX.X	XXXXX.X	XXX		
Polyunsaturated Fat	GRAM	XXXXX.X	XXXXX.X	XXXXX.X	XXX		
Monounsaturated Fat	GRAM	XXXXX.X	XXXXX.X	XXXXX.X	XXX		
Saturated Fat	GRAM	XXXXX.X	XXXXX.X	XXXXX.X	XXX		
Cholesterol	MG	XXXXX.X	XXXXX.X	XXXXX.X			
Calcium	MG	XXXXX.X	XXXXX.X	XXXXX.X			
Iron	MG	XXXXX.X	XXXXX.X	XXXXX.X			
Vitamin C	MG	XXXXX.X	XXXXX.X	XXXXX.X		XXX	
Vitamin A	IU	XXXXX.X	XXXXX.X	XXXXX.X		XXX	
Zinc	MG	XXXXX.X	XXXXX.X	XXXXX.X		XXX	
Magnesium	MG	XXXXX.X	XXXXX.X	XXXXX.X		XXX	
Thiamin	MG	XXXXX.X	XXXXX.X	XXXXX.X		XXX	
Riboflavin	MG	XXXXX.X	XXXXX.X	XXXXX.X		XXX	
Niacin	MG	XXXXX.X	XXXXX.X	XXXXX.X		XXX	
Crude Fiber	GRAM	XXXXX.X	XXXXX.X	XXXXX.X			
Alcohol	GRAM	XXXXX.X	XXXXX.X	XXXXX.X			

MDRD STUDY
NUTRIENT SUMMARY TABLE

ID: 156901
NAME CODE: BGIL

3-DAY FOOD RECORD
VISIT TYPE: B
VISIT NUMBER: 3.0

CLINICAL CENTER: 15
DIETITIAN: 15D01

DAY 1
DATE: 06/10/89

SQ #	M	L	FOOD NAME	SODM (MG)	POTA (MG)	CARBO (GM)	FAT (GM)	POLY (GM)	SAT (GM)	CHOL (MG)	VITA (IU)	CALC (MG)	IRON (MG)
1	B	H	Fruity Pebbles	XXXX	XXXX	XXXX	XXXX	XXXX	XXXX	XXXX	XXXXX	XXXX	XX.X
2	L	A	Bev. Cola Type	XXXX	XXXX	XXXX	XXXX	XXXX	XXXX	XXXX	XXXXX	XXXX	XX.X
3	D	H	Turk.dark meat only, Rstd	XXXX	XXXX	XXXX	XXXX	XXXX	XXXX	XXXX	XXXXX	XXXX	XX.X
4	S	H	Pretzels	XXXX	XXXX	XXXX	XXXX	XXXX	XXXX	XXXX	XXXXX	XXXX	XX.X
5	S	A	Banana, Raw	XXXX	XXXX	XXXX	XXXX	XXXX	XXXX	XXXX	XXXXX	XXXX	XX.X
			Total from Food Day 1	XXXX	XXXX	XXXX	XXXX	XXXX	XXXX	XXXX	XXXXX	XXXX	XX.X
			Total from Supplement Day 1	XXXX	XXXX	XXXX	XXXX	XXXX	XXXX	XXXX	XXXXX	XXXX	XX.X
			Total from Food and Supplement Day 1	XXXX	XXXX	XXXX	XXXX	XXXX	XXXX	XXXX	XXXXX	XXXX	XX.X

* Missing Value

5.7 How to Read Your MDRD Nutrient Summary Report

If you have any questions about your report, call your MDRD nutritionist at _____.

ID, Name Code: Your patient ID number and name code.

Visit Type, Visit Number, Day, Date: The visit, day, and date of the reported food record day.

Clinical Center, Dietitian: Your center and dietitian.

SQ # (sequence number): Each food is numbered. Note: The foods may not be in the same order as on your food record, but they should be under the correct meal (see below).

M (meal): B = Breakfast, L = Lunch, D = Dinner, S = Snack. All snack foods, no matter when you ate them during the day, will be listed at the end of the report.

L (location): H = Food prepared at home, A = Prepared away.

Food Name: A 20-character brief description of the food item stored in the computer that is the best match for what you wrote in your food record.

Quan (quantity): The number of standard portion sizes that you ate (see PORTION SIZE).

Portion Size: The computer stores certain standard portion sizes for each food. The QUAN (quantity) multiplied by the PORTION SIZE equals the amount you ate.

GM WT: The gram weight of the amount you ate. This is calculated by multiplying the number of standard portion sizes you ate (Quan) by the gram weight of the standard portion size. Note: there are 28.35 grams in one ounce.

PROT (GM): The grams of protein in the amount you ate. Your MDRD protein goal is _____ grams per day.

PR QL (protein quality): HI means the food is of high protein quality--that your body can use most of the protein for growth and maintenance. A blank means the protein quality of the food is low or unknown.

CALOR (KCAL): Calories (expressed as Kilocalories)

PHOS (MG): Phosphorus (milligrams)

Total From Food, Supplement, Food and Supplement: Totals for each nutrient. For PR QL (protein quality) the totals are the total grams of protein only from items marked HI in the PR QL column.

ID, Name Code: Your study identification number and name code.

Visit Type, Visit Number, Day, Date: The visit, day, and date of the reported food record day.

Clinical Center, Dietitian: A code for your clinical center and dietitian.

SQ # (sequence number): Each food is numbered. Note: The foods may not be in the exact order as they are in your food record, but they should be under the correct meal (see M (meal)).

M (meal): B = Breakfast, L = Lunch, D = Dinner, S = Snack. All snack foods, no matter when you ate them during the day, will be listed at the end of the report.

L (location): H = Food prepared at home, A = Food prepared away.

Food Name: A 20-character brief description of the food item stored in the computer that is the best match for what you wrote in your food record.

SODM (MG): Sodium (milligrams). Your MDRD sodium goal is ____ milligrams per day.

POTA (MG): Potassium (milligrams).

CARBO (GM): Total carbohydrate (grams).

FAT (GM): Total fat (grams).

POLY (GM): Polyunsaturated fat (grams).

SAT (GM) : Saturated fat (grams).

CHOL (MG): Cholesterol (milligrams).

VITA (IU): Vitamin A (International Units).

CALC (MG): Calcium (milligrams).

IRON (MG): Iron (milligrams).

Nutrient Averages

NUTRIENT: The nutrients that are averaged for each day.

UNIT: The unit of measure for each nutrient (GRAM, KCAL=kilocalories, MG=milligrams, or IU=International Units).

DAILY AVERAGE FROM:

FOOD: The total amount of nutrients from food from all of the days on your food record divided by the number of days on your food record.

SUPPLEMENT: The total amount of nutrients from study supplements from all of the days on your food record divided by the number of days on your food record.

TOTAL: The average from both food and study supplements.

PERCENT OF CALORIES: The percent of calories that come from protein, carbohydrate, total fat, polyunsaturated fat, monounsaturated fat, saturated fat, and alcohol.

PERCENT RDA FROM TOTAL: For seven nutrients only (Vitamin C, Vitamin A, zinc, magnesium, thiamine, riboflavin, and niacin). Compares your daily average (from both food and supplement) to the Recommended Dietary Allowances (RDAs).

RDAs are the amount of certain essential nutrients thought to meet the known nutrition needs of all healthy Americans. The RDAs are different for people of different ages and genders.

The RDAs are set at a level higher than most people need, so they include a "safety margin." Most people do not need 100 percent of the RDA for every nutrient every day. It is a good idea, though, to get at least two-thirds (or 67 percent) of the RDA for all nutrients.

If you don't get two-thirds of the RDA for a nutrient, it does not necessarily mean that you are deficient in that nutrient. It means that to be safe, MDRD patients of your age and sex should probably eat more than you did of foods rich in that nutrient, or take a study supplement that includes that nutrient.

The RDAs were established by a group of nutrition experts who are members of the Food and Nutrition Board of the National Research Council of the National Academy of Sciences.

PERCENT PROTEIN HI QL: This is the percent of your average protein intake from food and supplement that is of high quality. Your MDRD goal is _____ percent protein of high quality.

5.8 Biological Value on the MDRD Nutrient Data Base

5.8.1 Steps to Assigning Biological Value

To assign a biological value to the items in the MDRD nutrient data base, we followed these five steps:

Step 1. Reviewed the concept of biological value

Biological value = the percentage of absorbed nitrogen in a protein which is retained by an organism for maintenance and/or growth. First defined by Karl Thomas in 1909 as: how many parts of the body nitrogen can be replaced by 100 parts of food nitrogen. Depends on the protein's amino acid composition, digestibility, and, to some extent, the cooking method used (for example, dry heat can destroy certain amino acids, such as lysine, or render them indigestible; cooking with water increases the availability of certain amino acids such as methionine in wheat protein).

Egg protein is highest in biological value. Milk protein is also very high.

A method for calculating biological value was proposed in 1924 by Karl Thomas and Harold Mitchell:

1. A nitrogen-free diet is fed and urinary and fecal losses of nitrogen are measured.

2. The protein in question is fed; and if nitrogen losses are increased, less than 100% of the dietary nitrogen is retained.

3. This formula is used by the Food and Agriculture Organization/World Health Organization to calculate biologic value (1965): retained nitrogen divided by absorbed nitrogen times 100.

$$\frac{I - (F-Fk) - (U-Uk)}{I - (F-Fk)} \times 100$$

where I = Nitrogen intake (on test diet)
F = Fecal nitrogen (on test diet)
Fk = Endogenous fecal nitrogen (on nitrogen-free diet)
U = Urinary nitrogen (on test diet)
Uk = Endogenous urinary nitrogen (on nitrogen-free diet)

Limitations of this method of expressing protein quality include:

1. Biological value does not reflect the protein quality of the total diet, only of individual foods or specified mixtures.

2. Few animals other than rats will consume nitrogen-free diets long enough to complete the trial. (Three to four weeks are required for each experimental period because it takes 9 to 11 days to attain a new nitrogen balance.) So the biological value of foods for humans is usually inferred from animal experiments (often growing rats which have different essential amino acids and different requirements than adult rats and adult humans). Early researchers conducted experiments on themselves. Some researchers compare test proteins to egg protein rather than to a nitrogen-free diet (this measures egg replacement value).

3. Determining biological value is a complex and expensive procedure. Other less cumbersome methods are often used such as dividing the gain in body weight of an animal who is fed a test protein by the weight of the protein consumed (this measures the protein efficiency ratio or PER).

4. To accurately compare the biological value of various proteins, all should be studied using test diets with the same protein concentration. This has not always been done.

5. Nitrogen losses from skin, hair, nails, and sweat are not measured. The FAO/WHO estimates these to total 20 mg N/Kg, more under high humidity and temperatures.

Advantages of biological value as a measure of protein quality include:

1. The digestibility of a food is taken into account. This is not considered in some methods such as chemical or protein scoring which compares the essential amino acid content of a food to a standard, usually egg protein.

2. Nitrogen absorption is calculated from nitrogen intake and nitrogen losses. Some methods (such as net protein ratio, protein efficiency ratio, and nitrogen growth index) infer nitrogen absorption from the weight gains of animals on a protein-free diet versus animals fed a test protein diet. Weight gains may result from nonprotein components of the diets such as fat, water, and minerals, and the weight gains vary with the type of diet.

Step 2. Consulted a Food and Agriculture Organization (FAO) publication--Amino-Acid Content of Foods and Biological Data on Proteins, 1970--for biological values of common foods. The FAO sets world standards for protein quality.

Looked at the biological values of animal foods versus vegetable foods and found an overlap in biological value. Not all vegetable foods had a lower biological value than animal foods.

Decided to consider a food with a biological value of 70 or greater to be of high biological value.

See Table 5.8.1.

Step 3. For mixed foods, decided to estimate the percentage of high biological value protein in the mixture, and if estimated as at least 75% of the total protein, considered the mixed food of high biological value.

Step 4. Considered foods not on the FAO list to be of unknown or low biological value except for foods that we judged as clearly high biological value. (These exceptions were: lamb, turkey, any cheese, any seafood, any shellfish, luncheon meats, organ meats, and game meats. We averaged a value of 73 and a value of 67 for potatoes and considered them high.)

Step 5. Considered foods containing less than 1 gram of protein per typical serving as low biological value even if we estimated that at least 75% of the protein is of high biological value (for example, butter).

5.8.2 How to Interpret Total Grams of High Biological Value Protein

The total grams of high biological value protein appears on the Nutrient Summary Reports for three-day food records. In interpreting this total, study dietitians and participants should note:

1. Assigning biological value to mixed items in the MDRD data base has involved a considerable number of judgment calls largely because we do not have access to the recipes for most mixed items. If we were unsure, we tried to underestimate rather than overestimate biological value.

Table 5.8.1 FAO Biological Values

Food	Source A = Animal V = Vegetable	Biological Value
Cabbage	V	40
Red Bean	V	45
Lentils	V	45
Wheat Flour (white)	V	52
Groundnuts	V	55
Cowpeas	V	57
Pigeon Peas	V	57
Wheat Gluten	V	58
Bean (average)	V	58
Common Bean	V	59
Yeast (baker's)	V	59
Maize	V	60
Sesame Seed	V	62
Rice (polished)	V	64
Black Bean	V	64
Peas (dried)	V	64
Kale	V	64
Oat Meal (cooked)	V	65
Peas (fresh)	V	65
Butter Bean	V	66
Wheat (average)	V	66
Potatoes	V	67
Lima Beans	V	67
Sugar Beet	V	67
Yeast (brewer's)	V	67
Chick Peas	V	68
Coconut	V	69
Mung Beans	V	70
Sunflower Seed	V	70
Cheddar Cheese	A	71
Sardine	A	72
Rice (whole)	V	73
Soybeans	V	73
Potatoes	V	73
Wheat Germ	V	74
Beef and Veal	A	74
Chicken	A	74
Pork	A	74
Shrimp	A	74
Buckwheat (raw)	V	75
Rye	V	76
Fish (average)	A	76
Buckwheat (cooked)	V	77
Mushrooms	V	80
Casein	A	80
Barley	V	81
Cod	A	82
Squid	A	82
Haddock	A	83
Octopus	A	84
Milk (cow)	A	85
Lobster	A	88
Egg (hen)	A	94

2. Whenever possible, a mixed item consumed by a patient should be documented on a food record or recall by specifying the amount and full description of each individual ingredient. The data entry person will then enter each ingredient as a separate food item.

   If this level of documentation is not available, the entry person will enter the mixed item on the data base that is closest in description to what is on the food record/recall. In this case, the dietitian should interpret with caution the biological value listed on the Nutrient Summary Report; the recipe for the data base item may be very different than the recipe of the item consumed by the participant. The dietitian may want to add or subtract from the total grams of high biological value protein based on information about the composition of mixed items as consumed by the participant.

5.8.3 Selected References on Biological Value

Bigwood, E. J. (Ed.). 1972. Protein and Amino Acid Functions. Pergamon Press, New York. pp. 8-12, 34-45, 307-315, 368-373.

Amino-Acid Content of Foods and Biological Data on Proteins. 1970. Food Policy and Food Science Service, Nutrition Division, FAO. pp. 1-6. 165-186.

5.9 Abbreviations Commonly Used on MDRD Nutrient Summary Reports

MDRD Nutrient Summary Reports include a 20-character brief description for each food item. Many of these brief descriptions include abbreviations because the descriptions must contain enough information to distinguish each item on the nutrient database. Here are a few examples of the more complex discriptions:

Food Description	Translation
CRACKER,FLAT BRD,UNLV	Flat-bread, unleavened cracker
CRN,WH,COB,BL,W/SALT	Whole corn on the cob, boiled w/salt
DBLCHSBRGMAYBNNOTOM	Double cheeseburger w/mayonnaise, no tomato, on a bun
FLNDR,CHPBRO,DTFRZML	Flounder w/chopped broccoli, a diet frozen meal (Lean Cuisine, Weight Watchers, etc.)
FZDSTMOCAMXNODAIRCHC	Frozen dessert, mocha mix non-dairy chocolate
GRN BF,PTY,BRD,NSFAT	Ground beef patty, breaded, not specified as to fat
LOPROTCKYCHCHP,KNGM	Low protein chocolate chip cookie by Kingsmill Foods
MLKEVAPNSFATCOFFTEA	Milk, evaporated, not specified as to fat content, used in coffee or tea
BFSTWPTCARPEGRAVNOS	Beef stew w/potato, carrot, peas, gravy, no salt
BKFSTBROATGRANCHOCCT	Breakfast bar, with oatmeal, granola-type, chocolate coated
CKSTWPTCARCELTOSCNOS	Chicken, stewed, w/potato, carrots, celery, tomato sauce, no salt
CHXNK/RB,BK/FR,BRDSK	Chicken neck or rib, baked or fried, breaded w/skin

The following pages include definitions of the abbreviations most commonly used on MDRD Nutrient Summary Reports.

AA=ASC=Ascorbic Acid

AMT=Amount

APPX=Approximately

APRCT=Apricot

ART=Artificial

ASM=Assume

BAN=Banana

BEV=Beverage

BISCT=Biscuit

BF=Beef

BK=BKD=Baked

BKG=Baking

BL=BLD=Boiled

BN=Bone or Bean or Bun

BRBL=Broth or Bouillon

BRCU=Broth cubes

BRD=Bread or Breaded

BRG=Burger

BRL=Broil or Broiled

BRN=Brown or Bran

BRO=Broccoli

BRSD=Braised

BTR=Battered

BUT=Butter

BX=Box

C=Cup

CA PHOS=Calcium Phosphate

CA=Calcium

CAL=KCAL=Calories

CAR=Carrots

CB=Cob

CERL=Cereal

CF=Coffee

CH=CHS=Cheese

CHERR=Cherry

CHIX=CHX=CHICK=CK=Chicken

CHOC=Chocolate

CHP=Chop

CINN=Cinnamon

CK=CKD=Cooked

CKY=Cookie

CKT=Cocktail

CL=Class

CN=Can

CND=Canned

CNTNR=Container

COCNT=Coconut

COMMER=Commercial

CONC=Concentrate

COND=Condensed

CRCKRS=Crackers

CRM=Cream

CRMS=CRM SC=Cream Sauce

CROQ=Croquette

C/S/C=corn/soybean/cottonseed

CT=Coating or Cut or Cutlet

CTG=Cottage

CTTNSD=Cottonseed

CU IN=Cubic Inch

CUR=Cured

DEHY=Dehydrated

DI NA PHOS=Di Sodium Phosphate

DIAM=Diameter

DIL=Diluted

DRK=Dark or Drink

DRND=DRN=DR=Drained

DS=DSPEC=Dietary Specialties (supplier of low-protein products)

DST=DSRT=Dessert

DT=Diet

E=EN=Energy (supplier of low-protein products)

ENR=Enriched

EQ=Equal

EXT=Extruded

FDK=Fordhook

FE=Iron

FL OZ=Fluid Ounce

FLAV=FLV=Flavored

FLK=Flakes

FLR=Flour

FORT=Fortified

FR=From or Fried or Frozen or fresh

FR-FR=French Fries

FRSTD=Frosted

FRT=Fruit

FRTS=Fruits

FRZ=FZ=Frozen

FT=Fat

GAL=Gallon

GEL=Gelatin

GL=Glass

GM=Grams

GR=Grain or Ground or Gravy

GRAN=GNL=Granules

GRN=GRND=Ground

GRPE=Grape

GRV=Gravy

H20=Water

H+C=Herbs and Cheese

HI-PROT=High Protein

HLVS=Halves

HOM=HOME=HMMDE=Homemade

HYDR=Hydrogenated

IC=Icing

IMITN=Imitation

IN=Inch

INC=INCL=Include

INSTNT=Instant

J=JC=JCE=JU=JUC=Juice

JNR=Junior

KNGS=KINGS=Kingsmill (supplier of low-protein products)

L/F(%)=LN/FT(%)=Lean Fat Ratio

LB=Pound

LF=Loaf

LG=LRG=Large

LIQ=LQ=Liquids

LM=Lemon

LMB=Lamb

LN=Lean

LNG=Long

LOFT=Low Fat

LRD=Lard

LRG=Large

LT+DK=Light and Dark

LVS=Leaves

MARG=Margarine

MD=MEDDT=Med Diet (supplier of low-protein products)

MED=Medium

MG=Milligram

MILL=Milled

MIXNE=Mix and Eat

MK=MLK=Milk

MX=Mix

MW=Microwave

NA=Sodium

NA CAS=Sodium Casienate

NAT=Natural

NDL=NOOD=Noodle

NFDM=Nonfat Dry Milk

NFDMS=Nonfat Dried Milk Solids

NFMS=Nonfat Milk Solids

NFS=Not Further Specified

NOS=No Salt

NOSK=No Skin

NS=Not Specified

NT LUNC=Not Luncheon

NT WT=Net Weight

OZ=Ounce

PAST=Pasteurized

PB=Peanut Butter

PC=Piece

PDR=Powder or Powdered

PRK=PK=Pork

PK=Pack

PKD=Packed

PKG=Package

PKT=Packet

PNAPPL=Pineapple

POL=Polished

POT=PT=Potato

PR=Par Fried

PREP=PPD=Prepared

PRESWT=Presweetened

PROC=Processed

PROT=PRT=Protein

PST=Paste

PTTY=Patty

PWD=Powdered

PUD=PDNG=Pudding

QT=Quart

QTR=Quarter

R-T-C=Ready to Cook

REC=Recipe

RECT=Rectangular

REG=RG=Regular

REL=Relish

RF=Refuse

RS=Restructured (Potato Chip)

RSAV=Restaurant Prepared, Made with Animal Fat and Vegetable Oil

RSTD=RST=Roasted

RSVO=Restaurant Prepared, Made with Vegetable Oil

R-T-E=Ready to Eat

RW=Raw

S=Salt

S+L=Solids + Liquid

SA=SC=Sauce

SECT=Sections

SFLWR=Safflower

SKN=SK=Skin

SL=Salt

SLAW=Coleslaw

SLC=Slice or Slices

SLD=Salad

SLT=Salt

SM=Small

SMK=Smoked

SNFLWR=Sunflower

SODM=Sodium

SOL=Solids

SP=Soup

SP DT=SP DIET=SP DTY=Special Dietary Pack (no-salt-added for canned vegetables)

SPN=Spanish

SPIN=Spinach

SQ=Square

SRP=Syrup

ST=Style

STBL=Stabalizers

STFFNG=Stuffing

STK=Stick or Steak

STR=Strained

STRAW=Strawberry

STW=Stewed

SUG=Sugar

SULF=Sulfured

SW=Sweet

SWTN=Sweetened

SYBN=Soybean

SYSC=Soy Sauce

SZ=Size

TBLTS=Tablets

TBSP=Tablespoon

TNA=Tuna

TO=TOM=Tomato

TOSC=Tomato Sauce

TOT ED=Total Edible Portion

TST=TSTD=Toast or Toasted

TSP=Teaspoon

V=Vanilla

VAR=Variety or Varieties

VEG=VG=Vegetables

VEG-S=Vegetable Shortening

VIT A=Vitamin A

VIT C=Vitamin C

VOL=Volume

W/=With

WH=WHT=White or Wheat or Whole

WDG=Wedge

WHL=Whole

WHT=White or Wheat

WO=W/O=Without

WP=W-P=WLPLN=Well-Plan (for low-protein products)

WT=Weight

WTR=Water

WTWAT=Weight Watchers

X=Extra or Multi

YEL=Yellow

YLD=Yield

Section 6

Dietary Data Collection, Documentation, and Analysis and Reporting

6.1 Research Quality Dietary Data

6.1.1 Background

Scientific dietary intervention trials are key to testing and documenting the effectiveness of diet in preventing poor health outcomes. Nutrition professionals' dietary data collection and documentation performance is key to this process. Their ability to reliably and validly collect and document dietary intake changes is critical to testing diet and health hypotheses and to demonstrating the feasibility of implementing and sustaining those diet modifications. Dietary intake assessments are used to characterize usual dietary intakes of groups and/or individuals by nutrient intake and food patterns. Currently available assessment methods have important limitations and dietary collections methodologies for intervention trials are actively being researched. More precise dietary collection methodologies such as meal-provided studies, duplicate meal, and aliquot methods are inappropriate for out-patient trials such as MDRD. The reasons are their expense, their bias of eating behavior, and their inability to document sustained diet modification feasibility for free living populations. Other methods such as the 24-hour diet recall and food record are widely used in clinical trials since they are inexpensive, can be administered in a standardized fashion, and can provide reliable and valid information on nutrient intakes and food patterns.

6.1.2 Errors in Dietary Data

Dietary data, like other types of data, are subject to errors that can critically affect the reliability and validity of dietary estimates. Errors can occur at several points in the collection and processing of the data: choice of sample, errors in individual's data, errors occurring with data transformation for computer processing, and data analysis utilizing a food and nutrient database which contains errors. Examples of potential data transformation errors include transcription errors, coding errors involving inaccurate computations or inappropriate food item determinations or substitutions.

Variation in individual intake occurs normally and can represent day-to-day differences in eating choices and behavior. However, recording and reporting errors can also occur. Errors in patient dietary intake estimates can result from vague food descriptions, quantity not well specified, and missing food items "components". Not only can details be missing or unclear, but entire food items may be missing. Patient characteristics which can potentially influence

dietary intake reporting are memory, attention to detail, organizational skills, food knowledge, weighing and measuring skills, and willingness to be accurate. Data collector characteristics can also influence measurements. These include ability to engender rapport and trust, consistent application of research quality procedures, and skills maintenance.

6.1.3 Role of the Dietary Data Center

The MDRD-NCC Dietary Data Center's mission is to ensure research quality dietary data for scientific studies such as MDRD. The key components of this effort are: 1) study-specific tailoring and maintenance of a state-of-the-art food and nutrient database; 2) professional quality dietary data entry and processing; and 3) certification and recertification of dietary data collectors. Research quality data collection competency for clinical trials is characterized by standardization of dietary data collection procedures and ability to provide specificity, precision and completeness of the data collected.

6.2 MDRD Dietary Data Collection

6.2.1 Overview

MDRD clinical center dietitians will be assisting with the collection of two types of dietary data: patient-completed food records and dietitian-collected 24-hour diet recalls. The food record is a patient diary of their food intake recorded as soon as possible after eating. The 24-hour recall is a structured, open-ended interview designed to elicit patient food intake post-hoc.

The role of the MDRD nutrition professional is complicated by the simultaneous requirements of dietary change support and collection of unbiased patient dietary intake information. When financially feasible, trials have supported the services of a non-intervention nutrition professional to collect and document dietary intake information. In trials such as MDRD which cannot afford this luxury, investigators rely on the skills of clinical center dietitians to create a neutral and supportive environment in which patients can openly and fully report their actual intakes.

6.2.2 24-Hour Recall Interview

6.2.2.1 Introduction

The 24-hour dietary recall collection is a standardized open-ended interview designed to elicit actual patient dietary intake over a 24-hour period. The method, commonly employed by nutrition professionals as a counseling tool, can also be used for collection of research quality dietary data. The key

to ensuring research quality data is consistent and systematic application of standardized procedures. The following are the steps recommended by other research nutritionists to facilitate this data collection and ensure its quality.

6.2.2.2 The Collection Procedure

1. Setting the Stage

   - Set up the interview area: Layout MDRD measurement tools and MDRD forms and prompts you plan to use.

2. Preparing the Patient

   a. Establish a neutral, supportive tone.

   b. Brief the patient on:

      - The use and importance of the data;
      - The type of detail you will be eliciting;
      - The time period you will be covering and;
      - The MDRD measurement tools.

   c. Emphasize to the patient that you want information on exactly what they actually ate. They should be encouraged to report to you "anything and everything".

3. The Interview Flow

   a. Starting the Interview

      - Give a quick overview of the interview.
      - Re-emphasize neutral stance.

   b. Collecting yesterday's intake data

      - Move through the morning/afternoon/evening.
      - Use open-ended, non-directive questions to elicit food intake.
      - Use open-ended, non-directive probes to elicit needed food detail.
      - Employ MDRD measurement tools to assist in verifying food quantities.
      - Review collected information with the patient and ask if information is complete or whether they've remembered any other details.

c. Filling the "fasting" gap (if necessary)

- Ask the patient whether he or she skipped any usual eating because of the required visit "fast" for lab tests.

1. If the patient merely ate earlier (i.e. before the fast) or doesn't usually eat anything during that time and consumed what they would have normally eaten, the 24-hour recall is complete, as is.

   Examples: Mrs. Smith started her fast at 8 p.m., but ate her evening snack at 7:30 p.m. instead of her usual time of 9 p.m. Mr. Brown doesn't like to eat anything after 7:30 p.m. at night because he doesn't sleep well if he does. He started his fast at 8 p.m.

   A complete 24-hour period of dietary intake has been collected for these patients even though they fasted for part of this period.

2. If eating is skipped because of a fast, fill in the missing hours of recall by eliciting eating from the day-before-yesterday.

   For example, Mr. Jones did not eat his usual evening snack yesterday because he started his fast at 8 p.m. Ask Mr. Jones to recall the evening of the day-before-yesterday. Elicit what he'd eaten from 8 p.m. to midnight.

d. Closing the Interview

- Reiterate the importance of the data.
- Thank the patient for his/her efforts in reconstructing his/her intake.
- Thank the patient for being frank and open in providing this crucial information.

6.2.3 Three-Day Food Record

Technically, food record data is "collected" by the patient and represents a diary of his/her intake. However, this collection is importantly supported by the MDRD dietitian through initial and on-going patient training in foods awareness and knowledge, weighing and measuring skills, and patient ability to accurately detail their actual eating behavior. Patients are asked to complete and return Three-Day Food Records for most MDRD Study visits. These record sets are distributed at the previous visit. At the time of the

record sets' distribution, the dietitian and patient agree on the dates for which the "diaries" will be recorded. One of these three dates should include a weekend day but the dates need not be consecutive.

Information on the distribution and documentation of the Three-Day Food Record can be found in the MDRD Manual of Operations, Chapter 1, Section 8. A schedule of MDRD visits for distributing and receiving food records is summarized in the Manual of Operations, Chapter 1, Section 8.

6.3 Dietary Data Documentation

6.3.1 Introduction

Both 24-hour recall and food record data require checking to ensure research qualities of specificity, precision, and completeness. This dietary data review process, which is done by a certified documenter prior to submission for data processing, is termed "documentation". Several support materials are provided to assist documentation, including a list of probes for required food description details, a weighing and measuring guide and equipment, specific review procedures, and the assistance of a second certified documenter. The objective of data documentation is to provide clarity, precision and completeness to trial data. Dietary data documentation benefits clinical center dietitians by facilitating faster turnaround of data reports for patient counseling, better quality patient intake reports, and the ability to test the effect of diet in MDRD.

6.3.2 Supporting Patients in Food Recording and Reporting

Specific skills are needed by the patient for successful recording and reporting of food intakes for MDRD. The patient requires knowledge about foods and food details, such as components of mixed dishes and sauces and weights and measures of those components. Few patients enrolled in clinical trials enter with these skills. Rather MDRD nutrition professionals provide instruction and support to patients to ensure that research quality dietary data is consistently available for the study.

To assist the patient in this work, the following are provided: 1) collection instructions and guides which are included in the patient's Three Day Food Record packet; 2) a handbook to assist with quantity details--Guide to Weighing and Measuring; and 3) a set of standard measuring cups and spoons and a food scale.

6.3.3 Dietary Data Documentation by a Certified Documenter

Prior to transmittal of dietary data to the NCC, patient food record data must be reviewed by two certified documenters and 24-hour recall data must be reviewed by a certified documenter other than the actual data collector. The objective of the documentation review process is to provide clarifying details or specific information to facilitate food data processing. For example, quantities of unusual size are verified by the documenter.

MDRD requires that all dietary data sent to the NCC is reviewed by a second certified documenter. The first documentation of dietary data is done with the patient while the second is done solely with the data. The second documenter is responsible for clarifying any confusing or vague descriptions, amounts or food items; completing any missing information; and checking to ensure that all dietary data forms for transmittal are included. Clinical center performance will be enhanced by the second documenter since their work will result in better quality patient dietary intake information and faster turnaround of patient diet reports. Since queries will be significantly decreased, faster reporting will be possible.

Clinical centers should hold dietary data for second documentation for a maximum of three working days. At the end of this period, dietary data should be forwarded to the NCC with a note indicating the reason for the missing second document- ation. This note can be made on the Nutrition Cover Sheet (Form 61).

6.3.4 Sending Dietary Data Information to the NCC

Dietary data is ready for transmittal to the NCC after the second documentation has been completed. This material is sent by Express Mail if substantial delays have occurred in mail out or are anticipated in transit. For example, mail out during a holiday period. The reason for this request is to ensure that patient dietary data reports are returned to center dietitians prior to the patient's next visit date.

6.3.5 Dietary Data Documentation Equipment

6.3.5.1 Dietary Data Collection Material per Clinical Center (for dietitian use)

1 Electrical adapter for food scale

2 Corelle dinner plates

2 Corelle bowls

2 Corelle saucers/small plates

2 Corelle cups

2 Wine glasses

2 5 oz. juice glasses

2 10 oz. rock glasses

2 12 oz. tumbler glasses

2 coffee mugs

2 sets plastic disks
(size 1", 1 1/2", 2", 2 1/2", 3", 3 1/2", 4", 5", 6")

2 sets plastic squares
(size 1", 1 1/2", 2", 2 1/2", 3", 3 1/2", 4", 5", 6")

2 sets (in one bag) styrofoam balls
(size 1/2", 2", 2 1/2", 3", and 4")

2 Soehnle Food Scales

2 sets dry measuring cups
(4 piece set: 1/4 cup, 1/3 cup, 1/2 cup, 1 cup)

2 sets measuring spoons
(4 piece set: 1/4 tsp, 1/2 tsp, 1 tsp, 1 TBS)

2 8 fl. oz. liquid measuring cups (Pyrex with graduated lines to measure fluid ounces)

This equipment was shipped to each clinical center prior to the beginning of the study.

6.3.5.2 Dietary Data Collection Materials For Each MDRD Patient

1 Soehnle Food Scale

1 set dry measuring cups
(4 piece set: 1/4 cup, 1/3 cup, 1/2 cup, 1 cup)

1 set measuring spoons
(4 piece set: 1/4 tsp, 1/2 tsp, 1 tsp, 1 TBS)

1 8 fl. oz. liquid measuring cups (Pyrex with graduated lines to measure fluid ounces)

An initial equipment supply (based on projections of recruitment levels through March 1989) was sent to each clinical center to be received by January 2, 1989. Depending upon recruitment levels, the clinical centers should notify the NCC of the need to have equipment resupplied. Clinical Centers should notify the NCC when they have less than two months supply left. (Example, you are recruiting an average of eight people per month, notify the NCC when you have 16 or fewer sets to distribute to patients.) It takes six to eight weeks to reorder this equipment. This notification to reorder should be sent to the NCC Dietary Data Entry Manager via electronic mail. The NCC will notify you via electronic mail when to expect the reorder of this equipment.

6.3.5.3 Dietary Documentation Tools for the Dietitian

1. Guide to Weighing and Measuring
2. Dietitian's Probe List

6.3.6 Dietary Documentation Forms and Instructions

The following forms and instructions are included in this section but also can be found in the Manual of Operations, Volume 2.

Form 60 - Food Record/24-Hour Recall Packing Slip from clinical center to NCC

Form 61 - Nutrition Cover Sheet

Form 62 - Food Record Form

Form 63 - MDRD Recipe Form

Form 64 - Three-Day Food Record

Form 66 - Phantom Matching Form

Form 60
Page ___ of ___

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Food Record/24-Hour Recall Packing Slip from Clinical Center to NCC

Clinical Center: ___ ___ Date Sent: ___ ___/___ ___/___ ___

Certification Number of person filling out form: ___ ___ ___ ___ ___

Did you attach the Nutrition Cover Sheet (Form #61) to the recalls and records? _____ Yes

Line Number	Patient ID	Name Code	Date of Day 1	Visit Type	Visit Number	Form Number
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

TOTAL RECORDS	For Clinical Center use only: Number Sent	For NCC use only: Number Received
24-Hour Recalls		
3-Day Food Records		
Other: _____ (specify)		

Send original of this form to MDRD Study Nutrition Coordinating Center in an envelope with the food records/ 24-hour recalls listed above and retain copy of this form in your Clinical Center file.

For NCC use only: Date received: ___/___/___

By Whom: _____ Batch No. _____

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Instructions for completing Form 60

Food Record/24-Hour Recall Packing Slip from Clinical Center to NCC

Purpose: To be used as a cover letter when sending food records/recalls to the NCC.

Clinical Center

Fill in the two-digit code for your clinical center.

Date Sent

Date when the food records/recalls are sent to the NCC.

Certification Number of Person Filling Out Form

Certification Code of the person completing this form. The NCC will contact this person if information or records are missing from the package sent.

Did you attach the Nutrition Cover Sheet (Form 61) to the recalls or records?

Make sure each record/recall has a Nutrition Cover Sheet attached. If all records/recalls do have this form attached, please check yes.

Chart

For each record sent with this mailing fill in the patient ID, name code, the date of Day 1, visit type (B or F), visit number, and form number (Form 63 or Form 64).

Total Records

In the column marked "For Clinical Center use only: Number Sent," record the total number of 24-Hour Recalls and Three-Day Food Record forms sent with this packing slip. The "other" category refers to items that may be sent to the NCC in the future as part of an ancillary study. For an example having the NCC analyze a seven-day food record. This total should not be more than ten (the number of recalls/records listed individually on the packing slip). If more than ten records/recalls are being sent, please use more than one packing slip.

Send the original copy of the packing slip and the records/recalls to the NCC. Be sure to keep a copy of this packing slip in your files.

When the NCC receives the mailing from your center, a data entry staff member will confirm the number of records received, date the records received, indicate who received the mailing, and in which batch the records are placed.

At the end of each month, the NCC will notify each clinic by electronic mail which records were received from that clinic during that month. Please check this listing with your copy of the packing slip. If any records are missing from the NCC list, notify the NCC immediately.

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NUTRITION COVER SHEET

Attach to the front of the Food Record Form (24-Hour Recall) (Form 62), or Three-Day Food Record (Form 64).

Patient ID: ____ ____ ____ ____ ____ ____

Name Code: ____ ____ ____ ____

Clinical Center: ____ ____

Visit Type: ____

Visit Number: ____ ____.____

Form Type:
[ ] Form 62 - Food Record Form (24-Hour Recall)
[ ] Form 64 - Three-Day Food Record

Dietitian's contact with patient: [ ] 1) in person
[ ] 2) over the phone

Dietitian's opinion of information: [ ] 1) reliable
[ ] 2) unreliable (please comment)
_____

Patient's food intake was:
Day 1 or 24-hr recall: [ ] 1) Typical
[ ] 2) Not Typical (Check reason why.)
[ ] a) Holiday (National or Religious)
[ ] b) Medical/Dental Surgery or Test
[ ] c) Illness
[ ] d) Death in Family
[ ] e) Other (specify) _____

Day 2: [ ] 1) Typical
[ ] 2) Not Typical (Check reason why.)
[ ] a) Holiday (National or Religious)
[ ] b) Medical/Dental Surgery or Test
[ ] c) Illness
[ ] d) Death in Family
[ ] e) Other (specify) _____

Day 3: [ ] 1) Typical
[ ] 2) Not Typical (Check reason why.)
[ ] a) Holiday (National or Religious)
[ ] b) Medical/Dental Surgery or Test
[ ] c) Illness
[ ] d) Death in Family
[ ] e) Other (specify) _____

Dietitian's Certification Number: ____ ____ ____ ____ ____

Date Documented: ___ ____/ ___ ____/___ ___
month Day Year

Reviewer's Certification Number: ___ ___ ___ ___ ___

Date Reviewed: ___ ____/___ ____/___ ___
Month Day Year

For NCC use only:

Batch _____

Revised 10/6/88

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Instructions for Completing Form 61

Nutrition Cover Sheet

Purpose: To supply the NCC with additional information about the completed Food Record Form (24-Hour Recall) or Three-Day Food Record.

This form is to be completed by the dietitian during the completion of either a Food Record Form (24-Hour Recall) (Form 62) or Three-Day Food Record (Form 64).

Patient ID

Fill in the patient's six-digit identification code.

Name Code

Fill in the patient's four-letter name code.

Clinical Center

Write your Clinical Center two-digit code here.

Visit Type

Either B for Baseline or F for Follow-Up.

Visit Number

Example: 00.5 for B0.A Visit
15.0 for F15 Visit

Form Type

Check whether this sheet is attached to a Food Record Form (24-Hour Recall) or a Three-Day Food Record.
Note: If both a 24-Hour Recall and a Three-Day Food Record are completed at the same visit, a Nutrition Cover Sheet must be attached to the 24-Hour Recall and another Nutrition Cover Sheet must be attached to the Three-Day Food Record.

Dietitian's contact with patient

Check whether contact was in person or over the phone.

Dietitian's opinion of information

Check whether the information was reliable or unreliable. If unreliable, check the reason (example: other--the patient could not confirm what he had to eat during the three-day period).

Patient's food intake was:

For each day, check whether the patient's intake was typical of what he/she normally eats or not typical (either more or less eaten than usual or unusual types of food eaten). "Not typical" describes the situation where a person drastically changes the volume of food intake to an extreme for that day. If not typical, check the reason.

a. Holiday (National or Religious)

Examples: a huge Thanksgiving dinner or fasting for religious holiday.

b. Medical/Dental Surgery or Test

Note: This does not include fasting prior to MDRD GFR visits.

c. Illness

Examples: anorexia or nausea.

d. Death in Family

e. Other (specify)

Dietitian's Certification Number

Fill in your five-digit certification number.

Date Documented

The date in which the dietitian who collected the food record or recall completes the documentation of the record/recall.

Reviewer's Certification Number

The food record/recall must be reviewed by a NCC certified documenter other than the documenter who collected the record/recall. This reviewer should fill in his/her certification number.

Date Reviewed

The date in which the reviewer reviews the record/recall and fills in any incomplete information.

FOOD RECORD FORM

Form #62

Patient ID: ___/___/___/___/___/___ **Name Code:** ___/___/___/___ Page _____ of _____

Day _____ **of** _____ **Date of Intake:** ___ ___/___ ___/___ ___ **Day of the Week** _____

Did you take any supplements? _____ Yes _____ No If yes, describe below in the Food and Beverage Items section.

Recipes attached
____ yes ____ no
number attached_____

Meals:
B — Breakfast
L — Lunch
D — Dinner
S — Snack

Amounts:
C — cup
TB — tablespoon
Tsp — teaspoon
oz — net weight ounces
lb — net weight pounds
floz — fluid ounces (volume)
gr - net weight grams

1 = yes
2 = no
9 = unknown

Line No.	Time	Meal	Place Home	Place Away	Food and Beverage Items Vitamin and Mineral Supplements Medications and Seasonings	Amount Eaten	Food Description: What type of food, method of preparation, brand name, homemade or store bought, dimensions, % of each ingredient, restaurant name and type	Was salt added at the table? ***	Was salt added in preparation? ***	Was fat added in preparation? ***
01										
02										
03										
04										
05										
06										
07										
08										
09										
10										
11										

***If yes to these three columns, include as a separate item under Food Description section.

For Clinical Center Use Only:

Comments (give line no. when appropriate): _____

Did you attach the Nutrition Cover Sheet to the front of the 24-hour recall or 3-day food record?

Modification of Diet in Renal Disease Study

Instructions for Completing Form 62

Food Record Form (24-Hour Recall)

PURPOSE: To record the patient's food intake over a specified period of time. Individual sheets of Form 62 may be used to record the patient's 24-hour food recall. Sets of Form 62 have been incorporated into the Three-Day Food Record (Form 64).

The dietitian will complete the following sections:

Patient ID

Fill in the patient's six-digit ID code.

Name Code

Fill in the patient's four-letter name code.

The dietitian and/or patient will complete the following sections:

Page ___ of ___

How many pages did it take to record a 24-hour period of time? Example: 1 of 2.

Day ___ of ___

Which day does this form reflect (example: for a three-day food record, this should be 1 of 3, 2 of 3, or 3 of 3; for a 24-hour recall, this should be 1 of 1).

Remainder of the form:

Follow the instructions on pages 2 and 3 in the Three-Day Food Record (Form 64).

For Clinical Center Use Only
Comments (give line no. when appropriate)

This is an optional area set aside for the dietitian to comment on aspects of the three-day food record or 24-hour recall.

Form #63

MDRD Recipe Form

Patient ID: ___ / ___ / ___ / ___ / ___ / ___

Page _____ of _____

Name Code: ___ / ___ / ___ / ___

Recipe from day _____

Visit Type _____

Visit Number ___ ___ . ___

1. **Recipe name:** _____

2. **Recipe yield** (total amount made):

   Total servings per recipe: _____
   (example: 4 servings or 36 cookies)

   or Amount made: _____
   (example: 2 cups or 250 grams)

   or Total dimensions: _____
   (example: 9 x 13 x 2 — inch pan)

3. **Amount eaten** (fraction of total recipe): _____
   (example: 1/4 of recipe)

   or in the same unit as recipe yield: _____
   (example: 1 cup)

4. **Ingredients in recipe:**

Line No	Amount	Ingredient	Description of Ingredient and Preparation
01			
02			
03			
04			
05			
06			
07			
08			
09			
10			

5. **How the recipe was prepared:** (baked, fried, etc.)

For Clinical Center Use Only:

Recipe reviewed using documentation checklist by:

Dietitian's certification number: _____ / _____ / _____ / _____ / _____

Date reviewed: _____ _____ / _____ _____ / _____ _____
Month Day Year

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Instructions for Completing Form 63

MDRD RECIPE FORM

PURPOSE: To record recipes used by the patient in conjunction with either a Food Record Form (24-Hour Recall) (Form 62) or a Three-Day Food Record (Form 64). Sets of the Recipe Form are incorporated into the Three-Day Food Record.

The dietitian will complete the following sections:

Patient ID

Fill in the patient's six-digit ID code.

Name Code

Fill in the patient's four-letter name code.

Visit Type

Either B for Baseline or F for Follow-Up.

Visit Number

Example: 00.5 for B0.A Visit
15.0 for F15 Visit

The dietitian and/or patient will complete the following sections:

Page ___ of ___

How many pages did it take to record the recipe?
Example: Page 1 of 2.

Recipe From Day

Refers to the food record days (1, 2, or 3) in which the recipe was recorded. Note: Use Day 24 for recipes used during a 24-hour recall period.

Remainder of form:

Follow the instructions on page 4 of the Three-Day Food Record (Form 64).

For Clinical Center Use Only
Dietitian's Certification Number

The dietitian who documents the recipe should fill in his/her certification number here.

Date Reviewed

The date you complete documentation on the recipe.

Form #64

Three-Day Food Record

PLEASE PRINT

First Name _____

Middle Initial _____

Last Name _____

Date of Day 1 ___ ___ / ___ ___ / ___ ___
Month Day Year

Date of Day 2 ___ ___ / ___ ___ / ___ ___
Month Day Year

Date of Day 3 ___ ___ / ___ ___ / ___ ___
Month Day Year

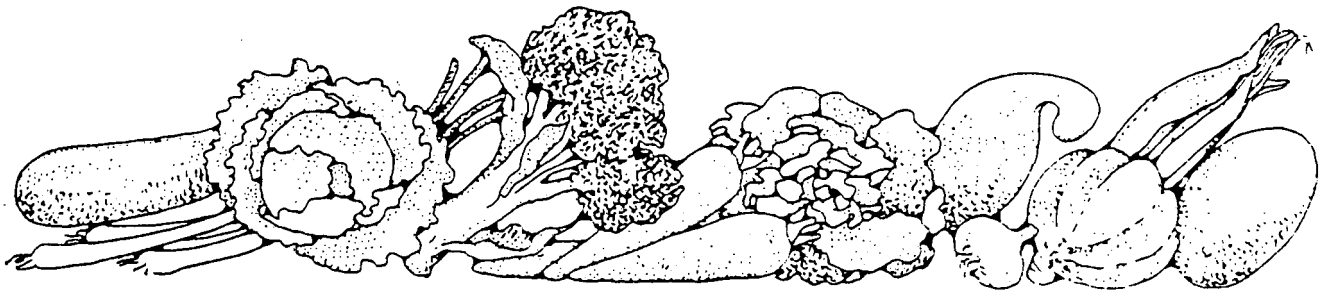
Visit Type _____

Visit Number _____ _____ . _____

Please remember that each day is a 24-hour period beginning at midnight and ending at 11:59 p.m.

FOR CLINICAL CENTER USE ONLY

Remember to attach the Nutrition Cover Sheet to the front of the 3-day food record before submitting to the NCC.



General Instructions

1) This is your three-day food record. It contains 8 sets (one page white and one page yellow) of food records (Form #62) and 4 sets of recipe forms (Form #63). Please **write clearly** throughout this booklet. As you complete each page, **flip the cardboard on the back cover of this booklet between the yellow page of the set you are using and the white page of the next set. This will allow the next set of pages to remain blank until you are ready to use them. Write only on the white pages. By using a ball point pen and pressing down firmly,** a clear copy of what you write on the white page will appear on the yellow page.

2) **Write down what you eat and drink immediately after you consume it.** Take this booklet with you when you eat away from home. Or take a separate sheet of paper, record what you eat and drink, then copy it into this booklet as soon as possible on the same day.

3) **Include everything** that you put into your mouth **beginning midnight on Day 1 through 11:59 p.m. on Day 3.** This includes all meals, snacks, beverages, medications, and supplements.

4) **Start each food on a separate line(s).** Use as many lines as you need for each food. For foods with several parts, write each **individual food on a separate line.** For example, to record a turkey sandwich you would record each part as a separate food (bread, turkey, mustard, etc.).

TO COMPLETE THE FOOD RECORD FORM (FORM #62)

FOOD RECORD FORM **Form #62**

(1) **Patient ID:** ___/___/___/___/___/___ **Name Code:** ___/___/___/___ Page _____ of _____

(2) **Day** _____ **of** _____ (3) **Date of Intake:** ___ ___/___ ___/___ ___ (4) **Day of the Week** _____

(5) **Did you take any supplements?** _____ Yes _____ No If yes, describe below in the Food and Beverage Items section.

(6) **Recipes attached**
____ yes ____ no
number attached_____

Meals:
B — Breakfast
L — Lunch
D — Dinner
S — Snack

Amounts:
C — cup
TB — tablespoon
Tsp — teaspoon
oz — net weight ounces
lb — net weight pounds
floz — fluid ounces (volume)
gr - net weight grams

(13) 1 = yes 2 = no 9 = unknown

Line No.	Time	Meal	Place Home	Place Away	Food and Beverage Items Vitamin and Mineral Supplements Medications and Seasonings	Amount Eaten	Food Description: What type of food, method of preparation, brand name, homemade or store bought, dimensions, % of each ingredient, restaurant name and type	Was salt added at the table? ...	Was salt added in preparation? ...	Was fat added in preparation? ...

The dietitian will fill in the patient ID and name code for you on each page.

For each day complete as follows:

1. **Page ____ of ____** —Write in how many pages you use for recording all the food you ate that day. (example: page 1 of 2.)
2. **Day ____ of ____** —Write whether it is day 1 of 3, day 2 of 3, or day 3 of 3. Be sure to start each day on a new page.
3. **Date of Intake**—Use numbers (example: 1/15/88).
4. **Day of the Week**—Monday, Tuesday, etc. **Remember one of the three days must be on a weekend.**
5. **Did you take any supplements?**—If you took any supplement, multivitamin, other vitamins, and/or keto acids for that day, please check yes. Be sure to include the supplement(s) in the Food and Beverage section, too.
6. **Recipes attached**—Check yes or no. If yes, mark the number attached for the white page you are completing. (That is, if you mention two recipes on a white page and include them on the recipe form (Form #63), mark 2 on that white page for the number of recipes attached). Instructions for recipes follow these directions.
7. **Time**—Be sure to include a.m. or p.m. (example: 7:15 a.m.).
8. **Meal**—
   B = breakfast
   L = lunch
   D = dinner
   S = snack

Page 1.1.69

9. **Place**—Check where the food item was **prepared,** either at home or away. For example, for foods that were prepared at home but eaten away, check home.

   If prepared away, write the place under the food description section (examples: friend's house, relative's house, vending machine, restaurant, take out, delicatessen). For restaurants, write the type of restaurant:

   a. Expensive (more than $10.00 per meal, not including alcoholic beverages)
   b. Inexpensive (less than $10.00 per meal, not including alcoholic beverages)
   c. Fast food

10. **Food and Beverage Items, Vitamin and Mineral Supplements, Medications and Seasonings**

    - **Include everything that you add to your food in cooking or at the table:**
      —all food, beverages, vitamin/mineral supplements and medications
      —seasonings (salt, pepper, spices etc.)
      —spreads (jam, jelly, butter, margarine, catsup, mayonnaise, mustard, etc.)
      —relishes (pickles, etc.)
      —tenderizers
      —milk, cream, creamers
      —sugar, sweeteners, syrups
      —garnishes if eaten (whipped cream, cherries, parsley, etc.)
      —sauces, gravy, marinades, bastings, or drippings
      —breadings, coatings
      —fats, seasonings, meats (salt pork, bacon grease, etc.) added to cooking water
      —fats used in cooking (include no-stick sprays or specify if meats are cooked in their own fat)
    - Include all ingredients used in foods prepared at home and away from home. For foods eaten away from home, ask someone such as the waiter, cook or your host for details about the foods.

11. **Amount Eaten**—See the back cover for a **Guide to Describing Amounts Eaten.**

12. **Food Description—Describe all foods in as much detail as possible.** Include:

    A. Brand names (also bring in labels for uncommon foods)
    B. Homemade or store bought (if homemade, give recipe)
    C. Fresh, frozen, canned, dried
    D. Whether regular or low protein, low sugar, low sodium, etc.
    E. Cooking methods (boiled, baked, broiled, roasted, etc.)—be specific.

    - For specific foods:

      Meats: Always note whether weighed or measured (in ounces or grams):
      —raw or after cooking
      —with or without skin, bone, or fat

      Eggs: small, medium, large or extra large

      Bread slice: standard size or diet (thin)

      Alcohol: Fluid ounces, cups or jiggers

      Snacks:
      —popcorn—whether measured popped or unpopped
      —chips, pretzels, nuts—in cups or number of pieces
      —candy, candy bars—in ounces

13. **Was salt added at the table?**—Mark 1 for yes and 2 for no. If yes, include salt as a separate item in the Food and Beverage section. Record as the number of shakes used.

    Was salt added in preparation? Was fat added in preparation?—Mark 1 for yes, 2 for no, and 9 for unknown. If yes, include as a separate item(s) in the Food and Beverage Section. Record as the number of shakes or amount (example: ¼ teaspoon) used.

14. The dietitian will complete the comments at the bottom of the Food Record Form.

    A completed food record form (form #62) is given on page 6 as an example.

TO COMPLETE THE MDRD RECIPE FORM (FORM #63)

Recipe Forms are at the back of this booklet.

For all homemade products:

A. On the Food Record Form (Form #62), list the recipe name for each homemade product and write "See Recipe" under the Food Description section.

B. Use the MDRD Recipe Form (Form #63) in the back of the food record booklet to write the recipe. Note: a completed sample of this form is on page 5.

C. The dietitian will complete the patient ID, name code, visit type, and visit number.

D. Page _____ of _____. Write in how many pages you use for recording the recipe.

E. Recipe from day _____ refers to the day which the recipe was recorded on the Food Record Form (Form #62).

F. Recording of recipe:

1. **Recipe name**—should match the name listed in the food record.

2. **Recipe yield** (total amount made)—This is the "yield" of the recipe. Either give:
   —the total number of servings per recipe (example: 4 servings or 36 cookies)
   or —amount made (example: 3 cups or 250 grams)
   or —the total dimensions (example: 9"x13"x2" pan).

3. **Amount eaten**
   as a fraction of the total recipe (example: 1/4 of the total recipe) or in the same unit as the recipe yield either serving or measure or dimension.

4. **Ingredients in recipe**
   Amount
   Ingredient
   Description of Ingredient and Preparation
   For each recipe ingredient, provide the amount, ingredient, and description. Be sure to include the same level of detail as for the rest of the food record (brand name, dimensions, etc.).

5. **How the recipe was prepared**
   Do **not** give the complete recipe instructions. Include only those details which would affect the content of the recipe (example: hamburger was browned and fat drained off; macaroni was cooked in boiling water to which 1/2 tsp. of salt was added, etc).

The dietician will complete the dietician's certification number and date reviewed.

Form #63

MDRD Recipe Form

Patient ID: 1, 2, 3, 4, 5, 6 Page 1 of 1

Name Code: X, Y, Z, A Recipe from day 1

Visit Type B

Visit Number 0 0 . A

1. **Recipe name:** Lemon Chicken Tetrazzini

2. **Recipe yield** (total amount made):

Total servings per recipe: 4
(example: 4 servings or 36 cookies)

or Amount made: _____
(example: 2 cups or 250 grams)

or Total dimensions: _____
(example: 9 x 13 x 2 — inch pan)

3. **Amount eaten** (fraction of total recipe): 1/4
(example: 1/4 of recipe)

or in the same unit as recipe yield: _____
(example: 1 cup)

4. **Ingredients in recipe:**

Line No	Amount	Ingredient	Description of Ingredient and Preparation
01	1 cup	egg noodles	dry - measured before cooking
02	3/4 tsp	Chicken bouillon	instant, low sodium chicken
03	4 tsp	Margarine	corn oil, stick, with salt
04	4 oz	chicken	Measured raw, breast, w/out bone
05	3/4 c	green beans	frozen, cooked in margarine
06	1/8 tsp	thyme	
07	1 shake	black pepper	
08	3/4 c	whipping cream	
09	4 tsp	lemon juice	Minute maid, reconstituted juice
10			

5. **How the recipe was prepared:** (baked, fried, etc.)

Chicken - weighed raw, without bone, without skin, breast
egg noodle - boiled in unsalted water
Chicken, green beans, and seasonings are sauteed in the margarine

For Clinical Center Use Only:

Recipe reviewed using documentation checklist by:

Dietitian's certification number: 0, 9, D, 0, 1

Date reviewed: 1 2 / 0 5 / 8 8
Month Day Year

FOOD RECORD FORM

Form #62

Patient ID: 1 2 3 4 5 6 Name Code: X Y Z A Page 1 of 2

Day 1 of 3 Date of Intake: 1 2 0 1 8 8 Day of the Week Thursday

Did you take any supplements? ✓ Yes ____ No If yes, describe below in the Food and Beverage Items section.

Recipes attached
✓ yes ____ no
number attached ____

Meals:
B — Breakfast
L — Lunch
D — Dinner
S — Snack

Amounts:
C — cup
TB — tablespoon
Tsp — teaspoon
oz — net weight ounces
lb — net weight pounds
floz — fluid ounces (volume)
gr - net weight grams

1 = yes
2 = no
9 = unknown

Line No.	Time	Meal	Place: Home	Place: Away	Food and Beverage Items Vitamin and Mineral Supplements Medications and Seasonings	Amount Eaten	Food Description: What type of food, method of preparation, brand name, homemade or store bought, dimensions, % of each ingredient, restaurant name and type	Was salt added at the table? ***	Was salt added in preparation? ***	Was fat added in preparation? ***
01	7:15 am	B	✓		Cereal - Corn Flakes	1 c.	Kellogg's Cornflakes	2	2	2
02	7:15 am	B	✓		Skim milk	4 floz		2	2	2
03	9:30 am	S		✓	coffee	8 floz	brewed, decaffeinated	2	2	2
04	9:30 am	S		✓	sugar	1/2 tsp	white - granulated	2	2	2
05	1:03 pm	L	✓		hot dog	44.8g (1.6oz)	Oscar Meyer - all beef hot dog	2	2	2
06	1:03 pm	L	✓		hot dog bun	1	white, enriched flour, from bakery	2	9	2
07	1:03 pm	L	✓		ice tea	12 floz	made from tea bags, no sugar, lemon or sweetener added	2	2	2
08	6:00 pm	D	✓		Lemon Chicken Tetrazzini	1/4 recipe	see recipe sheet	1	1	1
09	6:00 pm	D	✓		Salt	2 shakes	on chicken at table	1	1	2
10	6:00 pm	D	✓		Salad - lettuce	1 c.	iceberg, chopped	2	2	2
11	6:00 pm	D	✓		tomato	40.5g	red, chopped	2	2	2

*** If yes to these three columns, include as a separate item under Food Description section.

For Clinical Center Use Only:

Comments (give line no. when appropriate): ____

Did you attach the Nutrition Cover Sheet to the front of the 24-hour recall or 3-day food record?

FOOD RECORD FORM

Form #62

Patient ID: ___/___/___/___/___/___ **Name Code:** ___/___/___/___ Page _____ of _____

Day _____ **of** _____ **Date of Intake:** ___ ___/___ ___/___ ___ **Day of the Week** _____

Did you take any supplements? _____ Yes _____ No If yes, describe below in the Food and Beverage Items section.

Recipes attached
____ yes ____ no
number attached_____

8 sets NCR paper

Meals:
B — Breakfast
L — Lunch
D — Dinner
S — Snack

Amounts:
C — cup
TB — tablespoon
Tsp — teaspoon
oz — net weight ounces
lb — net weight pounds
floz — fluid ounces (volume)
gr - net weight grams

1 = yes
2 = no
9 = unknown

Line No.	Time	Meal	Place: Home	Place: Away	Food and Beverage Items Vitamin and Mineral Supplements Medications and Seasonings	Amount Eaten	Food Description: What type of food, method of preparation, brand name, homemade or store bought, dimensions, % of each ingredient, restaurant name and type	Was salt added at the table? ***	Was salt added in preparation? ***	Was fat added in preparation? ***
01										
02										
03										
04										
05										
06										
07										
08										
09										
10										
11										

***If yes to these three columns, include as a separate item under Food Description section.

For Clinical Center Use Only:

Comments (give line no. when appropriate): _____

Did you attach the Nutrition Cover Sheet to the front of the 24-hour recall or 3-day food record?

Form #63

MDRD Recipe Form

Patient ID: ___ / ___ / ___ / ___ / ___ / ___ Page _____ of _____

Name Code: ___ / ___ / ___ / ___ **Recipe from day** _____

Visit Type _____ 4 sets of NCR paper

Visit Number ___ ___ . ___

1. **Recipe name:** _____

2. **Recipe yield** (total amount made):

   Total servings per recipe: _____
   (example: 4 servings or 36 cookies)

   or Amount made: _____
   (example: 2 cups or 250 grams)

   or Total dimensions: _____
   (example: 9 x 13 x 2 — inch pan)

3. **Amount eaten** (fraction of total recipe): _____
   (example: 1/4 of recipe)

   or in the same unit as recipe yield: _____
   (example: 1 cup)

4. **Ingredients in recipe:**

Line No	Amount	Ingredient	Description of Ingredient and Preparation
01			
02			
03			
04			
05			
06			
07			
08			
09			
10			

5. **How the recipe was prepared:** (baked, fried, etc.)

For Clinical Center Use Only:

Recipe reviewed using documentation checklist by:

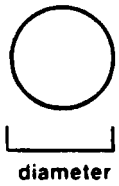
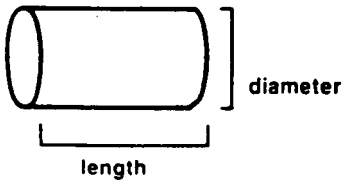
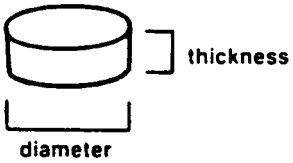
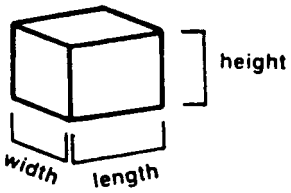
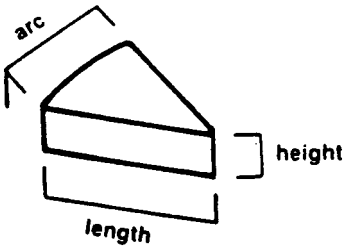
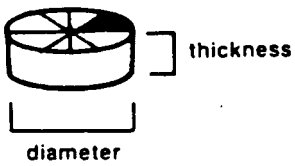
Dietitian's certification number: _____ / _____ / _____ / _____ / _____

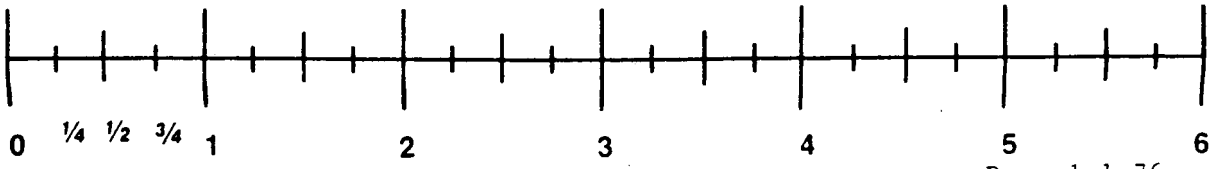
Date reviewed: _____ _____ / _____ _____ / _____ _____
Month Day Year

Guide to Describing Amounts Eaten

The amount eaten must be listed **very precisely.**

- **Use standard measuring cups** or **teaspoons** and **tablespoons** to measure liquids.
- Use the **scale** to weigh meats, vegetables, fruits, etc. Record in ounces or grams.
- Use a **ruler** to measure dimensions for whole vegetables, fresh fruits, baked items, etc. The ruler can be used when the scale is not available.

For dimensions, use:		Example food
• **diameter for round foods**		• 2 1/2″ diameter **orange**
• **diameter and length for cylindical foods**		• 2″ diameter x 4 1/2″ long **sweet potato**
• **diameter and thickness for disk foods**		• 3″ diameter x 1″ thick **hamburger patty** OR • 4″ diameter x 1/8″ thick **bologna slice**
• **height x width x length for rectangles or cubes**		• 1″ high x 3″ wide x 2″ long piece **cake** OR • 1/2″ high x 2″ wide x 3″ long piece **cheese**
• **arc by height by length for wedges** (pizza, cheese, etc.)		• 3″ arc by 1 1/2″ high by 4″ long wedge **of pumpkin pie**
• **fraction of the whole plus diameter and thickness of a total disk for wedges** (pizza, cheese, etc.)		• 1/8 of a 9″ diameter **pumpkin pie** that is 1 1/2″ thick



Modification of Diet in Renal Disease Study

Instructions for Completing Form 64

Three-Day Food Record

PURPOSE: To record the patient's food intake over a three-day period of time.

The Three-Day Food Record includes:

1. Instructions.
2. Samples of a completed MDRD Recipe Form (Form 63), page 5, and Food Record Form (Form 62), page 6.
3. Eight sets of blank Food Record Forms (Form 62) to be completed by the patient.
4. Four sets of blank MDRD Recipe Forms (Form 63) to be completed by the patient.

The dietitian is to complete the following items before giving the Three-Day Food Record booklet to the patient:

On the Cover

1. Patient's Name: first, middle initial, last.
2. Agreed upon dates for completion of the food record.
3. Visit Type: Either B for Baseline or F for Follow-Up.
4. Visit Number: example: 00.5 for B0A Visit
   15.0 for F15 Visit

Instructions for the patient are included in the Three-Day Food Record booklet on pages 1 through 6. Instructions for the dietitian can be found in the instructions for the Food Record Form (24-Hour Recall) (Form 62) and the MDRD Recipe Form (Form 63).

After reviewing the completed food record with the patient and documenting it, detach the white sheets of Form 62 and 63 (not the instructions), put them in the correct order, add any labels, drawings that help clarify any food item in the food record, staple together with the Nutrition Cover Sheet (Form 61) on top, and send to the NCC. The yellow sheets should remain in the booklet and be kept in the patient's file. Throw away the orange cover sheet, instructions and back cover, if there are no comments in these sheets to help describe the food items in the food record.

For DCC Use Only
Rev. 1 10/15/88

E ___
V ___
T ___

MDRD

Modification of Diet in Renal Disease Study
NCC Phantom Matching Form

This form is to be completed monthly when the Clinical Center sends a phantom 3-day food record to the NCC. The phantom food record should contain the complete information from a previous "real" food record, specified by the DCC, copied in the handwriting of the dietitian. The ID and name on the phantom record will be fake, generated by the DCC. The visit code on the phantom record will change from month to month following the normal sequence of visits as specified in the Manual of Operations. (Note: This form should be entered into Datalex)

To be completed by dietitian.

FORM # 6 6

Original 3-Day Food Record (to be copied)

1. Patient Identification Number ..... ___ ___ ___ ___ ___ ___
2. Patient Name Code ..... ___ ___ ___ ___
3. Clinical Center ..... ___ ___
4. Visit Type ..... ___
5. Visit Number ..... ___ ___ . ___
6. Date of Day 1 of Diet Record ..... ___ ___/___ ___/___ ___

Phantom 3-Day Food Record

7. Date of Day 1 ..... ___ ___/___ ___/___ ___
8. Visit Type ..... ___
9. Visit Number ..... ___ ___ . ___

101. Date this form completed ..... ___ ___/___ ___/___ ___
102. Certification number of person filling out this form ..... ___ ___ ___ ___ ___
103. Date form entered ..... ___ ___/___ ___/___ ___
104. Certification number of data entry person ..... ___ ___ ___ ___ ___

Retain a copy of this form for your files. Send the original to the MDRD Study Data Coordinating Center. *Do not send this form to the NCC.* Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
Department of Biostatistics & Epidemiology
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5196

PWO 1680

For DCC use only
Rev. 9/88

E ___
V ___
T ___

Modification of Diet in Renal Disease Study

NCC PHANTOM MATCHING FORM

PURPOSE: This form is to be completed monthly when the Clinical Center sends a phantom 3-day food record to the NCC. The phantom food record should contain the complete information from a previous "real" food record, specified by the DCC, copied in the handwriting of the dietitian.

The ID and name on the phantom record will be fake, generated by the DCC. The visit code on the phantom record will change from month to month following the normal sequence of visits as specified in the Manual of Operations. (Note: This form should be entered into Datalex)

To be completed by: Dietitian.

FORM #.....6 6

Original 3-Day Food Record (to be copied)

1. Patient Identification Number.....___ ___ ___ ___ ___ ___
2. Patient Name Code.....___ ___ ___ ___
3. Clinical Center.....___ ___
4. Visit Type.....___
5. Visit Number.....___ ___.___
6. Date of Day 1 of Diet Record.....___ ___/___ ___/___ ___

Phantom 3-Day Food Record

7. Date of Day 1.....___ ___/___ ___/___ ___
8. Visit Type.....___
9. Visit Number.....___ ___.___

101. Date this form completed.....___ ___/___ ___/___ ___
102. Certification number of person completing this form.....___ ___ ___ ___ ___
103. Date this form entered ..... ___ ___/___ ___/___ ___
104. Certification number of data entry person.....___ ___ ___ ___ ___

Retain a copy of this form for your files. Send the original to the MDRD Study Data Coordinating Center. Please use MDRD Study mailing labels.

MDRD Study Data Coordinating Center

Department of Biostatistics and Epidemiology
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, OH 44195-5196

6.4 Dietary Data Processing at the NCC

6.4.1 Introduction

The following sections explain the flow of dietary data within the NCC Dietary Data Entry Unit. The NCC is expecting a turnaround time of two weeks from receipt of food records at the NCC until corresponding Nutrient Summary Reports are sent to the clinical centers.

Dated logs are kept by the Data Entry Manager and Data Base Manager to monitor all aspects of MDRD nutrient data flow, including receipt of records, batching, inventory of identifying patient information, entry, and quality control procedures.

6.4.2 Receipt of Dietary Data

Upon receipt of the documented records or recalls, the packing slip is reviewed by one of the NCC data entry staff. The food records or recalls are then immediately entered into the NCC computer inventory programs called CLIP (Computer Log in Program) and FLIP (File Log in Program). CLIP identifies all new patients to the system. FLIP identifies which form, Three-Day Food Record or 24-Hour Recall, has been received and is being entered. All the information from the Nutrition Cover Sheet (Form 61) is entered into the FLIP program. The FLIP program groups records into batches that consist of up to 10 records each. A monthly report is generated from the CLIP and FLIP databases identifying which records have been received from each clinical center. This report is sent to the clinical center at the end of each month.

6.4.3 Entry

Each batch of records is processed by one of a staff of entry personnel. Entry personnel are trained for four or more weeks, depending on their qualifications and experience. Training consists of a thorough review of all data base materials, training on use of the University of Pittsburgh Dietary Data Center Nutrient Data Base Version 5 Computer Systems, practice entry with close supervision by the data manager, and tight quality control.

During data entry, entry personnel consult extensive entry guidelines (a list of coding rules) and a data base nutritionist before entering any questionable (problem) items. The solutions for all problem items are documented on line and in writing (see Problem Item Report under Quality Control).

6.4.4 Quality Control of Study Data

Quality control will include: routine editing at the point of entry to measure the entry quality of all items entered; routine editing after entry to measure entry quality of all records and accuracy of each entry person; the processing of quality control records to measure entry quality of a random subset of all records under test conditions and to compare the entry quality of different entry personnel; the processing of phantom records to measure the consistency of entry quality over time under everyday conditions; and the documentation and monitoring of entry judgment calls to monitor their consistency and accuracy and the completeness of the data base.

The quality control procedures are outlined below.

1. Routine Editing at Point of Entry

A. Purpose
   1. To measure entry quality of all items entered under routine conditions.

B. Sample Size and Frequency
   1. 100% of total number of items entered.
   2. Continuous.

C. Procedure

   1. Out-of-range edit checks prompt the entry person to confirm the amount entered for each item if above or below the specified range.

   2. A program entitled "Browse" allows the data entry person to review an entered record at any time during entry.

   3. A program entitled "Verify" must be run on each batch of records. This program prompts the data entry person to verify the accuracy and completeness of each item entered for each record in the batch.

   4. Whenever an entry judgment call is required (for example, entering an item as a substitute for a food record item not on the data base), the entry person consults a nutritionist or the documentation of previous judgment calls, then documents in writing the decision and source of information (see number 5 below, Problem Item Report). This documentation is reviewed by the Data Base Manager.

2. Routine Editing After Entry

A. Purpose

1. To measure entry quality of all records under routine conditions.

2. To monitor the entry quality of each entry person.

B. Sample Size and Frequency

1. 100% of total number of records.

2. Continuous.

C. Procedure

1. Check each entered food record for out-of-range nutrient totals for study-specific nutrients. The range limits are set based on the study population.

2. For records with out-of-range nutrient totals, check each food item for entry error.

3. Correct any errors.

3. Quality Control Records

A. Purpose

1. To measure entry quality of a random subset of all records under test conditions.

2. To compare the entry quality of different entry personnel.

B. Sample Size and Frequency

1. 10% of total number of records.

2. Monthly (assuming a minimum of approximately 30 records entered per month).

C. Procedure

1. Randomly select one record from each group of three batches (30 records total) for a quality control batch of three records.

2. Re-enter these three records by an entry person other than the one who entered the originals. The entry person is aware that these are quality control records.

3. Run a report comparing the original entry with the quality control entry (compare the percent difference between the daily totals for study-specific nutrients; also print the distribution of the percent differences for these nutrients).

4. Correct the original entry for those records with percent differences greater than a cutoff (less than 10 percent). The cutoff will be selected based on the distribution of percent differences.

5. Review with entry personnel.

4. Phantom Records

A. Purpose

1. To measure the consistency of entry quality over time under everyday conditions.

B. Sample Size and Frequency

1. One three-day record out of the total number of records entered per month.

C. Procedure

1. Unknown to the NCC, the DCC will generate a fictitious patient ID and name code for each clinical center and will specify a real food record (by ID, name code, and visit) once a month which a dietitian at that center will rewrite in his/her own handwriting with the fictitious I.D. and name. The visit code on the rewritten record will change from month to month following the normal sequence of visits as specified in the Manual of Operations.

2. NCC Phantom Matching Form (Form 66) is filled out and sent to the DCC via Datalex. The phantom food record is then sent to the NCC as a regular food record.

3. The NCC will enter this "phantom" record as if it were an original.

4. The DCC will compare the original entry with that of the phantom record and report the results to the NCC.

5. The NCC will correct the original based on the cutoff percent difference as described in number 3 of Procedures under Quality Control records.

6. The NCC will review any entry discrepancies with entry personnel.

5. Problem Item Report

A. Purpose

1. To monitor the consistency and accuracy of entry judgment calls.

2. To monitor the completeness of the data base.

B. Sample Size and Frequency
   1. All records.
   2. Bimonthly.

C. Procedure
   1. Whenever an entry person (after consulting a nutritionist and/or the entry guidelines) enters an item that is as close to the food record as possible but does not exactly match the food record, the entry person also enters a "problem item code".

      The problem item code includes up to three parts. First, the problem category is always included (1=food not clearly described or not enough details given; 2=amount can't be converted to what is in data base; 3=food not in data base; 4= miscellaneous).

      Second, a food group code is always included which designates the section in the Problem Items Notebook in which the solution is documented.

      Third, an ID number is also included if the problem has been encountered previously. The ID is from the food record in which the problem was first encountered. This ID is found documented in the Problem Items Notebook which includes, for every entry problem, the solution, source of the solution, and ID of the record in which the problem was first encountered. The Problem Items Notebook is continually reviewed by the Data Entry Manager and the sources of solutions must be either the Data Entry Manager, a standard reference with the page number(s) documented, or the written reply to a query sent to the clinical center at which the data was collected.

      After entering a problem item in category 2, 3, or 4, the entry person documents in the Problem Items Notebook the rationale for the chosen substitution (this applies only to the first time each problem item is encountered).

      When the entry person enters a problem item in category 1, the rationale for the chosen substitution must be based on a reply to a query sent to the clinical center or a

judgment call confirmed by the clinical center. If the clinical center does not confirm a judgment call or suggest another solution within three days, not including Sundays, the entry is based on the judgment call. Completed Problem Item Query forms and Problem Item Judgment Call forms are filed at the NCC as documentation.

2. Run the Problem Item Report which lists all items for which problem item codes were entered and the corresponding codes.

3. Review the consistency and accuracy of the judgment calls made by reviewing the Problem Item Report, written documentation, and the food records containing the items in question. Also review the completeness of the data base.

4. Make entry corrections as necessary.

5. Review with entry personnel.

6.5 Nutrient Analysis

The following nutrient calculations per three-day food record will be performed and provided to the clinical centers in a Nutrient Summary Table:

1. Nutrients per item and total nutrients per day (expressed as total from food, from supplement, and from food and supplement) for protein, calories, phosphorus, sodium, potassium, carbohydrate, total fat, polyunsaturated fat, saturated fat, cholesterol, vitamin A, calcium, and iron.

2. Average nutrients per day for the above nutrients.

3. Daily total and average protein intake, each reported in three ways: 1) total or average grams, 2) total or average grams of high biological value, and 3) percent of average grams of protein of high biological value.

4. Average % RDA from food plus supplement for specified sex-age categories for vitamin C, vitamin A, zinc, magnesium, thiamin, riboflavin, and niacin.

5. Percent calories from protein, total fat, monounsaturated, polyunsaturated, and saturated fat, carbohydrate, and alcohol.

Flags indicate missing nutrients.

See the Manual of Operations, Chapter 1, Section 5.6 for a mock-up of the MDRD Nutrient Summary Report.

6.6 Report Transmittal

6.6.1 Data to the DCC and from the NCC

Data to be sent daily from the NCC to the DCC using Crosstalk will include:

1. Whether data is from a 24-hour recall (From 62) or three-day food record (Form 64).
2. Patient ID
3. Patient name code
4. Clinical center code
5. Visit type
6. Visit number
7. All data from the Nutrition Cover Sheet (Form 61)
8. Date of day 1, 2, or 3
9. Day of day 1, 2, or 3
10. Daily total from food alone for 22 nutrients and high biological value protein
11. Daily total from supplements for 22 nutrients and high biological value protein

Data to be sent by electronic mail from the DCC to the NCC will include:

1. ID, name code, clinical center code, sex, and birth date for each patient (sent when the DCC receives Form 4 indicating that a BO visit was held).

2. ID, name code, clinical center, date of visit (or target if visit not held), visit type and number, and flag for whether or not visit was held (sent when the DCC receiver Form 5).

The NCC will respond to queries from the DCC using the DCC's SIR Query Database. When data changes are initiated from a center or the NCC, the NCC will send a revised data file to the DCC, a revised Nutrient Summary Report to the center, and notify by electronic mail both the DCC and center.

6.6.2 Communication with the Clinical Centers

The NCC will use electronic mail to communicate with the clinical centers regarding dietary data. In addition to routine mail messages, the following will be sent when appropriate:

1. Documentation of the records/recalls received by the NCC during the previous month (sent at the end of each month).

2. Notification of missing records/recalls.

3. Queries regarding unclear or missing dietary data documentation on records/recalls.

4. Request for confirmation of judgment calls made by the NCC regarding unclear or missing dietary data documentation.

5. Notification that a change in data has been made and a new Nutrient Summary Report will be sent to both the clinical center and the DCC.

The NCC will communicate regularly by phone and mail with food record documenters to provide feedback on documentation quality. A newsletter will be sent to documenters twice each year to provide additional feedback. Specific items that cause entry difficulties will be discussed, including items on the Problem Item Report (see Quality Control).

6.6.3 Logging of Data Flow

Dated logs are kept by the Data Entry Manager and Data Base Manager to monitor all aspects of MDRD nutrient data flow, including receipt of records, batching, inventory of identifying participant information, entry, and quality control procedures.

Section 7

Anthropometrics

7.1 Anthropometry

7.1.1 Definition and Purpose

Anthropometry is the study of the measurement of the human body in terms of the dimensions of bone, muscle, and adipose (fat) tissue.

Stature, weight and other body measurements, including skinfolds and arm circumference, will be collected for the purpose of assessing and monitoring nutritional status and for provision of reference data in a population with renal impairment.

Elbow breadth and stature will be measured at the Screening and Baseline 0 visits; stature is also taken annually. Skinfolds and arm circumference are recorded at Baseline 0A and 2, Follow-Up 6 and every 4 months thereafter on the Anthropometry Form (Form 65). Weight and stature are recorded on DCC Forms 03, 04, 05, 12, 13, and 47.

Reliability between examiners (certified dietitians) is monitored once a month.

7.1.2 Equipment: Products and Calibration Standards

To ensure standard methods of physical measurements at each center, standard equipment and certified trained personnel will collect all measurements. The standard equipment is:

- Bicondylar Vernier Calipers

  1. For taking elbow breadth measurements.

  2. The calipers are calibrated by using the calibration step wedge from 10 to 50 mm where appropriate. These calipers should be calibrated once every 3 months. The calibration data should be recorded in the Equipment Calibration Log.

- Stadiometer (Height Board)

  1. For measuring stature.

  2. Calibrate the height board at the beginning of each month.

3. Place the horizontal bar of the stadiometer firmly against the top of each calibration rod. Calibration rods are made of electrical conduit pipe. One rod should be 145 cm and the other 185 cm in length. If the rods are not exactly 145 and 185 cm, record the actual length in centimeters on the rods and in the Calibration Log. Use these actual numbers when calibrating the stadiometer. These rods should be handled carefully as they are easily bent. The calibration data should be recorded in the Equipment Calibration Log.

o Holtain Skinfold Calipers

1. For measurement of biceps, triceps, and subscapular skinfold thickness.

2. Calibrate the Holtain skinfold calipers once a week using the step wedge standard.

3. Zero the calipers before starting the calibration procedures. Place the step wedge standard between the caliper arms at each of the four steps, and check that the reading on the scale corresponds to the standard measurement.

4. Record the measurement taken at each step in the Equipment Calibration Log under the appropriate heading. An identical calibration should be done on the spare set of skinfold calipers and the corresponding measurements also recorded on the calibration log sheet. Be careful to record the values in the correct section for the instrument being calibrated: Set #1 or Set #2.

5. If the calipers are 1.0 mm or more out of calibration at any level, use the other set of calipers and notify the NCC. The calipers that are out of calibration will be returned to the manufacturer for adjustment.

o Clinical Scales

1. On each day that the scale is used, it should be prepared. Zero the horizontal beam. To do this, remove everything from the scale. Place the main and fractional sliding beam weights directly over their respective zeroes and, using the adjustment screws, move the adjustable zeroing weight until the beam is in zero balance.

2. Every three months confirm that the scale has been calibrated by the use of standard weights. Two 10-kg weight are provided for this purpose. The weight should be placed in the center of the scale platform (where the patient stands) and on top of each other when more than one weight is used.

3. Record the calibration data in the log book.

4. If the calibration is off more than 0.2 kilograms, ask a dealer to recalibrate the scales.

5. To avoid changes in calibration, the scales should remain in one location and <u>not</u> be moved about.

6. The scale should be placed on a hard, level surface. Carpeting is not acceptable. A piece of linoleum or other hard material may be placed under the scale, on top of the carpet, if carpeting is the only surface available.

Certification of personnel in use of the equipment will be by the Nutrition Coordinating Center. Such personnel will have participated in training sessions at the Nutrition Coordinating Center and will be recertified yearly.

7.1.3 <u>Role of the Anthropometric Examiner and Recorder</u>

The collection of anthropometric data requires two health technicians, one as the examiner and the other as the recorder. Certified study dietitians always assume the role of examiner; the recorder may be another dietitian or other clinic personnel.

The examiner is responsible for positioning the patient, taking each measurement, and saying the measurement aloud to the recorder. The recorder repeats the number, enters it onto the Anthropometry Form (65), and says the name of the next measurement listed on the form. The examiner should keep the measuring instrument set on the patient until the recorder repeats the number.

It is the recorder's role to "assist" the examiner in obtaining correct measurements. This includes helping the examiner correctly position the patient and checking to make sure the correct position is maintained.

The examiner has the responsibility of ensuring that correct data are entered onto the form.

7.1.4 Measuring and Recording Guidelines

Body measurements are preferably taken on the right side of the body. However, some measurements may be taken on the left side of the body because of casts, amputation, or other reasons. When this occurs, this is noted and the reason is recorded on the Anthropometry Form (65), items 5b and 9b.

All measurements, except skinfolds, should be taken to the nearest tenth of a centimeter or 1.0 millimeter. Skinfold measurements are taken to the nearest 0.1 millimeter. After each measurement is taken, its value is recorded in the appropriate space. If a recorder is present, the recorder should repeat the value that was called aloud by the examiner.

All measurements will be done twice. If the two measures differ by more than the acceptable amount, two additional measures are taken and recorded.

Acceptable limits for differences between measures are:

Weight:	Within 200 grams
Stature:	Within 1.0 cm
Elbow Breadth:	Within 2.0 mm
Arm Circumference:	Within 0.4 cm
Skinfolds:	Within 4.0 mm

If a skinfold is too tight to be measured, (such that it cannot be picked up for measurement), the code for "tight skin" (60.0) should be recorded in the space for that skinfold on the Anthropometry Form (65). If a skinfold is above the measurable limits of the calipers, the code 70.0 should be entered in the recording space for that skinfold on the Anthropometry Form.

7.1.4.1 Weight

To minimize variability in the weight measurement, patients should be requested to wear a disposable paper gown and to remove shoes before the weight is taken. Other steps to consider to reduce variability are: 1) Ask the patient to empty his/her bladder (for Non-GFR Visits) before weight is taken; 2) Schedule monthly appointments, as feasible, at approximately the same time of day; and 3) Encourage the patient to eat relatively the same volume of food at meals which precede an appointment. (For example, the patient should not skip breakfast--unless a fasting blood must be drawn--before one appointment and then eat a large breakfast before the next appointment.)

Ask the patient to stand in the center of the scale and not to touch or support themselves on anything. The patient should stand so that his/her weight is equally distributed on both feet. Two measures will be taken. The patient should step off the scale between measurements and the scale should be reset to zero. Repeated measurements should agree within 200 grams. If they do not, two more measures should be taken and recorded. Check the scale at "0" to be sure they balance each morning. The scale should be left with the weights at zero when not in use.

7.1.4.2 Stature

Ask the patient to stand with his/her back against the stadiometer, with the heels together, and both heels touching the board. The back (scapula) and buttocks should also be in contact with the board (see Figure 7.1.1).

Occasionally it will be impossible to position the patient's heels, buttocks, scapula, and the back of the head in one vertical plane against the board and still have him/her stand naturally and comfortably. His/her back may be arched due to the large size of the buttocks. If this occurs, move the patient forward and have only the buttocks and heels, if possible, in contact with the board.

Be sure that in this position the patient maintains erect posture, that is, no slouching. Heels should be together and the medial borders of the feet at an angle of about 45 degrees, with the weight equally distributed and the head in the "Frankfort Horizontal Plane". This requires the subject to look straight ahead. A line running from the opening of the ear to the corner of the eye should be parallel to the floor. The movable headboard is brought down firmly on top of the head. It may be necessary, upon occasion, to remove or alter the hairdress of some of the patients. This may be necessary for the headboard to maintain a right angle and to make contact with the top of the scalp.

Have the patient inhale deeply, again not altering position by, for example, raising the heels off the floor. Stature is measured just before the patient exhales. The measurement is recorded to the nearest millimeter and agreement between measurements must be within 1.0 cm.

7.1.4.3 Upper Arm Length

Have the patient stand erect with feet together and the right arm flexed 90 degrees at the elbow with the palm facing up. The examiner is positioned behind the patient. The most upper edge of the posterior border of the acromion process of the scapula is located and marked with a cosmetic pencil (see Figure 7.1.2). Hold the insertion tape at this

Figure 7.1.1 Position for Standing Height

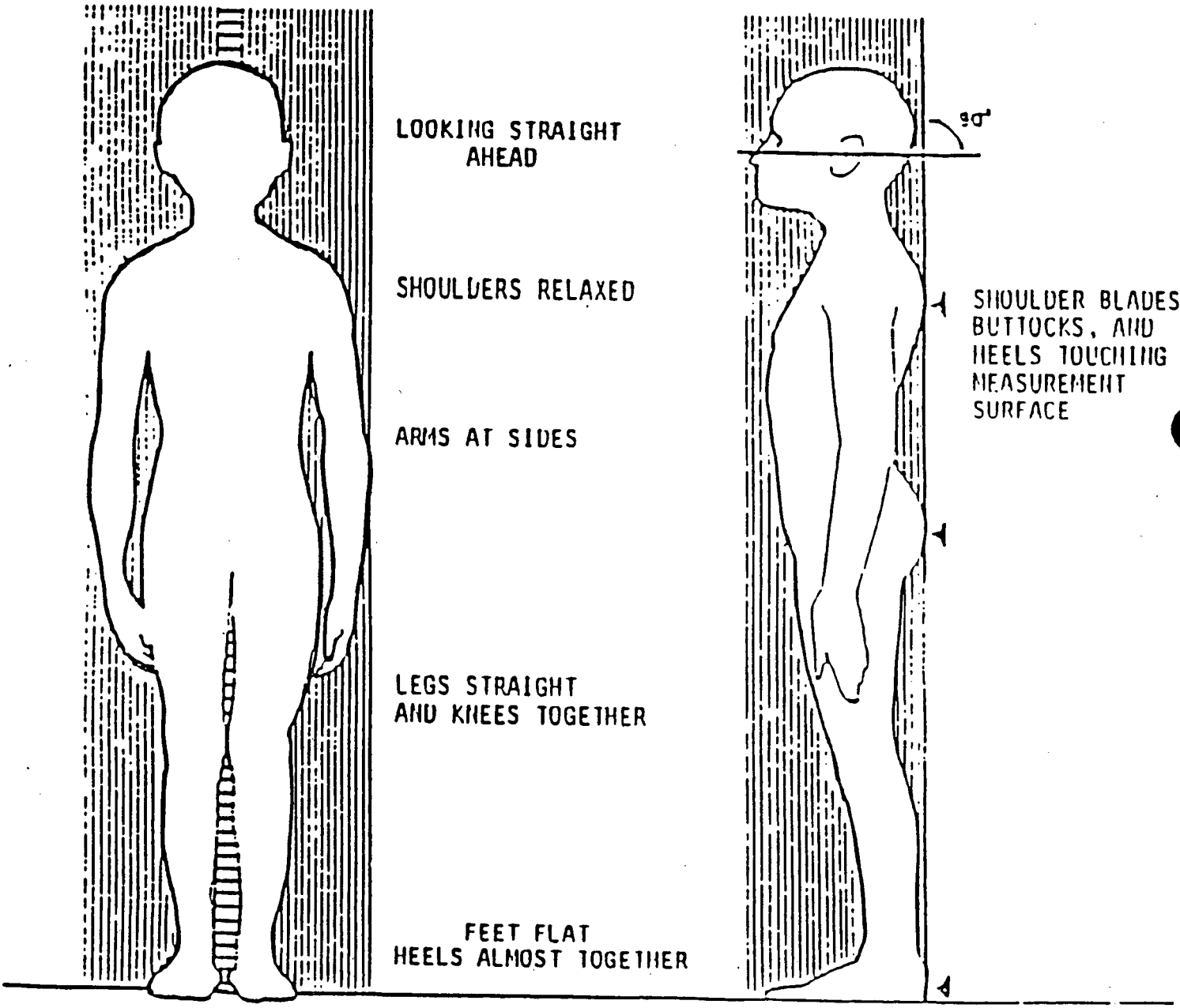
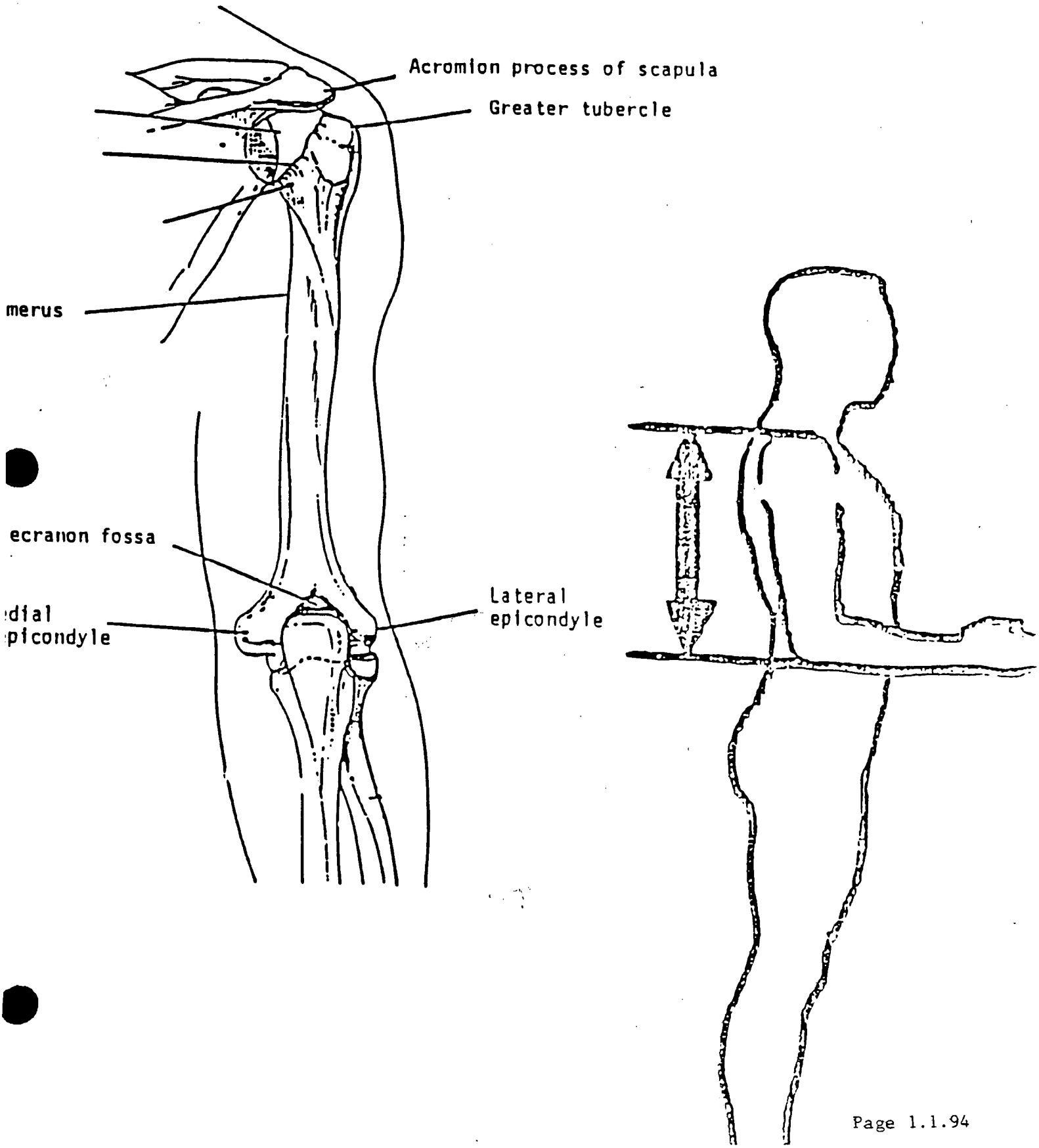


Figure 7.1.2 Position for Arm Length and Location for Upper Arm Midpoint



mark and extend the tape down the posterior surface of the arm to the tip of the olecranon process (the bony part of the mid-elbow). Keep the tape in position and locate half the distance from the acromion to the olecranon processes, i.e., the midpoint of the upper arm, as indicated by the black triangle on the tape. Mark a (+) at the midpoint on the posterior surface of the arm. A corresponding mark (+) is placed at the same level on the anterior surface in the midline of the upper arm.

7.1.4.4 Mid-arm Circumference

The patient is standing with the elbow relaxed so that the right arm hangs freely to the side. The tape is placed around the upper arm directly over the pencil mark at the midpoint on the posterior aspect of the upper arm, with the tape kept perpendicular to the shaft of the upper arm. The tape should be pulled snugly around the arm to ensure contact with the medial side of the arm and elsewhere, but not tight enough to cause "dimpling" of the skin. Record the measurement to the nearest millimeter. Repeated measurements should not differ by more than 0.4 cm.

7.1.4.5 Skinfolds

All skinfolds are measured with the Holtain skinfold calipers. The measurements are taken on the right side of the body. The fold of skin and underlying subcutaneous adipose tissue should be gently grasped between the examiner's left thumb and forefingers. The amount grasped depends upon the thickness of the subcutaneous adipose tissue. The examiner grasps enough skin and adipose tissue to form a distinct fold that separates from the underlying muscle. The sides of the fold should be roughly parallel.

The skinfold is grasped 2.0 cm above where the measurement is to be taken and is held gently with the thumb and forefinger. The jaws of the calipers are placed at the marked level, perpendicular to the length of the fold. The caliper tension is released, the fingers continue to hold the skinfold, and after about three seconds, the skinfold thickness is measured and recorded to the nearest 0.1 mm.

Triceps Skinfold

The patient stands with feet together, shoulders relaxed, and the arms hanging freely at the sides. The examiner stands behind the patient's right side. The point on the posterior surface of the right upper arm is located in the same area as the marked midpoint for the upper arm circumference.

A fold of skin and subcutaneous adipose tissue is grasped gently with thumb and fingers approximately 2.0 cm above the marked level with the skinfold parallel to the long axis of the upper arm (see Figure 7.1.3). The jaws of the calipers are placed at the marked level, perpendicular to the length of the fold, and the skinfold thickness is measured to the nearest 0.1 mm while the fingers continue to gently hold the skinfold. Repeated measurements should not differ by more than 4.0 mm.

Biceps Skinfold

The same procedure is followed as for the triceps skinfold, but the measurement is taken on the front of the upper arm (see Figure 7.1.4). The level is the same as for triceps and arm circumference, and the location is in the midline of the anterior part of the arm. In robust individuals, it may be necessary to rotate the arm slightly or ask the patient to shift it slightly away from the body so that you can measure the skinfold properly.

The examiner grasps a fold of skin and subcutaneous adipose tissue on the anterior surface of the upper arm, in the midline of the upper arm about 2.0 cm above the marked line on the middle of the arm. The skinfold thickness is measured to the nearest 0.1 mm while the fingers continue to hold the skinfold. Repeated measurements should not differ by more than 4.0 mm.

Subscapular Skinfold

The patient stands erect with shoulders and arms relaxed. The examiner opens the back of the examination gown or garment and palpates for the inferior angle of the right scapula. The examiner makes a (+) on the inferior angle of the scapula with the cosmetic pencil marker.

The examiner grasps a fold of skin and subcutaneous adipose tissue directly below (1.0 cm) and medial to the inferior angle. The skinfold forms a line about 45 degrees below the horizontal extending diagonally toward the right elbow (see Figure 7.1.5). The jaws of the caliper are placed perpendicular to the length of the fold about 2.0 cm lateral to the fingers with the top jaw of the caliper on the mark over the inferior angle of the scapula. The skinfold thickness is measured to the nearest 0.1 mm while the fingers continue to hold the skinfold. Repeated measurements should not differ by more than 4.0 mm.

7.1.4.6 Elbow Breadth

The patient stands erect with feet together facing the examiner. The right arm is extended forward until it is perpendicular to the body. The examiner then flexes the right arm of the patient so that the elbow forms a 90 degree angle with the fingers pointing up and the posterior part of the wrist toward the examiner.

Figure 7.1.3 Location of Triceps Skinfold

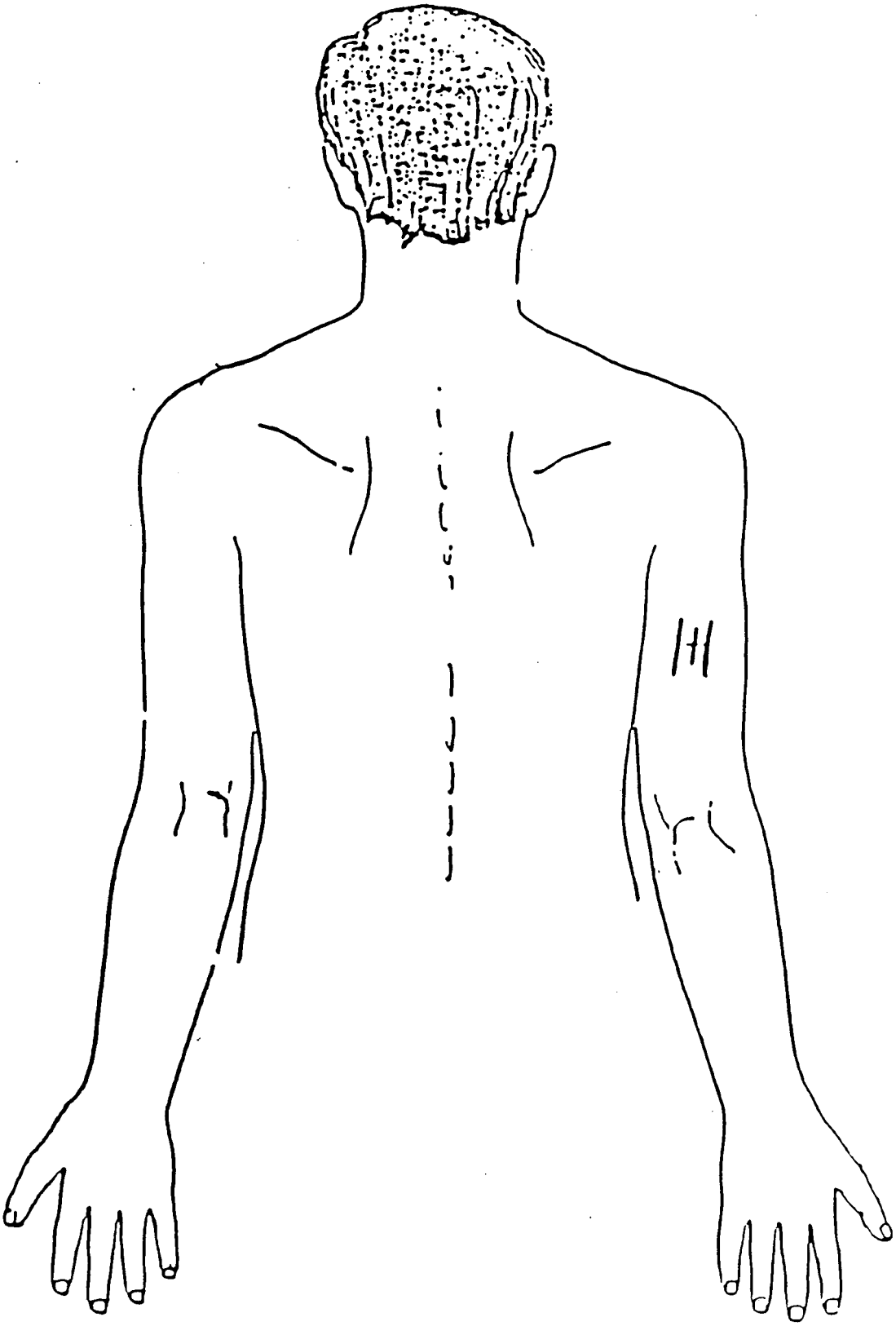


Figure 7.1.4 Location of Biceps Skinfold

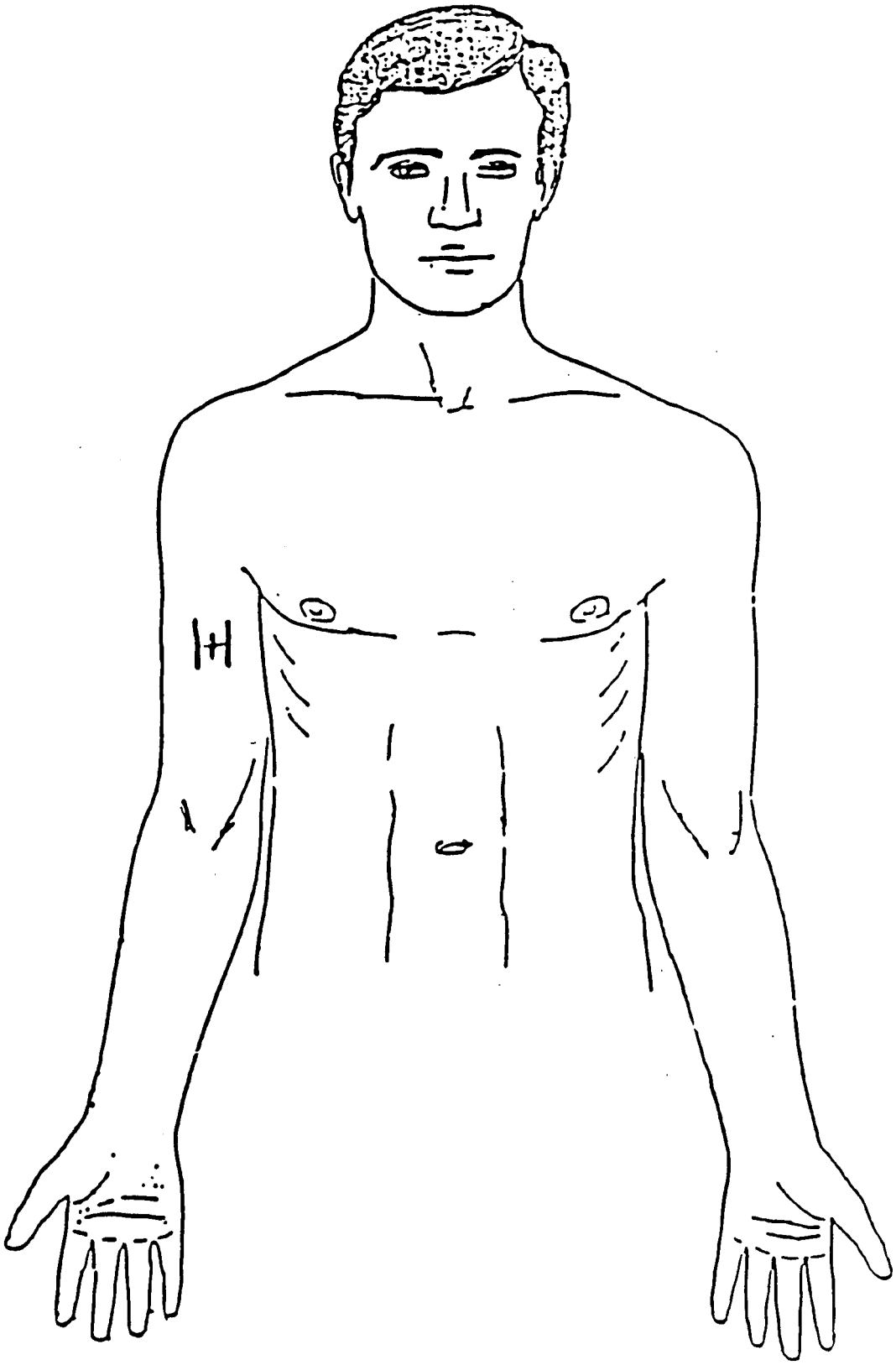
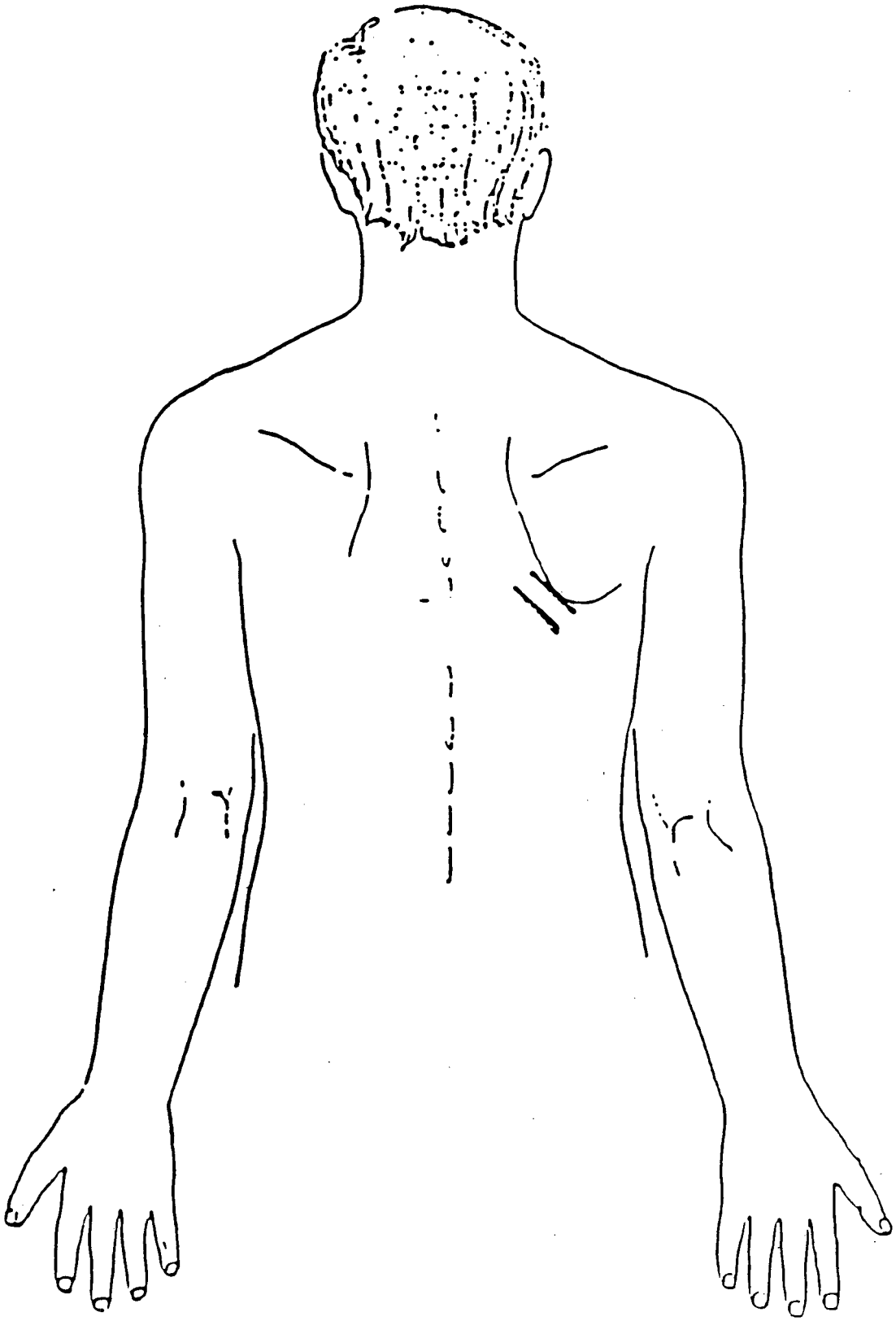


Figure 7.1.5 Location of Subscapular Skinfold



With the Bicondylar Vernier caliper (small sliding caliper) held at a 45 degree angle to the plane of the long axis of the upper arm, the greatest breadth across the epicondyles of the elbow are measured to the nearest 0.1 cm. This measurement may be taken with the calipers at a slight angle because the medial condyle is more distal than the lateral condyle (see Figure 7.1.6). Repeated measurements should not differ by more than 2.0 mm.

7.1.5 Counseling Patients Regarding Anthropometric Measurements

The desire to share and interpret anthropometric measures taken on patients is understandable. Most dietitians agree that if a patient has more knowledge and understanding, then compliance and rapport are enhanced.

However, sharing information also potentially biases a patient's behavior. For example, if a patient were told his/her percent body fat had increased, the patient might decide to pursue weight loss. This decision may contradict study goals. Hypocaloric diets combined with only low or moderate protein intakes place a patient at increased risk for protein depletion.

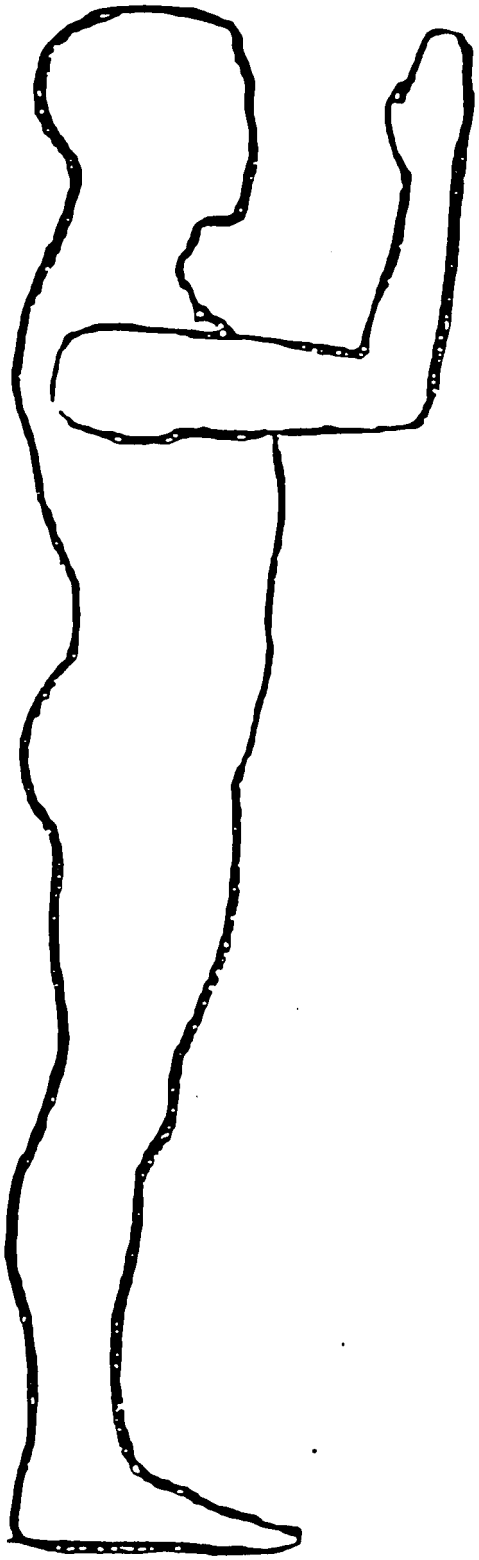
It is recommended that minimal information, therefore, be discussed. Reporting frame size, height, and weight measurements is reasonable. Further interpretation of data, such as skinfold measurements, percent body fat, and arm muscle area are discouraged. Provide a general explanation of why the measures are being collected, for example, as another way of monitoring nutritional status. You might also point out that these measures may not be sensitive enough to detect changes in individuals and that the data is primarily used to evaluate changes in groups. Suggest to the patient that if changes in the measures require alteration of their diet, you'll be sure to discuss this with them.

7.2 Use and Interpretation of Weight and Measures

7.2.1 Determination of Standard Body Weight

Weight for height tables compiled by A. Roberto Frisancho, Ph.D. (Ann Arbor, MI: Health Products, 1988) from NHANES I and II data are used as the standard to assign a Standard Body Weight (SBW) to each patient. The 50th percentile of the weight range for a given height and frame size is defined as the standard weight. The standard weight is used to determine eligibility using the following formula: Current Weight (kg)/SBW (kg) x 100. The percent of current weight relative to the standard must be within 80% - 160% for a candidate to be eligible for the study. The SBW is also used to define the total daily dietary protein prescription. For study purposes, SBW is defined following the BO visit whereupon the values obtained at the Screening and BO visits are averaged; this SBW remains constant throughout the study.

Figure 7.1.6 Position for Elbow Breadth



Elbow breadth is used to determine frame size from Table 7.2.1. Table 7.2.3 (males) or 7.2.4 (females) may then be entered at the appropriate height, frame size, and sex; the weight given is the standard weight. For example, a woman whose height is 159 cm and whose elbow breadth is 6.0 cm would have a medium frame and a standard body weight of 59.9 kg.

7.2.2 Weight as a Nutritional Action Item

An action item indicates the need for specific intervention. An undesired loss of more than 2.5 kg or 5% of SBW, whichever is less, at any time in a patient without edema, or loss of weight to less than 75% SBW requires an increase in energy intake. Successful resolution of the action item is defined by an increase in weight to goal or greater than 75% SBW (whichever is higher) (Protocol, Section 13.3).

An undesired increase in weight greater than 5% of the Baseline Visit 3 body weight in a patient without edema requires a reduction in energy intake until the weight has been reduced by 5% of the Baseline Visit 3 weight (Protocol, Section 13.3).

7.2.3 Weight as a Stop Point

Weight loss to a weight that is persistently below 75% of SBW for three months after dietary intervention is a Stop Point (Protocol, Section 13.4).

7.2.4 Arm Muscle Area[1]

Arm muscle area is a practical anthropometric marker for measuring and monitoring the body's active tissue mass.

Arm muscle area (AMA) is calculated from triceps skinfold thickness (TSF,mm) and midarm circumference (MAC, mm) from the following formula:

$$AMA = \frac{(MAC - \pi \times TSF)^2}{4}$$

A corrected AMA_C ("available" arm muscle area) is then calculated separately for men and women as follows:

$$\text{Men } AMA_C = AMA - 1900$$

$$\text{Women } AMA_C = AMA - 1550$$

[1]Heymsfield, S.B. et al. Am J Clin Nutr 36:680-690, 1982.

7.2.5 Percent Body Fat[2]

Percent body fat is determined from 1) a regression equation for the prediction of body density from the triceps, biceps, and subscapular skinfolds; and 2) an equation using the known relationship between body density and the proportion of fat in the body.

1. Body density (Y) is calculated as follows:

1. Body density (Y) is calculated as follows:

   $Y = C - M$ (log of the sum of the skinfolds)

   The coefficients C and M are obtained from Table 7.2.5 for the appropriate age and sex group.

2. Percent body fat is calculated as follows:

   $$\% \text{ Fat} = \left(\frac{4.95}{Y} - 4.5\right) \times 100$$

3. Example:

   A 45 year old female has a sum of the three skinfolds of 50 mm.

   $$Y = 1.1303 - 0.0635 \text{ (log 50)}$$
   $$= 1.0224$$

   $$\% \text{ Fat} = \left(\frac{4.95}{1.0224} - 4.5\right) \times 100 = 34.1$$

[2] Durnin, JVGA and Womersley, 32:77, 1974.

Table 7.2.1 Frame Index Based on Measurements of Elbow Breadth (cm)

Males			Females		
Small	Medium	Large	Small	Medium	Large
<6.7	6.7-7.5	>7.5	<5.8	5.8-6.6	>6.6

*from Frisancho, A. Roberto Instructions for using the frameter, weight, fat guide and anthropometric standards. Ann Arbor, MI: Health Products, 1988.

Table 7.2.2

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Table 7.2.3 Weight for Height Tables by Frame Size*
(from Frame Size Table 7.2.1)

MALES

(Weight in kilograms)

Height without shoes (cm)	Small Frame	Medium Frame	Large Frame
153	56.2	60.0	65.6
154	56.2	60.0	65.6
155	56.2	60.0	65.6
156	57.2	63.7	68.4
157	57.2	63.7	68.4
158	57.2	63.7	68.4
159	60.7	65.7	69.9
160	60.7	65.7	69.9
161	60.7	65.7	69.9
162	62.1	67.1	71.4
163	62.1	67.1	71.4
164	62.1	67.1	71.4
165	65.2	69.5	72.6
166	65.2	69.5	72.6
167	65.2	69.5	72.6
168	66.1	70.9	76.1
169	66.1	70.9	76.1
170	66.1	70.9	76.1
171	68.6	73.7	78.0
172	68.6	73.7	78.0
173	68.6	73.7	78.0
174	70.4	76.0	79.8
175	70.4	76.0	79.8
176	70.4	76.0	79.8
177	72.6	76.9	82.2
178	72.6	76.9	82.2
179	72.6	76.9	82.2
180	75.0	79.0	86.6
181	75.0	79.0	86.6
182	75.0	79.0	86.6
183	75.5	81.6	87.4
184	75.5	81.6	87.4
185	75.5	81.6	87.4
186	80.3	84.5	88.7
187	80.3	84.5	88.7
188	80.3	84.5	88.7
189	81.5	87.0	92.3
190	81.5	87.0	92.3
191	81.5	87.0	92.3
192	82.4	90.2	93.9
193	82.4	90.2	93.9
**194	82.5	90.3	95.0
195	82.6	90.4	95.5
196	82.7	90.5	96.0

Table 7.2.3 cont'd Weight for Height Tables by Frame Size*
(from Frame Size Table 7.2.1)

MALES

(Weight in kilograms)

Height without shoes (cm)	Small Frame	Medium Frame	Large Frame
197	83.3	90.6	97.0
198	83.8	90.7	97.6
199	84.4	90.9	98.1
200	84.9	91.4	98.6
201	85.4	92.0	99.1
202	86.0	92.6	99.6
203	86.5	93.1	100.2
204	87.1	93.7	100.7
205	87.6	94.3	100.8

*from Frisancho, A. Roberto Instructions for using the frameter, weight, fat guide and anthropometric standards. Ann Arbor, MI: Health Products, 1988.

** All values of 194 cm and over have been estimated from regression equations of weight on height for each frame size category (Frisancho, Personal Communication, 1989).

Dr. William Cameron Chumlea smoothed these values to remove uneven increments (Personal Communication, 1989).

Table 7.2.4 Weight for Height by Frame Size*
(from Frame Size Table 7.2.1)

FEMALES

(Weight in Kilograms)

Height without shoes (cm)	Small Frame	Medium Frame	Large Frame
141	48.0	53.1	59.0
142	48.0	53.1	59.0
143	48.0	53.1	59.0
144	49.0	54.0	60.5
145	49.0	54.0	60.5
146	49.0	54.0	60.5
147	50.3	55.4	62.9
148	50.3	55.4	62.9
149	50.3	55.4	62.9
150	51.5	56.1	65.0
151	51.5	56.1	65.0
152	51.5	56.1	65.0
153	52.7	57.3	66.6
154	52.7	57.3	66.6
155	52.7	57.3	66.6
156	53.9	58.1	67.3
157	53.9	58.1	67.3
158	53.9	58.1	67.3
159	54.5	59.9	67.9
160	54.5	59.9	67.9
161	54.5	59.9	67.9
162	56.8	61.0	68.0
163	56.8	61.0	68.0
164	56.8	61.0	68.0
165	57.7	61.8	71.1
166	57.7	61.8	71.1
167	57.7	61.8	71.1
168	59.1	63.6	72.0
169	59.1	63.6	72.0
170	59.1	63.6	72.0
171	61.1	65.0	76.8
172	61.1	65.0	76.8
173	61.1	65.0	76.8
174	63.8	66.7	77.9
175	63.8	66.7	77.9
176	63.8	66.7	77.9
177	65.0	68.5	80.1
178	65.0	68.5	80.1
179	65.0	68.5	80.1
180	66.7	71.4	82.4
181	66.7	71.4	82.4
**182	66.7	71.4	82.4
183	66.7	71.5	82.5
184	66.8	71.5	82.5
185	66.8	71.5	82.5
186	66.8	71.6	82.6

Table 7.2.4 cont'd Weight for Height by Frame Size*
(from Frame Size Table 7.2.1)

FEMALES

(Weight in Kilograms)

Height without shoes (cm)	Small Frame	Medium Frame	Large Frame
187	66.8	71.6	82.6
188	67.1	71.6	82.6
189	67.5	71.7	82.7

*from Frisancho, A. Roberto Instructions for using the frameter, weight, fat guide and anthropometric standards. Ann Arbor, MI: Health Products, 1988.

** All values 182 cm and over have been estimated from regression equations of weight on height for each frame size category (Frisancho, Personal Communication, 1989).

Dr. William Cameron Chumlea smoothed these values to remove uneven increments (Personal Communication, 1989).

Table 7.2.5

Linear Regression Coefficients for the Estimation of Body Density x 10^3 (kg/m^3) from the Logarithm of the Skinfold Thickness (Biceps, Triceps, and Subscapular)[1]

	Males		Females	
Age (years)	C	M	C	M
Age Categories				
17 - 19	1.1643	0.0727	1.1509	0.0715
20 - 29	1.1593	0.0694	1.1605	0.0777
30 - 39	1.1213	0.0487	1.1385	0.0654
40 - 49	1.1530	0.0730	1.1303	0.0635
50+	1.1569	0.0780	1.1372	0.0710
Overall				
17 -72	1.1689	0.0793	1.1543	0.0756

[1] Durnin, JVGA and Womersley, J. Br J Nutr 32:77, 1974.

7.3 Quality Control

Quality control procedures consist of:

A. Phase I - This period lasts from December 1988 through March 1989. During this time, dietitians who attended the first Nutrition Coordinating Center training program in November 1988 will measure two volunteers per week following completion of training. Each volunteer will be measured sequentially by two dietitians; measurements will be taken twice by each examiner. Measurements taken and recorded are: weight, stature, skinfolds (biceps, triceps, subscapular), and arm circumference.

   Data collected will be sent to the NCC monthly. In turn, this data will be forwarded to the consulting physical anthropologist for review and analysis of inter-and intra-observer reliability.

B. Phase II - The start of this period coincides with the first Follow-Up Visit (approximately mid-April, 1989). During this phase, two dietitians will measure the same patient.

   One dietitian (examiner #1) will take all anthropometric measures twice including weight, height, elbow breadth, arm circumference, and skinfolds. Measures will be repeated, if values fall outside acceptable limits. Data will be recorded on the Anthropometry Form (Form 65).

   Another dietitian, (examiner #2) will take the measurements on the same patient, recording values on a second Form 65. For quality control purposes, examiner #2 will use a quality control identification number and name code instead of the patient identification number and name code.

   The Central Lab QC ID Matching Form (Form 22) will be completed, also. The purpose of this form is similar to the NCC Phantom Matching Form in that it identifies in the DCC Database, the true patient identification number for the measures taken by examiner #2, allowing measures on the same patient to be tracked and evaluated.

   This procedure will be completed once a month.

C. In addition to annual recertification at the NCC Training Program, site visits will be made yearly by the NCC anthropometry trainer and/or the consultant. Quality control measures at site visits will consist of: 1) observation of the clinical center dietitian's technique by the trainer/consultant and 2) duplicate measures taken by the trainer/consultant on patients measured by the clinical center dietitian.

7.4 Calibration Log

Instructions for Use

Instruments used for taking anthropometric measurements must be calibrated on a regular basis. The required schedule follows:

Holtain Skinfold Calipers	Once a week
Stadiometer	Beginning of each month
Bicondylar Vernier Calipers	Every three months
Clinical Scales	Every three months

Refer to the Manual of Operations, Chapter 1, Anthropometry (or Section 3.1.2 of the Training Manual for MDRD Dietitians) for specific guidelines regarding the calibration procedures.

Examples are given at the top of each form, also.

Record the date and measurement as illustrated below:

DATE / MEASUREMENT		
	10-21-88	10-21-88
	145 mm	185 mm

The log should be maintained as scheduled; it will be reviewed at site visits.

CALIBRATION LOG

INSTRUMENT: Bicondylar Vernier Calipers

CALIBRATION METHOD: Step wedge at each of five steps (10 - 50)

FREQUENCY: Every three months

DATE / MEASUREMENT	Step 1	Step 2	Step 3	Step 4	Step 5

DATE / MEASUREMENT	Step 1	Step 2	Step 3	Step 4	Step 5

CALIBRATION LOG

INSTRUMENT: Holtain Skinfold Calipers

CALIBRATION METHOD: Step wedge at each of four steps (10 - 40)

FREQUENCY: Once a week

EXAMPLE:

Step 1	Step 2...
10-21-88	
10 mm	20mm

Calibrations are taken at four steps (10,20,30,40 mm). Record the date in the top of the "Step 1" box (it need not be recorded again for that measurement period).

SET #1

DATE / MEASUREMENT	Step 1	Step 2	Step 3	Step 4

SET #2

DATE / MEASUREMENT	Step 1	Step 2	Step 3	Step 4

CALIBRATION LOG

INSTRUMENT: Clinical Scales

CALIBRATION METHOD: Zero scale; place 10-kg weight in center, then second weight on top to calibrate at 20 kg. NOTE: Weights must be calibrated at local county Department of Weights and Measures. Actual weight, therefore, may not be 10 or 20 kg (for example, the set of weights at the NCC actually weigh 10.9 kg each). Record the actual weight and use that as the standard to check the calibration of the scale.

FREQUENCY: Every three months

EXAMPLE:

10.9 kg	21.8 kg
10-20-88	10-20-88
10.8	21.8

Record the actual weight of one standard weight in the blank above first column. Record the weight of both standard weights above the second. Record the date in the top portion the box, the measurement in the bottom.

Std. Weight: ____ kg ____ kg

DATE / MEASUREMENT	

____ kg ____ kg

CALIBRATION LOG

INSTRUMENT: Stadiometer

CALIBRATION METHOD: Calibration rods (145 and 185 cm)

FREQUENCY: Beginning of every month

EXAMPLE:

147 cm	185 cm
11-1-88	11-1-88
147	185

Enter the date in the top portion of the box. Record results in the bottom portion. Enter the actual length at the top of each column.

Std. Height: ___ cm ___ cm ___ cm ___ cm

DATE
MEASUREMENT

7.5 Ordering Anthropometric Equipment

The Nutrition Coordinating Center has purchased two sets of all anthropometry equipment for each clinical center. If additional equipment is needed, the clinical centers will order directly from the manufacturers.

Listed below are the names, addresses, and costs for ordering the anthropometry equipment:

SECA COMPANY
8920B, Rte. 108
Oakland Center
Columbia, MD 21045
(301) 964-3858

- Clinical Scale, Model #710, $210.00
- Height Board, Model #220600, $30.00

SERITEX COMPANY
450 Barell Avenue
Carlstadt, NJ 07072
(201) 939-4606
Fax: 939-3468

- Holtain Skinfold Calipers, Model #610, $270.00
- Bicondylar Vernier Calipers, Model #604, $225.00
- Steel Tapes, Model #110, $15.00
- Calibration Block, Model #121, $15.00

Section 8

Intervention

8.1 Introduction

This section is divided into three areas which are defined below:

Dietitians Schedules and Form Listings - Schedule 8.2.1 provides an overview of study-wide activities; Schedule 8.2.2 is a more specific list of materials and activities used by the dietitian at each visit. The Nutrition Forms List (8.2.3) summarizes by number the nutrition forms used in MDRD.

The Baseline Period - Includes an overview and background which provide information on the purpose of the visit. A detailed "Sequence of Activities" outlines, by time and activity, what will occur during the visit and approximately how long the visit will last. Complete lesson plans for this period may be found in the Training Manual for MDRD Dietitians.

The Follow-Up Period - Includes information about post-randomization procedures and follow-up visits. Detailed lesson plans for this area will be incorporated in the Intervention Manual for MDRD Dietitians.

8.2.1 MDRD Schedule of Patient Visits

CLINIC PROCEDURES;	BASELINE VISITS					
	Screening Visit	Visit 0	Visit 0A	Visit 1	Visit 2	Visit 3
Physical Exam.....		X		X	X	X
GFR Measurement.....	Creatinine Albumin only	X				X
Fasting Blood Test.....		X				X
24-hour urine returned..		X		X	X	X
Pill count #73 Distribute supplements						
EKG.....					X	
QUESTIONNAIRES: **						
Quality Well-Being #27.						X
Symptoms Check list #28.						X
Physical Activity #48...				X		
Dietary Satisfaction #74		X				X
DIETITIAN ACTIVITIES						
Anthropometry #65.....	Only wt, ht and elbow breadth	Only wt, ht, and elbow breadth	X	weight only	X	weight only
24-hour recall #62.....		X				X
Dist.3-day food rec #64.		X			X	
Review 3-day food record			X			X
Assign Baseline Diet RX.				X		
Assign Study Diet RX....						
Miscellaneous Forms.....	Nutrition History #78, & 78-P	Guide to weigh & measure		Base-line RX-#70		
Compliance Summary #76..						
Assign Self-Monitoring..			X	X	X	
Collect Self-Monitoring.				X	X	X
Dietitian's Time Log....		X	X	X	X	X

*Blood test Not Fasting ** Clinic forms are not included on this chart

RANDOMIZATION	FOLLOW-UP VISITS 1	1A	2	2A	3	4	5	6	7	8	9	10	11	12
	X		X		X	X	X	X	X	X	X	X	X	X
			X			X				X				X
			X			X		X *		X		X *		X
	X		X		X	X	X	X	X	X	X	X	X	X
	Distrib suplmts		X		X	X	X	X	X	X	X	X	X	X
							X						X	
								X						X
						X				X				X
												X		
						X				X				X
	weigh only	weigh only	weigh only	wt. only	wt. only	wt.	wt. only	X	wt.	wt.	wt.	X	wt.	weigh only
			X			X				X				X
		X		X	X	X	X	X	X	X	X	X	X	X
			X		X	X	X	X	X	X	X	X	X	X
	X													
	Study Diet RX #71													
	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		X	X	X	X	X	X	X	X	X	X	X	X	X
	X	X	X	X	X	X	X	X	X	X	X	X	X	X

8.2.2 MDRD Dietitian's Activity Schedule

DIETITIAN ACTIVITIES	BASELINE VISITS					
	Screening Visit	Visit 0	Visit 0A	Visit 1	Visit 2	Visit 3
Anthropometry #65.....	Only wt, ht and elbow breadth	Only ht and elbow breadth	X	weight only	X	weight only
24-hour recall #62.....		X				X
Dist.3-day food rec #64.		X			X	
Review 3-day food record			X			X
Assign Baseline Diet Rx.				X		
Assign Study Diet Rx....						
Miscellaneous Forms.....	Nutrition History #78, &78-P	Guide to weigh & measure		Base-line RX-#70		
Counseling Summary #76..						
Assign Self-Monitoring..			X	X	X	
Collect Self-Monitoring.				X	X	X
Dietitian's Time Log....		X	X	X	X	X
Anthropometry Monitoring	Once a month					

	FOLLOW-UP VISITS													
	1	1A	2	2A	3	4	5	6	7	8	9	10	11	12
RANDOMIZATION	weigh only	weigh only	weigh only	wt. only	wt. only	wt.	wt. only	X	wt.	wt.	wt.	X	wt.	weigh only
			X			X				X				X
		X		X	X	X	X	X	X	X	X	X	X	X
			X		X	X	X	X	X	X	X	X	X	X
	X													
	Study Diet RX #71													
	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		X	X	X	X	X	X	X	X	X	X	X	X	X
	X	X		X	X	X	X	X	X	X	X	X	X	X
	Once a Month													

8.2.3 MDRD Nutrition Forms List

NUMBER	NAME
60	Food Record/24-Hour Recall Packing Slip
61	Nutrition Cover Sheet
62	Food Record Form
63	MDRD Recipe Form
64	Three-Day Food Record
65	Anthropometric Form
66	NCC Phantom Matching Form
67	
68	
69	
70	Baseline Diet Prescription Form
71	Study Diet Prescription Form
72	Special Dietary Considerations Form
73	Pill Count Form
74	Dietary Satisfaction Questionnaire
75	
76	Counseling Summary Form
77	Patient Care Time Log
78/78P	Nutrition History Questionnaire
79	Special Products Order Form
80	

8.3 The Baseline Period

8.3.1 Screening Visit Summary

OVERVIEW: The Screening Visit is an extremely important visit since it is our first opportunity to meet with a potential study patient. These first impressions may be lasting and may influence a patient's motivation to join the study and his/her future behavior to comply with dietary goals.

The patient will meet with the MDRD Study Team for the first time and have the study explained to him/her by various staff members. A positive, confident and enthusiastic attitude by the study team is important. The patient should feel that no matter which diet group he/she may be assigned, he/she will benefit from the excellent nutritional and medical care provided by the MDRD Study.

The dietitian will spend additional time with the patient discussing the details of the study diets and changes that he/she may need to make to follow the diet. Some patients may feel more comfortable asking the dietitian questions. Other questions may be more appropriately answered by other team members. The dietitian should encourage patients to ask as many questions as necessary so that they fully understand their commitment.

BACKGROUND: Before the visit, if available, review the patient's previous serum creatinine and albumin levels. Estimate to which GFR Study Group (A or B) the patient may be assigned. Review the patient's medical chart or hospital record and note pertinent information: renal diagnosis, other medical conditions such as diabetes, hypertension, or hyperlipidemia, and/or history of weight or dietary changes.

SEQUENCE OF ACTIVITIES: The length of the visit may vary depending on the length of time the patient has spent with other staff members, the patient's degree of understanding and/or the number of questions the patient has related to the MDRD Study. This visit will last approximately 50 minutes.

5 minutes — Greet patient and explain the purpose and content of this visit.

10 minutes — Take weight, height, and elbow breadth measurements and record on screening form.

10 minutes — Explain in detail the dietary aspects of the Study, the rationale for a low protein, low phosphorus diet, and the general design of the Study. Refer to the MDRD Information Handbook.

10 minutes	Explore the patient's reasons for participating in the study and begin to assess motivation and ability to comply with dietary goals and data collection procedures.
5 minutes	Give the patient the Nutrition History Questionnaire. Review how to complete the form. Instruct the patient to mail the form back to the clinic.
10 minutes	Give the patient an opportunity to ask questions.

8.3.2 Baseline Visit 0 Summary

OVERVIEW: This is the patient's second visit and the first in a series of five baseline visits. This is the longest of all visits and is often the patient's first exposure to the GFR. This visit can be scheduled in two parts. The patient will interface with almost all study personnel. The dietitian will conduct a 24-hour recall and prepare the patient to collect his/her own dietary data at home. A brief overview of the study should occur at this visit as well as a summary of what will happen at this visit. Nutrition-related questions asked by the patient should be answered.

BACKGROUND: At the previous Screening Visit the patient was found to be initially eligible for the study and the MDRD Information Handbook was reviewed.

SEQUENCE OF ACTIVITIES: This visit will take approximately 81 minutes.

1 minute	Welcome patient.
5 minutes	Measurement of height, weight, and frame size.
5 minutes	Review Nutrition History.
5 minutes	Discuss dietary data collection procedures.
10 minutes	Explanation of 24-hour recall.
20 minutes	Conduct 24-hour recall interview.
10 minutes	Explanation of Three-Day Food Record.
10 minutes	Demonstrate use of Soehnle scale.
5 minutes	Summarize what has taken place.
5 minutes	Review what will take place at next visit.
5 minutes	Confirm when to complete three-day food record and time and date of next appointment.

8.3.3 Baseline Visit 0A Summary

OVERVIEW: This visit will focus upon review of the patient's Three-Day Food Record in order to assess his/her usual dietary intake and motivation for the study. Principles of self-monitoring will be introduced. Anthropometric data will also be collected.

BACKGROUND: The previous visit focused on various study-wide data collection activities. This session will provide an opportunity for the patient and dietitian to develop a counseling relationship without interruption by other study-related procedures.

SEQUENCE OF ACTIVITIES: This session will last approximately 90 minutes.

5 minutes	Welcome patient, thank him/her for coming and for completing the Three-Day Food Record and forms.
15 minutes	Review and document the Three-Day Food record line by line.
5 minutes	Discuss purpose of anthropometrics.
15 minutes	Perform skinfold measurements
10 minutes	Introduce principles of self-monitoring; review use of Keeping Track.
10 minutes	Ask patient to use Protein Counter to look up the protein content of several foods which he/she has eaten.
15 minutes	Demonstrate the Computerized Diet Design Tool (CDDT).
5 minutes	Review what has taken place today.
5 minutes	Review assignment for next visit and confirm date and time for next appointment.

8.3.4 Baseline Visit 1 Summary

OVERVIEW: The patient will be introduced to his Baseline Diet Prescription and to the principals of goal setting.

BACKGROUND: The previous visit focused on reviewing the patient's completed food record and on introducing the patient to the Protein Counter and principals of self-monitoring.

SEQUENCE OF ACTIVITIES: This session will be approximately 95 minutes.

5 minutes	Welcome patient
5 minutes	Review Self Monitoring
15 minutes	Discuss major protein food sources
30 minutes	Introduce Baseline Diet Prescription
15 minutes	Discuss goal setting
15 minutes	Establish protein goal for next visit
5 minutes	Assign self monitoring activity for next visit
5 minutes	Review what will happen at next visit

8.3.4.1 The Baseline Diet

The Baseline Diet is initiated at Baseline Visit 1 and continues through the baseline period to give the patient an opportunity to experience making dietary modifications and keeping dietary records. During this time the dietitian will evaluate the patient's ability to make these changes and to complete the necessary forms and records. Commitment to Study goals will also be assessed. Adherence to the Baseline Diet is evaluated by the Estimated Protein Intake/Urine Nitrogen Appearance (EPI/UNA) from the 24-hour urine collection at Baseline Visits 2 and 3, the 24-Hour Recall, and the Three-Day Food Record at Baseline Visit 3.

The Baseline Diet protein and calorie prescriptions are calculated by the DCC, and the report is sent to the clinical center via electronic mail. In the event the DCC is unable to report the diet prescription to the clinical center before the Baseline Visit 1, the dietitian can use the Baseline Diet Prescription Form (Form 70) to calculate protein and calories. The protein content of the Baseline Diet is considered a moderate intake, and is typically similar to an individual's usual protein intake.

The Baseline Diet Protein Prescription is based on the Usual Protein Intake which is an average of: 1) the EPI(UNA) obtained at Baseline Visit 0; and 2) the average dietary protein intake recorded on the Three-Day Food Record collected at Baseline Visit 0A. The prescription is then determined using the Usual Protein Intake in grams per kilogram and the GFR value from Baseline Visit 0.

The chart below (Protocol, Section 9.10) defines the Baseline Diet Prescription:

Baseline Diet Prescription

GFR (ml/min/1.73m^2)	Usual Protein Intake (g/kg/day)	Protein Prescription (g/kg/day)
≥25	≥0.90	0.90 - 1.30
	<0.90*	0.90 - 1.30
≤24	0.90 - 1.30	0.90 - 1.30
	≥0.60 - <0.90	0.60 - 0.90
	<0.60	0.60

For example, a patient with a GFR of 28 and a Usual Protein Intake of 1.1 gm/kg, would have a Baseline Diet Protein Prescription of 0.90 to 1.30 gm/kg/day.

or

A patient with a GFR of 18 ml/min and a Usual Protein Intake of 0.83 gm/kg/day, would have a Baseline Diet Protein Prescription of 0.60 to 0.90 gm/kg/day.

*NOTE: If a patient with a GFR ≥25 has a Usual Protein Intake less than 0.90 gm/kg/day, check to determine if protein intake has recently been restricted or if this is a temporary change in eating habits. Determine if the patient and the physician are willing to accept a Baseline Dietary Protein Prescription of 0.90 to 1.30 gm/kg/day. If the patient is not willing to increase his/her protein intake to 0.90 to 1.30 gm/kg/day, he/she should be excluded from further participation since it is unlikely the patient will be a candidate for randomization (Protocol, Section 9.10).

The recommended calorie range during the Baseline period is 30 to 45 kcals/kg standard body weight per day. However, if a patient has been following a calorie-modified diet (i.e. <30 kcals/kg) before entering Baseline, he/she may continue to follow their current eating plan. Patients desiring to initiate weight reduction at the start of or during the Baseline period should be advised to wait until the Follow-Up period unless extreme circumstances arise. Significant or rapid weight gain or loss (greater than 2 kg) is not recommended during the Baseline Period. Upper calorie ranges may be necessary for patients who are physically very active.

No other dietary modifications should be made during the Baseline period. If patients desire and/or if medically necessary, adjustments to their diets may be made after randomization.

8.3.5 Baseline Visit 2 Summary

OVERVIEW:	The patient will summarize his/her experiences following the Baseline Diet.
BACKGROUND:	At the previous session the patient was introduced to the Baseline Diet.
SEQUENCE OF ACTIVITIES:	This visit will take approximately 60 minutes.
05 minutes	Welcome patient.
10 minutes	Perform skinfold and arm measurements, weigh patient.
10 Minutes	Review self-monitoring.
05 minutes	Discuss goal attainment.
05 minutes	Review goal for next visit.
10 minutes	Utilize CDDT to confirm protein intake from self-monitoring and to generate new meal plans.
05 minutes	Assign the three-day food record.
05 minutes	Assign self-monitoring days.
05 minutes	Review what will happen at next visit.

8.3.6 Baseline Visit 3 Summary

OVERVIEW: The dietitian will collect dietary data for study purposes.

BACKGROUND: This is the final visit before randomization and all study-related concerns should be fully discussed.

SEQUENCE OF ACTIVITIES: This visit will take approximately 70 minutes.

05 minutes	Welcome patient.
15 minutes	Conduct 24-hour recall interview.
15 minutes	Review three-day food record.
10 minutes	Review self-monitoring.
05 minutes	Discuss protein goal attainment.
05 minutes	Discuss patient's likelihood of following prescribed diet after randomization.
05 minutes	Review differences in the study diets.
05 minutes	Review commitment to study.
05 minutes	Discuss randomization.
05 minutes	Discuss what will take place at the next visit.

8.3.7 Randomization Summary

OVERVIEW: Once all Baseline Period tests and procedures have been completed and the forms corresponding to these tests and procedures have been received by the Data Coordinating Center, the patient has signed a consent form and it has been determined that the patient meets all eligibility requirements including an acceptable level of compliance with study procedures, the clinical center will initiate Randomization Procedures (Review Protocol pages 10.1 through 11.9 for specific Randomization Procedures and details concerning dietary regimens.

The dietitian will review all of the relevant patient information collected during baseline, obtain the Study Diet Prescription Report, and complete the Study Diet Prescription (Form 71).

BACKGROUND: During the Baseline Period the patient has had the experience of following a moderate protein diet and the opportunity to self-monitor protein intake. The patient has kept food records and completed various forms and questionnaires. He/she should be well informed about study design, study diets, and study procedures. His/her ability and willingness to comply with study diets and procedures should have been evaluated.

SEQUENCE OF ACTIVITIES: These procedures may take approximately 60 minutes:

10 minutes: Obtain DCC and NCC reports: Study Diet Prescription Report, Patient Flow Sheet (Biochemistries), Compliance Flow Sheet, Nutrient Summary Report, and copies of the three-day food records received at Baseline Visit 0A and 3.

10 minutes: Review patient's medical records, biochemical and nutrient intake reports and questionnaires related to eating habits; (Forms 74 and 78).

10 minutes: Complete Study Diet Prescription (Form 71).

30 minutes: Prepare seven-day menu using CDDT.

8.3.7.1 The Study Diet

Randomization to one of the three study diets is initially determined based on the outcome of the GFR procedure. The patient will be assigned to Study Group A if his/her GFR is 25 to 55 ml/min/1.73m^2 or to Study Group B if his/her GFR is 13 to 24 ml/min/1.73m^2 (see charts below and on next page).

Patients in Study Group A will be assigned to: 1) a moderate protein intake (Diet M) which is close to the average protein intake in the United States (HANES, 1979)[1] a low protein intake (Diet L) which is near the level considered to be the minimum protein requirement (FAO, 1985)[2].

Study Group B patients will be assigned to either: 1) Diet L; or 2) very low protein intake (Diet K). Diet K contains the same amount of protein as Diet L except that half of the protein comes from dietary sources and half from an amino acid/keto acid supplement.

The protein and phosphorus levels of the study diets are:

Study Diet Prescription

	Protein gm/kg	Phosphorus mg/kg
Diet K	0.28	4-9
Diet L	0.575	5-10
Diet M	1.3	16-20

Blood pressure management is determined by random assignment to either a moderate MAP (mean arterial pressure) goal or a low MAP goal. The possible diet and blood pressure group assignments are illustrated below and on the following page:

STUDY A

(GFR 25 to 55 ml/min/1.73m^2)

Group 1 Moderate MAP Goal Diet M (Moderate Protein)	Group 2 Low MAP Goal Diet M (Moderate Protein)
Group 3 Moderate MAP Goal Diet L (Low Protein)	Group 4 Low MAP Goal Diet L (Low Protein)

STUDY B

(GFR 13 to 24 ml/min/1.73m^2)

Group 1 Moderate MAP Goal Diet L (Low Protein)	Group 2 Low MAP Goal Diet L (Low Protein)
Group 3 Moderate MAP Goal Diet K (Very Low Protein)	Group 4 Low MAP Goal Diet K (Very Low Protein)

The calculations for the Study Diet Prescription for protein, phosphorus, calories and keto acids are provided by the DCC on the Study Diet Prescription Report which is sent to the clinical center after randomization via electronic mail. The calculations are derived from the diet to which the patient is randomized and the patient's Standard Body Weight. The prescription is adjusted for protein lost in the urine. For Diet L patients, a specific portion (0.35 gm/kg. SBW) of the protein prescription must be of High Biological Value.

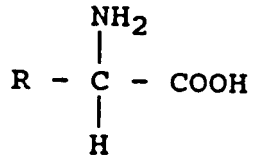
Because the primary nutrients for modification in the MDRD Study are protein and phosphorus, the focus of nutrition intervention will concentrate on these nutrients as well as calories. However, there may be indications for the inclusion of other dietary modifications to support management of blood pressure, diabetes, or hyperlipidemia. These modifications need to be considered, whenever possible, providing they do not compromise adherence to protein and/or phosphorus recommendations or adversely affect calorie intake.

If additional dietary modifications appear to be necessary for the patient, such as the reduction of sodium for blood pressure control, then these modifications should be incorporated into the Study Diet Prescription. It is recommended, however, that the implementation of these modifications be done using a phased approach. This will support adherence to the protein prescription and minimize complexity of the new dietary regimen.

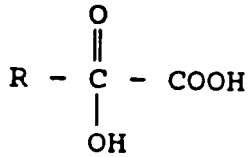
The Ketoacid Prescription

A mixture of certain amino acids and keto- and hydroxy-analogues of other amino acids are provided to supplement the intake of patients randomized to Diet K. The ketoacid or hydroxyanalogue is structurally the same as its corollary amino acid except that the amino group (NH_2) is replaced with a keto group (C=O) or hydroxy group (C=OH). See diagram below.

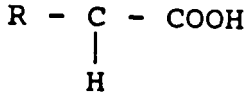
Amino Acid



Ketoacid

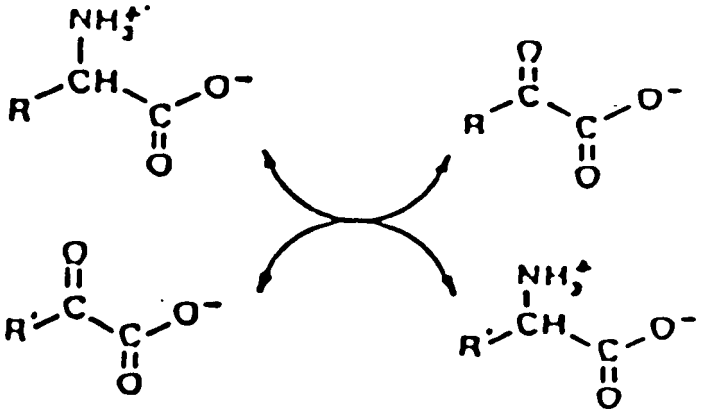


Hydroxyacid



The product is useful in the management of these patients as it reduces demand on kidney function by producing less nitrogenous metabolites than the same amounts of unmodified amino acids. The ketoacid and hydroxy-analogues are transmainated to their respective amino acids (see diagram), essentially "trapping" amino groups that might have contributed to urea or other waste product formation.

Transamination



The composition of the Ross Renal Ketoacid Product (RKAP) is:

RKAP COMPONENTS	g/100g
L-Ornithine α-Ketoisovalerate	22.53
L-Ornithine α-Ketoisocaproate	22.22
L-Lysine R,S-α-Keto-β-Methylvalerate	23.41
L-Histidine α-Ketoisocaproate	6.91
Calcium D,L-α-Hydroxy-γ-Methylthiobutyrate	2.05
L-Tyrosine	17.54
L-Tryptophan	0.30
L-Threonine	5.05

The first three compounds listed above are the ketoacids of valine, leucine, and isoleucine, respectively. The hydroxyacid of methionine is provided as a calcium salt. Tyrosine is added to the mixture because of the decreased ability of uremic patients to convert phenylalanine to tyrosine. The ketoacids of lysine and threonine are not used as humans do not appear to be able to transaminate these amino acids. The ketoacids of histidine and tryptophan are not used due to problems with stability and preparation.

The ketoacid mixture is administered in a daily dose of 2.8 gms per kg of standard body weight. For calculation of the ketoacid dose, the patient's standard body weight is rounded to the nearest 10 kg. The Study Diet Prescription Report, prepared by the DCC between Randomization and Follow-Up Visit 1, lists the prescribed number of ketoacid tablets or packets per day.

The mixture is provided in tablet and powder form. The patient may choose to take ketoacid tablets with one meal and ketoacid powder with the next, but from day to day the form of ketoacids taken at each meal must be consistent (for example, always tablets at breakfast and powder at lunch). If the patient finds that the current pattern is not suitable, it may be changed at the next monthly visit.

The ketoacid powder is mixed with water and the Ross Flavor System or fruit juice. The powder may be mixed in several concentrations with the flavor system. The following proportions of powder and flavor system are recommended as the optimum mixture for taste acceptability:

RKAP Packets	Flavor System	Water
1 packet	2 scoops (20 grams)	4 ounces
2 packets	4 scoops (40 grams)	8 ounces
3 packets	6 scoops (60 grams)	12 ounces

It is suggested by Ross Laboratories that when patients first receive the ketoacids, they be advised to mix them in the above proportions. Then patients may choose to increase or decrease the flavor system depending upon taste or caloric considerations. They may also choose to increase or decrease the amount of water.

Patients may need to be aware that the flavor system product, Golden Punch Flavor or Orange Flavor, is 98% sucrose. Thus 20 grams of the flavor system provides approximately 80 calories. The calories from the flavor system may be an important consideration if the patient has diabetes or has a need to either lose weight or increase weight.

Compliance to the ketoacid prescription is described in Chapter 1, Section 9.

Instructing the Patient in Mixing the Ketoacid Powder

1. Review Taking Your Ketoacids with the patient. (See the lesson plan for Follow-Up Visit 1.)

2. Have available samples of containers which could be used to mix the ketoacids. A 1 to 1 1/2-quart juice container with a lid may be appropriate for someone who wants to mix a double dose or a whole day's supply. Suggest that mixing in a glass container may be preferred because the ketoacid aroma may permeate plastic. If patients prefer to use a plastic container, suggest that they use that container only for ketoacids to prevent the transfer of the aroma to other foods.

3. When adding the ketoacids to the container, advise the patient to empty the packet carefully into the bottom of the container to reduce losing or inhaling the "dust" of the ketoacid powder.

4. Add the flavor system to the ketoacids and stir gently before adding water. This makes mixing easier when the water is added and it also reduces some "dust".

Refer to the Manual of Operations, Volume 4 (Intervention Manual), Follow-Up Visit 1 for more guidelines on mixing, storing, and taking the ketoacids.

Recommended Calorie Levels

Very careful attention needs to be focused on calorie levels for several reasons:

a) The Phase II data indicated a positive relationship between calorie intake at the final visit and GFR levels. Patients who had GFRs of >25 ml/min/1.73^2 had an average calorie intake of 28.3 kcal/kg/day. Those who had GFRs between 10-24 ml/min/1.73^2 had average intakes of 23.0 kcal/kg/day, and those who had GFRs <10 ml/min/1.73^2 had intakes of 23.1 kcal/kg standard body weight/day.

b) The Phase II data also suggested that with the lower GFR's there was a worsening trend toward decreased serum transferrin, body mass index, and in men, mid-arm muscle area, all parameters of nutritional status.

c) Various studies in animals and man suggest that increasing calorie intake enhances protein synthesis. Adequate calorie intake may be especially important when protein intake is at or near requirements or when the diet includes amino acids rather than intact protein.

Since one of the goals of the MDRD Study is to determine if malnutrition results from any of the study diets, it is recommended that every attempt be made to prevent a decline in nutritional status. Therefore, for most study patients, calorie intake should meet or exceed 30 kcal per kg standard body weight.

If weight loss is recommended by the dietitian and physician, a calorie range of 25 to 30 kcal per kg standard body weight may be prescribed, but careful monitoring of nutritional status is necessary.

At randomization, the dietitian will determine if the patient's weight has changed during Baseline. If the change is greater than ± 1.0 kilogram, modification of the calorie prescription should be considered. Clinical judgement is an important component of the decision. For example, if an overweight patient has gradually lost 1.5 kg over the three month Baseline period and this loss is mutually agreeable between the dietitian and the patient, the calorie prescription does not need to be changed. However, if a lean patient--especially one with a history of difficulty maintaining weight--should lose 1.5 kg during Baseline, steps should be taken to stop this loss by increasing the calorie prescription and/or by setting specific calorie goals with the patient.

If a patient either gains or loses weight as defined by the Protocol for an Action Item (see Section 13.3), a change in the calorie prescription and, in the case of weight loss, greater emphasis on increasing calorie intake should be implemented in the Follow-up period.

It will be important to carefully monitor weight changes throughout the Follow-up period. Preventive or remedial action needs to be initiated before the weight change becomes an Action Item. An undesired gain or loss of 1 kg should alert the dietitian to review calorie intake and/or other nutritional status parameters.

Nutritional Management of Blood Pressure

When lowering of blood pressure is necessary to meet Study Blood Pressure MAP goals, two levels of nutritional intervention will be recommended:

Level 1 should be implemented before weight reduction is recommended.

a. Reduce dietary sodium intake if clinically appropriate after consultation with the physician. Begin by eliminating table salt and limiting high sodium foods. Foods listed in the Protein Counter will be grouped according to sodium levels. A 30% reduction in urinary sodium has been suggested (forms 71 & 72) however, this degree of reduction may not be indicated in every patient.

b. Reduce alcohol intake if clinically appropriate after consultation with the physician.

Level 2 is implemented after it has been determined that the patient has been compliant to the above goals for four months and his/her blood pressure is still above the MAP goal and that he/she weighs more than 120% of standard body weight.

a. Reduce weight gradually, i.e., not more than two kilograms per month. Calorie intake should not fall below 25 kcal/kg standard body weight per day.

b. If possible, increase physical activity. Recommendations for moderate physical activity should be made on an individual basis with medical approval.

Other Dietary Considerations

The dietary recommendations should meet the specifications of the Nutrient Composition of the Study Diets as detailed in the Protocol, Section 11.2 and in the Manual of Operations, Section 4.

All Study patients receive a multi-vitamin supplement. Diet L and Diet K patients receive iron supplements. Calcium supplements will be provided to bring calcium intake within prescribed ranges.

The percent of calories derived from fat and carbohydrate may need to be adjusted for patients with non-insulin dependent diabetes or a history of hyperlipidemia or hypertriglyceridemia.

Other nutrients, such as potassium, may also need to be adjusted as determined by the physician.

The dietitian needs to use considerable clinical judgement to evaluate the cumulative effects of additional dietary modifications on compliance. Some patients may be receptive to recommendations to help them "fine tune" their dietary plan. Other patients may become overwhelmed and frustrated with the complexity of the dietary restrictions. These additional dietary modifications should be implemented only if they do not adversely effect adherence to the protein prescription, calorie intake, or overall compliance with study procedures.

In order to enhance compliance to the dietary goals, the dietary plan will be based on the patient's food preferences and his/her usual methods of food preparation. The Computerized Diet Design Tool (CDDT) will help the dietitian plan sample seven-day menus with the patient. The menus can then be analyzed to determine if they meet the Study Diet and prescription and incorporate other intended nutrient modifications.

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1 _____Average protein intake of U.S. Males Age 20-65+. Findings of the Health and Nutrition Examination Survey; DHEW Publications No. (PHS) 79-1221, 1979.

2 _____Food and Agriculture Organization estimated average requirements for protein. In: Energy and Protein Requirements. Report of a Joint FAO/WHO/UNU meeting. WHO Technical Report Series 724. World Health Organization. Geneva, 1985.

8.4 The Follow-Up Period

8.4.1 Follow-Up Visit 1 Summary

OVERVIEW: Follow-Up Visit 1 is the first opportunity to meet with a randomized study patient. The dietitian will provide an overview of the Follow-Up period, introduce the Study Diet Prescription, and instruct the patient on how to take study supplements.

BACKGROUND: The patient has met all eligibility requirements including an acceptable level of compliance with study procedures during Baseline and has been randomized into the MDRD Study. The dietitian has completed the Study Diet Prescription (Form 71).

SEQUENCE OF ACTIVITIES: This visit will take approximately 75 minutes.

5 minutes	Welcome and thank the patient for coming.
1 minute	Weigh patient and record values on Form 5.
5 minutes	Provide an overview of the Follow-Up period.
35 minutes	Introduce the Study Diet Prescription, distribute and explain how to take supplements. Compare Study Diet to patient's Baseline Diet.
20 minutes	Set protein goals for breakfast, lunch, dinner, snacks, and/or eating out.
1 minute	Assign self-monitoring.
5 minutes	Review prescription and goals for the next visit and confirm date and time of next appointment. Discuss what will take place at the next visit (shopping strategies and how to order and use low protein food products).

8.4.2 Follow-Up Visit 1A Summary

OVERVIEW: This visit introduces low protein shopping strategies and how to order and use low protein food products or use low protein recipes.

BACKGROUND: During the previous visit the patient was given his Study Diet Prescription and introduced to the study supplements. The patient set meal-specific protein goals and received reassurance that a low protein lifestyle can be an acceptable and healthy way to live.

SEQUENCE OF ACTIVITIES: This visit will take approximately 85 minutes.

5 minutes	Welcome and thank the patient for coming.
1 minute	Weigh patient.
10 minutes	Review self-monitoring.
10 minutes	Review progress toward goals and compliance to supplements.
15 minutes	Introduce low protein shopping strategies and low protein products and/or recipes.
10 minutes	Introduce and complete activity on weighing and measuring.
5 minutes	Introduce high biological value protein.
5 minutes	Set goals for next visit.
5 minutes	Assign self-monitoring.
5 minutes	Assign the Three-Day Food Record.
5 minutes	Review goals/assignments for next visit and confirm date and time of next appointment. Discuss what will take place at the next visit.

8.4.3 Follow-Up Visit 2 Summary

OVERVIEW: In this session, the patient will be given an opportunity to plan, discuss, and practice what to do and say in eating out situations that are part of his usual lifestyle.

BACKGROUND: In the previous session, patients discussed food shopping and label reading. Low protein food products and selected recipes were introduced. Patients were asked to try the special low protein products and several recipes.

Diet L and Diet K patients have been progressively lowering their protein intake and should be, on average, consuming no more than twice the grams of protein prescribed for Follow-Up (that is, about half way to their study goal).

SEQUENCE OF ACTIVITIES: This visit will take approximately 1 hour 40 minutes.

5 minutes	Welcome and thank the patient for coming.
15 minutes	Conduct 24-hour recall interview.
1 minute	Weigh patient.
15 minutes	Review and document the Three-Day Food Record.
10 minutes	Review self-monitoring.
10 minutes	Review compliance to supplements.
10 minutes	Review progress toward goals.
10 minutes	Discuss strategies for ordering from menus or making choices in fast food restaurants.
10 minutes	Practice speaking-up skills and ordering from menus from local restaurants.
5 minutes	Set goals for next visit.
5 minutes	Assign self-monitoring.
5 minutes	Review goals/assignments for next visit and confirm date and time of next appointment. Discuss what will take place at the next visit.

8.4.4 Follow-Up Visit 2A Summary

OVERVIEW: This is a dietitian only visit so the patient may feel more relaxed and may want to take time to ask questions and discuss his progress. This is the first visit during which data will be available for the dietitian to review with the patient. Patients may want to know their biochemical and nutrient intake values and how these values relate to their progress in the study and their nutritional status.

This visit will emphasize planning and preparing low protein evening meals. Ideas and strategies for using less meat and more vegetables and grains will be the focus.

BACKGROUND: The patient has been working toward his protein goal for 1-1/2 months and he may already have reached his Study Diet Protein Prescription. In the last visits he reviewed and discussed strategies for food shopping and eating out.

SEQUENCE OF ACTIVITIES: This visit will take approximately 81 minutes.

5 minutes	Welcome and thank the patient for coming.
1 minute	Weigh patient.
10 minutes	Review self-monitoring.
10 minutes	Review progress toward goals.
15 minutes	Explain and interpret Biochemistry Flowsheet.
5 minutes	Explain and chart protein intake and goals on the How Is It Going? graph.
20 minutes	Discuss principles of meal planning and preparing protein wise (and/or sodium light) evening meals.
5 minutes	Set goals for next visit.
5 minutes	Assign self-monitoring.
5 minutes	Assign the Three-Day Food Record.
5 minutes	Review goals/assignments for next visit and confirm date and time of next appointment. Discuss what will take place at the next visit.

8.4.5 Follow-Up Visit 3 Summary

OVERVIEW: This visit introduces strategies to help the patient develop support and cooperation from family and friends as he continues to learn about and adapt to his modified eating style. Compliance is assessed using the entire Counseling Summary Form (Form 76) and the compliance monitoring process is initiated (see Manual of Operations, Chapter 1, Section 9). The patient is encouraged to progress toward his protein goal, if not already attained.

BACKGROUND: During the previous visit the patient was introduced to the Biochemistry Flowsheet. Food shopping, eating out, meal planning, and ideas for low protein/low sodium evening meals have been discussed in previous visits.

SEQUENCE OF ACTIVITIES: This visit will take approximately 1 hour and 45 minutes.

5 minutes	Welcome and thank the patient for coming.
15 minutes	Conduct 24-hour recall interview.
1 minute	Weigh patient and provide appropriate feedback.
15 minutes	Review and document the Three-Day Food Record.
5 minutes	Review compliance to supplements.
10 minutes	Review self-monitoring.
10 minutes	Discuss ways to obtain support from family and friends.
10 minutes	Initiate compliance assessment using Counseling Summary Form (Form 76).
10 minutes	Review progress toward goals.
5 minutes	Set goals for next visit.
5 minutes	Assign self-monitoring.
5 minutes	Assign the Three-Day Food Record.
5 minutes	Distribute low protein products.
5 minutes	Review goals/assignments for next visit and confirm date and time of next appointment. Discuss what will take place at the next visit.

8.4.6 Follow-Up Visit 4 Summary

OVERVIEW: This visit provides a review of strategies the patient can use to maintain Protein Wise lunches. Since the visit includes the GFR procedure, quizzes to review some earlier topics have been included. By this visit, the patient is expected to reach his Study Diet Prescription.

BACKGROUND: The patient has been self-monitoring and working toward his study goals for four months. He has been introduced to menu planning, food shopping, use of low protein food products, recipes, and dining out strategies.

SEQUENCE OF ACTIVITIES: This visit will take approximately two hours.

5 minutes	Welcome and thank the patient for coming.
15 minutes	Conduct 24-hour recall interview.
1 minute	Weigh patient and provide appropriate feedback.
15 minutes	Review and document the Three-Day Food Record.
5 minutes	Review compliance to supplements.
10 minutes	Review self-monitoring.
10 minutes	Discuss strategies for Protein Wise lunches.
10 minutes	Review progress toward goals.
10 minutes	Enable the patient to test some recently learned skills and knowledge.
10 minutes	Complete compliance assessment using Counseling Summary Form (Form 76).
5 minutes	Set goals for next visit.
5 minutes	Assign self-monitoring.
5 minutes	Assign the Three-Day Food Record.
5 minutes	Distribute low protein products.
5 minutes	Review goals/assignments for next visit and confirm date and time of next appointment. Discuss what will take place at the next visit.

8.4.7 Follow-Up Visit 5 Summary

OVERVIEW: During this visit, which is the first formal compliance assessment visit, progress and problem areas are discussed and goal attainment evaluated. The patient's nutritional status is also assessed and reviewed with him, if appropriate. Goals for the next four-month period, as well as for the next visit, are set. Strategies to support these goals are developed. The patient's participation in the study is formally acknowledged with a certificate.

BACKGROUND: Since the first Follow-Up Visit, the patient has been modifying his diet and practicing various skills, including self-monitoring, discriminating foods based on their protein value, selecting appropriate grocery and restaurant items, and increasing variety at lunch. Ways to ask for help and support from family and friends have also been reviewed.

SEQUENCE OF ACTIVITIES: This visit will take approximately two hours.

5 minutes	Welcome and thank the patient for coming.
1 minute	Weigh patient and provide appropriate feedback.
15 minutes	Review and document the Three-Day Food Record and compliance to supplements.
40 minutes	Review four-month compliance period, including nutritional status and goal attainment.
10 minutes	Set goals for next four-month period.
10 minutes	Set goals for next visit.
5 minutes	Assign self-monitoring.
5 minutes	Assign the Three-Day Food Record.
5 minutes	Distribute low protein products.
5 minutes	Review goals/assignments for next visit and confirm date and time of next appointment. Discuss what will take place at the next visit.
15 minutes	Complete the Counseling Summary Form (Form 76).

Section 9

Compliance Assessment

9.1 Introduction

Compliance is the most important objective of the intervention program. This presents a major challenge for dietitians as they are primarily responsible for assisting patients in reaching their goal protein prescription.

To accomplish this objective, the clinical center dietitians will have a variety of resources available. Many of those listed here are described elsewhere either in the Protocol or Manual of Operations.

Patient Compliance Committee (Protocol, Section 19.4)

Clinical Management Committee (Protocol, Section 19.4)

Computerized Diet Design Tool (Manual of Operations, Chapter 1, Section 12)

Nutrient Summary Report (Manual of Operations, Chapter 1, Section 5)

Intervention Manual for MDRD Dietitians (forthcoming)

Counseling Summary Form (Form 76)(Manual of Operations, Chapter 1, Section 9)

Study Diet Prescription Form (Form 71)(Manual of Operations, Volume 2)

Special Dietary Considerations Form (Form 72) (Manual of Operations, Volume 2)

Biochemistry Flowsheet (Manual of Operations)

Plasma Alloisoleucine and Ornithine (Aminogram) (Protocol, Section 12.8)

Monthly and Four-Month Compliance Flowsheets (Manual of Operations, Chapter 1, Section 9)

Dietary Compliance Graph (How Is It Going?) (Manual of Operations, Chapter 1, Section 9)

Study Team (Manual of Operations, Chapter 2, Section 4.2)

Dietitians' Compliance Committee (Manual of Operations, Chapter 1, Section 9)

NCC Intervention Nutritionists (Manual of Operations, Chapter 1, Section 9)

The last two resources listed above are defined here as they have not been formally discussed elsewhere. The term "Intervention Nutritionist" will refer to the nutrition staff at the NCC who have a major responsibility of assisting the clinical center dietitians with compliance problems. The Dietitians' Compliance Committee is a group of clinical

center dietitians, one of whom is also a member of the Study Compliance Committee. The purpose of this group is to provide support and to facilitate communication among the dietitians regarding compliance problems.

9.2 Overall Compliance

MDRD is a very complex study and it is not surprising that the process of assessing patient compliance to the Study Diet Prescription is embedded in a network of complicated issues that also compete for patient attention. The multiple procedures required for participation, such as the frequent collection of urine and food intake data, diagnostic procedures such as the measurement of glomerular filtration rate, the responsibility of making major dietary changes, plus the psychological burden associated with the diagnosis of chronic renal disease, combine to produce an environment which may make it difficult for a patient to successfully engage in an active lifestyle intervention program. As a result, the management of compliance becomes a dynamic process. The dietitian's role is to help minimize the impact of the complex protocol requirements and to individualize the dietary program to facilitate compliance. At the same time, the dietitian must remain sensitive to and integrate other factors which may be affecting the patient's overall motivation.

9.3 Compliance to the Protein Prescription

Since protein plays such a major role in MDRD, the primary focus of this section will be on the procedures used to monitor protein compliance. Keep in mind, however, that because of the need to integrate other dietary modifications into the Study Diet Prescription, other areas of intervention are incorporated and monitored simultaneously.

Adherence to the protein prescription will be monitored by: 1) the analysis of the 24-hour urine data (Protocol 12.8), 2) dietary data (Protocol 12.8.2), 3) measurement of plasma alloisoleucine (Protocol 12.8.3), and 4) the intake of prescribed keto acid supplements.

The primary measure of adherence to the protein prescription is the agreement between the Estimated Protein Intake from the Urea Nitrogen Appearance (EPI(UNA)), and the Study Diet Prescription. A range of ± 30% of the protein prescription was selected based upon MDRD Phase II experience, a review of the compliance literature, and clinical judgement. Even though the EPI(UNA) has been selected as the "gold standard" or the primary way to express protein intake, other measures such as dietary data from the three-day food record should also be considered for compliance assessment. However, in resolving problems dealing with compliance using either measure, factors such as accuracy of collection must be evaluated. The major tools used in the monitoring process are defined below.

9.3.1 Compliance to the Ketoacid Prescription

Compliance to the ketoacid prescription is determined by serum alloisoleucine and ornithine levels.

Alloisoleucine is formed when the ketoacid of leucine (ketomethlyvaleric acid) is transaminated. Because the ketoacid supplement contains ketomethlyvaleric acid (see Chapter 1, Section 8.3.7.2), alloisoleucine would be present in the serum following ingestion of the supplement. Therefore, alloisoleucine may be used as an indicator of compliance. Ornithine may also be used as a marker of compliance because much of the ketoacid supplement is administered as ornithine salts, thus providing a significant load of ornithine upon ingestion of the supplement.

Fasting serum alloisoleucine levels of 40 to 60μM suggest the patient is compliant with the prescription. This is based on data from Ross labs where subjects were fed 0.28 to 0.42 g ketoacid/kg body weight/day for 29 days. Mean alloisoleucine concentrations declined to approximately 50μM after an overnight fast. Compliance is also confirmed by fasting ornithine concentrations of 30 to 70μM.

Some patients may attempt to appear compliant to the prescription by ingesting the ketoacid supplement before blood sampling, although the protocol instructs that this be a fasting sample. Ornithine levels increase markedly after ingestion of the supplement yet rapidly return to fasting levels; therefore, elevated ornithine levels, together with elevated alloisoleucine levels, suggest the supplement has been taken the morning of the appointment. Fasting serum alloisoleucine levels $\geq$ 18μM and ornithine levels > 100μM suggest the patient is not truely fasting and has ingested ketoacids 2 to 3.5 hours prior to blood sampling.

Fasting serum alloisoleucine levels of < 18μM suggests the patient is not ingesting the ketoacid supplement. This value, and those in the paragraph above, are defined as Action Items (Aminogram Out of Range) by the Protocol (see Section 13). Results are reported by the DCC on the Amino Acid Report; aminogram results are also summarized on the Monthly and Four-Month Compliance Flowsheets.

9.4 Materials and Procedures Used in Monitoring Compliance

9.4.1 Counseling Summary Form (Form 76)

The purpose of this form is to help the dietitian summarize patient progress areas, to identify or remediate problems leading to noncompliance, to plan goals for the next visit, and to record compliance strategies and intervention materials used. The summary also allows for the collection of important data which help to describe the intervention program used in MDRD. This form is completed at every Follow-up visit and after other counseling contacts with the patient (see Exhibit 9.4.1).

9.4.2 Biochemistry Flowsheet

This DCC flow sheet is sent to the clinical centers via electronic mail and summarizes on an ongoing basis all patient biochemistry information from each visit. As each patient visit is completed and the data is available, a new flow sheet is generated (see Exhibit 9.4.2).

9.4.3 Dietary Compliance Graph

A copy of the compliance graph, entitled How Is It Going?, is provided to the clinical centers. This graph is to be duplicated by the center; one graph is used for each patient. On the horizontal grid is the visit number. On the vertical axis is grams of protein per day. The dietitian is asked to keep a graph for each patient that displays the change in protein intake over time. This graph can be copied and given to patients as feedback about their progress. Other variables of special concern to the patient may be added and monitored on this form as well (see Exhibit 9.4.3).

9.4.4 Monthly and Four-Month Compliance Flowsheets

These flowsheets are distributed to the clinical centers via electronic mail from the DCC. The Monthly Compliance flowsheet will arrive at the centers within 23 days of the patient visit. The Four-Month Compliance Flowsheet is initiated after Follow-up visits 4, 8, 12, etc. and displays four month summary data. It should also arrive within approximately 23 days of the patient visit. These flowsheets are used to assess overall compliance. Guidelines for interpreting these flowsheets are included (see Exhibits 9.4.4 and 9.4.4.1).

9.4.5 Adherence Categories

Nine adherence categories have been identified to describe the possible relationships between the EPI(UNA), dietary protein intake and the Study Diet Prescription (Exhibit 9.4.5).

MDRD

Modification of Diet in Renal Disease Study
Counseling Summary Form

Purpose:
1. To summarize patient progress, problems, and strategies.
2. To plan goals for next visit.
3. To report compliance strategies, counseling activities, and intervention materials used by dietitians.
4. To document the action taken to remediate adherence problems.
5. To focus intervention on compliance to the protein prescription with secondary emphasis on compliance to other interventions: sodium intake, supplements, etc.

Completed By: Dietitian at Follow-up visits, dietitian only visits, adherence contacts, and other counseling contacts. Note: Items 6 and 15 are not entered into Datalex. For Follow-up Visits 1, 1A, 2, and 2A complete only items 1-4, 6 and 11-15.

TO CONDUCT THIS VISIT REVIEW THE FOLLOWING:

___Food/Nutrient Intake
self-monitoring, 24-hour recall, three-day food record, or Nutrient Summary Report
___How Is It Going Graph?
___Weight changes since previous visit
___Biochemistry Flowsheet(s)
___Compliance Flowsheet(s)
___Pill Count Form (Form 73)
___Counseling Summary Form (Form 76)
___Special Dietary Considerations Form (Form 72)
___Dietary Information Summary Report
___Study Diet Prescription Report

FORM # 76

1. Patient Identification Number ..... ___ ___ ___ ___ ___ ___

2. Patient Name Code ..... ___ ___ ___ ___

3. Clinical Center ..... ___ ___

4. a. Date of visit or contact ..... ___ ___/___ ___/___ ___

   b. Visit Type ..... E

   c. Visit number or Contact Code ..... ___ ___ . ___
      Visit number codes: (see Instructions)
      ___ ___ . 0 = Regular Follow-up Visit
      ___ ___ . 5 = Regular Dietitian Only Visit (ie: 1A, 2A,)
      ___ ___ . 8 = Adherence Category Contact
      ___ ___ . 9 = Other Contacts

Modification of Diet in Renal Disease Study
Counseling Summary Form

5. In the blank space provided, record the number of the adherence category.....___

Adherence Category	Percent of Prescription	Definition of Adherence
1. EPI(UNA) Reported Protein	70-130% 70-130%	Both within acceptable range
2. EPI(UNA) Reported Protein	70-130% <70%	EPI(UNA) within acceptable range Reported Protein below acceptable range
3. EPI(UNA) Reported Protein	70-130% >130%	EPI(UNA)within acceptable range Reported protein above acceptable range
4. EPI(UNA) Reported Protein	>130% >130%	Both above acceptable range
5. EPI(UNA) Reported Protein	<70% <70%	Both below acceptable range
6. EPI(UNA) Reported Protein	>130% <70%	EPI(UNA) above acceptable range Reported Protein below acceptable range
7. EPI(UNA) Reported Protein	>130% 70-130%	EPI(UNA) above acceptable range Reported Protein within acceptable range
8. EPI(UNA) Reported Protein	<70% >130%	EPI(UNA) below acceptable range Reported Protein above acceptable range
9. EPI(UNA) Reported Protein	<70% 70-130%	EPI(UNA) below acceptable range Reported Protein within acceptable range

6. PROGRESS AREAS: Encourage the patient to discuss his/her success, achievements, and progress in working toward or maintaining his/her dietary goals. Summarize what the patient says on the lines below. This section is not entered into Datalex.

_____

_____

_____

_____

Modification of Diet in Renal Disease Study
Counseling Summary Form

7. ATTITUDE ASSESSMENT

How do you feel your new eating pattern fits into your current lifestyle?

a. Patient has a positive attitude toward the study and the eating pattern. (1 = yes, 2 = no) Go on to 7b ..... ___

Does the patient indicate or do you perceive that the patient has a problem in any of the areas listed below. Additional spaces are included for you to write in other problems. Limit each to twenty characters. (For the following: 1 = yes, this is a problem area, 2 = no, this is not a problem area. Leave blank if not discussed or not known.)

POSSIBLE PROBLEM AREAS

b. perceives diet as being too difficult ..... ___

c. seems unwilling to make time or perceives lack of time ..... ___

d. has inconsistent food intake ..... ___

e. is unwilling to complete assignments or carry out strategies ..... ___

f. records only what dietitian "wants to hear" ..... ___

g. has given up ..... ___

h. does not wish to discuss condition, possible denial ..... ___

i. is unwilling to self-monitor ..... ___

j. is overly compulsive about diet ..... ___

k. is unwilling to use low protein foods ..... ___

l. prefers another study diet prescription (more or less protein) ..... ___

m. resists eating up to or down to prescription ..... ___

n. Problems related to sodium intervention ..... ___
Describe: _____

o. Problems related to supplement compliance ..... ___
Describe: _____

p. Problems related to weight loss or weight gain ..... ___
Describe _____

q. Other ..... ___
Describe: _____

Modification of Diet in Renal Disease Study
Counseling Summary Form

8. ENVIRONMENT/SOCIAL SUPPORT ASSESSMENT

How do you feel about the help and support that you get from your family, friends, or from people at work?

a. Patient finds his/her support systems adequate. (1 = yes, 2 = no) Go on to 8b.....___

Does the patient indicate or do you perceive that the patient has a problem in any of the areas listed below. Additional spaces are included for you to write in other problems. Limit each to twenty characters. (For the following: 1 = yes, this is a problem area, 2 = no, this is not a problem area. Leave blank if not discussed or not known.)

POSSIBLE PROBLEM AREAS

b. lacks support at home .....___

c. has had a change in primary food preparer/shopper .....___

d. has crisis/stress within the family .....___

e. has serious financial concerns .....___

f. has had a change in primary personal relationship .....___

g. has stress at work.....___

h. has a lack of support from employer/coworkers .....___

i. has problems parting with favorite foods.....___

j. Problems related to sodium intervention .....___

Describe: _____

k. Problems related to supplement compliance .....___

Describe: _____

l. Problems related to weight loss or weight gain.....___

Describe: _____

m. Other.....___

Describe: _____

Modification of Diet in Renal Disease Study
Counseling Summary Form

9. HEALTH ASSESSMENT

Please describe how your overall health has influenced your appetite or eating pattern in recent weeks.

a. Patient indicates appetite and overall health is adequate. (1 = yes, 2 = no) Go on to 9b.....___

Does the patient indicate or do you perceive that the patient has a problem in any of the areas listed below. Additional spaces are included for you to write in other problems. Limit each to twenty characters. (For the following: 1 = yes, this is a problem area, 2 = no, this is not a problem area. Leave blank if not discussed.)

POSSIBLE PROBLEM AREAS

b. is frequently hungry.....___

c. is discouraged by the increasing complexity of dietary regimen.....___

d. experiences early satiety/poor appetite.....___

e. is anorexic.....___

f. is depressed.....___

g. has had a short-term illness.....___

h. has deteriorating kidney function.....___

i. has had dietary prescription changed.....___

j. has had a change in taste.....___

k. has had weight loss.....___

l. has had weight gain.....___

m. is not taking ketoacids / supplements as prescribed.....___

n. blood pressure is not at goal.....___

o. Problem related to another medical condition.....___

Describe: _____

p. Other.....___

Describe: _____

Modification of Diet in Renal Disease Study
Counseling Summary Form

10. SOCIALIZATION ASSESSMENT

Please tell me how you feel your eating style affects your motivation to attend social functions, to eat out, or to travel.

a. Patient indicates he/she is able to manage most social situations or dining out. (1 = yes, 2 = no) Go on to 10b.....___

Does the patient indicate or do you perceive that the patient has a problem in any of the areas listed below. Additional spaces are included for you to write in other problems. Limit each to twenty characters. (For the following: 1 = yes, this is a problem area, 2 = no, this is not a problem area. Leave blank if not discussed.)

POSSIBLE PROBLEM AREAS

b. dines out frequently.....___

c. has interfering vacation/travel.....___

d. has had a change in frequency of social events.....___

e. drinks too much alcohol.....___

f. avoids eating out.....___

g. Other problems.....___
Describe: _____

h. Other problems.....___
Describe: _____

11. SKILL/KNOWLEDGE ASSESSMENT

In your opinion, as a dietitian, do you feel the patient has sufficient skills and knowledge to carry out study goals?

a. Patient has sufficient skills and knowledge. (1 = yes, 2 = no) Go on to 11b.....___

Do you perceive that the patient has a problem in any of the areas listed below. Additional spaces are included for you to write in other problems. Limit each to twenty characters. (For the following: 1 = yes, this is a problem area, 2 = no, this is not a problem area. Leave blank if not discussed.)

POSSIBLE PROBLEM AREAS

b. finds dietary restrictions too complex.....___

c. incomplete or inaccurate record keeping.....___

d. incomplete or inaccurate self-monitoring.....___

e. weighs and measures foods inaccurately.....___

Modification of Diet in Renal Disease Study
Counseling Summary Form

11. (Continued)
    f. refuses to weigh and measure foods ..... ___
    g. does not record recipes completely or accurately ..... ___
    h. discriminates protein values poorly ..... ___
    i. underestimates protein intake ..... ___
    j. lacks understanding ..... ___
    k. unable to modify recipes or food preparation ..... ___
    l. does not do his own record keeping ..... ___
    m. has poor reading skills ..... ___
    n. has poor handwriting ..... ___
    o. has language or cultural barrier ..... ___
    p. Problems related to sodium intervention ..... ___
       Describe: _____
    q. Problems related to supplement compliance ..... ___
       Describe: _____
    r. Problems related to weight loss or weight gain ..... ___
       Describe: _____
    s. Other ..... ___
       Describe: _____

12. Now that the patient has identified some factors that may be affecting his/her ability to comply, encourage the patient to develop goals or strategies to remediate the problem areas. Additional spaces are included so you can write in other strategies that the patient develops. Limit each to twenty characters. Use the following code to identify goals or strategies the patient currently uses or plans to use in the next month or until the next contact: 1 = yes - plans to use this strategy, or, 2 = no - the patient does not plan to use this strategy.

PATIENT STRATEGIES

    a. maintain frequency of self-monitoring ..... ___
    b. increase frequency of self-monitoring ..... ___
    c. self-monitor problem meal(s) only ..... ___
    d. focus on weekend eating ..... ___
    e. focus on dining out/social events strategies ..... ___

Modification of Diet in Renal Disease Study
Counseling Summary Form

12. (Continued)

f. increase time available to focus on meal planning/shopping ..... ___

g. increase time available to focus on meal preparation ..... ___

h. discuss goals and needs with spouse/significant other ..... ___

i. try additional low protein products ..... ___

j. try additional/new recipes ..... ___

k. try new convenience foods ..... ___

l. try meatless meals ..... ___

m. take lunch to work ..... ___

n. eat out less often ..... ___

sodium specific strategies

o. Describe: _____ ___

p. Describe: _____ ___

fat/cholesterol reducing strategies

q. Describe: _____ ___

r. Describe: _____ ___

specific strategies to improve compliance to supplements

s. Describe: _____ ___

t. Describe: _____ ___

weight loss strategies (reduce calories)

u. Describe: _____ ___

v. Describe: _____ ___

weight gain strategies (increase calories)

w. Describe: _____ ___

x. Describe: _____ ___

Modification of Diet in Renal Disease Study
Counseling Summary Form

13. INTERVENTION MATERIALS

Indicate the code number of intervention materials used at this session. This code is found in the lower right hand corner of all intervention handouts. Please limit codes to fifteen.

a. ___ ___ ___/___ ___	f. ___ ___ ___/___ ___	k. ___ ___ ___/___ ___
b. ___ ___ ___/___ ___	g. ___ ___ ___/___ ___	l. ___ ___ ___/___ ___
c. ___ ___ ___/___ ___	h. ___ ___ ___/___ ___	m. ___ ___ ___/___ ___
d. ___ ___ ___/___ ___	i. ___ ___ ___/___ ___	n. ___ ___ ___/___ ___
e. ___ ___ ___/___ ___	j. ___ ___ ___/___ ___	o. ___ ___ ___/___ ___

14. DIETITIAN COUNSELING ACTIVITIES

Summarize counseling activities that you included at this contact or that you plan to use in the next month. (For the following: 1 = yes, was included or is to be implemented, 2 = no, not to be included.)

COUNSELING ACTIVITIES

a. introduced or reviewed the Study Diet Prescription ..... ___

b. provided counseling regarding pill compliance ..... ___

c. reviewed Nutrient Summary Report(s) ..... ___

d. reviewed Compliance Flowsheet(s) ..... ___

e. reviewed Biochemistry Flowsheet(s) ..... ___

f. provided new or more low protein food products ..... ___

g. provided new or additional recipes ..... ___

h. provided additional menus ..... ___

i. provided guidelines for sodium modification ..... ___

j. provided guidelines for cholesterol/fat modification ..... ___

k. provided guidelines for phosphorus modification ..... ___

l. provided guidelines for potassium modification ..... ___

m. provided guidelines for increasing calories ..... ___

n. provided guidelines for decreasing calories ..... ___

o. provided guidelines for increasing high biological value foods ..... ___

Modification of Diet in Renal Disease Study
Counseling Summary Form

14. (Continued)
    p. reviewed label reading ..... ___
    q. had patient demonstrate skills for you ..... ___
    r. provided a food tasting session ..... ___
    s. used a food demonstration session ..... ___
    t. planned for increased telephone contact ..... ___
    u. introduced or updated How is It Going? ..... ___
    v. used CDDT at the visit ..... ___
    w. will use CDDT after the visit ..... ___
    x. will send postcard reminders or other forms of mail contact ..... ___
    y. planned for a special meeting with study team or PI ..... ___
    z. planned for a special meeting with family/significant other ..... ___
    aa. planned a special group session ..... ___
    bb. planned a home visit ..... ___
    cc. planned a restaurant visit ..... ___
    dd. referred patient to another health professional/organization ..... ___
    ee. Other ..... ___
        Describe: _____
    ff. Other ..... ___
        Describe: _____

15. **PROGRESS NOTES**: This section is not entered into Datalex.

_____
_____
_____
_____
_____
_____
_____

Modification of Diet in Renal Disease Study
Counseling Summary Form

15. **PROGRESS NOTES** (Continued)

_____

_____

_____

_____

_____

_____

_____

_____

101. Date this form completed..... ___ ___/___ ___/___ ___

102. Certification number of dietitian completing this form..... ___ ___ ___ ___ ___

103. Date form entered..... ___ ___/___ ___/___ ___

104. Certification number of data entry person ..... ___ ___ ___ ___ ___

Retain a copy of this form for your files. Send the original to the MDRD Study Data Coordinating Center and send a copy to the MDRD Nutrition Coordinating Center. Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
Department of Biostatistics & Epidemiology
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5196

MDRD Nutrition Coordinating Center
Department of Epidemiology
Graduate School of Public Health
University of Pittsburgh
130 DeSoto Street
Pittsburgh, PA 15261

Modification of Diet in Renal Disease Study

COUNSELING SUMMARY FORM

PURPOSE:
1. To summarize patient progress, problems and strategies.
2. To plan goals for next visit.
3. To report compliance strategies, counseling activities, and intervention materials used by dietitians.
4. To document the action taken to remediate adherence problems.
5. To focus intervention on compliance to the protein prescription with secondary emphasis on compliance to other interventions: sodium intake, supplements, etc.

COMPLETED BY: Dietitian at Follow-up visits, dietitian only visits, adherence contacts, and other counseling contacts. Note: Items 6 and 15 are not entered into Datalex. For Follow-up Visits 1, 1A, 2, and 2A complete only items 1-4, 6 and 11-15.

The following are instructions for completing specific questions on Form 76.

4. c. Visit or Contact Code.....____ ____.____

__ __.0 A whole number, such as 3.0, is used to designate a regular Follow-up visit.

__ __.5 The whole number of the visit plus .5, such as 01.5, is used to designate a dietitian only visit after a regular Follow-up visit (ie: 1A, 2A).

__ __.8 The whole number of the visit plus .8 is used to designate a visit or contact made as a result of data placing the patient in Adherence Category #4-9. For example, contact with a patient to discuss an adherence problem between Follow-up visits 4 and 5 would be coded 04.8

__ __.9 Contacts with patients that are made for purposes other than those noted above are coded XX.9. For example, a patient contact occurring by telephone between follow-up visits 3.0 and 4.0 to further discuss strategies for sodium reduction would be coded as 3.9.

Adherence Categories

5. In the space provided, fill in the number of the adherence category which best describes the patient's current or most recent level of adherence. If you are completing this form at a regular Follow-up visit (_x_ _x_ .0) or another counseling contact (_x_ _x_.9) refer to the most recent Patient Compliance Flowsheet for the adherence category. If this is an adherence contact identified as a _x_ _x_.8, you will need to determine the adherence category. (See Manual of Operations, Chapter 1, Section 9.)

Progress Areas

6. Begin the counseling session by giving the patient time to describe how he has felt since the last contact. Encourage the patient to begin with positive experiences. Use the space provided to summarize what the patient tells you about his successful strategies. This section is not entered into Datalex.

General Assessment Areas

7-10. These four questions have the same format and deal with assessing four different areas of patient compliance. They begin with a sample opening statement that you could use with the patient. In order to make an attempt to standardize the completion of this form, it is suggested that you begin with the statement provided or carefully plan one to use as an alternate. After you have asked the patient the question, pause and give him time to respond.

Code 1 for yes, if the patient's response is positive;
code 2 for no, if the patient's response is negative.
Possible Problem Areas-if the patient goes on to describe problems that he is encountering, review the possible problem list and
code 1 for yes, if the patient describes this as a problem. Also code 1 for yes if it is obvious from what you know about the patient that this is a problem for him (even if he does not specifically state the problem).
Code 2 for no, if the patient does not have a problem in that area.
The space after the problem can be left blank (not coded) if the patient does not indicate a problem in that area. **Do not read the possible problem list to the patients.**

At the end of each listing are additional lines to describe problems related to sodium, supplements, weight, or other. Statements which describe these problems must be limited to less than 20 characters including blanks.

11. Skill/Knowledge Assessment - This question allows you to assess whether the patient has sufficient skills and knowledge to meet the protein prescription and other study goals. The same coding scheme used in questions 7 - 10 is repeated. For this question respond to each statement under the possible problem list and code whether or not this is a problem for the patient. Leave blank (do not code) only if you do not know whether it is a problem for the patient. The problems listed focus mainly on protein intervention. Additional lines are provided where you can describe problems related to compliance to sodium, supplements, or weight intervention. Statements which describe the problem must be limited to less than 20 characters including blanks.

12. Patient Strategies - Strategies used by the patient will be coded. Code 1 = yes, if the strategy is currently used or will be used by the patient in the next month or until the next contact; code 2 for no, if the patient does not plan to use the strategy. Each statement should have a code. Additional lines are provided where you can describe other strategies. Descriptions must be limited to twenty characters.

13. Intervention Materials - Intervention materials are identified by a code number. You are to use the third and fourth part of the code that is typed at the bottom of almost all intervention materials. The third part, which allows for up to three digits, is the Visit Code or OPT for optional followed by a slash (/). These characters should be flush against the slash. If the visit code is only two characters, i.e. F2, use a leading zero i.e. 0F2. The fourth part is the handout or resource number (numbered sequentially within each visit). This allows for up to two digits. (Example _ _ _ / _ _). Spaces are provided so you can list the code for each intervention material used at the visit. There is room to code only 15 intervention handouts per visit. Acceptable codes are listed in Manual of Operations, Volume 4, Appendix A.

14. Dietitian Counseling Activities - Counseling activities used by the dietitian will be coded. Code 1 = yes, if the activity was included at the visit or is to be included. Code 2 = no, if the activity was not used. Each statement should have a code. This section provides an opportunity for you to summarize the counseling activities which were included at the visit or which will be implemented before the next visit. Additional lines are provided for you to describe other activities not listed. These descriptions are limited to twenty characters.

15. Progress Notes In this area you can summarize in your on words anything about the contact or visit that was not included elsewhere on the form. This is a good place to include your assessment of the contact, your impression of the patient's attitude, etc., and ideas of what you feel should be included in the next contact. This is a good place to communicate in writing information that other dietitians will need to know. This section is not entered into Datalex.

Exhibit 9.4.2 Biochemistry Flowsheet

MODIFICATION OF DIET IN RENAL DISEASE PATIENT FLOW SHEET
REPORT PREPARED: SEP 29, 1988

PATIENT IDENTIFICATION:
CLINICAL CENTER

STANDARD WEIGHT
HEIGHT

START YEAR: 1986	B 0.0 02/17	B 2.0 05/07	B 3.0 05/22
BLOOD MEASUREMENTS			
TRANSFERR(mg/dl)	232C		211C
ALBUMIN(g/dl)	4.0C		3.9C
CREAT(mg/dl)	4.0C		4.9C
UREA NIT(mg/dl)	56C		50C
SODIUM(mEq/L)	136		138
POTASSIUM(mEq/L)	4.1		4.6
CHLORIDE(mEq/L)	108.0		109.0
BICARB(mEq/L)			16
GLUCOSE(mg/dl)	88		75
CALCIUM(mg/dl)	9.0		8.3
PHOSPH(mg/dl)	4.6		4.6
IRON(mcg/dl)	81		31
MAGNESIUM(mg/dl)	1.9		2.3
WBC(x10/mm)	7.9		7.1
HEMOGLOBIN(g/dl)	10.7		10.4
HEMATOCRIT(%)	31.6		31.7
URIC ACID(mg/dl)			4.8C
BILIRUBIN(mg/dl)			.3C
SGOT(IU/L)			8.0C
LDH(IU/L)			108.0C
TOT CHOL(MG/DL)			188C
TRIGLY(MG/DL)			105C
LDL CHOL(MG/DL)			135C
HDL CHOL(MG/DL)			32C
URINE MEASUREMENTS			
CREAT(mg/day)	706C	687C	833C
UREA NIT(g/day)	5.2C	5.3C	5.8C
PROTEIN(g/day)	.4C	.3C	.2C
PHOSPH(mg/day)	517C	489C	505C
VOLUME(ml)	2138C	2020C	1700C
SODIUM(mEq/day)	81C	79C	61C
POTASS(mEq/day)	41C	53C	49C
EPI(g/kg/day)	.8C	.8C	.9C
DIET RECORD MEASUREMENTS			
PROTEIN INTAKE			
PHOSPHORUS INTAKE			
CALORIES			
WEIGHT(kg)			

"C" denotes a Central Laboratory Measurement

Exhibit 9.4.3 Dietary Compliance Graph

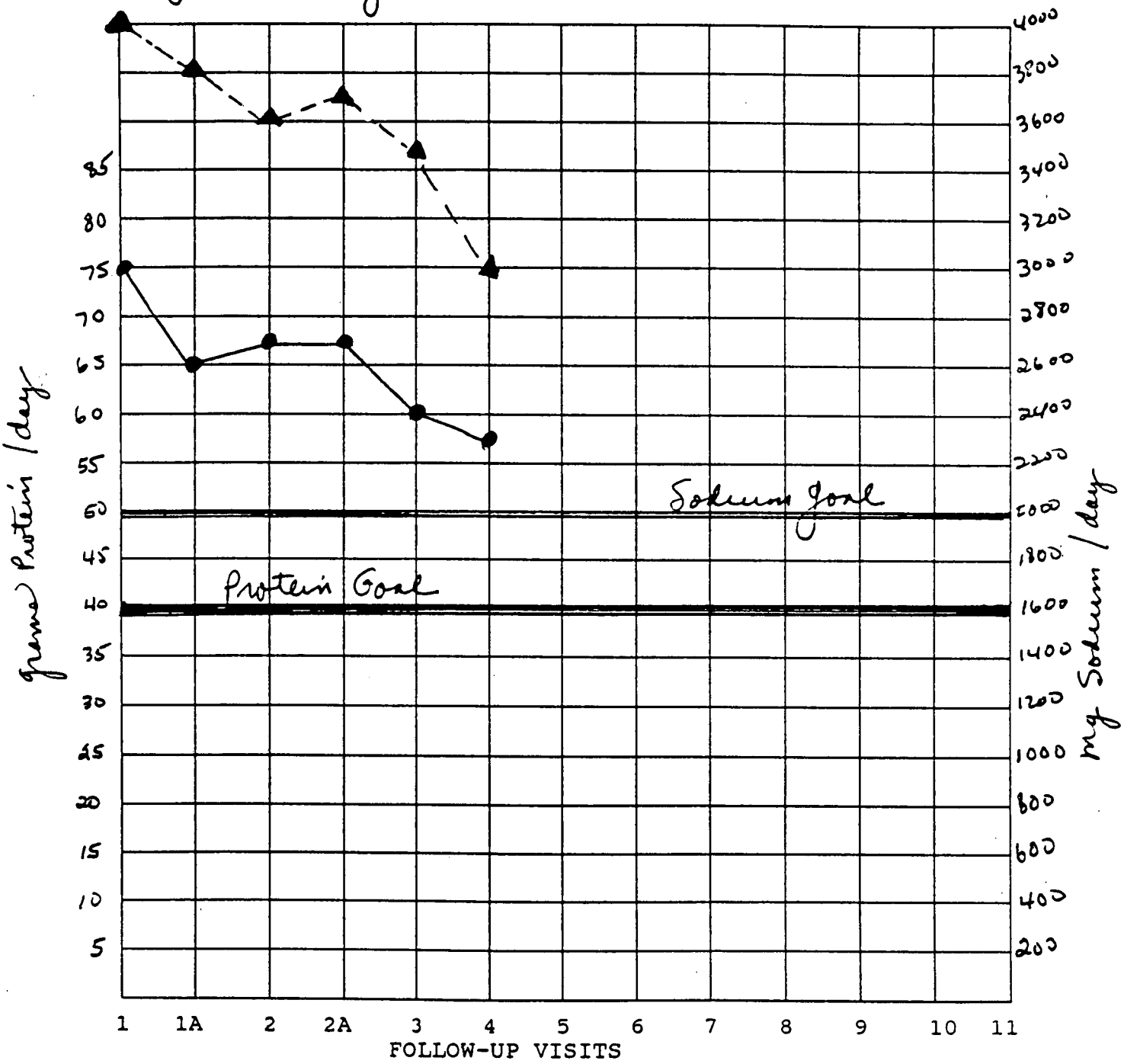
Name Mr. Smith

Diet Group Assignment L

Goal 40 gr protein daily

Blood Pressure Group Assignment Low

Goal 2000 mg Na. daily



Date:	2/89	3/89	4/89	5/89	6/89	7/89							
Weight: (pounds)	190	190	188	189	191	190							

Exhibit 9.4.4

MODIFICATION OF DIET IN RENAL DISEASE
MONTHLY COMPLIANCE FLOW SHEET

PATIENT ID: 153456 ABCD
CLINCAL CENT 1
SBW: 53.8 KG

PROTEIN GOAL (gm/day) 30.94
PROTEIN GOAL (gm/kg) 0.575
PHOS. GOAL: 269-538

	B0.0	B0.5	B1.0	B2.0	B3.0
START YEAR: 1989	01/03	01/17	02/14	03/14	04/10
DIET RECORD MEASUREMENTS:					
PROTEIN INTAKE (GM/DAY)		50.0		42.0	45.0
P INTAKE (MG/DAY)		1200		900	1050
CALORIES (KCAL/DAY)		2500		2350	2300
CALORIES (KCAL/KG)		46.5		43.7	42.8
SODIUM (MG/DAY)		3000		2600	2500
% CHANGE FROM B0A FOOD RECORD:					
PROTEIN: (%)				-16.0%	-10.0%
PHOSPHORUS: (%)				-25.0%	-12.5%
CALORIES: (%)				-6.0%	-8.0%
SODIUM: (%)				-13.3%	-16.7%
% AGREEMENT (WITH STUDY RX):					
EPI (UNA): (%)					
REPORTED PROTEIN: (%)					
AGREEMENT REPORTED PROTEIN AND EPI (UNA):					
REPORTED PROTEIN (GM/KG)				0.78	0.84
EPI (UNA) (GM/KG)				1.10	1.00
% AGREEMENT				71.0%	83.6%
ADHERENCE CATEGORY					
% PILL COUNT					
MDRD VITAMINS					
CALCIUM					
IRON					
KETO ACIDS					
URINE MEASUREMENTS:					
URINE SODIUM (mEq):	130		125	120	110
URINE SODIUM (%) (COMPARISON BASE)					
TOTAL CREAT./24 HOURS					
ANTHROPOMETRY:					
WEIGHT (KG)		57.0	57.5	57.0	56.5
% SBW (SCR-B0)		105.9%	106.9%	105.9%	105.0%
CHANGE FROM B3-(KG)					
% CHANGE FROM B3					
ARM MUSCLE AREA (mm)		275.0		275.0	
% BODY FAT		30.0%		30.0%	
% CHANGE BODY FAT (B0A)				0.0%	

MODIFICATION OF DIET IN RENAL DISEASE
MONTHLY COMPLIANCE FLOW SHEET

PATIENT ID: 153456 ABCD
CLINCAL CENT 1
SBW: 53.8 KG

PROTEIN GOAL (gm/day 30.94
PROTEIN GOAL (gm/kg) 0.575
PHOS. GOAL: 269-538

	F1.0	F1.5	F2.0	F2.5	F3.0	F4.0
START YEAR: 1989	05/10	05/24	06/09	06/23	07/11	08/11
DIET RECORD MEASUREMENTS:						
PROTEIN INTAKE (GM/DAY)			36.0		38.0	35.0
P INTAKE (MG/DAY)			800		850	825
CALORIES (KCAL/DAY)			1875		1900	2000
CALORIES (KCAL/KG)			34.9		35.3	37.2
SODIUM (MG/DAY)			2400		2300	2300
% CHANGE FROM B0A FOOD RECORD:						
PROTEIN: (%)			-28.0%		-24.0%	-30.0%
PHOSPHORUS: (%)			-33.3%		-29.2%	-31.3%
CALORIES: (%)			-25.0%		-24.0%	-20.0%
SODIUM: (%)			-20.0%		-23.3%	-23.3%
% AGREEMENT (WITH STUDY RX):						
EPI (UNA): (%)			156.5%		173.9%	139.1%
REPORTED PROTEIN: (%)			116.4%		122.8%	113.1%
AGREEMENT REPORTED PROTEIN AND EPI (UNA):						
REPORTED PROTEIN (GM/KG)			0.67		0.71	0.65
EPI (UNA) (GM/KG)			0.90		1.00	0.80
% AGREEMENT			74.3%		70.6%	81.3%
ADHERENCE CATEGORY			7		7	7
% PILL COUNT						
MDRD VITAMINS			82.0%		87.0%	85.0%
CALCIUM			90.0%		85.0%	86.0%
IRON			70.0%		72.0%	75.0%
KETO ACIDS						
URINE MEASUREMENTS:						
URINE SODIUM (mEq):	100		97		95	98
URINE SODIUM (%) (COMPARISON BASE)	-17.4%		-19.8%		-21.5%	-19.0%
TOTAL CREAT./24 HOURS						
ANTHROPOMETRY:						
WEIGHT (KG)	56.8				54.0	
% SBW (SCR-B0)	104.1%				100.4%	
CHANGE FROM B3-(KG)	-0.5				-2.5	
% CHANGE FROM B3	-0.98%				-4.42%	
ARM MUSCLE AREA (mm)						
% BODY FAT						
% CHANGE BODY FAT (B0A)						

MODIFICATION OF DIET IN RENAL DISEASE
FOUR MONTH COMPLIANCE FLOW SHEET

PATIENT ID:	153456	PROTEIN GOAL (gm/day)	30.94
CLINICAL CENTER:	1	PROTEIN GOAL (gm/kg)	0.575
SBW:	53.8 KG	PHOS. GOAL:	269-538

	F1.0-F4.0	F5.0-F8.0	F9.0-F12.
START YEAR: 1989			
BIOCHEMISTRIES:			
TRANSFERRIN (AV.)-2	175		
ALBUMIN (AV.)-2	4.8		
TOTAL CHOLESTEROL (MOST RECENT)	178		
LDL CHOLESTEROL	114		
HDL CHOLESTEROL	43		
TRIGLYCERIDES	106		
URINE SODIUM-mEg (AV.)	97.5		
% CHANGE FROM B0-3 (AV.)	-19.5%		
ALLOISOLEUCINE			
ACTION ITEMS/FREQUENCY:			
POTASSIUM-HIGH	2		
DIET RECORD MEASUREMENTS (AV.):			
PROTEIN INTAKE (GM/DAY)	36.3		
P INTAKE (MG/DAY)	825		
CALORIES (KCAL/KG)	35.8		
SODIUM (MG/DAY)	2333		
% AGREEMENT (AV.) (WITH STUDY RX):			
EPI (UNA): (%)	156.5%		
REPORTED PROTEIN: (%)	117.3%		
ADHERENCE CATEGORY:			
MONTH 1:			
MONTH 2:	7		
MONTH 3:	7		
MONTH 4:	7		
% PILL COUNT (AV.)			
MDRD VITAMINS	84.7%		
CALCIUM	87.0%		
IRON	72.3%		
KETO ACIDS			
ANTHROPOMETRY:			
WEIGHT (AV.)	55		
% SBW (AV.)	102.2%		
AV. CHANGE-KG.(B3)	-1.5		
AV. CHANGE-%(B3)	-2.7%		
BLOOD PRESSURE:			
MAP MONTH 1:	93		
MONTH 2:	93		
MONTH 3:	93		
MONTH 4:	93		

Monthly Compliance Flowsheet

Guidelines for Interpretation

Diet Record Measurements: Nutrients reported are from the average of the three-day food record. Calories are reported in both kcal/day and kcal/kg of Standard Body Weight (SBW) per day.

Percentage Change from BOA Food Record: These calculations compare nutrients from the current three-day food record to the nutrients from the BOA three-day food record. The formula used for deriving the values is:

$$\frac{\text{current average - baseline average}}{\text{baseline average}} \times 100$$

Percent Agreement with Study Prescription: These calculations show 1) the agreement between the estimated protein intake (EPI) (as calculated from the UNA) and the study diet prescription:

$$\frac{\text{EPI (UNA)}}{\text{Protein Prescription}} \times 100$$

and 2) the agreement between the average reported protein (from the three-day food record) and the study diet prescription:

$$\frac{\text{Average Reported Protein (gm/kg/day)}}{\text{Protein Prescription (gm/kg/day)}} \times 100$$

Agreement Between Diet Protein Intake and EPI (UNA): The average protein intake from the three-day food record and the estimated protein intake (EPI) from the UNA are compared to show how closely the measures agree with each other. The results are derived from:

$$\frac{\text{Average Reported Protein Intake (gm/kg/day)}}{\text{EPI (UNA) (gm/kg/day)}} \times 100$$

Adherence Category: The adherence category (see Form 76, item 5) which has been assigned for the month is reported. Each of these is defined based on the agreement between: (a) the EPI(UNA) and the prescription and (b) the average protein from the three-day food record and the protein prescription.

Percent Pill Count: This summarizes, by percentage, the degree to which the patient adheres to the prescription for each pill.

Urine Measurements: Urine sodium in milliequivalents per day is reported for each visit at which a collection is obtained. "Urine sodium (%)" compares the urine sodium in the follow-up period to the average of the four urine sodium values obtained during the baseline period. The calculation is:

$$\frac{\text{Current Urine Na (mEq) - Average of BO,B1,B2,B3 Na}}{\text{Average of BO,B1,B2,B3 Urine Na}} \times 100$$

Completeness of the 24 hour collection can be determined from the total urine creatinine value (mg/day) provided on the flowsheet. If the value is less than .5 (women) or .75 (men) grams, it is highly likely that the urine collection is incomplete. An incomplete urine may also be indicated if the creatinine value is substantially less than the value for previous collections.

Anthropometry:

Weight (kg): Actual weight at visits is reported. Note that weight is not reported at GFR visits.

Percent SBW: This is derived from $\frac{\text{current weight}}{\text{SBW}} \times 100$

The standard body weight defined for study purposes is the average of the standard body weights calculated at the Screening and the Baseline Visit 0 visits.)

Change from Baseline Visit 3 (kg): This indicates the absolute weight loss/gain from the Baseline 3 visit to the current visit.

Percent change from Baseline 3: This value indicates the loss or gain, by percent, from the Baseline 3 visit weight as compared to the current weight. This is derived from:

$$\frac{\text{Current Weight - Baseline 3 Weight (kg)}}{\text{Baseline Visit 3}} \times 100$$

Percent Body Fat: This value is reported by the DCC after visits at which skinfolds are measured.

Percent Change Body Fat (BOA): This indicates the percentage change in body fat at the current visit as compared to the BOA visit. It is calculated from:

$$\frac{\text{Current \% Body Fat - BOA \% Body Fat}}{\text{BOA \% Body Fat}} \times 100$$

Four-Month Compliance Flowsheet

Guidelines for Interpretation

BIOCHEMISTRIES

Transferrin, albumin: Each of these are reported as averages of the two values reported during the four-month compliance assessment period.

Cholesterol, lipoproteins, triglycerides: Values reported are those from blood drawn most recently during the four-month compliance assessment period. (Values are drawn only once.)

Urine sodium: The average of the four values obtained during the assessment period is reported.

Percent change from BO: This value compares the current mean urine sodium value (above) to the average from the four values obtained during the baseline period:

$$\frac{\text{Urine Sodium (4-month avg.)} - \text{Baseline Average}}{\text{Baseline Average}} \times 100$$

Alloisoleucine: The presence or absence of alloisoleucine is reported for each four-month assessment period.

ACTION ITEMS/FREQUENCY

Up to four Action Items may be listed in the far left column (example lists "potassium-high"). The number of occurences, or frequency, is reported for each item in the column for the appropriate four-month assessment period.

DIET RECORD MEASUREMENTS

The average intake of protein, phosphorus, calories, and sodium from each of the three-day food records collected during the assessment period is reported.

PERCENT AGREEMENT WITH STUDY PRESCRIPTION

The agreement between the EPI (UNA) and the study diet prescription is averaged for the four-month assessment period:

$$\frac{\text{Avg. EPI (UNA) over 4 months}}{\text{Protein Prescription}} \times 100$$

The agreement between the diet protein intake (from three-day food records) is similarly compared to the study diet prescription:

$$\frac{\text{Avg. Protein from Food Records}}{\text{Protein Prescription}} \times 100$$

ADHERENCE CATEGORY

Adherence categories which have been assigned (1 - 9) are listed for each month during the assessment period.

PERCENT PILL COUNT

The average proportion of pills taken during the four-month period is reported in percent.

ANTHROPOMETRY

Weight: The average of the two weights reported during the four-month assessment period is reported. (Weights taken at GFR visits are not reported.)

Percent SBW: The average of weights reported (above) is compared to the SBW:

Average change from Baseline 3 (kg): The absolute change in weight from the Baseline 3 visit as compared to the average weight for the current four-month period is reported in kilograms:

$$\text{Baseline 3 Weight} - \text{Average Weight (4-month)}$$

Average percent change from Baseline 3: The average percentage increase or decrease in the weight from the current four-month period as compared to the weight at the Baseline 3 visit:

$$\frac{\text{Average Weight (4-month)} - \text{Baseline 3 Weight}}{\text{Baseline 3 Weight}} \times 100$$

BLOOD PRESSURE

Mean arterial pressure (MAP) is reported for each month during the assessment period.

For patients in category one, ((EPI(UNA) within the acceptable range) the dietitian should acknowledge their performance and encourage continual progress toward goals. For patients who fall into categories two and three, where their dietary protein is inconsistent with the prescription, the dietitian should continue to develop strategies to improve the accuracy of the patient's three-day food record. These efforts, however, in terms of the dietitian's time, may be of lower priority as compared to time spent with patients who are outside of the ± 30% range for EPI(UNA).

Categories 4-9 describe situations where EPI(UNA) is outside of the ± 30% range. The focus of the compliance monitoring process will be on these six nonadherent categories and approaches to bring these patients closer to compliance.

Exhibit 9.4.5

Categories of Adherence to EPI(UNA) and Reported Protein as Compared to the Study Diet Prescription

Adherence Category	Percent of Prescription	Definition of Adherence
1. EPI(UNA)	70-130%	
Reported Protein	70-130%	Both within acceptable ranges
2. EPI(UNA)	70-130%	EPI(UNA) within acceptable ranges
Reported Protein	<70%	Reported Protein below acceptable ranges
3. EPI(UNA)	70-130%	EPI(UNA) within acceptable ranges
Reported Protein	>130%	Reported protein above acceptable ranges
4. EPI(UNA)	>130%	
Reported Protein	>130%	Both above acceptable ranges
5. EPI(UNA)	<70%	
Reported Protein	<70%	Both below acceptable ranges
6. EPI(UNA)	>130%	EPI(UNA) above acceptable ranges
Reported Protein	<70%	Reported Protein below acceptable ranges
7. EPI(UNA)	>130%	EPI(UNA) above acceptable ranges
Reported Protein	70-130%	Reported Protein within acceptable ranges
8. EPI(UNA)	<70%	EPI(UNA) below acceptable ranges
Reported Protein	>130%	Reported Protein above acceptable ranges
9. EPI(UNA)	<70%	EPI(UNA) below acceptable ranges
Reported Protein	70-130%	Reported Protein within acceptable ranges

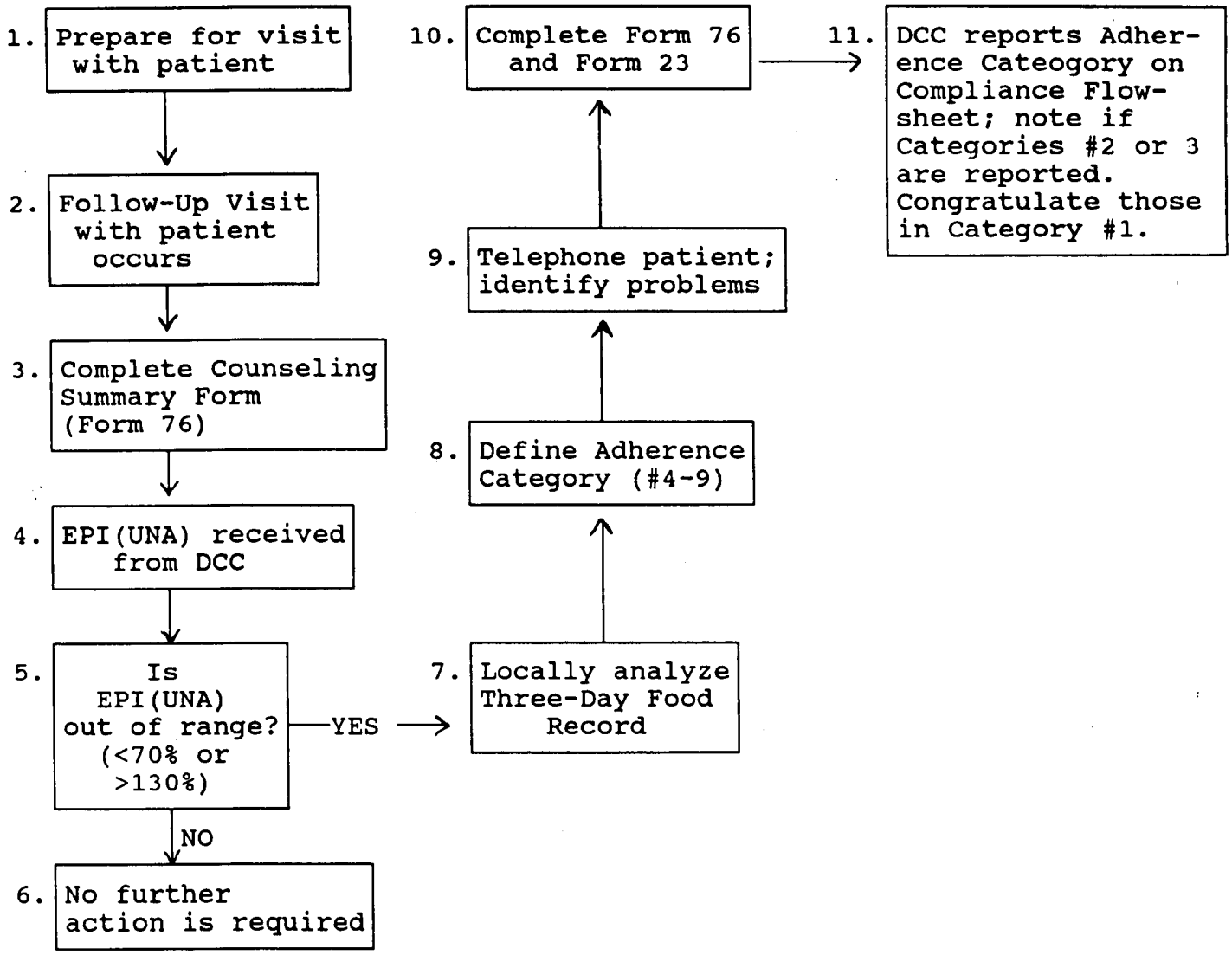
9.5 Monthly Compliance Monitoring

To maximize compliance, a well-defined monitoring process has been developed. This process involves a formal assessment of compliance at each Follow-up visit beginning with Follow-up 2 using the Counseling Summary Form (Form 76). Bimonthly contact procedures are initiated in response to an EPI(UNA) outside of the ± 30% range.

A schematic which describes the monthly compliance monitoring process lists the steps the dietitian should follow to assess compliance on a monthly basis (Exhibit 9.5.1). This schematic addresses adherence to the protein prescription. Each step is described below.

STEPS	ACTION PLAN
1	The dietitian prepares for the follow-up visit.
2	The patient attends the visit. The dietitian begins to assess compliance by asking the patient questions from Form 76.
3	The dietitian completes Form 76.
4	Within five working days of receipt of the urine specimen at the Central Lab, the DCC will report to the clinical center the EPI(UNA) via the Biochemistry Flowsheet and/or the Urine Report.
5	The dietitian will determine whether the EPI(UNA) is in or out of the adherence range (<70% or >130%). This is calculated by the formula: $\frac{\text{EPI(UNA) g/kg/SBW/day}}{\text{Protein prescription g/kg}} \times 100$
6	If the EPI(UNA) is within range (Categories 1-3), the dietitian can wait for the Nutrient Summary data from the NCC and does not need to locally analyze the three-day food record.
7	If the EPI(UNA) is outside of the adherence range (<70% or >130%) the dietitian will analyze the three-day food record completed for that monthly visit using the CDDT system. The mean dietary protein intake will be calculated. The percent agreement between the mean protein in gms/kg/day and the protein prescription will next be calculated: $\frac{\text{x protein (g/kg/SBW/d)}}{\text{Protein prescription g/kg}} \times 100$
8	The dietitian will compare the dietary protein intake and the EPI(UNA) to the Study Diet Prescription and determine the category (4-9) which describes the relationship between these three values (Exhibit 9.4.5).

Exhibit 9.5.1 Monthly Compliance Monitoring Flow



9 Within 12 days of the visit, the dietitian will telephone the patient to identify problems. Then the dietitian can assist the patient in identifying new strategies which will help him/her begin to remediate the problem before the next visit.

10 The dietitian will then complete the Action Item Response Form (Form 23) and the Counseling Summary Form (Form 76) indicating by the visit number that an adherence contact has occurred (see Instructions to Form 76). Contact with the patient and completion of the forms should occur within 12 working days of the last visit.

11 After receipt of Nutrient Summary Report from the NCC, the DCC will report the Adherence Category on the Monthly Compliance Flowsheet. The dietitian should review the Monthly Compliance Flowsheet to confirm the adherence category (1-9). For patients in categories 2 and 3 where EPI(UNA) is within acceptable range but dietary protein values from the three-day food record are above or below the prescription, the dietitian should prepare a counseling plan for the next visit to address the discrepancy.

For patients in adherence category 1, where both EPI(UNA) and dietary protein are within an acceptable range, the next visit should include acknowledgement of the patient's achievement and encourage progress toward goal for the next visit.

9.6 Four-Month Compliance Monitoring

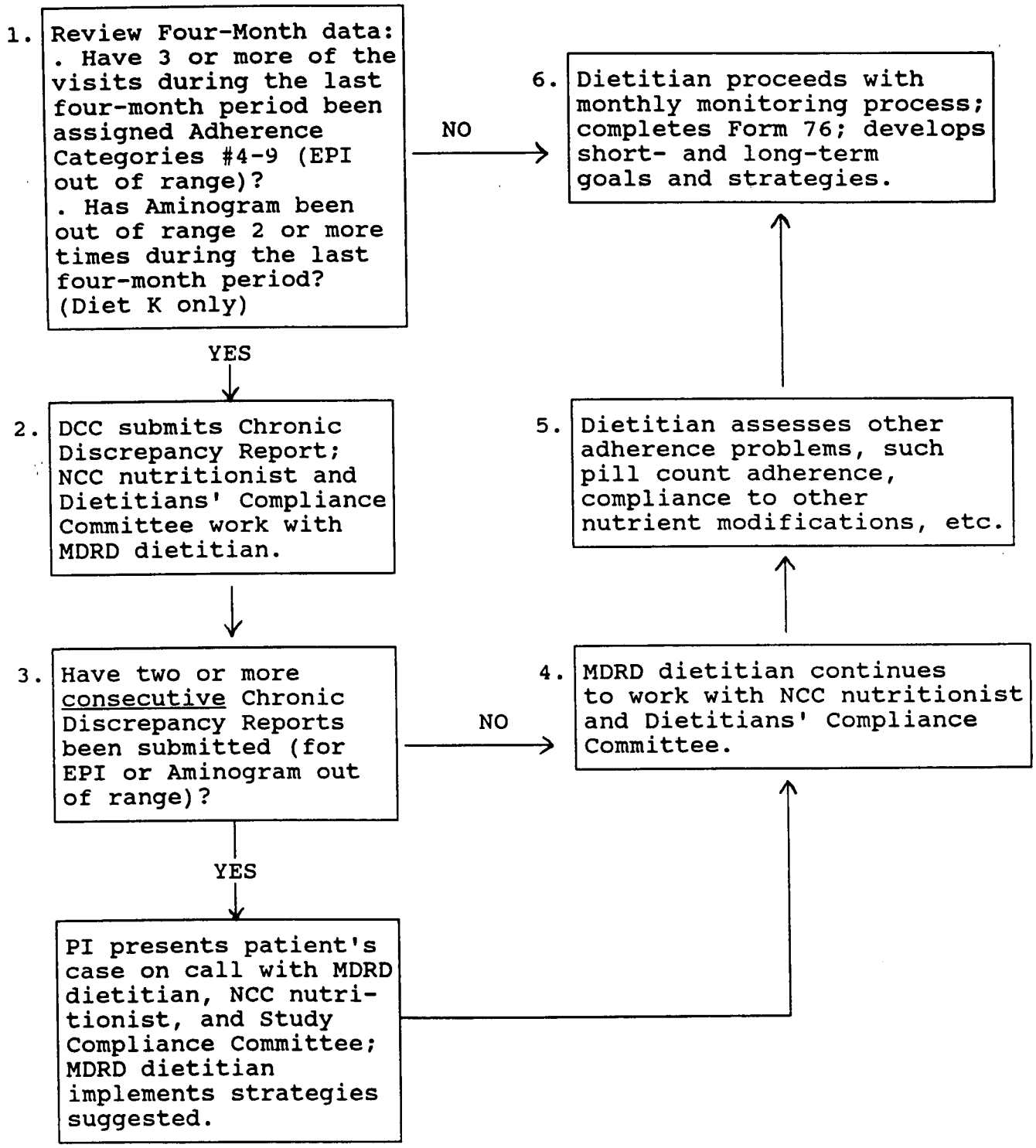
Every four months, beginning with Follow-Up Visit 5, the DCC will distribute the Four-Month Compliance Flowsheet. The four-month compliance monitoring process is initiated by the dietitian at Follow-up visits 5, 9, 13, 17, etc. The dietitian is asked to review this data in order to assess the patient's overall performance. The process for monitoring patients in adherence categories 1-3, will be the same as steps 3-10 in the monthly process. For patients in categories 4-9 who are outside of the compliance range, the four-month process will require a more aggressive approach in order to help these patients who are developing a more "chronic" adherence problem.

The dietitian and other members of the study team should meet jointly before the next follow-up visit to formulate plans for intervention in the next four-month period. The counseling plan should incorporate strategies to improve a patient's overall performance and compliance.

Specific steps for the four-month monitoring process are outlined below and a schematic representation follows (Exhibit 9.6.1). Again the focus is on patients who fall into adherence categories 4-9 or those patients who are having problems with caloric intake.

STEPS	ACTION Plan
1	The dietitian should review the Four-Month Compliance Flowsheet to identify patients who are having persistent adherence problems and evaluate the previous four-month monitoring period to assess whether: A. Adherence categories #4-9 have occurred three or more times in the past four months; B. For patients on Diet K: Aminogram values have been out of range two or more times in the past four months; C. Other adherence problems are occurring and to what degree they are interfering with adherence to the Study Diet Prescription (see Manual of Operations, Section 8.2.7.1);
2	If 1A or B has occurred, the DCC will submit a Chronic Discrepancy Report to the Clinical Center and the NCC. (The Chronic Discrepancy Report is based on discrete four-month compliance assessment periods, e.g. F1.0-4.0, F5.0-8.0, etc.; it is not a running evaluation with reports based on visits F5.0-8.0, F6.0-9.0, and so on.) An Intervention Nutritionist from the NCC will be assigned to work with the clinical center dietitian. Members of the Dietitians' Compliance Committee will be available to offer support, ideas, solutions, and strategies. Note: Whenever EPI(UNA) or the Aminogram is out of range, the dietitian should complete the Action Item Response Form (Form 23).
3	If two consecutive Chronic Discrepancy Report Forms have been submitted, the PI will present the patient's case on a conference call with the clinical center dietitian, the Study Compliance Committee, and the NCC Intervention Nutritionist. The dietitian will incorporate the recommendations of the Committee and the NCC and will continue to work with the NCC and the Dietitian's Compliance Committee to improve the patient's overall adherence.

Exhibit 9.6.1 Four-Month Compliance Monitoring Flow



4 If only one Chronic Discrepancy Report Form has been submitted, or if more than one has been submitted nonconsecutively, the clinical center dietitian will continue to work with the NCC Intervention Nutritionist and the Dietitian's Compliance Committee regarding the compliance problem previously identified.

5 For persistent compliance problems (for example if three or more consecutive Chronic Discrepancy Report Forms have been submitted) the PI should re-examine the case and present the patient to the Study Compliance Committee only at his/her request and/or if new issues have arisen.

6 The dietitian should review other adherence problems, such as adherence to pill counts or compliance to phosphorus or sodium goals. (See Step previous 1.D.)

7 The patient attends Follow-up Visits 5, 9, 13, 17 etc. and the dietitian completes Form 76 and begins the usual monthly compliance monitoring process. It is important, however, that the counseling strategies developed with the patient at this compliance assessment visit incorporate solutions to problems identified after assessing the one month and four month flowsheets.

8 Alloisoleucine and ornithine (Aminogram) levels - the Study Compliance Committee will review all patients whose aminogram levels suggest noncompliance (see Protocol, Section 13 and Manual of Operations, Chapter 1, Section 9.3.1).

Section 10

MDRD Low Protein Food Products

10.1 Product Selection

Listed below are Low Protein food products which have been recommended for use in the MDRD Study. The decision to include these foods was based on four sources:

1. A summary of Phase II dietitians' evaluations of food products (from a survey conducted by a Phase II dietitian).

2. A journal article: Van Duyn, M.A. Acceptability of selected low protein products for use in a potential diet therapy for chronic renal failure. Journal of the American Dietetic Association, Vol. 87, pp. 909-914, July, 1987.

3. Taste panels of MDRD NCC staff.

4. A listing of orders of low protein products placed by clinical centers in Phase II.

The products with the greatest acceptability are supplied by these distributors:

Med-Diet Laboratories Inc., (Kingsmill and Aglutella brands)
1409 Fairfield Wood Street
Minnetonka, MD 55343
1-800-633-3438
Pat Marksberry, Acct. Manager

Dietary Specialties (Wel-Plan and Aproten brands)
P.O. Box 227
Rochester, NY 14601
(716) 263-2787
1-800-544-0099
Katherine G. Marchetti, General Manager

R and D Laboratories, Inc. (Ratatouille and Sauces)
4204 Glencoe Ave.
Marina del Ray, CA 90292
(213) 305-8053
1-800-338-9066
Rhoda Makoff, Ph.D., President

10.2 Recommended Low Protein Food Products

Med-Diet:

- Kingsmill All Purpose Mix--Unimix
  one 13.2 oz. pouch makes one loaf

- Low Protein Dairy Drink Mix
  one 27.5 oz. package makes 1 quart

- LO PRO Vacuum Packed Rice Bread
  (19.8 oz. loaf)

- Med-Diet Chocolate Chip Cookies
  (7 oz. package)

- Med-Diet Spice Cookies
  (6 oz. package)

Dietary Specialties:

- Wel-Plan: Macaroni,
  Short Cut Spaghetti,
  Spaghetti Rings
  (8-3/4 oz. box makes 5 servings)

- Wel-Plan Cream Filled Vanilla Wafers
  (3-1/2 oz. package)

- Prono Low Pro Gelled Dessert Mix
  (one 3 oz. package makes 6 servings)

- Aproten Rusks
  8-1/2 oz. box (24/box)

R and D Laboratories:

- Ratatouille
  (10 oz. rerort package)

- Creamy Lemon Herb Sauce
  (25 gm. package)

- Herb Garlic Sauce
  (25 gm. package)

- Tomato Sauce
  (42 gm. package)

Other low protein foods, in addition to those recommended above, may be ordered at the discretion of the dietitian in order to enhance patient compliance. Other low protein food items which may also be acceptable include:

- Kingsmill Cake and Cookie Base
- other Aproten Pastas
- Wel-Plan Sweet Cookies
- Wel-Plan Cream Filled Chocolate Wafers

10.3 Receiving and Storage

The NCC is responsible for supplying the clinical centers with low protein products for their patients. The clinical centers will receive an initial shipment of the foods listed above in March 1989. Shipments should be checked for completeness of the order, expiration dates and condition of the packages. If the order is not complete or the shipment is damaged, please contact the NCC. The products need to be

stored in a clean, dry place and checked periodically for expiration dates.

10.4 Ordering Low Protein Food Products

The clinical centers will need to maintain a perpetual inventory and will reorder low protein products as necessary.

Special Food Products Order forms for each of the food distributors are available on 4-part NCR paper. The dietitian will order from each distributor by completing the forms and sending the copies as follows:

- the white and yellow copies to the food distributor
- the pink copy to the NCC
- retain the gold copy for the clinical center files

These forms are not official MDRD forms and are NOT entered into Datalex. The NCC will track this information for budgetary purposes.

If the clinical center does not receive the products from the distributors as ordered, first contact the distributor to correct the situation. If it is not corrected by the distributors, contact the NCC.

10.5 Distribution of Low Protein Food Products

10.5.1 Introductory Package

An "Introductory Package" will be provided for all Diet K and Diet L patients at the Follow-Up 1-A visit. This will provide the patient an opportunity to try these foods at home and decide which foods he would like to use.

The introductory package provided in small white shopping bags may include:

Food Item	Amount
- LO PRO Imitation Dairy Drink Mix	1 pkg
- Kingsmill Unimix Baking Mix	1 box
- Wel-Plan pasta	1 box
- Aproten Rusk	1 box
- Low Protein Cookies	1 pkg
- Ratatouille	1 pkg

The dietitian will complete page 1 and the right column of page 2 of the Special Food Products Order Form #79 to record which foods were distributed at this visit. Form #79 is then entered into Datalex.

The patient will also receive a new copy of page 2 of Form #79. The patient is encouraged to try the Special Food Products at home and return the form at his next visit. He is asked to return Form #79 with the left column of page 2 completed indicating which food products and the amounts he would like for the next month.

10.5.2 Monthly Food Package

When the patient returns page 2 of Form #79 each month at his regular monthly visit, the dietitian will provide him with his Special Food Package in a large white shopping bag and complete page one and the right column of page 2 of the forms. When the right column of page 2 is completed, Form #79 can be entered into Datalex.

Thereafter, at each visit, the patient receives a new copy of page 2 of Form #79 with each monthly order of Special Food Products to complete and return at his next visit. The dietitian completes page one and the right column of page two.

Section 11

Special Studies After Stop Points

11.1 Study C

Study A patients who reach a GFR stop point are eligible to enter Study C (Protocol Section 14). The goal of Study C is to compare the effects of a change from Diet M or Diet L to Diet K without a change in blood pressure regimen in the same patient with progressive change in GFR. Patients in Study C are followed per the protocol for Study B patients assigned to Diet K.

11.2 Other Patients Reaching Stop Points

After reaching stop points, Study A patients not entering Study C, Study B patients, and Study C patients are followed even if no longer on a study diet according to Protocol.

If the patient has been receiving keto acids, the physician may choose to continue these if it is in the best interest of the patient. However, the MDRD Study is not obligated to provide the the keto acids (Protocol Section 13.4).

Post Stop Point Visits are scheduled every four months until Close Out (Protocol, Section 12.12). At each visit a 24-hour recall and anthropometric data are collected.

Section 12

The Computerized Diet Design Tool

12.1 Purpose and Features

The Computerized Diet Design Tool (CDDT) is a software package that was developed through a cooperative effort of a committee of Phase II dietitians, the Case Western Reserve Nutrition Coordinating Center, and the CBORD Company. The system was developed during Phase II of the MDRD Study with implementation during Phase III. The main data base, the Food Dictionary, contains over thirteen hundred food items. Each item is analyzed for sixteen nutrients.

The CDDT is an interactive program that can be used at the local center to assist the dietitian in a number of ways when working with patients. For example, the CDDT allows the dietitian to create an individualized data base for the patient by key entering all the foods that the patient likes while excluding foods that the patient dislikes.

In planning menus for the patient, the system enables the dietitian to control many nutrients simultaneously and allows the patient to have an active role in the process. The monitor shows a "running total" of all selected nutrients from the food items entered in the menu worksheet. Immediate adjustments to the menu may be made to insure that the patient is within his/her target goal for the day.

The system provides for on-site analysis of three-day food records and twenty-four hour recalls. For these days the dietitian is also able to obtain averages of nutrients and graphically display the nutrient information.

With the recipe analysis program the dietitian can further customize the data base to the patient. Recipes are entered, analyzed for nutrient content, and filed in the data base. This aspect of the CDDT is particularly useful when patients are followed over a long period of time.

The Computerized Diet Design Tool allows the dietitian to give the patient immediate feedback in regard to his/her compliance to the prescribed diet. As described above, local analysis enables the patient to see how closely he/she is to target and can immediately reveal how changing food selections could result in improved compliance.

For further detail and information, refer to the Reference Guide and Tutorial for Self-Teaching: Computerized Diet Design Tool.