

Modification of Diet in Renal Disease Study

Instructions for Completing Form 70

BASELINE DIET PRESCRIPTION FORM

PURPOSE: To provide a calculation and summary of the
Baseline Diet Prescription

COMPLETED BY: Dietitian after Baseline OA and before Baseline
Visit 1. To complete this form you will need:
DCC Flow Sheet and Report of BOA Three-Day Food
Record
(Note: This form should be entered into Datalex).

Following are instructions for completing specific questions on
Form 70.

Page 1Item

5. Usual Daily Dietary Protein Intake** is an average
calculated from the EPI and the Average Dietary Protein
Intake.

- a) EPI (estimated protein intake) gm/kg/day is from the
DCC flow sheet. This is a calculation using urea
nitrogen plus a factor (0.031) for nitrogen loss in
feces and non-urea nitrogen losses times standard body
weight. To convert nitrogen to protein, this is
multiplied by 6.25. U Prot is the 24 hour urine
protein excretion in excess of 5 g/day and is added to
the equation.

$$\text{EPI} = 6.25 \times \frac{\text{Urea Nitrogen} + [0.031 \times \text{Std Bd Wt}]}{\text{Standard Body Weight}} + \text{U Prot}$$

- b) Average Dietary Protein Intake (gm/day) - use the
average of the Three-day food record obtained at
Baseline Visit OA. Code which method was used to
analyze the Three-Day Food Record.

1 = NCC Data Base Nutrient Summary
2 = CDDT (Computerized Diet Design Tool)

- c) Divide Protein Intake in grams per day by Standard Body
Weight to get gram/kg/day.
- d) Total items 5a and 5c
- e) Divide the total in 5c by 2. This gives the average of
the EPI and the dietary protein intake in grams per kg
per day.

**Note calculations should not be completed unless both EPI and
average Dietary Protein Intake Values are available.

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Item6. Baseline Diet Protein Prescription

Use the chart to determine the protein prescription based on the usual protein intake, 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 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 had recently been restricted or if this was 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 protein intake to 0.90 to 1.30 gm/kg/day, he should be excluded from further participation since it is unlikely he will be a candidate for randomization. (Also see Protocol, Page 9.7)

7. Baseline Diet Calorie Prescription

- a) Code which method was used to analyze Three-Day Food Record from baseline visit OA:

1 = NCC Data Base (Nutrient Summary Report)
2 = CDDT (Computerized Diet Design Tool)

- b) Enter the Average Calorie Intake from BVOA Three-Day Food Record.

- c) Estimated Calorie Range

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.

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- d) Baseline Diet Calorie Prescription is a range based on:
- b) the average calorie intake at BVOA
 - c) the estimated calorie range
 - d) clinical judgement

It may be useful to give a wide calorie range during Baseline to enable the patient to have flexibility in his eating choices and then to more closely assess his caloric needs for his Study Diet Prescription.

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For DCC Use Only
Rev. 3 1/15/89

E ___
V ___
T ___

Form # 70
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**Modification of Diet in Renal Disease Study
Baseline Diet Prescription Form**

Purpose: To provide a calculation and summary of the BASELINE DIET PRESCRIPTION.

To be completed by the dietitian after Baseline 0A and before Baseline Visit 1. To complete this form you will need the DCC Flow Sheet and the report of B0A 3-Day Food Record. (Note: This form should be entered into Datalex.)

FORM # Z 0

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center.....
4. a. Date of Visit at which this prescription is given..... / /
- b. Visit Type..... B
- c. Visit Number..... 0 1 0

5. Usual Daily Dietary Protein Intake

This is an average calculated by the following:

- a. EPI from DCC flowsheet gm/kg/day (from B0 Visit).....
- b. Method used to determine Average Dietary Protein Intake (gm/kg/day) obtained from the Baseline Visit B0A 3-Day Food Record
 - 1 = NCC Data Base
 - 2 = CDDT

c. Average Protein intake from 3-day food record (gm/kg/day):

$$\begin{array}{rcl}
 \text{Protein Intake from} & \div & \text{Standard Body Weight} \\
 \text{3-day food record} & & \text{(from DCC Flow Sheet)} \\
 \text{(grams per day)} & & \\
 \hline
 & = &
 \end{array}$$

- d. Total items 5a and 5c (gm protein/kg/day).....
 - e. Usual Protein Intake (g/kg/day) Total (from 5d) divided by 2.....
6. Baseline diet protein prescription range (gm/kg/day) Use chart below.
- a. Minimum protein prescription
 - b. Maximum protein prescription

| GFR (ml/min/1.73m ²) | Usual Protein Intake (g/kg/day) (item 5e) | 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 |

[▼] At end of baseline, would not be eligible to be randomized

**Modification of Diet in Renal Disease Study
Baseline Diet Prescription Form**

7. Baseline Diet Calorie Prescription

a. Method used to determine Average Calorie Intake obtained from Baseline Visit B0A
3-Day Food Record.....
1 = NCC Data Base
2 = CDDT

b. Average Calorie Intake (Kcal/day).....

c. Estimated Calorie Range

i. Minimum:

$$30 \text{ Calories} \times \frac{\text{_____ kg}}{\text{Std Body Weight (DCC Flow Sheet)}} = \text{_____ Kcals}$$

ii. Maximum:

$$45 \text{ Calories} \times \frac{\text{_____ kg}}{\text{Std Body Weight (DCC Flow Sheet)}} = \text{_____ Kcals}$$

d. Calorie Prescription is a range based on clinical judgment, Average Calorie Intake (Question 7b) and Estimated Calorie Range (Question 7c).

i. Minimum Baseline Diet Calorie Prescription (Kcal/day).....

ii. Maximum Baseline Diet Calorie Prescription (Kcal/day).....

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. *Do not send this form to the NCC.* Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
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