

Modification of Diet in Renal Disease Study

Instructions for Completing Form 72

SPECIAL DIETARY CONSIDERATIONS FORM

PURPOSE: To provide a calculation and summary of any changes to the Study Diet or additional Dietary Supplements or Prescriptions.

COMPLETED BY: Dietitian ONLY for patients who require changes in diet prescription due to Action Items or additional dietary considerations at any time during Follow-Up.

(Note: This form should be entered into Datalex)

To complete this form you will need:

DCC Flow Sheet

Nutrient Summary Report from NCC

Dietary Information Summary Report

INSTRUCTIONS:

For Study C patients - Post stop point use visit type = K. Only visit numbers with .0 or 1.5 and 2.5 are allowed. No .8 or .9's are acceptable.

Item 8: Alteration in Energy and Protein Prescription for Albumin and Transferrin Action Items and for Patients on Diet K not Taking Ketoacids and Whose Unadjusted EPI is <0.40 g/kg/day.

A) Energy

For patients with an Action Item for declining or low serum albumin or transferrin, the following steps should be taken (see Protocol, Section 13):

1. Repeat the measurement in one month.
2. If it persists, alter energy prescription as indicated below:

DIET	WEIGHT (%SBW)	ACTION
All	≤ 120% (≤ 115% in diabetics)	Increase energy intake (until patient objects)
All	> 120% (> 115% in diabetics)	Increase energy intake (until patient objects or gains weight)*

*Interpretation: The goal is to provide sufficient calories to resolve the Action Item but not to the degree that the patient gains excessive weight.

The measurement should be evaluated again after one month of increased caloric intake. Whether further action should be instituted at this time, such as increasing protein intake, depends on evaluation of change in the measurement (if any) and clinical judgement.

For example, if serum albumin or transferrin has not declined further, or has slightly increased (yet not to normal), the goal would be to continue increasing the caloric intake without instituting an increase in the protein prescription.

If, however, after one month a patient were unable to increase caloric intake sufficiently enough to maintain or increase the albumin or transferrin, and it is your assessment that this will not change, an increase in protein intake would be warranted (see below).

If after two to three months of increased caloric intake the measure does not begin to increase, or increases at such a marginal rate that the patient is at potential risk, an alteration in the protein intake should be made.

(Changes in calorie prescription must be noted on Form 72, Item 10.)

B) Protein

3. For patients on Diet K who are not taking keto acid supplements and whose unadjusted EPI < 0.4 g/kg/day and where the Compliance Committee, in consultation with the P.I., recommends increasing the protein prescription, the prescription should be changed to 0.575 g/kg/day.
4. For albumin and transferrin action items, refer to Table 13.1, Section 13 of the Protocol for alterations in the protein prescription. Examples for each diet follow.

Diet M - Most recent EPI (UNA) 1.0 g/kg/day:

1. Do not alter protein prescription or intake. Continue to monitor serum albumin or transferrin level. Continue to encourage adequate calorie intake.

Diet M - Most recent EPI (UNA) < 1.0 g/kg/day:

1. Increase protein intake to 1.0 g/kg/day. (Note that the prescription is 1.3 g/kg/day. However, this is an example where - despite the prescription - the patient is ingesting less than 1.0 g/kg/day. Thus, the prescription does not change.)

2. The added protein should be of high biological value (HBV). For example, if the patient is ingesting 0.8 g/kg/day (defined by EPI/UNA), 0.2 g/kg/day (1.0 - 0.8) should be HBV. Make note of any action taken on the Action Item Response Form (Form 23) and on the Summary of Counseling Plan (Form 76).

Diet L - Most recent EPI (UNA) 0.7 g/kg/day:

1. Do not alter protein prescription or intake. Continue to monitor serum albumin or transferrin level. Continue to encourage adequate calorie intake.

Diet L - Most recent EPI (UNA) 0.55 - 0.69 g/kg/day:

1. Increase protein prescription to 0.7 g/kg/day.
2. Complete Special Dietary Considerations Form (72).
3. Note that half of the protein that is added must be HBV. To calculate the new prescription, follow these steps:

Example: Patient ingesting 0.55 g/kg/day,
SBW = 60.0 kg

a.
$$\begin{array}{rcll} 0.70 & \times & 60.0 & = & 042.0 \\ \text{New Protein Rx} & & \text{SBW} & & \text{gms protein} \end{array}$$

- b. See Study Diet Rx Report, item 5, for portion of former Total Protein Rx that must be HBV: 12.1^* gms/day

* (Former rx of 34.5gms protein/day \times 0.35 = 12.1 for this example)

- c. Take the difference between the current intake (0.55 g/kg) and the new prescription (0.70 g/kg); divide by 2:

$$(0.70 - 0.55)/2 = 0.075 \text{ g/kg/day}$$

(This provides half of the added protein as HBV.)

- d. Multiply (c) by the SBW to obtain gms protein/day: $0.075 \times 60.0 = 4.5 \text{ gms}$

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- e. Add (b) and (d) to obtain the portion of the new protein prescription that must be high biological value: $12.1 + 4.5 = 16.6$

New Protein Prescription = 42.0 gms/day
(0.70 g/kg)
Amount which must be HBV = 16.6 gms/day

Diet L: - Most recent EPI (UNA) < 0.55 g/kg/day:

1. Increase protein intake to 0.55 gm/kg/day:

$$\frac{0.55 \times \text{SBW}}{\text{New Protein Intake}} = \frac{\text{gms protein/day}}{\text{gms protein/day}}$$
2. Calculate portion of new intake which must be HBV Protein:

$$\text{Gms Protein/Day} \times 0.35 = \text{_____} . \text{_____}$$
3. Note that the actual prescription does not change (stays at 0.575 g/kg/day). Dietary intake, however, is increased to 0.55 g/kg/day. Record action taken on the Action Item Response Form (23) and in the Summary of Counseling Plan (Form 76). Note: Form 72 does not need to be initiated as the prescription did not change.

Diet K - Most recent EPI (UNA) 0.40 * g/kg/day:

1. Do not alter protein prescription or intake. Continue to monitor serum albumin or transferrin levels. Encourage adequate calorie intake.

*DCC calculates EPI(UNA) values for Diet K based on dietary intake only; the contribution from the ketoacid supplement is not included.

Diet K - Most recent EPI (UNA) 0.28 - 0.39 g/kg/day:

1. Increase protein prescription to 0.4g/kg/day.
2. Complete Special Dietary Considerations Form (Form 72).

Diet K - Most recent EPI (UNA) < 0.28 g/kg/day:

1. Increase protein intake to 0.28 g/kg/day.

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2. Note that the actual prescription does not change (stays at 0.28 g/kg/day). The remedial action is to increase intake to 0.28 g/kg/day. This should be noted on the Action Item Response Form (23) and on the Summary of Counseling Plan (Form 76).

Item 9: Altered Phosphorus Prescription

- a) Enter either 1=Yes or 2=No. If "2" is entered, 9b and 9c may be left blank.
- b) Refer to Table 13.2, Section 13 of the Protocol for alterations in the phosphorus prescription. Examples for each diet follow.

TREATMENT OF HIGH SERUM PHOSPHORUS**Diet M**

Phosphorus intake (from most recent Three-Day Food Record as analyzed by the NCC)

> 20 mg/kg/day:

1. Reduce intake to 16-20 mg/kg/day
2. Prescription does not change.
3. Note action taken on the Action Item Response Form (23) and Summary of Counseling Plan (Form 76).
4. Continue to monitor phosphorus intake and serum phosphorus levels.

Phosphorus intake 16-20 mg/kg/day:

1. Reduce phosphorus intake to less than 16 mg/kg/day (new goal depends on serum level, patient's ability to reduce intake, physician's recommendation).
2. Do not reduce protein intake to less than 1 g/kg/day.
3. Complete Special Dietary Considerations Form (72) to record new prescription.

Phosphorus intake <16 mg/kg/day:

1. Add phosphorus binders (physician prescription).
2. Reduce phosphorus prescription to <16 mg/kg/day; complete Form 72.
3. Monitor phosphorus intake with the goal of maintaining intake at < 16mg/kg/day without reducing protein intake to less than 1 g/kg/day. (Primary treatment is addition of binders).

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Diet L

Phosphorus intake > 10 mg/kg/day:

1. Reduce intake to 5-10 mg/kg/day.
2. Prescription does not change.
3. Note action taken on the Action Item Response Form (23) and Summary of Counseling Plan (Form 76).

Phosphorus intake ≤ 10 mg/kg/day:

1. Add phosphorus binders (physician prescription).
2. Prescription does not change. Maintain intake at 5-10 mg/kg/day.
3. Complete Special Dietary Considerations Form.

Diet K

Phosphorus intake > 9 mg/kg/day:

1. Reduce phosphorus intake to 4-9 mg/kg/day.
2. Prescription does not change.
3. Note action taken on the Action Item Response Form (23) and Summary of Counseling Plan (Form 76).

Phosphorus intake ≤ 9 mg/kg/day:

1. Add phosphorus binders (physician prescription).
2. Prescription does not change. Maintain intake at 4-9 mg/kg/day.
3. Complete Special Dietary Considerations Form (Form 72).

Item 10: Altered Calorie Prescription

- a) Enter either 1=Yes or 2=No. If "2" is entered, 10b and 10c may be left blank.
- b) Refer to the most recent Dietary Information Summary Report and enter the current calorie prescription in kcal/day.
- c) Enter the number code describing the reason for the calorie adjustment in the blank. If "other" is selected, up to 20 characters may be used (including letters and spaces) to note the reason.
- d) Record the altered prescription in kcal/day.

Item 11: Altered Calcium Supplement Prescription

- a) Enter either 1=Yes or 2=No. If "2" is entered, skip to next item. Otherwise, indicate reasons for change by answering each of the next three questions.
- b) The recommended intake may be less than 1300 mg or greater than 1700 mg based on the clinical judgement of the physician.
- c) Enter the estimated calcium intake in mg/day using the most recent NCC analysis value.
- d) Record the altered prescription by:
 1. Subtracting 11c from 11b or
 2. By entering another adjustment.
- e) Enter the name of the calcium supplement and code as listed below:

<u>Name</u>	<u>Dosage of Elemental Calcium</u>
1 = BIO CAL 250	250 mg
2 = BIO CAL 500	500 mg del 7-10-89
3 = CALTRATE	600 mg
4 = CAL SUP	300 mg
5 = OS CAL (also chewables)	500 mg
6 = TUMS - REGULAR	200 mg
7 = TUMS - EXTRA STRENGTH	300 mg
8 = ROXANE (GENERIC)	500 mg
9 = Calcium Citrate	200 mg
10 = Tums Liquid	400 mg per tsp.
11 = OsCal	250 mg
12 = Calcium glubionate (liquid)	115 mg
13 = Calcium citrate (effervescent)	500 mg
14 = Roloids	130 mg
15 = Phos-Ex	250 mg
16 = Phos-Ex	125 mg
17 = Phos-Ex	167 mg
18 = Phos-Ex	62 mg

- f) Enter the dosage of elemental calcium per tablet (mg).
- g) Divide the calcium supplement prescription (11d) by the dosage per tablet (11f) to determine the altered number of calcium tablets prescribed per day. if the result is not a whole number, usual rounding rules may not apply. You may need to round up or round down to best meet the prescription; either method is satisfactory.
- h) Enter the amount of calcitriol (ug/day) prescribed (for patients with a persistent adjusted serum calcium < 8.5 mg/dl and phosphorus < 4.5 mg/dl). See Protocol, Section 13.

Note: Changes in source of calcium (e.g., a change from calcium carbonate to citrate) need only be recorded on Form 5. Form 72 does not need to be completed in this case.

Item 12: Altered Sodium Prescription

- a) Enter reason for adjustment (1-4). If "4" is entered, 12b-d may be left blank. Discuss sodium adjustment with the physician.

- b) If the adjustment in the sodium prescription is to be the recommended 30% reduction in intake, enter the average urine sodium excretion (mEq) from the last three visits and calculate as noted on the form. An adjustment other than 30% may be used if clinically appropriate. In this case, follow this example:

$$\frac{\text{Average Urine Sodium Excretion from the Last Three Visits}}{\text{mEq}} \times 23 \times \frac{0.75}{\text{Atomic Weight}} = \text{This constitutes a reduction of 30\%}$$

0.80
This constitutes
a reduction of 20%

There is no data entry range check on the number of milligrams of sodium per day.

- c) If a different adjustment is to be implemented, enter up to 20 characters to note the reason example:
(comment: or 20% reduction used)
- d) Enter the altered prescription (mg/day) from either 12b or 12c. The prescription should not be below 1200 mg per day.

Item 13: Altered Alcohol Intake

- a) Enter 1=Yes or 2=No. If "2" is entered, 13b may be left blank.
- b) Enter the altered number of alcohol equivalents per day as recommended after consultation with the physician. Two alcohol equivalents are recommended however there is no data entry range check on the number of drink equivalents that you determined.

One alcohol equivalent=
1 1/2 oz. 80 proof distilled spirits
4 oz. dinner wine
12 oz. beer

Item 14: Altered Dietary Potassium Prescription

- a) Enter 1=Yes or 2=No. If "2" is entered, item 14b may be left blank.
- b) Enter the altered potassium prescription (physician prescription) in mg/day.

Item 15: Altered Magnesium Supplement Prescription

- a) Enter 1=Yes or 2=No. If "2" is entered, item 15b may be left blank.
- b) Enter the altered magnesium supplement prescription in mg/day.

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Item 16: Vitamin A Prescription

- a) Enter 1=Yes or 2=No. If "2" is entered, items 16b-d may be left blank.
- b) Indicate if a supplement is being prescribed (1=Yes, 2=No).
- c) If a supplement is being prescribed, enter the amount in IU/day. If a supplement is not being prescribed, enter "0".
- d) Code whether the patient has been counseled to increase Vitamin A intake solely from dietary sources, rather than from a supplement, by entering 1=Yes or 2=No.

Item 17: Altered Iron Supplement Prescription

- a) Enter 1=Yes or 2=No. If "2" is entered, item 18b may be left blank.
- b) Enter the altered iron supplement prescription in mg elemental Fe/day.
- c) Code and enter the type of iron supplement:
 - 1 = ferrous sulfate
 - 2 = ferrous fumarate
 - 3 = polysaccharide - iron complex

Item 18: Altered Percent of Calories from Fat

- a) Enter 1=Yes or 2=No. If "2" is entered, item 18b may be left blank.
- b) Enter the altered percent of calories from fat. The altered percent should be as low as feasible while keeping in mind protein and calorie goals. Recommended is less than 45%.

Item 19: Altered Percent of Calories from Carbohydrates

- a) Enter 1=Yes or 2=No. If "2" is entered, item 19b may be left blank.
- b) Enter the altered percent of calories from carbohydrates. Recommended is 45% to 60%; assess diagnosis and ability to maintain study goals with altered prescription to determine percent.

Item 20: Other Dietary Adjustments

- a) Enter 1=Yes or 2=No.
- b) If dietary changes other than those noted above were made, enter up to 20 characters to describe.

For DCC Use Only
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E ___
V ___
T ___



Modification of Diet in Renal Disease Study Special Dietary Considerations Form

Purpose: To provide a calculation and summary of any changes to the Study Diet, Dietary Supplements, or Prescriptions.

To be completed by the dietitian ONLY for patients who require changes in diet prescription due to Action Items or additional dietary considerations at any time during Follow-Up. (Note: This form should be entered into Datalex)

When medications are changed be sure to indicate on Form 5.

To complete this form you will need the DCC Flow Sheet, the Nutrient Summary Report from the NCC and the Dietary Information Summary Report.

FORM # 72

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 E
- c. Visit Number.....
5. Standard Body Weight (kg).....
6. Randomization Diet Assignment from DCC (K, L, M).....
7. Blood Pressure Group Assignment.....
8. **Altered Protein Prescription**
For patients with Action Items for serum albumin or transferrin. Also for Diet K patients not taking keto acids whose unadjusted EPI is <0.40 g/kg/day. (Must be reviewed by Compliance Committee.) See Protocol Section 13 and Instructions for Form #72, for calculations.
 - a. Is protein prescription being altered? (1 = yes, 2 = no).....
 If no, skip to item 9.
 - b. Altered Protein Prescription (g/kg/day).....
 - c. Portion of Altered Protein Prescription that must be High Biological Value. If none, enter "0"
9. **Altered Phosphorus Prescription**
For patients with an Action Item for serum phosphorus > 4.5 mg/dl or < 2.5 mg/dl - See Protocol Section 13.
 - a. Is phosphorus prescription being altered? (1 = yes, 2 = no).....
 If no, skip to item 10.

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Modification of Diet in Renal Disease Study Special Dietary Considerations Form

9. (Continued)

Altered Phosphorus Prescription (mg/day)

b. _____ mg x _____ = _____
Lower range Std body wt. (kg)
of Altered
Phosphorus Rx
(if applicable)

c. _____ mg x _____ = _____
Upper range
of Altered
Phosphorus Rx

10. Altered Calorie Prescription

For patients with these Action Items (See Protocol Section 13): undesired weight loss or weight gain, recommended weight loss or weight gain, declining or low serum albumin or transferrin, or other reasons noted below in 10c.

a. Is calorie prescription being altered? (1 = yes, 2 = no)..... _____

If no, skip to item 11.

b. Review Study Diet Calorie Prescription - See Form 71 (item #5f)

i. Minimum Diet Calorie Prescription (kcal/day) _____

ii. Maximum Diet Calorie Prescription (kcal/day)..... _____

c. Code reason for calorie adjustment..... _____

- | | |
|--|---------------------------|
| 1 = Recommended weight loss | 5 = Diabetes management |
| 2 = Recommended weight gain | 6 = Low serum albumin |
| 3 = Recommended for weight maintenance | 7 = Low serum transferrin |
| 4 = Blood pressure management | 8 = Other (Specify) |

(20 characters maximum)

d. Altered Calorie Prescription (kcal/day) based on above considerations and clinical judgment.

i. Minimum Altered Diet Calorie Prescription (kcal/day)..... _____

ii. Maximum Altered Diet Calorie Prescription (kcal/day)..... _____

11. Altered Calcium Supplement Prescription

For patients with Action Items for low or high serum calcium, low dietary calcium intake, or other reason.

Note: Changes in calcium source (e.g., carbonate to citrate) need only be recorded on Form 5.

a. Is calcium prescription being altered? (1 = yes, 2 = no)..... _____

If no, skip to item 12.

i. For patient with action items for low or high serum calcium or low dietary intake (1 = yes, 2 = no)..... _____

**Modification of Diet in Renal Disease Study
Special Dietary Considerations Form**

12. (Continued)
d. Sodium prescription (mg/day)*
* Sodium prescription should not be below 1200 mg per day.
13. **Altered Alcohol Intake**
a. Is reduction necessary for blood pressure management or other conditions? (1 = yes, 2 = no)
If no, skip to item 14.
b. If yes: Number of alcohol equivalents per day
Limit intake to two or fewer alcohol equivalents per day (see Instructions for Form #72) or as recommended by physician.
14. **Altered Dietary Potassium Prescription**
For patients with an Action Item for high serum potassium. See Protocol section 13. Also if there is a specific physician prescription for potassium.
a. Is potassium prescription being altered? (1 = yes, 2 = no)
If no, skip to item 15.
b. Altered Potassium Prescription (mg/day)
15. **Magnesium Supplement Prescription**
For patients with an Action Item for low serum magnesium. See Protocol section 13.
a. Is magnesium prescription being altered? (1 = yes, 2 = no)
If no, skip to item 16.
b. Magnesium supplement (mg/day)
16. **Vitamin A Prescription**
For patients with an Action Item for low average daily dietary intake of vitamin A and carotene (<3300 IU/day). See Protocol and Manual of Operations Chapter 1.
a. Is Vitamin A prescription being altered? (1 = yes, 2 = no)
If no, skip to item 17.
b. Is a supplement being prescribed? (1 = yes, 2 = no)
c. If yes, indicate IU/day
d. Is patient being counseled to increase intake via dietary sources? (1 = yes, 2 = no)
17. **Altered Iron Supplement Prescription**
For patients with an Action Item for low serum iron or other reason.
See Protocol section 13.
Note: Changes in Iron source (e.g., sulfate to fumarate) need only be recorded on Form 5.
a. Is iron supplement prescription being altered? (1 = yes, 2 = no)
If no, skip to item 18.
b. Altered iron supplement (mg/day elemental Fe)

