Modification of Diet in Renal Disease Study

Instructions for Completing Form 71

STUDY DIET PRESCRIPTION FORM

PURPOSE: To provide a concise summary of the STUDY DIET PRESCRIPTION for calories, ketoacids, supplements, and other special dietary considerations.

COMPLETED BY: Dietitian after Randomization and before Follow-Up Visit 1. (Note: This form should be entered into Datalex)

To complete this form you will need:
- DCC Flow Sheet
- Study Diet Prescription Report from DCC
- Dietary Information Summary Report from DCC

Following are instructions for completing specific questions on Form 71.

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Item

5. Individualized Calorie Prescription

a) Review and enter the calorie prescription of the Baseline Diet reported on the Study Diet Prescription Report.

b) Circle the correct response to the question regarding patient's weight change since the screening visit.

c) Code and enter (1=Yes, 2=No) if weight loss is currently recommended for management of blood pressure, diabetes or hyperlipidemia.

d) Circle the correct response to the question regarding the patient's desire to change weight.

e) Code and enter if Study Diet calorie goals are recommended for:

1 = weight loss   2 = weight gain   3 = maintenance

2.250

f)   Total Calorie Prescription should not be less than 30 kcal/kg/ SBW/day unless weight loss is recommended for management of blood pressure, diabetes or hyperlipidemia, or if the patient desires to lose weight and the dietitian also recommends weight loss. The calories prescribed should not be less than 25 kcal/kg/day. If the lower end of the recommended calorie range is less than 25 kcal/kg, state the rationale. (Use a maximum of 20 characters to enter reason for low calorie prescription.)

Calories may be prescribed up to 45 calories/kg/day for patients who are physically very active. If calories are recommended above 45/kg/day, enter the rationale.

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Item

6.   **Standard Prescription for Vitamin Mineral Supplement**

a)   MDRD Multi-Vitamin Tablet - enter the number of tablets prescribed per day (all study patients are prescribed 1 tablet per day.)

b)   Iron Supplement - enter the iron supplement prescribed in mg of elemental iron per day (study K and L patients should receive at least 60 mg per day). If no iron supplement is prescribed, enter zero.

c)   Code and enter type of iron supplement:

     1 = ferrous sulfate
     2 = ferrous fumarate

7.   **Calcium Supplement Prescription**

a)   The recommended MDRD calcium intake is between 1450 and 1550 mg per day. Use clinical judgement or 1500 mg as a recommended intake.

b)   Calculate and enter the estimated amount of dietary calcium prescribed based on a CDDT analysis of the 7-day menu. If the 7-day menu is not available, estimate the dietary calcium prescribed by the number of servings of dairy products included in the menu plan.

c)   Subtract the estimated dietary calcium intake of the 7-day menu (7b) from the recommended calcium intake (7a) and enter the calcium prescription in mg.

2.251

d)   Enter the name of the Calcium Supplement prescribed and code as listed below:

Name	Dosage of Elemental Calcium	
1 = BIO CAL - 250	250 mg	
////2/≠/BIO/CAL/≠/300////////////////////////300/mg	300/mg	deleted 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 teaspoon	
11 = OsCal	250 mg	
12 = Calcium glubionate (liquid)	115 mg per teaspoon	
13 = Calcium citrate (effervescent)	500 mg	
14 = Rolaids	130 mg	
15 = Phos-Ex	250 mg	
16 = Phos-Ex	125 mg	
17 = Phos-Ex	167 mg	
18 = Phos-Ex	62 mg	

e)   Enter the dosage of elemental calcium per tablet (mg)

f)   Divide the Calcium Prescription (7c) by the dosage per tablet (7e) to determine the 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 down to best meet the prescription; either method is satisfactory.

8.   Ketoacid Tablets Prescription - only for Diet K patients who are prescribed tablets. For all others, enter zero.

a)   Enter the number of Ketoacid tablets prescribed per day. (See the Study Diet Prescription Report. Daily dose = 0.28 mg per kg standard body weight. One tablet contains 0.93 gm ketoacids.)

b)   Divide the number of Ketoacid tablets between the meals eaten based roughly on the calorie distribution of the meals. For example, if a patient's usual calorie intake at breakfast is approximately 1/4 of total calories for the day, then allocate the number of ketoacid tablets in a similar distribution. If a patient skips a meal, he would divide the tablets between the remaining meals.

9.   Ketoacid Packets Prescription - only for Diet K patients who are prescribed packets. For all others enter zeros.

a)   Enter the total number of Ketoacid packets prescribed per day (See the Study Diet Prescription Report. Daily dose = one packet [2.8 gm] per 10 kg Standard Body Weight.)

2.252

b)   Divide the number of Ketoacid packets between the meals eaten based roughly on the calorie distribution of the meals. For example, if a patient's usual calorie intake at breakfast is approximately 1/4 of his total calories for the day, then divide the number of ketoacid packets in a similar distribution.
If a patient skips a meal, he would divide the packets between the remaining meals.

10. Other Dietary Consideration

a)   Sodium - The decision to limit sodium intake should be discussed with the physician. Then enter the code which best describes the adjustment necessary. (1-4)

   1 = blood pressure management
   2 = other reason or condition
   3 = both of the above
   4 = no reduction of sodium is necessary

Note: If a patient enters the study already following a sodium restricted eating pattern, yet the physician does not feel that this reduction is necessary, the answer to 10(a) should be "4". The decision should be made at the clinical center as to whether the patient may stay at that level of intake or be counseled to increase sodium.

If the patient is already following a sodium restricted eating pattern and the physician feels that no further adjustment is necessary, enter "4" in item 10(a).

However, if the patient enters following a sodium restricted eating pattern and the physician prescribes one that is lower, the answer to 10(a) should be "1", "2", or "3".

b)   If reduction is recommended for blood pressure management calculate the reduction using an average of the urine sodium values (mEq) from the 24-hour urine collections from Baseline Visits 0, 1, 2, and 3 (See Study Diet Rx Report). To convert mEq to mg multiply by 23. A reduction of 30% of the average urine sodium excretion is recommended for management of blood pressure. Multiply urine sodium excretion in mg by 0.70 to obtain a 30% reduction; enter the sodium prescription in 10d. The percent reduction of 30% is a recommendation which should be evaluated on a patient to patient basis. An adjustment other than 30% may be used if clinically appropriate. For example, if a patient has already reduced his sodium intake a 20% reduction might be recommended. In this case follow this example by crossing out the .70 and use the .80% reduction:

___ ___ ___ mEq   x   23   x   0.70 = ___ ___ ___ ___
Average Urine Sodium   Atomic   This constitutes
Excretion from   Weight   a reduction
Visits 0,1,2, and 3   of 30%
(See Study Diet Rx
 Report)

0.80 =
This constitutes a
reduction of 20%

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

c)   If sodium reduction is necessary for a condition other than blood pressure and/or if amount is adjusted by physician, enter the condition or note MDRX (use a maximum of 20 characters). This is a good place to enter the exact percent used in 10.b. In this way this information becomes part of the data base. For example: (Comment: 20% reduction used)
                        (20 characters maximum)

d)   Enter Sodium Prescription in mg. The Sodium prescription should be the number obtained in 10b. Dietary sodium should not be less than 1200 mg.

11. Alcohol Intake

a)   Code and enter if reduction is necessary for:

        1 = blood pressure
        2 = other reasons or conditions
        3 = both
        4 = no reduction is necessary

b)   If alcohol reduction is necessary for a condition other than blood pressure, enter the condition. (Use a maximum of 20 characters)

c)   Enter the number of alcohol equivalents per day:

     1 alcohol equivalent =

        1 1/2 oz 80 proof distilled spirits (whiskey, gin, vodka, etc.)

        4 oz dinner wine

        12 oz beer

2.354

Limit intake to 2 or fewer alcohol equivalents per day or as recommended after consulting the physician. This recommendation is to be evaluated on a patient to patient basis. There is no data entry range to check on the number of drink equivalents that you determined.

12. Potassium Prescription

   a)   Code and enter (1 = yes, 2 = No) if a special prescription is necessary for dietary potassium intake. The recommended intake is 50 - 150 mEq or
        1050 - 5850 mg per day

   b)   Enter Potassium Prescription in mg. (If no special prescription, leave blank.)

13. Phosphorus Prescription

   a)   Code and enter (1 = yes, 2 = no) if a special prescription is necessary for dietary phosphorus. This is determined by the serum value. If the value is out of range (<2.5 or >4.5 mg/dl), the prescription should be determined by the physician.

   b)   Enter Phosphorus Prescription in mg. (If no special prescription, leave blank.)

14. Percent of Calories from nutrients - Code and enter (1 = yes, 2 = No) if percent of calories needs to be adjusted for:

        a) diabetes
        b) hyperlipidemia
        c) other (specify) using a maximum of 20 characters.

   If yes:

        d) Enter percent of calories from fat. Recommended distribution is less than 45%.

        e) Enter percent of calories from carbohydrate. Recommended distribution is 45 to 60 percent.

2.254.1

MDRD

Modification of Diet in Renal Disease Study
Study Diet Prescription Form

Purpose: To provide a concise summary of the <u>STUDY DIET PRESCRIPTION</u> for calories, keto acids, supplements, and other special dietary considerations.

To be completed by the dietitian after Randomization and before Follow-Up Visit 1. (Note: This form should be entered into Datalex)

To complete this form you will need the DCC Flow Sheet and the Study Diet Prescription Report.

FORM # .... Z 1

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. **Individualized Calorie Prescription**
   a. Review Baseline Diet Calorie Prescription (See Study Diet Rx Report)

      i. Minimum Baseline Diet Calorie Prescription .... ___ ___ ___ ___

      ii. Maximum Baseline Diet Calorie Prescription .... ___ ___ ___ ___

   b. Has patient's weight changed since Screening Visit? .... ___
      1 = Lost
      2 = Gained
      3 = No Weight Change

   c. Is weight loss recommended for management of: (1 = yes, 2 = no)
      i. Blood Pressure .... ___

      ii. Diabetes .... ___

      iii. Hyperlipidemia .... ___

   d. Does patient desire to change weight? .... ___
      1 = Lose
      2 = Gain
      3 = Does not want to change

Modification of Diet In Renal Disease Study
Study Diet Prescription Form

5. (Continued)
    e. Study calorie goals are recommended for: (Code 1, 2, or 3)...................................____
        1 = Weight loss
        2 = Weight Gain
        3 = Maintenance

    f. **Total Calorie Prescription (Kcal/day)** Adjust calorie range as necessary based on the above considerations and clinical judgment
        i. Minimum Total Calorie Prescription..____ ___ ___ ___

        ii. Maximum Total Calorie Prescription...____ ___ ___ ___

        iii. If calorie range is less than 30 or greater than 45 calories/kg, note rationale:

        _____
        (20 characters maximum)

6. **Standard Prescription for Vitamin Mineral Supplements**
    a. MDRD Multi-Vitamin Tablets (tablets/day) (All study participants should be prescribed 1 tablet per day.)..____

    b. Iron Supplement (mg/day) (Study Diet L and K: at least 60 mg/day elemental iron). Enter "0" if not prescribed. ....____ ___ ___

    c. Source of Iron:...____
        1 = Ferrous Sulfate
        2 = Ferrous Fumarate

7. **Calcium Supplement Prescription**
    a. Recommended MDRD Calcium Intake (must be between 1450 mg and 1550 mg per day) is based on clinical judgment (mg/day).....................____ ___ ___ ___

    b. Estimated calcium intake (mg/day) is based on analysis of 7-day menu plan or prescribed number of servings of dairy products...............____ ___ ___ ___

    c. Calcium Prescription (mg/day) (Subtract 7b from 7a) ....____ ___ ___ ___

    d. Calcium Supplement Code Number...____ ___

    Name of Calcium Supplement _____
    　　　　　　　　　　　　　　　　　　　　　　(name)

    e. Dosage of elemental calcium per tablet (mg) ....____ ___ ___

    f. Number of Calcium Tablets calculated by: (If decimal obtained, round up to the nearest whole number.)

    ___ ___ ___   ÷   ___ ___ ___   =   ___ ___
    Ca++   divided   dosage/tablet
    Supplement   by   (7e)
    Prescription
    (7c)

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Study Diet Prescription Form

8. **Keto Acid Tablets Prescription**--For participants on Diet K who are on prescribed <u>tablets</u>. (Daily dose = 0.28 gm per kg Standard Body Weight. One tablet contains 0.93 gm keto acids.) If not prescribed, enter "0".

    a. Total Number of Keto Acid Tablets Prescribed Daily ....___ ___
       (See Study Diet Prescription Report)

    Distribute tablets based roughly on calorie distribution of meals:
    b. Number of tablets at morning meal ....___ ___

    c. Number of tablets at midday meal...___ ___

    d. Number of tablets at evening meal ....___ ___

9. **Keto Acid Packets Prescription**--For participants on Diet K who are on prescribed <u>packets</u>. (Daily dose = one packet (2.8 gm) per 10 kg Standard Body Weight.) If not prescribed, enter "0".

    a. Total Number of Keto Acid Packets Prescribed Daily ....___ ___
       (See Study Diet Prescription Report)

    Distribute packets based roughly on calorie distribution of meals:
    b. Number of packets at morning meal...___ ___

    c. Number of packets at midday meal ....___ ___

    d. Number of packets at evening meal..___ ___

OTHER DIETARY CONSIDERATIONS

10. **Sodium**

    a. Is reduction necessary for blood pressure management or other medical conditions?..___
        1 = BP
        2 = Other
        3 = Both
        4 = No reduction necessary

If no reduction necessary, skip to item 11.

    b. Recommended reduction for blood pressure management calculated by:

$$\underline{\ \ \ \ \ }\ \underline{\ \ \ \ \ }\ \underline{\ \ \ \ \ }\ mEq \quad \times \quad 23 \quad \times \quad 0.70 \quad = \quad \underline{\ \ }\ \underline{\ \ }\ \underline{\ \ }\ \underline{\ \ }$$

        Average Urine Sodium   Atomic   This constitutes
        Excretion from Baseline Weight   a reduction
        Visits 0, 1, 2 and 3   of 30%
        (See Study Diet Rx Report)

AND / OR

    c. Other adjustment (Comment:_____)
                   (20 characters maximum)

    d. Sodium prescription (mg/day)*...___ ___ ___ ___
       * Sodium prescription should not be below 1200 mg per day.

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11. **Alcohol Intake**
    a. Is reduction necessary for blood pressure management or other conditions?............___
        1 = BP
        2 = Other
        3 = Both
        4 = No reduction necessary

    If no reduction necessary, skip to item 12.

    b. Other adjustment (Comment:_____)
                                        (20 characters maximum)

    If yes, limit intake to 2 or fewer alcohol equivalents per day (see Instructions for Form #71)
    or as recommended by physician.

    c. Number of Alcohol Equivalents/day ....___

12. **Potassium Prescription** (mg/day) by physician.
    a. Is a special potassium prescription necessary? (1 = yes, 2 = no).................................___

    If no, skip to item 13.

    b. Potassium Prescription by physician (mg/day).......................................___ ___ ___ ___

13. **Phosphorus Prescription** (mg/day) by physician.
    a. Is a special phosphorus prescription necessary? (1 = yes, 2 = no)............................___

    If no, skip to item 14.

    b. Phosphorus Prescription by physician for serum values out of range
        (mg/day) ....___ ___ ___ ___

14. Does Percentage of Calories from nutrients need to be adjusted for: (1 = yes, 2 = no)

    a. Diabetes ....___

    b. Hyperlipidemia..___

    c. Other (specify): _____..............___
                                        (20 characters maximum)

    If yes:

    d. Percent of calories from fat (Recommended = <45%) ....___ ___

    e. Percent of calories from carbohydrate (Recommended = 45% to 60%)...............___ ___

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101. Date this form completed...__ __/__ __/__ __

102. Certification number of dietitian completing 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:

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