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MDRD Local Manual of Operations

Volume 3,

Chapter 6

Drug Distribution Center

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Local Manual of Operations

Drug Distribution Center

Chapter 6

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Chapter 6

MDRD DRUG DISTRIBUTION CENTER

MANUAL OF OPERATIONS

I. RESPONSIBILITIES OF THE DRUG DISTRIBUTION CENTER

Responsibilities of the Drug Distribution Center will include:

1. Procurement and distribution of keto acid mixture, flavors, multivitamin tablets, enalapril tablets and diltiazem tablets for the study.
2. Inventory control and storage of the supplements
3. Design and implementation of a distribution system for the supplements.
4. Communication with the appropriate members of the MDRD study team about issues relating to supplements used in the study.
5. Providing information to clinical center pharmacists and other team members about pharmacy-related issues pertaining to the study.
6. Maintaining adequate records to fulfill requirements of Federal and State regulatory agencies and requirements of the MDRD protocol.
7. Administrative functions such as forecasting, budgeting, and communication with other central laboratories and clinical centers regarding the supplements listed in (1).

II. RESPONSIBILITIES OF CLINICAL CENTER PHARMACIES:*

Clinical center pharmacies will be responsible for:

1. Ordering supplements from the Drug Distribution Center for patients at the clinical center.
2. Filling prescriptions for MDRD study patients.
3. Maintaining records as required by the protocol and applicable regulations.
4. Submitting periodic reports to the Drug Distribution Center concerning the above activities.

*NOTE: While not legally required, storage and dispensing of supplements by a licensed Pharmacy at Clinical Centers is recommended.

III. COMMUNICATION

Telephone communications with the Drug Distribution Center should be directed to:

Peggy Basch, R.Ph.
(216) 444-1128

or

Edward H. Jones, Pharm.D.
(216) 444-1128

Written inquiries should be addressed to Mrs. Basch at:

Hospital Pharmacy HB-3
The Cleveland Clinic Foundation
One Clinic Center
9500 Euclid Avenue
Cleveland, Ohio 44195-5102

All orders should be placed by using the forms and instructions shown in Figures 1a, 1b, and 1c.

IV. ACQUISITION OF SUPPLIES, INVENTORY CONTROL AND DISBURSEMENT:

The Drug Distribution Center will maintain no less than a 30 day supply of all inventory items at all times in order to ensure continuous supply to the Clinical Centers.

V. SUPPLY PROCEDURE FOR CLINICAL CENTERS

Initially, the Drug Distribution Center will send a 90-day supply of vitamins, keto acid mixture, and one bottle of 100 enalapril tablets in both 5mg and 10mg strengths to each clinical center pharmacy based on usage. After the initial shipment, pharmacists at the clinical centers will be responsible for maintaining supply levels at their centers. Orders may be placed with the Drug Distribution Center according to a 60-day cycle which will be developed. The order form shown in Figure 1c must be used to place orders.

VI. INVENTORY RECORDS

Clinical center pharmacies will maintain inventory records of the keto acid mixture, MDRD

multivitamins, enalapril tablets and diltiazem tablets. The form and procedure to be used for this will be the Investigational Drug Accountability Record used by the National Center Institute (form NIH-2564) (Figure 2). Electronic records are acceptable in place of the NIH form as long as a hard copy report can be produced when needed.

VII. NOTIFICATION OF RANDOMIZATION

When a patient is randomized to one of the study diets, the Data Coordinating Center sends a message via electronic mail to the clinical center, the DDC, and the Nutrition Coordinating Center specifying the diet for the patient and advising the clinical center team concerning which supplements will be needed. A MDRD prescription form is completed and forwarded to the clinical center pharmacy by the principal investigator or other authorized physician. See Figure 3a for an example of the prescription form. Use of this form is optional but recommended.

VIII. PRESCRIPTION FILLING AT THE CLINICAL CENTER

PRESCRIPTIONS WILL BE FILLED BY THE PHARMACY AT THE CLINICAL CENTER. Some procedures will vary to suit circumstances at the individual clinical center. The following procedures are suggested:

1. A 35-day supply of keto acid mixture* should be dispensed on the first prescription filled. If the mixture is used, flavoring should be provided. Refills may be for 30 days supply or another appropriate quantity corresponding to the patient follow-up schedule. The physician's prescriptions should be checked against the keto acid mixture dispensing scheme (Figure 4) to verify the dose. Doses should not vary from protocol.

2. The prescription label should contain the patient's name, prescriber's name, prescription number assigned by the pharmacy, date of dispensing, directions to the patient, MDRD patient study number, and any other information required by state or local regulations.

3. MDRD multivitamins should be labeled as a prescription medication. It is suggested that containers of 100 tablets be dispensed.

4. Relevant information is to be recorded on the MDRD Prescription Refill Record Form (Figure 3b). This includes item dispensed, date of filling, quantity, pharmacist's initials, lot number and expiration date of the item dispensed.

5. Each prescription filled (including the first one) is recorded on the back of the MDRD prescription form and on the Investigational Drug Accountability Record for that item. *Note: keto acid mixture tablets and powder requires refrigeration.

APPENDIX

FIGURE 1A

MODIFICATION OF DIET IN RENAL DISEASE STUDY

PROCEDURE FOR ORDERING SUPPLEMENTS

Instructions:

1. Calculate order quantities according to the worksheet (Figure 1b).
2. Enter quantities needed in the "QTY" column on the left side of the order sheet (Figure 1c). Use black ink if possible.
3. Send order to MDRD Drug Distribution Center

   Peggy Basch, R.Ph
   c/o Hospital Pharmacy HB-3
   Cleveland Clinic Foundation
   One Clinic Center
   9500 Euclid Avenue
   Cleveland, OH 44195-5102

   Retain a photocopy if you wish.
4. Please send orders according to your schedule. Try to minimize exceptions.
5. The DDC will fill your orders and return a copy of the order form to you as a packing list.
6. Enter quantity received on your copy, initial, and using the self-addressed, stamped envelope, return to the DDC, retaining a photocopy for your records. Notify DDC of discrepancies in quantity, lot# or items shipped.

FIGURE 1B
MDRD Clinical Center
Worksheet For Calculating Order Quantities

KETO-ACID MIXTURE PACKETS

# of Pts_____x 7 pkts/day* x 90 days = Amount Needed _____
Subtract Amount on Hand - _____
Total Amount Needed = _____

*Based on an average dose

KETO-ACID MIXTURE TABLETS

# of Pts_____x 21 tabs/day* x 90 days = Amount Needed _____
Subtract Amount on Hand - _____
Total Amount Needed = _____

*Based on an average dose

MDRD MULTIVITAMINS

# of Pts_____ x 90 days = # of tablets Needed _____
Subtract Amount on Hand - _____
Total Amount Needed = _____

ENALAPRIL TABLETS - 5mg

# of Pts_____ x 90 days = # of tablets Needed _____
Subtract Amount on Hand - _____
Total Amount Needed = _____

ENALAPRIL TABLETS - 10mg

# of Pts_____ x 90 days = # of tablets Needed _____
Subtract Amount on Hand - _____
Total Amount Needed = _____

DILTIAZEM TABLETS - 90mg

# of Pts_____ x 90 days = # of tablets Needed _____
Subtract Amount on Hand - _____
Total Amount Needed = _____

DILTIAZEM TABLETS - 120mg

# of Pts_____ x 90 days = # of tablets Needed _____
Subtract Amount on Hand - _____
Total Amount Needed = _____

Figure 1c

MODIFICATION OF DIET IN RENAL DISEASES
ORDER FORM FOR SUPPLEMENTS
MDRD DRUG DISTRIBUTION CENTER
c/o Hospital Pharmacy - HB-03
Cleveland Clinic Foundation
One Clinic Center
9500 Euclid Avenue
Cleveland, Ohio 44195-5102
Phone: (216) 444-4303

FOR DDC USE
ORDER RECEIVED DATE _____
SHIPPING DATE _____

Clinical Center Name:_____
Street Address:_____
City, State, Zip Code:_____
Attention:_____
Principal Investigator:_____

Shipping Address (if different from above):
Clinical Center Name:_____
Street Address:_____
City, State, Zip Code:_____
Attention:_____

ORDER DATE_____

			FOR DDC USE ONLY					
QTY	UNITS	ITEM	QYT FILLED	FILLED BY	LOT NUMBER	EXP.	QTY REC'D	REC'D BY
	50's	Keto-Acid Mixture Packets						
	100's	Keto-Acid Mixture Packets						
	100's	MDRD Multivitamins						
	100's	Enalapril 5mg Tablets						
	100's	Enalapril 10mg Tablets						
	100's	Diltiazem 90mg Tablets Sustained release						
	100's	Diltiaxem 120mg Tablets Sustained release						
	400 gm Cans	Flavoring-Golden Punch						
	400 gm Cans	Flavoring-Orange						

NOTE: Keto-Acid Mixture Tablets and Packets require refrigeration.

Order Submitted By:_____
Pharmacist Signature

FIGURE 2

OMB NO. 0925-0240
EXPIRES: 9/30/87

National Institutes of Health
National Cancer Institute

PAGE NO. _____

CONTROL RECORD ☐

SATELLITE RECORD ☐

Investigational Drug Accountability Record

Name of Institution

Protocol No. (NCI)

Drug Name, Dose Form and Strength

Protocol Title

Dispensing Area

Investigator

Line No.	Date	Patient's Initials	Patient's I.D. Number	Dose	Quantity Dispensed or Received	Balance Forward / Balance	Manufacturer and Lot No.	Recorder's Initials
1.								
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								
11.								
12.								
13.								
14.								
15.								
16.								
17.								
18.								
19.								
20.								
21.								
22.								
23.								
24.								

NIH-2564
9-85

FIGURE 3a
PRESCRIPTION FORM
MODIFICATION OF DIET IN RENAL DISEASE STUDY

Patient Name:_____Patient Number:_____

Patient Weight (SBW)_____Kg

Name of Clinical Center:_____

Needed by Patient: Date:_____ Time:_____

Will Pick Up in Pharmacy:_____(YES)_____(NO) Deliver To:_____

Check Medications Required

_____ 1. Keto-Acid Mixture 2.8g (2.8g/10kg/DAY) #_____
Sig: Take_____ Packets daily as directed
Refills as needed for 1 year.

_____ 2. Keto-Acid Tablets #_____
3 Tablets/10Kg/Day
Sig: Take_____ Tablets daily as directed

_____ 3. MDRD Multi-Vite (Tishcon) #100
Sig: Take 1 tablet every day
Refills as needed for 1 year

_____ 4. Enalapril Tablets _____mg
Sig: Take as directed
Refills as needed for 1 year

_____ 5. Diltiazem Tablets _____mg
Sig: Take as directed
Refills as needed for 1 year

_____ _____
Physician Date

Refer questions about this prescription to the MDRD drug distribution center at (216) 444-4303.
I request that the above medications not be dispensed in child resistant packaging.

_____ _____
Physician Date

FIGURE 3B
MDRD PRESCRIPTION REFILL RECORD

ITEM	DATE REQ.	QUANT.	RX. NO.	DATE FILLED	R.Ph. INITIALS	LOT & EXP. DATE

FIGURE 4
MDRD STUDY
KETO-ACID MIXTURE DISPENSING SCHEME

	40 kg	50 kg	60 kg	70 kg	80 kg	90 kg
30 day Supply	120 Packets 4 packets/day or 12 tablets/day	150 Packets 5 packets/day or 15 tablets/day	180 Packets 6 packets/day or 18 tablets/day	210 Packets 7 packets/day or 21 tablets/day	240 Packets 8 packets/day or 24 tablets/day	270 Packets 9 packets/day or 27 tablets/day
35 day Supply	140 Packets 4 packets/day or 12 tablets/day	175 Packets 5 packets/day or 15 tablets/day	210 Packets 6 packets/day or 18 tablets/day	245 Packets 7 packets/day or 21 tablets/day	280 Packets 8 packets/day or 24 tablets/day	315 Packets 9 packets/day or 27 tablets/day

Calculations as Follows:

1. All weights are standard body weight

2. Dosage based on 1 packet or 3 tablets/10 Kg/day

3. An additional 5.0 kg will be rounded up; less than 5.0 kg will be rounded down. For example, a weight of 65.0 kg rounds up to 70 kg while a weight of 64.9 kg rounds down to 60 kg.