

Major Kidney Clinical Research Studies and Projects Inventory*

Modification of Diet in Renal Disease (MDRD) Study

1. Administrative Data

(a) Name of study/research project and acronym:

Modification of Diet in Renal Disease (MDRD) Study

(b) Type of study/research project (randomized clinical trial, epidemiological study, database, etc.):

Randomized clinical trial

(c) Funding status (currently funded, study/project completed):

Currently funded for long-term follow-up of cohort.

(d) Recruitment status (recruitment completed, currently recruiting):

Recruitment complete

(e) For studies/project currently recruiting: indicate total sample size/ number currently enrolled, anticipated period of recruitment:

840 people, randomized

(f) Data coordinating center principal investigator contact information (mailing address, phone, fax, e-mail address):

Data Coordinating Center, Principal Investigator:

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Chair, Steering Committee:

Kidney Disease Clinical Studies Initiative, Major Kidney Clinical Research Studies and Projects Inventory, Modification of Diet in Renal Disease

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Project Officer:

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Division of Kidney, Urologic, and Hematologic Diseases
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(g) Number of recruiting sites, list of principal investigators at recruiting sites and contact information as in (f) above:

15 clinical centers. See Appendix A.

(h) List of principal investigators at central laboratories/facilities (identify type of central facility) and contact information as in (f) and (g) above:

See Appendix B.

(i) Roster of Data and Safety Monitoring Board/Scientific Advisory Committee or other oversight committee(s):

External Monitoring Committee:

Robert Luke, M.D., Chair, University of Cincinnati; Raymond P. Bain, Ph.D., George Washington University; James E. Grizzle, Ph.D., Cancer Prevention Center; C. Morton Hawkins, M.P.H., Sc.D., The University of Texas; Malcomb Holliday, M.D., University of California, San Francisco; Keith Peters, M.D., University of Cambridge Clinical School; Paul K Whelton, M.D., Ph.D., Massachusetts Institute of Technology.

(j) Private-sector support (type of support, e.g., financial, donation of drugs/placebo, etc.)

Marion Merrill Dow, Kansas City, MO—Diltiazem and calcium carbonate

Merck and Company, West Point, PA—Enalapril

2. Study Design

For objective, study design, major inclusion criteria, major exclusion criteria, description of the intervention(s), baseline/eligibility visit schedule (number of visits, major assessments), follow-up contact schedule (frequency, type of visit/phone, in-clinic, major assessments), primary outcome, secondary outcomes, brief summary of power estimates used to justify sample size/duration, including critical assumptions (i.e., effect-size estimates, estimated event rates or rate of change in outcome measure), see the following publications:

Design:

Beck G, Berg R, Coggins C, Gassman J, Hunsicker L, Schlachter M, Williams G. Design and statistical issues of the modification of diet in renal disease study. *Controlled Clinical Trials* 1991;12:566-586, 1911 (Two trials depending on baseline level of GFR: Study A—GFR 25-55 ml/1.73m²; Study B—GFR 12-24 ml/173 m²)

Primary Results:

Klahr S, Levey A, Beck G, Caggiula A, Hunsicker L, Kusek J, Striker G. The effects of dietary protein restriction and blood-pressure control on the progression of chronic renal disease. *N Eng J Med* 1994;330:877-84.

3. Data and Biological Sample Resources

(a) Biological samples collected in ongoing studies/research projects (specify the type of sample, e.g., blood, urine, etc., the amount, and the point in the study when samples were collected, e.g., baseline visit #1, baseline visit #2, follow-up visit #1; specify months after randomization/study entry):

No further biological samples are being collected.

(b) Biological samples currently in storage from completed trials (grid showing sample collection time, type of sample, amount, and number of study participants sample was collected from, and physical location of where the samples are stored):

Blood samples are stored at the Department of Biochemistry, Cleveland Clinic Foundation, Cleveland, Ohio.

Blood samples were drawn after an overnight fast at specific visits and shipped to the MDRD Central Biochemistry Laboratory and stored at -70° C. Table 1 lists the currently available samples by visit for Studies A and B.

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Table 1. MDRD Study— Stored Serum Samples				
Visit	Study A, # Pts.	Study A	Study B, # Pts.	Study B
Baseline 3 mo.	570	276 with one 0.5 ml tube plus 3.6 ml tube to split five ways; 294 with five 0.5 ml tubes	252	126 with one 0.5 ml tube plus 3.6 ml tube to split five ways; 126 with five 0.5 ml tubes
Follow-up 12 mo.	504	265 with one 0.5 ml tube plus 3.6 ml tube to split five ways; 239 with five 0.5 ml tubes	201	106 with one 0.5 ml tube plus 3.6 ml tube to split five ways; 95 with five 0.5 ml tubes
Follow-up 24 mo.	301 with 1.8 ml tube	373 with 3.6 ml tube	125 with 1.8 ml tube	130 with 3.6 ml tube
Follow-up 36 mo.	94 with 1.8 ml tube	96 with 3.6 ml tube	46 with 1.8 ml tube	47 with 3.6 ml tube
Closeout	400 with 1.8 ml tube	446 with 3.6 ml tube	117 with 1.8 ml tube	127 with 3.6 ml tube
Post Closeout 1	397 with 1.8 ml tube	414 with 3.6 ml tube	113 with 1.8 ml tube	122 with 3.6 ml tube
Post Closeout 2	401 with 1.8 ml tube	433 with 3.6 ml tube	127 with 1.8 ml tube	125 with 3.6 ml tube

Urine samples collected from 24-hour urine collection in acetic acid at specified visits and shipped to the NDRD Central Biochemistry Laboratory and stored at -70 °C. Table 2 lists the currently available samples by visit for Studies A and B. In addition to the regular protocol, extra blood and urine was requested to be collected from patients at their closeout visit in order to obtain heparinized plasma, EDTA plasma, buffy coat, and 24-hour and freshly voided urine. Table 3 lists the currently available closeout samples for Studies A and B.

Table 2. MDRD Study—Stored Urine Samples						
Visit	Study A 1.8 ml	Study A 3.6 ml	Study B 1.8 ml	Study B 3.6 ml	Total A+B 1.8 ml	Total A+B 3.6 ml
Baseline 3 mo.	499	263 split four ways	231	116 split four ways	730	1,109
Follow-up 12 mo.	490	259 split four ways	193	102 split four ways	683	683
Follow-up 24 mo.	309	309	128	129	437	—
Follow-up 36 mo.	95	95	45	45	140	—
Closeout	480	481	132	132	612	—
Post Closeout 1	436	437	125	125	561	—
Post Closeout 2	439	439	102	104	541	—

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Table 3. MDRD Study—Stored Closeout Specimens					
Type of Specimen	Study	1 Tube	2 Tubes	3 Tubes	4 Tubes
# Pts. Heparinized Plasma (1.8 ml)	A	3	398	—	—
# Pts. EDTA Plasma (1.8 ml)	A	3	394	—	—
# 24-Hour Urine (4.5 ml)	A	1	1	—	384
# Pts. Freshly Voided Urine (4.5 ml)	A	1	1	—	384
# Pts. Buffy Coat	A	275	—	—	—
# Pts. Heparinized Plasma (1.8 ml)	B	2	186	—	—
# Pts. EDTA Plasma (1.8 ml)	B	6	179	—	—
# 24-Hour Urine (4.5 ml)	B	—	—	—	182
# Pts. Freshly Voided Urine (4.5 ml)	B	1	2	3	181
# Pts. Buffy Coat	B	114	—	—	—

(c) Brief summary of typical informed consent provisions (template informed consent form acceptable), including major variables in participant consents, if applicable (e.g., “use for other studies or not”, “allow genetic studies or not”). Does consent include use of samples in other studies that are not part of the main study?

Original consent did not discuss use of stored samples. The template consent form stated the following:

Consent Section 15

I understand that my identity and all the medical records of my participation in the study will be kept confidential. I am aware that a qualified representative of the NIH or the Food and Drug Administration may inspect these research records. In any reports or publications, no results or information identifiable with specific individuals will be discussed. I understand that my Social Security or Medicare numbers will be recorded to help the MDRD Study Team and HCFA find out if I have been hospitalized or have gone onto dialysis or received a transplant.

For the extra blood and urine sample at the closeout visit, the template consent stated:

Additional Consent Section #1 Closeout MOP

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You are being invited to participate in a protocol addition to the original MDRD Study. We are asking the MDRD participants to have additional blood drawn for a genetic study separate from the usual blood test done as part of the MDRD Study.

A. A 50 milliliter blood sample (equivalent to three tablespoonfuls) taken from you will be saved to try to identify genes. The purpose of this sample is to obtain leukocyte fractions for isolation of DNA. Purified genetic material (DNA) from the cells in your blood will be prepared, and at a later time permanent cell lines may also be established so that additional genetic studies can be done. These specimens will belong to the MDRD Research Group and, as such, will be used for research purposes only.

B. You are being asked to allow storage of DNA; exactly what tests will be completed, such as HLA typing, will be decided at a later time.

(d) Data collected (grid of data collection by time/clinic visit with specificity on the type of information collected, e.g., quality of life with SF-MOS 36, measurement of kidney function by GFR, serum creatinine measurement, etc.):

See the design paper, *Controlled Clinical Trials* 1999;12:566-86.

See Appendix C, Forms and Completion Schedule of MDRD Forms Manual of Operations.

(e) Any provisions for distributing resources outside of the study? What is the sharing plan?

Data and biological specimens have been shared with external investigators, see 4(b). The procedure to obtain access has been to send the DCC a request detailing goals of the study and data/samples needed. Requests are reviewed by the DCC, NIDDK Project Officer John Kusek, Ph.D., and Dr. Andrew Levey, New England Medical Center. After review, approved projects are provided the data/samples requested after (beginning 2002) the investigator signs a Cleveland Clinic Foundation sub-investigator IRB agreement. The stored data and samples will become part of the NIDDK Repository. Procedures for access to Repository data/samples are not known at this time.

4. Ancillary Studies

(a) Process and contact person (name, address, phone, fax, and e-mail address) for application to perform ancillary studies:

Gerald Beck, Ph.D.
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Cleveland Clinic Foundation
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(b) List of ancillary studies approved, completed, and ongoing (including source of funding and amount):

Ancillary studies approved:

- MacKenzie Walser, M.D., Johns Hopkins University: Risk factors for progression of chronic kidney disease. A 50% sample of baseline and 12-month serum and urine samples were provided.
- Mark Sarnak, M.D., and Andrew Levey, M.D., New England Medical Center: (1) homocysteine, cysteine, and B vitamins as predictors of kidney disease progression; (2) determinants of serum leptin in chronic disease. Baseline and 12-month serum samples in random 380 patients were provided.
- Vandana Menon, M.D., Mark Sarnak, M.D., and Andrew Levey, M.D., New England Medical Center: Relationship between inflammation, nutrition, and cardiovascular disease in chronic kidney disease patients. Baseline and 12-month serum samples in random 380 patients were provided.
- Josef Coresh, M.D., Ph.D., Johns Hopkins University: Validation of MDRD GFR prediction equation. Two hundred (200) baseline serum samples were provided to determine serum creatinine.
- Thomas Hostetter, M.D., NIDDK, and Vincent Ricchuti, Ph.D., Brigham and Women's Hospital, Boston: Urinary aldosterone. Baseline urine samples in random 50% of patients will be provided.

Data requests:

- Andrew Levey, M.D., and Mark Sarnak, M.D., New England Medical Center: Standard baseline and follow-up SAS analysis files for analyses relating new measurements of afterthought specimens to other factors.
- Harold Feldman, M.D., M.P.H., University of Pennsylvania: Standard baseline and follow-up baseline SAS analysis files for design of CRIC Study.
- Mark Schluchter, Ph.D., Case Western University; Edward Vonesh, Ph.D., Baxter Healthcare; Hemant Ishwaran, Cleveland Clinic Foundation; Diane Fairclough, Ph.D., Harvard University: Standard analyses file for Study B to address informative censoring issues for investigation of methodological issues.
- Abigail Jager, Ph.D., and Paul Rathouz, Ph.D., University of Chicago: Standard baseline and follow-up SAS analysis files for investigation of methodological issues related to causal analysis and compliance in clinical trials.

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- Phillip Miller, Ph.D., Washington University: Serum creatinine and other select variables for design of the HALT PKD Study.
- Tom Songer, Ph.D., University of Pittsburgh: Special baseline and follow-up analysis files, including specific requested data for cost-effectiveness analyses.

5. List of Publications and Presentations (full citations, also note manuscripts in progress)

See Appendix D

Appendix A. Principal Investigators and Centers

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* Indicates those PIs who are no longer at the center.

Appendix B. Central Facilities

Nutrition Coordinating Center
Arlene W. Caggiula, Ph.D., R.D.
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* Indicates those PIs who are no longer at the center.

Appendix C. MDRDS: Forms and Outline of Events

Unscheduled Forms

Form #

- 10 Unscheduled Medical Attention Form
- 11 Stop Point Form
- 12 Abbreviated Follow-up Form (Study F, stop point—every four months)
- 14 Multiple Missed Visits Form
- 15 Death Notification Form
- 20 Local Lab QC Form —1 form per month
- 21 CAP QC Form —every 4 months
- 22 QC ID Matching Form —2 times per year per center
- 23 Action Item Response Form —Monthly for any patient who reached action item.
- 24 Out of Range Data Form
- 25 Data Change Form
- 30 Patient Transfer Form
- 31 Study C Assignment Form
- 34 Central tab Quality Control Form—every 4 months
- 39 Peer Group Range Form —every 4 months by central lab
- 40 Stop Point Review Form
- 41 Death Review Form
- 47 Studies F and G Form —every 4 months or annually
- 66 NCC Phantom Matching (monthly)
- 72 Special Dietary Considerations

Appendix C (cont.). MDRDS: Forms and Outline of Events

Categories of Forms

- A. Recruitment
 - 1. Recruitment Form (00)
 - 2. 800 Phone Line Log

- B. Screening
 - 1. Chart Review (01)
 - 2. Eligible for Visit but Does Not Have One (02)
 - 3. Screening Form (03)
 - 4. Nutrition History (78)
 - 5. Informed Consent

- C. Randomization
 - 1. Secondary Screening (08)
 - 2. Informed Consent
 - 3. Randomization Form (09)
 - 4. Studies A & B Randomization (37)

- D. Routine Monthly Visits
 - 1. Examination Forms (04,05)
 - Form 4 at B0 only
 - Form 5 once per month thereafter
 - 2. Lab Forms (Mailing and Reports)
 - a. Local Lab Form (06)
 - b. Blood Pressure (46)
 - c. Anthropometry (65)
 - d. Pill Count (73)
 - e. Mailing Forms and Central Lab Report Forms
 - i. GFR(16/42)
 - ii. 24-Hour Urine (17/32)
 - iii. Blood (17/33)
 - iv. EKG(18/35)
 - v. AminoAcids(19/36)
 - 3. Patient Questionnaires
 - a. Patient Symptom Form (26)
 - b. Quality of Well Being (27)
 - c. Symptom Check List (28)
 - d. Leisure Time Physical Activity (48)
 - e. Dietary Satisfaction (74)
 - 4. Other Baseline Forms (Baseline Visit 1)
 - a. Renal Diagnosis Form (07)

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- b. Economic Data (29)
- c. Baseline Diet Prescription (70)

E. Special Events

- 1. Abbreviated Follow-Up after a Stop Point (12)
- 2. Study F & G Form (47)
- 3. Annual Follow-Up (13)
- 4. Reasons for Missed Visits (14)
- 5. Unscheduled Attention (10)
- 6. Action Item Response (23)
- 7. Stop Point (11)
- 8. Death (15)
- 9. Study C (31)
- 10. Patient Transfer (30)
- 11. Committee Forms
 - a. Stop Point Review (40)
 - b. Death Review (41)
- 12. Study Diet Prescription (71)
- 13. Special Dietary Considerations (72)

F. Quality Control

- 1. Biochemistry (Clinical Centers)
 - a. Local Lab Quality Control (20)
 - b. CAP Quality Control (21)
 - c. Central Lab QC ID Matching (22)
- 2. Biochemistry (Central Lab)
 - a. Central CAP QC (34)
 - b. Peer Group Ranges (39)
- 3. Anthropometry
 - a. Training QC (non-patient) (67)
 - b. Local Anthropometry QC (?)
 - c. NCC Phantom Matching Form (66)

G. Data Management

- 1. Data Out-of-Range (24)
- 2. Data Change (25)

H. Other Nutrition Forms

- 1. Compliance Forms (75,76,77)
- 2. Food Record Forms (60 through 64)

Appendix C (cont.). MDRDS: Forms and Outline of Events

Non-Nutrition Forms

Forms	Purpose
Recruitment Form (00)	Form #00 is to be completed for phone calls from patients inquiring about the study.
Chart Screening Form (01)	Form #01 must be completed for all patients considered for a screening visit.
Screening Visits Not Done (02)	Any patients meeting eligibility via a Chart Review who are eligible for a Screening Visit but do not have one, should be listed.
Screening Form (03)	All patients who have an MDRD screening visit, should have Form #03 completed.
Primary Informed Consent Form	All patients who meet the eligibility criteria in the Screening Period will be asked to complete this form and consent to enter the Baseline Period.
Demographic and Baseline (04)	Form #04 will be completed at the first clinic visit (Visit 0) during the baseline period for each patient.
Monthly Examination Form (05)	Every month following the first baseline visit, (Visit 0), Form #05 will be used to record data collected during scheduled monthly visits for the entire study period. It is required even if the visit is missed.
Local Laboratory Measurement (06)	Local laboratory measurements done for purposes of Study should be recorded on Form #06.
Local Blood Pressure Form (46)	Form #46 will be completed at screening and every month when blood pressure is measured; every 4 months in conjunction with Forms 12 or 47; and also every fourth month for one patient a second form will be completed where blood pressure is measured by a second person.
Renal Diagnosis Form (07)	At Baseline Visit 1, Form #07 will be completed for each patient to record renal diagnosis history.
Secondary Screening/Baseline (08)	After Baseline Visit 3, Form #08 will document any Dropout Form changes in eligibility prior to possible randomization. If a patient drops out prior to the end of Baseline, use this form to record the reason.
Secondary Informed Consent	Those patients who still meet all eligibility requirements at the end of baseline will be asked to sign this form and consent to be randomized to a study diet.

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Renal Diagnosis Form (07)	At Baseline Visit 1, complete Form #07 for each patient to record renal diagnosis history.
Secondary Screening/Baseline Dropout Form (08)	After Baseline Visit 3, Form #08 will document any changes in eligibility prior to possible randomization. If a patient drops out before the end of baseline, use this form to record the reason.
Secondary Informed Consent	Those patients who still meet all eligibility requirements at the end of baseline will be asked to sign this form and consent to be randomized to a study diet.
Study A & B Randomization (37)(DCC)	At the end of baseline, after consent forms are signed, each eligible patient will be randomized by the DCC to a blood pressure goal and a diet to be followed for the follow-up period of the study (Form #37).
Randomization Form (CC) (09)	When the patient has been randomized (over the phone, Form #09 will be completed at the Clinical Center.
Unscheduled Medical Attention (10)	Whenever a hospitalization occurs, this form (Form #10) must document the visit.
Stop Point Form (11)	Whenever a stop point is reached, Form #11 will document when and why.
Study C Informed Consent Form	Those patients who meet criteria to enter Study C will be asked to sign the appropriate form.
Study C Assignment Form (31)	When a patient becomes part of Study C, Form #31 should be completed.
Abbreviated Follow-Up Form (12)	After a stop point has been reached, the patient will continue to be followed every four months (unless he/she becomes part of Study C). Form #12 will replace the monthly Exam Form for these patients.
Study F Form (47)	Form #47 should be completed every six months for Study F patients. It is used to follow up these patients.
Central Laboratory Mailing (17)	This form should be completed by Clinical Center study Form (Form #17) technician or coordinator and sent with any blood or urine samples going to the Central Lab for analysis. It is required whenever samples should be sent, whether they were or not.

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EKG Mailing Form (18)	An electrocardiogram will be done at Baseline 2 and every six months thereafter. The EKG tracing and Form #18 will be sent to the DCC, who will deliver it to the Central EKG Lab. Complete for ALL required EKG's whether done or not.
Amino Acid Mailing Form (19)	Form #19 should be completed, transmitted and sent with all amino acid samples done for the Study. The number of hours fasting and the diet the patient is on should be documented on this form. It is required whenever samples should be sent whether they are or not.
Central Lab Urine (32)	Form #32 includes central 24-Hour urine analysis results.
Central Lab Blood Report (33)	Form #33 includes all central blood measurement results.
Central Laboratory EKG (35)	Form #35 will be completed at the central EKG Lab at Baseline Visit 2 and every six months (starting at Follow-Up Visit 5).
Amino Acid Data (36)	The Central Amino Acid Lab personnel will complete this form (Form #36) for all analyses done.
Local Lab Quality Control (20)	Form #20 will be used at each Clinical Center on one patient each month. It will contain data on duplicate samples sent through the Clinical Center laboratory.
CAP QC Form (21)	Form #21 will be used to collect data on the quality control of Clinical Center laboratory measurements from samples sent from the Central Lab every four months.
Central Quality Control (34)	Data on external samples will be collected every four months and checked against external ranges for acceptability. Only the Central Biochemistry Lab will use Form #34.
Central Lab QC ID Matching (22)	Form #22 will record which real patient sample to match with QC ID data. It is completed by the Clinical Center and not communicated to the Central Lab.
Action Item Response (23)	Form #23 will detail efforts made at the centers to respond to each action item. It is completed monthly
Data Out of Range Form (24)	Form #24 is to be used whenever a value is outside the Datalex Entrypoint 90 range and must be entered separately.
Data Change Form (25)	Form #25 will be used to notify the DCC of any changes to be made to existent database entries.

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Patient Symptom Form (26)	Form #26 is completed monthly by the patient starting at BO to indicate symptoms the patients may be having.
Quality of Well Being (27)	The Quality of Life Scale (Form #27) is used to record and measure the degree to which patients' activities are limited by renal disease and its treatment. Complete at B3 and every six months thereafter.
Symptom Check List (28)	Form #28 serves as is an inventory designed to reflect patient's psychological symptom patterns. It will be completed by the patient at the end of baseline, and every four months thereafter.
Economic Information Form (29)	Complete this insurance information form (Form #29) during screening or at BO for all patients entering Baseline and annually thereafter.
Patient Transfer Form (30)	In the event that a patient moves and becomes another study physician's patient, the destination center should complete this Form #30.
Peer Group Range Form (39)	The Central Biochemistry Lab will complete Form #39 for each center to ease the reporting of CAP results.
Stop Point Review Form (40)	Form #40 will be completed with the consensus of the patient safety committee's review of each stop point.
Death Review Form (41)	Form #41 will be completed with the Patient Safety Committee's review of each patient's cause of death.
GFR Data Form (42)	Form #42 is an example format of the data entered by the Central GFR Laboratory
Leisure Time Physical Activity (48)	Form #48 is to be completed annually on all Studies A and B patients to record their assessment of activities.

Appendix C(cont.). MDRDS: Forms and Outline of Events

Nutrition-Related Forms

Form #	Description	Who Completes	Usage
60	Packing Slip	Packing Slip	
61	Nutrition Cover	Dietitian	#60-63 are part of food records sent to the NCC for analysis.
62	Diet Recall	Dietitian	
63	MDRD Recipe	Dietitian	
64	3-day Food Record	Patient	
65*	Anthropometry	Dietitian	To record measures at B2 ,F6 and every 4 months after.
66*	Phantom Matching	Dietitian	To identify real patient to match with QC
67	Anthropometry Monitoring	Dietitian	Not completed on patients. Send hard copies to NCC.
7Q*	Baseline Diet Prescription	Dietitian	To record baseline Prescription for each patient
71*	Study Diet Prescription	Dietitian	To record Follow-Up Rx prior to discussing with patient at FU 1
72*	Special Dietary Considerations	Dietitian	Every time a FU Rx changes this must be completed
73*	Pill Count adherence to	Anyone	To keep track of supplements
74*	Dietary Satisfaction	Patient	To monitor degree of satisfaction with diet BO, B3, and every 4 months

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76*	Summary of Counseling Plan	Dietitian	To summarize progress
78/78P*	Nutrition History	Dietitian & Patient	To be completed at screening to indicate history of eating patterns, etc. for each patient

* To be entered into Entrypoint 90

Appendix C (cont.). MDRDS: Forms and Outline of Events

Nutrition-Related Forms Completed at Clinical Centers by Visit

Prior to Screening Visit	01
Screening	03, 29, 46, 78/78P, 50, 51 (when necessary)
B0	04, 06, 16, 17, 26, 46, 74, 77
B0A	65
B1	05, 07, 17, 26, 46, 48, 77
B2	05, 17, 18, 26, 27 (preparation), 46, 65, 77
B3	05, 06, 08, 16, 17, 19, 26, 28, 46, 52, 77
Randomization	09
F1	05, 17, 26, 46, 71, 76, 77
F1A, F2A	76
F3, P7, F9, F13, F15, F19, P21 F25, F27, F31, F33, F37, F39, F43, F45	05, 17, 26, 46, 73 ⁰ , 76, 77
F5, F11, F17, F23, P29, F35, F41, F47	05, 17, 18 ⁺ , 26, 27 (preparation), 46, 73 ⁰ , 76, 77
F2	05, 06, 16, 17, 19*, 26, 46, 73 ⁰ , 76, 77
F6, F14, F18, F26, F30, F38, F42	05, 06, ~7, 26, 46, 52 [^] , 65, 73 ⁰ , 74 ⁺⁺ , 76, 77
F10, F22, F34, F46	05, 06, 17, 26, 46, 48, 65, 73 ⁰ 76, 77
F4, F8, F16, F20, F28, F32, F40, F44	05, 06, 16, 17, 19**, 26, 28, 46, 73 ⁰ , 76, 77
F12, F24, F36, F48	05, 06, 13, 16, 17, 19*, 26, 28, 29, 46 ⁻ , 52, 73, ⁰ 74, 76, 77

Food Record and 24-Hour Recalls Not Included

++ Only at F6, not at any others

* Diet K Only at F2, F12, and F36. All patients at F24 and F48

** Diet K only at F4, F20, F28 and F44. All patients at F8, F16, F32, and F40

- 2 Form 46s⁻ for sitting and one for standing blood pressures

+ Not at F5 or F17 or F29 or F41; only at 11 aid F23 aid F35 aid F47

0 Diet K only

^ F6, F18, F30, F42 only

Appendix D. MDRDS: Publications and Presentations (as of October 2002)

(Prepared by the MDRDS Data Coordinating Center)

PAPERS

Klahr S. The Modification of Diet in Renal Disease Study. The New England Journal of Medicine 320:864-866, 1989.

Modification of Diet in Renal Disease (MDRD) Study Group (Prepared by Kopple ID, Berg R, Houser H, Steinman TI and Teschan P). Nutritional status of patients with different levels of chronic renal insufficiency. Kidney International 36:Suppl. 27, 5184-5194, 1989.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Levey AS, Berg RL, Gassman JJ, Hall PM and Walker WG). Creatinine filtration, secretion and excretion during progressive renal disease. Kidney International 36:Suppl. 27, S73-S80, 1989.

Perrone RD, Steinman TI, Beck GJ, Skibinski CI, Royal HID, Lawlor M, Hunsicker LG and the Modification of Diet in Renal Disease Study. Utility of radioisotopic filtration markers in chronic renal insufficiency: Simultaneous comparison of ¹²⁴I-Iothalamate, ¹⁶⁹Yb-DTPA, ^{99m}Tc-DTPA and inulin. American Journal of Kidney Diseases 16:224-235, 1990.

Schluchter MD and the Modification of Diet in Renal Disease Study. Estimating correlation between alternative measures of disease progression in a longitudinal study. Statistics in Medicine 9:1175-1188, 1990.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Levey, AS, Gassman JJ, Hall PM, and Walker WG). Assessing the progression of renal disease in clinical studies: effects of duration of follow-up and regression to the mean. Journal of the American Society of Nephrology 1:1087-1094, 1991.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Beck GJ, Berg RL, Coggins CH, Gassman JJ, Hunsicker LG, Schluchter MD, and Williams GW). Design and statistical issues of the Modification of Diet in Renal Disease Trial. Controlled Clinical Trials 12:566-586, 1991.

Yamamoto ME, Averbach FM, Caggiula AW, Jones FL, Gillis BP, and the Modification of Diet in Renal Disease (MDRD) Study. The production of quality dietary data: A collaborative effort of the Modification of Diet in Renal Disease Study. Journal of Renal Nutrition 2:117-125, 1992.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Anderson A, Caggiula AW, Klahr S, Kusek JW, Levey AS, and Williams GW). The Modification of Diet in Renal Disease Study: Design, methods, and results from the feasibility study. American Journal of Kidney Diseases 29:18-33, 1992.

Kidney Disease Clinical Studies Initiative, Major Kidney Clinical Research Studies and Projects Inventory, Modification of Diet in Renal Disease

- Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Greene T, Bourgoignie JJ, Habwe V, Kusek JW, Snetselaar L, Soucie JM, and Yamamoto M). Baseline characteristics in the Modification of Diet in Renal Disease Study. Journal of the American Society of Nephrology 3:1819-1834, 1993 (original version); 4:1221-1236, 1993 (corrected version).
- Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Kusek JW, Coyne T, deVelasco A, Drabik MJ, Finlay RA, Gassman JJ, Kiefer S, Powers SN, and Steinman TI). Recruitment experience in the Full-Scale Phase of the Modification of Diet in Renal Disease Study. Controlled Clinical Trials 14:538-557, 1993.
- Levey AS, Greene T, Schluchter MD, Cleary PA, Teschan PE, Lorenz RA, Molitch ME, Mitch WE, Siebert C, Hall PM, Steffes MW, and the Modification of Diet in Renal Disease (MDRD) Study and the Diabetes Control and Complications Trial (DCCT) Research Group. Glomerular filtration rate measurements in clinical trials. Journal of the American Society of Nephrology 4:1159-1171, 1993.
- Gillis BP, Caggiula AW, Jones FL, Maurer E, Meehan RM, Yamamoto ME, and the MDRD Study Group. Features of the nutrient database and analysis system for the Modification of Diet in Renal Disease Study. Controlled Clinical Trials 15:44-58, 1994.
- Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Laidlaw SA, Berg RL, Kopple JD, Naito H, Walker G, Walser M). Patterns of fasting plasma amino acid levels in chronic renal insufficiency: Results from the Feasibility Phase of the Modification of Diet in Renal Disease Study. American Journal of Kidney Diseases 23:504-513, 1994.
- Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Coggins CH, Dwyer IT, Greene T, Petot G, Snetselaar LG, and Van Lente F). Serum lipid changes associated with modified protein diets: from the Feasibility Phase of the Modification of Diet in Renal Disease Study. American Journal of Kidney Diseases 23:514-523, 1994.
- Klahr S, Levey AS, Beck GJ, Caggiula AW, Hunsicker LG, Kusek JW, and Striker GE for the Modification of Diet in Renal Disease (MDRD) Study Group. The effects of dietary protein restriction and blood pressure control on the progression of chronic renal disease: The Modification of Diet in Renal Disease Study. New England Journal of Medicine 330:877-884, 1994.
- Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Snetselaar L, Dwyer J, Adler S, Petot GJ, Berg R, Gassman J, and Houser H). Reduction of dietary protein and phosphorus in the Modification of Diet in Renal Disease Feasibility Study. Journal of the American Dietetic Association 94:986-990, 1994.
- Modification of Diet in Renal Disease Study Group. (Prepared by Klahr S, Breyer JA, Beck GJ, Dennis VW, Hartman JA, Roth D, Steinman TI, Wang S-R, Yamamoto, ME). Dietary protein restriction, blood pressure control, and the progression of polycystic kidney disease. Journal of the American Society of Nephrology 5:2037-2047, 1995.
- Gillis BP, Caggiula AW, Chiavacci AT, Coyne T, Doroshenko L, Milas, NC, Nowalk MP, Kinzel-Scherch L for the Modification of Diet in Renal Disease Study Group. Nutrition

Kidney Disease Clinical Studies Initiative, Major Kidney Clinical Research Studies and Projects Inventory, Modification of Diet in Renal Disease

intervention program of the Modification of Diet in Renal Disease Study: A self-management approach. Journal of the American Dietetic Association 95:1288-1294, 1995.

Milas NC, Nowalk MP, Akpele L, Castaldo L, Coyne T, Doroshenko L, Kigawa L, Korzec-Ramirez D, Kinzel-Scherch L, Snetselaar L for the Modification of Diet in Renal Disease Study Group. Factors associated with adherence to the dietary protein intervention in the Modification of Diet in Renal Disease Study. Journal of the American Dietetic Association 95:1295-1300, 1995.

Coyne T, Olson M, Bradham K, Garcon M, Gregory P, Kinzel-Scherch L for the Modification of Diet in Renal Disease Study Group. Dietary satisfaction correlated with adherence in the Modification of Diet in Renal Disease Study. Journal of the American Dietetic Association 95:1301-1306, 1995.

Dolecek TA, Olson MB, Caggiula AW, Dwyer JT, Milas NC, Gillis BP, Hartman JA, DiChiro JT for the Modification of Diet in Renal Disease Study Group. Registered dietitian time requirements in the Modification of Diet in Renal Disease Study. Journal of the American Dietetic Association 95:1307-1312, 1995.

Peterson JC, Adler S, Burkart JM, Greene T, Hebert LA, Hunsicker LG, King AJ, Klahr S, Massry SG, Seifter JL for the Modification of Diet in Renal Disease Study Group. Blood pressure control, proteinuria and the progression of renal disease: The Modification of Diet in Renal Disease Study. Annals of Internal Medicine 123:754-762, 1995.

Levey AS, Adler S, Caggiula AW, England BK, Greene T, Hunsicker LG, Kusek JW, Rogers NL, Teschan PE for the Modification of Diet in Renal Disease (MDRD) Study Group. Effects of dietary protein restriction on the progression of advanced renal disease in the Modification of Diet in Renal Disease (MDRD) Study. American Journal of Kidney Diseases 27:652-663, 1996.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Levey AS, Bosch JP, Coggins CH, Greene T, Mitch WE, Schluchter MD, Schwab SJ). Effects of diet and antihypertensive therapy on creatinine clearance and serum creatinine in the Modification of Diet in Renal Disease Study. Journal of the American Society of Nephrology 7: 556-565, 1996.

Buckalew VM, Berg RL, Wang S-R, Porush JG, Rauch S, Schulman G by the Modification of Diet in Renal Disease Study Group. Prevalence of hypertension in 1,795 subjects with chronic renal disease: The Modification of Diet in Renal Disease Study baseline cohort. American Journal of Kidney Diseases 28: 811-821, 1996.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Levey AS, Adler S, Caggiula AW, England BK, Greene T, Hunsicker LG, Kusek JW, Rogers NL, Teschan PE). Effects of dietary protein restriction on the progression of moderate renal disease in the Modification of Diet in Renal Disease Study. Journal of the American Society of Nephrology 7:2616-2626, 1996.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Levey AS, Beck GJ, Bosch JP, Caggiula AW, Greene T, Hunsicker LG, Klahr S). Short-term effects of protein

Kidney Disease Clinical Studies Initiative, Major Kidney Clinical Research Studies and Projects Inventory, Modification of Diet in Renal Disease

intake, blood pressure, and antihypertensive therapy on glomerular filtration rate in the Modification of Diet in Renal Disease Study. Journal of the American Society of Nephrology 7:2097-2109, 1996.

Lazarus JM, Bourgoignie JJ, Buckalew VM, Greene T, Levey AS, Milas NC, Paranandi L, Peterson JC, Porush JG, Rauch S, Soucie JM, Stollar C for the Modification of Diet in Renal Disease (MDRD) Study Group. Achievement and safety of a low blood pressure goal in chronic renal disease. Hypertension 29:641-650, 1997.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Yamamoto ME, Olson MB, Fine J, Powers S, Stollar C). The effect of sodium restriction and weight reduction on blood pressure patients with hypertension and chronic renal failure. Journal of Renal Nutrition 7:25- 2, 1997.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Hebert LA, Kusek JW, Greene T, Agodoa LY, Jones CA, Levey AS, Breyer JA, Faubert PF, Rolin HA, Wang S-R). Effects of blood pressure control on progressive renal disease in blacks and whites. Hypertension 30 (pt 1):428-435, 1997.

Modification of Diet in Renal Disease (MDDRD) Study Group. (Prepared by Hunsicker LG, Adler S, Caggiula A, England BK, Greene T, Kusek JW, Rogers NL, Teschan PE). Predictors of the progression of renal disease in the Modification of Diet in Renal Disease Study. Kidney International 51:1908-1919, 1997.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Kopple ID, Levey AJ, Greene T, Chumlea WC, Gassman JJ, Hollinger DL, Maroni BJ, Merrill D, Scherch LK, Schulman G, Wang S-R, Zimmer GS). Effect of dietary protein restriction on nutritional status in the Modification of Diet in Renal Disease (MDRD) Study. Kidney International 52:778-791, 1997.

Rocco MV, Gassman JJ, Wang S-R, Kaplan RM and the Modification of Diet in Renal Disease Study Group. Cross-sectional study of quality of life and symptoms in chronic renal disease patients: The Modification of Diet in Renal Disease Study. American Journal of Kidney Diseases 29:888-896, 1997.

Ciggins CH, Lewis JB, Caggiula AW, Castaldo LS, Klahr S, Wang S-R). Differences between women and men with chronic renal disease. Nephrology, Dialysis and Transplantation 13:1430-1437, 1998.

Teschan PE, Beck GJ, Dwyer J, Greene T, Klahr S, Levey AS, Mitch WE, Snetselaar L, Steinman T, Walser M. Effect of a ketoacid-aminoacid supplemented very low protein diet on the progression of advanced renal disease: The MDRD Feasibility Study. Clinical Nephrology 50:273-283, 1998.

Levey AS, Bosch JP, Breyer Lewis J, Greene T, Rogers N, Roth D for the Modification of Diet in Renal Disease Study Group. A more accurate method to estimate glomerular filtration rate from serum creatinine: A new prediction equation. Annals of Internal Medicine 130:461-470, 1999.

Kidney Disease Clinical Studies Initiative, Major Kidney Clinical Research Studies and Projects Inventory, Modification of Diet in Renal Disease

Levey AS, Greene T, Beck GJ, Caggiula AW, Kusek JW, Hunsicker LG, Klahr S. Dietary protein restriction and the progression of chronic renal disease: What have all the results of the MDRD Study shown? Journal of the American Society of Nephrology 10:2426-2439, 1999.

Modification of Diet in Renal Disease Study Group. (Prepared by Kopple ID, Greene T, Chumlea WC, Hollinger O, Maroni BJ, Merrill D, Scherch LK, Schulman G, Wang SR, Zimmer GS). Relationship between nutritional status and GFR: Results from the MDRD Study. Kidney International 57: 1688-1703, 2000.

Schluchter MD, Greene T and Beck G. Analysis of change in the presence of informative censoring: Application to a longitudinal clinical trial of progressive renal disease. Statistics in Medicine 20: 989-1007, 2001.

Greene T. A model for a proportional treatment effect on disease progression. Biometrics 57: 354-360, 2001.

Coresh J, Astor B, McQuillan G, Kusek J, Greene T, Van Lente F, Levey A. Calibration and random variation of the serum creatinine assay as critical elements of using equations to estimate glomerular filtration rate. American Journal of Kidney Disease 39:920-929, 2002.

Sarnak MJ, Coronado B, Greene T, Wang S, Kusek JW, Beck GJ, Levey AS and the MDRD Study Group. Cardiovascular disease risk factors in chronic renal insufficiency. Nephrology 5:327-335, 2002.

Sarnak MJ, Wang SR, Beck GJ, Kusek JW, Seihub J, Greene T, Levey AS. Homocysteine, cysteine, and B vitamins as predictors of kidney disease progression. American Journal of Kidney Disease 40:932-939, 2002.

Coresh J, Astor J, Greene T, Eknoyan G, Levey A. Prevalence of Reduced Kidney Function and Chronic Kidney Disease in the Adult US Population: Third National Health and Nutrition Examination Survey. American Journal of Kidney Disease, In Press (2002)

Sarnak MJ, Poindexter A, Wang SR, Beck G, Kusek J, Markovina S, Greene T, Levey A. C-reactive protein and leptin as risk factors for kidney disease progression in the Modification of Diet in Renal Disease (MDRD) Study. Kidney International. In press.

Hebert LA, Greene T, Levey A, Falkenhain ME, Wang SR, Klahr S. High urine volume and low urine osmolality are risk factors for faster progression of renal disease. Journal of the American Society of Nephrology. (Under review, 2002).

Songer T, Ettaro L, Caggiula A, Levey A, Greene T, Kusek J, Olson M. Cost-effectiveness of dietary protein restriction in moderate renal disease. (Under review, 2002).

Menon V, Wang X, Greene T, Beck G, Kusek J, Marcovina S, Levey A, Sarnak M. Determinants of serum leptin in patients with reduced glomerular filtration rate. (To be submitted).

Kidney Disease Clinical Studies Initiative, Major Kidney Clinical Research Studies and Projects Inventory, Modification of Diet in Renal Disease

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Caggiula AW, Milas NC, Burkart JM, DiChiro J, Kigawa L, Powers S, Saum D, Snetselaar L, Wang S-R). Dietary adherence in the Modification of Diet in Renal Disease Study. Controlled Clinical Trials (To be submitted).

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Caggiula AW, Coyne T, Hartman J, Milas CN, Mueller D, Olson MB, Powers S, Snetselaar L, Zimmer G). Nutritional activities and results from the baseline period of the Modification of Diet in Renal Disease (MDRD) Study. Controlled Clinical Trials (To be submitted).

PROCEEDINGS AND BOOK CHAPTERS

Fatica KJ, Leatherman JR, Gassman JJ and the MDRD Study Group. Use of SIR in a multi-center clinical trial. In: *Moving in New Directions: Proceedings from the 1987 USIR Annual Conference, October 18-21, 1987, Washington, D.C., The International Society of SIR Users, Washington, D.C., 109-121, 1988.*

Gillis EP, Caggiula AW, Jones FL, Mauer EA, Meehan RM, Petot GJ, Yamamoto ME, and the MDRD Study Group. Development of the nutrient database for the Modification of Diet in Renal Disease (MDRD) Study. Proceedings from the 14th National Nutrient Databank Conference. Iowa City, Iowa, June 19-21, 1989.

Kusek J, Caggiula A, Williams G, Klahr S and the Modification of Diet in Renal Disease Study Group. An overview of the Modification of Diet in Renal Disease Study. In: Nutritional and Pharmacological Strategies in Chronic Renal Failure, Contributions in Nephrology, eds. Albertazzi A, et al., Easel, Karger, 81:50-60, 1990.

Yamamoto ME, Jones FL, Meehan RJ, Riccio ME, Walter CA and the MDRD Study Group. Meeting the challenge of the changing food marketplace: the MDRD Study experience. Proceedings from the 19th National Nutrient Databank Conference, St. Louis, Missouri, May 22-24, 1994.

LETTERS TO THE EDITOR

Perrone R, Steinman T, Beck GJ, Skibinski CI, Royal HID, Lawlor M, Hunsicker LG. Letter to the Editor. American Journal of Kidney Diseases 17:724-726, 1991.

ABSTRACTS

Powers SN and the MDRD Study Group. Microcomputers in clinical trials for dietary management. Controlled Clinical Trials 7:234, 1986.

MDRD Study Group (Presented by Mitch WE and Steinman TI). Objectives and design of the cooperative study, Modification of Diet in Renal Disease. Kidney International 31:210, 1987.

- Kidney Disease Clinical Studies Initiative, Major Kidney Clinical Research Studies and Projects Inventory, Modification of Diet in Renal Disease
- Perrone R, Steinman T, Royal H, Lawlor M, Hunsicker L and the MDRD Study Group. Markers of GFR: Comparison of ⁹⁹Tc-DTPA, ¹⁶⁹Yb-DTPA and ¹²⁵I-iothalamate to Inulin. Kidney International 31:213, 1987.
- Beck GJ, Williams GW and the MDRD Study Group. Sample size determination for comparison of rates of change with lognormal distributions. Controlled Clinical Trials 8:299, 1987.
- Gassman JJ, Leatherman JR, Naito HIK and the MDRD Study Group. Laboratory quality control in a study with local and central laboratories. Controlled Clinical Trials 8:303, 1987.
- Gassman JJ, Drabik MJ and the MDRD Group. Development of a data transmission system for a multi-center clinical trial with distributed data entry. Controlled Clinical Trials 9:269, 1988.
- Gassman JJ, Leatherman JR and the MDRD Group. Closing out the pilot phase of a multicenter clinical trial. Controlled Clinical Trials 9:268, 1988.
- Petot GJ, Cornell BF and MDRD Study Group. Development of food exchanges for protein and phosphorus controlled diets. Controlled Clinical Trials 9:275, 1988.
- Powers SN, Barnes CM, Matsumoto JA, Raizman DJ, Kurtzman DA and MDRD Study Group. A computerized approach to individualized dietary assessment, education, and counseling. Controlled Clinical Trials 9:277, 1988.
- Sandberg AM, Gassman JJ, and the MDRD Study Group. Recruitment and enrollment experience in the pilot phase of the Modification of Diet in Renal Disease (MDRD) Study. Controlled Clinical Trials 9:281, 1988.
- Sandberg AM, Williams GW, Levey AS and the MDRD Study Group. Ethical considerations in the design of a randomized clinical trial of nutritional therapy for chronic renal disease. Controlled Clinical Trials 9:254, 1988.
- Gassman JJ, Leatherman JR, Fatica KJ, Drabik MJ, McPhearson JA and the MDRD Study Group. Development and use of distributed data entry and electronic communication in a multi-center study of progressive renal disease. Kidney International 35:226, 1989.
- MDRD Study Group (Prepared by Klahr S, Levey AS, Sandberg AM and Williams GW). Major results of the feasibility study of the Modification of Diet in Renal Disease (MDRD) Study. Kidney International 35:195, 1989.
- Modification of Diet in Renal Disease (MDRD) Study Group (Prepared by Levey AS, Gassman JJ, Hall PM and Walker WG). Poor correlation of rates of change of creatinine clearance, reciprocal serum creatinine and GFR. Kidney International 35:197, 1989.
- Steinman TI, Perrone RD, Hunsicker LG, Beck GJ and the MDRD Study Group. GFR determination in chronic renal failure by 3 radionuclide markers and inulin: Coefficient of variation of the methods. Kidney International 35:201, 1989.

Kidney Disease Clinical Studies Initiative, Major Kidney Clinical Research Studies and Projects Inventory, Modification of Diet in Renal Disease

Beck GJ, Berg RL, Hunsicker LG, Schluchter MD, Williams GW and the MDRD Study Group. Design of a randomized clinical trial with slope as the outcome: The Modification of Diet in Renal Disease (MDRD) Study. Controlled Clinical Trials 10:316, 1989.

Gassman JJ, Kovacs MM, Fatica KJ, Leatherman JR and the MDRD Study Group. Management of data queries and responses with a query database in a multi-center clinical trial with distributed data entry. Controlled Clinical Trials 10:327, 1989.

Modification of Diet in Renal Disease (MDRD) Study Group (Powers SN, Kurtzman DA, Petot GJ, Raizman DJ and Wetstein L). Promoting dietary compliance through computer assisted education, assessment and counseling. Kidney International 36:Suppl. 27, S306, 1989.

Gassman JJ, Leatherman IL, Drabik MJ and the MDRD Study Group. Evaluating the need for sending paper forms to the Data Coordinating Center in a clinical trial with distributed data entry. Controlled Clinical Trials 11:271, 1990.

Modification of Diet in Renal Disease (MDRD) Study Group. (Presented by Kusek JW, Coyne T, deVelasco A, Gassman JJ, Kiefer S, Powers S, Steinman T). Recruitment experience in the full-scale phase of the Modification of Diet in Renal Disease (MDRD) Study. Controlled Clinical Trials 12:678, 1991.

Modification of Diet in Renal Disease (MDRD) Study Group. (Presented by Gassman JJ, Berg RL, Byington RP, Hebert LA, Lambdin KB, Tanna A). Selecting a point estimator of blood pressure from consecutive measurements. Controlled Clinical Trials 12:709-710, 1991.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Hunsicker LG, Adler S, Caggiula A, England B, Greene T, Kusek J, Rogers N, Teschan P). Relationship among baseline proteinuria (P), mean arterial blood pressure (MAP) during Follow-Up, and decline in glomerular filtration rate (AGFR) in the Modification of Diet in Renal Disease Study. Journal of the American Society of Nephrology 4:254, 1993.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Klahr S, Beck G, Breyer J, Dennis V, Hartman J, Roth D, Steinman T, Yamamoto M). Dietary protein restriction and reduced blood pressure goal in adults with polycystic kidney disease (APKD). Journal of the American Society of Nephrology 4:263, 1993.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Kusek JW, Agodoa L, Greene T, Jones C). Comparison of decline of GFR in Blacks versus Non-Blacks in the MDRD Study. Journal of the American Society of Nephrology 4:253, 1993.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Levey AS, Beck GJ, Caggiula AW, Greene T, Hunsicker LG, Kusek JW, Klahr S). A hypothesis for the results of the Modification of Diet in Renal Disease (MDRD) Study. Journal of the American Society of Nephrology 4:253, 1993.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Levey AS, Bosch JP, Coggins CH, Greene T, Mitch WE, Schluchter MD). Effects of diet and blood pressure on creatinine clearance (CcR) and serum creatinine (PCR) in the MDRD Study. Journal of the American Society of Nephrology 4:253, 1993.

Kidney Disease Clinical Studies Initiative, Major Kidney Clinical Research Studies and Projects Inventory, Modification of Diet in Renal Disease

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Peterson JC, Burkart J, Greene T, Hebert L, King A, Klahr S, Massry S, Seifter J). The effect of blood pressure control on progression of renal disease depends on level of proteinuria (P) at baseline evaluation. Journal of the American Society of Nephrology 4:254, 1993.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Rocco MV, Coyne T, Eastin S, Faubert J, Gassman JJ, Gregory P, Kaplan RM, Midcalf V). Patient symptoms and quality of life in the MDRD Study at enrollment-Correlation with GFR. Journal of the American Society of Nephrology 4:254, 1993.

Greene T, Beck J, Gassman J, Paranandi L, Schluchter M, Wang S-R, and the MDRD Study Group. Considering changing the primary outcome of a clinical trial after examining the data: The Modification of Diet in Renal Disease (MDRD) Study. Controlled Clinical Trials 15:57S, 1994.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Kopple ID, Chumlea WC, Gassman JJ, Hollinger DL, Maroni BJ, Merrill D, Kinzel-Scherch L, Schulman G, Zimmer GS). Nutritional response to diet prescription in the MDRD Study. Journal of the American Society of Nephrology 5:335, 1994.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Kopple ID, Chumlea WC, Gassman JJ, Hollinger DL, Maroni BJ, Merrill D, Kinzel-Scherch L, Schulman G, Zimmer G). Relationship between GFR and nutritional status—results from the MDRD Study. Journal of the American Society of Nephrology 5:335, 1994.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Levey AS, Beck GJ, Caggiula AW, Greene T, Kusek JW, Striker GE, Klahr S. Trends toward a beneficial effect of a low protein diet during additional follow-up in the Modification of Diet in Renal Disease Study. Journal of the American Society of Nephrology 5:336, 1994.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Peterson JC, Greene T, Klahr S, Burkart JM, Hebert LA, King AJ, Massry SG, Seifter JL). Effect of reducing proteinuria (PR) on subsequent glomerular filtration rate (GFR) decline in patients with chronic renal failure (CRF). Journal of the American Society of Nephrology 5:339, 1994.

Greene T, Beck GJ, Gassman JJ, Kutner Mu, Paranandi L, Wang S-R and the MDRD Study Group. Comparison of time-to-event and slope-based analyses in nephrology clinical trials. Controlled Clinical Trials 16:65S, 1995.

Paranandi L, Wang S-R, Greene T, Gassman JJ, Beck GJ, Lazarus JM and the MDRD Study Group. Considerations regarding “measurement visits” during follow-up of clinical trials. Controlled Clinical Trials 16:1205-1215, 1995.

Kusek J, Beck G, Caggiula A, Levey A, Klahr S and the MDRD Study Group. Maintenance of adherence to a dietary intervention 9 months after completion of a clinical trial. Controlled Clinical Trials 16:132S, 1995.

Kidney Disease Clinical Studies Initiative, Major Kidney Clinical Research Studies and Projects Inventory, Modification of Diet in Renal Disease

Olson M, Coyne T, Caggiula A, Gregory P and the MDRD Study Group. Patient satisfaction with a dietary intervention: The Modification of Diet in Renal Disease Study. Controlled Clinical Trials 16:107S, 1995.

Olson M, Dolecek T, Caggiula A, Dwyer J and the MDRD Study Group. Time required for the protein intervention in the Modification of Diet in Renal Disease Study. Controlled Clinical Trials 16:129S-130S, 1995.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Levey AS, Beck GJ, Bosch JP, Caggiula AW, Greene T, Hunsicker LG, Klahr S). Short-term effects of protein intake, blood pressure, and antihypertensive therapy on GFR in the MDRD Study. Journal of the American Society of Nephrology 6:395, 1995.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Porush JG, Lazarus JM, Bourgoignie JJ, Buckalew VM, Greene T, Milas NC, Paranandi L, Peterson JC, Rauch S, Soucie IM, Stollar C). Efficacy of anti-hypertensive interventions in reducing blood pressure in the MDRD Study. Journal of the American Society of Nephrology 6:400, 1995.

Yamamoto ME, Olson MB, Stollar C for the Modification of Diet in Renal Disease (MDRD) Study Group. Effects of weight and Na⁺ change on blood pressures of hypertensive MDRD Study patients. Journal of the American Society of Nephrology 6:408, 1995.

Beck G, Caggiula A, Greene T, Kusek J, Levey A. A pilot study for feasibility of long-term patient follow-up after the end of a clinical trial. Controlled Clinical Trials 17(2S): 95S, 1996.

Olson MB, Coyne T, Caggiula A for the MDRD Study Group. Social factors influence dietary satisfaction in the Modification of Diet in Renal Disease Study. Controlled Clinical Trials 17(2S): 133S, 1996.

Coronado B, Beck GJ, Greene T, Kusek JW, Levey AS. Cardiovascular disease risk factors and GFR in the MDRD Study. Journal of the American Society of Nephrology 8: 135A, 1997.

Levey AS, Bosch JP, Breyer JA, Greene T, Rogers N, Roth P and the MDRD Study Group. Predicting GFR from serum creatinine in the MDRD Study. Journal of the American Society of Nephrology 8: 141A, 1997.

Modification of Diet in Renal Disease Study Group. (Prepared by Levey AS, Bosch JP, Breyer Lewis JA, Greene T, Rogers N, Roth D). Predicting GFR from serum creatinine in the MDRD Study: A correction. Journal of the American Society of Nephrology 9:153A, 1998.

Levey AS, Greene T, Burkart J and MDRD Study Group. Comprehensive assessment of the level of renal function at the initiation of dialysis in the MDRD Study. Journal of the American Society of Nephrology 9:153A, 1998.

Wang SR, Greene T, Beck G, Gassman J, Kusek J, Levey A, and the MDRD Study Group. Variability of indices of kidney function in studies of chronic renal disease. Controlled Clinical Trials 20:80S,

Kidney Disease Clinical Studies Initiative, Major Kidney Clinical Research Studies and Projects Inventory, Modification of Diet in Renal Disease

1999.

Yan G, Greene T, Beck G, Kusek J, Leung J, Levey A, Paronandi L, and the HEMO and MDRD Study Groups. Bias in longitudinal assessments of protein intake due to seasonal variations in studies of patients with kidney disease. Controlled Clinical Trials 20:63S, 1999.

Greene T, Beck G, Wang S, Kusek J, Levey A, and the MDRD Study Group. The effect of low protein diet in the MDRD Study A is dependent on the underlying rate of disease progression. Journal of the American Society of Nephrology 10: 165A, 1999.

Hebert LA, Greene T, Hunsicker LG, Levey AS, Wang S, and the MDRD Study Group. Relationship of urine volume and urine osmolality to the progression of renal disease in the Modification of Diet in Renal Disease (MDRD) Study. Journal of the American Society of Nephrology 10: 165-166A, 1999.

Levey AS, Greene T, Kusek JW, Beck J and the MDRD Study Group. A simplified equation to predict glomerular filtration rate from serum creatinine. Journal of the American Society of Nephrology 11:155A, 2000.

Dixon BS, Greene T, Hunsicker LG, Levey AS and the MDRD Study Group. Estimating urine creatinine excretion: application to estimate 24-hour urine protein from a spot urine sample. Journal of the American Society of Nephrology 12:99A, 2001

Hebert LA, Greene T, Falkenhain ME, Levey A, Hunsicker L, Wang SR, Beck G, Klahr S and the MDRD Study Group. Greater urine volume is associated with greater proteinuria in both the polycystic kidney disease (PKD) and non-PKD patients of the Modification of Diet in Renal Disease (MDRD) Study. Journal of the American Society of Nephrology 12:73A, 2001.

Uhlig K, Wang S, Beck G, Kusek J, Marcovina S, Greene T, Levey A, Sarnak M. Association of level of kidney function on lipoprotein (a) levels in non-diabetic kidney disease. Journal of the American Society of Nephrology 13:467A, 2002.

Uhlig K, Wang SR, Beck GJ, Kusek JW, Marcovina SM, Greene T, Levey AS, Sarnak MJ. Are lipoprotein (a) level and apoprotein (a) size risk factors for progression of non-diabetic kidney disease. Journal of the American Society of Nephrology, 13:465A, 2002.

PRESENTATIONS AND POSTERS

Gassman JJ and the MDRD Study Group. Central training of data managers of a multi-center clinical trial with distributed data entry. Society for Clinical Trials Seventh Annual Meeting, Montreal, Quebec, Canada, May 11-14, 1986.

Powers SN and the MDRD Study Group. Microcomputers in clinical trials for dietary management. Society for Clinical Trials Seventh Annual Meeting, Montreal, Quebec, Canada, May 11-14, 1986.

Kidney Disease Clinical Studies Initiative, Major Kidney Clinical Research Studies and Projects Inventory, Modification of Diet in Renal Disease

MDRD Study Group (Presented by Mitch WE and Steinman TI). Objectives and design of the cooperative study, Modification of Diet in Renal Disease. The American Society of Nephrology 19th Annual Meeting, Washington, D.C., December 7-10, 1986.

Perrone R, Stemman T, Royal H, Lawlor M, Hunsicker L and the MDRD Study Group. Markers of GFR: Comparison of 99TC-DTPA, 169YB-DTPA and 125-Iothalamate to Inulin. The American Society of Nephrology 19th Annual Meeting, Washington, D.C., December 7-10, 1986.

Beck GJ, Williams GW and the MDRD Study Group. Sample size determination for comparison of rates of change with lognormal distributions. Society for Clinical Trials Eighth Annual Meeting, Atlanta, Georgia, May 17-20, 1987.

Gassman JJ, Leatherman JR, Naito HK and the MDRD Study Group. Laboratory quality control in a study with local and central laboratories. Society for Clinical Trials Eighth Annual Meeting, Atlanta, Georgia, May 17-20, 1987.

Fatica KJ, Leatherman JR, Gassman JJ and the MDRD Study Group. Use of SIR in a multi-center clinical trial. SIR User's Group Meeting, Washington, D.C., October 18-21, 1987.

Gassman JJ, Drabik MJ and the MDRD Study Group. Development of a data transmission system of a multi-center clinical trial with distributed data entry. Society for Clinical Trials Ninth Annual Meeting, San Diego, California, May 22-25, 1988.

Gassman JJ, Leatherman JR and the MDRD Study Group. Closing out the pilot phase of a multi-center clinical trial. Society for Clinical Trials Ninth Annual Meeting, San Diego, California, May 22-25, 1988.

Petot GJ, Cornell BF and the MDRD Study Group. Development of food exchanges for protein and phosphorus controlled diets. Society for Clinical Trials Ninth Annual Meeting, San Diego, California, May 22-25, 1988.

Powers SN, Barnes CM, Matsumoto JA, Raizman DJ, Kurtzman DA, and the MDRD Study Group. A computerized approach to individualized dietary assessment, education, and counseling. Society for Clinical Trials Ninth Annual Meeting, San Diego, California, May 22-25, 1988.

Sandberg AM, Gassman JJ and the MDRD Study Group. Recruitment and enrollment experience in the pilot phase of the Modification of Diet in Renal Disease Study. Society for Clinical Trials Ninth Annual Meeting, San Diego, California, May 22-25, 1988.

Sandberg AM, Williams GW, Levey AS and the MDRD Study Group. Ethical considerations in the design of a randomized clinical trial of nutritional therapy for chronic renal disease. Society for Clinical Trials Ninth Annual Meeting, San Diego, California, May 22-25, 1988.

DiChiro J, McKay SM, Adler S, Dwyer J, Gassman JJ, Petot GJ, Snetselaar LG and the MDRD Study Group. Correlation between dietary recalls, diaries, and urea nitrogen appearance for estimating dietary protein intake in chronic renal failure. Fifth International Congress on Nutrition and Metabolism in Renal Disease, Strasbourg, France, September 1-3, 1988.

Kidney Disease Clinical Studies Initiative, Major Kidney Clinical Research Studies and Projects Inventory, Modification of Diet in Renal Disease

Kopple JD, Houser HB, Steinman T, Teschan P and the MDRD Study Group. Nutritional assessment and status in patients with different levels of chronic renal insufficiency. Fifth International Congress on Nutrition and Metabolism in Renal Disease, Strasbourg, France, September 1-3, 1988.

Laidlaw SA, Kopple JD, Walser M, Walker WG, Naito H and the MDRD Study Group. Plasma amino acid patterns at different levels of renal function (MDRD Study). Fifth International Congress on Nutrition and Metabolism in Renal Disease, Strasbourg, France, September 1-3, 1988.

MDRD Study Group (Presented by Hunsicker LG, Klahr S, Sandberg AM and Williams GW). Design and implementation of clinical trials for assessing the effect of diet on progression of renal disease. Fifth International Congress on Nutrition and Metabolism in Renal Disease, Strasbourg, France, September 1-3, 1988.

MDRD Study Group (Presented by Levey AS, Gassman JJ, Hall PM, and Walker WG). Methods for measuring renal function during progressive renal disease. Fifth International Congress on Nutrition and Metabolism in Renal Disease, Strasbourg, France, September 1-3, 1988.

MDRD Study Group (Presented by Powers SN, Kurtzman DA, Petot GJ, Raizman DJ and Wetstein L). Promoting dietary compliance through computer assisted education, assessment, and counseling. Fifth International Congress on Nutrition and Metabolism in Renal Disease, Strasbourg, France, September 1-3, 1988.

MDRD Study Group (Presented by Martin AA). Modification of Diet in Renal Disease (MDRD) Study: Objectives, design and recruitment goals. National Kidney Foundation/Council of Nephrology Nurses and Technicians Annual Meeting, San Antonio, Texas, December 8-11, 1988.

MDRD Study Group (Presented by Snetselaar L). Update on the Modification of Diet in Renal Disease (MDRD) Study. Eighteenth Annual Scientific Meeting of the National Kidney Foundation, San Antonio, Texas, December 8-11, 1988.

MDRD Study Group (Prepared by Klahr S, Levey AS, Sandberg AM and Williams GW). Major results of the feasibility study of the Modification of Diet in Renal Disease (MDRD) Study. American Society of Nephrology 21st Annual Meeting, San Antonio, Texas, December 11-14, 1988.

Modification of Diet in Renal Disease (MDRD) Study Group (Prepared by Levey AS, Gassman JJ, Hall PM and Walker WG). Poor correlation of rates of change of creatinine clearance, reciprocal serum creatinine and GFR. American Society of Nephrology 21st Annual Meeting, San Antonio, Texas, December 11-14, 1988.

Steinman TI, Perrone RD, Hunsicker LG, Beck GJ and the MDRD Study Group. GFR determination in chronic renal failure by 3 radionuclide markers and inulin: Coefficient of variation of the methods. The American Society of Nephrology 21st Annual Meeting, San Antonio, Texas, December 11-14, 1988.

- Kidney Disease Clinical Studies Initiative, Major Kidney Clinical Research Studies and Projects Inventory, Modification of Diet in Renal Disease
- Beck GJ, Berg RL, Hunsicker LG, Schluchter MD, Williams GW and the MDRD Study Group. Design of a randomized clinical trial with slope as the outcome: The Modification of Diet in Renal Disease (MDRD) Study. Society of Clinical Trials Tenth Annual Meeting, Minneapolis, Minnesota, May 15-18, 1989.
- Gassman JJ, Kovacs MM, Fatica KJ, Leatherman JR and the MDRD Study Group. Management of data queries and responses with a query database in a multi-center clinical trial with distributed data entry. Society of Clinical Trials Tenth Annual Meeting, Minneapolis, Minnesota, May 15-18, 1989.
- Gillis BP, Caggiula AW, Jones FL, Mauer EA, Meehan RM, Petot GJ, Yamamoto ME, and the MDRD Study Group. Development of the nutrient database for the Modification of Diet in Renal Disease (MDRD) Study. Fourteenth National Nutrient Databank Conference. Iowa City, Iowa, June 19-21, 1989.
- Kusek JW, Caggiula AW, Williams GW, Klahr S and the MDRD Study Group. Overview of the Modification of Diet in Renal Disease Study. International Meeting on Nutritional and Pharmacological Strategies in Chronic Renal Failure. Chieti, Italy, September 29-30, 1989.
- Caggiula AW, Milas NC, Yamamoto M and Amoroso W. MDRD: Modification of Diet in Renal Disease administrative prospective: collaborative teamwork. American Dietetic Association 72nd Annual Meeting, Kansas City, Missouri, October 23, 1989.
- Averbach FM, Brooks LL, Coyne ET, DiChiro JT, Gillis BP, Levy CS, Kinzel-Scherch L for the MDRD Study. Development of the MDRD (Phase III) patient resources to assess and monitor nutrient intake. National Kidney Foundation/Council on Renal Nutrition Annual Meeting, Washington, D.C., December 1-3, 1989.
- Jones FL, Caggiula AW, Gillis BP, Naujelis JA, Pelles DM, Yamamoto ME and the MDRD Study Group. All eggs are not created equal—dietary data documentation for clinical trials: The Modification of Diet in Renal Disease (MDRD) Study. Council of Renal Nutrition Annual Meeting, Washington, D.C., December 1-3, 1989.
- Modification of Diet in Renal Disease (MDRD) Study Group (Milas NC, Adler S, Coyne T, Kusek J, Olson M, Kinzel-Scherch L, Snetselaar L, and Stollar C). Maximizing dietary compliance in the MDRD Study. National Kidney Foundation/Council on Renal Nutrition Annual Meeting, Washington, D.C., December 1-3, 1989.
- Yamamoto ME, Averbach F, Caggiula AW, Gillis BP, Jones FL and the MDRD Study Group. Research quality dietary data for dietary intervention clinical trials: The Modification of Diet in Renal Disease Study (MDRD). National Kidney Foundation/Council on Renal Nutrition Annual Meeting, Washington, D.C., December 1-3, 1989.
- Kusek J. Overview of the Modification of Diet in Renal Disease Study. European Study Group. Heidelberg, Germany, May 3-6, 1990.
- Gassman JJ, Leatherman JL, Drabik MJ and the MDRD Study Group. Evaluating the need for sending paper forms to the Data Coordinating Center in a clinical trial with distributed data

Kidney Disease Clinical Studies Initiative, Major Kidney Clinical Research Studies and Projects Inventory, Modification of Diet in Renal Disease

entry. Society for Clinical Trials Eleventh Annual Meeting, Toronto, Canada, May 6-9, 1990.

Yamamoto ME, Averbach FA, Caggiula AW, Gillis BG, Jones FL, Meehan RM, Naujelis JA and the MDRD Study Group. Food details for data coding: implementation for controlled clinical trials and the MDRD Study. Fifteenth National Nutrient Databank Conference. Blacksburg, Virginia, June, 1990.

Averbach FM, Caggiula AW, Chiavacci AT, Gillis BP, Kurtzman DA, Meehan RM, Olson MB, Pedersen ME, Powers SN, Yamamoto ME and the MDRD Study Group. Tailoring the MDRD (Phase III) nutrient data base for use with the CBORD Group Inc. Professional Diet Analyzer. Fifteenth National Nutrient Databank Conference, Blacksburg, Virginia, June 1990.

Jones FL, Amoroso WP, Averbach FA, Bony DW, Caggiula AW, Gillis BP, Martin JP, Maurer EA, Meehan RM, Naujelis JA, Yamamoto ME and the MDRD Study Group. Computerized recipe nutrient analysis for clinical trials—The Modification of Diet in Renal Disease (MDRD) Study. Fifteenth National Nutrient Databank Conference, Blacksburg, Virginia, June 1990.

Yamamoto ME, Averbach FM, Caggiula AW, Gillis BP, Jones FL, Meehan RM, Naujelis JA and the MDRD Study Group. Common missing food details and their impact on estimates of patients' protein and phosphorus intakes. National Kidney Foundation/Council of Renal Nutrition Annual Meeting, Washington, D.C., December 1990.

MDRD Study (Presented by Caggiula AW, Bosch JP, Habwe VQ, Kusek J, McLeroy S, Milas NC, Kinzel-Scherch L, Stollar C). Dietary compliance patterns in the Modification of Diet in Renal Disease (MDRD) Study, Phase III. The American Society of Nephrology 23rd Annual Meeting, Washington, D.C., December 1990.

Modification of Diet in Renal Disease (MDRD) Study Group. (Presented by Kusek JW, Coyne T, deVelasco A, Gassman JJ, Kiefer S, Powers S, Steinman T). Recruitment experience in the full-scale phase of the Modification of Diet in Renal Disease (MDRD) Study. Society for Clinical Trials/International Society for Clinical Biostatistics Joint Meeting, Brussels, Belgium, July 8-12, 1991.

Modification of Diet in Renal Disease (MDRD) Study Group. (Presented by Gassman JJ, Berg RL, Byington RP, Hebert LA, Lambdin KE, Tanna A). Selecting a point estimator of blood pressure from consecutive measurements. Society for Clinical Trials/International Society for Clinical Biostatistics Joint Meeting, Brussels, Belgium, July 8-12, 1991.

Schluchter MD, Beck GJ, Berg RL, Gassman JJ, Williams GW, and the Modification of Diet in Renal Disease Study Group. Choice of a group-sequential procedure in a clinical trial with slope as an outcome. The 1991 Joint Statistical Meetings, Atlanta, Georgia, August 18-22, 1991.

Modification of Diet in Renal Disease Study (MDRD) Group. (Presented by Caggiula AW, Adler S, Milas NC, Coyne T, Snetselaar L, Rauch S, Kusek J, and Berg R). Patterns of patient compliance in the Modification of Diet in Renal Disease (MDRD) Study, Phase m.

Kidney Disease Clinical Studies Initiative, Major Kidney Clinical Research Studies and Projects Inventory, Modification of Diet in Renal Disease

Sixth International Congress on Nutrition and Metabolism in Renal Disease, Harrogate, England, August 26-30, 1991.

Yamamoto ME, Averbach FA, Caggiula AW, Gillis BG, Jones FL, Meehan RM, Naujelis JA and the MDRD Study. Factors influencing patients' diet report quality in a long-term multicentered clinical trial: the first two years' experience. National Kidney Foundation/Council of Renal Nutrition Annual Meeting, Baltimore, Maryland, November, 15-16, 1991.

Coyne T, Kusek JW, DiChiro I, Eyerman M, Mueller D, Stollar C, Zimmer G and the Modification of Diet in Renal Disease (MDRD) Study. Recruitment of patients for the Modification of Diet in Renal Disease (MDRD) Study—Contribution by dietitians. National Kidney Foundation/Council on Renal Nutrition Meeting, Baltimore, Maryland, November 15-16, 1991.

Levey AS, Schluchter MD, Cleary PA, Teschan PE, Lorenz RA, Molitch ME, Siebert C, Hall PM, Steffes MW, Modification of Diet in Renal Disease (MDRD) Study, and Diabetes Control and Complications Trial (DCCT). GFR measurements in clinical trials. The American Society of Nephrology 24th Annual Meeting, Baltimore, Maryland, November 17-20, 1991.

Jones EH, Basch M, Benfell K, Cooper R, Gassman J, and the MDRD Study Group. Drug Distribution Center for the Modification of Diet in Renal Disease Study. 26th American Society of Hospital Pharmacists Mid-Year Clinical Meeting, New Orleans, Louisiana, December 8-12, 1991.

Jones FL, Averbach FM, Caggiula AW, Gillis BP, Meehan RJ, Naujelis JA, Yamamoto ME, and the MDRD Nutrition Coordinating Center (NCC). Discovering the Great Unknowns: Describing the Composition of Mixed and Ethnic Dishes Consumed in Clinical Trials—The Modification of Diet in Renal Disease (MDRD) Study. Seventeenth National Nutrient Databank Conference, Baltimore, Maryland, June 7-10, 1992.

Yamamoto ME et al. Coding of problem food mixtures: The MDRD Study experience. NHANES Recipe Coding Workshop, September 15-16, 1992.

Klahr S and the MDRD Study Group. The Modification of Diet in Renal Disease Study. The National Kidney Foundation Spring Clinical Nephrology Meetings, Chicago, Illinois, April 1993.

Yamamoto ME, Averbach FM, Caggiula AW, Gillis BP, Jones FL, Meehan R, Naujelis JA, and the MDRD Study. Maximizing dietary quality through application of quality control findings: The MDRD Phase 3 Study experience. 18th National Nutrient Databank Conference, Baton Rouge, Louisiana, May 23-26, 1993.

Jones FL, Averbach FM, Caggiula AW, Gillis BP, Meehan RJ, Naujelis JA, Yamamoto ME, and the MDRD Study. Documenting entry substitutions with similar-food codes: Experiences from the MDRD Study. 18th National Nutrient Databank Conference, Baton Rouge, Louisiana, May 23-26, 1993.

Kidney Disease Clinical Studies Initiative, Major Kidney Clinical Research Studies and Projects Inventory, Modification of Diet in Renal Disease

Levey AS. Dietitians Seminar: Results of the Modification of Diet in Renal Disease Study. XII International Congress of Nephrology, Jerusalem, Israel, June 16, 1993.

Levey AS. Results of the Modification of Diet in Renal Disease Study. International Society of Nephrology Satellite Symposium Progression of Renal Disease, Tiberias, Israel, June 22, 1993.

Stollar C, Kinzel-Scherch L, Adler S, Kusek J, Caggiula A, and the MDRD Study Group. Patterns of dietary compliance in the Modification of Diet in Renal Disease (MDRD) Study. Phase III. XIIth International Congress of Nephrology, Jerusalem, Israel, June 12, 1993.

Klahr S and the MDRD Study Group. Modification of Diet and Renal Disease: Results from the full-scale study. XIIth International Congress of Nephrology, Jerusalem, Israel, June 1993.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Berg R, Buckalew V, Pearce G, Porush J, Rauch S, Schulman G). Differences between hypertensive and normotensive patients in MDRD cohort. XIIth International Congress of Nephrology, Jerusalem, Israel, June 13-18, 1993.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Hunsicker LG, Adler S, Caggiula A, England B, Greene T, Kusek J, Rogers N, Teschan P). Relationship among baseline proteinuria (P), mean arterial blood pressure (MAP) during follow-up, and decline in glomerular filtration rate (AGFR) in the Modification of Diet in Renal Disease Study. The American Society of Nephrology 26th Annual Meeting, Boston, Massachusetts, November 14-17, 1993.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Klahr S, Beck G, Breyer J, Dennis V, Hartman J, Roth D, Steinman T, Yamamoto M). Dietary protein restriction and reduced blood pressure goal in adults with polycystic kidney disease (APKD). The American Society of Nephrology 26th Annual Meeting, Boston, Massachusetts, November 14-17, 1993.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Kusek JW, Agodoa L, Greene T, Jones C). Comparison of decline of GFR in Blacks versus Non-Blacks in the MDRD Study. The American Society of Nephrology 26th Annual Meeting, Boston, Massachusetts, November 14-17, 1993.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Levey AS, Beck GJ, Caggiula AW, Greene T, Hunsicker LG, Kusek JW, Klahr S). A hypothesis for the results of the Modification of Diet in Renal Disease (MDRD) Study. The American Society of Nephrology 26th Annual Meeting, Boston, Massachusetts, November 14-17, 1993.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Levey AS, Bosch JP, Coggins CH, Greene T, Mitch WE, Schluchter MD). Effects of diet and blood pressure on creatinine clearance (C_{CR}) and serum creatinine (P_{CR}) in the MDRD Study. The American Society of Nephrology 26th Annual Meeting, Boston, Massachusetts, November 14-17, 1993.

Kidney Disease Clinical Studies Initiative, Major Kidney Clinical Research Studies and Projects Inventory, Modification of Diet in Renal Disease

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Peterson IC, Burkart I, Greene T, Hebert L, King A, Klahr S, Massry S, Seifter J). The effect of blood pressure control on progression of renal disease depends on level of proteinuria (P) at baseline evaluation. The American Society of Nephrology 26th Annual Meeting, Boston, Massachusetts, November 14-17, 1993.

Doreshenko L and the MDRD Study Group. Intervention results from the Modification of Diet in Renal Disease Study. Meeting of the MDRD Study Referring Physicians, Bowman Gray School of Medicine, Winston-Salem, North Carolina, February 3, 1994.

Saum D and the MDRD Study Group. Intervention results from the Modification of Diet in Renal Disease Study. Philadelphia Dietetic Association Annual Meeting, Council on Renal Nutrition Educational Workshop, Plymouth Meeting, Pennsylvania, February 24, 1994.

Dichiro J and the MDRD Study Group. The MDRD Study—What did we learn and where do we go from here? Northwest Renal Dietitians Conference, Vancouver, British Columbia, March 3, 1994.

Milas NC, Nowalk MP, Gillis BP and the MDRD Study. Factors associated with sustained adherence to nutrition intervention goals. 34th Annual Conference on Cardiovascular Disease, Epidemiology and Prevention, Tampa, Florida, March 16-19, 1994.

Eckard L and the MDRD Study Group. Renal nutrition and the Modification of Diet in Renal Disease Study. Fayetteville Area Health Education Center Meeting, Fayetteville, North Carolina, March 22, 1994.

Klahr S and the MDRD Study Group. MDRD Study: Introduction, study design and intention to treat results. NIH Renal Disease Symposium on Prevention of Progression in Chronic Renal Disease: Development of Management Recommendations, Bethesda, Maryland, April 4-6, 1994.

Klahr S and the MDRD Study Group. MDRD Study: Predictors of progression. NIH Renal Disease Symposium on Prevention of Progression in Chronic Renal Disease: Development of Management Recommendations, Bethesda, Maryland, April 4-6, 1994.

Peterson JC and the MDRD Study Group. MDRD Study: Blood pressure intervention. NIH Renal Disease Symposium on Prevention of Progression in Chronic Renal Disease: Development of Management Recommendations, Bethesda, Maryland, April 4-6, 1994.

Hunsicker LG and the MDRD Study Group. MDRD Study: Diet intervention. NIH Renal Disease Symposium on Prevention of Progression in Chronic Renal Disease: Development of Management Recommendations, Bethesda, Maryland, April 4-6, 1994.

Breyer JA and the MDRD Study Group. MDRD Study: Polycystic kidney disease. NIH Renal Disease Symposium on Prevention of Progression in Chronic Renal Disease: Development of Management Recommendations, Bethesda, Maryland, April 4-6, 1994.

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Agodoa L and the MDRD Study Group. MDRD Study: African Americans. NIH Renal Disease Symposium on Prevention on Progression of Chronic Renal Disease: Development of Management Recommendations, Bethesda, Maryland, April 4-6, 1994.

Levey AS and the MDRD Study Group. MDRD Study: Renal function measurements. NIH Renal Disease Symposium on Prevention of Progression in Chronic Renal Disease: Development of Management Recommendations, Bethesda, Maryland, April 4-6, 1994.

Caggiula AW and the MDRD Study Group. MDRD Study: Dietary adherence. NIH Renal Disease Symposium on Prevention of Progression in Chronic Renal Disease: Development of Management Recommendations, Bethesda, Maryland, April 4-6, 1994.

Korzec-Ramirez DL and the MDRD Study Group. Successful intervention in renal disease. Massachusetts Dietetic Association Annual Meeting, Boston, Massachusetts, April 6, 1994.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Caggiula AW, Klahr S, Levey A, Kusek J, Beck G, Greene T). Does dietary adherence persist after a clinical trial? The experience in the Modification of Diet in Renal Disease Study (MDRD). The National Kidney Foundation Spring Clinical Nephrology Meetings, Chicago, Illinois, April 7-10, 1994.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Lazarus J, Buckalew V, Bourgoignie J, Greene T, Milas C, Paranandi L, Peterson J, Porush J, Rauch S, Soucie M, Stollar C). Blood pressure compliance and safety in the MDRD Study. The National Kidney Foundation Spring Clinical Nephrology Meetings, Chicago, Illinois, April 7-10, 1994.

Modification of Diet in Renal Disease (MDRD) Study Group. (Presented by Levey AS). Secondary Outcomes. The National Kidney Foundation Spring Clinical Nephrology Meetings, Chicago, Illinois, April 7-10, 1994.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Levey A, Adler S, Caggiula A, England B, Greene T, Hunsicker L, Kusek J, Rogers N, Teschan P). Association of increased protein intake with progression of renal disease in patients with advance renal insufficiency. The National Kidney Foundation Spring Clinical Nephrology Meetings, Chicago, Illinois, April 7-10, 1994.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Milas NC and Nowalk MP). Self-monitoring supports protein changes. The National Kidney Foundation Spring Clinical Nephrology Meetings, Chicago, Illinois, April 7-10, 1994.

Gillis BP, Caggiula A, Doroshenko L, Milas NC, Nowalk MP, and the MDRD Study Group. Outstanding long-term dietary compliance: Participants rate usefulness in intervention components. Society of Behavioral Medicine 15th Anniversary Meeting, Boston, Massachusetts, April 13-16, 1994.

Milas NC, Gillis BP, Caggiula AW, Nowalk MP, and the MDRD Study Group. Self-monitoring of protein intake and compliance to dietary goals among patients with renal disease.

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Society of Behavioral Medicine 15th Anniversary Meeting, Boston, Massachusetts, April 13-16, 1994.

Coyne T, Olson M, Caggiula AW, Bradham K, Garcon M, Gregory P and the MDRD Study Group. The association between dietary satisfaction and adherence to protein modification in individuals with chronic renal disease. Society of Behavioral Medicine 15th Anniversary Meeting, Boston, Massachusetts, April 13-16, 1994.

Snetselaar L and the MDRD Study Group. Renal disease and diet modifications. Illinois Dietetic Association Annual Meeting, Illinois, April 29, 1994.

Snetselaar L and the MDRD Study Group. The Modification of Diet in Renal Disease Study: Implications for dietary counseling. Harvard Medical School Continuing Medical Education, May 5, 1994.

Greene T, Beck G, Gassman J, Paranandi L, Schluchter M, Wang S-R, and the MDRD Study Group. Considering changing the primary outcome of a clinical trial after examining the data: The Modification of Diet in Renal Disease (MDRD) Study. Society for Clinical Trials Fifteenth Annual Meeting, Houston, Texas, May 8-11, 1994.

Parris B and the MDRD Study Group. Intervention results from the Modification of Diet in Renal Disease Study. Gainesville Dietetic Association Meeting, Gainesville, Florida, May 10, 1994.

Gillis BP, Caggiula AW, Chiavacci AT, Doroshenko L, Milas NC, Nowalk MP, and the MDRD Study Group. Which activities were conducted most often in renal nutrition program with outstanding long-term dietary adherence? Pennsylvania Dietetic Association Annual Meeting, Allentown, Pennsylvania, May 13, 1994.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Jones FL, Averbach FM, Bruno EJ, Meehan RJ, Naujelis J, Yamamoto ME). Timely feedback for diet intervention support: A unique feature of the MDRD Study. 19th National Nutrient Databank Conference, St. Louis, Missouri, May 22-24, 1994.

Yamamoto ME, Jones FL, Meehan RJ, Riccio ME, Walter CA and the MDRD Study Group. Meeting the challenge of the changing food marketplace: the MDRD Study experience. 19th National Nutrient Databank Conference, St. Louis, Missouri, May 22-24, 1994.

Yamamoto ME, Averbach FM, Jones FL, Olson M and the MDRD Study Group. Time requirements for documenting dietary data for research applications: The MDRD Study experience. 19th National Nutrient Databank Conference, St. Louis, Missouri, May 22-24, 1994.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Levey A, Adler S, Caggiula A, England B, Greene T, Hunsicker L, Kusek J, Rogers N, Teschan P). Association of increased protein intake with progression of renal disease in patients with advance renal insufficiency. 7th International Congress on Nutrition and Metabolism in Renal Disease, Stockholm, Sweden, May 29-June 1, 1994.

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Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Bosch J, Breyer J, Greene T, Levey A, Rogers N, Roth D). Predicting GFR from serum creatinine in the MDRD Study. 7th International Congress on Nutrition and Metabolism in Renal Disease, Stockholm, Sweden, May 29- June 1, 1994.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Lazarus J, Buckalew V, Bourgoignie J, Greene T, Milas NC, Paranandi L, Peterson J, Porush J, Rauch S, Soucie M, Stollar C). Blood pressure compliance and safety in the MDRD Study. 7th International Congress on Nutrition and Metabolism in Renal Disease, Stockholm, Sweden, May 29- June 1, 1994.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Milas NC, Nowalk MP, Gillis P). Factors related to adherence to nutrition intervention goals. 7th International Congress on Nutrition and Metabolism in Renal Disease, Stockholm, Sweden, May 29- June 1, 1994.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Caggiula AW, Milas NC, Kinzel-Scherch L, Coyne T, Hollinger D, Olson M). Long-term dietary adherence and nutritional status in the Modification of Diet in Renal Disease Study. 7th International Congress on Nutrition and Metabolism in Renal Disease, Stockholm, Sweden, May 29- June 1, 1994.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Caggiula AW, Klahr S, Levey A, Kusek J, Beck G, Greene T). Does dietary adherence persist after a clinical trial? The experience in the Modification of Diet in Renal Disease Study (MDRD). 7th International Congress on Nutrition and Metabolism in Renal Disease, Stockholm, Sweden, May 29-June 1, 1994.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Kopple ID, Chumlea WC, Gassman J, Hollinger D, Maroni B, Merrill D, Kinzel-Scherch L, Schulman G, Zinuner G). Nutritional response to diet prescription in the MDRD Study. 7th International Congress on Nutrition and Metabolism in Renal Disease, Stockholm, Sweden, May 29- June 1, 1994.

DiChiro J and the MDRD Study Group. Therapeutic low protein diets in liver, renal and metabolic disorders. Washington State Council on Renal Nutrition Conference on Low Protein Diets, Seattle, Washington, June 4, 1994.

DiChiro J and the MDRD Study Group. Low protein diets: Educating the public; Study results: The MDRD Study. Florida Dietetic Association Annual Meeting, Palm Beach, Florida, June 10, 1994.

Parris B and the MDRD Study Group. Intervention results from the Modification of Diet in Renal Disease Study. Florida Dietetic Association Annual Meeting, Palm Beach, Florida, June 29, 1994.

Caggiula AW, Doroshenko L, Snetselaar L, Milas NC and the MDRD Study Group. Improving adherence in patients with renal disease and/or diabetes: Ideas from Two Clinical Trials, the Modification of Diet and Renal Disease Study and the Diabetes Control and

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Complications Trial. The 77th Annual Meeting and Exhibition of the American Dietetic Association, Orlando, Florida, October 17, 1994.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Kopple ID, Chumlea WC, Gassman JJ, Hollinger DL, Maroni BJ, Merrill D, Kinzel-Scherch L, Schulman G, Zimmer GS). Nutritional response to diet prescription in the MDRD Study. The American Society of Nephrology 27th Annual Meeting, Orlando, Florida, October 26-29, 1994.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Kopple ID, Chumlea WC, Gassman JJ, Hollinger DL, Maroni BJ, Merrill D, Kinzel-Scherch L, Schulman G, Zinmer G). Relationship between GFR and nutritional status—results from the MDRD Study. The American Society of Nephrology 27th Annual Meeting, Orlando, Florida, October 26-29, 1994.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Levey AS, Beck GJ, Caggiula AW, Greene T, Kusek JW, Striker GE, Klahr S). Trends toward a beneficial effect of a low protein diet during additional follow-up in the Modification of Diet in Renal Disease Study. The American Society of Nephrology 27th Annual Meeting, Orlando, Florida, October 26-29, 1994.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Peterson JC, Greene T, Klahr S, Burkart JM, Hebert LA, King AJ, Massry SG, Seifter JL). Effect of reducing proteinuria (PR) on subsequent glomerular filtration rate (GFR) decline in patients with chronic renal failure (CRF). The American Society of Nephrology 27th Annual Meeting, Orlando, Florida, October 26-29, 1994.

Yamamoto ME, Caggiula AW, Jones FL, Olson MB, Snetselaar LG for the Modification of Diet in Renal Disease Study. Agreement between protein intake assessed by urinary urea nitrogen appearance (UNA) and 3-day food records. Second International Conference on Dietary Assessment Methods, Boston, Massachusetts, January 22-24, 1995.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Milas NC, Nowalk MP, Gillis B, Caggiula AW). Relationship between self-monitoring and long-term adherence: MDRD Study. Society of Behavioral Medicine 16th Annual Meeting, San Diego, California, March 22-25, 1995.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Gillis B, Caggiula AW, Doroshenko L, Milas NC, Nowalk MP). Patient self-management and long-term adherence. The MDRD Study nutrition intervention program. Society of Behavioral Medicine 16th Annual Meeting, San Diego, California, March 22-25, 1995.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Coyne T, Olson M, Caggiula A, Bradham K, Garcon M, Gregory P). Long-term adherence to modified protein intakes and dietary satisfaction in the Modification of Diet and Renal Disease Study. Society of Behavioral Medicine Meetings, San Diego, California, March 22-25, 1995.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Gillis B, Caggiula AW, Milas NC). Review of educational materials developed from the results of the

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Modification of Diet in Renal Disease Study. Fourth Annual Spring Clinical Nephrology Meetings of the National Kidney Foundation, Washington, D.C., March 23-26, 1995.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Coyne T, Olson MB, Bradhani K, Caggiula AW, Garcon M, Gregory P, Kinzel-Scherch L) Use of a dietary satisfaction questionnaire in counseling for protein modification. Council on Renal Nutrition Meeting, Washington, D.C., March 23-26, 1995.

Greene T, Beck GJ, Gassman JJ, Kutner MH, Paranandi L, Wang S-R and the MDRD Study Group. Comparison of time-to-event and slope-based analyses in nephrology clinical trials. Society for Clinical Trials Sixteenth Annual Meeting, Seattle, Washington, April 30-May 3, 1995.

Paranandi L, Wang S-R, Greene T, Gassman JJ, Beck GJ, Lazarus JM and the MDRD Study Group. Considerations regarding "measurement visits" during follow-up of clinical trials. Society for Clinical Trials Sixteenth Annual Meeting, Seattle, Washington, April 30-May 3, 1995.

Kusek J, Beck G, Caggiula A, Levey A, Klahr S and the MDRD Study Group. Maintenance of adherence to a dietary intervention 9 months after completion of a clinical trial. Society for Clinical Trials Sixteenth Annual Meeting, Seattle, Washington, April 30-May 3, 1995.

Olson M, Coyne T, Caggiula A, Gregory P and the MDRD Study Group. Patient satisfaction with a dietary intervention: The Modification of Diet in Renal Disease Study. Society for Clinical Trials Sixteenth Annual Meeting, Seattle, Washington, April 30-May 3, 1995.

Olson M, Dolecek T, Caggiula A, Dwyer J and the MDRD Study Group. Time required for the protein intervention in the Modification of Diet in Renal Disease Study. Society for Clinical Trials Sixteenth Annual Meeting, Seattle, Washington, April 30-May 3, 1995.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Snetselaar LG, Olson MB, Caggiula AW, Dwyer JT). The effect of the Modification of Diet in Renal Disease (MDRD) dietary protein intervention on selected risk factors for cardiovascular disease. Scientific Conference on the Efficacy of Hypocholesterolemic Dietary Interventions, San Antonio, Texas, May 3-5, 1995.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Levey AS, Beck GJ, Bosch JP, Caggiula AW, Greene T, Hunsicker LG, Klahr S). Short-term effects of protein intake, blood pressure, and antihypertensive therapy on GFR in the Modification of Diet in Renal Disease Study. XXXIIInd Congress of the European Renal Association, European Dialysis and Transplant Association, Athens, Greece, June 11-14, 1995.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Levey AS, Beck GJ, Caggiula AW, Greene T, Kusek JW, Striker GE, Klahr S). Trends toward a beneficial effect of a low protein diet during additional follow-up in the Modification of Diet in Renal Disease Study. XXXIIInd Congress of the European Renal Association, European Dialysis and Transplant Association, Athens, Greece, June 11-14, 1995.

Kidney Disease Clinical Studies Initiative, Major Kidney Clinical Research Studies and Projects Inventory, Modification of Diet in Renal Disease

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Hunsicker LG). Secondary analyses of the Modification of Diet in Renal Disease (MDRD) Study. International Society of Nephrology, Madrid, Spain, July 2-6, 1995.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Yamamoto ME, Olson MB, Stollar C). Prevalence of sodium modifications in hypertensive patients with compromised renal function. American Dietetic Association 78th Annual Meeting, Chicago, Illinois, October 30-November 2, 1995.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Levey AS, Beck GJ, Bosch JP, Caggiula AW, Greene T, Hunsicker LG, Klahr S). Short-term effects of protein intake, blood pressure, and antihypertensive therapy on GFR in the MDRD Study. 28th American Society of Nephrology Annual Meeting, San Diego, California, November 5-8, 1995.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Porush JG, Lazarus JM, Bourgoignie JJ, Buckalew VM, Greene T, Milas NC, Paranandi L, Peterson JC, Rauch S, Soucie JM, Stollar C). Efficacy of anti-hypertensive interventions in reducing blood pressure in the MDRD Study. 28th American Society of Nephrology Annual Meeting, San Diego, California, November 5-8, 1995.

Yamamoto M, Olson MB, Stollar C for the MDRD Study Group. The effect of sodium restriction and weight reduction on change in blood pressure in patients with chronic renal disease. General Clinical Trials Conference, Crystal City, Virginia, March 6-9, 1996.

Beck G, Caggiula A, Greene T, Kusek J, Levey A. A pilot study for feasibility of long-term patient follow-up after the end of a clinical trial. Society for Clinical Trials Seventeenth Annual Meeting, Pittsburgh, Pennsylvania, May 5-8, 1996.

Olson MB, Coyne T, Caggiula A for the MDRD Study Group. Social factors influence dietary satisfaction in the Modification of Diet in Renal Disease Study. Society for Clinical Trials Seventeenth Annual Meeting, Pittsburgh, Pennsylvania, May 5-6, 1996.

Coyne T, Nowalk MP, Boyle D, Garcia D, Jenks B, Levy C, Paris B, Zimmer G. Relationship between the use of low-protein food products and adherence to modified protein eating patterns in individuals with chronic renal disease. 16th International Congress of Nutrition, Montreal, Canada, July 27-August 1, 1997.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Coronado B, Beck GJ, Greene T, Kusek JW, Levey AS). Cardiovascular disease risk factors and GFR in the MDRD Study. The American Society of Nephrology 30th Annual Meeting, San Antonio, Texas, November 2-5, 1997.

Modification of Diet in Renal Disease (MDRD) Study Group. (Prepared by Levey AS, Bosch JP, Breyer JA, Greene T, Rogers N, Roth D). Predicting GFR from serum creatinine in the Modification of Diet in Renal Disease Study. The American Society of Nephrology 30th Annual Meeting, San Antonio, Texas, November 2-5, 1997.

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- Levey AS, Greene T, Burkart J and MDRD Study Group. Comprehensive assessment of the level of renal function at the initiation of dialysis in the MDRD Study. The American Society of Nephrology 31st Annual Meeting, Philadelphia, Pennsylvania, October 25-28, 1998.
- Wang SR, Greene T, Beck G, Gassman J, Kusek J, Levey A, and the MDRD Study Group. Variability of indices of kidney function in studies of chronic renal disease. Society for Clinical Trials Twentieth Annual Meeting, Anaheim, California, May 2-5, 1999.
- Yan G, Greene T, Beck G, Kusek I, Leung J, Levey A, Parandi L, and the HEMO and MDRD Study Groups. Bias in longitudinal assessments of protein intake due to seasonal variations in studies of patients with kidney disease. Society for Clinical Trials Twentieth Annual Meeting, Anaheim, California, May 2-5, 1999.
- Greene T, Beck G, Wang S, Kusek J, Levey A, and the MDRD Study Group. The effect of low protein diet in the MDRD Study A is dependent on the underlying rate of disease progression. 32nd American Society of Nephrology Annual Meeting, Miami Beach, Florida, November 5-8, 1999.
- Hebert LA, Greene T, Hunsicker LG, Levey AS, Wang S, and the MDRD Study Group. Relationship of urine volume and urine osmolality to the progression of renal disease in the Modification of Diet in Renal Disease (MDRD) Study. 32nd American Society of Nephrology Annual Meeting, Miami Beach, Florida, November 5-8, 1999.
- Levey AS, Greene T, Kusek JW, Beck G and the MDRD Study Group. A simplified equation to predict glomerular filtration rate from serum creatinine. American Society of Nephrology 23rd Annual Meeting, Toronto, Canada, October 13-16, 2000.
- Dixon, BS, Greene T, Hunsicker LG, Levey AS and the MDRD Study Group. Estimating urine creatinine excretion: application to estimate 24-hour urine protein from a spot urine sample. First World Congress of Nephrology Meeting, San Francisco, California, October 12-17, 2001.
- Hebert LA, Greene T, Falkenhain ME, Levey A, Hunsicker L, Wang SR, Beck G, Klahr S, and the MDRD Study Group. First World Congress of Nephrology Meeting, San Francisco, California, October 12-17, 2001.
- Ulilig K, Wang S, Beck G, Kusek J, Marcovina S, Greene T, Levey A, Sarnak M. Association of level of kidney function on lipoprotein (a) levels in non-diabetic kidney disease. American Society of Nephrology 35th Annual Meeting, Philadelphia, Pennsylvania, October 30 - November 4, 2002.
- Ulilig K, Wang SR, Beck GJ, Kusek JW, Marcovina SM, Greene T, Levey AS, Sarnak MJ. Are lipoprotein (a) level and apoprotein (a) size risk factors for progression of non-diabetic kidney disease. American Society of Nephrology 35th Annual Meeting, Philadelphia, Pennsylvania, October 30 - November 4, 2002.