Major Kidney Clinical Research Studies and Projects Inventory*

Hemodialysis (HEMO) Study

1. Administrative Data

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

Hemodialysis (HEMO) 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.

(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:

1,846 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:

Garabed Eknoyan, M.D.

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Project Officer:

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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:

Nutrition Coordinating Center:

Johanna T. Dwyer, D.Sc., R.D.
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Central Biochemistry Laboratory:

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

Roland Blantz, M.D., Chair, VA Medical Center
William Harmon, M.D., Children's Hospital
Larry Hunsicker, M.D., University of Iowa Hospitals
Joel Kopple, M.D., Harbor-UCLA Medical Center
William Mitch, M.D., University of Texas, Galveston
Allen Nissenson, M.D., UCLA
John B. Stokes, M.D., University of Iowa
William Vollmer, Ph.D., Kaiser Permanente Center for Health Research
Robert Wolfe, Ph.D., University of Michigan

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

Baxter Healthcare Corporation: dialyzers
Fresenius Medical Care, North America: dialyzers
R & D Labs, Inc.: vitamins
Ross Products: nutritional supplements

2. Study Design

For design, see *Controlled Clinical Trials* 2000; 21:502-525
For primary results, see *N Engl J Med* 2002; 347:20100-2019

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 the sample was collected from, in addition to physical location of where the samples are stored):

Blood samples are stored at Spectra East, Rockleigh, NJ. Extra afterthought fasting blood specimens (50 ml) were collected at baseline and at yearly visits. Table 1 lists the available samples.

(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" and whether consent includes use of samples in other studies that are not part of the main study):

No specific statement was given in the template consent form in regard to the use of the stored blood samples. What was stated on confidentiality is as follows:

Template Consent Form #7
Your rights of privacy will be maintained in the following manner:
1. All data obtained on you during the course of this study will be kept confidential and will be accessible only to the principal investigator and his/her assistants on this project, except as stated elsewhere.
2. Should the results of this paper be published, you will be referred to only by number.

(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 design paper in *Controlled Clinical Trials* 2000; 21:502-525 and tables giving forms and completion schedule in Appendix B.

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

Requests for data are sent to the Data Coordinating Center (DCC) and then reviewed by the HEMO Study Monitoring Committee (Dr. Garabed Eknoyan, Chair, Steering Committee; Dr. Gerald Beck, PI, DCC; Dr. Tom Greene, DCC; Dr. John Kusek, NIDDK Project Officer; and Dr. Andrew Levey, Chair, Outcome Committee). After review, approved projects are provided the data 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. Procedure for access to the NIDDK Repository data/samples is 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:

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Cleveland Clinic Foundation

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Fax: 216-445-2781
E-mail: gbeck@bio.ri.ccf.org

(b) List of ancillary studies approved, completed, and ongoing (including source of funding and amount):

- Michael Rocco, M.D., Wake Forest University: homocysteine study
- Alfred Cheung, M.D., University of Utah: lipids study
- George Kaysen, M.D., Ph.D., University of California, Davis: hypoalbuminemia study
- V. Balakrishnan, M.D., New England Medical Center: neutrophils functional cytokine function. Baseline and outcome data provided on 210 patients from two HEMO Study Boston clinical centers
- John E. Ware, Jr., Ph.D., Quality Metric, Inc., Lincoln, RI, and Klemens Meyer, M.D., New England Medical Center: field testing of the computerized adaptive version of the functional health in chronic kidney disease assessment. Baseline quality of life SF-36 and KD QOL data were provided.

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

See Appendix C.

Appendix A. HEMO Clinical Centers and Principal Investigators

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Appendix B. HEMO Study Forms (from Manual of Operations)

FORM	REVISION DATE
Page 3: Baseline Forms Completion Schedule	April 4, 1996
Page 4: Follow-Up Forms Completion Schedule	February 26, 1997
Page 5: Hospitalization Form Schedule	February 26, 1997
Page 6: Other Forms to be Completed as Needed	February 26, 1997
Page 8: Log A: Namecode and ID Assignment	July 10, 1995
Page 9: Log B: Baseline Forms Checklist	July 10, 1995
Page 10: Log C Follow-Up Forms Checklist	February 26, 1997
Form 0: Prescreening Urea Clearance	October 11, 1996
Form 1: Screening Form	April 26, 1995
Unit Code List	June 9, 1998
Form 2: Demographic Form	March 25, 1997
Dialyzer Code List	May 21, 1998
Form 3: Baseline/Annual Comorbidity Assessment Form	May 9, 1995
Form 4: Brief Information for Selected Follow-Up Dialysis Sessions	November 1, 1996
Form 5: Detailed Dialysis Session for a Kinetic Modeling Day	August 18, 1997
Form 6: Access Related Conditions Form	February 26, 1997
Form 7: CBL Urine Mailing Form (Not Available)	
Form 8: Documentation Folder Mailing Form	September 13, 1995
Form 9: Central Biochemistry Laboratory Mailing Form	March 1995
Form 10: Local Biochemistry Lab Form	October 2, 1996
Form 11: Local Lab Reference Ranges and Methods (Not Available)	
Form 12: Re-Enrollment of a Previously Excluded Patient	June 5, 1996
Form 13: Clinical Center Hospitalization Notification Form	March 12, 1997
Form 14: Clinical Center Hospitalization Review Form	October 17, 1996
Code List of Diagnoses and Procedures (Forms 14 & 15)	August 6, 1997
Form 15: Outcome Committee Hospitalization Review Form	February 2, 1996

Form 16: Clinical Center Death Notification Form	July 2, 1995
Form 17: Clinical Center Death Review Form	October 8, 1997
Form 18: Outcome Committee Death Review Form	October 10, 1995
Code List of Causes of Death (Forms 17 & 18)	October 9, 1996
Form 19: Stop Point or Loss to Routine Follow-up Documentation Form	November 4, 1996
Form 20: Outcome Committee Safety Stop Point Review Form	October 11, 1995
Form 21: Semi-Annual Follow-up after Loss to Routine Follow-Up Form	May 31, 1997
Form 22: Eligibility for Randomization or Baseline Dropout Form	September 24, 1996
Form 23: Planning Non-Adherence to Target eKt/V and Flux	August 7, 1996
Form 24: Response to Observed Non-Adherence to Target eKt/V and Flux	August 16, 1996
Form 25: QC I.D. Matching Form	January 16, 1996
Form 26: Follow-up Access Related Conditions Form (Not Available)	
Form 29: Anthropometry Form	January 12, 1998
Form 30: Diet Diary Assisted Recall Form	March 2, 1995
Form 30 Supplement	April 3, 1995
Form 33: Diet Prescription and Supplement Documentation Form	February 26, 1997
List of Supplements	February 26, 1997
Form 34: Appetite Assessment Form	March 4, 1997
Form 35: Supplement Distribution Form	February 26, 1997
Form 37: The Karnofsky Index (KI) of Functional Ability	May 4, 1995
Form 38: Adherence Committee Review Form	February 10, 1997

Form 39: Index of Physical Impairment	May 9, 1995
Form 41: Clinical Center Hospitalization lCD 9 and DRG Form	February 9, 1995
Form 48: Quality of Life Assessment (Self-Administered	August 15, 1995
Form 49: Quality of Life Assessment (Interviewer-Administered)	July 5, 1995
Spanish 48: Tasa de Calidad de Vida (No Date)	
Spanish 49: Tasa de Calidad de Vida (No Date)	
Form 50: Amyloid Questionnaire	August 12, 1997
Form 60: Reasons for Not Entering (Not Available)	

HEMO Study
Completeness of Afterthought Collection
as of 01/11/02

	Baseline		1 Year		2 Years		3 Years		4 Years	
Center	Obtained/ Expected	% of Expected	Obtained/ Expected	% of Expected	Obtained/ Expected	% of Expected	Obtained/ Expected	% of Expected	Obtained/ Expected	% of Expected
1	96/100	96.00	67/74	90.54	44/49	89.80	33/35	94.29	21/24	87.50
2	100/106	94.34	79/92	85.87	57/68	83.82	49/56	87.50	27/36	75.00
3	106/120	88.33	82/92	89.13	57/61	93.44	31/33	93.94	16/18	88.89
4	82/114	71.93	75/91	82.42	67/71	94.37	47/50	94.00	35/36	97.22
5	92/107	85.98	76/91	83.52	55/64	85.94	24/49	48.98	28/35	80.00
6	130/140	92.86	93/98	94.90	57/60	95.00	35/36	97.22	22/25	88.00
7	95/134	70.90	89/95	93.68	55/62	88.71	33/36	91.67	17/18	94.44
8	84/120	70.00	93/100	93.00	69/77	89.61	51/54	94.44	33/42	78.57
9	130/141	92.20	96/99	96.97	62/66	93.94	39/45	86.67	26/27	96.30
10	110/115	95.65	70/82	85.37	63/65	96.92	42/45	93.33	25/27	92.59
11	105/110	95.45	79/88	89.77	49/59	83.05	36/40	90.00	23/26	88.46
12	105/109	96.33	78/80	97.50	60/61	98.36	41/42	97.62	27/28	96.43
13	117/122	95.90	82/90	91.11	50/54	92.59	33/33	100.00	18/18	100.00
14	104/119	87.39	77/86	89.53	50/56	89.29	35/36	97.22	25/25	100.00
15	126/129	97.67	89/92	96.74	56/59	94.92	48/51	94.12	33/34	97.06
Overall	1582/1786	88.58	1225/1350	90.74	851/932	91.31	577/641	90.02	376/419	89.74

FORMS COMPLETION SCHEDULE

BASELINE FORMS

Time	Forms															
	1	2	3	4	5	6	9	10	22	29	30	33	34	37	39	48/49
Prior to enrollment into Baseline	x															
Week 1a		x			x		x	x*		x*	x*		x*			
Week 2a					x		x	x*		x*	x*		x*			
Week 3																
Week 4					x	x	x					x				
Week 5			x		x		x							x	x	x
Week 6					[x]		[x]		(x)							
Week 7					[x]		[x]		(x)							
Week 8					[x]		[x]		(x)							
Week 9					[x]		[x]		(x)							
Week 10					[x]		[x]		(x)							
Week 11					[x]		[x]		(x)							
Week 12					[x]		[x]		(x)							
Week 13					[x]		[x]		(x)							
Week 14					[x]		[x]		(x)							

a test for residual renal function -- suggested in Week 1 or 2 -- urine must be collected between a dialysis session immediately preceding a modelling session and the modelling session itself

* complete *either* Week 1 *or* Week 2

[ ] if necessary

( ) complete Form 22 as first step for randomization after KM report indicates that delivered eKt/V is at least 1.3 on two of three consecutive kinetic-modelling sessions

Appendix C. Publications and Presentations

MMHD-HEMO Study (as of January 2003)

Prepared by the HEMO Data Coordinating Center

PAPERS

Eknoyan G, Levey AS, Beck GJ, Agodoa LY, Daugirdas JT, Kusek JW, Levin NW, Schulman G for the HEMO Study Group. The Hemodialysis (HEMO) Study: Rationale for selection of interventions. Seminars in Dialysis 9:24-33, 1996.

Burrowes JD, Powers SN, Cockram DB, McLeroy SL, Dwyer JT, Cunniff PJ, Paranandi L, Kusek JW. Use of appetite and diet assessment tool in the pilot phase of a hemodialysis clinical trial: Mortality and Morbidity in Hemodialysis Study. Journal of Renal Nutrition 6:229-232, 1996.

Leypoldt JK, Cheung AK, Agodoa LY, Daugirdas JT, Greene T, Keshaviah PR for the Hemodialysis (HEMO) Study. Hemodialyzer mass transfer-area coefficients for urea increase at high dialysate flow rates. Kidney International 51:2013-2017, 1997.

HEMO Study Group (Prepared by Daugirdas IT, Depner TA, Gotch FA, Greene T, Keshaviah P. Levin NW, Schulman G). Comparison of methods to predict equilibrated Kt/V in the HEMO Pilot Study. Kidney International 52:1395-1405, 1997.

HEMO Study Group (Prepared by Dwyer JT, Cunniff PJ, Maroni BJ, Kopple ID, Burrowes ID, Powers SN, Cockram DB, Chumlea WC, Kusek JW, Makoff R, Goldstein J, Paranandi L). The Hemodialysis (HEMO) Pilot Study: Nutrition program and participant characteristics at baseline. Journal of Renal Nutrition 8:11-20, 1998.

Burrowes ID. The HEMO Study: Rationale, design, and role of nutrition in a prospective hemodialysis study. Renal Nutrition Forum 17:1-5, 1998

Cheung AK, Agodoa LY, Daugirdas JT, Depner TA, Gotch FA, Greene T, Levin NW, Leypoldt JK and the Hemodialysis (HEMO) Study Group. Effects of hemodialyzer reuse clearances of urea and $f3_2$-microglobulin. Journal of the American Society of Nephrology 10:117-127, 1999.

Depner T, Beck G, Daugirdas J, Kusek J, Eknoyan G. Lessons from the Hemodialysis (HEMO) Study: An improved measure of the actual hemodialysis dose. American Journal of Kidney Disease 33:142-149, 1999.

Kidney Disease Clinical Studies Initiative, Major Kidney Clinical Research Studies and Projects Inventory, Hemodialysis Study (HEMO)

Depner TA, Greene T, Gotch FA, Daugirdas JT, Keshaviah PK, Star RA and the Hemodialysis Study Group. Imprecision of the hemodialysis dose when measured directly from urea removal. Kidney International 55:635-647, 1999.

Uribarri J, Levin NW, Delmez J, Depner TA, Ornt D, Owen W, Yan G. Association of acidosis and nutritional parameters in hemodialysis (HID) patients. American Journal of Kidney Disease 34:493-499, 1999.

Daugirdas JT, Greene T, Depner TA, Gotch FA, Star RA and the Hemodialysis (HEMO) Study Group. Relation between apparent (single-pool) and true (double-pool) urea distribution volume in the HEMO Study. Kidney International 56:1928-1933, 1999.

Cheung AK, Levey AS, Dwyer JT, Heyka RJ, Rocco MV, Sarnak MJ, Teehan BP, Yan G and the Hemodialysis (HEMO) Study Group. Atherosclerotic cardiovascular disease risks in chronic hemodialysis patients. Kidney International 58:353-362, 2000.

Allon M, Ornt DB, Schwab SJ, Rasmussen C, Delmez JA, Greene T, Kusek JW, Martin AA, Minda S and the Hemodialysis (HEMO) Study Group. Factors associated with the prevalence of arteriovenous fistulas in hemodialysis patients in the HEMO Study. Kidney International 58:2178-2185, 2000.

HEMO Study Group (Prepared by Greene T, Beck GJ, Gassman JJ, Gotch FA, Kusek JW, Levey AS, Levin NW, Schulman G, Eknoyan G). Design and statistical issues of the Hemodialysis (HEMO) Study. Controlled Clinical Trials 2 1:502-525, 2000.

Kaysen GA, Dubin JA, Müller HG, Rosales LM, Levin NW and the HEMO Study Group. The acute-phase response varies with time and predicts serum albumin levels in hemodialysis patients. Kidney International 58:346-352, 2000.

Kaysen GA, Dubin JA, Müller HG, Mitch WE, Levin NW and the HEMO Study Group. Levels of α1 acid glycoprotein and ceruloplasmin predict future albumin levels in hemodialysis patients. Kidney International. 60(6):2360-6, 2001.

Leung J, Dwyer J, Miller J, Patrick S, Rocco M, Uhlin L and the HEMO Study Group. The role of the dietitian in a multi-center clinical trial of dialysis therapy: the Hemodialysis (HEMO) Study. Journal of Renal Nutrition 11:101-108, 2001.

Miskulin DC, Athienites NV, Yan G, Martin AA, Ornt DB, Kusek JW, Meyer KB, Levey AS and the HEMO Study Group. Comorbidity assessment using the Index of Coexistent Disease (ICED) in a multicenter clinical trial: the Hemodialysis (HEMO) Study. Kidney International. 60 (4): 1498-1510, 2001.

Rocco MV, Yan G, Heyka RJ, Benz R, Cheung AK and the HEMO Study Group. Risk factors for hypertension in chronic hemodialysis patients: baseline data from the HEMO Study. American Journal of Nephrology. 21:280-288, 2001.

Allen KL, Miskulin D, Guofen Y, Dwyer JT, Frydrych A, Leung J, Poole D and the Hemodialysis (HEMO) Study Group. Association of nutritional markers with physical and mental health in prevalent hemodialysis patients from the HEMO Study. Journal of Renal Nutrition. 12 (3):160-169, 2002.

Burrowes JD, Cockram DB, Dwyer JT, Larive B, Paranandi L, Bergen C, Poole D and the HEMO Study Group. Cross-sectional relationship between dietary protein and energy intake, nutritional status, functional status and comorbidity in older vs. younger hemodialysis patients. Journal of Renal Nutrition. 12 (2):87-95, 2002.

Leypoldt JK, Cheung AK, Delmez I, Gassman JJ, Levin NW, Lewis JB, Lewis JL, Rocco MV and the HEMO Study Group. Relationship between volume status and blood pressure during chronic hemodialysis. Kidney International. 61:266-275, 2002.

Rocco MV, Paranandi L, Burrowes JD, Cockram DB, Dwyer JT, Kusek JW, Leung J, Makoff R, Maroni B, Poole D and the HEMO Study Group. Nutritional Status in the HEMO Study cohort at baseline. American Journal of Kidney Disease. 39(2):245-256, 2002.

Rocco MV, Yan G, Gassman JJ, Lewis JB, Ornt D, Weiss B, Levey AS and the HEMO Study Group. Comparison of causes of death using HEMO Study and HCFA ESRD death notification classification systems. American Journal of Kidney Disease. 39(1):146-153, 2002.

Cheung AK, Yan G, Greene T, Daugirdas JT, Dwyer JT, Levin NW, Ornt DB, Schulman G, Eknoyan G and the HEMO Study Group. Seasonal Variations in Clinical and Laboratory Variables among Chronic Hemodialysis Patients. Journal of the American Society of Nephrology. 13: 2345-2352, 2002.

Beddhu S, Kaysen GA, Yan G, Sarnak M, Agodoa L, Ornt D, Cheung AK for the HEMO Study Group. Association of serum albumin and atherosclerosis in chronic hemodialysis patients. American Journal of Kidney Disease. 40(4):721-727, 2002.

Eknoyan G, Beck GJ, Cheung AK, Daugirdas JT, Greene T, Kusek JW, Allon M, Bailey J, Delmez JA, Depner TA, Dwyer JT, Levey AS, Levin NW, Milford E, Ornt DB, Rocco MV, Schulman G, Schwab SJ, Teehan BP, Toto R for the HEMO Study Group. Effect of dialysis dose and membrane flux on mortality and morbidity in maintenance hemodialysis patients: Primary Results of the HEMO Study. New England Journal of Medicine. 347:2010-2019, 2002.

Chumlea WC, Dwyer J, Paranandi L, Bergen C, Burkart J, Cockrarn D, Frydrych A, Kusek J, McLeroy S and the HEMO Study Group. Nutritional status assessed from anthropometric measures in the HEMO Study. Journal of Renal Nutrition. In press.

Dwyer JT, Larive B, Leung J, Rocco M, Burrowes J, Chumlea C, Frydrych A, Kusek JW, Uhlin L and the Hemodialysis (HEMO) Study Group. Quality of life, comorbidity, and

nutritional status in Hemodialysis (HEMO) Study patients at baseline. Journal of Renal Nutrition. In press.

Kaysen GA, Dubin JA, Müller HG, Mitch WE, Rosales L, Levin NW and the HEMO Study Group. The impact of albumin synthesis rate and the acute phase response in the dual regulation of fibrinogen levels in hemodialysis patients. Kidney International. In Press.

Frydrych A, Burrowes JD, Leung J, McLeroy S, Dwyer J, Uhlin L, Maijoram S, Weiss B, Cockram D, and the HEMO Study Group. The Role of the Dietitian as Study Coordinator. Applied Clinical Trials. In Press.

SUBMITTED MANUSCRIPTS

Unruh M, Yan G, Radeva M, Hays Rd, Benz R, Athienites NV, Kusek J, Levey AS, Meyer KB and the HEMO Study Group. Health status and satisfaction in the HEMO Study: A comparison of self-administered and interviewer-administered measures. American Journal of Kidney Disease Re-submitted.

Depner T, Greene T, Daugirdas J, Cheung A, Gotch F, Leypoldt J, and the HEMO Study. Dialyzer performance in the HEMO Study: In vivo K_0A and true blood flow determined from a model of cross-dialyzer urea extraction. Re-submitted.

Daugirdas J, Greene T, Depner T, Chumlea C, Rocco M, and Chertow G. Anthropometric formulas for total body water overestimate urea volume in hemodialysis patients: Effects of age, race, and gender. Kidney International. Re-submitted.

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