

Range checks.

Contact the DCC if any of the following unlikely events occur. You will not be able to enter your data without help from the DCC if:

- | | | |
|------|----------------------------------|--|
| 5.a. | Dry weight | Less than <u>50</u> lbs
Less than <u>20</u> kilos
Greater than <u>350</u> lbs
Greater than <u>150</u> kilos |
| 6. | Age Range | <u>Ranges</u> |
| | Both Eligible/Not Eligible (Avg) | 3 - 100
18 - 80 |
| 10: | Date of first dialysis | Before 1960 |

If a Form 1 needs to be changed to make an ineligible patient eligible, the DCC recommends that you submit one inquiry to delete the old Form 1 from the database and that you resubmit a new (updated) Form 1. However, if you prefer to submit, item by item, data change requests, we will process them.

Note: If you submit data change requests, don't forget to change consent status, eligibility status and any other item that needs to be updated to reflect current eligibility.

Write the patient's name and local chart ID below. (This will not be keyentered.)

HEMO Study Form 1. Screening Form

This form is to be completed when a patient's chart is reviewed. Each center should complete this form for every prevalent patient at its dialysis units who is on dialysis on January 20, 1995 and has been randomly selected by the DCC for inclusion in this study. This form is also to be completed for every patient enrolling in Baseline.

1. Patient Identification Number. _____
2. Patient Name Code _____
3. a. Dialysis Unit (see code list) _____
- b. Was this patient selected as part of the prevalence study?
(0=no, 1=yes) _____
- c. Patient's usual shift (1=morning, 2=afternoon, 3=evening, 4=night) _____
4. Sex (1=male, 2=female) _____
5. a. Dry Weight _____
- b. Pounds or Kilos (1=pounds, 2=kilos) _____
6. Date of Birth ____/____/____
- a. Age ____
- b. Between 18 and 80? (0=no, 1=yes) ____
7. Race _____
 - 1 = American Indian/Alaskan Native
 - 2 = Asian (includes Pacific Islanders, Oriental, Asian Indians)
 - 3 = Black/African-American
 - 4 = White
 - 9 = Unknown

- 8. Ethnicity ___
 - 1 = Hispanic
 - 2 = Not Hispanic
 - 9 = Unknown

- 9. Primary Underlying Renal Diagnosis ___
 - 1 = Glomerular Disease
 - 2 = Polycystic Kidney Disease
 - 3 = Hypertensive Nephrosclerosis
 - 4 = Tubulointerstitial Diseases
 - 5 = Urinary Tract Diseases (including obstruction)
 - 6 = Absence of One Kidney (Without Other Known Cause)
 - 7 = Diabetic Nephropathy
 - 8 = Hereditary Nephritis
 - 9 = Unknown with Proteinuria > 3 g/day
 - 10 = Unknown with Proteinuria 1-3 g/day
 - 11 = Unknown with Proteinuria < 1 g/day
 - 12 = Ischemic Renal Disease
 - 13 = Acute Renal Disease
 - 14 = Other
 - 99 = Unknown

- 10. Date of first chronic maintenance dialysis ESRD ___/___/___

- 11. Is the patient currently on antihypertensive meds? (0=no, 1=yes, 9=unknown) ___

- 12. **Comorbidity** Does the chart show a history of, or does the patient currently have:
Answer yes if the chart shows it. If it does not appear, answer no.
 - a. cerebrovascular disease? (0=no, 1=yes) ___
 - b. ischemic heart disease? (0=no, 1=yes) ___
 - c. congestive heart failure? (0=no, 1=yes) ___
 - d. cardiac arrhythmias or conduction problems? (0=no, 1=yes). ___
 - e. pericardial disease or pericarditis? (0=no, 1=yes) ___
 - f. respiratory disease? (0=no, 1=yes) ___
 - g. a positive HIV test? (0=no, 1=yes) ___
 - h. diabetes mellitus? (0=no, 1=yes-NIDDM, 2=yes-IDDM, 3=yes-type unknown) ___

- i. hypertension (0=no, 1=yes) ___
- j. malignancy? (0=no, 1=yes, in the past 5 years, 2=yes, but more than 5 years ago) ___
- k. peripheral vascular disease? (0=no, 1=yes) ___

Health Related Behaviors

- 13. Is there a history of smoking or does the patient currently smoke? (0=no, 1=yes, but more than 20 years ago, 2=yes, in the past 20 years, 3=current) ___
- 14. a. Is there a history of drug abuse or does the patient currently abuse drugs? (0=no, 1=yes, but more than 5 years ago, 2=yes, in the past 5 years, 3=current) ___
- b. Is there a history of alcohol abuse or does the patient currently abuse alcohol? (0=no, 1=yes, but more than 5 years ago, 2=yes, in the past 5 years, 3=current) ___

Answer yes if the chart shows it. If it does not appear, answer no.

Inclusion Criteria (code 0=no, 1=yes)

- 15. Is the patient currently on hemodialysis three times a week?..... ___
- 16. Has the patient been on hemodialysis constantly for the last three months? ___

Exclusion Criteria (code 0=no, 1=yes)

- 17. Is the patient trying to get pregnant or currently pregnant? (code 0 for males) ___
- 18. Is there a scheduled living donor renal transplant?..... ___
- 19. Have there been less than six months since patient returned to hemodialysis after renal transplantation? ___
- 20. Are there current active malignancies for which the patient is on or could be on chemotherapy or radiation therapy? ___
- 21. Is there currently severe congestive heart failure (New York Heart Association Class IV) even when the patient has been treated by maximal therapy? ___
- 22. Does the patient have unstable angina pectoris? ___

Note: Unstable angina is defined by NYHA as follows: new onset of angina (angina that began in the last three months) or an increase in the frequency, duration, or severity of angina in the last three months.

- 23. Does the patient have AIDS?
- 24. Does the patient have active tuberculosis or other active systemic infection?.....
- 25. Does the patient have severe chronic obstructive pulmonary disease requiring supplemental oxygen?.....
- 26. Does the patient have a history of encephalopathy or currently active encephalopathy or abnormal PT due to liver disease as defined by local lab limits?
- 27. Is the patient expected to be unavailable for ≥ 20 dialysis treatments in a year?.....
- 28. Does the patient take any investigational drugs?
- 29. Is the patient enrolled in any other research protocols with active interventions?.....
- 30. Does the patient appear to be unable to follow the protocol?.....
- 31. Does the patient appear to be unlikely to follow the protocol, on the basis of your opinion or of a history of poor cooperation or poor compliance (late sessions, missing sessions, excessive weight gain between sessions, early exits)?
- 32. If the patient produces ≥ 200 ml/day of urine, is urea clearance measured from interdialytic urine collection > 1.5 ml/min (per 35L of total urea volume)? (0=no, either produces <200 ml/day or urea clearance ≤ 1.5 ml/min, 1=yes, 9=unknown, to be determined during Baseline)
- 33. Does the patient appear unlikely to be able to achieve Kt/V of 1.3 due to access?
- 34. Does the patient appear to be unable to achieve Kt/V of 1.3 in 4.5 hours due to patient size?.....
- 35. Is the patient currently residing in an acute- or chronic-care hospital?
- 36. Is the patient severely malnourished? (operational definition: a serum albumin concentration < 2.60 gm/dl)

Eligibility on the Basis of Screening Information:

- 37. Is the patient eligible on the basis of the above information? (0=no, 1=yes).....
- 38. Was the patient in the hospital on January 20, 1995? (0=no, 1=yes).....
- 39. Informed Consent Plan

0 = The patient is not eligible, so the patient will not be asked to come in for the study.

1 = The patient will be asked to come in for the study.

2 = The patient will not be asked to come in for the study because he or she has already indicated unwillingness to be in a study.

3 = The patient will not be asked to come in for the study due to study team preference. The team does not feel this patient is appropriate for enrollment.

201. Date this form completed __ __ / __ __ / __ __ __ __

202. Certification number of person completing this form __ __ __ __ __ __

Clinical Center Use Only	
Date Form Entered	__ __ / __ __ / __ __ __ __ Verified? _____
Person Entering This Form _____	

Dialysis Unit Code List

Clinical Center	Dialysis Unit	Urban	Rural
01 Beth Israel	101 North102 South	210	0
	103 Mt. Sinai 94th Street	70	0
	104 Mt. Sinai Madison Avenue	0	0
	105 Lenox Hill Hospital	0	0
	106 Upper Manhattan	0	0
02 Bowman Gray	201 Salem	140	0
	202 Piedmont	232	0
	203 Lexington	0	80
	204 High Point Dialysis Center	0	0
	205 Triad Dialysis Center		
	206 Northside Dialysis Center		
03 Brigham & Women's	301 Westwood	69	0
	302 Mary Mahoney	77	0
	303 Boston	85	0
	304 Brockton	109	0
	305 BMA Kidney Center	96	0
	306 NMC Framingham	68	0
	307 BMA Waltham Metro West	30	0
	308 Quality Care Medford	70	0
	309 Hyde Park	0	0
04 Duke	401 Durham	94	0
	402 Henderson	0	88
	403 Roxboro	0	32
	404 Duke	45	0
05 Emory	501 Gambro Healthcare Atlanta	172	0
	502 Gambro Healthcare Piedmont	70	0
	503 Gambro Healthcare Decatur	25	0
	504 DCI Crawford Long	81	0
	505 DCI West Peachtree	84	0
	506 Gambro Healthcare Peachtree	0	0
	507 Gambro Healthcare West Atlanta		
06 Lankenau	601 Haverford	100	0
	602 Main Line	50	0
	603 Bryn Mawr	50	0
	604 RCG Wynnewood	0	0
07 N.E. Medical Center	701 DCI Boston	93	0
	702 St. Elizabeth's	100	0
	703 Weymouth Dialysis Center	80	0
	704 South Suburban		

**Dialysis Unit Code List
(Continued)**

Clinical Center	Dialysis Unit	Urban	Rural
08 University of Alabama	801 Gambro HealthCare, Birmingham Central	240	0
	803 Gambro HealthCare, Bessemer	0	0
	804 Gambro HealthCare, Ensley	0	0
	805 Gambro Health Care, Roebuck	0	0
	806 Gambro HealthCare, Birmingham North		
09 Univ. of California	901 University	120	0
	902 South Gate	60	0
	903 Madison Avenue Clinic	0	0
	904 TRC - Alhambra Dialysis Clinic		
	905 Fairfield Dialysis Clinic		
	906 TRC - Florin Dialysis Clinic		
	907 South Sacramento Dialysis Clinic		
10 Univ. of Illinois	1001 W. Suburban	145	0
	1002 Oak Park	159	0
	1003 University	63	0
	1004 Chicago Dialysis Center	0	0
	1005 LaGrange Dialysis Center	0	0
	1006 Southside Dialysis Center	0	0
	1007 Jackson Park Dialysis Center	0	0
	1008 Naperville Dialysis Center	0	0
	1009 Greenwood Dialysis		
	1010 North Avenue Dialysis		
11 Univ. of Rochester	1101 Highland	78	0
	1102 Clinton Crossings	145	0
	1103 Strong	42	0
	1104 St. Mary's	0	0
	1105 Rochester General Hospital	0	0
	1106 Park Ridge Hospital		
12 Univ. of Texas	1201 Parkland	50	0
	1202 Dallas VA	40	0
	1203 Town Gate	100	0
	1204 Collin County	74	0
	1205 Farmers Branch	64	0
	1206 North Dallas	50	0
	1207 Mockingbird	0	0
	1208 UTSW Ren Gambro Healthcare	0	0
	1209 Swiss Avenue Dialysis	0	0
	1210 Dallas East Dialysis Center	0	0
	1211 Elmbrook	0	0
	1212 Oak Cliff Dialysis Center		
	1213 Dallas South Dialysis Center		
	1214 FMC McKinney		
	1215 FMC Waxahachie		
	1216 Southwestern Dialysis Center		

**Dialysis Unit Code List
(Continued)**

Clinical Center	Dialysis Unit	Urban	Rural
13 Univ. of Utah	1301 Castleview	0	15
	1302 Kolff	27	0
	1303 Bonneville	90	0
	1304 Midvale	42	0
	1305 Gem State	0	54
	1306 Provo	27	0
	1307 Dixie	0	30
	1308 VA	23	0
	1309 Lakeside		
14 Vanderbilt	1401 Village	100	0
	1402 Hayes	100	0
	1403 VA	40	0
	1404 Gambro		
	1405 Gambro Healthcare Franklin		
15 Washington Univ.	1501 Chromalloy	156	0