DMMS Wave I
Special Study Data Forms

- **DMMS Wave I Special Study Data Forms**
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INSTRUCTIONS
USRDS DIALYSIS MORBIDITY AND MORTALITY STUDY

Questions? Feel free to call the USRDS Coordinating Center anytime for clarification of any of the instructions pertaining to completion of the forms for the DMMS. Call 313 998-6611 and ask to speak with Corbin Wood or Liz Holzman.

Please read all instructions thoroughly before beginning your first record abstraction. The quality of the data collected depends on correctly completing the abstraction forms.

General Instructions and Overview

Data abstraction of patient records for the Dialysis Morbidity and Mortality Study (hereafter referred to as the DMMS) is to be completed by personnel at the dialysis facilities. **Take all information from the facility/unit records, including medical records, billing records, dialysis logs, patient rosters, hospital records and personal physician records**. **Do not take information from copies of HCFA ESRD Forms.**

Please complete the forms in blue or black ink or dark pencil.
Please PRINT legibly in CAPITAL LETTERS.

Study Start Date

The Study Start Date for the DMMS is December 31, 1993. The Study Start Date delineates the starting point from which data becomes relevant to the study. Thus, a patient who died on December 20, 1993 should not be included in the study since there will be no relevant data on this patient. However, a patient who died on January 4, 1994 must be included in the study since data from the period of December 31, 1993-January 4, 1994 is relevant to the study.

Keeping Track of Completed Abstractions/Verifying Patient Demographic Information

Each dialysis facility has been given a **batch of forms** for data abstraction. The first page of each set of patient abstraction forms is the **"Patient Tracking Form/Patient Identification as of 12/31/93".** This form needs to be completed for each patient by the dialysis unit abstractor. This form helps us to keep track of completed abstractions and provides us with information about why an abstraction may not have been completed. This form assists you in locating the correct patient for record abstraction. *This form also*

indicates which abstraction forms are to be completed for that particular patient. Please be sure to complete the abstraction forms that are specifically requested. On the Patient Tracking Form/Patient Identification as 12/31/93 form, we have asked you to verify the patient's sex, date of birth, social security number, HIC number and modality of care.

The sample of patients for the DMMS has been selected randomly. **It is very important that all the data abstraction forms requested be completed on each and all of these patients**. Completion of forms on each patient ensures the randomness of the sample which is critical to the validity of all the data collected and analyzed. Thus, it is critical that you locate each patient's record. It is very important that you indicate the reason if you are unable to locate a record on a selected patient. The reason codes for not being able to locate a patient's records include:

A: Patient stopped receiving treatment at this unit and transferred to another facility prior to the Study Start Date of December 31, 1993.
B: Patient died prior to January 1, 1994 or on the Study Start Date of December 31, 1993.
C: Patient was never treated at this unit.
D: Other; Please specify with a written explanation.

On the **Patient Tracking Form/Patient Identification as of 12/31/93** there is a place to indicate the Reason Code and a Reason Explanation, if necessary. Only complete the Reason Explanation if Reason Code "D" has been used.

Returning Forms to the ESRD Network

Copies of completed forms should be submitted to the Network monthly. You have been provided with a **Batch Cover Sheet** which lists all the patients included in your batch of sets of patient abstractions forms. Please be sure to use the **Batch Cover Sheet** to indicate the **date** that each set of patient abstraction forms is returned to the Network. **Each month, when you return forms to the Network, make a copy of the Batch Cover Sheet and return it along with the completed forms. Be sure to retain your original Batch Cover Sheet**. Be sure to copy the Batch Cover Sheet and send it along with the forms every month that you return forms to the Network.

Skipping Items

If the answer to an item cannot be determined, **leave the item blank by leaving the box on the right empty** and **put a check mark in the small box to the left of the item number.** This will indicate that you looked for the information in all available records and decided that you could not determine an answer for the item. When information is not available to answer a question, checking the box on the left is important because it indicates that the item was not inadvertently skipped or forgotten.

Dates

Dates are either in month (mm) day (dd) and year (yy) format ,or in month and year format. **In all cases, month and day must be expressed in 2 digits.** For example, January is ∅1 and November is 11. The first day of the month is ∅1; the fifteenth day of the month is 15. The year is expressed by the last two digits of the year; e.g. 94 for 1994.

If you are able to report partial information only, do so but also put a check in the small box to the left of the item number. For example, if the records give the year of a transplant but not the month or day, enter the year in the appropriate box, leave the month and day blank and check the box to the left of the item number.

Right Justification

Right justify all entries. For example, if a patient has a serum creatinine of 9.8 (Item D:8), enter the item as follows:

	9	**.**	**8**

Comments Box

Each set of patient abstraction forms contains an Abstractor's "Comments Box". Please use this box to write any information that you believe is important to explain the response to an item. For some items, there are specific instructions to use the "Comments Box" for an explanation to a response.

Use of Abstractor Judgment

A medical record may not state explicitly all the information that these abstraction forms are designed to capture. **The integrity of the data collection effort rests on the expertise and professionalism of the abstractors in interpreting the information contained in the medical record**. In many instances where specific information for an item is not in the record, the abstractor may be able to logically infer the answer to the item from other information in the record. For example, elevated blood pressure over a long period of time implies hypertension. **Abstractors should not make inferences without very careful consideration but should make inferences when they believe that the record supports drawing a conclusion. An inference can be made when the abstractor feels that 8 or 9 out of 10 abstractors reviewing the same record would agree**. Such inference can, however, only be made from information dated before the Study Start Date of 12/31/93. Use of abstractor judgment helps in obtaining the most complete set of data about a patient's history and medical status as possible.

Detailed Instructions by Questionnaire

DMMS Core Questionnaire

Section A: Patient and Facility Identification

General Notes

If you cannot answer an item from 1-8 or if you find only partial information for any of these items, you must note the item number and the reason why in the "Comments Box". Also remember to put a check in the small box to the left of the item number if the information is either not available or if only partial information is available.

Item	Description	Abstractor Instructions
1.	Abstractor initials	Enter your initials.
2.	Date Completed	Enter the date that you complete the form.
3.	Race	Enter the appropriate code for race.
4.	Ethnicity	Enter the appropriate code for ethnicity.
5.	Patient Zip Code	Enter the zip code for the patient's address. If more than one is available, please provide the one closest to the Study Start Date of 12/31/93.
6.	Year of First ESRD Service	
	a. Year of first chronic maintenance dialysis, regardless of setting	Please enter the year (yy) in which the patient began receiving a regular course of maintenance dialysis (at least weekly dialysis treatments) for permanent and irreversible chronic renal failure, whether in a hospital, outpatient or home setting.
	b. Earliest known year of chronic dialysis	Complete this item only if 6a above is unknown. Enter the year of earliest known chronic dialysis treatments.

7.	Current (or last known insurance)	Please answer for all categories of insurance. Indicate whether or not the patient has each of these types of insurance using the appropriate code. (More than one may be answered "yes".)
8.	Was patient enrolled in an HMO since starting chronic maintenance dialysis?	Please indicate using the appropriate code whether the patient was enrolled in a Health Maintenance Organization (HMO) at any time since starting chronic maintenance dialysis.

Section B: Patient History Prior to Study Start Date of 12/31/93

General Notes

"Hx" means history and "Dx" means diagnosis.

Abstractor judgment is very important in this section. If there is no specific mention of a particular disease, (e.g. hypertension) but there is convincing evidence that the patient has a history of this disease (e.g. elevated blood pressure readings), you should answer "suspected" (code 3). If an otherwise very complete medical record contains no information on whether the patient has a history of a particular disease, you should assume that there is no history of that disease (code 2). However, if all the available medical records are very sketchy and there is no mention of a history of a particular disease, the item should be considered indeterminate. In this case, leave the item blank and check the small box on the left.

Be careful to put checks in the small left hand boxes only for those questions for which you cannot determine an answer but not for items which the form specifically instructs you to skip. For example, if the patient does not have a history of diabetes, item B:6, enter "2" for no and skip items B:6a and B:6b and **do not check the left hand boxes for the appropriately skipped items. Remember to use the Abstractor's "Comments Box" if you need to further explain any of your answers.**

Any "yes" responses to the questions in Section B will signify that the stated disease process was present within ten years prior to the Study Start Date of 12/31/93. In other words, if a patient was diagnosed with lung disease in February of 1989, then the answer to question B:7 is "Yes" (code 2). If a patient has a cerebrovascular accident in February of 1994 and did not have known cerebrovascular disease as of 12/31/93, then the answer to question B:3a is "No".

Item	Description	Abstractor Instructions
1.	Regular cigarette smoking status prior to 12/31/93	Enter the correct code. "Active" means that the patient was a smoker as of 12/31/93. "Former" means that the patient was a smoker and stopped smoking any time prior to 12/31/93. "Smoker, current status unknown" means that the patient has a history of smoking but it is unknown whether the patient currently smokes or not. "Non-smoker" means that the record states that the patient was never a smoker **or** an otherwise complete record does not mention that the patient was ever a smoker.
2.	Hx of Coronary Heart Disease (CHD) or Coronary Artery Disease (CAD)	Enter yes, no or suspected for items 2a through 2g.
3.	Hx of Cerebrovascular Disease	Enter the code for yes, no or suspected for each of the two events listed. If 3a is yes, skip item 3b.
4.	Hx of Peripheral Vascular Disease (PVD)	Enter the appropriate code of yes, no or suspected, for items 4a through 4e.
5.	Hx of Heart Disease (other than CHD or CAD)	Enter the appropriate code of yes, no or suspected for items 5a and 5b.
6.	Prior Dx of Diabetes	Enter the appropriate code for yes, no or suspected. Note that the answer to this question can be yes even if diabetes was not considered the cause of ESRD. If no, skip to number 7.
	Was diabetes the cause of ESRD?	For 6a enter the code for yes, no or suspected.
	Insulin therapy during 1993?	For 6b enter the code for "active", "former" or "never". If the patient was on insulin therapy as of December 31, 1993 then the correct answer is "active". If the patient received insulin therapy anytime prior to December 31, 1993 (between Jan 1, 1994 and December 30, 1993) then the correct answer is "former". If the patient did not receive insulin therapy anytime in the past 10 years then the correct answer is "never".

7.	Hx of Lung Disease	Enter the appropriate code for yes, no or suspected.
8.	Neoplasms	Enter the appropriate code for yes, no or suspected. If no, skip to item 9. For 8. enter the appropriate code of 10-25 for the primary site of the neoplasm. You may enter up to two primary sites. Skin cancer other than melanoma need not be recorded. For item 8b, enter the 2 digit year of the date of first diagnosis of neoplasm.
9.	HIV Status	Enter the appropriate code for positive, negative, unknown or unable to disclose.
10.	AIDS Diagnosis	Enter the appropriate code for positive, negative, unknown, or unable to disclose.

Section C: Information at Start of Study

General Notes

With regard to items 2-5, please follow the directions below in determining the time frame for answering the questions. If, however, a change occurs in the month of December, 1993, please provide the **latest information for December.** For example, if a patient had a change in vascular access from a temporary line (subclavian) in the beginning of December, 1993 to AV fistula later in December, 1993, please indicate AV fistula as the vascular access in use.

With regard to questions 6-13, use information from the most recent psychosocial evaluation prior to 12/31/93. However, you may use data from older evaluations if necessary for completeness.

Remember to use the Abstractor's "Comments Box" if you need to further explain any of your answers.

Item	Description	Abstractor Instructions
1.	Height	Enter the height in feet and inches or centimeters. **This item is required. Please make every attempt to obtain this information.** (This information can be from anytime during adult life.) If the patient is a bilateral amputee, please give the original height of the patient and check the box indicating that the patient is an amputee.

2.	Dry Weight as ordered	Enter the prescribed dry weight from December, 1993. If unavailable, list the lowest post dialysis weight within the last 2 weeks of 1993.
3.	Undernourished or cachectic	Enter the appropriate code for yes, no or suspected. Base your answer on information from the medical record in the period of October, 1993-December, 1993.
4.	Blood pressure (average of last 3 values from last week of 1993)	Use the average of the last 3 values from the last week of 1993.
	Predialysis	For item 4a, enter the average of the 3 systolic and diastolic blood pressure readings taken **before** each dialysis session during the last 3 treatments of December, 1993. Please indicate whether blood pressure was taken from a sitting position using the appropriate code for yes or no.
	Postdialysis	For item 4b, enter the average of the 3 systolic and diastolic blood pressure readings taken **after** each dialysis session during the last 3 treatments of December, 1993. Please indicate whether blood pressure was taken from a sitting position using the appropriate code for yes or no.
5.	Dialysis Information	Answers to questions about dialysis information should be based on data in the medical record from December of 1993.
	a. Dialysate	Enter the appropriate code for bicarbonate or acetate dialysate.
	b. Prescribed or usual hours per treatment	Enter the prescribed hours and minutes.
	c. # of dialysis sessions per week	Enter the prescribed or usual # of dialysis sessions **per week** during the month of December, 1993.
	d. Blood flow rate	Enter the blood flow rate in milliliters per minute. If the flow varies, enter the prescribed or most common "high" rate. If there is a range of the prescribed blood flow rate, then enter the mid of that range.

	e. Is the patient usually using a reused dialyzer?	Enter the appropriate code for yes or no.
	f. If reuse does not occur, please indicate the reason	Enter the appropriate code for why reuse does not usually occur.
	g. Highest weight loss during dialysis	Enter the highest weight loss (pre to post dialysis) within the last two weeks of December, 1993, rounded to the nearest pound or kilogram.
	h. Dialyzer type	See the code list on the back of the form for four digit codes for dialyzer type. If you use code 9999 (other), please enter on the lines provided the manufacturer and dialyzer model.
	i. Vascular access in use	Enter the appropriate code for the vascular access type, using the most recent information from December, 1993.
6.	Date of psychosocial evaluation	Enter the date of the evaluation in month, day and year format.
7.	Activities of daily living	For 7a, 7b, and 7c, please enter the appropriate yes or no code for each activity. Consider the patient to be capable of independent ambulating even if he/she can ambulate only with an assistive device (e.g. walker, crutches).
8.	Marital status	Enter the appropriate code.
9.	Living alone	Enter the appropriate code.
10.	Education	Enter the most appropriate code.
11.	Primary occupation before onset of ESRD	Enter the most appropriate code. Before ESRD means prior to the first maintenance dialysis treatment as reported in A:6.
12.	Employment level according to the following scale	For items 12a-12h, enter the appropriate code for yes or no. **You may provide up to <u>two "yes" answers</u> in the column labeled "before ESRD". For instance, a patient who was employed full time for most of his adult life may have become disabled six months prior to the start of maintenance dialysis. <u>Please indicate "disabled" only if the disability kept the patient from working for more than 3 months</u>. However, <u>only one "yes" answer</u> should be given in the column labeled "on 12/31/93".**

Section D: Laboratory Data

General Notes

For items 1 and 2, use a time frame of all of calendar year 1993 in order to answer yes or no to these questions. For items 3-8, use information from December, 1993. If there are no data available from December, 1993, you may use data from November of 1993. For items 9 and 10, you must use data from December of 1993. For items 11, 12, and 13, use the most recent data from July-December, 1993.

Predialysis in this section means before the dialysis treatment of that day.

Remember to use the Abstractor's "Comments Box" if you need to further explain any of your answers.

Item	Description	Abstractor Instructions
1.	Cardiomegaly by X-Ray	Enter code for yes or no. Use any available information from calendar year 1993.
2.	Left ventricular hypertrophy	For items 2a., and 2b. enter the code for yes or no. Use any available information from calendar year 1993.
3.	Serum calcium, predialysis	Enter the predialysis value to the **nearest tenth.** Use data from December, 1993. Only if necessary, use data from November, 1993. Use the most recent information available.
4.	Serum phosphorus or phosphate, predialysis	Enter the predialysis value to the **nearest tenth.** Use data from December, 1993. Only if necessary, use data from November, 1993. Use the most recent information available.
5.	Serum bicarbonate, predialysis	Enter the predialysis value to the **nearest tenth.** The patient's lab report may indicate "serum bicarbonate" or may indicate "CO_2". Use data from December, 1993. Only if necessary, use data from November, 1993. Use the most recent information available.

6.	Hematocrit	For hematocrit information, please make every attempt to provide data from a lab report, not from a hematocrit spun in the dialysis unit. If the only source of information is a hematrocrit spun in the dialysis unit, you may provide this data. Use data from December, 1993. Only if necessary, use data from November, 1993. Use the most recent information available.
	Hematocrit	For item 6a, enter the hematocrit percentage. If transfused, give the value before transfusion. Use data from December, 1993. Only if necessary, use data from November, 1993. Use the most recent data available.
	Hemoglobin	For item 6b, enter the value to the nearest tenth. If transfused, give the value before the transfusion. Use data from December, 1993. Only if necessary, use data from November, 1993. Use the most recent data available.
	Transfused in Dec, 1993	For item 6c, enter the appropriate code for yes or no based on whether or not there was a transfusion in the month of December, 1993. **Use data from December, 1993 only**. If the answer to 6c is no then skip to item 7.
	Number of transfusions	For item 6d, enter the number (from 0 to 9) of transfusions that occurred during the month of December 1993. If there were more than 9 transfusions, enter a 9. **Use data from December, 1993 only**.
7.	Was the patient taking EPO anytime in December of 1993?	Enter the appropriate code for yes or no. **Use data from December, 1993 only**.
8.	Serum creatinine, predialysis	Enter the predialysis value to the **nearest tenth.** Please **record an average of at least two values**. Use data from December, 1993. Only if necessary, use data from November, 1993. Use the most recent information available.
9.	# of dialysis treatments skipped during December 1-23, 1993.	Enter a number from 0-9 for the number of treatments skipped during the period of **December 1-23, 1993**. **Dialysis treatments received elsewhere (e.g. inpatient setting) should NOT count as skipped treatments**.

10.	Number of treatments in December, 1993 shortened by more than 10 minutes	Enter the number, from 0-13 of *shortened* treatments during December, 1993. Do not include skipped treatments.
11.	Lipids	For items 11a and 11b enter the appropriate **whole numbers** using **the most recent value from July-December, 1993**.
12.	Serum intact PTH	Enter the value, **using the most recent data from July-December, 1993.**
13.	Serum aluminum	Enter the value, **using the most recent data from July-December, 1993. If this data comes from measurements taken during a desferol test, please be sure to use the baseline measurement.**
14.	Date of first ever chronic dialysis treatment.	Answer this question, only if the patient was newly diagnosed with ESRD in 1993. Enter the date of the first chronic maintenance dialysis treatment ever, using month, day and year format. Skip items 14 and 15 if ESRD was diagnosed before 1993.
15.	Serum creatinine before first ever dialysis treatment	Enter the value to the nearest tenth of the serum creatinine on the day of the first ever dialysis treatment.
16.	BUN and Weight	Note: If NONE of the information is available for a given month, skip that column in the table. **Do not enter zeros**.
	Date	Date: For each month, enter the day to which the values apply. If values are available for more than one day in a month, use the first day on which pre and post values are available.
	BUN	BUN: Enter the predialysis BUN and the postdialysis BUN for the day entered in the date row. If a postdialysis BUN is not available for that month, record the predialysis BUN only. Enter a second predialysis BUN value **only** if this value is available for the dialysis session **exactly two days after the session for which the first two (pre and post) values are entered**.

	Weight	Weights: Enter the predialysis weight and the postdialysis weight for the day entered in the date column, rounded to the nearest pound or kilogram. Check the appropriate units box to indicate if measurements recorded are in pounds or kilograms. Enter a second predialysis weight **only** if this value is available for the dialysis session **exactly two days after the session for which the first two (pre and post) values are entered**. NO weight needs to be recorded if NO BUN is recorded.
17.	Predialysis serum albumin	For item 17., enter the patient's predialysis serum albumin from the same day as referenced in the date row. However, if this data is not available, use any **value from the month entered in the date row**, to the nearest tenth. Complete 17 for each month of July, 1993 through December, 1993.
18.	Duration of dialysis	Enter the duration of the dialysis session. This should be the same dialysis session as the one referred to for the first value of predialysis BUN and weight. (NOT the dialysis session referred to for the second pre dialysis value of BUN and weight.).

Section E: Change in Patient Status

General Notes

This section is to be completed by the Network. The Dialysis Facility/Unit should leave this section blank and proceed to the next page. The Network should use the Network database to obtain the information to complete this section. Items in this section refer to events occurring to patients during the interval from the Study Start Date of December 31, 1993 to the date of Network abstraction. Information is provided about **any changes in the patient's status after December 31, 1993**. This section is very important and every attempt should be made to obtain the information requested. Leave items 1-4 blank if the event(s) did not occur but otherwise record any and all events that did occur. **If the patient remained on center hemodialysis during the period of December 31, 1993 to the date of Network abstraction, items 1-4 will all be blank. If and only if items 1-4 are all left blank, complete item 5.**

Remember to use the Abstractor's "Comments Box" if you need to further explain any of your answers.

Item	Description	Abstractor Instructions
1.	Date first switched off center hemodialysis	Enter the date that the patient **first** switched off center hemodialysis. If more than one switch occurred between December 31, 1993 and the date of Network abstraction, be sure to enter the **first** date of switch. If a switch did occur, please enter the appropriate code for the reason.
2.	Date of death	In month, day and year format, please enter the date that the patient died.
3.	Date patient moved out of the Network region	In month, day and year format, please enter the date that the patient moved out of the Network region and became lost to follow-up
4.	Date of transfer to another dialysis unit within the Network	In month, day and year format, please enter the date that the patient transferred to another dialysis unit within the **same** Network. This does not include temporary transfers due to hospitalization. .
5.	Date of last known center hemodialysis treatment	**This item should be completed only if E1-E4 are blank**. In month, day and year format, record the date of the last known center hemodialysis treatment .

Anemia Questionnaire

General Notes

Be sure to right justify all of the values entered in this section.

Remember to check the small boxes on the left if an item cannot be determined. If an item is skipped because the instructions have directed you to do so, then do not check the small box on the left.

<u>It is important to pay close attention to the time frame referenced for each of the questions in this section.</u>

Remember to use the Abstractor's "Comments Box" if you need to further explain any of your answers.

<u>Item</u>	**<u>Description</u>**	**<u>Abstractor Instructions</u>**
1.	Serum iron	Enter the appropriate value in whole numbers. Use the most recent information available from October through December, 1993. .
2.	Total iron binding capacity (TIBC)	Enter the appropriate whole numbers. Use the most recent information from October through December, 1993. .
3.	Ferritin	Enter the appropriate whole numbers. Use the most recent information from October through December, 1993. .
4.	Transferrin saturation (if available)	Enter the appropriate percent. Use the most recent information from October through December, 1993.
5.	Hematocrit as of <u>October, 1993</u>	Enter the patient's hematocrit (percentage) **<u>for October, 1993</u>**
6.	Iron	For item 6a, enter the appropriate code for whether parenteral iron (called Iron dextran, Imferon, or Infed) was used during 1993. If the answer was no, skip items 6b-6e and go to item 7. If the answer was yes, continue on and answer items 6b.-6e.
	Route of parental iron administration	For item 6b., enter the appropriate code for route of parenteral iron administration (parenteral means intravenous (i.v.) or intramuscular (i.m.) not oral, not p.o.).

	Date of last i.v. or i.m. p. iron administration during 1993	For item 6c, enter the date of last administration during 1993.
	Dose of iron per administration **in mg** (most current)	For item 6d, enter the dose of iron per administration in mg in 1993. **If the information is available in ml, be sure to convert to mg**. Use data from the most current dose administered. (1 ml=50 mg).
	Administrations of iron per week	For item 6e enter the # of administrations per week in 1993.
7.	Was patient taking oral iron at the end of December, 1993?	Enter the appropriate code.
8.	EPO (Prescribed or Administered)	For item 8, enter yes if the patient was on EPO as if 1/1/94 (+/- one week). If not, then go on to item 7.
	Units of EPO per administration	For item 8a, enter the # of units of EPO per administration for the week of January 1, 1994 (± 1 week). This number should be in 1000's of units. If this data is not available, give the prescribed EPO administration.
	Units of EPO per week (sum total)	For item 8b, enter the total units of EPO administered for the same week as referenced in item 8a. Again, this number should be in 1000's of units.
	Administrations of EPO per week	For item 8c, enter the total # of administrations for the same week referenced in items 8a and 8b
	Route of EPO administration	For item 8d, enter the appropriate code for the route of administration of EPO.
	EPO start date, if after ESRD	For item 8e, enter the start date for EPO if the start date was after the patient was diagnosed with ESRD. If the start date was before the patient was diagnosed with ESRD, check the appropriate box.
	Most recent hematocrit before EPO start date	For item 8f enter the most recent hematocrit before the EPO start date entered in item 8e. This item will be left blank if EPO was started before a diagnosis of ESRD.

Nutrition Questionnaire

General Notes

The table to be completed for this section requests the same information as requested in item D:16, D:17 and D:18 of the Core Questionnaire but is for the time period of January, 1994 through November, 1994. Information pertaining to pre and post BUN, pre and post patient weight and serum albumin is requested for the following months in **1994**: January, March, May, July, September and November.

Remember to use the Abstractor's "Comments Box" if you need to further explain any of your answers.

Item	Description	Abstractor Instructions
1.	BUN and Weight	Note: If NONE of the information is available for a given month, skip that column in the table. **Do not enter zeros**.
	Date	Date: For each month, enter the day to which the values apply. If values are available for more than one day in a month, use the first day on which a set of values is available.
	BUN	BUN: Enter the predialysis BUN and the postdialysis BUN for the day entered in the date row. If a postdialysis BUN is not available for that month, record the predialysis BUN only. Enter a second predialysis BUN value **only** if this value is available for the dialysis session **exactly two days after the session for which the first two (pre and post) values are entered**.
	Weight	Weights: Enter the predialysis weight and the postdialysis weight for the day entered in the date column, rounded to the nearest pound or kilogram. Check the appropriate units box to indicate if measurements recorded are in pounds or kilograms. Enter a second predialysis weight **only** if this value is available for the dialysis session **exactly two days after the session for which the first two (pre and post) values are entered**. NO weight needs to be recorded if NO pre and post BUN is recorded.

2.	Predialysis Serum Albumin	For item 2., enter the patient's predialysis serum albumin from the same day as referenced in the date row. However, if this data is not available, use any **value from the <u>month</u> entered in the date row**, to the nearest tenth.
3.	Duration of dialysis	Enter the duration of the dialysis session. This should be the same dialysis session as the one referred to for the first value of predialysis BUN and weight and predialysis serum albumin (NOT the dialysis session referred to for the second pre dialysis value of BUN and weight).

Vascular Access Questionnaire

General Notes

Please note that at the top of this questionnaire is a space for providing the date of the patient's first chronic maintenance dialysis treatment. (This date was also abstracted for the Core Questionnaire, Item 14 on page 3). Please be sure to complete this item.

This section covers information pertaining to vascular access. **The following codes should be used throughout this section for type of vascular access:**

1-AV-Fistula
2-PTFE graft, e.g. Goretex, Impra, Teflon
3-bovine graft
4-permanent catheter, e.g. subclavian Permcath (any site)
5-temporary internal jugular (IJ) catheter
5-temporary subclavian catheter
7-temporary femoral catheter
8-other

The following codes should be used for types of revisions:

1-medical declotting, e.g. urokinase thrombolysis
2-balloon angioplasty with thrombolysis
3-balloon angioplasty without thrombolysis
4-surgical declotting, e.g. thrombectomy, Fogarty
5-surgical revision of existing access
6-creation of new AV fistula
7-creation of new PTFE graft (Gortex)
8-creation of other permanent access
9-other

This section should be filled out only if the patient began chronic dialysis during calendar year 1993 (1/1/93-12/31/93).

Please pay close attention to the date(s) referenced for each question. A window of +/- 1 week means that if data is not available for the date requested, you can obtain the data from the week prior or the week following the date requested.

Remember to use the Abstractor's "Comments Box" if you need to further explain any of your answers.

Item	Description	Abstractor Instructions
1.	Was a permanent access placed or attempted before the onset of ESRD?	Enter the appropriate code for yes, no or unable to determine.
2.	What type of access was in use at the initiation of hemodialysis	Enter the appropriate code for the type of vascular access in use at the initiation of hemodialysis
3.	What type of access was in use 1 month after the start of hemodialysis regardless of setting.	Enter the appropriate code for the type of vascular access in use at 1 month after the start of hemodialysis. **If you enter code 5, 6, or 7, for a temporary access, then stop abstraction and do not go on to answer any further items**.
4.	When was this access (item 3) placed?	Enter the date of placement of the access referred to in item 3.
5.	Highest blood flow during the 4th week of chronic hemodialysis.	Enter the highest blood flow (ml/min) during the 4th week of chronic hemodialysis..(Use information from 3 dialysis flow sheets.)
6.	Highest venous pressure at this highest blood flow.	Enter the venous pressure (mmHg) at the highest blood flow recorded in item 5.
7.	First date of dialysis with all blood flows below 200 during any dialysis after the first month of chronic hemodialysis.	Enter the date of the first occurrence of all blood flows below 200 during any dialysis **after the 1st month of chronic hemodialysis**.
8.	Was recirculation tested after the 1st month of chronic hemodialysis?.	Enter the appropriate code for yes or no. IF YES, enter the first date of recirculation, the test result and the blood flow at this recirculation test.
9.	Did switch to PD occur during this period.	Enter the appropriate code for yes or no for whether or not a switch to PD occurred during the period of one month after the start of chronic hemodialysis to the date of abstraction. IF YES, enter the date that the patient switched to PD.

10.	Were any procedures or revisions made to the access in use at 1 month?	Enter the appropriate code for yes or no. IF YES, please give, for up to two revisions or procedures, the date(s) and the type(s). Please use the codes on the questionnaire provided for the type of revision. For each occurrence of a procedure or revision, please indicate using the appropriate code whether the access was completely clotted (i.e. the procedure or revision was not prophylactic).
11.	Did vascular access infection occur anytime from one month after the start of chronic dialysis to the date of abstraction or 18 months?	Enter the appropriate code for yes or no. **Do not go beyond an 18 month period from one month after the start of dialysis to the date of abstraction.** IF YES, enter up to two dates for two possible occurrences of vascular access infection. Along with each of these dates, enter the appropriate code for yes, no or not done.

USRDS Dialysis Morbidity and Mortality Study

Dialysis Facility/Unit Questionnaire

General Notes

This questionnaire is to be filled out once only by each dialysis facility/unit participating in the USRDS Dialysis Morbidity and Mortality Study (DMMS).

If the answer to an item cannot be determined, **leave the item blank by leaving the box on the right empty** and **put a check mark in the small box to the left of the item number.** This will indicate that you looked for the information in all available records and decided that you could not determine an answer for the item. When information is not available to answer a question, checking the box on the left is important because it indicates that the item was not inadvertently skipped or forgotten.

Dates

Dates are either in month (mm), day (dd) and year (yy) format or in month and year format. **In all cases, month and day must be expressed in 2 digits.** For example, January is 01 and November is 11. The first day of the month is 01; the fifteenth day of the month is 15. The year is expressed by the last two digits of the year; e.g. 94 for 1994.

If you are able to report partial information only, do so but also put a check in the small box to the left of the item number. For example, if the records give the year of starting reuse but not the month or day, enter the year in the appropriate box, leave the month and day blank and check the box to the left of the item number.

Item	Description	Instructions
1.	Network	Enter the 2 digit number assigned to you network (For example, 03 for Network 3.)
2.	Abstractor	Enter your initials.
3.	Date completed	Enter the date that this questionnaire was completed.
4.	Provider number	Enter the provider number for your unit. Please note that a large facility may have multiple provider numbers, i.e. one for its transplant facility and one for its dialysis unit. Be sure to enter the number pertaining to the dialysis unit. **Do not enter the billing number**.
5.	Facility name	Please PRINT the full name of the unit/facility.

6.	Was it the practice of this unit to reuse dialyzers during December of 1993?	Enter the appropriate code for whether or not it was the practice of this unit to re-use dialyzers during December of 1993. If you answer yes to this question, go on to answer items 6a-6d. If you answer no to this question, skip 6a-6d and go on to item 7.
	Date that reuse was originally started at this unit.	For item **6a**, enter the date that reuse was originally started at this unit. Check the "present" box if reuse is still practiced. If reuse was discontinued, enter the date that this occurred. The month boxes need to be indicated only for year 1992 and 1993.
	Reuse technique(s)	For item **6b**, enter the appropriate code for the reuse technique that was practiced on 12/31/93. Then enter the appropriate code for the reuse technique practiced as of the date of this abstraction. If **automated reuse** was practiced, enter the code for the type of machine that was used.
	Dialyzer disinfectant used?	For item **6c**, enter the appropriate ("yes" or "no") code for the reuse agents used, both on 12/31/93 and at the time of this abstraction. Do not mark the disinfectant used solely for the dialysis machine.
	Was blood tubing reused as of 12/31/93?	For item **6d** enter the appropriate code for whether or not blood tubing was reused at your facility as of 12/31/93.
7.	Type of water source	Enter the appropriate code for the predominant type of water source that your facility uses.
8.	Types of water treatment	Enter the appropriate ("yes" or "no") code for the types of water treatment used by your facility **for reprocessing of dialyzers** and **for dialysate**. Indicate all that are normally in use but do not include backup. If your facility does not reuse dialyzers, the column for reprocessing of dialyzers will not be filled out.
9.	What type of KT/V or URR is calculated.	Enter the appropriate code for the type of KT/V or URR calculation that is practiced at your facility.
10.	Timing of postdialysis BUN sample (policy in December, 1993)	Enter the appropriate code for the timing of post BUN samples at your facility according to policy or, if not available, according to common practice as of December, 1993.

11.	Most common hemodialysis machine	Enter the manufacturer name and the manufacturer model of the hemodialysis machine most commonly used by your dialysis facility.
12.	% of all machines in use	Enter the percentage of machines that the most commonly used machine represents (i.e., the # of machines of the most common model divided by the total # of machines in your unit).
13.	Lower limit of normal range for serum albumin from lab report	Enter the lower limit for serum albumin **from the lab report** both at the study start date of 12/31/93 **and** at the date of abstraction.
14.	Routine vascular access surveillance practiced in December, 1993 (Doppler etc.)	Please indicate the frequency of routine vascular access surveillance practice of your facility, as practiced in December, 1993..

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DIALYSIS UNIT/FACILITY QUESTIONNAIRE

Check box to left of item, IF unable to determine and leave item (right) blank.

Study Start Date: 12/31/93

1. Network..... ☐☐ 2. Abstractor initials..... ☐☐

3. Date this questionnaire was completed ☐☐ mm ☐☐ dd ☐☐ yy

4. Medicare provider number..... ☐☐☐☐☐☐ (Not billing #)

5. Facility name: _____

6. Was it the practice of this unit to reuse dialyzers during Dec. 1993?..... ☐
1-Yes 2-No

If YES, please answer parts a through d. If NO, go to item 7:

a) Date that reuse was originally started at this unit:

☐☐ mm ☐☐ yy to present ☐ (check if appropriate) **OR** if discontinued or changed during 1994: ☐☐ mm ☐☐ yy

b) Reuse technique(s)..... on 12/31/93 ☐ Time of abstraction ☐
1-Manual 2-Automated 3-Both

If answered Automated (2) please see below. If not automated go to item 6c.

If automated reuse was practiced which machine was used on 12/31/93?..... ☐
1-Fresenius "DRS-4" 2-Mesa Labs "Echo" 3-Renal Sys. "Renatron" (single and multiple) 4-National Medical Care "semi-automated" 5-Other

c) Dialyzer disinfectant used

1-Yes 2-No	on 12/31/93	At time of abstraction
Bleach in dialyzer	☐	☐
Formalin (formaldehyde) in dialyzer	☐	☐
Paracetic acid (Renalin) in dialyzer	☐	☐
Glutaraldehyde in dialyzer	☐	☐
Heat only (no disinfectant)	☐	☐

d) Was blood tubing reused as of 12/31/93?..... ☐
1-Yes 2-No

7. Type of water source..... ☐
1-Public water system 2-Well

- 8. Types of water treatment. Indicate all that are normally in use. (Do not include backup) 1-Yes 2-No

	for Reprocessing Dialyzers	for Dialysate
Softener	☐	☐
Activated charcoal	☐	☐
Reverse osmosis	☐	☐
Deionization	☐	☐
U-V light	☐	☐
Ultrafilter	☐	☐

- 9. What type of Kt/v or URR is calculated?..... ☐
1 - Kt/V from pre, post, and pre BUN
2 - Kt/V or URR from pre and post BUN
3 - Kt/V from pre and post BUN AND pre and post weight
4 - none
- 10. Timing of post dialysis BUN sample (policy in December 1993) ☐
1 - immediately at the end of dialysis without slowing blood flow
2 - immediately at end of dialysis after slowed or stopped blood flow
3 - 20 to 60 seconds after end of dialysis
4 - 1 to 2 minutes after end of dialysis
5 - 3 to 15 minutes after end of dialysis
6 - more than 15 minutes after end of dialysis
- 11. Most common hemodialysis machine:

Manufacturer: _____

Model: _____

- 12. This machine is ☐☐☐ % of all actively used machines. (not including back-up machines or acute facility machines)
- 13. Lower limit of normal range for serum albumin from lab report:

☐.☐ g/dl at study start date ☐.☐ g/dl at date of abstraction

- 14. Routine vascular access surveillance practiced in Dec 1993 (Doppler etc.)? ☐
1-monthly 2-yearly 3-as needed/other

Confidential Report

USRDS - VASCULAR ACCESS IN INCIDENT PATIENTS

This form to be filled out only if the patient began chronic dialysis during 1993 (1/1/93-12/31/93)

Check box to left of item, IF unable to determine leave item (right) blank.

Please copy date of first chronic maintenance dialysis below (see Core page 3 item 14)

☐☐ ☐☐ ☐☐

Study Start Date: 12/31/93

Vascular access at 1 month after start of chronic dialysis (any setting):

- 1. Was a permanent access placed or attempted before the onset of ESRD? ☐
  1-Yes 2-No 3-Unable to determine
- 2. What type of access was in use at the initiation of hemodialysis?..... ☐
  (1 through 8 below)
- 3. What type of access was in use 1 month after the start of hemodialysis regardless ☐

1-AV Fistula 2-PTFE graft (e.g. Gortex, Impra, Teflon) 3-Bovine graft
4- permanent catheter e.g. subclavian Permcath (any site)
5-temporary internal jugular (IJ) catheter 6- temporary subclavian catheter
7-temporary femoral catheter 8-Other

IF access at 1 month (item 3) was a temporary access (codes 5, 6, or 7) then stop abstraction of this form here

- 4. When was this access (item 3) placed? ☐☐ ☐☐ ☐☐ (mm dd yy)
- 5. Highest blood flow during the 4th week of dialysis..... ☐☐☐ ml/min
- 6. Highest venous pressure at this highest blood flow..... ☐☐☐ mmHg

Vascular Access Problems from One Monthto Date of Abstraction

- 7. First date of dialysis with all blood flows below 200 during any dialysis after 1st month of chronic hemodialysis: ☐☐ ☐☐ ☐☐ (mm dd yy)
- 8. Was recirculation tested after the 1st month?..... ☐
  1-Yes 2-No
  IF YES, first date: ☐☐ ☐☐ ☐☐ (mm dd yy) Result: ☐☐ %
  What was the blood flow at this recirculation test? ☐☐☐ ml/min
- 9. Did switch to peritoneal dialysis occur during this period (one month from 1st dialysis to the date of abstraction)?.....
  1-Yes 2-No
  IF YES, Date: ☐☐ ☐☐ ☐☐ (mm dd yy)
- 10. Were any procedures or revisions made to the access in use at 1 month..... of setting? (1 through 8 below ☐
  1-Yes 2-No

IF YES: Please give the first two dates and the type of revisions that were made:

Date 1 : ☐☐ ☐☐ ☐☐ (mm dd yy) Type of revision* ☐

At the time of revision was this access completely clotted (i.e. procedure was not prophylactic) 1-Yes completely clotted 2-No not completely clotted ☐

Date 2 : ☐☐ ☐☐ ☐☐ (mm dd yy) Type of revision* ☐

At the time of revision was this access completely clotted (i.e. procedure was not prophylactic) 1-Yes completely clotted 2-No not completely clotted ☐

****Type of Revision: 1-medical declotting 2-balloon angioplasty with thrombosis 3-balloon angioplasty without thrombosis 4-surgical declotting 5-surgical revision of existing access 6-creation of new AV fistula 7-creation of new PTFE graft (Gortex) 8-creation of other permanent access***

- 11. Did vascular access infection occur during this period (one month from 1st dialysis to the date of abstraction or 18 months)?..... ☐
  1-Yes 2-No

IF YES, Date 1: ☐☐ ☐☐ ☐☐ (mm dd yy) Positive blood culture? ☐
1-Yes 2-No 3-Not Done

Date 2: ☐☐ ☐☐ ☐☐ (mm dd yy) Positive blood culture? ☐
1-Yes 2-No 3-Not Done

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old form

Check box to left of item if unable to determine, and leave item (right) blank.

Study Start Date: 12/31/93

A. Patient and Facility Identification

1. Abstractor Initials ☐☐

2. Date Completed: ☐☐ mm ☐☐ dd ☐☐ yy

- **3. Race:** ☐
  1 - White 2 - Black 3 - Asian
  4 - Native American 5 - Other
- **4. Ethnicity:** ☐
  1 - Hispanic Origin 2 - Not of Hispanic Origin
- **5. Patient's Zip Code:** ☐☐☐☐☐

6. Year of First ESRD service:

- a. **Year of first chronic maintenance dialysis, regardless of setting**: ☐☐ yy

➔ ***(If a not available, answer item 6b)***

- **b. Earliest known year of chronic dialysis:** ☐☐ yy

- **7. Current (or last known) insurance (answer all):**
  1 - Yes 2 - No
  a. Blue Cross/Blue Shield: ☐
  b. Private (other than BC/BS): ☐
  c. Medicare: ☐
  d. Medicaid: ☐
  e. VA: ☐
  f. Other: ☐
  g. None: ☐

- **8. Was patient enrolled in an HMO since starting chronic mainteance dialysis?** 1- Yes 2 - No ☐

B. Patient History Prior to 12/31/93

- **1. Regular cigarette smoking status prior to study start date:** ☐
  1 - Active 2 - Former
  3 - Smoker, current status unknown
  4 - Non Smoker

➔ ***Comorbid conditions present within 10 years prior to 12/31/93 (items 2-10)***

2. Hx* of Coronary Heart Disease (CHD) or Coronary Artery Disease (CAD)

***Hx means history, Dx means diagnosis**

For a through g code 1 - Yes 2 - No 3 - Suspected

- a. Prior Dx of CHD/CAD: ☐
- b. Angina: ☐
- c. Myocardial infarction (MI): ☐
- d. Bypass surgery: (CABG) ☐
- e. Coronary angioplasty (PTCA): ☐
- f. Coronary angiography: ☐
  - Abnormal? ☐
- g. Cardiac arrest: ☐

3. Hx of Cerebrovascular Disease:

For a & b code 1-Yes 2- No 3-Suspected CVA or TIA

- a. Dx of Cerebrovascular Accident (CVA, Stroke) ☐

➔ ***(If item 3a is Yes, skip to item 4.)***

- b. Any Transient Ischemic Attacks (TIA)? ☐

4. Hx of Peripheral Vascular Disease (PVD):

For a through e code 1 - Yes 2 - No 3 - Suspected ☐

- a. Prior Dx of PVD: ☐
- b. Amputation due to PVD: ☐
- c. Limb amputation (other): ☐
- d. Absent foot pulses: ☐
- e. Claudication: ☐

5. Hx of Heart Disease (other than CAD/CHD):

For all code: 1 - Yes 2 - No 3 - Suspected

- a. Congestive heart failure: ☐
- b. Pericarditis: ☐

- **6. Prior Dx of Diabetes:** ☐
  1 - Yes 2 - No 3 - Suspected

➔ ***If no, skip to item 7.***

- a. Was diabetes the cause of ESRD: ☐
  1 - Yes 2 - No
- b. Insulin therapy: ☐
  1 - Active 2 - Former 3 - Never

7. Hx of Lung Disease:

- Chronic obstructive pulmonary disease (COPD) ☐
  1 - Yes 2 - No 3 - Suspected

- **8. Neoplasms (other than skin):** ☐
  1 - Yes 2 - No 3 - Suspected

➔ ***If no, skip to item 9.***

- a. Primary sites (up to 2): ☐☐ ☐☐

10 - Lung
11 - Stomach/Esophagus
12 - Breast
13 - Pancreas
14 - Prostate
15 - Liver
16 - Colon/Rectal
17 - Myeloma
18 - Lymphoma/Leukemia
19 - Brain
20 - Ovary/Uterus
21 - Melanoma of skin
22 - Bladder
23 - Oral/Larynx
24 - Kidney
25 - Other, Unknown

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Check box to left of item if unable to determine, and leave item (right) blank.

Study Start Date: 12/31/93

- b. Year of first dx: ..... yy

- **9. HIV Status:** .....
  1 - Positive 2 - Negative 3 - Unknown 4 - Can't disclose
- **10. AIDS Diagnosis:** .....
  1 - Positive 2 - Negative 3 - Unknown 4 - Can't disclose

C: Information at Start of Study

1. Height (at any time): (REQUIRED)

ft. in. or cm.

If bilateral amputee give original height and check this box

- **2. Dry weight as ordered in December 1993:**

If unavailable list lowest postdialysis weight within last two weeks

wt: lbs. or . kgs.

- **3. Undernourished or cachectic (malnourished) in October - December 1993** .....
  1 - Yes 2 - No 3 - Suspected

4. Blood pressure (average of last 3 values from last week of 1993; please right justify entry):

- a. Predialysis:

SBP / DBP

- Was Bp taken sitting (preferred)
  1-Yes 2-No

- b. Postdialysis:

SBP / DBP

- Was Bp taken sitting (preferred)

1-Yes 2-No

5. Dialysis Information (December 1993):

- a. Dialysate: .....
  1 - Bicarbonate 2 - Acetate
- b. Prescribed hours per treatment: : hr. min.
- c. Prescribed # of dialysis sessions per week: .....
- d. Blood flow rate (BFR):..... ml/min

If BFR varies please enter the prescribed or the most common "high" rate

- e. Patient usually reusing dialyzer:: .....
  1 - Yes 2 - No
- f. If reuse does not occur, please indicate reason:
  1 - Unit does not reuse 2 - Patient refuses
  3 - Hepatitis 4 - Other Medical
- g. Highest weight loss (during dialysis) within last 2 weeks of December 1993:

(Rounded) lbs. **or** . kgs.

- h. Dialyzer type (see codes on back of face page):

If code 9999, please specify below:

manufacturer _____

dialyzer model _____

- i. Vascular access in use: .....

1-AV Fistula
2-PTFE graft eg. Gortex, Impra, Teflon
3-Bovine graft
4-Permanent catheter eg. Permcath (any site)
5-Temporary internal jugular (IJ) catheter
6-Temporary subclavian catheter
7-Temporary femoral catheter
8-Other

➔Complete the following with information from the psychosocial evaluation most recent before the STUDY START DATE of 12/31/93 (older versions may be used for completeness). Use social worker's evaluation supplemented by the nurse's, and/or dietitian's records; may use your interpretation of the records. You may want to consult with the social worker or dietitian.

- **6. Date of psychosocial evaluation:** mm dd yy
- **7. Activities of daily living (currently or recently):**
  1 - Yes 2 - No
  a. Independent eating: .....
  b. Independent transferring: .....
  c. Independent ambulating: (includes ambulating with an assistance device) .....
- **8. Marital status:** .....
  1 - Single 2 - Married
  3 - Widowed 4 - Divorced
  5 - Separated
- **9. Living alone:** .....
  1 - Yes 2 - No
  3 - Nursing home, institution 4 - Homeless
- **10. Education:** .....
  1 - Less than 12 Yrs. 2 - High School Grad
  3 - Some College 4 - College Grad
- **11. Primary occupation before ESRD:** .....
  1 - Clerical
  2 - Professional
  3- Tradeperson
  4 - Manual Labor
  5- Student
  6- Other
  7 - Not Employed Outside of Home

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old form

Check box to left of item if unable to determine, and leave item (right) blank.

Study Start Date: 12/31/93

8 - Homemaker
9- Disabled

- **12. Employment Level according to the following scale:**

1-Yes 2-No

	Before ESRD	On 12/31/93
a - Employed full time or full time student	☐	☐
b - Employed part time or part time student	☐	☐
c - Homemaker	☐	☐
d - Retired	☐	☐
e- Never Employed	☐	☐
f - Unemployed	☐	☐
g - Disabled	☐	☐
h - Other (specify)	☐	☐

D: Laboratory Data

→ Complete Items 1 and 2 with any available information from 1993.

- **1. Cardiomegaly by X-ray:** ..... ☐

1 - Yes 2 - No

2. Left ventricular hypertrophy by:

1 - Yes 2 - No

- a. by EKG ..... ☐
- b. by echocardiography ..... ☐

→ Complete Items 3 to 10 with the most recent information from Dec 1993.

- **3. Serum calcium, predialysis:** ☐☐.☐ mg/dl ☐☐ ☐
- **4. Serum phosphorus, predialysis:** • mg/dl
  (or serum phosphate, predialysis)
- **5. Serum bicarbonate, predialysis:** ☐☐.☐ mEq/l
  or CO_2
- **6. Hematocrit information (from the lab report)**
  - a. Hematocrit (If transfused, give value before transfusion) ☐☐.☐ **%**
  - b. Hemoglobin: ☐☐.☐ g/dl
  - c. Transfused in December 1993?..... ☐
    1 - Yes 2 - No

(If no, skip to item 7)

  - d. If transfused, number of transfusions in December 1993?..... ☐
- **7. Was the patient taking EPO (Erythropoetin) anytime in December 1993**..... ☐
  1 - Yes 2 - No
- **8. Serum Creatinine, predialysis:** ☐☐.☐ mg/dl

(Record average of at least two values for item 9)

- **9. Number of treatments skipped during December 1-23, 1993:** ..... ☐
- **10. Number of treatments during December 1993 shortened by more than 10 minutes (do not include skipped treatments):** ..... ☐

Use most recent value from July-December 1993 for questions 11, 12, & 13:

11. Lipids

- a. Cholesterol Total..... ☐☐☐ mg/dl
- b. Triglycerides..... ☐☐☐☐ mg/dl

- **12. Serum intact PTH**..... ☐☐☐☐ pg/ml ☐☐☐☐
- **13. Serum Aluminum (Random)** µg/l

For patients starting ESRD during 1993 please answer questions 14 & 15:

- **14. Date of first ever chronic maintenance dialysis treatment:** ☐☐ mm ☐☐ dd ☐☐ yy
- **15. Serum Creatinine on day of first ever dialysis** ☐☐.☐ mg/dl

Please continue to item 16, on page 4.

Abstractor:

Please use this space to enter any comments or explanations to a particular item

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old form

Check box to left of item if unable to determine, and leave item (right) blank.

Study Start Date: 12/31/93

BUN, Weight, and Albumin, July 1993 to December 1993:

***The second predialysis value must be exactly two days after the stated date; otherwise, do not record.**

16. BUN and Weight (If no value please leave blank, do not enter zeros)

	mm dd yy	mm dd yy	mm dd yy	mm dd yy	mm dd yy	mm dd yy
DATE:	07 / / 93	08 / / 93	09 / / 93	10 / / 93	11 / / 93	12 / / 93
BUN (mg/dl)						
• Pre						
• Post						
• Pre *						
WEIGHT:						
• Pre						
• Post						
• Pre *						

Please note that NO weight needs to be entered if NO Pre & Post BUN is recorded. Please round to only whole numbers.

Units (✓ one) ☐ **LBS.** ☐ **KGS.**

17. ALBUMIN

• Predialysis Serum Albumin Value (g/dl)	.	.	.	.	.	.
18. Duration of dialysis	:	:	:	:	:	:

E: CHANGE IN PATIENT STATUS

Dialysis Unit Do Not Complete This Section

TO BE COMPLETED BY NETWORK AFTER THE REST OF THE FORM HAS BEEN COMPLETED BY THE FACILITY UNIT

→ ***Record any changes that occurred after December 31, 1993.***

- **1. Date switched off Center Hemodialysis** ☐☐ ☐☐ ☐☐ (mm dd yy)

If switched from center hemodialysis, the reason?..... ☐

1 - Transplant 2 - Peritoneal dialysis
3 - Home Hemodialysis 4 - Recovered renal function

- **2. Date of Death:**..... ☐☐ ☐☐ ☐☐ (mm dd yy)
- **3. Date patient moved out of region:** ..... ☐☐ ☐☐ ☐☐ (mm dd yy)
- **4. Date of transfer within the Network** ..... ☐☐ ☐☐ ☐☐ (mm dd yy)

If none of E:1 - E:4 occurred, then complete E:5

- **5. If patient is lost to follow-up please give date of last known center hemodialysis:** ☐☐ ☐☐ ☐☐ (mm dd yy)

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USRDS - ANEMIA

Check box to left of item, IF unable to determine and leave item (right) blank.

Study Start Date: 12/31/93

Anemia: Laboratory Values

- **1. Serum iron (mg/dl).....** ☐☐☐
  (most recent Oct. through Dec. 1993)
- **2. Total iron binding capacity (TIBC) (mg/dl).....** ☐☐☐
  (most recent Oct. through Dec. 1993)
- **3. Ferritin (mg/L).....** ☐☐☐☐
  (most recent Oct. through Dec. 1993)
- **4. Transferrin saturation (if available).....** ☐☐ **%**
  (most recent July-December 1993)
- **5. Hematocrit as of October 1993.....** ☐☐.☐ **%**

Medications as of 1/1/94 (+/- 1 week)

6. Iron:

- **a) Was parenteral iron (i.v. or i.m.) used during 1993?.....** ☐
  1-Yes 2-No

If answered no to item 6, then go to item 7.
If answered YES to item 6, please answer the following questions:

- **b) Route of parenteral iron administration.....** ☐
  1-intravenous (i.v.) 2-intramuscular (i.m.)
- **c) Date of last i.v. or i.m., p. iron administration during 1993:**
  ☐☐ ☐☐ ☐☐
  mm dd yy
- **d) Dose of iron per administration in mg** ☐☐☐ **mgs.**
  (most current) (1 ml = 50 mg)
- **e) Administrations of iron per week.....** ☐☐

- **7. Was patient taking oral iron at the end of December 1993?** ☐
  1-Yes 2-No
- **8. Erythropoietin (EPO) administered.....** ☐
  1-Yes 2-No

If answered no to item 8, then end of questionnaire.
If answered YES to item 8, please answer the following questions:

- **a) Units of EPO per administration:**
  (if not available give prescribed) ☐☐,☐☐☐
- **b) Units of EPO per week (sum total) :** ☐☐,☐☐☐
- **c) Administrations of EPO per week.....** ☐
- **d) Route of EPO administration.....** ☐
  1-intravenous 2-subcutaneous
- **e) EPO start date, if after ESRD.....** ☐☐ ☐☐ ☐☐
  mm dd yy
  If EPO start before ESRD check here → ☐
- **f) Most recent hematocrit before EPO start date:**
  ☐☐.☐ **%**

Confidential Report
USRDS DMMS - NUTRITION

Check box to left of item, IF unable to determine and leave item (right) blank.

Study Start Date: 12/31/93

BUN, Weight, and Albumin, January 1994 to November 1994

***The second predialysis value must be exactly two days after the stated date; otherwise, do not record.**

1. BUN and Weight (If no value please leave blank, do not enter zeros)

Date:	1/ □□ /94	3/ □□ /94	5/ □□ /94	7/ □□ /94	9/ □□ /94	11/ □□ /94
BUN (mg/dl)						
• Pre	□□□	□□□	□□□	□□□	□□□	□□□
• Post	□□□	□□□	□□□	□□□	□□□	□□□
• Pre*	□□□	□□□	□□□	□□□	□□□	□□□

WEIGHT: **Please note that NO weight needs to be entered if NO Pre & Post BUN is recorded. Please round to only whole numbers.**

• Pre	□□□	□□□	□□□	□□□	□□□	□□□
• Post	□□□	□□□	□□□	□□□	□□□	□□□
• Pre*	□□□	□□□	□□□	□□□	□□□	□□□

Units (✓ one) □ **LBS.** □ **KGS.**

• 2. Predialysis Serum Albumin (g/dl)	□.□	□.□	□.□	□.□	□.□	□.□
• 3. Duration of dialysis	□:□□	□:□□	□:□□	□:□□	□:□□	□:□□

Patient Tracking Form/Patient Identification as of 12/31/93 **Network: 02**

Dialysis Unit Data Abstractor Should Complete This Form

Dialysis Unit Name _____ DMMS ID# _____

Unit Provider # _____

Pt. Name and Identifiers	**Info Correct? Circle Yes or No**	**Corrected Info If Necessary**	**Forms to Be Completed**	**Form Completed? Circle Yes or No**	**If no, Reason Code**	**Reason Explanation**
			Core	Yes No		
SEX:	Yes No		Anemia	Yes No		
DOB:	Yes No		Nutrition	Yes No		
SSN:	Yes No		Vascular Access	Yes No		
HIC#	Yes No					
Modality(12/31/93): **Center Hemo**	Yes No					

Reason Code: If a patient records could not be located, please indicate using the codes below, the reason why the record could not be located.

A: Patient stopped receiving treatment at this unit and transferred to another facility prior to the Study Start Date of December 31, 1993.
B: Patient died prior to January 1, 1994 or on the Study Start Date of December 31, 1993.
C: Patient was never treated at this unit.
D: Other; Please specify with a written explanation.

Reason Explanation: Complete this item only if the Reason Code used when records could not be located was Reason Code "D".

- **DMMS Wave II Special Study Data Forms**
  - *Cover Sheet & Patient Consent form*
  - *Instruction Manual*
  - *Dialysis Facility/Unit Questionnaire Instructions*
  - *Dialysis Patient Qustionnaire*
  - *Medical Questionnaire Confidential Report*
  - *USRDS DMMS Prospective Followup Study-Instructions*
  - *Cover Sheet for Medical Update Questionnaire*
  - *Medical Update & Questionnaire*
  - *Cover Sheet & Patient Consent form*
  - *Dialysis Patient Questionnaire*
  - *Patient Tracking & Identification form*

USRDS
UNITED STATES RENAL DATA SYSTEM
315 W. Huron, Suite #240, Ann Arbor, MI 48103 (TEL) 313 998-6611; (FAX) 313 998-6620; internet: USRDS@UMICH.EDU

United States Renal Data System Prospective Dialysis Patient Study

Dialysis Patient Questionnaire
COVER SHEET AND PATIENT CONSENT FORM

Dear Dialysis Patient:

Under the Direction of the National Institute of Health, the United States Renal Data System, an organization devoted to research about patients with kidney disease, is asking for your participation in a study of quality of life, rehabilitation and medical care before dialysis. Your answers will help us understand and improve the care of dialysis patients. The information we collect from you and other patients will be used to answer many important questions about how to provide better treatment for kidney patients. **Your participation in this study is strictly voluntary and confidential and the information that you provide will not be shared with any staff from your dialysis unit. If you choose not to participate, this will not affect your treatment or insurance status in any way**.

With your permission we would like to ask you some questions about the state of your health and family by having you complete the attached Dialysis Patient Questionnaire. You may ask for assistance from the staff or from family or friends but the answers should be from **you**. Completing this questionnaire should take you no more than one hour. In 6 months we will be asking you to repeat some of these questions and others about your experiences and your treatment choices. This information will help us understand the needs of **new patients** and improve treatment at this critical time.

Protecting your privacy is very important to us. If you agree to participate in this study, all of the information which you provide will be kept confidential.

If you have any questions or concerns about your participation in this study, please feel free to make a collect phone call to Liz Holzman or Caitlin Carroll at the United States Renal Data System. The phone number is **1-800-707-0044**.

If you agree to participate in this study, please sign this consent form in the space provided below. Thank you very much for your important contribution to research about patients with kidney disease.

I, _____ (printed name), have read the above description of the USRDS's study and agree to participate in this study by completing the Dialysis Patient Questionnaire. I understand that information obtained about me will be kept confidential.

Signed: _____ Date: _____

Attached to this questionnaire, you will find an 8x11 envelope. When you have completed this questionnaire, please place it in the envelope, seal it and return it to the dialysis unit staff person who asked you to participate in this study. This procedure will ensure the confidentiality of the information that you have provided. Thank you once again.

NIDDK legislative authority to conduct research is granted under
Public Health Service Act 42-USC-241, Section 301

INSTRUCTION MANUAL

USRDS DIALYSIS MORBIDITY AND MORTALITY STUDY (PROSPECTIVE)
MEDICAL QUESTIONNAIRE
and
DIALYSIS PATIENT QUESTIONNAIRE

Questions? Feel free to call the USRDS Coordinating Center anytime for clarification of any of the instructions pertaining to completion of the forms for the DMMS. Please call and ask to speak with Liz Holzman or Caitlin Carroll. Our new toll free number is:

1-800-707-0044

GENERAL INSTRUCTIONS AND OVERVIEW

Please be sure to carefully read the entire section on "General Instructions and Overview", pp. 1-9. You will need to understand the material covered in this section in order to correctly select patients for enrollment in the study and correctly follow procedures for data collection. Pages 10-22 of the Instruction Manual provide detailed instructions pertaining to the Medical Questionnaire. You do not need to read this section unless there is an item on the Medical Questionnaire that you do not understand. In such a case, you need only refer to the instructions for that particular item.

Questionnaires for the DMMS

There are three data collection instruments for the Dialysis Morbidity and Mortality Study (DMMS). All of these questionnaires will be relevant to all dialysis units.

1.) The Medical Questionnaire is to be completed by personnel at the dialysis facilities. Data abstraction of patient records for the Medical Questionnaire is to be completed by personnel at the dialysis facilities. Take all information from the facility/unit records, including medical records, billing records, dialysis logs, patient rosters, hospital records and personal physician records. **Please feel free to obtain information directly from the patient if the information is not available in any of the medical records.**

Having complete medical records available will make it much easier to complete the Medical Questionnaire. To assist you in obtaining these records, we have included a batch of forms that you

can use to request the patient's records from his/her referring physician. This form is entitled, "Request For Patient Medical Records". We have provided each dialysis unit with 10 of these forms but feel free to make more copies of these forms if there is a need.

In general, the Medical Questionnaire should not take more than 1 1/2 hours to complete. If dialysis unit staff are spending more than 1 1/2 hours *on average* completing these questionnaires, please contact Liz Holzman or Caitlin Carroll at the USRDS Coordinating Center (1-800-707-0044). In these cases, it is likely that the information is too difficult to obtain.

2.) The Dialysis Patient Questionnaire is to be given to all patients enrolled in the DMMS. Completion of this questionnaire is voluntary for patients. Your task is to discuss this form with the patients and encourage them to complete it. **Please distribute and discuss this form with patients as soon as they are enrolled in the study. Please make sure that these questionnaires are completed within 30 days and returned to the Network on at least a monthly basis**. Any patient who agrees to complete the Dialysis Patient Questionnaire will need to read through and sign the Cover Sheet and Patient Consent Form which is the first page of the Dialysis Patient Questionnaire.

Please be sure that any patient completing the Dialysis Patient Questionnaire has read the consent form and signed it. The consent form should remain stapled to the Dialysis Patient Questionnaire. ***In addition, we are requesting that dialysis unit staff assist at least one patient who requires assistance with this questionnaire.*** We understand that there are patients who are unable to complete this questionnaire on their own because of either a lack of education or a physical disability such as impaired vision. Some patients may also choose to take the Dialysis Patient Questionnaire home and have a family member provide assistance with completing it. However, once a questionnaire leaves the dialysis unit there is clearly a greater risk of it not being completed. Therefore, our preference in terms of completion of the Dialysis Patient Questionnaire is as follows:

1.) Patient completes questionnaire him/herself at the dialysis unit.
2.) Patient completes questionnaire with assistance from a dialysis unit staff member.
3.) Patient completes questionnaire with assistance from a capable family member, preferably at the dialysis unit but, if necessary, at home.

<u>The Medical Questionnaire and the Dialysis Patient Questionnaire should be completed on ALL patients enrolled in this study. You should have received a batch of **YELLOW BOOKLETS** which contain 1 each of the Medical Questionnaire and the Dialysis Patient Questionnaire.</u>

3) The Dialysis Unit/Facility Questionnaire is to be completed by a staff person at the dialysis unit only once, preferably a nurse or technician, sometime during the month of April or May, 1996 and should then be returned to the ESRD Network. Separate instructions for this questionnaire can be found attached to the Dialysis Unit/Facility questionnaire.

Please complete the forms in blue or black ink or dark pencil.
Please PRINT legibly in CAPITAL LETTERS.

Study Start Date/Definition of "Regular" Dialysis

- The DMMS is a **PROSPECTIVE STUDY** of incident (new) adult dialysis patients who have recently started regular maintenance dialysis.

- The Study Start Date for each patient entered in DMMS is calculated as 60 days after the first regular dialysis treatment. Regular dialysis, for the purpose of the DMMS is defined as at least once weekly dialysis for chronic renal failure, **regardless of whether dialysis occurs in an inpatient, acute or outpatient setting**.

- The Study Start Date delineates the starting point from which data becomes relevant to the study. As an example, a patient who became incident (had his/her first regular chronic dialysis treatment) on March 1, 1996 will have a study start date of May 1, 1996.

- Please exclude patients who are receiving sporadic (not regular) dialysis treatments for fluid overload or heart failure.

- Please exclude patients who are new to your dialysis unit but who are NOT new to dialysis, i.e. transfer patients or patients returning to dialysis after a failed transplant.

How to Select Patients for Enrollment in the DMMS

Please enter ONLY ADULT dialysis patients, **18 years of age or older**, who are incident (new to ESRD). **This includes new PD patients (CAPD, CCPD, and other PD) and hemodialysis patients. This also includes both Medicare and non-Medicare patients**. We are requesting that **ALL new peritoneal dialysis** patients and **20% of new hemodialysis** patients be entered into this study. If a patient has regularly been treated with hemo or peritoneal dialysis for 60 days, then this patient can be entered in the study. The following are guidelines for determining which patients are eligible to be entered.

DAY 1=The date of the first regular dialysis (at least once weekly hemo or PD with NO prior kidney transplantation), regardless of whether the setting is an inpatient, acute or outpatient setting.

DAY 60=Study Start Date calculated as 60 days from the start of regular dialysis.

- Patient is on PD on Day 60 of regular dialysis. **Enter ALL new adult PD patients** into the study. (PD=any form of peritoneal dialysis including CAPD, cycler, IPD, etc.). Complete a Medical Questionnaire and ask patient to complete a Dialysis Patient Questionnaire (YELLOW booklet).

- Patient is on hemo on Day 60 of regular dialysis To achieve **20% of new adult Hemo patients enter,** only those patients who have a "2" or a "9" for the last digit of their Social Security Number. Complete a Medical Questionnaire and ask patient to complete a Dialysis Patient Questionnaire (YELLOW booklet).

- Most patients stabilize on one modality or another by Day 60 dialysis. In rare instances, a patient may still be changing back and forth between hemo and PD on Day 60. In such a case, you can wait up to an extra ten days beyond Day 60 for the patient to stabilize on one modality or another and then enter the patient into the study. The patient's treatment modality on Day 70 should be used to determine the patient's modality for the purposes of the study. Therefore, ALL patients entered into this study will have been "stabilized" on a modality of treatment (regularly treated on the **same** modality) for a minimum of one week.

Keeping a Cumulative Record of ALL Incident Patients at Your Dialysis Unit

Please read this section carefully. It is very important that you provide your Network with this information:

In order to ensure that ALL adult incident PD patients and 20% of adult incident hemodialysis patients have been entered into this study, we ask that you keep a **Cumulative List of All Incident Patients** that includes the name, Social Security Number, modality of treatment and date of first regular dialysis treatment for **ALL (PD and Hemo) incident patients** at your dialysis unit. Please indicate which of these patients have been entered into the study by putting a large check mark in the "entered?" column. Your list as of March 31, 1996 should resemble the following EXAMPLE:

Name	Social Security#	Modality @ Day 60	1st Regular Dialysis Tx	Date of Birth	Entered?
Joe Smith	112-14-1578	PD	1/3/96	5/9/45	Ö
Ann Brown*	312-44-5678	PD	1/17/96	6/21/84*	
Robert Black	356-89-6431	Hemo	1/18/96	2/20/65	
May Smith	578-89-2456	Hemo	1/19/96	3/14/56	
David Doe	135-78-9032	Hemo	1/23/96	4/12/51	Ö
Amy Green	312-89-5097		2/5/96	3/20/46	
Frank Jones	241-89-5239		3/24/96	4/21/52	
Jennifer Row	456-90-5632		3/27/96	6/21/59	

**** Patient is Pediatric (Age 17 years or younger)***

Patients who have not yet reached Day 60 will have "modality @ Day 60" blank. Since some patients will also have died, been transplanted or transferred to another

facility, you can fill out this column with one of five options: “PD”, “hemo”, “death”, “transplant” or “transferred”. At the back of this Instruction Manual you will find 5 copies of the form, “Cumulative List of All Incident Patients”. You may want to make a few copies of a blank one in case you need more latter.

Please start with incident (new) patients from January and February of 1996. Since data collection will begin in the first week of March, 1996, patients who are incident as of January 1, 1996 will be eligible for enrollment, so long as they meet the other criteria (all adult PD patients and adult hemo patients whose last digit of the social security number ends in “2” or “9”).

Starting at the end of March, 1996, please be sure to submit a copy of this cumulative list to your Network on a monthly basis along with all completed questionnaires. Five blank forms to complete this task are provided at the back of this manual. We ask that you make your own copies of this form as necessary.

Remember that only new adult hemo patients whose last digit of the Social Security Number ends in “2” or “9” are entered into the study and that ALL new adult PD patients are entered into the study.

If you have any questions about whether a patient fits the criteria for entering the study, please do not hesitate to call Liz Holzman or Caitlin Carroll at the USRDS Coordinating Center. The phone number is: 1-800-707-0044

The next page has been provided to assist you in selecting patients for enrollment in the DMMS. You may want to tear this page out and keep it posted where it can always be quickly referred to:

Selecting Patients for Enrollment in the DMMS

Step 1: ***Identify ALL Incident (NEW) Dialysis Patients*** and maintain a list of these patients that includes their dates of birth, modality of treatment at Day 60 and social security numbers.

Step 2: ***Identify all incident dialysis patients that are 18 years of age or older*.** Pediatric patients are NOT included in the DMMS.

Step 3: ***60 days after 1st regular maintenance dialysis***, identify the modality of treatment, i.e. hemodialysis or peritoneal dialysis.

PD Patients

ß

Enter ALL incident adult PD Patients into Wave II.

ß

ß

Enter patient into study.

Complete BOTH the Medical and Dialysis Patient Questionnaire (YELLOW Booklet).

Hemodialysis Patients

ß

Enter 20% of adult hemo patients into Wave II.

ß

What is the last digit of the patient's social security #?

ß

Enter ONLY patients with the last digit of "2" or "9".

Complete BOTH the Medical and Dialysis Patient Questionnaire (YELLOW Booklet).

Keeping Track of Completed Questionnaires/Verifying Patient Demographic Information

Each dialysis facility has been given **a batch of questionnaires, i.e. YELLOW booklets** for patient data collection. These booklets each contain one copy of the Medical Questionnaire and the Dialysis Patient Questionnaire. Each booklet has a unique ID# which helps us to keep track of completed questionnaires.

The first page of each questionnaire is the **"Patient Tracking and Identification Form".** This form needs to be completed for each patient by the dialysis unit abstractor. *This form also has a space for you to indicate whether the patient agreed to complete the Dialysis Patient Questionnaire.* On the Patient Tracking and Identification Form, we have asked you to fill in the patient's sex, date of birth, social security number, HIC number, Medicare status and modality of care.

Handling Questionnaires and Placement of Dialysis Patient Questionnaires in Sealed Envelopes

Each of the yellow booklets contains a Medical Questionnaire (stapled), a Dialysis Patient Questionnaire, with an attached "Cover Sheet and Patient Consent Form"(stapled) and an 8 x 11 envelope. These three items are held together by a binder clip. **IT IS CRITICAL THAT THESE 3 ITEMS ARE USED FOR THE SAME PATIENT AND THAT THE MEDICAL QUESTIONNAIRE FOR A GIVEN PATIENT HAS THE SAME UNIQUE ID # AS THE DIALYSIS PATIENT QUESTIONNAIRE AND THE 8 X 11 ENVELOPE.**

Please instruct each patient to place the completed Dialysis Patient Questionnaire, and the attached "Cover Sheet and Patient Consent Form" into the 8 x 11 envelope (which should have the same ID# as the Dialysis Patient Questionnaire), seal it and return it to you. This procedure ensures the confidentiality of the information that the patient has provided. These envelopes must remain sealed and be returned in this form to the ESRD Network. (We want the patients to feel comfortable answering questions with the knowledge that the information they provide will be kept confidential.)

Reaching a "Cap" on the Number of Questionnaires

The number of patients your dialysis unit will enroll will depend on the size of your unit and your rate of new incident patients. The *average* dialysis unit will enroll six patients over the course of the study. Larger units will enroll more patients and smaller units will enroll fewer patients. We have sent to each dialysis unit a pre-calculated number of Yellow Booklets to be used for data collection. The number of questionnaires that you have received is based on the expected incident (new) number of patients which has been estimated according to your unit's incident count during 1994. Added to the expected incidence is a "margin of excess" that takes into account 95% of all random variability, as well as a 10% growth rate for expected increases in the number of dialysis patients from year to year. Also taken into account is a recent breakdown of PD and hemo patients at your dialysis unit.

The number of booklets you have received is the absolute maximum number of questionnaires that you will be expected to complete. **Most dialysis units will not experience a rate of incidence high enough to make it necessary to complete all the questionnaires received.** But if this does occur, you do not need to complete any more questionnaires beyond this absolute maximum even if there are patients who qualify for enrollment. If you do complete the maximum number of questionnaires, please advise your Network.

Requesting Replacement Questionnaires

If you should lose or misplace your questionnaires, please do **not** make copies (except of the Spanish Version of the Dialysis Patient Questionnaire as discussed below) because we want to provide you with questionnaires that have DMMS ID #'s on them. **If you need replacement questionnaires, call the Coordinating Center at 1-800-455-7300 and ask for Liz Holzman or Caitlin Carroll.**

Spanish Version of the Dialysis Patient Questionnaire

Attached to this Instruction Manual is one copy of a Spanish Version of the Dialysis Patient Questionnaire. If a patient is Spanish speaking, please make a copy of the Spanish Version for the patient to complete and substitute the Spanish Version for the English Version. **Please be sure to put the DMMS ID# from the English version on the Spanish Version so that this questionnaire can be tracked correctly. Also be sure that the patient still has the 8x11 envelope with the DMMS ID# on it where it can be inserted and sealed after it has been completed. Please be sure to destroy that patient's English version to avoid any confusion.**

Returning Completed Questionnaires to Your ESRD Network

Copies of completed questionnaires should be submitted to the ESRD Network monthly along with the a xerox copy of the CUMULATIVE LIST OF ALL INCIDENT PATIENTS.

Skipping Items

If the answer to an item cannot be determined, **leave the item blank by leaving the box on the right empty** and **put a check mark in the small box to the left of the item number.** This will indicate that you looked for the information in all available records and, if appropriate tried to obtain the information from the patient and then decided that you could not determine an answer for the item. When information is not available to answer a question, checking the box on the left is important because it indicates that the item was not inadvertently skipped or forgotten. For Example on page 1 of the Medical Questionnaire question #3 reads:

- **3. Ethnicity :**..... ☐

1 - Hispanic Origin 2 - Not of Hispanic Origin

If this information cannot be obtained, please put a check in the small box to the left of the question.

Date Formats

Dates are either in month (mm) day (dd) and year (yy) format, or in month and year format. **In all cases, month and day must be expressed in 2 digits.** For example, January is 01 and November is 11. The first day of the month is 01; the fifteenth day of the month is 15. The year is expressed by the last two digits of the year; e.g. 94 for 1994.

If you are able to report partial information only, do so but also put a check in the small box to the left of the item number.

Right Justification

Right justify all entries. For example, if a patient has a serum creatinine of 9.8 enter the item as follows:

	9	**.**	**8**

Comments Box

On the back of page 5, (which also contains the Dialyzer Codes) of the Medical Questionnaire is the Abstractor's "Comments Box". Please use this box to write any information that you believe is important to explain the response to any item.

Use of Abstractor Judgment

A medical record may not state explicitly all the information that these abstraction forms are designed to capture. **The integrity of the data collection effort rests on the expertise and professionalism of the abstractors in interpreting the information contained in the medical record**. In many instances where specific information for an item is not in the record, the abstractor may be able to logically infer the answer to the item from other information in the record. For example, elevated blood pressure over a long period of time implies hypertension. **Abstractors should not make inferences without very careful consideration but should make inferences when they believe that the record supports drawing a conclusion. An inference can be made when the abstractor feels that 8 or 9 out of 10 abstractors reviewing the same record would agree**. Use of abstractor judgment helps in obtaining the most complete set of data about a patient's history and medical status as possible.

Detailed Instructions for the DMMS "Medical Questionnaire"

You do NOT need to read the entire "Detailed Instructions for the DMMS Medical Questionnaire". Please use these instructions as a reference manual. Refer to these instructions only in cases where you are unsure about how to answer a particular item.

Please feel free to obtain information directly from the patient if the information is not available in any of the medical records.

Detailed Instructions for the DMMS "Medical Questionnaire" (To be completed by abstractor from dialysis unit)

You do not need to read through this entire section. Rather, it should be used as a reference manual to assist you when you require further or more detailed instructions about how to answer a particular item.

In the top left hand corner of Page 1 please fill in the patient's name, social security number and Medicare number. (The last 1 or 2 boxes in the Medicare number may be blank.) Please fill in the patient's name and social security number in the top left hand corner of pages 3 and 5 as well.

Section A: Patient and Facility Identification

General Notes

If you cannot answer an item from 1-9 or if you find only partial information for any of these items, you must note the item number and the reason why in the "Comments Box". Also remember to put a check in the small box to the left of the item number if the information is either not available or if only partial information is available.

Item	Description	Abstractor Instructions
A1.	Abstractor initials	Enter your initials.
A2.	Date Completed	Enter the date that you complete the form.
A3.	Ethnicity	Enter the appropriate code for ethnicity.
A4.	Race	Enter the appropriate code for race.

Items A5-A9

A5. Patient Zip Code

Enter the zip code for the patient's address.

A6. Date of first regular dialysis

Enter the date that the patient first started receiving regular dialysis treatments for chronic renal failure. "Regular" is defined as either hemodialysis or peritoneal dialysis at least once a week. Please do NOT include patients receiving intermittent dialysis treatments solely for treatment of fluid overload or heart failure. **Please put this date in the space provided in the top right hand corner of each and every page of this questionnaire.**

A7. Study Start Date

The Study Start Date is calculated as 60 days from the first regular dialysis treatment. The Study Start Date is ideally day 60 of ESRD. This date may be as late as 10 days past Day 60 (i.e. Day 70). (Thus, we would expect that all patients entering this study will be "stabilized" on a modality of treatment for a minimum of 7-10 days. In rare cases a patient may not yet be stabilized on Day 70. If so, still enter the patient based on their modality of care on Day 70. You might also want to note this in the "Comments Box".) This is item A7 and this date will be referred to repeatedly throughout the Medical Questionnaire. Please put this date in the space provided in the top right hand corner of each and every page of this questionnaire.

A8. Date of earliest known dialysis-same as A.6.?

Some patients may have had irregular dialysis treatments as needed prior to the first regular dialysis treatment. Please answer "no" if this is the case. Answer "yes" if there were no treatments prior to the start of regular dialysis treatments.

A9. Insurance

Please answer for all categories of insurance for both the one month period before the date at A6 and at the date at A7. Indicate whether or not the patient has each of these types of insurance using the appropriate code. (More than one may be answered "yes".) If a patient does not have Medicare as of the Study Start Date (at date A7), then please indicate whether Medicare is pending. If a patient does have Medicare as of the Study Start Date (at date A7) then please indicate if Medicare is the secondary insurer, if known.

Section B: Patient History Within 10 Years Prior to Study Start Date (date at A7)

General Notes

Abstractor judgment is very important in this section. If there is no specific mention of a particular disease, (e.g. coronary artery disease) but there is convincing evidence that the patient has a history of this disease (e.g.chest pain), you should answer "suspected" (code 3). If an otherwise very complete medical record contains no information on whether the patient has a history of a particular disease, you should assume that there is no history of that disease (code 2). However, if all the available medical records are very sketchy and there is no mention of a history of a particular disease, the item should be considered indeterminate. In this case, leave the item blank and check the small box on the left. **You or the physician may ask the patients appropriate questions to find the correct answer**.

Be careful to put checks in the small left hand boxes only for those questions for which you cannot determine an answer but not for items which the form specifically instructs you to skip. For example, if the patient does not have a history of diabetes, item B.7, enter "2" for no and skip item B.7.a. and B.7.b. and **do not check the left hand boxes for the appropriately skipped items. Remember to use the Abstractor's "Comments Box" if you need to further explain any of your answers.**

Item	Description	Abstractor Instructions
B1.	Primary cause of ESRD	Enter the code for the primary cause category of the patient's ESRD.
B2.	Regular cigarette smoking status	Enter the correct code.
B3.	Hx of Coronary Heart Disease (CHD) or Coronary Artery Disease (CAD)	Enter yes, no or suspected for items 3a through 3g.
B4.	Hx of Cerebrovascular Disease	Enter the code for yes, no or suspected for each of the two events listed. If 4a is yes, skip item 4b and go on to item 5
B5.	Hx of Peripheral Vascular Disease (PVD)	Enter the appropriate code for yes, no or suspected for items 5a through 5e.
B6.	Hx of Heart Disease (other than CHD or CAD)	Enter the appropriate code for yes, no or suspected for items 6a through 6c.

B7.	Prior Dx of Diabetes	Enter the appropriate code for yes, no or suspected. Note that the answer to this question can be yes even if diabetes was not considered the cause of ESRD. If no, skip to item 8.
	Insulin therapy	For 7a enter the code for "active", "former" or "never". If the patient is currently on insulin therapy then the correct answer is "active". If the patient received insulin therapy anytime in the ten years prior to the Study Start Date (date as of A7) but NOT at Study Start Date then the correct answer is "former". If the patient did not receive insulin therapy anytime in the past 10 years then the correct answer is "never".
B8.	Hx of Lung Disease	Enter the appropriate code for yes, no or suspected.
B9.	Neoplasms (other than skin)	Enter the appropriate code for yes, no or suspected. If no, skip to item 10. For 9a. enter the appropriate code of 10-25 for the primary sites of the neoplasms. You may enter up to two primary sites. *Skin cancer with the exception of melanoma should not be recorded*. For item 9b, enter the 2 digit year of the date of first diagnosis of neoplasm.
B10.	HIV Status	Enter the appropriate code for positive, negative, unknown or unable to disclose.
B11.	AIDS Diagnosis	Enter the appropriate code for positive, negative, unknown, or unable to disclose.

Section C: Information at Study Start Date (Date at A7)

Remember to use the Abstractor's "Comments Box" if you need to further explain any of your answers.

For Section C, you may use information from the period between 30 days prior to the date at A7 to 30 days after the date at A7. Unless otherwise indicated, please use information closest to Study Start Date.

Items C1-C4

Item	Description	Abstractor Instructions
C1.	Height	Enter the height in feet and inches or centimeters. **This item is required. Please make every attempt to obtain this information.** (This information can be from anytime during adult life.) If unavailable, measure the patient or ask the patient. **This value should fall within the range of 3ft 3in to 7ft 5in or 100 centimeters to 230 centimeters.** If the patient is a bilateral amputee, please give the original height of the patient and check the box indicating that the patient is an amputee.
C2.	Dry Weight as ordered	Enter the prescribed dry weight as ordered nearest the Study Start Date (date at A7).
C3.	Undernourished or cachectic (malnourished)	Enter the appropriate code for yes, no or suspected. Base your answer on information from the medical record in the period between 30 days prior to the date at A.7. to 30 days after the date at A.7.
C4.	Blood pressure and weight	
	a.Predialysis	For item 4a, enter the three most recent readings (preferably from a sitting position) for blood pressure (systolic and diastolic) and weight before date A7. Be sure to indicate whether the weight is measured in pounds or kilograms. **For hemo patients, please be sure to enter predialysis readings**. For PD patients, enter any readings (but still please use the three most recent readings before the date at A7).
	b.Postdialysis	Answer item 4b only for hemo patients and enter the 3 most recent systolic and diastolic blood pressure readings (sitting preferred) and weight taken **after** each dialysis session.

Items C5a-C5j

C5.	Hemodialysis prescription at date A7 (**Answer only if patient was on hemo on the date at A7)**	**Items 5a-5o should be answered only if the patient was a hemodialysis patient on the date at A7. (If patient was a PD patient on date at A7 then skip to item C6)**
	a. Dialysate	Enter the appropriate code for bicarbonate or acetate dialysate, as prescribed or usually used.
	b. Prescribed or usual hours per treatment	Enter the prescribed hours and minutes.
	c. Prescribed # of dialysis sessions per week	Enter the prescribed or usual # of dialysis sessions **per week**. **(C5b x C5c should fall between 6 hours and 13.5 hours per week.)**
	d. Blood flow rate	Enter the blood flow rate in milliliters (or cc) per minute. If the flow varies, enter the prescribed or most common "high" rate. If there is a range of the prescribed blood flow rate, then enter the mid of that range.
	e. Is the patient usually treated using a reused dialyzer?	Enter the appropriate code for yes or no. **(Unknown is not acceptable.)**
	f. If reuse does not occur, indicate the reason	Enter the appropriate code.
	g. Dialyzer type	See the code list on the back of Page 5 for the four digit codes for dialyzer type. **If you use code 9999 (other), enter on the lines provided the manufacturer and dialyzer model.**
	h. Vascular access in use	Enter the appropriate codes for the vascular access type in use at date A6 and date A7.
	i. Side of THIS access	Enter the code for right or left, indicating the side of the access in use at date A6 and A7.
	j. **First permanent** vascular access created or attempted before date at A7	Using the codes from 5h, indicate the type of first permanent vascular access created or attempted , the date that this access was created or attempted and the date of first use of this access. If the first permanent access created or attempted was NEVER used before date at A7 then leave this record date blank. Indicate, using the codes provided, whether the first permanent access required either a revision or failed. Indicate whether this access failed to mature before the date at A7.

	k. Temporary access in central vein <u>anytime</u> before date A7	Please indicate whether the patient had a temporary access in the central vein anytime before date A7. **If NO then skip to item 5l.** If yes then indicate, using the appropriate code for right, left, right and left, or neither, whether temporary access was subclavian or internal jugular. **(You may ask the patient if necessary**).
	l. Number of hemodialysis treatments skipped by the patient during 30 days prior to the date at A7.	Please indicate the number of hemodialysis treatments that the patient skipped during the 30 days prior to the date at A7.
	m. Number of shortened hemodialysis treatments **by more than 10 minutes** during 30 days prior to the date at A7. Do NOT include skipped treatments.	Indicate the number of shortened hemodialysis treatments by more than 10 minutes.
	n. Did this patient have any peritoneal dialysis treatments before the Study Start Date (date A7)?	Please indicate whether the patient had **<u>any</u>** PD treatments prior to the date at A7. **If YES, then please also answer item 5o. If NO, go to item 8 (psychosocial evaluation).**
	o. Date of PD catheter placement	Please enter the date that the patient had a PD catheter placed.
C6	Peritoneal dialysis prescription at Study Start Date (Date at A7)	If the patient was not on PD at date A7 then skip item "C6" altogether and go to Psychosocial Evaluation (Item "8").
	a. dialysis location	Enter the code for the dialysis location.
	b. Type of dialysis	Enter the code for the type of dialysis.
	c. Peritoneal dialysis prescription	Please indicate in the table the # of exchanges per day (cycler and/or manual), the liters per exchanges (cycler and/or manual), the total hours per day (cycler) and the days per week (cycler and/or manual).

	C5c (continued)	**Lastly, please indicate the total dialysate volume in a 24 hour period.** The liters/exchange prescribed for some patients will vary during a given 24 hour period since some patients can tolerate more fluid at night than during the day; therefore, the total liters of fluid exchanged may not always be a straightforward calculation of the # of exchanges multiplied by the liters/exchange provided in the table. As such, we are asking that you provide the total volume of fluid (in liters) exchanged in a 24 hour period.
	d. Type of PD catheter in use at date A7	Enter the code for the type of PD catheter in use at date A7.
	e. Date of placement of THIS catheter	Please enter the placement date of the catheter in use at date A7.
	f. Was this the first peritoneal catheter for this patient?	Please indicate whether the PD catheter in use at date A7 was the first peritoneal catheter for this patient.
	g. Was this patient treated with hemodialysis before the Study Start date (date A7)?	Please enter the appropriate code for yes or no.
	h. Did this patient have a permanent **vascular** access before date A7?	Please enter the code for yes or no. **If the answer to 6h is YES then please go back to item C5j (first permanent vascular access created or attempted on or before date A7) and complete it. Then move forward to item 8 (Psychosocial Evaluation).**
C7.	24 hour dialysate Urea N and creatinine in period of A6 to A6 + 30 days.	Enter the values in the boxes provided for total volume (drained); dialysate Urea N, dialysate creatinine, BUN (same day), Serum creatinine.
C8.	Activities of daily living (currently or recently)	For 8a, 8b, and 8c, please enter the appropriate yes or no code for each activity. Consider the patient to be capable of independent ambulating even if he/she can ambulate only with an assistive device (e.g. walker, crutches).
C9.	Marital status	Enter the appropriate code.
C10.	Living alone	Enter the appropriate code.

C11.	Education	Enter the most appropriate code.
C12.	Primary occupation before onset of ESRD	Enter the most appropriate code. Before ESRD means prior to the first regular dialysis treatment as reported in A6.
C13.	Employment level	For the two periods of time indicated, 24 months prior to ESRD through 6 months prior to ESRD; and 6 months prior to ESRD through date at A7, please indicate the **single most appropriate category** of employment for the patient. **In each column please check one box only**. If in either column you have checked "unemployed", please indicate whether or not the patient is (or was) looking for a job.

Section D: Laboratory Data

General Notes

In this section, please complete items 1-13 **using information closest to the Study Start Date (Date at A7). You may, if necessary, use information from the period of 3 months prior to the Study Start Date (A7) to 1 month after the study start date (A7+30).**

For Item 14 (Residual renal function), please obtain information from within the period of date A6 (first regular dialysis treatment) to 30 days after date A7 (A7+30).

Remember to use the Abstractor's "Comments Box" if you need to further explain any of your answers.

Item	Description	Abstractor Instructions
D1.	Cardiomegaly by X-Ray	Enter code for yes or no. **Use information closest to Study Start Date (A7). You may use information from the period of 3 months prior to Study Start Date (A7) to 1 month after the study start date (A7+30).**
D2.	Left ventricular hypertrophy	For items 2a., and 2b. enter the code for yes or no. **Use information closest to Study Start Date (A7). You may use information from the period of 3 months prior to Study Start Date (A7) to 1 month after the study start date (A7+30).**

Items D3-D6d

D3.	Total serum calcium, predialysis	Enter the predialysis value to the **nearest tenth. Use information closest to Study Start Date (A7). You may use information from the period of 3 months prior to Study Start Date (A7) to 1 month after the study start date (A7+30).**
D4.	Serum phosphorus or phosphate, predialysis	Enter the predialysis value to the **nearest tenth. Use information closest to Study Start Date (A7). You may use information from the period of 3 months prior to Study Start Date (A7) to 1 month after the study start date (A7+30).**
D5.	Serum bicarbonate or CO_2 predialysis	Enter the predialysis value to the **nearest tenth.** The patient's lab report may indicate "serum bicarbonate" or may indicate "CO_2". **Use information closest to Study Start Date (A7). You may use information from the period of 3 months prior to Study Start Date (A7) to 1 month after the study start date (A7+30).**
D6.	Hematocrit (from the lab report)	For hematocrit information, please make every attempt to provide data from a lab report, not from a hematocrit spun in the dialysis unit. If the only source of information is a hematrocrit spun in the dialysis unit, you may provide this datum. **Use information closest to Study Start Date (A7). You may use information from the period of 3 months prior to Study Start Date (A7) to 1 month after the study start date (A7+30).**
	a.Hematocrit	For item 6a, enter the hematocrit percentage. If transfused, give the value **before** transfusion. **(Must fall within range of 14 to 55)**
	b.Hemoglobin	For item 6b, enter the value to the nearest tenth. If transfused, give the value before the transfusion.
	c. Transfused in first 60 days of dialysis (between date A6 and date A7)	For item 6c, enter the appropriate code for yes or no based on whether or not there was a transfusion in the 60 days between date A6 and date A7. If NO skip to item 7.
	d. Number of transfusions	For item 6d, enter the number (from 0 to 9) of transfusions that occurred during the 60 days between the date at A6 and the date at A7. If there were more than 9 transfusions, enter 9.

D7. Was the patient taking EPO?

a. During the first 60 days of dialysis (the period between date at A6 and date at A7)

Enter the appropriate code for whether the patient was taking EPO in the first 60 days of regular dialysis.

If yes, please enter the code for whether EPO is given by i.v. or subcutaneously.

b. During the month **before ESRD.**

Enter the appropriate code for whether the patient was taking EPO **in the 30 days prior to the date at A6.**

D8. Serum creatinine

a. Before first regular dialysis

Enter the value to the **nearest tenth for the patient's serum creatinine on the day of the first regular dialysis treatment or closest day prior to first regular dialysis treatment (date A6).**

b. Nearest day 60

Enter the value to the **nearest tenth for the patient's serum creatinine. Use information from as close to day 60 (date at A7) as possible.**

D9. BUN or urea values

Please check the box to the right if your lab reports urea concentrations instead of BUN.

a. Before first regular dialysis

Enter the patient's BUN **on the day of the first regular dialysis treatment or closest day prior to the first regular dialysis treatment (A6).**

b. Nearest day 60

Enter the patient's predialysis and postdialysis BUN. **Use information from as close to day 60 (date at A7) as possible. The predialysis and postdialysis measurements MUST be from the SAME DATE. (Pre BUN must fall within range of 25 to 240. Post BUN must fall within rang e of 10 to 150.)**

c. Weights pre and post dialysis

Please enter the patient's weight taken pre and post dialysis. **These measurements MUST be from the SAME DAY as the measurements taken for item 9b**. Please indicate if weight has been measured in pounds or kilograms. **(Must fall within range of 25 to 215 kilograms or 50 to 470 pounds.)**

Items D10-D14a

D10.	Predialysis Serum Albumin	Please enter the patient's predialysis serum albumin. **Use information closest to Study Start Date (A7). You may use information from the period of 3 months prior to Study Start Date (A7) to 1 month after the Study Start Date (A7+30).**
D11.	Lipids	**Use information closest to Study Start Date (A7). You may use information from the period of 3 months prior to Study Start Date (A7) to 1 month after the Study Start Date (A7+30).**
	a. Cholesterol Total	Enter value from the patient's lab report
	b.HDL cholesterol	Enter value from the patient's lab report
	c. LDL cholesterol	Enter value from the patient's lab report
	b. Triglycerides	Enter value from the patient's lab report
D12.	Serum intact PTH	**Use information closest to Study Start Date (A7). You may use information from the period of 3 months prior to Study Start Date (A7) to 1 month after the study start date (A7+30).**
D13.	Serum aluminum (random)	**Use information closest to Study Start Date (A7). You may use information from the period of 3 months prior to Study Start Date (A7) to 1 month after the study start date (A7+30). If this data comes from measurements taken during a DFO (desferol or deferoxamine) test, please be sure to use the <u>baseline</u> measurement.**
D14	Residual Renal Function	This section is important but is not an official requirement. Please give all the available information and/or obtain the urine collection and measurements **<u>within the period of the date at A6 to 30 days after the date at A7 (A7+30).</u>** Completion of items in this section is voluntary.
	a. urine collection	Please indicate the date (month and day) and the exact time of day (the hour, minutes and am/pm) that urine collection started. Please also indicate the date and exact time that urine collection ended. For purposes of verification, please also indicate the total hours of urine collection.

	b. Lab Values	Please enter the total volume of urine collected. Also indicate the urine creatinine and urine urea nitrogen and the unit of measurement that was used for these values. Please enter the blood pre and post creatinine and BUN. Please enter values taken ideally at the beginning (pre) and end (post) of **URINE collection**. If this is not possible then: **For hemo patients** enter values from measurements taken pre and post DIALYSIS on a date as close as possible to the dates of urine collection. **For PD patients** enter values taken on a date as close to the date of urine collection as available. **Enter in the space for PRE.**
D15.	Medications at time of Study Start Date (A7).	Please copy the patient's list of medications, using either the generic or trade name in the spaces provided. You do not need to indicate the dosage.
D16.	Was the patient receiving at date A7 injectable vitamin D (calcijex)?	Enter the appropriate code.

USRDS Dialysis Morbidity and Mortality Study (Prospective)
Dialysis Facility/Unit Questionnaire

QUESTIONS? Please feel free to call Liz Holzman or Caitlin Carroll at the USRDS Coordinating Center. Please call us at our toll free number: 1-800-707-0044

General Notes

This questionnaire is to be filled out once only by each dialysis facility/unit participating in the USRDS Dialysis Morbidity and Mortality Study (DMMS-Prospective). **Please complete this form and submit it to your Network office in April or May of 1996.**

If the answer to an item cannot be determined, **leave the item blank by leaving the box on the right empty** and **put a check mark in the small box to the left of the item number.** This will indicate that you looked for the information in all available records and decided that you could not determine an answer for the item. When information is not available to answer a question, checking the box on the left is important because it indicates that the item was not inadvertently skipped or forgotten.

Dates

Dates are either in month (mm), day (dd) and year (yy) format or in month and year format. **In all cases, month and day must be expressed in 2 digits.** For example, January is 01 and November is 11. The first day of the month is 01; the fifteenth day of the month is 15. The year is expressed by the last two digits of the year; e.g. 94 for 1994.

If you are able to report partial information only, do so but also put a check in the small box to the left of the item number. For example, if the records give the year of starting reuse but not the month or day, enter the year in the appropriate box, leave the month and day blank and check the box to the left of the item number.

In the top right hand corner, please be sure to complete the date that this questionnaire was completed. Please complete sometime during the months of April-May, 1996.

Item	Description	Instructions
1.	Network	Enter the 2 digit number assigned to you network (For example, 03 for Network 3.)

2.	Medicare provider number	Enter the provider number for your unit. Please note that a large facility may have multiple provider numbers, i.e. one for its transplant facility and one for its dialysis unit. Be sure to enter the number pertaining to the dialysis unit. **Do not enter the billing number**.
3.	Facility name	Please PRINT the full name of the unit/facility.
4.	Does this facility offer PD?	Enter the appropriate code for yes or no
	a. If no, give reason code	Enter appropriate code
	b. If yes, give location code	If facility offers PD, give appropriate code for whether facility treats PD patients at this facility, refers to another center with the same MD or refers to another center with different MDs.
	c. If facility refers PD patients to another center, then how many PD cases were referred in the last 12 months?	Enter appropriate code for the number of cases.
5.	From lab report for April-May of 1996 please provide	
	a. lower limit of normal for serum albumin	Enter the lower limit for serum albumin **from your lab using lab reports** during the period of April-May, 1996.
	b. upper limit of normal for PTH	Enter the upper limit for PTH **from your lab using lab reports during the period of April-May, 1996.**
	c. type of lab asssay for Albumin	Enter the appropriate code
	c. type of lab assay for PTH	Enter the appropriate code
6.	Was it the practice of this unit to reuse dialyzers during April-May, 1996?	Enter the appropriate code for whether or not it was the practice of this unit to re-use dialyzers during April-May, 1996. If you answer <u>yes</u> to this question, <u>go on to answer items 6a-6d</u>. If you answer <u>no</u> to this question, skip 6a-6d and go on to item 7.

	a. Before a new dialyzer is used for the first time, do you apply the re-use technique?	Enter the appropriate code for yes or no.
	b. Reuse technique	For item **6b**, enter the appropriate code for the reuse technique that was practiced during April-May, 1996. If **automated reuse** was practiced, enter the code for the type of machine that was used.
	c. Dialyzer disinfectant used?	For item **6c**, enter the appropriate ("yes" or "no") code for the disinfectants used during April-May, 1996. Do not mark the disinfectant used solely for the dialysis machine.
	d. When did the present reuse technique start being used in this facility?	Please enter the month and year that the present reuse technique started being used by this facility.
7.	What type of KT/V or URR is calculated?	Enter the appropriate code for the type of KT/V or URR calculation that is practiced at your facility.
8.	Types of water treatment	Enter the appropriate ("yes" or "no") code for the types of water treatment used by your facility **a) for reprocessing of dialyzers** (if re-use is practiced) and **b) for dialysate**. Indicate all that are normally in use but do not include backup. If your facility does not reuse dialyzers, the column for reprocessing of dialyzers will not be filled out, otherwise both columns should be completed.
9.	Type of water source	Enter the appropriate code for the predominant type of water source that your facility uses.
10.	Timing of postdialysis BUN sample (policy in April-May, 1996)	Enter the appropriate code for the timing of post BUN samples at your facility according to policy or, if a policy is not available, according to common practice as of April-May, 1996.
11.	Most common hemodialysis machine	Enter the manufacturer name and the manufacturer model of the hemodialysis machine most commonly used by your dialysis facility.

12.	% of all machines in use	Enter the percentage of machines that the most commonly used machine represents (i.e., the # of machines of the most common model divided by the total # of machines in your unit).
13.	Routine vascular access surveillance practiced in April-May, 1996 (Doppler etc.)	Please indicate the frequency of routine vascular access surveillance practice of your facility, as practiced in April-May, 1996.
14.	For PD patients which best reflects the frequency of a) PET and b) 24 hour dialysate testing in April-May, 1996?	Please indicate the frequency of routine PET testing and measurement of 24 dialysate urea and creatinine concentration testing as practiced at your facility as of April-May, 1996..
15.	Does the same physician see the patient routinely on dialysis or is this rotated among physicians?	Enter the appropriate code for whether it is the same physician or a rotating physician.
16.	On average, how often in ONE MONTH does the physician see most or all patients as an outpatient (face to face contact) either in the office or during dialysis treatment?.	Enter the appropriate code for the average number of monthly physician face to face contacts most or all patients have as outpatients.

• Abstractor initials: .....

Check box to left of item, IF unable to determine, and leave item (right) blank.

Confidential Report

DIALYSIS UNIT/FACILITY Questionnaire

• Date this questionnaire was completed:

mm dd yy

• 1. Network:.....

• 2. Medicare provider number:..... (Not billing #)

• 3. Facility name:_____

• 4. Does this facility offer PD:.....
1-Yes 2-No

a.• If no, give reason:.....
1 -PD offers no advantage 2 - no trained staff 3 - other

b.• If yes, give location:.....
1 - at this center 2 - referral to other center (same MD)
3 - referral to other center (different MDs)

c.• If facility refers PD pts out to other centers, then how many cases were referred in the last 12 months:.....
1 - zero 2 - one or two 3 - three to five 4 - more than five

• 5. From lab report for April - May 96 provide:

• a) lower limit of normal for serum albumin: ..... • g/dl

• b) upper limit of normal for PTH: units

• c) type of lab assay for Albumin.....
1-Brom cresol purple 2-Brom cresol green 3-don't know

• d) type of lab assay for PTH.....
1-Intact 2-N-terminal 3- C-terminal 4-don't know

• 6. Was it the practice of this unit to reuse dialyzers April - May 1996?.....
1-Yes 2-No

If YES, please answer parts 6a - d. If NO, go to item 7:

• a. Before a new dialyzer is used do you apply the reuse procedure
1- yes 2- No

• b. Reuse technique April - May 1996

☐ 1-Manual 2-Automated 3-Both

If answered Automated (2) please see below. Otherwise, go to item 6c.

• If automated reuse was practiced, which machine was used during April - May 1996?.....
1 - Fresenius "DRS-4"
2 - Mesa Labs "Echo"
3 - Renal Sys. "Renatron" (single and multiple)
4 - National Medical Care "semi-automated"
5 - Other

• c. Dialyzer disinfectant used April - May 1996
1 - Yes 2 - No (answer all)

Bleach in dialyzer:.....
Formalin (formaldehyde) in dialyzer:.....
Peracetic acid (Renalin) in dialyzer:.....
Glutaraldehyde in dialyzer:.....
Heat only (no disinfectant):.....

• d. When did the present reuse technique start being used at this facility?..... mm yy

• 7. What data are used for URR or Kt/V calculation?.....
1 - Predialysis and post dialysis BUN only, for URR
2 - Predialysis and post dialysis BUN only, for Kt/V
3 - Predialysis , post dialysis and next pre dialysis BUN for Kt/V
4 - Predialysis BUN and weight , post dialysis BUN and weight for Kt/V
5 - other. If so, please specify_____
6 - none

• 8. Types of water treatment. Indicate all that are normally in use.
(Do not include backup) 1 - Yes 2 - No
Complete both columns

	for Reprocessing Dialyzers (If re-using)	for Dialysate
Softener.....		
Activated charcoal.....		
Reverse Osmosis.....		
Deionization.....		
U-V light.....		
Ultrafilter.....		

• 9. Type of water source:.....
1 - Public water system 2 - Well

• 10. Timing of post dialysis BUN sample (policy near May 1996).....
1 - immediately at the end of dialysis without slowing blood flow (to below 100)
2 - immediately at end of dialysis after slowed or stopped blood flow
3 - 20 to 60 seconds after end of dialysis
4 - 1 to 2 minutes after end of dialysis
5 - 3 to 15 minutes after end of dialysis
6 - more than 15 minutes after end of dialysis

• 11. Most common hemodialysis machine:
Manufacturer:_____
Model:_____

• 12. This machine is % of all actively used machines
(not including back-up machines or acute facility machines)

• 13. Routine vascular access surveillance practiced in April - May 1996 (Doppler, etc.)?.....
1 - monthly 2 - quarterly 3 - yearly 4 - only as needed

If facility does not have PD patients, skip #14

• 14. For PD patients, which of options 1-5 best reflects the frequency of
a) performing Peritoneal Equilibration Tests (PET)....
b) obtaining 24 hour dialysate collections for urea and/or creatinine measurement.....
1 - not performed
2 - performed only for clinical problems
3 - performed routinely, yearly
4 - performed routinely, quarterly
5 - performed more frequently than quarterly

15. Does the same physician see the patient routinely on dialysis or is this rotated among physicians? .....
1-same 2-rotating

16. On average, how often in a month does the physician see most or all patients as an outpatient (face to face contact) either in the office or during dialysis treatment? .....
1) greater than 10 times 2) 6-10 times 3) 3-5 times
4) 1-2 times 5) less than once

COMPLETE IN APRIL OR MAY, 1996 AND RETURN TO YOUR NETWORK

Unique Patient ID #_____ Date _____

United States Renal Data System

DIALYSIS PATIENT QUESTIONNAIRE

Part 1: Quality of Life Questionnaire (KDQOL SF™)[1]

1. In general, would you say your health is:

(Circle One Number)

Excellent 1
Very good.....2
Good.....3
Fair 4
Poor 5

2. Compared to one year ago, how would you rate your health in general now?

(Circle One Number)

Much Better now than one year ago.....1
Somewhat better now than one year ago.....2
About the same as one year ago 3
Somewhat worse now than one year ago 4
Much worse now than one year ago.....5

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

(Circle One Number on each line)

	Yes, Limited a lot	Yes, Limited a little	No Not Limited at all
3. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
4. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
5. Lifting or carrying groceries	1	2	3
6. Climbing several flights of stairs	1	2	3
7. Climbing one flight of stairs	1	2	3
8. Bending, kneeling, or stooping	1	2	3
9. Walking more than a mile	1	2	3
10. Walking several blocks	1	2	3
11. Walking one block	1	2	3
12. Bathing or dressing yourself	1	2	3

[1] Hays RD, Kallich JD, Mapes DL, Coons SJ, Amin N, Carter WB. (1995) Kidney Disease Quality of Life Short Form (KDQOL-SF ™), Version 1.1: A Manual for Use and Scoring. Santa Monica, Ca:RAND, p-7928.

During the last 30 days, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

(Circle One Number on Each Line)

	Yes	No
13. Cut down the amount of time you spent on work or other activities?	1	2
14. Accomplished less than you would have liked?	1	2
15. Were limited in the kind of work or other activities?	1	2
16. Had difficulty performing work or other activities (for example, it took extra effort)?	1	2

During the last 30 days, have you had any of the following problems with your work or other regular daily activities as a result of emotional problems such as anxiety or depression?

(Circle One Number on Each Line)

	Yes	No
17. Cut down the amount of time you spent on work or other activities?	1	2
18. Accomplished less than you would have liked?	1	2
19. Didn't do work or other activities as carefully as usual?	1	2

20. During the last 30 days, to what extent have your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

(Circle One Number)

Not at all.....1
Slightly.....2
Moderately.....3
Quite a bit.....4
Extremely.....5

21. How much bodily pain have you had during the last 30 days?

(Circle One Number)

None.....1
Very mild.....2
Mild.....3
Moderate.....4
Severe.....5
Very severe.....6

22. During the last 30 days, how much did pain interfere with your normal work (including work both outside the home and housework)?

(Circle One Number)

Not at all.....1
A little bit.....2
Moderately.....3
Quite a bit.....4
Extremely.....5

These questions are about how you feel and how things have been with you during the last 30 days. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the last 30 days....

(Circle One Number on Each Line)

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
23. Did you feel full of pep?	1	2	3	4	5	6
24. Have you been a very nervous person?	1	2	3	4	5	6
25. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
26. Have you felt calm and peaceful?	1	2	3	4	5	6
27. Did you have a lot of energy?	1	2	3	4	5	6
28. Have you felt downhearted and blue?	1	2	3	4	5	6
29. Did you feel worn out?	1	2	3	4	5	6
30. Have you been a happy person?	1	2	3	4	5	6
31. Did you feel tired?	1	2	3	4	5	6

32. During the last 30 days, how much of the time have your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

(Circle One Number)

All of the time 1
Most of the time 2
Some of the time 3
A little of the time.....4
None of the time 5

How TRUE or FALSE is each of the following statements for you?

(Circle One Number on Each Line)

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
33. I seem to get sick a little easier than other people	1	2	3	4	5
34. I am as healthy as anybody I know	1	2	3	4	5
35. I expect my health to get worse	1	2	3	4	5
36. My health is excellent	1	2	3	4	5

YOUR KIDNEY DISEASE

How TRUE or FALSE is each of the following statements for you? (Circle One Number on Each Line)

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
37. My kidney disease interferes too much with my life	1	2	3	4	5
38. Too much of my time is spent dealing with my kidney disease	1	2	3	4	5
39. I feel frustrated dealing with my kidney disease	1	2	3	4	5
40. I feel like a burden on my family	1	2	3	4	5

These questions are about how you feel and how things have been with you during the last 30 days. For each question, please give the one answer that comes closest to the way you have been feeling. **How much of the time during the last 30 days...**

(Circle One Number on Each Line)

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
41. Did you isolate yourself from people around you?	1	2	3	4	5	6
42. Did you react slowly to things that were said or done?	1	2	3	4	5	6
43. Did you act irritable toward those around you?	1	2	3	4	5	6
44. Did you have difficulty doing activities involving concentration and thinking?	1	2	3	4	5	6
45. Did you get along well with other people?	1	2	3	4	5	6
46. Did you become confused and start several activities at a time?	1	2	3	4	5	6

During the last 30 days, to what extent were you bothered by each of the following?
(Circle One Number on Each Line)

	Not at all	Somewhat	Moderately	Very much	Extremely
47. Soreness in your muscles?	1	2	3	4	5
48. Chest Pain?	1	2	3	4	5
49. Cramps?	1	2	3	4	5
50. Itchy skin?	1	2	3	4	5
51. Dry skin?	1	2	3	4	5
52. Shortness of breath?	1	2	3	4	5
53. Faintness or dizziness?	1	2	3	4	5
54. Lack of appetite?	1	2	3	4	5
55. Washed out or drained?	1	2	3	4	5
56. Numbness in hands or feet?	1	2	3	4	5
57. Nausea or upset stomach?	1	2	3	4	5
58. Problems with your access or catheter site?	1	2	3	4	5

EFFECTS OF KIDNEY DISEASE ON YOUR LIFE

Some people are bothered by the effects of kidney disease on their daily life, while others are not. How much does kidney disease bother you in each of the following areas?

(Circle One Number on Each Line)

	Not at all	Somewhat	Moderately	Very much	Extremely
59. Fluid restrictions?	1	2	3	4	5
60. Dietary restrictions?	1	2	3	4	5
61. Your ability to work around the house?	1	2	3	4	5
62. Your ability to travel?	1	2	3	4	5
63. Being dependent on doctors and other medical staff?	1	2	3	4	5
64. Stress or worried caused by kidney disease?	1	2	3	4	5
65. Your sex life?	1	2	3	4	5

The next two questions are personal, but your answers are important in understanding how kidney disease impacts on people's lives.

How much of a problem was each of the following during the last 30 days?

(Circle One Number on Each Line)

	No problem	A little problem	Somewhat of a problem	Very much a problem	Severe problem
66. Inability to relax and enjoy sex	1	2	3	4	5
67. Difficulty in becoming sexually aroused	1	2	3	4	5

For each of the following statements, please indicate whether these describe you today and are related to your state of health.

(Circle One Number on Each Line)

	Yes	No
68. I lie down more often during the day in order to rest	1	2
69. I sleep or nap more during the day	1	2
70. I sleep less at night, for example, wake up too early, don't fall asleep for a long time, awaken frequently	1	2

71.On a scale from 0 to 10, how would you rate the quality of your sleep during the last 30 days?

|--------|----------|--------|--------|---------|--------|--------|---------|---------|---------|
0 1 2 3 4 5 6 7 8 9 10
Poor Quality High Quality

In terms of your satisfaction with family and social life, circle one number to rate each of the following:

(Circle One Number on Each Line)

	Poor	Fair	Good	Very Good	Excellent
72. The amount of togetherness you have with your family and friends	1	2	3	4	5
73. The support and understanding your family and friends give you	1	2	3	4	5

74. Are you now able to work?

(Circle One Number on Each Line)

	Yes	No
a. Part-time?	1	2
b. Full-time?	1	2

75. During the last 30 days, were you:

(Circle One Number)

Working full-time 1
Working part-time..... 2
Unemployed, laid off, or looking for work..... 3
Retired..... 4
Disabled 5
In school..... 6
Keeping house..... 7
None of the above 8

76. Think about the care you receive at this facility for kidney dialysis. In terms of your satisfaction, how would you rate the friendliness and interest shown in you as a person?

(Circle One Number)

Very poor 1
Poor 2
Fair 3
Good..... 4
Very Good..... 5
Excellent 6
The Best 7

How TRUE or FALSE is each of the following statements?

(Circle One Number on Each Line)

	Definitely True	Mostly True	Neither True or False	Mostly False	Definitely False
77. Dialysis staff encourage patients to lead as normal a life as possible	1	2	3	4	5
78. Dialysis staff here counsel me on achieving full potential for rehabilitation	1	2	3	4	5

Part 2: Medical Care Before Regular Dialysis

For the next series of questions, think back to the time **prior to** starting regular dialysis.

1. When were you first told that your kidney function was abnormal?

   1. More than 1 year prior to starting dialysis
   2. Between 4 months and 1 year before starting dialysis
   3. Between 2 month and 3 months
   4. Between 1 and 4 weeks before starting dialysis
   5. Less than a week before starting dialysis or not at all
   6. Not sure

2. Within the two years prior to starting regular dialysis, did you first receive a blood test from a physician (internist, family physician, general practitioner, etc.) other than a kidney specialist (nephrologist)?

   1. Yes, between 1 and 2 years prior to starting dialysis
   2. Between 4 months and 1 year before starting dialysis
   3. Between 1 month and 3 months
   4. Less than 1 month
   5. Not sure

3. Prior to starting regular dialysis, when did you first receive medical attention from a kidney specialist (nephrologist)?

    1. More than 1 year prior to starting dialysis
    2. Between 4 months and 1 year before starting dialysis
    3. Between 1 month and 3 months
    4. Less than 1 month
    5. Did not receive medical care from a nephrologist prior to starting dialysis
    6. Not sure

4. In the year prior to starting dialysis, about how many visits did you make to a kidney specialist (nephrologist)?

    1. 5 or more visits
    2. 2-4 visits
    3. 1 visit
    4. No visits
    5. Not sure

5. Prior to starting dialysis, were you ever seen by or did you talk to a dietitian about your kidney problem?

    1. Once
    2. More than once
    3. No, never

6. About how long before your first dialysis did you lose your appetite? *(Circle one)*

    1. More than 6 months
    2. 3-6 months
    3. 1-2 months
    4. Less than 1 month
    5. I did not lose my appetite.
    6. Not sure

7. About how long before your first dialysis did you experience nausea or vomiting from your kidney failure? *(Circle one)*

    1. More than 6 months
    2. 3-6 months
    3. 1-2 months
    4. Less than 1 month
    5. I did not experience nausea or vomiting
    6. Not sure

8. Prior to starting dialysis were you treated with any of the following medications?

   a. Bicarbonate? 1. Yes 2. No 3. Not sure
   (Sodium bicarbonate, citrate, baking soda)

   b. Erythropoietin? 1. Yes 2. No 3. Not sure
   (Procrit, Epogen, EPO)

9. Were you told to avoid blood draws or intravenous lines in either arm in order to protect the veins for a permanent hemodialysis access? *(Circle one)*

   1. Yes ⇨ When? _____ months before starting dialysis
   2. No
   3. Not sure

Part 3: Choosing the Treatment for Your Kidney Failure

For the next set of questions, think back to the time when the type of treatment for your kidney failure was being decided.

1. What options were described and discussed for your initial treatment of your kidney failure? (Please circle all that apply)
   1. Hemodialysis in a dialysis unit
   2. Hemodialysis at home
   3. Continuous ambulatory peritoneal dialysis (CAPD) at home
   4. Peritoneal dialysis using a cycling machine
   5. Peritoneal dialysis at a center or nursing home
   6. Transplantation
   7. Other [specify _____]

2. Which of the following best describes the process of choosing your method of treatment ?

   1. I took the lead in selecting my treatment.
   2. The medical team (physician, nurse, social worker) took the lead in selecting my treatment.
   3. The medical team and I contributed equally to selecting my treatment.

3. How did you learn about your options for dialysis treatment? (Please circle all that apply.)
   1. Individual discussion with physician
   2. Individual discussion with social worker or nurse
   3. Group discussion or class to explain treatment options
   4. Discussion with family, friends or other patients
   5. Videotape materials
   6. Written materials
   7. None of the above [specify _____]

4. Has your doctor or medical team discussed the option of kidney transplantation with you? *(Circle one)*

   1. Yes
   2. No
   3. Not sure

5. Have you been or are you currently being evaluated for a kidney transplant? *(Circle one)*

   1. Yes
   2. No
   3. Not sure

6. Are you currently on a transplant waiting list? *(Circle one)*

   1. Yes
   2. No
   3. Not sure

7. For the following factors, indicate how important they were in your decision to be treated at this dialysis facility rather than at another facility: *(Circle one per line)*

	no effect	small effect	some effect	important	very important	don't know
Travel time/convenience of location	1	2	3	4	5	6
Convenience of treatment schedule	1	2	3	4	5	6
Type of dialysis offered (hemo, CAPD)	1	2	3	4	5	6
Dialyzer reuse policy	1	2	3	4	5	6
Recommended by physician or other health professional	1	2	3	4	5	6
Comfort of facility (TV, etc.)	1	2	3	4	5	6

8. For the following series of statements please indicate to what extent you believe the statement to be true:

	I BELIEVE THIS STATEMENT IS TRUE :					
	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Don't Know
a) Peritonitis (infection) is a common complication of peritoneal dialysis.	1	2	3	4	5	6
b) Hemodialysis takes up more of my available time than peritoneal dialysis.	1	2	3	4	5	6
c) Peritoneal dialysis allows me more flexibility than hemodialysis.	1	2	3	4	5	6
d) My diet is less strict on hemodialysis.	1	2	3	4	5	6
e) Fluid restriction is less on peritoneal dialysis.	1	2	3	4	5	6
f) I do not like needles/injections.	1	2	3	4	5	6
g) Peritoneal dialysis is more stressful for me than hemodialysis.	1	2	3	4	5	6
h) Hemodialysis makes it difficult for me to continue work or school.	1	2	3	4	5	6
i) Hemodialysis is a burden to my family.	1	2	3	4	5	6
j) I like to socialize with other dialysis patients and staff.	1	2	3	4	5	6
k) I live far away from a hemodialysis unit.	1	2	3	4	5	6
l) Medical problems did not allow me the choice of other treatment types	1	2	3	4	5	6

9. Which of the previous reasons (a-l) was the MOST IMPORTANT reason in selecting your type of treatment? Write the question letter from 8. in here:_____

10. When comparing hemodialysis and peritoneal dialysis, do you believe that quality of life (Circle one best answer):
    ____1. is better for patients treated with hemodialysis
    ____2. is better for patients treated with peritoneal dialysis
    ____3. is equal for both peritoneal and hemodialysis
    ____4. don't know

11. Comparing hemodialysis and peritoneal dialysis, which treatment do you believe helps patients live longer?
    ____1. Hemodialysis
    ____2. Peritoneal dialysis
    ____3. Peritoneal and hemodialysis are about the same
    ____4. Don't know

The next questions are for <u>patients on peritoneal dialysis</u>. If you are not on peritoneal dialysis, skip to Part 4 (Transportation) below.

12. If you are on CAPD, how many times have you missed an exchange during the last 7 days? (Circle one best answer)
    ___ 7 or more times
    ___ 4 to 6 times
    ___ 2 to 3 times
    ___ once
    ___ not at all
    ___ I am not on CAPD

13. If you use a cycler for peritoneal dialysis, how many days did you miss a treatment in the last 2 weeks? (Circle one best answer)

    ___ four times or more
    ___ three times
    ___ twice
    ___ once
    ___ not at all
    ___ I am not on a cycler

14. If you use a cycler for peritoneal dialysis, how many times have you shortened the treatment (or not using all the dialysis fluid) during the last 2 weeks? (Circle one best answer)
    ___ four times or more
    ___ three times
    ___ twice
    ___ once
    ___ not at all
    ___ I am not on a cycler

<u>Part 4: Transportation</u>

For the next questions, please think about the first month **after** starting dialysis. Unless otherwise noted, please circle one best answer.

1. How long does it usually take you to get to your dialysis unit or center (one way)?

    1. 15 minutes or less
    2. 16 minutes to half an hour
    3. 31 minutes to one hour
    4. More than one hour

Questions 2-6 below are for patients who are on hemodialysis. **If you are not on hemodialysis, skip to Part 5 (Employment)**

2. How do you usually get to dialysis?

   1. Drive myself ⇨ Skip to questions 4 and 5 below.
   2. Walk ⇨ Skip to questions 4 and 5 below.
   3. By car driven by someone else (not provided by dialysis unit)
   4. The dialysis unit/hospital sends transportation to pick me up.
   5. By taxi
   6. By bus or subway/train
   7. By ambulance

3. Why do you not drive yourself? (Please circle all that apply.)

   1. I do not own or have access to a car, vehicle.
   2. I do not know how to drive.
   3. I am no longer able to drive a car.
   4. I require assistance with walking or climbing stairs.
   5. I am too weak or sick to drive after dialysis.
   6. I must be transported on a stretcher or gurney.
   7. Other

4. If someone helps you get to your dialysis treatment, is that person:

   1. Spouse or partner
   2. Any other relative (unpaid)
   3. A friend or volunteer (unpaid)
   4. A paid person
   5. A medical professional

5. Who bears the cost (pays for) your transportation to your dialysis unit? Circle all that apply.

   1. Myself and/or my family
   2. Dialysis Unit
   3. Public agency or charity organization
   4. Other

6. During your first month of dialysis, have transportation problems caused you to

   a. shorten a hemodialysis treatment? 1. Yes 2. No
   b. skip or miss a hemodialysis treatment? 1. Yes 2. No

Part 5: Employment

1. If you are employed, what is your present hourly rate (before taxes)?

   $_____ dollars per hour
   (**Skip to #3 if you are currently working and have answered this question**)
   _____ I am not currently employed. (Check if this applies)

2. If not currently employed and you were to take a job now, what do you think would be your approximate hourly rate?
   $_____dollars per hour

3. Are you limited in the kind of work for pay you can do because of your health?

   1. Yes
   2. No

4. Are you limited in the amount of work for pay you can do because of your health?
   1. Yes
   2. No

Part 6: Rehabilitation

1. How often do you exercise (do physical activity during your leisure time)?

	(Circle One)
Daily or almost daily	1
4-5 times a week	2
2-3 times a week	3
About once a week	4
Less than once a week	5
Almost never or never	6

2. How good a job do you feel you are doing in taking care of your health? (Please circle one)

   1. excellent 2. very good 3. good 4. fair 5. poor

3. If not currently employed and you worked in the past, why did you stop working?(Please circle all that apply)

   1. I am too sick/had too much time off
   2. My job is physically too tiring
   3. I am retired
   4. I am needed for other duties
   5. My dialysis treatment is too demanding
   6. My employer had no other job, hours, etc
   7. I didn't want/need to work any more
   8. My dialysis facility schedule is not flexible
   9. I would lose benefits which are close to what I could earn

4. Given the opportunity, would you like to return to work? (please circle one best answer)

   1. Full time 2. Part time 3. Not at all 4. Not sure

If you are retired or a homemaker or are on CAPD you may skip to question 6.

5. Which statement reflects the impact of your dialysis treatment sessions on your work schedule? (extremely - quite a bit - moderately - slightly - not at all)

	I AGREE WITH THIS STATEMENT: (Circle one per line)				
	Extremely	Quite a bit	Moderately	Slightly	Not at all
a) My current dialysis schedule does not/would not interfere with a work schedule.	1	2	3	4	5
b) If it was necessary, my dialysis schedule could probably be changed to allow me to work.	1	2	3	4	5
c) There is not a shift available that would allow me to work	1	2	3	4	5

6. Were you assisted in completing this form?

Yes	No
1	2

7. If Yes, who helped?

Family member	Unit personnel	Other
1	2	3

END OF QUESTIONNAIRE, THANK YOU!!

Patient Name_____ DMMS ID#

Patient Soc. Sec. # ☐☐☐-☐☐-☐☐☐☐

Patient Medicare # ☐☐☐-☐☐-☐☐☐☐-☐☐

Confidential Report
Medical Questionnaire
(DMMS -Prospective)

First Dialysis Date (A6): ☐☐ mm ☐☐ dd ☐☐ yy

Study Start Date (A7): ☐☐ mm ☐☐ dd ☐☐ yy

Check box to left of item if unable to determine, and leave item (right) blank.

A. Patient and Facility Identification

1. **Abstractor Initials:** ☐☐
2. **Date Completed:** ☐☐ mm ☐☐ dd ☐☐ yy
- 3. **Ethnicity :** ☐ (1 - Hispanic Origin 2 - Not of Hispanic Origin)
- 4. **Race:** ☐ (1 - White 2 - Black 3 - Asian 4 - Native American 5 - Other)
- 5. **Patient's Zip Code:** ☐☐☐☐☐
- 6. **Date of first regular dialysis <u>for chronic renal failure</u>: (at least once weekly; regardless of setting). Please exclude intermittent dialysis treatments only for fluid overload or heart failure.**
  ☐☐ mm ☐☐ dd ☐☐ yy
- 7. **Study Start Date (Date #A6 plus 60 days):**
  ☐☐ mm ☐☐ dd ☐☐ yy
  Please copy these dates from A6 and A7 to the upper hand right corner of each page
- 8. **Was date of earliest known dialysis - same as #A6?** ☐ **(i.e. were there no <u>intermittent</u> treatments prior to date at A6?)** (1 - Yes 2 - No)

➔ ***(If item 8 is "no," give earliest date):***

☐☐ mm ☐☐ dd ☐☐ yy

- 9. **Insurance (answer all that apply in both columns):**

1 - Yes 2 - No	in the month before date A6	at or near date A7
• a. Blue Cross/Blue Shield :	☐	☐
• b. Private (other than BC/BS): .	☐	☐
• c. Medicare:	☐	☐
• if "no," is Medicare pending?		☐
• if "yes," is Medicare secondary?	☐	☐
• d. Medicaid:	☐	☐
• e. VA:	☐	☐
• f. Other:	☐	☐
• g. None:	☐	☐
• h. Enrolled in an HMO?	☐	☐

B. Patient History Within 10 Years Prior to Study Start Date (date A7)

- 1. **Primary cause of ESRD:** ☐
  1 - Diabetes
  2 - Hypertension
  3 - Primary glomerulonephritis
  4 - Other
- 2. **Regular cigarette smoking status:** ☐
  1 - Active (still smoking)
  2 - Former, stopped <1 year ago
  3 - Former, stopped >1 year ago
  4 - Smoker, current status unknown
  5 - Non Smoker

3. **History of Coronary Heart Disease (CHD) or Coronary Artery Disease (CAD)**

For a through g code 1 - Yes 2 - No 3 - Suspected

- a. Prior diagnosis of CHD/CAD: ☐
- b. Angina: ☐
- c. Myocardial infarction (MI): ☐
- d. Bypass surgery (CABG): ☐
- e. Coronary angioplasty (PTCA): ☐
- f. Coronary angiography: ☐
  - Abnormal? ☐
- g. Cardiac arrest: ☐

4. **History of Cerebrovascular Disease:**

For a & b code 1-Yes 2- No 3-Suspected CVA or TIA

- a. Diagnosis of Cerebrovascular Accident (CVA, Stroke) ☐

➔ ***(If item 4a is "yes," skip to item 5.)***

- b. Any Transient Ischemic Attacks (TIA)? ☐

5. **History of Peripheral Vascular Disease (PVD, PVOD):**

For a through e code 1 - Yes 2 - No 3 - Suspected

- a. Prior diagnosis of PVD: ☐
- b. Amputation due to PVD: ☐
- c. Limb amputation (other): ☐
- d. Absent foot pulses: ☐
- e. Claudication: ☐

Date A6 : ☐☐ ☐☐ ☐☐

Date A7: ☐☐ ☐☐ ☐☐

mm dd yy

Check box to left of item if unable to determine, and leave item (right) blank.

6. Hx of Heart Disease (other than CAD/CHD):
For all code: 1 - Yes 2 - No 3 - Suspected

- a. Congestive heart failure: ☐
- b. Pericarditis : ☐
- c. Pulmonary edema: ☐

- **7. Prior diagnosis of diabetes:** ☐
  1 - Yes 2 - No 3 - Suspected

➔ ***If item 7 is "no," skip to item 8.***

- a. Insulin therapy: ☐
  1 - Active 2 - Former 3 - Never
- b. Diabetes pills: ☐
  1 - Active 2 - Former 3 - Never

- **8. History of Lung Disease:**
  Chronic obstructive pulmonary disease (COPD) ☐
  1 - Yes 2 - No 3 - Suspected

- **9. Neoplasms (other than skin):** ☐
  1 - Yes 2 - No 3 - Suspected

➔ ***If item 9 is "no," skip to item 10.***

- a. Primary sites (up to 2) ☐☐ ☐☐

10 - Lung
11 - Stomach/Esophagus
12 - Breast
13 - Pancreas
14 - Prostate
15 - Liver
16 - Colon/Rectal
17 - Myeloma
18 - Lymphoma/Leukemia
19 - Brain
20 - Ovary/Uterus
21 - Melanoma of skin
22 - Bladder
23 - Oral/Larynx
24 - Kidney
25 - Other, Unknown

- b. Year of first dx: 1 9 ☐☐

- **10. HIV Status:** ☐
  1 - Positive 2 - Negative 3 - Unknown 4 - Can't disclose
- **11. AIDS Diagnosis:** ☐
  1 - Positive 2 - Negative 3 - Unknown 4 - Can't disclose

C: Information at Study Start Date (Date A7)

You may use information from the period between 30 days prior to date at A7 to 30 days after date at A7

1. Height (at any time): (REQUIRED)

☐ ft. ☐☐ in. **OR** ☐☐☐ cm.

If bilateral amputee give original height and check this box ☐

- **2. Dry weight as ordered nearest study start date:**

wt: ☐☐☐ lbs. **OR** ☐☐☐.☐ kgs.

- **3. Undernourished or cachectic (malnourished) at study start date (A7)** ☐
  1 - Yes 2 - No 3 - Suspected

4. Blood pressure and weight (most recent 3 readings before date (A7); please right justify entry):

- a. Predialysis BP (sitting preferred) for HD (any readings for PD patients):

			weight (rounded)
SBP ☐☐☐	/ DBP ☐☐☐		☐☐☐
SBP ☐☐☐	/ DBP ☐☐☐		☐☐☐
SBP ☐☐☐	/ DBP ☐☐☐		☐☐☐

Required:
weight in pounds (lbs) ☐ **or in kg.** ☐ **rounded (check one)**

- b. Postdialysis BP (sitting preferred) for HD (skip for PD patients):
  1-Yes 2-No

			weight (rounded)
SBP ☐☐☐	/ DBP ☐☐☐		☐☐☐
SBP ☐☐☐	/ DBP ☐☐☐		☐☐☐
SBP ☐☐☐	/ DBP ☐☐☐		☐☐☐

HEMODIALYSIS (if used on date A7)

➔ ***If patient is using peritoneal dialysis, skip to PD section***

5. Hemodialysis prescription at date A7:

- a. Dialysate: ☐
  1 - Bicarbonate 2 - Acetate
- b. Prescribed hours per treatment: ☐ hr. : ☐☐ min.
- c. Prescribed # of dialysis sessions per week: ☐
- d. Blood flow rate (BFR): ☐☐☐ ml/min

If BFR varies please enter the prescribed or the most common "high" rate.

- e. Patient usually reusing dialyzer: ☐
  1 - Yes 2 - No
- f. If reuse does not occur, please indicate reason: ☐
  1 - Unit does not reuse 2 - Patient refuses
  3 - Hepatitis 4 - Other Medical
- g. Dialyzer type (see codes on back of page 5):

Only if you have entered code 9999, please specify below the manufacturer and dialyzer model: ☐☐☐☐

manufacturer _____

dialyzer model _____

Patient Name_____ DMMS ID#

Patient Soc. Sec. # ☐☐☐-☐☐-☐☐☐☐

Confidential Report
USRDS DMMS - Prospective

Date A6: ☐☐ ☐☐ ☐☐

Date A7: ☐☐ ☐☐ ☐☐ (mm dd yy)

Check box to left of item if unable to determine, and leave item (right) blank.

at date A6 at date A7

- h. Vascular access in use: ..... ☐ ☐
  1 - AV Fistula
  2 - PTFE graft e.g. Gortex, Impra, Teflon
  3 - Bovine graft
  4 - Permanent catheter e.g. Permcath (any site)
  5 - Temporary internal jugular (IJ) catheter
  6 - Temporary subclavian catheter
  7 - Temporary femoral catheter
  8 - Other

at date A6 at date A7

- i. Side of THIS access: ..... ☐ ☐
  1 - Right 2 - Left

j. First permanent vascular access created or attempted on or before date A7:

- Type (use codes 1-4 from item 5h above):..... ☐
- Date of surgery: ☐☐ ☐☐ ☐☐ (mm dd yy)
- Date of first use of THIS access before A7: (leave blank if never used before date A7) ☐☐ ☐☐ ☐☐ (mm dd yy)
- Did this access require revision ☐ or did it fail ?.... ☐
  (Be sure to answer both boxes)
  1 - No, not before date A7
  2 - Yes, before date A6
  3 - Yes, between date A6 and date A7
- Did this access fail to mature before date A7?..... ☐
  1 - Yes 2 - No
- k. Temporary access in central vein anytime before date A7..... ☐
  1 -Yes 2 -No

➔ *If item 5k is "no," skip to item 5l.*

- Any Subclavian (SC)..... ☐
- Any Internal jugular (IJ)..... ☐

1 - Right 2 - Left 3 - Right and Left 4 - Neither

- l. Number of HD treatments skipped by patient during 30 days prior to A7..... ☐☐ (do not include time in the hospital)
- m. Number of prescribed HD treatments shortened by more than 10 minutes by the patient during the 30 days prior to A7 (do not include skipped treatments):..... ☐☐
- n. Did this patient have any peritoneal dialysis before date A7 (study start date)?..... ☐
  1 -Yes 2 -No

➔ *If item 5n is "no," skip to item 8 (Psychosocial Evaluation)*

- o. Date of placement for PD catheter: ☐☐ ☐☐ ☐☐ (mm dd yy)

If patient is on hemodialysis on date A7, skip to page 4, Psychosocial Evaluation, item C8

PERITONEAL DIALYSIS (if used on date A7)

➔ *If patient did not receive PD, then skip to Psychosocial Evaluation.*

6. Peritoneal dialysis prescription at study start date (Date A7):

- a. Dialysis location:..... ☐
  1 - Home 2 - Home Training 3 - In-center
- b. Type:..... ☐

1 - CAPD only 2 - Cycler(full when off cycler) 3 - Cycler (empty off cycler) 4.- Combined

- c. Peritoneal Dialysis Prescription:

	Cycler	Manual
# of exchanges/ day	☐☐	☐
liters/exchange (most common)	☐.☐	☐.☐
total hours/day on cycler	☐☐	N/A
days/week	☐	☐
Total dialysate volume per 24 hrs	☐☐☐.☐	

- d. Type of PD catheter in use at date A7: ..... ☐
  1 - single cuff 2 - double cuff 3 - no cuff
- e. Date of placement for THIS catheter: ☐☐ ☐☐ ☐☐ (mm dd yy)
- f. Was this the first peritoneal catheter for this patient?..... ☐
  1 - Yes 2 - No
- g. Was this patient treated with hemodialysis before date A7 (study start date)?..... ☐
  1 - Yes 2 - No
- h Did this patient have a permanent vascular access before date A7 (study start date)?..... ☐
  1 - Yes 2 - No

➔ *If item 6h is "yes," go back to item 5j (go left) and complete 5j.*

7. Please give, on a voluntary basis, 24 hour dialysate urea N and creatinine in period of A6 to A7 + 30 days.

Total volume (drained) ..... ☐☐☐.☐

Dialysate Urea N - .mg/dl ..... ☐☐☐☐.☐

Dialysate Creatinine .- mg/dl ..... ☐☐.☐

BUN (same day) .- mg/dl..... ☐☐☐☐.☐

Serum creatinine .- mg/dl..... ☐☐.☐

Date A6: ☐☐ ☐☐ ☐☐

Date A7: ☐☐ ☐☐ ☐☐

mm **dd** **yy**

Check box to left of item if unable to determine, and leave item (right) blank.

PSYCHOSOCIAL EVALUATION
Complete this section for both PD and Hemo patients

➔Complete the following with information from the psycho-social evaluation most recent before the STUDY START DATE (or up to 30 days after A7). Use social worker's evaluation supplemented by the nurse's, and/or dietitian's records. You may want to consult with the social worker, dietitian, or ask the patient.

- **8. Activities of daily living (currently or recently):** 1 - Yes 2 - No
  - a. Able to eat independently :..... ☐
  - b. Able to transfer independently:..... ☐
  - c. Able to ambulate independently (includes ambulating with an assistance device)..... ☐
- **9. Marital status:** ☐
  1 - Single 2 - Married
  3 - Widowed 4 - Divorced 5 - Separated
- **10. Living alone:** ☐
  1 - Yes 2 - No
  3 - Nursing home, institution 4 - Homeless
- **11. Education:** ☐
  1 - Less than 12 Yrs. 2 - High School Grad
  3 - Some College 4 - College Grad
- **12. Primary occupation before ESRD:** ☐
  1 - Clerical
  2 - Professional
  3 - Tradeperson
  4 - Manual Labor
  5 - Student
  6 - Other
  7 - Not Employed Outside of Home
  8 - Homemaker
  9 - Disabled

- **13. Employment Level:**
- a Please indicate the one most appropriate employment category for the patient during the periods of time indicated.
  Please enter one number only in each box from the list below.

	24 mo. prior to ESRD - 6 mo. prior to ESRD	near date at A7
1 - Employed full time or full time student.....	☐	☐
2 - Employed part time or part time student		
3 - Homemaker		
4 - Retired		
5 - Never Employed		
6- Unemployed		
7 - Disabled		
8 - Other (specify)		

- b. If unemployed, is patient looking for employment:..... ☐
  1 - Yes 2 - No

D: Laboratory Data

Complete with information closest to study start date (A7) from a period of up to3 months before study start date (A7) and one month after study start date (A7+ 30 days).

- **1. Cardiomegaly by X-ray:** ☐
  1 - Yes 2 - No
- **2. Left ventricular hypertrophy:**
  1 - Yes 2 - No
  - a. by EKG ..... ☐
  - b. by echocardiography ..... ☐
- **3. Total serum calcium, predialysis:** ☐☐.☐ mg/dl
- **4. Serum phosphate or phosphorus, predialysis:** ☐☐.☐ mg/dl
- **5. Serum bicarbonate or CO_2, predialysis:** ☐☐.☐ mEq/l

6. Hematocrit information (from the lab report)

- a. Hematocrit (If transfused, give value before blood transfusion):..... ☐☐.☐ **%**
- b. Hemoglobin (If transfused, give value before transfusion..... ☐☐.☐ g/dl
- c. Transfused in first 60 days of dialysis? ☐
  1 - Yes 2 - No

If item 6c is "no," skip to item 7.

- d. If transfused, number of transfusions in first 30 days of dialysis:..... ☐

7. Was the patient taking EPO (Erythropoietin)? ☐
1 - Yes 2 - No

- a. During first 60 days of dialysis (between A6 and A7):..... ☐

If yes: iv.=1, subcutaneous = 2 ..... ☐

- b. During last month before ESRD:..... ☐
  (30 days prior to A6)

8. Serum Creatinine:

- a. Before first regular dialysis.. ..... ☐☐.☐ mg/dl
  (on day of first regular dialysis or on the closest day prior to date A6)
- b. Nearest day 60 (A7):..... ☐☐.☐ mg/dl

9. BUN or urea values: **Check here if urea:** ☐

- a. Before first regular dialysis: ..... ☐☐☐ mg/dl
  (on day of 1st regular dialysis or on the closest day prior to date A6)

Patient Name_____ DMMS ID#

Patient Soc. Sec. # ☐☐☐-☐☐-☐☐☐☐

Confidential Report
USRDS DMMS - Prospective

Date A6: ☐☐ ☐☐ ☐☐

Date A7: ☐☐ ☐☐ ☐☐
mm dd yy

Check box to left of item if unable to determine, and leave item (right) blank.

- b. Nearest day 60 (measurements must be from same date):

Predialysis:..... ☐☐☐ mg/dl required

Postdialysis:..... ☐☐☐ mg/dl required

c. Weights pre and post dialysis (must be on same day as 9b):

weight in lb. ☐ or kg. ☐ rounded (check one)

- predialysis:..... ☐☐☐ required
- postdialysis:..... ☐☐☐ required

➔ ***Dates for pre and post BUN values and pre and post weights MUST match.***

- **10. Predialysis or random Serum Albumin:** ☐.☐ g/dl

Complete with information closest to study start date (A7) from a period of up to 3 months before study start date (A7) to 1 month after study start date (A7+30)

11. Lipids:

- a. Cholesterol Total:..... ☐☐☐ mg/dl
- b. HDL cholesterol:..... ☐☐☐ mg/dl
- c. LDL cholesterol:..... ☐☐☐ mg/dl
- d. Triglycerides:..... ☐☐☐☐ mg/dl

- **12. Serum intact PTH:**..... ☐☐☐☐ pg/ml
- **13. Serum Aluminum:** ..... ☐☐☐☐ µg/l

(Random or if DFO, please use base line measurement)

14. Residual Renal Function:
This section is important but is not an official requirement.

Please give all available information and/or obtain the measurements within period of date A6 to date A7 + 30 days, (i.e.days 0 -90 days ESRD) on a voluntary basis if at all possible:

- a. Urine collection time:

start..... ☐☐ ☐☐ ☐☐:☐☐ ☐
mm dd hr min AM=1 PM=2
Date Time

end..... ☐☐ ☐☐ ☐☐:☐☐ ☐
mm dd hr min AM=1 PM=2
Date Time

Total hours of urine collection (Verification)..... ☐☐

- b. Lab Values

	Value	Units
Urine Volume	☐,☐☐☐	ml or cc
Urine Creatinine	☐,☐☐☐	indicate units • mg/vol • mg/24 hrs. • mg/dl=mg%
Urine Urea Nitrogen	☐,☐☐☐	
Pre Creatinine*	☐☐.☐	mg/dl
Pre BUN*	☐☐☐	mg/dl
Post Creatinine*	☐☐.☐	mg/dl
Post BUN*	☐☐☐	mg/dl

* For the pre and post blood creatinine and BUN, please provide values taken ideally at the beginning (pre) and end (post) of URINE collection If this is not possible:
For hemo patients, enter values from measurements taken pre and post dialysis on a date as close as possible to the dates of urine collection.
For PD patients, enter blood creatinine and BUN values taken on a date as close as possible to the date of urine collection available.

15. Medications at time of A7, please copy the list of all medications as generic or trade name. (The dosage is not required)

1												
2												
3												
4												
5												
6												
7												
8												
9												
10												
11												
12												
13												
14												
15												

16. Was patient receiving at time of A7 injectable vitamin D (Calcijex) ..... ☐
1 - yes 2 - no

Dialysis Morbidity and Mortality Study-Prospective
PATIENT TRACKING AND IDENTIFICATION FORM

Dialysis Unit Provider:# ..... _____
Dialysis Unit Name: ..... _____

Patient Name: ..... _____
Social Security #: ..... _____
Sex: ..... _____
Date of Birth: ..... _____
HIC #: ..... _____
Modality of Treatment (Hemo or PD?): ..... _____

Did the patient complete the Dialysis Pt Questionnaire (Circle One): Yes No

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USRDS Coordinating Center
315 W. Huron, Suite 240
Ann Arbor Michigan 48103
800 707-0044 (Phone)
313 998-6620 (Fax)

United States Renal Data System
DMMS Prospective Follow-Up Study

Instructions

General Overview

Your dialysis facility is currently participating in the Prospective Dialysis Morbidity and Mortality Study (DMMS). This study will address many important treatment issues including:

- the adequacy of hemodialysis and peritoneal dialysis
- the efficacy of dialyzer re-use
- mortality and morbidity in peritoneal dialysis versus hemodialysis patients
- the relationship between vascular access and hospitalization of dialysis patients
- quality of life of dialysis patients
- assessment of pre-ESRD nephrology care
- rehabilitation of dialysis patients
- choice of dialysis modality

In order to address questions related to vascular access outcome and patient quality of life, the USRDS is now initiating the **"DMMS Prospective Follow-Up Study".** Obtaining follow-up data on patients who have already been enrolled in the Prospective DMMS will make it possible to answer important questions about patient quality of life and treatment options for vascular access.

Patients Selected for Participation in the DMMS Prospective Follow-Up Study

- You will find included in your packet of materials a list of patients selected for the Prospective DMMS Follow-Up Study.
- **All the patients on this list are patients your dialysis unit enrolled in the Prospective DMMS and for whom you completed a DMMS Prospective Medical Questionnaire**. All the patients on this list should have "Dates of Day 60 of ESRD" (Date A.7 on the Prospective DMMS Medical Questionnaire) between November 1, 1996 and February 28, 1997, although a small number of patients outside this range will be included.

Questionnaires for the DMMS Prospective Follow-Up Study

There are two questionnaires for the DMMS/PFS:

Dialysis Patient Questionnaire

- Please ask **all living patients** to complete a Dialysis Patient Questionnaire. Completion of this questionnaire is voluntary. Your task is to discuss this form with the patients and encourage them to complete it. Please distribute and discuss this questionnaire with patients as soon as possible. Any patient who agrees to complete the Patient Questionnaire will need to read through and sign the Cover Sheet and Patient Consent Form which is the first page of the Dialysis Patient Questionnaire.

- Please be sure that any patient completing the Dialysis Patient Questionnaire has read the consent form and signed it. The consent form should remain stapled to the Dialysis Patient Questionnaire.

- **In addition, we are requesting that dialysis unit staff assist at least one patient who requires assistance with this questionnaire.** We understand that there are patients who are unable to complete this questionnaire on their own because of either a lack of education or a physical disability such as impaired vision. Some patients may also choose to take the Dialysis Patient Questionnaire home and have a family member provide assistance with completing it. However, once a questionnaire leaves the dialysis unit there is clearly a greater risk of it not being completed. Therefore, our preference in terms of completion of the Dialysis Patient Questionnaire is as follows:

  1. Patient completes questionnaire him/herself at the dialysis unit.
  2. Patient completes questionnaire with assistance from a dialysis unit staff member.
  3. Patient completes questionnaire with assistance from a capable family member, preferably at the dialysis unit but, if necessary, at home.

- **Please instruct each patient to place the completed Dialysis Patient Questionnaire, and the attached "Cover Sheet and Patient Consent Form" into the personalized 8 x 11 envelope (Patient's Name and DMMS ID# pre-printed on the front), seal it, and return it to you.** This procedure ensures the confidentiality of the information that the patient has provided. These envelopes must remain sealed and be returned in this form to the ESRD Network. (We want the patients to feel comfortable answering questions with the knowledge that the information they provide will be kept confidential.)

- A **Spanish Version of the Dialysis Patient Questionnaire** has been provided for all patients who completed the Spanish Version when first enrolled in the Prospective DMMS. **If a Spanish-speaking patient has inadvertently NOT received the Spanish Version or is completing the Patient Questionnaire for the first time, please contact Liz Holzman or Bob Ziegelmann at (800) 707-0044 and we will be happy to provide you with the Spanish Version.**

Important Note: If a patient has expired, please write in LARGE RED LETTERS at the top of the first page of the Dialysis Patient Questionnaire, "Patient Expired".

Medical Update Questionnaire:

- Information to complete the Medical Update Questionnaire can be obtained from the facility/unit records, including medical records, billing records, dialysis logs, patient

rosters, hospital records and personal physician records. **Please do NOT obtain information directly from the patient. We need data for both living and expired patients to come from the same data source, i.e. the medical records. Obtaining data directly from living patients would create a situation in which the data for both living and expired patients would *not* be coming from the same source, with the possible creation of bias. (This is in contrast to the instructions provided for the Prospective DMMS Medical Questionnaire where it was stated that information could be obtained from the patient. In the Prospective DMMS, all patients were living at the time of their enrollment in the study which was Day 60 of ESRD; no patients had yet expired.)**

- Section A should be completed for **ALL patients**, regardless of any changes in the patient's status or modality.
- Section B should be completed **only for hemodialysis and PD patients currently being treated in your facility**. Please be sure to complete items B.1, B.2 and B.3. However, item B.4 is voluntary.
- Section C (Vascular Access) should be completed **only for patients who were on hemodialysis at Day 60 of ESRD, regardless of any changes in status or modality.** The modality at Day 60 of ESRD is clearly indicated on the Cover Sheet of the Medical Update Questionnaire and in the top right hand corner of the Medical Update Questionnaire.

Requesting Replacement Questionnaires

If you should lose or misplace questionnaires, please do **not** make copies because we want to provide you with questionnaires that have been customized for that particular patient. **If you need replacement questionnaires, call the USRDS Coordinating Center at 1-800-707-0044 and ask for Liz Holzman.**

Returning Completed Questionnaires to Your ESRD Network

Please return all completed questionnaires to your ESRD Network. Do NOT return completed questionnaires to the USRDS Coordinating Center.

Skipping Items

If the answer to an item in Sections A, B, or C cannot be determined, **leave the item blank by leaving the box on the right empty** and **put a check mark in the small box to the left**

of the item number. This will indicate that you looked for the information in all available records and then decided that you could not determine an answer for the item. When information is not available to answer a question, checking the box on the left is important because it indicates that the item was not inadvertently skipped or forgotten.

Date Formats

Dates are either in month (mm) day (dd) and year (yy) format, or in month and year format. **In all cases, month and day must be expressed in 2 digits.** For example, January is 01 and November is 11. The first day of the month is 01; the fifteenth day of the month is 15. The year is expressed by the last two digits of the year; e.g. 94 for 1994. **If you are able to report partial information only, do so but also put a check in the small box to the left of the item number.**

Comments

If you have any comments that you wish to share, please write them on the back of the Cover Sheet for the Medical Update Questionnaire.

Use of Abstractor Judgment

A medical record may not state explicitly all the information that these abstraction forms are designed to capture. **The integrity of the data collection effort rests on the expertise and professionalism of the abstractors in interpreting the information contained in the medical record**. In many instances where specific information for an item is not in the record, the abstractor may be able to logically infer the answer to the item from other information in the record. For example, elevated blood pressure over a long period of time implies hypertension. **Abstractors (those who fill out the Medical Update Questionnaire) should not make inferences without very careful consideration but should make inferences when they believe that the record supports drawing a conclusion. An inference can be made when the abstractor feels that 8 or 9 out of 10 abstractors reviewing the same record would agree**. Use of abstractor judgment helps in obtaining the most complete set of data about a patient's history and medical status as possible.

Detailed Instructions and Explanations for Medical Update Questionnaire

As you complete the Medical Update Questionnaire, please pay careful attention to the instructions found right on the questionnaire. These will tell you how to complete a particular item depending on whether or not the patient is still living, the patient has transferred to another dialysis unit or the patient is still dialyzing in your dialysis unit. Even if the patient has expired or transferred, there are still many items on the questionnaire that can be completed using information obtained from the patient's medical records.

Cover Sheet: Patient and Facility Identification

Facility Name: The name of your dialysis unit should appear in the top left hand corner.

HCFA Provider Number: Your dialysis unit's provider number should be in the top left hand corner.

For the following items, please correct any information that is incorrect in the space provided.

Patient Name: The name of the patient has been provided in this space.

Date of Birth: The patient's date of birth has been provided in this space.

Social Security Number: The patient's social security number has been provided.

Day 60 of ESRD (Date A.7) from Medical Questionnaire: The date of Day 60 of ESRD was provided on the Medical Questionnaire for the Prospective DMMS and was item A.7 on that questionnaire. This date has been provided. This date should fall between November 1, 1996 and February 28, 1997, although a small number of patients outsiede this range will be included.

Modality at Day 60 of ESRD from Medical Questionnaire: The modality of treatment, either hemo or PD, that the patient was receiving when the DMMS Prospective Medical Questionnaire was completed has been provided. It is important to note this modality as you complete the Medical Update Questionnaire. In particular, the patient must have been receiving hemodialysis at Day 60 of ESRD in order to complete Section C (Vascular Access).

Section A: Patient Status Since Day 60 of ESRD

In the top left hand corner, please provide the Abstractor's Initials (person who fills out the questionnaire) and Today's Date.

We need to know the sequence of changes in patient modality since Day 60 of ESRD (Date A.7 from the Prospective DMMS Medical Questionnaire.) The date of modality at Day 60 has been provided on the Cover Sheet and in the top right hand corner of the questionnaire.

A.1 What was the date of the FIRST change in patient status or modality since Day 60 of ESRD? Please enter the date of the FIRST change. Enter Today's Date if there was no change in the patient's status or modality. For the date entered, please enter the code for the change in patient status or modality.

A.2 What is the patient's current status? Please enter the code for the patient's current status. If the patient died, please provide the date of death. If the patient is living or lost to follow-up, please enter the date that the patient was last known to be alive.

Section B: BUN and Residual Renal Function

Please complete this section only for patients currently on hemodialysis or peritoneal dialysis at your facility. Use information as close as possible to today's date that is not more than 60 days from today's date.

B.1 What is the patient's current modality of treatment, hemodialysis or peritoneal dialysis? Enter the appropriate code in the box provided.

B.2 What is the approximate urine output of the patient currently? Enter the appropriate code in the box provided.

B.3 BUN and Weight. All values for BUN and weight must be from the same date.

> **Pre-dialysis BUN and weight**: Please enter the patient's pre-dialysis BUN and weight. For PD patients, please use the most recent BUN and weight.
>
> **Post-dialysis BUN and weight:** Please enter the patient's post-dialysis BUN and weight. This item should be completed for hemo patients only.

B.4 Residual Renal Function: Do NOT complete Residual Renal Function if the patient's urine volume is less than 200 ml/day. This item is voluntary.

a. **Urine collection time**: Please enter the **date and time** of the **START and END** of urine collection. For hemo patients, START is post-dialysis and END is usually the next pre-dialysis treatment time. Please enter the total hours of urine collection for verification.

b. Lab values: Please provide the lab values requested. For PD patients, enter only ONE set of serum creatinine and BUN values (in the boxes for "Start") taken on a date as close as possible to the date of urine collection. For hemo patients, lab values should be from the same dates as "Start" and "End" dates used for urine collection "Start" and "End".

Section C: Vascular Access Update

Complete this section ONLY if the patient was on hemodialysis at Day 60 of ESRD. We need to know the status of this patient's FIRST PERMANENT VASCULAR ACCESS. Please complete items in this section with information from the patient's medical records. **Please complete this section even if the patient has died or changed modality**.

C.1 Has a permanent vascular access EVER been created or attempted in this patient? Enter the appropriate code for "yes" or "no".

Important Note: ***If a permanent vascular access has NEVER been created or attempted in this patient, do NOT complete the rest of this section on Vascular Access.***

C.2 From this patient's Medical Questionnaire (from the Prospective DMMS) we have provided the date of Day 60 of ESRD and the type of FIRST permanent access indicated on the Medical Questionnaire**.**

If the type of access indicated on the Medical Questionnaire is INCORRECT, please provide the correct type of access using codes 1-4 from above.

If the space for type of first permanent access if BLANK, what was the FIRST permanent vascular access created or attempted? Again, use codes 1-4 from above.

What SIDE was this first permanent access placed on? Please enter the code for right or left.

C.3 For this item, we have provided, from the patient's Medical Questionnaire, the date of surgery for the creation of the first permanent access.

If the date provided is incorrect, or if the space for the date is blank, please provide the date of the surgery for the creation of the first permanent vascular access.

C.4 Was the patient's FIRST permanent access ever used for dialysis? Enter the code for yes or no.

If YES, what was the first date that this first permanent access was used for dialysis? Please enter the date.

If NO, did this first permanent access fail to mature adequately for dialysis? Please enter the code for yes or no.

C.5 Did the patient's FIRST permanent access fail after being used for dialysis? Enter the code for yes, no or unknown.

If YES, please provide the date of the FIRST failure.

If NO or UNKNOWN, please provide the last known date that the access was used for dialysis.

C.6 Were there revisions or procedures made to this patient's FIRST permanent access? Enter the code for yes, no or unknown.

If YES, please give the FIRST TWO DATES and TYPE of revisions (or procedures) that were made subsequent to the date provided in C.3 (the date of surgery for creation of the FIRST permanent access). Please use the codes provided for the type of revision or procedure.

Second Revision or Procedure: Was there a second revision or procedure made to the FIRST permanent vascular access within two weeks of the first revision or procedure? If yes, again give the date and type. Again use codes 1-7 for the type of revision or procedure.

Facility Name: **Network:**
HCFA Provider Number:

USRDS
Prospective Dialysis Morbidity and Mortality *Follow-Up* Study
Cover Sheet for Medical Update Questionnaire

Introduction
In order to address questions related to patient outcome and changes in patient quality of life, the USRDS is initiating the **"Prospective DMMS *Follow-Up* Study".** Data are to be collected for patients who were studied as part of their enrollment in the Prospective DMMS (initiated in March, 1996). Obtaining follow-up data on patients who have already been studied will make it possible to answer important questions about patient quality of life, vascular access, and other patient outcomes.

The Medical Update Questionnaire consists of 3 sections:
Section A: This section is called "Patient Status Since Day 60 of ESRD (Date A.7)". **(The date of Day 60 of ESRD was provided on the Medical Questionnaire for the Prospective DMMS and was item A.7 on that questionnaire.)** In this section, data are collected pertaining to the patient's status since the patient was initially studied as part of the Prospective DMMS. We are interested in knowing the patient's status since Day 60 of ESRD in terms of the first change in modality, transfer to other facilities, recovery of renal function, transplantation and death.

Section B. This section is called **"**BUN and Residual Renal Function**". This section should be completed ONLY for patients from your unit that are *currently* receiving in-center hemodialysis, CAPD or CCPD.** Please be sure to answer items 1, 2 and 3 of Section B. **Item 4 of this section is voluntary but please complete if possible.**

Section C: This section is called "Vascular Access Update (Patients Who Were on Hemo at Day 60 of ESRD)". In this section data about the patient's FIRST permanent vascular access are collected. **The Medical Update Questionnaire will include this section ONLY if the patient was on hemo at Day 60 of ESRD**. Otherwise, the back page of this questionnaire will be blank. Please complete this section even if there has been a change in the patient's status or modality of treatment since Day 60 of ESRD.

The attached Medical Update Questionnaire should be completed for the patient whose name appears below. Other patient information has also been provided. Please correct any information that is incorrect.

Item	Information from DMMS Prospective Medical Questionnaire	Please provide correct information if necessary
Patient Name		
Date of birth		
Social Security #		
Date of Day 60 of ESRD (Date A.7) from DMMS Prospective Medical Questionnaire		
Modality at Day 60 of ESRD (Date at A.7) from DMMS Prospective Medical Questionnaire		

USRDS

UNITED STATES RENAL DATA SYSTEM

315 W. Huron, Suite #240, Ann Arbor, MI 48103 (TEL) 313 998-6611; (FAX) 313 998-6620; internet: USRDS@UMICH.EDU

United States Renal Data System Prospective Dialysis Patient Study

Dialysis Patient Questionnaire
COVER SHEET AND PATIENT CONSENT FORM

Dear Dialysis Patient:

Under the Direction of the National Institute of Health, the United States Renal Data System, an organization devoted to research about patients with kidney disease, is asking for your participation in a study of quality of life, rehabilitation and medical care before dialysis. The purpose of the study is to find ways to improve the treatment and medical care for dialysis patients.

In order to answer important questions about dialysis treatment and patient outcomes, we are asking you to complete the attached Dialysis Patient Questionnaire.

You should know that there are absolutely no risks to you associated with the study and your cooperation is strictly voluntary. If you choose not to participate, this will not affect your treatment or insurance status in any way.

You may ask for assistance from the staff or from family or friends but the answers should be from **you**. Completing this questionnaire should take you no more than one hour.

Protecting your privacy is very important to us. If you agree to participate in this study and complete the attached questionnaire, all of the information which you provide will be kept confidential.

If you have any questions or concerns about your participation in this study, please feel free to make a toll free call to Liz Holzman at the United States Renal Data System. The phone number is **1-800-707-0044**.

If you agree to complete the attached questionnaire, please sign this consent form in the space provided below. Thank you very much for your important contribution to research about patients with kidney disease.

I, _____ (printed name), have read the above description of the USRDS's study and agree to participate in this study by completing the Dialysis Patient Questionnaire. I understand that information obtained about me will be kept confidential.

Signed: _____ Date: _____

Attached to this questionnaire, you will find an 8x11 envelope. When you have completed this questionnaire, please place it in the envelope, seal it and return it to the dialysis unit staff person who asked you to participate in this study. This procedure will ensure the confidentiality of the information that you have provided. Thank you once again.

NIDDK legislative authority to conduct research is granted under
Public Health Service Act 42-USC-241, Section 301

[1] Hays RD, Kallich JD, Mapes DL, Coons SJ, Amin N, Carter WB. (1995) Kidney Disease Quality of Life Short Form (KDQOL-SF ™), Version 1.1: A Manual for Use and Scoring. Santa Monica, Ca:RAND, p-7928.

Patient Name:
Social Security Number:
Please fill in today's date:_____

United States Renal Data System

DIALYSIS PATIENT QUESTIONNAIRE

Part 1: Quality of Life Questionnaire (KDQOL-SF™)[1]

1. In general, would you say your health is:

(Circle One Number)

Excellent.....1
Very good.....2
Good.....3
Fair.....4
Poor.....5

2. Compared to one year ago, how would you rate your health in general now?

(Circle One Number)

Much better now than one year ago.....1
Somewhat better now than one year ago.....2
About the same as one year ago.....3
Somewhat worse now than one year ago.....4
Much worse now than one year ago.....5

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

(Circle One Number on each line)

	Yes, Limited a lot	Yes, Limited a little	No, Not Limited at all
3. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
4. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
5. Lifting or carrying groceries	1	2	3
6. Climbing several flights of stairs	1	2	3
7. Climbing one flight of stairs	1	2	3
8. Bending, kneeling, or stooping	1	2	3
9. Walking more than a mile	1	2	3
10. Walking several blocks	1	2	3
11. Walking one block	1	2	3
12. Bathing or dressing yourself	1	2	3

During the last 30 days, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

(Circle One Number on Each Line)

	Yes	No
13. Cut down the amount of time you spent on work or other activities?	1	2
14. Accomplished less than you would have liked?	1	2
15. Were limited in the kind of work or other activities?	1	2
16. Had difficulty performing work or other activities (for example, it took extra effort)?	1	2

During the last 30 days, have you had any of the following problems with your work or other regular daily activities **as a result of emotional problems such as anxiety or depression**?

(Circle One Number on Each Line)

	Yes	No
17. Cut down the amount of time you spent on work or other activities?	1	2
18. Accomplished less than you would have liked?	1	2
19. Didn't do work or other activities as carefully as usual?	1	2

20. During the last 30 days, to what extent have your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

(Circle One Number)

Not at all.....1
Slightly.....2
Moderately.....3
Quite a bit.....4
Extremely.....5

21. How much bodily pain have you had during the last 30 days?

(Circle One Number)

None.....1
Very mild.....2
Mild.....3
Moderate.....4
Severe.....5
Very severe.....6

22. During the last 30 days, how much did pain interfere with your normal work (including work both outside the home and housework)?

(Circle One Number)

Not at all 1
A little bit 2
Moderately 3
Quite a bit 4
Extremely 5

These questions are about how you feel and how things have been with you during the last 30 days. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the last 30 days....

(Circle One Number on Each Line)

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
23. Did you feel full of pep?	1	2	3	4	5	6
24. Have you been a very nervous person?	1	2	3	4	5	6
25. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
26. Have you felt calm and peaceful?	1	2	3	4	5	6
27. Did you have a lot of energy?	1	2	3	4	5	6
28. Have you felt downhearted and blue?	1	2	3	4	5	6
29. Did you feel worn out?	1	2	3	4	5	6
30. Have you been a happy person?	1	2	3	4	5	6
31. Did you feel tired?	1	2	3	4	5	6

32. During the last 30 days, how much of the time have your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

(Circle One Number)

All of the time.....1
Most of the time.....2
Some of the time... 3
A little of the time 4
None of the time.....5

How TRUE or FALSE is each of the following statements for you?

(Circle One Number on Each Line)

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
33. I seem to get sick a little easier than other people	1	2	3	4	5
34. I am as healthy as anybody I know	1	2	3	4	5
35. I expect my health to get worse	1	2	3	4	5
36. My health is excellent	1	2	3	4	5

YOUR KIDNEY DISEASE

How TRUE or FALSE is each of the following statements for you? (Circle One Number on Each Line)

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
37. My kidney disease interferes too much with my life	1	2	3	4	5
38. Too much of my time is spent dealing with my kidney disease	1	2	3	4	5
39. I feel frustrated dealing with my kidney disease	1	2	3	4	5
40. I feel like a burden on my family	1	2	3	4	5

These questions are about how you feel and how things have been with you during the last 30 days. For each question, please give the one answer that comes closest to the way you have been feeling. **How much of the time during the last 30 days...**

(Circle One Number on Each Line)

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
41. Did you isolate yourself from people around you?	1	2	3	4	5	6
42. Did you react slowly to things that were said or done?	1	2	3	4	5	6
43. Did you act irritable toward those around you?	1	2	3	4	5	6
44. Did you have difficulty doing activities involving concentration and thinking?	1	2	3	4	5	6
45. Did you get along well with other people?	1	2	3	4	5	6
46. Did you become confused and start several activities at a time?	1	2	3	4	5	6

During the last 30 days, to what extent were you bothered by each of the following?
(Circle One Number on Each Line)

	Not at all	Somewhat	Moderately	Very much	Extremely
47. Soreness in your muscles?	1	2	3	4	5
48. Chest Pain?	1	2	3	4	5
49. Cramps?	1	2	3	4	5
50. Itchy skin?	1	2	3	4	5
51. Dry skin?	1	2	3	4	5
52. Shortness of breath?	1	2	3	4	5
53. Faintness or dizziness?	1	2	3	4	5
54. Lack of appetite?	1	2	3	4	5
55. Washed out or drained?	1	2	3	4	5
56. Numbness in hands or feet?	1	2	3	4	5
57. Nausea or upset stomach?	1	2	3	4	5
58. Problems with your access or catheter site?	1	2	3	4	5

EFFECTS OF KIDNEY DISEASE ON YOUR LIFE

Some people are bothered by the effects of kidney disease on their daily life, while others are not. How much does kidney disease bother you in each of the following areas?

(Circle One Number on Each Line)

	Not at all	Somewhat	Moderately	Very much	Extremely
59. Fluid restrictions?	1	2	3	4	5
60. Dietary restrictions?	1	2	3	4	5
61. Your ability to work around the house?	1	2	3	4	5
62. Your ability to travel?	1	2	3	4	5
63. Being dependent on doctors and other medical staff?	1	2	3	4	5
64. Stress or worry caused by kidney disease?	1	2	3	4	5
65. Your sex life?	1	2	3	4	5

The next two questions are personal, but your answers are important in understanding how kidney disease impacts people's lives.

How much of a problem was each of the following during the last 30 days?

(Circle One Number on Each Line)

	Not a problem	A little problem	Somewhat of a problem	Very much a problem	Severe problem
66. Inability to relax and enjoy sex	1	2	3	4	5
67. Difficulty in becoming sexually aroused	1	2	3	4	5

For each of the following statements, please indicate whether these describe you today and are related to your state of health.

(Circle One Number on Each Line)

	Yes	No
68. I lie down more often during the day in order to rest	1	2
69. I sleep or nap more during the day	1	2
70. I sleep less at night; for example, wake up too early, don't fall asleep for a long time, awaken frequently	1	2

71.On a scale from 0 to 10, how would you rate the quality of your sleep during the last 30 days?

(Circle One Number)

|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|

0 1 2 3 4 5 6 7 8 9 10

Poor Quality — High Quality

In terms of your satisfaction with family and social life, circle one number to rate each of the following:

(Circle One Number on Each Line)

	Poor	Fair	Good	Very Good	Excellent
72. The amount of togetherness you have with your family and friends	1	2	3	4	5
73. The support and understanding your family and friends give you	1	2	3	4	5

74. Are you now able to work?

(Circle One Number on Each Line)

	Yes	No
a. Part-time?	1	2
b. Full-time?	1	2

75. During the last 30 days, were you:

(Circle One Number)

Working full-time	1
Working part-time	2
Unemployed, laid off, or looking for work	3
Retired	4
Disabled	5
In school	6
Keeping house	7
None of the above	8

76. Think about the care you receive at this facility for kidney dialysis. In terms of your satisfaction, how would you rate the friendliness and interest shown in you as a person?

(Circle One Number)

Very poor	1
Poor	2
Fair	3
Good	4
Very good	5
Excellent	6
The best	7

How TRUE or FALSE is each of the following statements?

(Circle One Number on Each Line)

	Definitely True	Mostly True	Neither True nor False	Mostly False	Definitely False
77. Dialysis staff encourage patients to lead as normal a life as possible	1	2	3	4	5
78. Dialysis staff here counsel me on achieving full potential for rehabilitation	1	2	3	4	5

Part 2: Medical Care on Dialysis

1. Since starting dialysis, how often have you talked to a dietitian about foods that you should avoid as a dialysis patient?

    1. Once
    2. More than once
    3. Never

2. How often do you see or speak with your dialysis physician?

    1. Once or more a week
    2. Once every two to three weeks
    3. Once a month
    4. Less than once a month

3. At the present time how much urine do you pass in 24 hours?

    1. A normal amount (near one quart or more)
    2. About 1 pint
    3. About 6-12 ounces
    4. Less than 6 ounces

Part 3: Choosing the Treatment for Your Kidney Failure

1. Has your doctor or medical team discussed the option of kidney transplantation with you? *(Circle one)*

   1. Yes
   2. No
   3. Not sure

2. Have you been or are you currently being evaluated for a kidney transplant? *(Circle one)*

   1. Yes
   2. No
   3. Not sure

3. Are you currently on a transplant waiting list? *(Circle one)*

   1. Yes
   2. No
   3. Not sure

Please check the appropriate box to indicate if you are a Peritoneal Dialysis Patient (CAPD, CCPD, IPD) or Hemodialysis patient.

I am on Hemodialysis : ☐ **SKIP TO PART 4 (EMPLOYMENT)**

I am on Peritoneal Dialysis: ☐ **ANSWER QUESTIONS 4-6**

4. If you are on CAPD, how many times have you missed an exchange during the last 7 days? (Check one best answer)

   ___ 7 or more times
   ___ 4 to 6 times
   ___ 2 to 3 times
   ___ once
   ___ not at all
   ___ I am not on CAPD

5. If you use a cycler for peritoneal dialysis, how many days did you miss a treatment in the last 2 weeks? (Check one best answer)

   ___ 4 times or more
   ___ 3 times
   ___ 2 times
   ___ once
   ___ not at all
   ___ I am not on a cycler

6. If you use a cycler for peritoneal dialysis, how many times have you shortened the treatment (or not using all the dialysis fluid) during the last 2 weeks? (Check one best answer)
___ 4 times or more
___ 3 times
___ 2 times
___ once
___ not at all
___ I am not on a cycler

Part 4: Employment

What is your age? Please check the appropriate box:

I am 60 years of age or older: ☐ **SKIP TO PART 5 (Rehabilitation)**

I am 59 years of age or younger: ☐ **Persons 59 years of age and younger, please complete this Question and *either* Question 2 or 3.**

1. Please circle your current work status and follow line from your selection to either question 2 or 3 as appropriate.
   1. Employed full time
   2. Employed part-time
   3. Self-employed
   4. Unemployed
   5. Homemaker
   6. Retired
   7. Never employed
   8. Disabled

2. If you are **currently employed**, what is your present hourly rate (before taxes)? $_____ per hour. **(Leave blank if you are currently unemployed.)**

3. If you are **currently not working outside the house** and you were to take a job now, what do you think would be your approximate hourly rate? $_____ per hour. We recognize that you may be unable to return to work. However, we would like to have an idea of what your job opportunities might be if you could work. **(Leave blank if you are currently employed.)**

Part 5: Rehabilitation

1. How often do you exercise (do physical activity during your leisure time)?

(Circle One)

Daily or almost daily..... 1
4-5 times a week..... 2
2-3 times a week..... 3
About once a week..... 4
Less than once a week 5
Almost never or never 6

2. How good a job do you feel you are doing in taking care of your health? (Please circle one)

1. Excellent
2. Very good
3. Good
4. Fair
5. Poor

3. If currently unemployed and you worked in the past, why did you stop working? (Please circle all that apply) **(Skip if currently employed.)**

1. I am too sick/had too much time off
2. My job is physically too tiring
3. I am retired
4. I am needed for other duties
5. My dialysis treatment is too demanding
6. My employer had no other job, hours, etc
7. I didn't want/need to work any more
8. My dialysis facility schedule is not flexible
9. I would lose benefits which are close to what I could earn

4. Given the opportunity, would you like to return to work?
(Please circle one best answer)

1. Full time
2. Part time
3. Not at all
4. Not sure

If you are retired or a homemaker or are on CAPD you may skip to question 6.

5. How does each of the following statements reflect the impact of your dialysis treatment sessions on your work schedule?

	I AGREE WITH THIS STATEMENT: (Circle one per line)				
	Extremely	Quite a bit	Moderately	Slightly	Not at all
a) My current dialysis schedule does not/would not interfere with a work schedule	1	2	3	4	5
b) If it was necessary, my dialysis schedule could probably be changed to allow me to work	1	2	3	4	5
c) There is not a shift available that would allow me to work	1	2	3	4	5

6. Were you assisted in completing this form?

Yes	No
1	2

7. If Yes, who helped?

Family member	Dialysis unit personnel	Other
1	2	3

END OF QUESTIONNAIRE, THANK YOU!!

Abstractor's Initials ☐☐

Today's Date: ☐☐ ☐☐ ☐☐ (mm dd yy)

USRDS
DMMS Follow-Up Study
Medical Update Questionnaire

Patient Name_____

DMMS ID#_____

Date at Day 60 of ESRD (Date A.7)_____

Modality at Day 60 of ESRD (Date A.7)_____

(If Hemo, please fill out section on Vascular Access on back of page)

Check box to left of item if unable to determine, and leave item (right) blank.

A. Patient Status Since Day 60 of ESRD (Date A.7)

☐ 1. We need to know the first change in patient status or modality since _____ (Day 60 of ESRD). The date of this **FIRST** change in patient status or modality since Day 60 of ESRD was:

Please enter date of **FIRST** change

Date: ☐☐ ☐☐ ☐☐ (MM DD YY)

(**Please enter Today's Date if there was no change in the patient's status or modality**. If unavailable, give month and year or year only.)

For the date you just entered, give the code for patient status:

Codes for Change in Status or Modality ☐

1=had no change in status or modality
2=changed to PD (for at least 2 weeks)
3=changed to hemodialysis (for at least 2 weeks)
4=changed to home hemodialysis (for at least 2 weeks)
5=had return of renal function
6=transferred to another facility
7=received a kidney transplant
8=died
9=was lost to follow-up
10=withdrew from dialysis

☐ 2. The patient's **current** status is (please enter code): ☐

1-alive 2-died 3-lost to follow-up

If the patient died, please enter the date of death. If the patient is living or lost to follow-up, please enter the date that the patient was last know to be alive.

Date: ☐☐ ☐☐ ☐☐ (MM DD YY)

B. BUN and Residual Renal Function

Complete this section only for patients from your unit who are currently on in-center hemodialysis or peritoneal dialysis. Use information as close as possible to today's date, that is not more than 60 days from today's date.

☐ 1. The patient's current modality of treatment is: ☐
1-hemo 2-PD (CAPD or CCPD)

☐ 2. The approximate urine output of the patient is currently: ☐
1 - greater than 200 ml/day
2 - less than 200 ml/day (200 ml is about 1 cup)

3. BUN and weight:
All values for a. and b. must be from same date

☐ a. Pre-dialysis BUN ☐☐☐ mg/dl
(most recent if PD)

Pre-dialysis Weight
☐☐☐ lbs ***or*** ☐☐☐.☐ kg

☐ b. Post-dialysis BUN ☐☐☐ mg/dl
(Hemo Patients Only)

Post-dialysis Weight
☐☐☐ lbs ***or*** ☐☐☐.☐ kg

Question #4 is Voluntary.

4. Residual Renal Function **(Do not complete this item if urine volume is less than 200 ml/day.)**

☐ a. Urine collection time:

Start: (Post dialysis for hemo patients)

☐☐ ☐☐ ☐☐ / ☐☐ : ☐☐ ☐
mm dd yy hr min AM=1 PM=2
Date Time

End: (Usually next pre-dialysis treatment for hemo patients)

☐☐ ☐☐ ☐☐ / ☐☐ : ☐☐ ☐
mm dd yy hr min AM=1 PM=2
Date Time

Total hours of urine collection (Verification)..... ☐☐

☐ b. Lab Values

	Value	Units
Urine Volume	☐,☐☐☐	ml or cc
Urine Creatinine	☐,☐☐☐	check one ☐mg/vol
Urine Urea Nitrogen	☐,☐☐☐	☐mg/24 hrs. ☐mg/dl=mg%
Start Serum Creatinine*	☐☐.☐	mg/dl
Start BUN*	☐☐☐	mg/dl
End Serum Creatinine*	☐☐.☐	mg/dl
End BUN*	☐☐☐	mg/dl

** For PD patients, enter only one set of serum creatinine and BUN values (START) taken on a date as close as possible to the date of urine collection. ***Start*** and ***End*** refer to the same point in time as in 4a above.

USRDS
DMMS Follow-Up Study

Medical Update Questionnaire

Patient Name_____

DMMS ID#_____

Date at Day 60 of ESRD (Date A.7)_____

Modality at Day 60 of ESRD (Date A.7)_____

Check box to left of item if unable to determine, and leave item (right) blank.

C. Vascular Access Update (Patients who were on Hemo on Day 60 of ESRD)

Complete this section only if patient was on hemo at Day 60 of ESRD. We need to know the status of this patient's **FIRST PERMANENT VASCULAR ACCESS**. Please complete the following items with information from the patient's medical record. **Please complete this section even if the patient has died or changed modality.**

Codes to be used for type of vascular access

1-AV fistula
2-PTFE graft
3-Bovine graft
4-Permcath 5-Other

☐ 1. Has a permanent vascular access **ever** been created or attempted in this patient? ☐ 1-Yes 2-No

If NO, please do not complete the rest of this section on Vascular Access (Items 2-6)

☐ 2. This patient's Medical Questionnaire indicated that on or before _____(Date 60 of ESRD), the patient had the following type of **first permanent access**: _____.

If this is incorrect, please provide the correct answer using codes 1-4 from above. ☐
(If C.2 is correct, please leave this box blank)

If C.2 above is blank, what was the **first permanent vascular access** created or attempted? ☐
(Use one of codes 1-5 from above.)

☐ What **SIDE** was this **first permanent access** placed on? ☐ 1-Right 2-Left

☐ 3. The patient's Medical Questionnaire indicated that the date of surgery for creation of first permanent vascular access was:

Date: ☐☐ ☐☐ ☐☐
MM DD YY

If incorrect or blank, please provide the date of the surgery for creation of the **first permanent vascular access:**

Date: ☐☐ ☐☐ ☐☐
MM DD YY

☐ 4. Was this first permanent access ever used for dialysis? ☐ 1-Yes 2-No

If **YES**, what was the first date that this permanent access was used for dialysis?

☐ Date: ☐☐ ☐☐ ☐☐
MM DD YY

If **NO,** did this first permanent access fail to mature adequately for dialysis? ☐ 1-Yes 2-No

☐ 5. Did this first permanent access fail after being used for dialysis? ☐
1-Yes 2-No 3-Unknown

If **YES**, please provide the date of first failure.

Date: ☐☐ ☐☐ ☐☐
MM DD YY

If **NO** or **UNKNOWN**, please provide the last known date the access was used for dialysis.

Date: ☐☐ ☐☐ ☐☐
MM DD YY

☐ 6. Were there any revisions or procedures made to this first permanent access? ☐
1-Yes 2-No 3-Unknown

If **YES,** please give the FIRST two dates and type of revisions (or procedures) that were made subsequent to the date provided in C.3. Please use the codes provided.

1-Thrombolysis
2-Balloon angioplasty with or without thrombolysis
3-Surgical repair or declotting
4-creation of a new AV fistula
5-creation of a new PTFE graft (e.g. Goretex)
6-creation of another permanent access (e.g. Permcath)
7-other

First Revision or Procedure:

Date: ☐☐ ☐☐ ☐☐
MM DD YY

Type: ☐ (use codes 1-7 above)

Second Revision or Procedure: Was there a second revision or procedure **within two weeks of the first one**? If yes, please indicate the type using codes 1-7 from above and the date**:**

Date: ☐☐ ☐☐ ☐☐
MM DD YY

Type: ☐ (use codes 1-7 above)

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE!

DMMS Wave III, IV, & FACS
Special Study Data Forms

- **DMMS Wave III-IV Special Study Data Forms**
  Instruction Manual for Clinical Questionnaire
  Clinical Questionnaire
  Confidential Report: Clinical Questionnaire
  Patient Tracking
- **DMMS FACS Special Study Data Forms**
  Dialysis Facility/Unit Questionnaire

USRDS
Dialysis Morbidity and Mortality Study (DMMS)
Instruction Manual for Clinical Questionnaire

Questions? Feel free to call the USRDS Coordinating Center anytime for clarification of any of the instructions pertaining to completion of the forms for the DMMS. Please call and ask to speak with Liz Holzman.

1-800-707-0044

General Overview

Questionnaires for the DMMS

There are two data collection instruments for the Dialysis Morbidity and Mortality Study (hereafter referred to as the DMMS).

1) **The Clinical Questionnaire** should be completed for all patients selected for the DMMS and is designed to collect patient-specific information. On average, the Clinical Questionnaire should not take more than 1 ¼ hours to complete. If dialysis unit staff are spending more than 1 ¼ hours *on average* completing these questionnaires, please contact Liz Holzman at the USRDS Coordinating Center (1-800-707-0044). In these cases, it is likely that some of the information is too difficult to obtain.
2) **The Dialysis Unit/Facility Questionnaire** is to be completed by a staff person at the dialysis unit only once, preferably by a nurse or technician and should then be returned to the ESRD Network. Separate instructions for this questionnaire can be found attached to the Dialysis Unit/Facility questionnaire.

Please complete the forms in blue or black ink or dark pencil.
Please PRINT legibly in CAPITAL LETTERS.

Who Should Complete the DMMS Clinical Questionnaire?

Data abstraction of patient records for the Dialysis Morbidity and Mortality Study (hereafter referred to as the DMMS) is to be completed by personnel at the dialysis facilities. The Clinical Questionnaire is best completed by someone with a clinical dialysis background, such as an R.N. **Take all information from the facility/unit records, including medical records, billing records, dialysis logs, patient rosters, hospital records and personal physician records.**

Study Start Date

The Study Start Date for the DMMS is December 31, 1993. The Study Start Date provides a selection criterion for drawing a sample of random patients to be studied. To be randomly drawn for inclusion in the DMMS, a patient had to be alive and on incenter hemodialysis on 12/31/93. Thus, a patient who died on December 20, 1993, (prior to the Study Start Date) should NOT be included in the study. However, a patient who died on January 4, 1994 MUST be included in the study. You will notice that many of the patients selected for the DMMS have died. Since we want to understand the differences between patients who live and patients who die, it is very important that a Clinical Questionnaire is completed on all patients, both those who have lived and those who have died.

Patient Tracking Form/Patient Identification as of 12/31/93

Each dialysis facility has been given a batch of Clinical Questionnaires to be completed. The first page of each Clinical Questionnaire is the **"Patient Tracking Form/Patient Identification as of 12/31/93".** This form needs to be completed for each patient by the dialysis unit abstractor. This form helps us to keep track of completed questionnaires and provides us with information about why an abstraction may not have been completed. This form assists you in locating the correct patient for record abstraction. On the Patient Tracking Form/Patient Identification as of 12/31/93 form, we have asked you to verify the patient's sex, date of birth, social security number, Medicare number and modality of care.

The sample of patients for the DMMS has been selected randomly. **It is very important that all the Clinical Questionnaires requested be completed on each and every one of these patients**. By completing all the Clinical Questionnaires you will help ensure the randomness of the sample. A random sample is critical to the validity of all the data collected and analyzed. Thus, it is critical that you do your best to locate each patient's record and complete each questionnaire. If you cannot complete a questionnaire, it is very important that you indicate the reason on the Patient Tracking Form. The following reason codes have been provided:

A. Patient stopped receiving treatment at this facility and transferred to another facility **prior to the Study Start Date of December 31, 1993**.
B. Patient died **prior** to January 1, 1994 or on the Study Start Date of December 31, 1993.
C. Patient was never treated at this unit.
D. Patient was not an incenter hemodialysis patient in the week of 12/31/93.
E. Patient had not received any treatments at this unit as of 12/31/93 but did receive treatments at this unit after 12/31/93.
F. Other: Please specify with a written explanation.

Please be aware that hospitalizations are NOT a reason for exclusion. If a patient was hospitalized in December of 1993, you should still complete a Clinical Questionnaire.

If you cannot complete a questionnaire, please use these codes to indicate the reason. Only complete the Reason Explanation section if Reason Code "F" has been used.

Please note that there is a section on the "Patient Tracking Form/Patient Identification as of 12/31/93" that is to be completed by the Network. Please do NOT complete this section. It will be completed by Network personnel after you return the completed Clinical Questionnaire to the Network.

Returning Forms to the ESRD Network

Copies of completed Clinical Questionnaires should be submitted to the Network monthly. You have been provided with a **Batch Cover Sheet** which lists all the patients included in your batch of Clinical Questionnaires. Please be sure to use this form to indicate the **date** that each Clinical Questionnaire is returned to the Network. Each month, when you return forms to the Network, make a copy of the Batch Cover Sheet and return it along with the completed forms. Be sure to retain your original Batch Cover Sheet. It is important that you make a copy of the Batch Cover Sheet and send it along with completed questionnaires to your Network each month.

Skipping Items

If the answer to an item cannot be determined, **leave the item blank and put a check mark in the small box to the left of the item number.** This will indicate that you looked for the information in all available records and, if appropriate, tried to obtain the information from the patient and then decided that you could not determine an answer for the item. When information is not available to answer a question, checking the box on the left is important because it indicates that the item was not inadvertently skipped or forgotten. For Example on page 1 of the Clinical Questionnaire question #3 reads:

☑ 3. Ethnicity:..... ☐ If this information cannot be obtained, please put a check in the small box to the left of the question.

1 - Hispanic Origin 2 - Not of Hispanic Origin

Date Formats

Dates are either in month (mm) day (dd) and year (yy) format, or in month and year format. **In all cases, month and day must be expressed in 2 digits.** For example, the first day of January 1996 is 01/01/96. The year is expressed by the last two digits of the year; e.g. 94 for 1994.

If you are able to report partial information only, do so but also put a check in the small box to the left of the item number.

Right Justification

Right justify all entries. For example, if a patient has a serum creatinine of 9.8 enter the item as follows:

		9	**.**	**8**

Abstractor's Comments Box

On the last page of the Clinical Questionnaire, there is an Abstractor's Comments Box. Please use this box to write any information that you believe is important to explain the response to an item. Please be sure to indicate to which item you are referring.

Use of Abstractor Judgment

A medical record may not state explicitly the information that the Clinical Questionnaire is designed to capture. **The integrity of the data collection effort rests on the expertise and professionalism of the abstractors in interpreting the information contained in the medical record**. In many instances where specific information for an item is not in the record, the abstractor may be able to logically infer the answer to the item from other information in the record. For example, elevated blood pressure over a long period of time implies hypertension. **Abstractors should not make inferences without very careful consideration but should make inferences when they believe that the record supports drawing a conclusion. An inference can be made when the abstractor feels that 8 or 9 out of 10 abstractors reviewing the same record would agree**. Use of abstractor judgment helps in obtaining the most complete set of data about a patient's history and medical status as possible.

Detailed Instructions for the DMMS Clinical Questionnaire

You do NOT need to read the entire "Detailed Instructions for the DMMS Clinical Questionnaire. Please use these instructions as a reference manual. Refer to these instructions only in cases where you are unsure about how to answer a particular item.

Section A: Patient Background Information

Please remember to put a check in the small box to the left of the item number if the information is either not available or if only partial information is available.

Item	Description	Instructions
A.1	Abstractor initials	Enter your initials.
A.2	Date Completed	Enter the date that you complete the form.
A.3	Patient's Ethnicity	Enter the appropriate code for ethnicity.
A.4	Patient's Race	Enter the appropriate code for race.
A.5	Patient's Zip Code	Enter the zip code for the patient's address.
A.6	Date of first ever regular dialysis	Enter the date that the patient first started receiving regular dialysis treatments for chronic renal failure. If the entire date is unavailable, please give the year only. "Regular" is defined as either hemodialysis or peritoneal dialysis at least once a week. Please do NOT include sporadic dialysis treatments provided solely for treatment of fluid overload or heart failure.

Section B: Insurance Information at 12/31/93

B.1-B.12	Insurance information at 12/31/93	Please indicate if the patient had the following types of insurance in **December of 1993** and whether it was primary or secondary. Indicate only ONE insurance as primary. All other payment sources should be indicated as secondary. You may want to obtain information from your billing clerk.

Section C: Patient History Within 10 Years Prior to Study Start Date of 12/31/93

Abstractor judgment is very important in this section. If there is no specific mention of a particular disease, (e.g. coronary artery disease) but there is convincing evidence that the patient has a history of this disease (e.g. chest pain), you should answer "suspected" (code 3). If an otherwise very complete medical record contains no information on whether the patient has a history of a particular disease, you should assume that there is no history of that disease (code 2). However, if all the available medical records are very sketchy and there is no mention of a history of a particular disease, the item should be considered indeterminate. In this case, leave the item blank and check the small box on the left.

Be careful to put checks in the small left hand boxes only for those questions for which you cannot determine an answer but not for items which the form specifically instructs you to skip. For example, if the patient does not have a history of cancer, item C.25, enter "2" for no and **skip items C.26 and C.27 and do not check the left hand boxes for the appropriately skipped items.** Remember to use the Abstractor's "Comments Box" if you need to further explain any of your answers.

Item	Description	Instructions
C.1	Primary cause of ESRD	Enter the code for the primary cause category of the patient's ESRD.
C.2	Regular cigarette smoking status at 12/31/93	Enter the correct code.
C.3-C.10	Hx of Coronary Heart Disease (CHD) or Coronary Artery Disease (CAD) at 12/31/93	Enter yes, no or suspected for items C.3-C10. If C. 8 is "no", skip to item C.10.
C.11-C.12	Hx of Cerebrovascular Disease at 12/31/93	Enter the code for yes, no or suspected for each of the two events listed.
C.13-C17	Hx of Peripheral Vascular Disease (PVD) at 12/31/93	Enter the appropriate code for yes, no or suspected for items C.13-C.17.
C.18-C.20	Hx of Heart Disease (other than CHD/CAD) at 12/31/93	Enter the appropriate code for yes, no or suspected for items C.18-C.20
C.21-C.23	History of Diabetes at 12/31/93 Insulin therapy and diabetic pills	Enter the appropriate code for yes, no or suspected. Note that the answer to this question can be yes even if diabetes was not considered the cause of ESRD. If C.21 is "no", skip to item C.24. For items C.22 and C.23 enter the code for "active", "former" or "never". If the patient was on insulin therapy or diabetic pills as of

		12/31/93 then the correct answer is "active". If the patient received insulin therapy or diabetic pills at any time in the ten years prior to 12/31/93 but NOT at 12/31/93 then the correct answer is "former". If the patient did not receive insulin therapy or diabetic pills at any time in the past 10 years then the correct answer is "never".
C.24	Hx of Lung Disease at 12/31/93	Enter the appropriate code for yes, no or suspected.
C.25-C27	History of Cancer at 12/31/93	For item C.25, enter the appropriate code for yes, no or suspected. Do not include skin cancer. If no, skip to item C.28. For C.26, enter the appropriate code of 10-25 for the primary sites of the neoplasms. You may enter up to two primary sites. *Skin cancer with the exception of melanoma should not be recorded.* For item C.27, enter the 2 digit year of the date of first diagnosis of cancer.
C.28	HIV Status at 12/31/93	Enter the appropriate code for positive, negative, unknown or unable to disclose. A positive HIV status implies a positive serologic (blood) test result for the virus that causes AIDS.
C.29	AIDS Diagnosis at 12/31/93	Enter the appropriate code for positive, negative, unknown, or unable to disclose. A diagnosis of AIDS implies a positive HIV status and clinical disease such as infections or neoplasms.

Section D: Patient Information at Study Start Date of 12/31/93

For Section D, you may use information from the period extending from 30 days prior to 12/31/93 to 30 days after 12/31/93. Unless otherwise indicated, please use information closest to 12/31/93. Remember to use the Abstractor's "Comments Box" if you need to further explain any of your answers.

Item	Description	Instructions
D.1	Height	Enter the patient's height in feet and inches or centimeters. **This item is required. Please make every attempt to obtain this information.** If unavailable, measure the patient or ask the patient. **This value should fall within the range of 3 ft 3 in to 7 ft 5 in or 100 centimeters to 230 centimeters. Please check the appropriate box if the value entered falls outside the range. Explain in Abstractor's Comments Box.** If the patient is a bilateral amputee, please give the original height of the patient and check the box indicating that the patient is an amputee.
D.2	Dry Weight as ordered	Enter the prescribed dry weight as ordered nearest 12/31/93

D.3	Undernourished or cachectic (malnourished)	Enter the appropriate code for yes, no or suspected. Base your answer on information from the medical record in the period between 30 days prior to 12/31/93 to 30 days after 12/31/93.
D.4	In what shift did the patient usually receive dialysis treatments in December 1993.	Enter the appropriate code for morning shift, afternoon shift or evening/night shift according to treatment starting time.
D.5	Predialysis blood pressure and weight	For item D.5, enter the three most recent predialysis readings **before 12/31/93** for blood pressure, preferably from a sitting position (systolic and diastolic); enter predialysis weights, taken on the same day as the blood pressure readings. Be sure to indicate whether the weight is measured in pounds or kilograms.
D.6	Postdialysis BP and weight	For item D.5, enter the three most recent postdialysis readings **before 12/31/93** for blood pressure, preferably from a sitting position (systolic and diastolic); enter postdialysis weights, taken on the same day as the blood pressure readings. Be sure to indicate whether the weight is measured in pounds or kilograms.
D.7	Prescribed Dialysate	Enter the appropriate code for bicarbonate or acetate dialysate, as prescribed or usually used in December 1993.
D.8	Prescribed length of treatment	Please enter the prescribed length of treatment in total minutes in December 1993.
D.9	Prescribed number of dialysis sessions per week	Enter the prescribed number of dialysis sessions per week in December 1993. **When you multiply D.9 by D.8, this value should fall between 360 minutes and 810 minutes. If the value falls outside the range, please check the appropriate box and explain in Abstractor's Comments Box.**
D.10	Actual blood flow rate (BFR) in the last week before 12/31/93	Enter the blood flow rate. If variable give the usual or most common reading.
D.11	Dialysate flow rate from prescription or flow sheet in the last week before 12/31/93.	Enter the dialysate flow rate.
D.12	Was patient usually using a reprocessed/reused dialyzer at 12/31/93?	Enter the appropriate code. If YES, skip to item D.14.
D.13	If reuse did not occur, please indicate reason	Please enter code for reason that reuse did not occur in December, 1993.
D.14	Dialyzer type used	Please enter, using the codes provided on the last page of this questionnaire, the type of dialyzer used in December 1993. If you enter code 9999, please specify the manufacturer and dialyzer

		model.
D.15	Vascular access in use at 12/31/93	Please enter the code for the vascular access in use at 12/31/93.
D.16	Date of placement of this access (if available)	Please enter the date that the access in use at 12/31/93 was placed. If not available, enter the year only.
D.17	Number of hemodialysis treatments skipped by the patient during the 30 days prior to 12/31/93	Please enter the # of treatments skipped. Do NOT include treatments missed while the patient was in the hospital.
D.18	Number of prescribed hemodialysis treatments shortened by more than 10 minutes during the 30 days prior to 12/31/93	Please enter the number of shortened treatments. Do NOT include skipped treatments.
D.19	Did the patient have a renal transplant before 12/31/93?	Please enter the appropriate code.
D.20	Did the patient have a bilateral nephrectomy (i.e., anephric) before 12/31/93?	Please enter the appropriate code.

Section E: Psychosocial Evaluation

Complete this section with information from the psychosocial evaluation most recent before 12/31/93. Use social worker's evaluation supplemented by the nurse's and/or dietitian's records. You may need to consult with the social worker.

E.1-E.5	Activities of daily living at 12/31/93.	For items E.1-E.5 enter the appropriate code as of 12/31/93.
E.6	Marital status at 12/31/93	Enter the appropriate code.
E.7	Living arrangements at 12/31/93	Enter the appropriate code.
E.8.	Education	Enter the most appropriate code.
E.9	Primary occupation before onset of ESRD	Enter the most appropriate code. Before ESRD means before the first ever dialysis treatment or kidney transplant.
E.10	Employment level at 12/31/93.	Enter the code for the one most appropriate employment category for the patient at 12/31/93.
E.11	If unemployed, was patient	Enter the appropriate code.

	looking for employment at 12/31/93	

Section F: Laboratory Data

For hematocrit and EPO information, you may use information from December 1, 1993-January 31, 1994. For all other information in this section, you may use information from the period of October 1, 1993 through January 31, 1994 to complete this section. Always use information as close as possible to 12/31/93.

Item	Description	Instructions
F.1	Cardiomegaly by X-ray	Please enter code for yes or no. Use information from X-ray report as close as possible to 12/31/93.
F.2	Left ventricular hypertrophy by EKG	Please enter code for yes or no. Use information as close as possible to 12/31/93.
F.3.	Left ventricular hypertrophy by echocardiography	Please enter code for yes or no. Use information as close as possible to 12/31/93.
F.4.	Total serum calcium, predialysis	Please enter the value using information as close as possible to 12/31/93.
F.5	Serum phosphate or phosphorous, predialysis	Please enter the value using information as close as possible to 12/31/93.
F.6	Serum bicarbonate or CO_2, predialysis	Please enter the value using information as close as possible to 12/31/93.
F.7	Serum creatinine, pre-dialysis	Please enter the value using information as close as possible to 12/31/93.
F.8	Serum creatinine before **first ever** dialysis	For patients first diagnosed with ESRD in 1993, please give the serum creatinine before first dialysis.
F.9	Total white blood count	Please enter the value using information as close as possible to 12/31/93.
F.10	Neutrophil or PMN %	Please enter the percentage using information from F.9 report.
F.11	Lymphocyte %	Please enter the percentage using information from F.9 report.
F.12	Hematocrit	Please enter the hematocrit percentage. If transfused, give the value **before** transfusion. **Should fall within range of 14 to 55. If value falls outside range, please check the appropriate box and explain in Abstractor's Comments Box.** Remember that information should be from the period of one month prior to 12/31/93 to one month after 12/31/93 and should always be the closest available to 12/31/93.

F.13	Hemoglobin	Please enter the value to the nearest tenth. If transfused, give the value before the transfusion. Please try to give value from same date as item F.12. Remember that information should be from the period of one month prior to 12/31/93 to one month after 12/31/93 and should always be the closest available to 12/31/93.
F.14	Transfused in December 1993	Please enter the code for yes or no. If NO, please skip to item 16. Remember that this information should be only for the month of December 1993.
F.15	If transfused, number of transfusions in December 1993	Please enter the number of transfusions (i.e, number of units of blood) given during December 1993.
F.16	Was patient receiving EPO during December 1993?	Please enter the code for yes or no. If yes, please give the latest date in December 1993 that EPO was administered.
F.17	Was patient receiving EPO 60 days prior to the date provided in item 16?	For example, if the date provided in item 16 was December 15, 1993, was the patient receiving EPO on October 15, 1993.
F.18	Units of EPO per administration on date provided in item 16.	Indicate the units of EPO per administration at date provided in item 16. If the delivered units per administration is not available, please give the prescribed. Also give the total WEEKLY dose during December 1993. If delivered is not available, give prescribed.
F.19	Number of administrations of EPO per week during December 1993.	Enter the number of administrations per week. If delivered is not available, please enter the prescribed number of administrations per week. Please also indicate the route of administration.
F.20	BUNs	Please provide BUNs for Sept-Dec 1993. Please be sure to use BUNs for pre and post dialysis that are from the same date within each month. For example, if the predialysis BUN for Sept is from Sept 23 then the post dialysis BUN should also be from Sept 23. **Pre BUN should fall within a range of 25 to 240 mg/dl. If value(s) fall outside range, please check the appropriate box. Post BUN must fall within a range of 10 to 150 mg/dl. If value(s) fall outside range, please check the appropriate box. Also please explain values that fall outside range in the Abstractor's Comments Box.**
F.21	Weight	Please provide pre and post dialysis weights for the months of Sept-Dec 1993. Again, be sure to use the same dates used for item F.16. For example, if BUNs for Sept are from Sept 23 then the pre and post dialysis weights for Sept should also be from this date.

		Please be sure to indicate the unit of measurement used (pounds or kilograms). Weights should fall within a range of 25 to 215 kilograms or 50 to 470 pounds. If value(s) fall outside range, please check the appropriate box. Also please explain values that fall outside range in the Abstractor's Comments Box.
F.22	Predialysis serum albumin	Please provide serum albumin for the months of September through December 1993. These values may be from a different day in the same month.
F.23	Duration of dialysis **in minutes.**	Please provide the duration of dialysis using the same dates used for items F.20 and F.21. for each of the months of September through December 1993. Please use actual duration; if not available, please use prescribed.
F.24-F.29	Lipids, etc. at 12/31/93	For each of items F.24-F.29, please provide the values requested. Please use information as close as possible to 12/31/93.

Section G: Medications

Item	Description	Instructions
G.1	Medications at 12/31/93	Please copy the list of all medications (prescribed and over the counter) as of 12/31/93, as either generic or trade names. Please provide the dosage (amount and units) and frequency as well.
G.2	Was the patient receiving injectable vitamin D (Calcijex) at 12/31/93?	Please enter the code for yes, no or uncertain.
G.3	Were blood pressure medications withheld before dialysis in December 1993?	Please enter the code for yes, no or uncertain.

Section H: Patient Status Since 12/31/93

Item	Description	Instructions
H.1	First event after 12/31/93	Please indicate which was the FIRST event after 12/31/93. Switches to PD or Home Hemo should be for more than 2 weeks to be counted as a switch. Transfers to another dialysis facility should be for more than one month to be counted as a switch. ALL TRANSPLANTS should be counted as a switch, even if the transplant fails and the patient almost immediately returns to incenter hemodialysis.
H.2	Date of first event	Please indicate the date of the FIRST event referred to in item H.1.

		If unavailable, please provide the year only. Please leave this item blank if the patient is still alive and never switched off incenter hemo. If patient status is unknown, please enter the date of the last know incenter hemodialysis treatment at this dialysis unit.
H.3	Did the patient die since 12/31/93?	If the first event referred to in item H.1 was NOT a death, did the patient die since 12/31/93? If yes, please provide the date of death. If unavailable, please give the year only.

Thank you for your help in completing the DMMS Clinical Questionnaire!

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DMMS
Clinical Questionnaire

STUDY START DATE 12/31/93

Check the box to the left of item if unable to determine the correct answer, and leave box (right) blank.

A. Patient Background Information

1. Abstractor initials..... ☐☐
2. Date completed ..... ☐☐-☐☐-☐☐
   mm dd yy
3. Patient's ethnicity..... ☐
   1. Hispanic Origin
   2. Not of Hispanic Origin
4. Patient's race..... ☐
   1. White
   2. Black
   3. Asian
   4. Native American
   5. Other
5. Patient's zip code..... ☐☐☐☐☐
6. Date of first ever regular dialysis for chronic renal failure (at least once weekly, regardless of hospital or facility setting). Please exclude sporadic dialysis treatments for fluid overload or heart failure.

   (If month and day unavailable, give year only)

   ☐☐-☐☐-☐☐
   mm dd yy

B. Insurance Information at 12/31/93

Please indicate if the patient had the following types of insurance and whether it was primary or secondary in December 1993. (If not known to be primary or secondary, list in secondary payer column.)

For each field indicate: 1 = Yes 2 = No

☐ Insurance Carrier	Primary Payer	Secondary Payer
1. Blue Cross		
2. Private Insurance		
3. HMO		
4. Medicare Part A & Part B		
5. Medicare Part A only		
6. Medicare Part B only		
7. Medicaid		
8. VA		
9. Medicare Pending		
10. No Insurance		
11. Charity Care		
12. Other (Specify)		

C. Patient History within 10 Years prior to Study Start Date of 12/31/93

1. Primary cause of ESRD..... ☐
   1. Diabetes
   2. Hypertension
   3. Primary glomerulonephritis
   4. Polycystic kidney disease
   5. Other_____

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STUDY START DATE 12/31/93

Check the box to the left of item if unable to determine the correct answer, and leave box (right) blank.

2. Regular cigarette smoking status at 12/31/93 ☐

   1. Active (still smoking)
   2. Former, stopped <1 year ago
   3. Former, stopped >1 year ago
   4. Smoker, status unknown
   5. Non-smoker

History of Coronary Heart Disease (CHD) or Coronary Artery Disease (CAD) at 12/31/93

1 = Yes 2 = No 3 = Suspected

3. Prior diagnosis of CHD/CAD ☐
4. Angina. ☐
5. Myocardial infarction (MI) ☐
6. Bypass surgery ☐
7. Coronary angioplasty (PTCA) ☐
8. Coronary angiography ☐

(If 8 is "no", skip to item 10)

9. Was coronary angiography abnormal? ☐
10. Cardiac arrest ☐

History of Cerebrovascular Disease at 12/31/93

1 = Yes 2 = No 3 = Suspected

11. Diagnosis of cerebrovascular accident (CVA, stroke) ☐
12. Any transient ischemic attacks (TIA)? ☐

History of Peripheral Vascular Disease (PVD, PVOD) at 12/31/93

1 = Yes 2 = No 3 = Suspected

13. Prior diagnosis of PVD ☐
14. Limb amputation due to PVD ☐
15. Limb amputation due to other causes ☐
16. Absent foot pulses ☐
17. Claudication ☐

History of Heart Disease (other than CAD/CHD) at 12/31/93

1 = Yes 2 = No 3 = Suspected

18. Congestive heart failure ☐
19. Pulmonary edema ☐
20. Pericarditis ☐

History of Diabetes at 12/31/93

1 = Yes 2 = No 3 = Suspected

21. Diagnosis of Diabetes. ☐

(If 21 is "no", skip to item 24)

22. Insulin therapy ☐

1 = Active 2 = Former 3 = Never

23. Diabetic pills (Oral hypoglycemic agents) ☐

1 = Active 2 = Former 3 = Never

Check the box to the left of item if unable to determine the correct answer, and leave box (right) blank.

History of Lung Disease at 12/31/93

1 = Yes 2 = No 3 = Suspected

24. Chronic obstructive pulmonary disease (COPD) ..... ☐

History of Cancer at 12/31/93

1 = Yes 2 = No 3 = Suspected

25. Cancer/neoplasm (other than skin) at 12/31/93 ..... ☐

(If 25 is "no", then skip to item 28)

26. Primary sites (report up to 2 sites) ..... ☐☐ ☐☐

10. Lung
11. Stomach/Esophagus
12. Breast
13. Pancreas
14. Prostate
15. Liver
16. Colon/Rectal
17. Myeloma
18. Lymphoma/Leukemia
19. Brain
20. Ovary/Uterus
21. Melanoma of skin
22. Bladder
23. Oral/Larynx
24. Kidney
25. Other_____

27. Year of first cancer diagnosis ..... 19☐☐

History of HIV at 12/31/93

28. HIV status ..... ☐

0 = Negative 1 = Positive 2 = Unknown 3 = Can't disclose

29. AIDS diagnosis ..... ☐

0 = Negative 1 = Positive 2 = Unknown 3 = Can't disclose

D. Patient Information at Study Start Date of 12/31/93

You may use information from the period extending from 30 days prior to 12/31/93 to 30 days after 12/31/93.

1. Height (at any time) **(Required)**

☐ft ☐☐in OR ☐☐☐cm

Should fall within range of 3'3" to 7'5" or 100 to 230 centimeters.

If value outside this range, please check this box ..... ☐

If bilateral amputee give original height and check this box.... ☐

2. Dry weight as ordered nearest study start date of 12/31/93

☐☐☐ lbs ☐☐☐.☐ kgs

3. Was patient undernourished or cachectic (malnourished) at 12/31/93?

..... ☐☐

1 = Yes 2 = No 3 = Suspected

4. What time of day did hemodialysis treatments for this patient start in December 1993? ..... ☐

1 = a.m. (5 a.m. - 12 noon) 2 = p.m. (12 noon - 6 p.m)
3 = Evening or Night (6 p.m. - 12 Midnight)

Blood pressure and weight; 3 most recent readings before 12/31/93.

5. Predialysis BP (sitting preferred) and weight

Please right justify entries

SBP	DBP	Weight
☐☐☐	☐☐☐	☐☐☐.☐
☐☐☐	☐☐☐	☐☐☐.☐
☐☐☐	☐☐☐	☐☐☐.☐

Check box **lbs☐ or kgs☐**

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STUDY START DATE 12/31/93

Check the box to the left of item if unable to determine the correct answer, and leave box (right) blank.

6. Postdialysis BP (sitting preferred) and weight

Please right justify entries

SBP	DBP	Weight
☐☐☐	☐☐☐	☐☐☐.☐
☐☐☐	☐☐☐	☐☐☐.☐
☐☐☐	☐☐☐	☐☐☐.☐

Check box lbs☐ or kgs☐

Hemodialysis prescription/actual at 12/31/93 (i.e., last week of December 1993)

7. Prescribed Dialysate..... ☐
   1 = Bicarbonate 2 = Acetate

8. Prescribed length of treatment: (Please give in **total minutes**)
   (Example: 3 ½ hours = 210 minutes)..... ☐☐☐ minutes

9. Prescribed number of dialysis sessions per week..... ☐
   D.8 x D.9 should fall within the range of 360 and 810 minutes per week. If value falls outside this range, please check this box. ☐

10. Actual blood flow rate (BFR) in last week before 12/31/93..... ☐☐☐ ml/min

11. Dialysate flow rate from prescription or flow sheet in last week before 12/31/93..... ☐☐☐ ml/min

12. Was patient usually using a reprocessed/reused dialyzer on or about 12/31/93?..... ☐
    1 = Yes 2 = No
    (If 12 is "no", skip to item 14)

13. If reuse did not occur, please indicate reason..... ☐
    1 = Unit does not re-use 2 = Patient refuses 3 = Hepatitis 4 = Other medical

14. Dialyzer type used in December 1993 (see codes on page 9)..... ☐☐☐☐

If you entered code 9999, please specify below the manufacturer and dialy er model

Manufacturer _____

Dialyzer Model _____

15. Vascular access in use at 12/31/93 ..... ☐
    1. AV fistula
    2. PTFE graft, (e.g. Gortex, Impra, Teflon)
    3. Bovine graft
    4. Permanent catheter with cuff (e.g. Permcath)
    5. Temporary internal jugular (I.J.) catheter
    6. Temporary subclavian catheter
    7. Temporary femoral catheter
    8. Other

16. Date of placement of this access.
    (If month and day unavailable, give year only)
    ☐☐-☐☐-☐☐ mm dd yy

17. Number of HD treatments skipped by patient during 30 days prior to 12/31/93. **Do not include treatments missed while in hospital.**..... ☐☐

18. Number of prescribed HD treatments shortened by more than 10 minutes by the patient during 30 days prior to 12/31/93. **Do not include skipped treatments.**..... ☐☐

19. Did the patient have a renal transplant before 12/31/93?..... ☐
    1 = Yes 2 = No

20. Did the patient have a bilateral nephrectomy (i.e., patient anephric) before 12/31/93? ..... ☐
    1 = Yes 2 = No

Check the box to the left of item if unable to determine the correct answer, and leave box (right) blank.

E. Psychosocial Evaluation

Complete the following questions with information from the most recent psycho-social evaluation before the STUDY START DATE of 12/31/93. Use social worker's evaluation supplemented by the nurse's and dietitian's records.

Activities of daily living at Study Start Date of 12/31/93

1 = Yes 2 = No

1. Able to eat independently?. ☐
2. Able to walk without assistance or assistive device? ☐
3. Walks with assistance? (e.g. person, cane, walker) ☐
4. Requires wheelchair? ☐
5. Able to transfer independently? ☐
6. Marital status ☐
   1. Single
   2. Married
   3. Widowed
   4. Divorced
   5. Separated
7. Living alone? ☐
   1. Yes
   2. No
   3. Nursing home, institution
   4. Homeless
8. Education ☐
   1. Less than 12 years
   2. High school graduate
   3. Some college
   4. College graduate
9. Primary occupation before ESRD ☐
   1. Clerical
   2. Professional
   3. Tradeperson
   4. Manual labor
   5. Student
   6. Not employed outside of home or homemaker
   7. Disabled
   8. Other _____
10. Employment level at 12/31/93. (Please indicate the one most appropriate employment category for the patient at 12/31/93) ☐
    1. Employed full time
    2. Employed part time
    3. Full time student
    4. Part time student
    5. Retired
    6. Not employed outside of home or homemaker
    7. Unemployed
    8. Disabled
    9. Other (specify)_____
11. If unemployed, was patient looking for employment at 12/31/93?.... ☐
    1 = Yes 2 = No

F. Laboratory Data, -ray, E

Complete this section with information <u>closest to study start date of 12/31/93</u> from a period extending to 3 months before 12/31/93 and one month after 12/31/93.

1. Cardiomegaly by X-ray.. ☐
   1 = Yes 2 = No 3 = Not done
2. Left ventricular hypertrophy by EKG ☐
   1 = Yes 2 = No 3 = Not done
3. Left ventricular hypertrophy by echocardiography ☐
   1 = Yes 2 = No 3 = Not done

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Check the box to the left of item if unable to determine the correct answer, and leave box (right) blank.

4. Total serum calcium, predialysis ..... ☐☐.☐ mg/dl
5. Serum phosphate or phosphorus, predialysis..... ☐☐.☐ mg/dl
6. Serum bicarbonate or CO_2, predialysis..... ☐☐.☐ mEq/L
7. Serum creatinine, predialysis ..... ☐☐.☐ mg/dl
8. For patients first diagnosed with ESRD in 1993, please give serum creatinine before first ever dialysis ..... ☐☐.☐ mg/dl

White Blood Count at 12/31/93

9. Total WBC..... ☐☐.☐ x 10^3 /mm^3
10. Neutrophil or PMN % ..... ☐☐ %
11. Lymphocyte %..... ☐☐ %

Hematocrit and EPO information at 12/31/93

Complete using information closest to 12/31/93 from a period extending to one month before 12/31/93 and one month after 12/31/93.

12. Hematocrit. (If transfused in December 1993, give value before blood transfusion)..... ☐☐.☐ %

This value should fall within range of 1 to 55. If value falls outside range, please check this box. ..... ☐

13. Hemoglobin. (If possible, give value from same date as item 12) ..... ☐☐.☐ g/dl
14. Transfused in December 1993? ..... ☐
    1 = Yes 2 = No
    (If 14 is "no", skip to item 16)
15. If transfused, number of transfusions in December 1993. ..... ☐
16. Was patient receiving EPO (Erythropoietin) during December 1993?.. ☐
    1 = Yes 2 = No
    (If 16 is "no", skip to item 20)
    If 16 is "yes", please give latest date in December 1993 that EPO was administered. ☐☐-☐☐-☐☐ (mm dd yy)
17. Was patient receiving EPO 60 days prior to date provided in item 16? ☐
    1 = Yes 2 = No
18. Indicate units of EPO per administration on date provided in item 16.
    If delivered is not available, please give prescribed.
    ☐ Delivered:..... ☐☐,☐☐☐
    ☐ Prescribed:..... ☐☐,☐☐☐
    If dose was variable, give total weekly dose.
    If delivered is not available, please give prescribed.
    ☐ Delivered:..... ☐☐,☐☐☐
    ☐ Prescribed:..... ☐☐,☐☐☐
19. Number of administrations of EPO per week during December 1993.
    If delivered is not available, please give prescribed.
    ☐Delivered ..... ☐
    ☐Prescribed..... ☐

Indicate the route of administration during the last week of December 1993.

1 = Intravenous 2 = Subcutaneous..... ☐

Confidential Report
DMMS
Clinical Questionnaire

STUDY START DATE 12/31/93

Check the box to the left of item if unable to determine the correct answer, and leave box (right) blank.

BUN, weight, serum albumin and duration of dialysis

Please provide BUN, weight, serum albumin and duration of dialysis as indicated. **Please be sure that in each of the months BUN, weight and duration are from the same day**. For example, if pre & post BUN are from 9/21/93 then the weight and duration of dialysis for September 1993 should also be from 9/21/93.

	09/□□/93	10/□□/93	11/□□/93	12/□□/93
Date: Please indicate the date used for obtaining the values.				
20. **BUN: Predialysis BUNs should fall within range of 25 to 2 0. If value(s) fall outside range please check box.....□** **Postdialysis BUNs should fall within range of 10 to 150. If value(s) fall outside range please check box.....□**				
□ predialysis	□□□ mg/dl	□□□ mg/dl	□□□ mg/dl	□□□ mg/dl
□ postdialysis	□□□ mg/dl	□□□ mg/dl	□□□ mg/dl	□□□ mg/dl
21. **Weight in lbs □ or □kgs. Please indicate units. Weights should fall within range of 25 to 215 kilograms or 50 to 70 lbs. If value(s) fall outside range, please check this box.....□**				
□ predialysis	□□□.□	□□□.□	□□□.□	□□□.□
□ postdialysis	□□□.□	□□□.□	□□□.□	□□□.□
22. Predialysis serum albumin (may be from different day in same month)	□.□ g/dl	□.□ g/dl	□.□ g/dl	□.□ g/dl
23. Duration of this dialysis **in minutes**. Example: 3 ½ hours = 210 min. (Actual preferred; if not available give prescribed.)	□□□ min	□□□ min	□□□ min	□□□ min

Lipid (etc.) information closest to study start date of 12/31/93 from a period of up to 3 months before 12/31/93 to one month after 12/31/93

24. Cholesterol total ..... □□□ mg/dl
25. HDL cholesterol..... □□□ mg/dl
26. LDL cholesterol ..... □□□ mg/dl
27. Triglycerides..... □□□□ mg/dl
28. Serum intact PTH..... □□□□ pg/ml
29. Serum Aluminum*..... □□□□ µg/ml

If aluminum available only from DFO test, please use base line measurement.

Check the box to the left of item if unable to determine the correct answer, and leave box (right) blank.

. Medications at 12/31/93

1. Please copy the list of all (prescribed and over the counter) medications as generic or trade names. Please give dosage (amount and units) and frequency. Leave dosage blank if unknown.

Codes for Frequency

1 = QD
2 = BID
3 = TID
4 = QID
5 = Every dialysis
6 = prn
= Less frequently than every dialysis
= More frequently than QID
= Unknown

	Medication	Dose	Freq.
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			

2. Was patient receiving at 12/31/93 injectable Vitamin D (Calcijex)?. ☐

1 = Yes 2 = No 3 = Uncertain

3. Were blood pressure medications withheld before dialysis in December 1993?..... ☐

1 = Yes 2 = No 3 = Uncertain

H. Patient Status Since 12/31/93

1. We need to know the sequence of changes in patient modality. Of the following, which was the **FIRST** event after 12/31/93?..... ☐

1. Switch to PD (for 2 or more weeks)
2. Switch to Home Hemodialysis (for 2 or more weeks)
3. Recovery of renal function
4. Transfer to another facility (for more than one month; **Do not include hospitali ations**)
5. Transplant
6. Death
7. Never switched off incenter hemodialysis
8. Patient status unknown

2. What was the date of the FIRST event referred to in item "1"?

(If month and day unavailable, give year only)

☐☐-☐☐-☐☐
mm dd yy

Leave blank if patient never switched off incenter hemodialysis; if patient status unknown in, enter date of last known incenter hemodialysis treatment.

3. If the FIRST event referred to in item "1" was **NOT a death**, did the patient die since 12/31/93?..... ☐

1 = Yes 2 = No 3 = Unknown

If yes, please provide the date of death.

(If month and day unavailable, give year only)

☐☐-☐☐-☐☐
mm dd yy

Abstractors Comments:

Dialy er Codes

ALTHIN CD

Code	Description
1108	ALTRA FLUX-140
1110	ALTRA FLUX-140 G
1111	ALTRA FLUX-170
1113	ALTRA FLUX-170 G
1145	ALTRA FLUX-200 G
1114	ALTRA NOVA-140
1116	ALTRA NOVA-140G
1117	ALTRA NOVA-170
1119	ALTRA NOVA-170 G
1136	ALTRA NOVA-200
1137	ALTRA NOVA-200 G
1120	ALTREX-140
1122	ALTREX-140 G
1138	ALTREX-200 G
1135	MCA-130
1139	MCA 130 S
1129	MCA-160
1140	MCA 160 S
1130	MCA-180
1141	MCA-200

ASAHI

Code	Description
1211	AM-SD 40M
1212	AM-SD 50H
1213	AM-SD 50M
1214	AM-SD 50U
1215	AM-SD 65H
1217	AM-SD 65U
1219	AM-SD 75U
1229	AM-SD 90U
1227	AM-UP 65
1228	AM-UP 75
1220	PAN-DX 110
1225	PAN-DX 65
1226	PAN-DX 85
1235	PAN-03
1236	PAN-06
1237	PAN-10

BAXTER

Code	Description
1307	CA 110
1308	CF 12
1309	CF 1211
1311	CF 15
1312	CF 1511
1313	CA 150
1314	CA 170
1315	CA 210
1316	CF 23
1317	CF 2308
1318	CF 25
1319	CA 50
1320	CA 70
1321	CA 90
1322	CT 110G
1323	CT 190G

C H MEDICAL

Code	Description
Cobe	
1400	CENTRYSYSTEM 100 HG
1401	CENTRYSYSTEM 200
1402	CENTRYSYSTEM 200 HG
1403	CENTRYSYSTEM 300
1404	CENTRYSYSTEM 300 HG
1405	CENTRYSYSTEM 400
1406	CENTRYSYSTEM 400 HG
1407	CENTRYSYSTEM 500 HG
Code	Description
Gambro	
1624	LUNDIA I.C. -3H
1625	LUNDIA I.C. - 3L
1626	LUNDIA I.C. - 3N
1628	LUNDIA I.C. - 4N
1629	LUNDIA I.C. - 5H
1630	LUNDIA I.C. - 5L
1631	LUNDIA I.C. - 5N
1633	LUNDIA I.C. - 6N
1636	MINI-MINOR
1640	ALPHA 400
1641	ALPHA 500
1642	ALPHA 600
1650	GFS PLUS 12-Allwall
1651	GFS PLUS 20-Allwall
Code	Description
Hospal	
1700	BIOSPAL 1200S ETO
1701	BIOSPAL 1800S ETO
1702	BIOSPAL 2400S Gamma
1703	BIOSPAL 3000GS Gamma
1708	FILTRAL-10
1709	FILTRAL-12
1710	FILTRAL-16
1711	FILTRAL-20

FRESENIUS

Code	Description
1509	F3
1500	F4
1502	F5
1504	F6
1512	F7
1507	F8
1501	F40
1503	F50
1513	F60A
1514	F60B
1515	F80A
1516	F80B
1510	F60M
1511	F80M

NMC

Code	Description
1803	FOCUS 120
1804	FOCUS 120H
1805	FOCUS 160
1806	FOCUS 160H
1807	FOCUS 70
1808	FOCUS 70H
1809	FOCUS 90
1810	FOCUS 90H
Code	Description
2200	PRIMUS 1000
2201	PRIMUS 1350
2202	PRIMUS 2000

TERUMO

Code	Description
2011	CL-C10NL
2012	CL-C12NL
2013	CL-C15NL
2000	CL-C061
2001	CL-C081
2002	CL-C101
2003	CL-C121
2020	CL-C151
2004	CL-M081
2005	CL-M101
2006	CL-M121
2007	CL-M151
2008	CL-T150L
2009	CL-T175L
2010	CL-T220L

TORAY

Code	Description
2100	B1-1.3H
2101	B1-1.6H
2112	B1-2.1U
2103	BK-1.0U
2104	BK-1.6U
2105	BK-2.1U
2113	BK-2.1P
2107	B2-0.5
2108	B2-1.0
2109	B2-1.0H
2110	B2-1.2H
2111	B2-1.5H
2114	B2-2.0

OTHER
9999 Please specify type on questionnaire

USRDS
Dialysis Morbidity and Mortality Study (DMMS)
Instructions for Facility/Unit Questionnaire

Questions? Feel free to call the USRDS Coordinating Center anytime for clarification of any of the instructions pertaining to completion of the forms for the DMMS. Please call and ask to speak with Liz Holzman. Our toll free number is 800-707-0044

General Notes

This questionnaire is to be filled out once only by each dialysis facility/unit participating in the USRDS Dialysis Morbidity and Mortality Study (DMMS-Prospective). **Please complete this form and submit it to your Network office.**

If the answer to an item cannot be determined, **leave the item blank by leaving the box on the right empty** and **put a check mark in the small box to the left of the item number.** This will indicate that you looked for the information in all available records and decided that you could not determine an answer for the item. When information is not available to answer a question, checking the box on the left is important because it indicates that the item was not inadvertently skipped or forgotten.

Dates

Dates are either in month (mm), day (dd) and year (yy) format or in month and year format. **In all cases, month and day must be expressed in 2 digits.** For example, January is 01 and the first day of the month is 01. The year is expressed by the last two digits of the year; e.g. 94 for 1994.

If you are able to report partial information only, do so but also put a check in the small box to the left of the item number. For example, if the records give the year of starting reuse but not the month or day, enter the year in the appropriate box, leave the month and day blank and check the box to the left of the item number.

In the top right hand corner of the first page, please be sure to complete the date that this questionnaire was completed.

Item	Description	Instructions
1.	Network	Enter the 2 digit number assigned to your network (For example, 03 for Network 3.)

2.	Medicare provider number	Enter the provider number for your unit. Please note that a large facility may have multiple provider numbers, i.e. one for its transplant facility and one for its dialysis unit. Be sure to enter the number pertaining to the dialysis unit. **Do not enter the billing number**.
3.	Facility name	Please PRINT the full name of the unit/facility.
4.	Laboratory information from reports at 12/31/93	
	a. Lower limit of normal for serum albumin	Enter the lower limit for serum albumin **from your lab using lab reports from December of 1993.**
	b. Upper limit of normal for PTH	Enter the upper limit for PTH **from your lab using lab reports from December 1993.**
	c. Type of lab assay for albumin	Please enter the appropriate code.
	d. Type of lab assay for PTH	Please enter the appropriate code.
5.	Does/Did the dialysis unit practice dialyzer re-use?	Enter the appropriate code for yes or no for both 12/31/93 and for the date of abstraction. If the answer is "no" for both 12/31/93 and for date of abstraction then skip to item 6.
	a. Before a <u>new</u> dialyzer was/is used, did/do you apply the re-use procedure?	Please enter the appropriate code for yes or no for both 12/31/93 and the date of abstraction. It refers to the usual procedure before the <u>first</u> use of a dialyzer.
	b. What was/is the re-use technique used in your facility?	Please enter the appropriate code for both 12/31/93 and the date of abstraction.
	c. Which machine was/is used for re-use?	Please enter the appropriate code for both 12/31/93 and the date of abstraction.
	d. Which dialyzer disinfectants were/are used?	Please enter the appropriate code for yes or no for <u>each</u> disinfectant for both 12/31/93 and the date of abstraction.
6.	Most common prescribed dialysate calcium concentration	Please enter the most common prescribed dialysate calcium concentration for both 12/31/93 and date of abstraction.
7.	Does/Did this unit use variable (modeled) dialysate sodium?	Please enter the appropriate code for yes or no for both 12/31/93 and date of abstraction. If answer is "yes" for either date, answer items 8 and 9. If answer is "no" for both dates, answer 8 only.

8.	Most common dialysate sodium prescription at start of hemodialysis treatment.	Enter the most common dialysate sodium prescription at start of treatment for both 12/31/93 and the date of abstraction.
9.	Most common dialysate sodium prescription at end of hemodialysis treatment	Enter the most common dialysate sodium prescription at end of treatment for both 12/31/93 and the date of abstraction.
10.	What data were used for URR or Kt/V calculation at 12/31/93?	Please check all the options that apply. If none of the options apply, please specify what data were used for URR or Kt/V calculation.
11.	Was residual renal function included in reported Kt/V at 12/31/93?	Please enter the appropriate code for yes or no.
12.	Types of water treatment. Indicate all that were normally used at 12/31/93.	Please enter the appropriate code for yes or no for each of the categories of water treatment at 12/31/93 for both reprocessing dialyzers (if re-using) and dialysate. Indicate all that are normally in use but do not include backup. If your facility does not reuse dialyzers, the column for reprocessing of dialyzers will not be filled out, otherwise both columns should be completed.
13.	Type of water source at 12/31/93	Enter the appropriate code for the predominant type of water source.
14.	Timing of post-dialysis BUN sample	Please enter the appropriate code for the timing of the post-dialysis BUN sample for both 12/31/93 and date of abstraction according to policy or, if a policy is not available, according to common practice. If "other", please specify timing of post dialysis BUN sample.
15.	Most common hemodialysis machine in use at 12/31/93.	Please answer by entering one of the codes provided. If you enter "999", please provide the manufacturer and model of most common hemodialysis machine used at 12/31/93.
16.	This machine (referred to in item 15) was what percentage of all actively used machines in December of 1993.	In answering this question, please do not include back-up machines or machines used for acute dialysis.
17.	Routine vascular access surveillance in December 1993.	Enter the code for the frequency of routine vascular access surveillance practiced in December of 1993.
18.	Were individual patients assigned to one physician or a team of rotating physicians in December 1993?	Enter the appropriate code for one physician or a team of rotating physicians. Of course, one physician may be covered by another during vacation.
19.	On average, how many times in a month did the typical patient have face-to-face contact with a physician either during hemodialysis or as an outpatient in December 1993?	Please enter the appropriate code for the average number of times the typical patient was seen by a physician in December 1993.

Thank you for your help in completing the Dialysis Unit/Facility Questionnaire

DIALYSIS UNIT/FACILITY QUESTIONNAIRE

DATE THIS QUESTIONNAIRE WAS COMPLETED

mm dd yy

If unable to determine the correct answer check the box to the left of item and leave (right) blank

➢ ☐ 1. Network.....☐☐

☐ 2. Medicare provider number (Not billing #).....☐☐☐☐☐☐

☐ 3. Facility name_____

☐ 4. Laboratory information from reports at 12/31/93

☐ a. Lower limit of normal for serum albumin.....☐.☐ g/dl

☐ b. Upper limit of normal for PTH.....☐☐☐.☐ units

☐ c. Type of lab assay for albumin.....☐

1 = Brom cresol purple 2 = Brom cresol green 3 = Unknown

☐ d. Type of lab assay for PTH.....☐

1 = Intact 2 = N-terminal 3 = C-terminal 4 = Unknown

☐ 5. Does/did the dialysis unit practice dialyzer re-use?

1 = Yes 2 = No

At 12/31/93 ☐ At Date of Abstraction ☐

(If 5 was "no" for both 12/31/93 and the Date of Abstraction, skip to item 6)

☐ a. Before a new dialyzer was/is used, did/do you apply re-use procedure?

1 = Yes 2 = No

At 12/31/93 ☐ At Date of Abstraction ☐

☐ b. What was/is the re-use technique used in your facility?

At 12/31/93 ☐ At Date of Abstraction ☐

1 = Manual 2 = Automated 3 = Semi-Automated 4 = Combination

☐ c. Which machine was/is used for re-use?

Enter appropriate code

At 12/31/93 ☐ At Date of Abstraction ☐

1 = Fresenius "DRS = 4"

2 = Mesa Labs "Echo"

3 = Renal System "Renatron" (single or multiple)

4 = National Medical Care "semi-automated"

5 = Other? Please specify_____

☐ d. Which dialyzer disinfectants were/are used?

Answer for each® 1 = Yes 2 = No

	At 12/31/93	At Date of Abstraction
Bleach in dialyzer	☐	☐
Formalin (Formaldehyde) in dialyzer	☐	☐
Peracetic Acid (Renalin) in dialyzer	☐	☐
Glutaraldehyde in dialyzer	☐	☐
Heat sterilization (e.g. with citric acid)	☐	☐

☐ 6. Most common prescribed dialysate calcium concentration.

At 12/31/93 ☐.☐☐ At Date of Abstraction ☐.☐☐

Calcium Units: ☐ 1 = mEq/L 2 = mM/L 3 = mg/dl 4 = Unknown

☐ 7. Does/did this unit use variable (modeled) dialysate sodium?

1 = Yes 2 = No

At 12/31/93 ☐ At Date of Abstraction ☐

(If "yes" at either date, answer items 8 and 9. If "no" at both dates, answer 8 only.)

☐ 8. Most common dialysate sodium prescription at start of hemodialysis treatment.

At 12/31/93 ☐☐☐ mEq/L At Date of Abstraction ☐☐☐ mEq/L

☐ 9. Most common dialysate sodium prescription at end of hemodialysis treatment.

At 12/31/93 ☐☐☐ mEq/L At Date of Abstraction ☐☐☐ mEq/L

DIALYSIS UNIT/FACILITY QUESTIONNAIRE

If unable to determine the correct answer check the box to the left of item and leave (right) blank

→ ☐ 10. What data were used for URR or Kt/V calculation at 12/31/93?
Check all that apply:

Pre-dialysis and post-dialysis BUN only, for URR ☐
Pre-dialysis and post-dialysis BUN only, for Kt/V ☐
Pre-dialysis, post-dialysis and next pre dialysis BUN for Kt/V ☐
Pre-dialysis BUN and weight, post-dialysis BUN and weight for Kt/ V ☐
Kt/V based on dialyzer clearance, not based on BUN ☐
None ☐
Other? If so please specify_____

☐ 11. Was residual renal function included in reported Kt/V at 12/31/93? ☐
1 = Yes 2= No

☐ 12. Types of water treatment. Indicate all that were normally in use at 12/31/93. **(Do not include backup.)**

Answer for each® 1 = Yes 2 = No

Complete both columns

	For Reprocessing Dialyzers (If re-using)	For Dialysate
Softener	☐	☐
Activated Charcoal	☐	☐
Reverse Osmosis	☐	☐
De-ionization	☐	☐
U-V light	☐	☐
Ultra-filter	☐	☐

☐ 13. Type of water source at 12/31/93 ☐
1 = Public water system 2 = Well water

☐ 14. Timing of post-dialysis BUN sample

At 12/31/93 ☐ At Date of Abstraction ☐

1 = Immediately at the end of dialysis without slowing blood flow
2 = Immediately at the end of dialysis stopping blood flow
3 = 15 to 60 seconds after slowing blood flow to 100 or less
4 = Promptly after returning the extracorporeal blood
5 = 2 to 15 minutes after end of dialysis
6 = More than 15 minutes after end of dialysis
7 = Other? If so, please specify_____

☐ 15. Most common hemodialysis machine in use at 12/31/93 .. .. ☐☐☐
Please use codes listed below. If you entered 999, please give the following information:

Manufacturer: _____
Model: _____

Code		Code	
100	Althin/Drake 480	501	Braun HD Secura
101	Althin/Drake 480UF	401	Cobe C2 & C2RX
102	Althin/Drake 1000	402	Cobe C2RX UFCM
102	Althin/Drake 4521	402	Cobe CS 3
104	Althin/Drake 4009	201	Fresenius 2008C
301	Baxter 350	202	Fresenius 2008D
302	Baxter 450	203	Fresenius 2008E
303	Baxter 550	204	Fresenius 2008H
304	Baxter 1550	601	Gambro AK10
305	Baxter SPS 450	602	Gambro Monitrol
		999	Other

☐ 16. This machine was ☐☐☐% of all actively used machines in December of 1993**. (Do not include back-up machines for acute renal failure or I.C.U. treatment.)**

☐ 17. Routine vascular access surveillance practiced in December 1993 (Doppler, etc.).. ☐
1 = Monthly 3 = Twice a year 5 = Only as needed
2 = Quarterly 4 = Yearly

☐ 18. Were individual patients assigned to one physician or to a team of rotating physicians in December 1993? ☐
1 = One physician 2 = Team

☐ 19. On average, how many times in a month did the typical patient have face-to-face contact with a physician either during hemodialysis or as an outpatient in December 1993? ☐
1 = Greater than 10 times 4 = 1 to 2 times
2 = 6 to 10 times 5 = Less than once
3 = 3 to 5 times

Patient Tracking Form/Patient Identification as of 12/31/93 Network:

Dialysis Unit Data Abstractor Should Complete This Section of the Form DMMS ID:

Facility Name: **Facility Provider Number**:

Pt. Name and Identifiers	Info Correct? Circle Yes or No	Corrected Info If Necessary	Clinical Questionnaire Completed? Circle Yes or No	If no, Reason Code	Reason Explanation
			Yes No		
SEX:	Yes No				
DOB:	Yes No				
SSN:	Yes No				
MEDICARE#:	Yes No				
Modality(12/31/93): **Center Hemo**	Yes No				

Reason Code: If the Clinical Questionnaire was not completed because the patient's records could not be located or because the patient was inappropriately selected for the DMMS, please indicate using one of these codes.

A: Patient stopped receiving treatment at this unit and transferred to another facility prior to the Study Start Date of December 31, 1993.
B: Patient died prior to January 1, 1994 or on the Study Start Date of December 31, 1993.
C: Patient was never treated at this unit.
D. Patient was not an in-center hemodialysis patient in the week of 12/31/93.
E. Patient had not received any treatments at this unit as of 12/31/93 but did receive treatments at this unit after 12/31/93.
F: Other: Please specify with a written explanation. Use blank space anywhere on this page.

Reason Explanation: Complete this item only if the Reason Code used when records could not be located was Reason Code "F".

Hospitalization is NOT a reason for exclusion; please complete the Clinical Questionnaire.

Dialysis Unit Personnel should NOT complete this section. This section should be completed by the NETWORK after the Clinical Questionnaire has been completed and returned to the Network. Please use Network records only to complete this section.

Patient Status Since 12/31/93

1. We need to know the sequence of changes in patient modality. Of the following, which was the FIRST event after 12/31/93? ☐

1=switch to PD (for 2 or more weeks)
2=switch to Home Hemo (for 2 or more weeks)
3=recovery of renal function
4=transfer to another facility (for more than one month; do NOT include hospitalizations)
5=transplant
6=death
7=never switched off in-center hemo
8=patient status unknown

2. What was the date of the FIRST event referred to in item "1"?
(If unavailable, give year only.)

☐☐ ☐☐ ☐☐
MM DD YY

Leave blank if patient never switched off incenter hemo; if patient status unknown, enter date of last known incenter hemo treatment at this dialysis unit.

3. If the FIRST event referred to in item "1" was NOT a death, did the patient die since 12/31/93? ☐
1=Yes 2=No 3=Unknown
If "yes", please provide the date of death. (If unavailable, give year only.)

☐☐ ☐☐ ☐☐
MM DD YY

4. Please enter TODAY's date.

☐☐ ☐☐ ☐☐
MM DD YY

Clinical Quest Cover Sheet