

# Chapter IV

## The USRDS Dialysis Morbidity and Mortality Study (Wave 2)

*Key Words:*

Residual renal function  
Automated peritoneal dialysis  
CAPD  
Cycling peritoneal dialysis  
Dialysate volume

Tenckhoff catheter  
Phosphate binders  
Pre-ESRD care  
Vascular access

The USRDS Dialysis Morbidity and Mortality Study (DMMS) is an observational study in which demographic, comorbidity, laboratory, treatment, socioeconomic and insurance data are being collected for a large, random sample of U.S. dialysis patients, using the patient's dialysis records. The study is planned to include 4 phases ("waves") of data collection on a total of 22,000-25,000 dialysis patients over 3 years. Waves 1, 3 and 4 are historical prospective studies in which data are collected for patients receiving in-center hemodialysis on December 31, 1993, and are each planned to include 6000 patients. Wave 1 data collection was completed in August 1995 and preliminary descriptive results were reported in the 1996 Annual Data Report. Wave 2, which began in 1996 and is currently in progress, is planned to include 4,500 patients. It is unique in that it is a true prospective study, it includes a random sample of incident patients initiating dialysis in 1996, and it includes peritoneal dialysis in addition to hemodialysis patients. In this study, PD patients are oversampled by a factor of 5 to result in comparable numbers of PD and HD patients.

Each "wave" includes a data collection instrument for collecting "core" data, that will allow collection of a consistent set of fundamental data for research questions that require a large sample size. These include questions related to adequacy of dialysis, dialyzer membranes, and dialyzer reuse. The "core" data will also be used to develop a "comorbidity

infrastructure" that will be useful for the investigation of many other important research questions. In addition, Waves 1 and 2 both include a "non-core" component designed to address additional research questions that require smaller sample sizes. For example, in addition to the "core" data collected on all patients in Wave 1, data were also collected on anemia, nutrition, and vascular access on subsamples of patients included in the "core" component. For Wave 2, additional data was collected on peritoneal dialysis prescription and delivery, residual renal function, and medications. Wave 2 is also unique in that an extensive patient questionnaire was administered at baseline with questions pertaining to quality of life, pre-ESRD care, modality choice, transportation, and rehabilitation. Medical status and patient questionnaires are again being administered after 9-12 months. As in all "waves" of the DMMS, patient status will be followed from the study start date through the earliest of date of death, transplant, change in modality, or transfer to another facility.

This chapter reports on some of the highlights of preliminary descriptive analyses of patient data received by March 1, 1997 for this wave (N= 3468 patients).

## Methods

### Sample Frame and Patient Selection

Wave 2 of the DMMS is a prospective study of incident hemodialysis and peritoneal dialysis patients (Medicare and non-Medicare) who initiated ESRD therapy in 1996. For the purposes of this study, the definition of an incident patient is one who is receiving regular in-center hemodialysis or any type of peritoneal dialysis treatments for chronic renal failure at least once weekly for the first time. This does not include patients receiving intermittent dialysis treatments for fluid overload or heart failure. Modality type was identified on day 60 of ESRD. Patients treated with peritoneal dialysis or hemodialysis on this date (day 60) were eligible. The modality assignment for patients on HD but who were training for PD on day 60 was deferred 10 days. Patients were excluded if they were on another form of therapy e.g. home hemodialysis, if they had a previous transplant or if they were less than 18 years of age. The study start date was considered the date that the modality type was defined (about day 60 of ESRD).

The dialysis units included in Wave 2 are a random selection of 25 percent of the dialysis units in the United States listed on the Master List of Medicare Approved Dialysis Facilities as of December 31, 1993 and all new dialysis units opening after January 1, 1994. The Master List exists as part of the annual Medicare Survey of Dialysis Facilities. The number of participating dialysis units was 799. Patients initiating ESRD therapy in 1996 in the selected dialysis units and who met the inclusion/exclusion criteria were eligible for sampling. To obtain comparable numbers of PD and HD patients within the sample, PD patients were oversampled. All eligible incident PD patients were included whereas only twenty percent of all corresponding HD patients were included, selecting only those whose social security number ended with "2" or "9".

The selection of dialysis units occurred at the USRDS Coordinating Center. Data collection materials were distributed to the ESRD Networks who in turn distributed materials to the 799 participating facilities. Patient selection and enrollment occurred at the dialysis units according to instructions provided by the USRDS Coordinating Center. Patient enrollment commenced in March of 1996.

### Data Collection

Patient-specific data is collected at the time of enrollment (study start) and after 9-12 months of followup. Data collected at the time of enrollment includes the following:

1. **Medical Questionnaire:** This questionnaire includes the "core" data common to all of the DMMS "waves" in addition to some "non-core" items and are completed by personnel at each dialysis unit by patient medical record abstraction. Personnel were also instructed to feel free to obtain information directly from the patient. Patient-specific data pertaining to demographics, prior medical history, laboratory results, residual renal function, psychosocial history, dialysis prescription, dialysis delivery, vascular access, and medications were collected using this questionnaire.
2. **Patient Questionnaire:** All hemodialysis and peritoneal dialysis patients enrolled in Wave 2 are asked to complete this questionnaire. The Patient Questionnaire collects data pertaining to quality of life using the Kidney Disease Quality of Life Short Form (KDQOL SF), a kidney specific quality of life questionnaire developed and published through a collaboration between Rand Corporation and Amgen Inc. It also collects data regarding medical care prior to chronic dialysis, choice of modality, transportation, employment, and rehabilitation.

Followup questionnaires administered 9 to 12 months after enrollment include the following:

1. **Medical Update Questionnaire:** This form is completed for all patients enrolled. Data regarding patient status, dose of dialysis, residual renal function, and, for hemodialysis patients, vascular access, is collected.
2. **Patient Questionnaire:** All patients who completed a patient questionnaire at baseline are requested to complete a followup questionnaire which includes the KDQOL SF, as well as questions pertaining to modality choices, compliance, employment, and rehabilitation.

A Facility Questionnaire was also completed by each participating dialysis unit (one time only). Data pertaining to dialyzer re-use, water treatment, URR or Kt/V calculation, and other practice patterns were collected using this instrument.

A pre-test of the baseline medical and patient questionnaires was conducted in the Fall of 1995. Four ESRD networks volunteered to participate in the pre-test and recruited a total of 2 to 4 dialysis units for participation. The pre-test focused on the selection and enrollment of patients, and on the overall feasibility of collecting both the medical and patient questionnaires (interpretation, time required, etc.). The data collection instruments were developed by the USRDS Coordinating Center. Copies of these forms are in Appendix B of this report. Data collection commenced in March of 1996.

sampling methodology (oversampling of PD), in most instances data is presented for the PD sample and for the HD sample separately.

### Analysis

This chapter includes univariate statistics for baseline data generated from Wave 2 of the DMMS. No adjustments have been made for demographic, comorbid or treatment parameters, and therefore the data presented is to be considered only descriptive in nature. The relationship of these baseline variables with outcomes are also not presented as sufficient outcome data are not yet available. In view of the

### Results

As of March 1, 1997, data were collected on 3468 patients who started dialysis in 1996. Of these, 1686 were reported to be on peritoneal dialysis and 1782 were on hemodialysis on the study start date which was around day 60 of ESRD. The average age of the study population is 58 years. Sixty-three percent are White, 28 percent are Black, 2.4 percent Asian, 1.2 percent Native American, and 4.8 percent other race. Ten percent were of Hispanic ethnicity. Females accounted for 47.1 percent of the population. The cause of ESRD was reported to be diabetes in 43 percent, hypertension in 25 percent, glomerulonephritis in 8 percent, and the remainder were classified as other (23 percent). The patient questionnaire was completed by 2379 patients (1265 HD and 1114 PD).

## First Seen by Nephrologist Pre-ESRD, Incident Patients by Modality\* in 1996

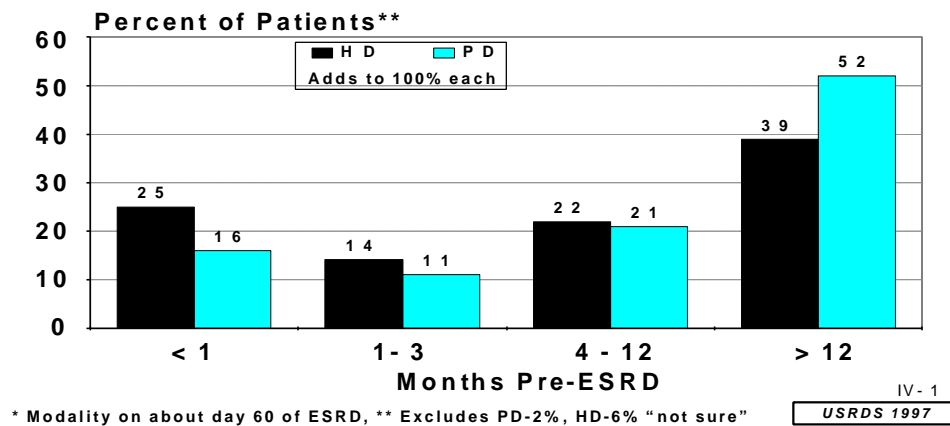


Figure IV-1

Distribution of patients by the number of pre-ESRD visits to a nephrologist, DMMS WAVE 2 Special Study, 1996. Patients are incident, either on PD or HD on about day 60 of ESRD and include Medicare and non-Medicare. Results are preliminary, based on about 2400 completed patient questionnaires. Source: Special Analysis

### Visits with a Dietitian Pre-ESRD, Incident Patients in 1996

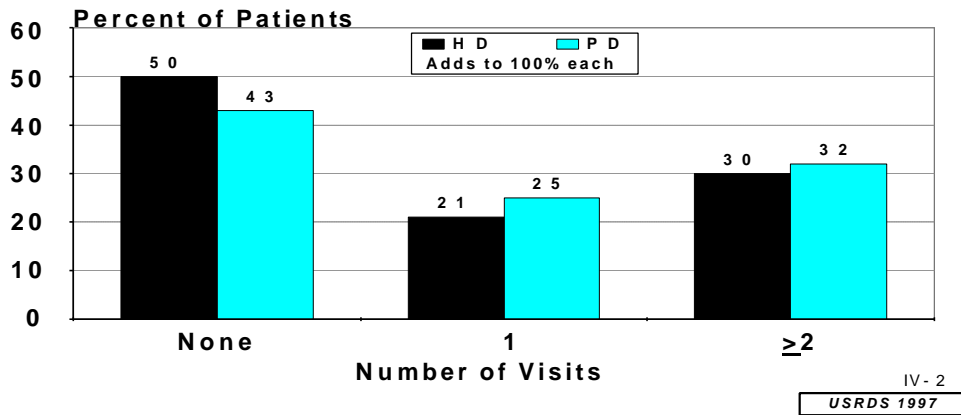


Figure IV - 2

Distribution of patients by the number of pre-ESRD visits to a dietitian, DMMS WAVE 2 Special Study, 1996. Patients are incident, either PD or HD on about day 60 of ESRD and include Medicare and non-Medicare. Results are preliminary, based on about 2400 completed patient questionnaires. Source: Special Analysis

#### Medical Care Before ESRD

A main objective of the DMMS-2 is to describe the medical care received by the pre-ESRD patient and to determine how it affects a variety of patient outcomes. Other studies have shown considerable delay or absence of referral of patients with chronic

renal failure to nephrologists, and have found that this results in excess morbidity (Ifudu 1996, Eadington 1996, Jungers 1993). The data on pre-ESRD medical care for this study was self reported by the patient by means of the patient questionnaire. Figure VI-1 shows the distribution of when patients were first seen by a nephrologist, separately for PD

### Duration of Pre-ESRD Nausea / Vomiting, Incident Patients in 1996

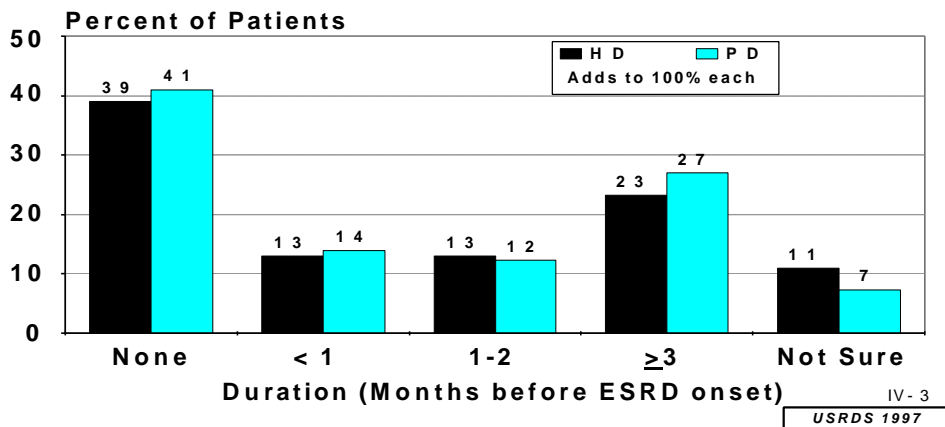


Figure IV - 3

Distribution of patients by the number of months of pre-ESRD nausea or vomiting, DMMS WAVE 2 Special Study. Patients are incident, either PD or HD on about day 60 of ESRD and include Medicare and non-Medicare. Results are preliminary, based on about 2400 completed patient questionnaires. Source: Special Analysis

**Treatment Modality Options for Initial Treatment Described and Discussed with Patient<sup>1,2</sup>, (DMMS, Wave 2)**

Treatment Options	Percent Discussed	
	Peritoneal	
	Dialysis N= 1074	Hemodialysis N=1175
In Unit Hemodialysis	68.2	89.7
Home Hemodialysis	21.2	24.6
Home CAPD	81.7	25.3
Home Automated [Cycling] PD	60.1	20.0
Center/Nursing Home PD	11.7	10.5
Transplantation		
Younger than 60 years	60.6	43.8
Age 60-65 years	38.6	24.1
Older than 65 years	20.1	13.9

<sup>1</sup> per patient reported questionnaire

<sup>2</sup> PD and HD defined near day 60 of ESRD

Table IV-1

USRDS 1997

**Table IV - 1**

and HD treated patients. Thirty-nine percent of HD patients and 27 percent of PD patients reported that they were first seen by a nephrologist 3 or less months prior to starting dialysis, with 25 percent of HD and 16 percent of PD reporting that they were first seen less than 1 month before (Figure IV-1). Twenty two percent of HD and 21 percent of PD patients were first seen between 4 to 12 months before and 39 percent of HD and 52 percent of PD patients reported being seen more than 12 months before. Although it is not known in how many patients in this sample CRF was advanced when first detected or whether patients rejected help until symptomatic, these data suggest that there may be a high prevalence of delayed referral on a national level. Of all patients treated with PD, it appears that a greater proportion presented early (>12 months) and a smaller proportion presented late (< 3 months) compared to patients treated with HD. This difference from HD is likely a result of the fact that patients first presenting to a nephrologist at end-stage and requiring acute treatment are generally initiated on HD and are probably more likely to continue on this therapy chronically.

In patients with progressive renal failure, proper nutritional support, and education regarding dietary phosphate restriction are recommended (NIH Consensus Statement 1993; Hakim 1995). However, fifty percent of HD patients and 43 percent of PD patients reported that they had not seen a dietitian prior to initiation of dialysis (Figure IV-2). Thirty

percent of HD and 32 percent of PD treated patients reported that they had seen a dietitian on two or more occasions.

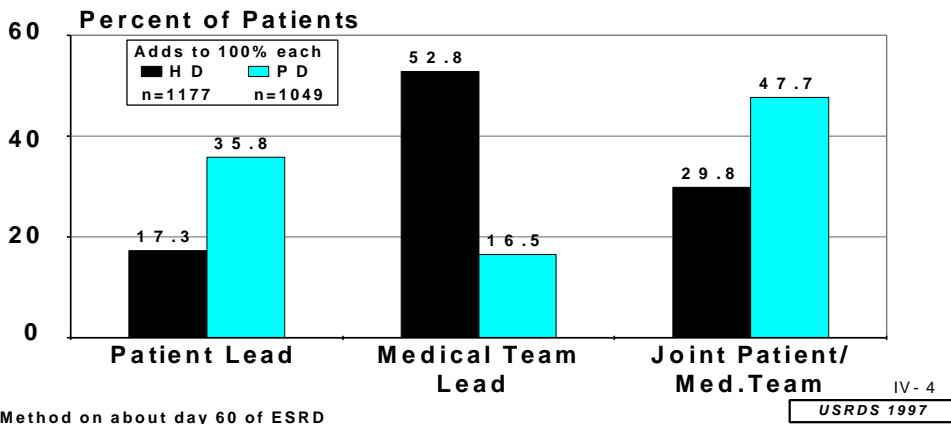
Nephrologists usually recommend initiation of dialysis based on the observed evolution of subjective symptoms and laboratory indices (Hakim 1995). Approximately fifty percent of the patients sampled in this study (both PD and HD) reported experiencing nausea or vomiting prior to the initiation of dialysis (Figure IV- 3). About one quarter of patients reported experiencing nausea or vomiting for 3 or more months. This suggests that a substantial fraction of patients may have had impaired nutrition for a prolonged period before starting dialysis.

Pre-ESRD care related to vascular access is discussed in a subsequent section (Vascular Access subsection).

**Choice of Dialysis Modality**

Several factors are important in choosing a modality for renal replacement therapy including medical limitations, patient preferences, preferences of medical personnel (nephrologists, nurses, renal social workers), and social circumstances. Several questions pertaining to these issues are included in the patient questionnaire. For example, patients were asked to think back to the time when the type of treatment for their renal failure was being decided and to indicate which treatment modality options were described and discussed for their

### Patient Reported Process of Modality Choice, Incident Patients by Modality\*, 1996



\* Method on about day 60 of ESRD

Figure IV - 4

Distribution of patients by patient reported process of modality choice, DMMS WAVE 2 Special Study, 1996. Patients are incident, either PD or HD on about day 60 of ESRD and include Medicare and non-Medicare. Results are preliminary, based on about 2400 completed patient questionnaires. Source: Special Analysis.

initial treatment for ESRD. Preliminary results are shown separately for patients treated with PD and HD

in Table IV-1. Of patients treated with PD, 68 percent reported that in-unit HD was discussed. However of patients on HD only 25 percent reported that CAPD

### Demographics of Incident Dialysis Patients by Modality<sup>1</sup>, 1996 (DMMS, Wave 2)

	Peritoneal Dialysis n=1686	Hemodialysis n=1782
Age, years (SD)	56 (15.4)	61 (15.6)
<b>Race</b>		
% White	68	57
% Black	22	34
% Asian	3	2
% Native American	1	1
% Other	5	5
<b>Ethnicity</b>		
% Hispanic	9	11
<b>Sex</b>		
% Female	47	48
<b>Primary Cause of ESRD</b>		
% Diabetes	43	43
% Hypertension	22	28
% Glomerulonephritis	10	7
% Other	24	21

<sup>1</sup> PD and HD defined near day 60 of ESRD, Sample from 658 Dialysis Units

Table IV-2

USRDS 1997

Table IV - 2

**Comorbidity among Incident Dialysis Patients by Modality<sup>1</sup>, 1996 (DMMS, Wave 2)**

Comorbid Condition <sup>2</sup>	Percent with Condition	
	Peritoneal	Hemodialysis
	Dialysis n=1686	n=1782
Prior Dx of Diabetes	48	50
Coronary Heart Disease <sup>3</sup>	36	42
Prior CABG or Angioplasty	12	13
Cardiac Arrest	2	2
Cerebrovascular Disease	12	16
Peripheral Vascular Disease <sup>4</sup>	20	23
Amputation	4	6
Congestive Heart Failure	31	40
Pulmonary Edema	18	21
Pericarditis	3	3
COPD	9	12
Neoplasm <sup>5</sup>	8	11
Smoker	17	17
LVH ( by EKG or ECHO)	18	22
Cardiomegaly by X-ray	23	29
HIV positive	1	1
AIDS	1	1
Undernourished	20	19
Unable to ambulate independently	7	17
Unable to eat independently	2	4
Unable to transfer independently	5	14

<sup>1</sup> PD and HD defined near day 60 of ESRD

<sup>2</sup> within 10 yrs prior to day 60 of ESRD

<sup>3</sup> includes history of coronary heart disease or coronary artery disease, coronary artery bypass surgery, coronary angioplasty or abnormal coronary angiogram

<sup>4</sup> includes history of peripheral vascular disease, amputation, absent pulses, or claudication

<sup>5</sup> excludes basal cell and squamous cell carcinoma of skin

**Table IV-3**  
**USRDS 1997**

**Table IV - 3**

was discussed. Automated peritoneal dialysis was reportedly presented as an option in 60 percent of patients on PD. Transplantation was more likely to be presented/discussed among patients treated with PD compared to HD. Among patients less than 60 years, only 60 and 44 percent of PD and HD patients respectively reported this and as expected the percentages were smaller with increasing age. When asked which best described the process of selecting their method of treatment, 84 percent of patients treated with PD appeared to contribute substantially to the decision (Figure IV-4). In 36 percent they reported that they took the lead in the selection and 48 percent reported that it was a joint decision with the medical team. Among patients treated with HD, the medical team clearly played a larger role in

selecting this treatment. 53 percent of HD patients reported that the medical team took the lead in selecting their treatment and in only 17 percent did the patient take the lead. In 30 percent it was a joint decision.

**Comparison of Incident Peritoneal and Hemodialysis Treated Patients**

Another of the major objectives of Wave 2 is to evaluate comparative outcomes of peritoneal and hemodialysis. Once outcome data is available, this prospective study of randomly selected incident patients will be the best designed observational study to date to evaluate this question, both in terms of mortality and quality of life. Recent studies in the United States have found higher mortality associated

with peritoneal dialysis among some subgroups of patients (Held 1994, Bloembergen 1995, Lowrie 1995). Baseline differences in the patients selected to these modalities may be a potential explanation for these findings. Table IV-2 shows the demographic description of PD compared to HD patients in the study sample to date. Patients treated with PD are on average about 5 years younger than HD patients (56 vs. 61 years). Blacks were less likely to utilize PD as only 22 percent of the PD population is Black whereas 34 percent of the HD population is this race. The proportion of patients that were Asian or Native American was small and was relatively similar among PD and HD treated patients. The sex distribution is similar for the HD and PD patient sample. Patients treated with PD are more likely to have glomerulonephritis as a cause of ESRD, whereas patients treated with HD are more likely to have ESRD due to hypertension. Both groups are equally likely to have diabetes as a cause of ESRD.

Comorbidity was measured by a number of individual comorbid conditions present within 10 years prior to the onset of ESRD. As shown in Table IV-3, most comorbid conditions were more prevalent among HD compared to PD treated patients. It should

be noted that these data are not adjusted for demographic differences between the PD and HD patients and these comorbidity differences are due in part to the younger age of the PD population. The largest differences were in coronary artery disease (42 percent among HD vs. 36 percent among PD), cerebrovascular disease (16 vs. 12 percent), congestive heart failure (40 vs. 31 percent), cardiomegaly (29 vs. 23 percent), inability to ambulate independently (17 vs. 7 percent) and inability to transfer independently (14 vs. 5 percent). Peripheral vascular disease, COPD, neoplasm, and LVH were more similar although still more prevalent among HD treated patients. PD patients were slightly more likely to be undernourished (20 vs. 19 percent).

Data to calculate residual renal function was requested near day 60 of ESRD on a voluntary basis. It was available for only 20 HD patients (1.1 percent) and 540 PD patients (32 percent). The average residual renal function among this small sample of patients was 3.4 ml/min among HD treated patients and 4.9 ml/min among PD treated patients (Figure IV-5). However, given the low response rate, particularly among HD treated patients, these figures may not be representative of the dialysis population.

### Residual Renal Function Among Incident Patients by Modality\*, 1996

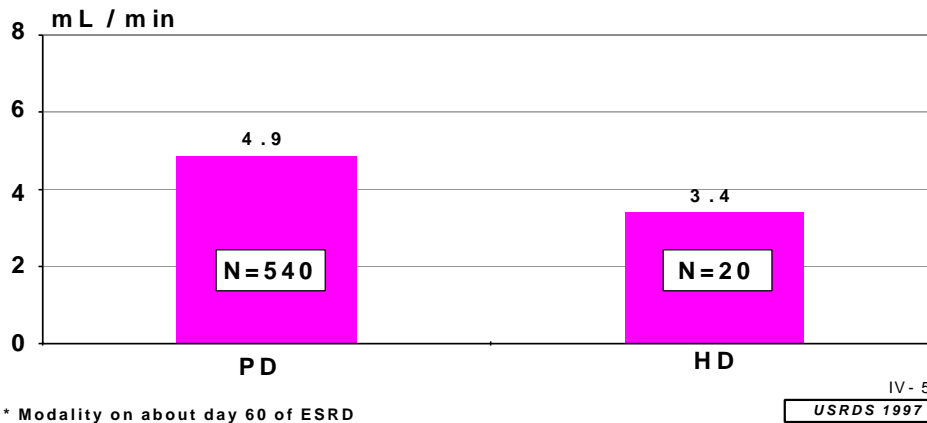


Figure IV - 5

Mean residual renal function among DMMS WAVE 2 Special Study patients for whom data was available, 1996. Patients are incident, either PD or HD on about day 60 of ESRD and include both Medicare and non-Medicare. Results are preliminary, based on about 3500 Wave 2 patients. Source: Special Analysis.



### Method of Peritoneal Dialysis Used by Incident PD\* Patients, 1996

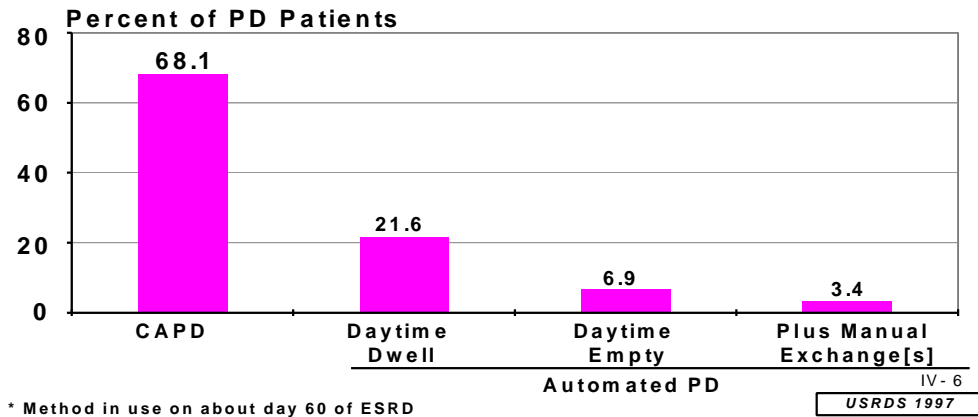


Figure IV - 6

Method of peritoneal dialysis used by PD Patients, DMMS WAVE 2 Special Study, 1996. Automated indicates use of a cycler. Patients are incident, on PD on about day 60 of ESRD and include Medicare and non-Medicare. Results are preliminary, based on about 3500 Wave 2 patients. Source: Special Analysis.

#### Delivery of Peritoneal Dialysis

Recent studies have found an association of lower mortality with higher clearances of urea and creatinine among PD treated patients (CANUSA), and have emphasized the need for higher doses of peritoneal dialysis in order to achieve better survival rates among this population. There is frequently a

limit to the number and volume of exchanges patients will accept with conventional continuous ambulatory peritoneal dialysis (CAPD). Furthermore, in patients who are large, who have minimal or absent residual renal function or who have low membrane permeability characteristics, it may be impossible to deliver adequate doses of PD using CAPD.

### Prescribed Inflow Dialysate Volume per Day, Incident PD\* Patients, 1996

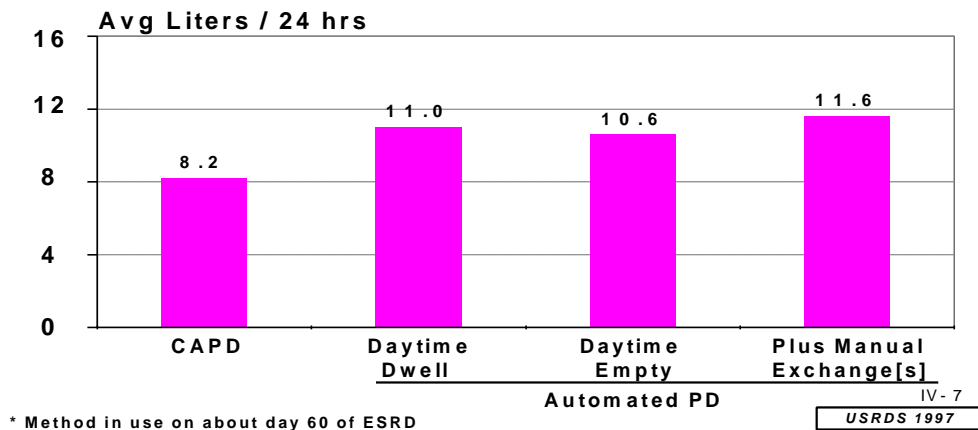
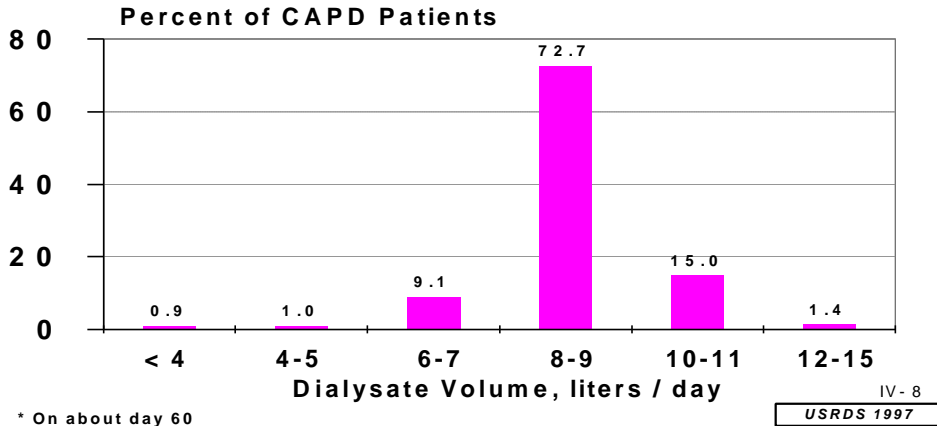


Figure IV - 7

Distribution of prescribed dialysate volume per day by PD type, DMMS WAVE 2 Special Study, 1996. Patients are incident, PD on about day 60 of ESRD, and include Medicare and non-Medicare. Results are preliminary, based on about 3500 Wave 2 patients. Source: Special Analysis.

## Prescribed Inflow Dialysate Volume per day, Incident CAPD\* Patients, 1996



**Figure IV - 8**

*Distribution of patients by prescribed dialysate volume per day, DMMS WAVE 2 Special Study, 1996. Patients are incident, on CAPD on about day 60 of ESRD and include Medicare and non-Medicare. Results are preliminary, based on about 3500 Wave 2 patients. Source: Special Analysis.*

Automated PD (APD) techniques (the use of a cycler), previously used by patients mainly for vocational or social reasons, may allow the delivery of higher doses of dialysis in these situations. Nationally, there has been a dramatic rise in the utilization of automated PD over the past decade as shown in Chapter III. This is confirmed by data from the DMMS-2.

The method of peritoneal dialysis used by new patients in 1996 is shown in Figure IV-6. CAPD was reportedly used in 68.1 percent of PD treated patients. Automated peritoneal dialysis was used in a total of 31.9 percent of patients, with “daytime dwell” (also referred to as CCPD or continuous cycling peritoneal dialysis) used in 21.6 percent and “daytime empty” (also referred to as NIPD or nightly intermittent peritoneal dialysis) in 6.9 percent. A combination of APD and CAPD (use of cycler and at least one manual exchange per day) was reportedly used by 3.4 percent of all PD patients.

The prescribed dialysate volume per 24 hours by each PD method is shown in Figure IV-7. The average number of liters prescribed for conventional CAPD was 8.2, for APD daytime full and daytime empty 11.0 and 10.6 respectively, and for “APD plus manual exchange(s)” was 11.6. It is generally more feasible to provide larger volumes of dialysate per day with APD. However, larger dialysate volumes are also necessary to provide adequate dialysis dose, as

the dialysate does not equilibrate as well in APD as in CAPD.

Figure IV-8 shows the distribution of prescribed dialysate volume per 24 hours for patients treated with CAPD. Approximately 73 percent of patients are prescribed 8 to 9 liters per day with 16.4 percent prescribed more and 11 percent less than this. The distribution of dialysate volume prescribed for patients using an automated technique (including “APD plus manual exchange(s)”) is shown in Figure IV-9. The majority of patients (65.2 percent) are prescribed 10 to 14 liters per day. Twenty four percent of patients using automated PD are prescribed less than this and 10.8 percent are prescribed more. A small percentage (1.0 percent) are reportedly prescribed 20-24 liters per day.

### Dialysis Access

#### Vascular Access

Figure IV-10 shows the type of vascular access in use about 60 days after start of HD, when the patient is generally well established on therapy. Dialysis treatments were performed using a functioning fistula in only 17.9 percent and using a PTFE/Bovine graft in 50.3 percent. Combined, in 1996, only 68.2 percent of new patients had a functioning permanent AV access (fistula or graft) at 60 days after HD initiation. A similar figure was presented for patients initiating HD in 1993 in the 1996 Annual Data Report

### Prescribed Inflow Dialysate Volume per Day, Incident Automated PD\* Patients, 1996

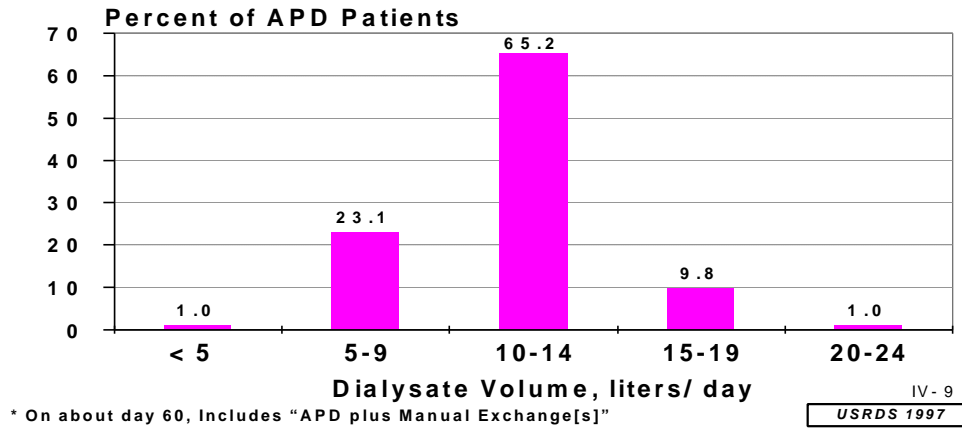


Figure IV - 9

Distribution of patients by prescribed dialysate volume per day, DMMS WAVE 2 Special Study, 1996. Patients are incident, on automated or automated plus manual exchange at least once on about day 60 of ESRD and include Medicare and non-Medicare. Results are preliminary, based on about 3500 Wave 2 patients. Source: Special Analysis.

with the exception that it showed the distribution of access in use at 1 month (rather than at 60 days).

Despite the longer time on dialysis, the number of patients with a fistula is not substantially higher and the use of a graft is only slightly higher in the 1996 incident patients. In 1996, 18.9 percent of patients were using a cuffed permanent catheter at 60 days as compared to 9.7 percent at 1 month in the 1993

incident sample. At 60 days after initiating dialysis, 12.9 percent of patients were still using a temporary catheter. Despite concerns of the development of subclavian vein stenosis (Schillinger 1991), the subclavian vein was used as the access site for about two thirds of patients with a temporary access, although this was a reduction from the 1993 incident sample of HD patients where the subclavian site was

### Distribution of Vascular Access Types in Use at 60 Days After Start of HD, 1996

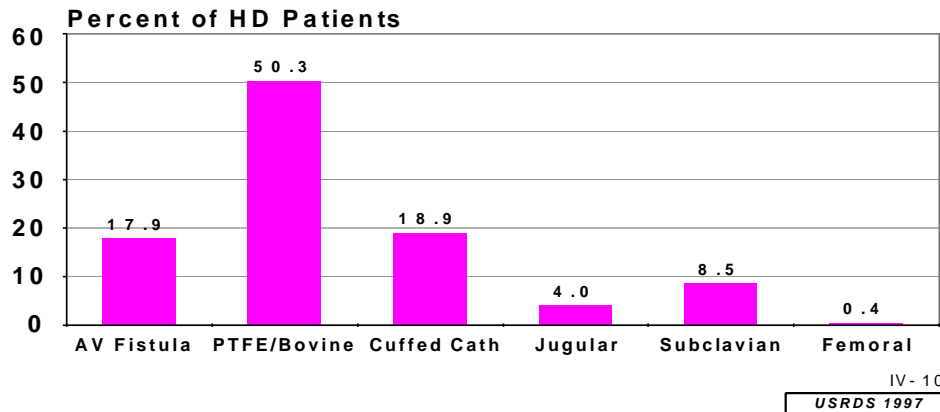


Figure IV -10

Distribution of HD patients by vascular access type in use at 60 days after start of HD, DMMS Wave 2 Special Study, 1996. Patients are incident, on HD on about day 60 of ESRD and include Medicare and non-Medicare. Results are preliminary, based on about 3500 Wave 2 patients. Source: Special Analysis

### Use of Temporary\* Catheters in HD Incident Patients < 60 Days After First HD, 1996

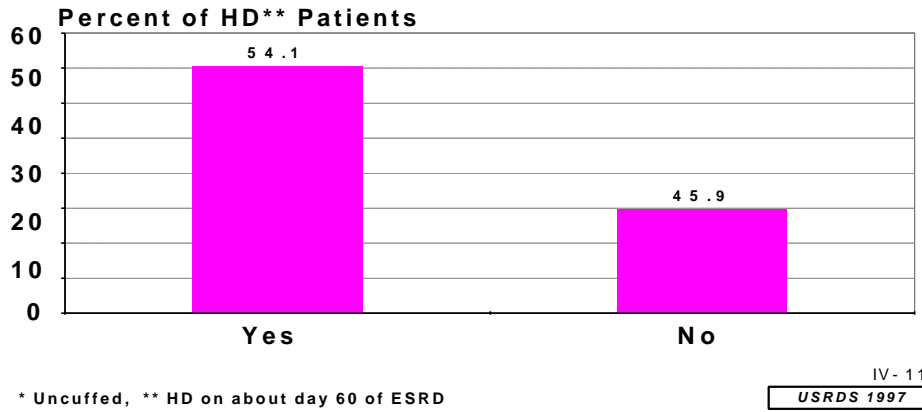


Figure IV -11

Distribution of patients by use of temporary access in central vein anytime before study start date, DMMS Wave 2 Special Study, 1996. Patients are incident, on HD on about day 60 of ESRD and include Medicare and non-Medicare. Results are preliminary, based on about 3500 Wave 2 patients. Source: Special Analysis.

used for 79 percent of patients with a temporary access. Figure IV-11 shows that over 50 percent of patients required the use of a temporary (uncuffed) catheter at some time within the first 60 days of hemodialysis. This finding is likely in part due to the large percentage of patients who present to a nephrologist late, as shown in Figure IV-1.

relative to a PTFE or bovine graft (Woods 1997), there has been a trend to decreasing use of fistulas over the past years (Hirth 1996). As part of the Patient Questionnaire, patients were asked if they were told to avoid blood draws or IV lines in either arm to protect the veins for a permanent access. Although this is generally believed to enhance the probability of a functional fistula, 47.3 percent of

Despite the superior survival of an AV fistula

### Preserving Forearm Veins Prior to Hemodialysis, Incident HD Patients in 1996

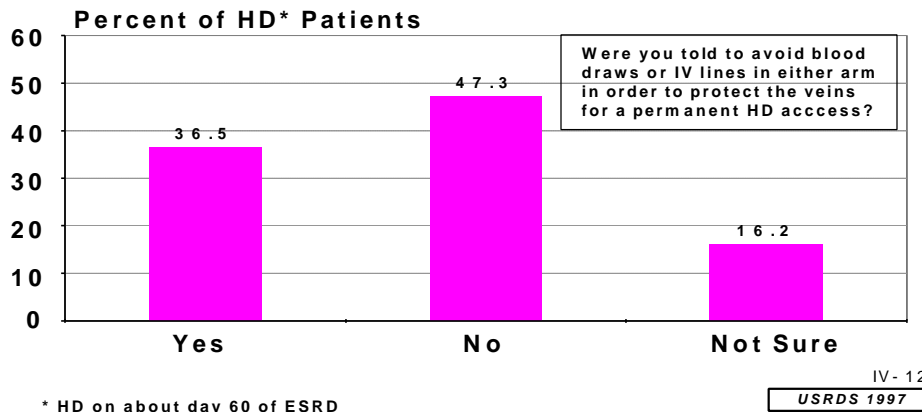


Figure IV - 12

Distribution of patients preserving forearm veins for a permanent HD access by avoiding blood draws or iv lines, DMMS Wave 2 Special Study, 1996. Patients are incident, on HD on about day 60 of ESRD and include Medicare and non-Medicare. Results are preliminary, based on about 2400 completed patient questionnaires. Source: Special Analysis.

### Type of Peritoneal Dialysis Catheter in Use at 60 Days After Starting Dialysis, 1996

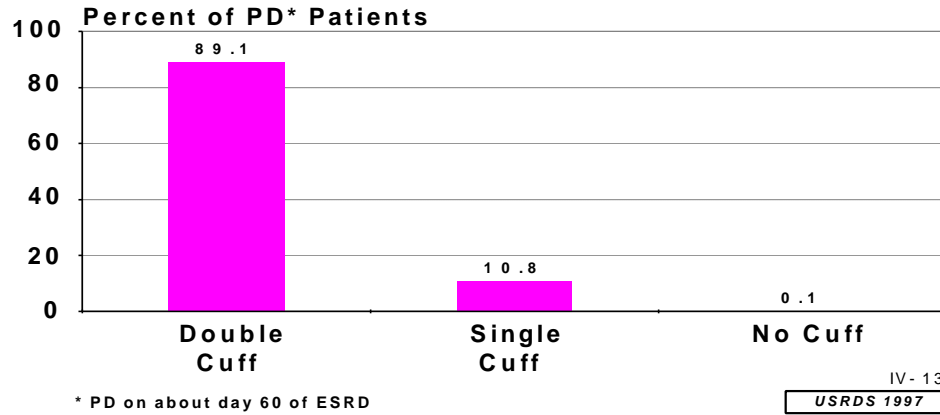


Figure IV - 13

Distribution of PD patients by type of PD catheter in use at 60 days after starting dialysis, DMMS Wave 2 Special Study, 1996. Patients are incident, on PD on about day 60 of ESRD and include Medicare and non-Medicare. Results are preliminary, based on about 3500 Wave 2 patients. Source: Special Analysis.

respondents indicated they were not advised of this and 16.2 percent were not sure (Figure IV-12).

#### Peritoneal Dialysis Access

The distribution of the types of peritoneal dialysis catheters in use at 60 days after starting dialysis is shown in Figure IV-13. A double cuff catheter was used in 89.1 percent, single cuff catheter in 10.8

percent, and an uncuffed catheter in a very small percentage. In some studies, double cuff catheters have been shown to be associated with lower peritonitis risk (USRDS 1992, Diaz-Buxo 1984), however other studies have found no difference (Golper 1996, Kim 1984). This question therefore remains controversial.

### HD Patient Compliance: Number of Sessions Skipped/shortened in 1 Month, 1996

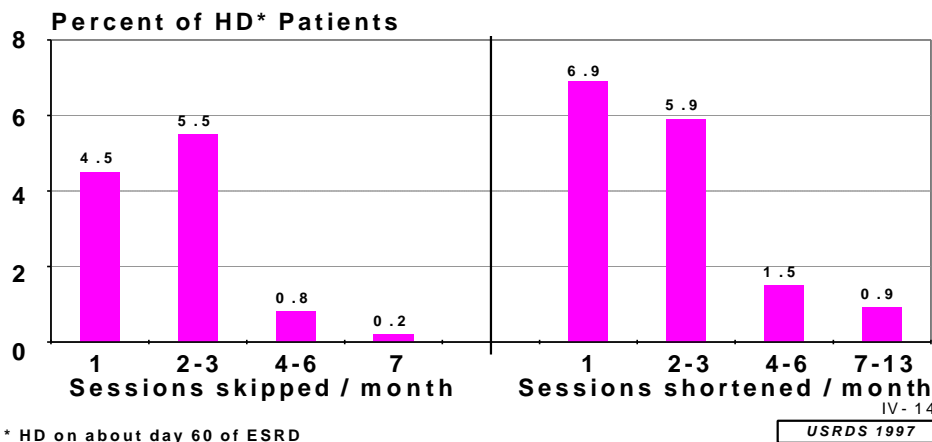


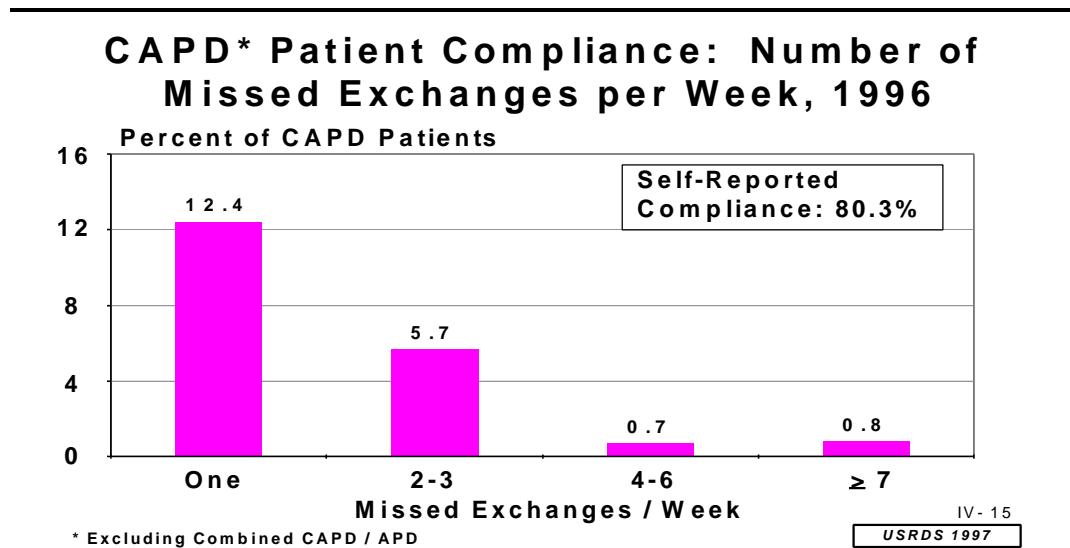
Figure IV - 14

Distribution of patients by HD compliance as measured by the number of sessions skipped or shortened (by more than 10 minutes) during the 30 days prior to study start date, DMMS WAVE 2 Special Study, 1996. Patients are incident, on HD on about day 60 of ESRD, and include Medicare and non-Medicare. Results are preliminary, based on about 3500 Wave 2 patients. Source: Special Analysis.

**Compliance**

The substantial interest in delivered dose of dialysis over the past decade has also stimulated consideration of patient compliance to the prescribed therapy and its relationship with outcome. It has been suggested that the frequency of non-compliance may be higher in the United States than in Europe (Hull 1990). Many of the previous descriptions of the magnitude of non-compliance in this population have been of data from single centers (Rocco 1993; Kimmel 1995). The DMMS Wave 2 data will allow a national description of this phenomenon. The prevalence of skipped or shortened hemodialysis sessions in a one month period for this patient sample, by patient report, is shown in Figure IV-14. Over 10 percent of HD patients skipped at least one session. Over 5 percent skipped 2 to 3, 0.8 percent 4 to 6, and 0.2 skipped 7 out of the 13 possible sessions. Approximately 15 percent of HD patients shortened at least one session. Almost six percent shortened 2 to 3 sessions, and 1.5 and 0.9 percent shortened 4 to 6 and 7 to 13 sessions respectively. Rocco et al (Rocco 1993) have previously shown that in a single center, approximately 55 percent of shortened sessions were due to medically related problems whereas most of the remainder occurred because of either personal obligations or noncompliance with the dialysis prescription.

Lack of compliance to the prescribed PD program is a major reason for PD technique failure (Banks 1992) and has also been proposed as a potential cause of excess mortality among PD treated patients (Bloembergen 1995, Port 1996). As part of the patient questionnaire, patients were asked questions regarding compliance with their PD prescription. Approximately 12 percent of patients on CAPD reported that on average they miss one exchange per week, approximately six percent miss 2 to 3 exchanges per week, about 1 percent miss 4 to 6 per week, and a small fraction miss over 7 exchanges per week (Figure IV-15). Approximately 80 percent of patients report that they rarely miss an exchange. Patients treated with automated PD were asked the number of times they either skipped or shortened a treatment in a 2-week period. Approximately six percent reported skipping one treatment, 2.5 percent two treatments, 0.7 percent three treatments, and 1.8 percent over 4 treatments (Figure 16). Approximately 9 percent reported shortening one treatment in 2 weeks, and 2.9 , 2.9, and 1.8 percent reported shortening two, three, and four or more treatments respectively. Approximately 89 percent of patients treated with APD reported that they rarely skipped a treatment and approximately 83 percent reported that they rarely shortened a treatment.



**Figure IV - 15**

*Distribution of patients by CAPD compliance as measured by the number of missed exchanges per week, 1996. Patients are incident, CAPD on about day 60 of ESRD and completed the DMMS WAVE 2 Special Study. Includes Medicare and non-Medicare. Results are preliminary, based on about 2400 completed patient questionnaires. Source: Special Analysis.*

### Automated PD\* Patient Compliance: Number of APD Treatments Skipped/shortened per 2 Weeks, 1996

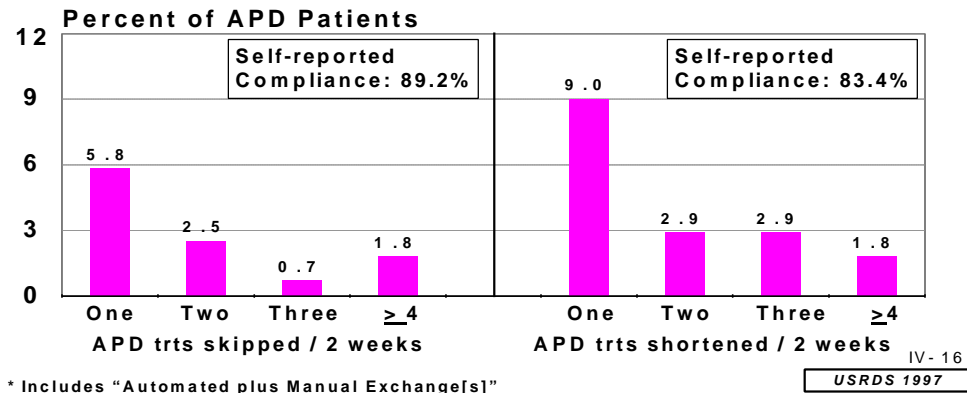


Figure IV - 16

Distribution of patients by automated PD compliance as measured by the number of sessions skipped or shortened (including not using all the dialysis fluid) during the most recent 2 weeks, 1996. Patients are incident, on automated or combined PD on about day 60 of ESRD, and completed the DMMS WAVE 2 Special Study. Includes Medicare and non-Medicare. Results are preliminary, based on about 2400 completed patient questionnaires. Source: Special Analysis.

#### Medication Use

For each patient, medications in use at the start of the study were recorded by medical chart abstraction. Among HD patients, 76 percent were using a phosphate binder (Figure IV-17). By far the majority of patients were using a calcium containing binder

alone (71 percent). Aluminum containing binders were used alone in 2 percent and together with a calcium containing binder in 3 percent. Utilization of phosphate binders was very similar among PD treated patients. The utilization of vitamin D analogues is shown in Figure IV-18. Vitamin D was used more frequently among HD than PD treated patients (44

### Use of Calcium and Aluminum Phosphate Binders by Modality\*, Incident Patients in 1996

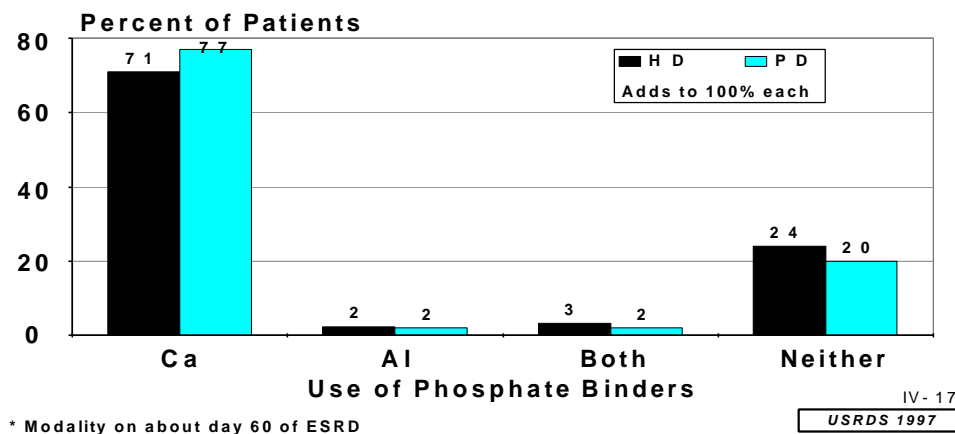


Figure IV - 17

Distribution of patients by use of calcium and aluminum phosphate binders, DMMS WAVE 2 Special Study. Patients are incident, either PD or HD on about day 60 of ESRD and include Medicare and non-Medicare. Results are preliminary, based on about 3500 Wave 2 patients. Source: Special Analysis.

### Use of IV & Oral Vitamin D by Modality\*, Incident Patients in 1996

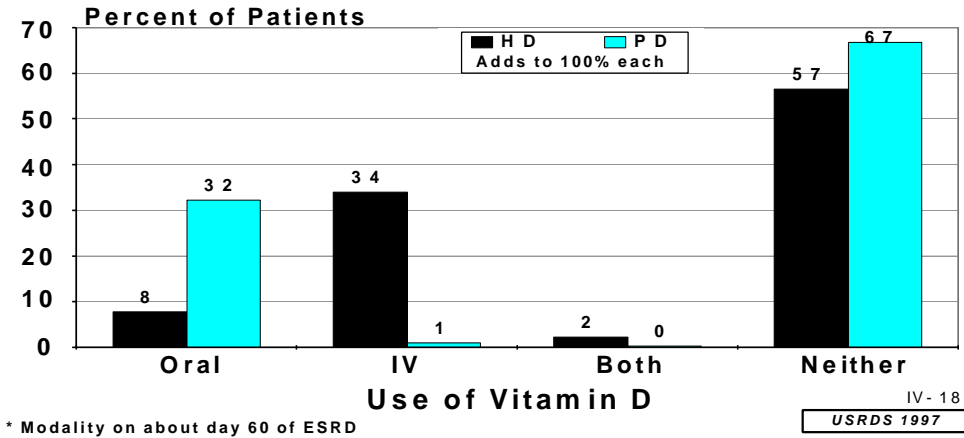


Figure IV - 18

Distribution of patients by use of iv & oral vitamin D, DMMS WAVE 2 Special Study. Patients are incident, either PD or HD on about day 60 of ESRD and include Medicare and non-Medicare. Results are preliminary, based on about 3500 Wave 2 patients. Source: Special Analysis

versus 33 percent). As expected, the use of IV vitamin D was much higher among HD (34 percent) than among PD treated patients (1 percent).

#### Quality of Life

The KDQOL-SF™ includes 78 questions related to quality of life. In one question the patient is asked to rank their overall health from one to five. Figure IV-19 shows the results of this question by age and

modality for patients at baseline (about 60 days after starting ESRD therapy). Patient reported general health is slightly better for PD than HD patients. There is a trend to lower patient reported general health with age. Figure IV-20 shows results by diabetes status and modality. Non diabetics have better self reported general health than diabetics. Again, PD patients report better health than HD patients.

### Self-Reported General Health by Modality and Age, Incident Patients in 1996

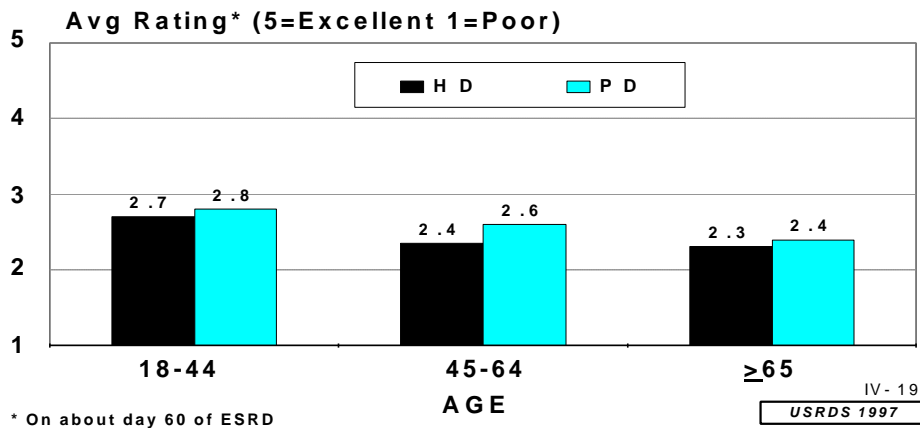


Figure IV - 19

Mean rating of patients self-reported general health by age, DMMS WAVE 2 Quality of Life Study, 1996. Patients were asked to rate their health on a scale of 1 to 5. Patients are incident, either PD or HD on about day 60 of ESRD and include Medicare and non-Medicare. Results are preliminary, based on about 2400 completed patient questionnaires. Source: Special Analysis.



### Self-Reported General Health by Modality and Diabetes, Incident Patients in 1996

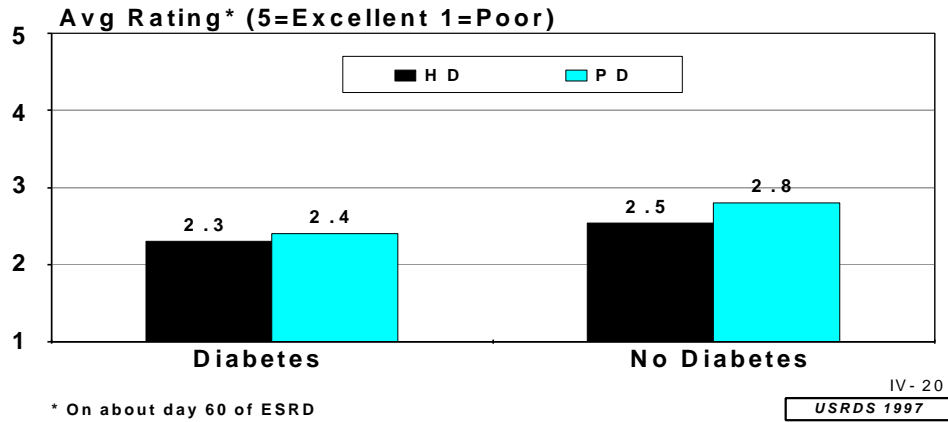


Figure IV - 20

Mean rating of patients self-reported general health by diabetes, DMMS WAVE 2 Quality of Life Study, 1996. Patients were asked to rate their health on a scale of 1 to 5. Patients are incident, either PD or HD on about day 60 of ESRD and include Medicare and non-Medicare. Results are preliminary, based on about 2400 completed patient questionnaires. Source: Special Analysis.

#### Employment Status

When Medicare coverage for ESRD began in 1973, the expectation was that many of those whose lives were prolonged would contribute to society through work and taxes. However, since then the patient population has changed dramatically with the acceptance of older and sicker patients and now the

majority do not work. The employment status of new patients (at 60 days) is shown in Figure IV-21 for all ages and for patients less than 60 shown separately. Among all ages, 35.9 percent of patients report that they are disabled, 32.3 percent are considered retired, 10.5 percent work full time, 3.9 percent work part time, 1.9 percent are looking for work, 7.7 percent are keeping house, and a very small percent are in school.

### Employment Status of Incident Patients\* by Age, 1996

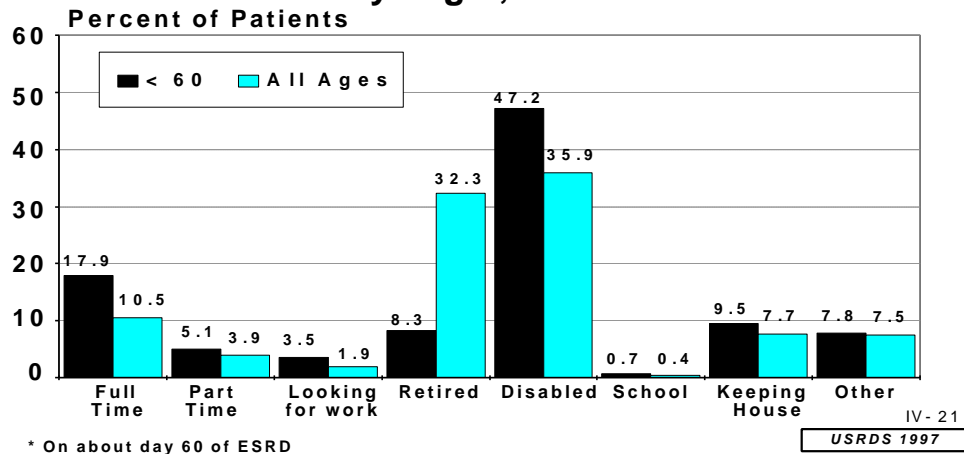
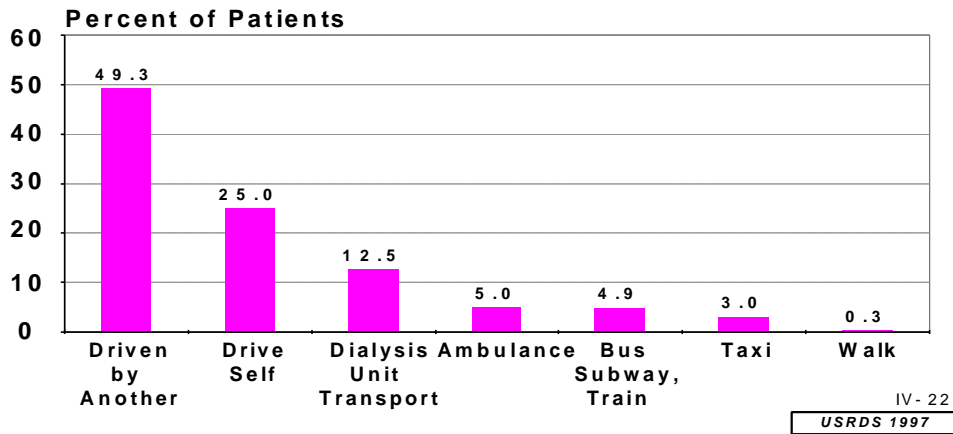


Figure IV - 21

Distribution of patients by employment status in the previous 30 days and patient age, DMMS WAVE 2 Special Study, 1996. Patients are incident, either PD or HD on about day 60 of ESRD and include Medicare and non-Medicare. Results are preliminary, based on about 2400 completed patient questionnaires. Source: Special Analysis.

## Mode of Transportation to Dialysis, Incident Hemodialysis Patients, 1996



**Figure IV - 22**

*Distribution of patients by usual mode of transportation to dialysis unit, DMMS WAVE 2 Special Study, 1996. Patients are incident, either PD or HD on about day 60 of ESRD and include Medicare and non-Medicare. Results are preliminary, based on about 2400 completed patient questionnaires. Source: Special Analysis.*

Among patients under the age of 60, less were retired (8.3 percent) but almost fifty percent reported that they were disabled. Only 17.9 percent were employed full time, 5.1 percent were employed part-time, 9.5 percent were keeping house, and 3.5 percent were looking for work.

### Transportation

Another objective of the DMMS Wave 2 was to describe the mode of transportation used by hemodialysis patients to travel to their dialysis facility. Approximately one half of patients were driven by someone else, and a further one quarter drove themselves (Figure IV-22). The dialysis unit provided transportation for 12.5 percent, bus/subway/train was used by 4.9 percent, ambulance was used by 5.0 percent, taxi 3.0 percent, and 0.3 percent of the patients sampled walked.

### Conclusions

The preliminary results presented in this chapter highlight some of the important data which will be available from the DMMS Wave 2. Once data collection is complete, more detailed analyses are planned including the evaluation of the possible associations of these factors with a number of important patient outcomes.

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