



Monument Valley, Navaho Tribal Park, Utah

REHABILITATION/QUALITY OF LIFE & NUTRITION SPECIAL STUDIES

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The Comprehensive Dialysis Study (CDS) was a joint effort between the Nutrition Special Studies Center (SSC) and the Rehabilitation/Quality of Life SSC, enrolling incident dialysis patients between September 1, 2005, and June 1, 2007 from a stratified random sample of dialysis facilities throughout the U.S.

All participants were asked to respond to a patient questionnaire (PQ) by telephone, focusing on physical activity and quality of life, and patients initiating dialysis in a prespecified subset of facilities were also asked to respond to a brief food frequency questionnaire (FFQ) and to provide baseline and quarterly serum samples. A total of 1,678 participants were enrolled from 296 facilities, of whom 399 participated in the nutrition substudy.

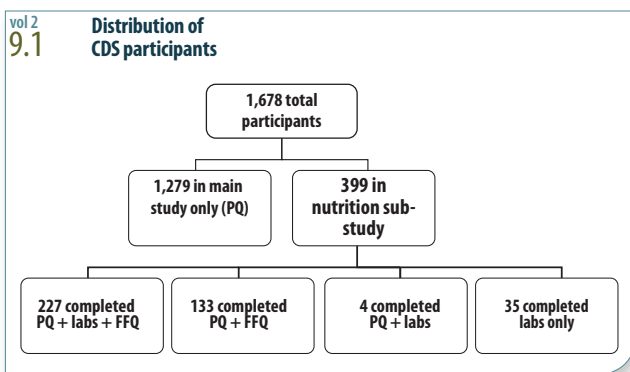
In this chapter the Rehabilitation/Quality of Life SSC examines early awareness of peritoneal dialysis and transplant as treatment options among CDS participants.

The Nutrition SSC then looks at health status among participants, examining data on physical activity, frailty, sleep issues, depression, and dietary intake. These results emphasize a subset of what was collected in the CDS. These data can be used to explore relationships among nutritional intake, markers of nutritional status and inflammation, and physical activity, functioning, symptoms and health-related quality of life. In addition, linkage with the broader USRDS datasets will allow for prospective analyses of the associations of these parameters with outcomes such as hospitalization and survival.

Table 9.a lists elements of the patient activity and quality of life questionnaire, Figure 9.1 illustrates the distribution of study participants, and Table 9.b shows their sociodemographic characteristics. CDS participants were slightly younger than the overall population of patients who started dialysis in 2005 and had a slightly greater percentage of patients initiating on peritoneal dialysis (10 percent). » **Figure 9.1 & Tables 9.a–b**; see page 443 for analytical methods. *CDS participants who started treatment between June 1, 2005 & June 1, 2007.*

What is life? It is the flash of a firefly in the night. It is the breath of a buffalo in the wintertime. It is the little shadow which runs across the grass and loses itself in the sunset.

CROWFOOT



vol 2 9.a Patient activity & quality of life questionnaire	
Patient criteria	
Sociodemographics	Age, sex, race, ethnicity, educational status, smoking status
Treatment characteristics	Dialysis modality, dialysis access type, treatment time
Patient-reported health status	SF-12
Quality of life	KDQOL symptoms, effects of kidney disease, burden of kidney disease, cognitive function, other symptoms (restless legs, sleep, postdialysis fatigue)
Satisfaction with care	KDQOL satisfaction with care
Physical activity	Human Activity Profile
Usual activity/exercise	Physical Activity Score
Depressed mood	PHQ-2 2-item depression screener
Employment status	Working for pay, able to work, Social Security disability status
Pre-ESRD treatment	BP and cholesterol lowering medications, modality choice
Transplant discussion	Transplant discussed since dialysis started
Abbreviations SF-12: Medical Outcomes Study Short Form 12 item questionnaire; KDQL: Kidney Disease Quality of Life Instrument; PHQ-2: Patient Health Questionnaire -2	

Peritoneal dialysis (PD), a home-based, self-care therapy, and kidney transplantation are renal replacement therapy (RRT) options with potential rehabilitation and quality of life advantages for ESRD patients compared to in-center hemodialysis (HD). Both are associated with survival outcomes similar or superior to survival on in-center HD. Wider use of both options would also be cost-effective for Medicare's ESRD program.

Patients' lack of early information about PD and kidney transplantation may, however, limit their consideration of these treatment options. PD was used by only 6.1 percent of dialysis patients in 2009, compared to 17 percent in 1979, soon after the therapy was introduced. Individuals who are potentially eligible candidates for kidney transplantation may not pursue this option because of fears and reservations about the transplant procedure and about what is needed to successfully manage life with a transplant.

One goal of the 2010 Medicare Improvements for Patients and Providers Act, in the Kidney Disease Education (KDE) benefit, is to provide comprehensive information about treatment options to Stage 4 chronic kidney disease patients in advance of their need to begin RRT.

The Comprehensive Dialysis Study (CDS), a USRDS special study, asked a national sample of patients who had recently begun regular dialysis whether PD and kidney transplantation had been discussed with them before they began RRT. Overall, of dialysis patients initiating between June 1, 2005 and June 1, 2007, 61 and 50 percent, respectively, were informed of peritoneal dialysis or transplant as treatment options. Using survey responses from patients who participated in the CDS, the study went on to explore predictors and outcomes of patients' early awareness of PD and kidney transplantation.

Variables associated with patient-reported early discussion of these treatment options were examined. Patients' survey responses were then linked with their treatment modality history information in the USRDS standard analysis files. Findings are summarized first for early awareness of PD, then for early awareness of kidney transplantation. Patients whose data are summarized here started regular dialysis before the KDE benefit was enacted and therefore do not provide a "test" of the effectiveness of the KDE benefit. However, data from CDS participants may provide a benchmark to use in new research, in order to gauge changes in modality selection that may be associated with the KDE benefit.

The sampling frame for the CDS was obtained by selecting outpatient dialysis units from clinics in the April 2005 Dialysis Facility Compare database of the Centers for Medicare and Medicaid Services (CMS), after merging with information from the USRDS ESRD Facility File. The list of dialysis units was sorted by ESRD Network, by adjacent states within Network, and by the size measure of annual incident patients per facility (SAS PROC SURVEYSELECT). A sample of 335 facilities was selected using equal probability systematic random sampling. Systematic random sampling in conjunction with the sorted facility list yielded implicit geographical stratification (Network and state within Network) for the sample facilities. The selected units matched the total population of clinics closely on number of patients and dialysis stations, facility type (free-standing, hospital-based), dialysis chain/non-chain affiliation, dialysis modalities offered (PD, HD), and ESRD Network.

Eligibility for the CDS required that participants had no prior transplantation or other RRT before their current start of dialysis as their regular treatment for ESRD. Patients age 18 and older who initiated chronic dialysis between June 1, 2005 and June 1, 2007 at one of the selected dialysis clinics were identified to the USRDS Coordinating Center by the CMS Standard Information Management System when they had been receiving chronic dialysis for at least two months but no more than three months. Patient lists were provided monthly to the USRDS Coordinating Center, which then contacted patients to request their participation in the study. Patients who consented were asked to participate in a structured interview administered by professional interviewers using a computer-assisted telephone interviewing system.

Interviewed patients numbered 1,643, and they had each been on dialysis approximately four months. They were affiliated with 296 different dialysis clinics, located across all 18 ESRD Networks and in all states except Alaska and Vermont. CDS participants were, on average, somewhat younger and healthier than the overall population of patients who started dialysis during the same time period. They were also more likely to be employed.

	All participants (n= 1,678) mean age at initiation 59.7 ±14.2		Nutrition study subset (n=399) mean age at initiation 60.9 ±13.8	
	N	Percent	N	Percent
<40	143	8.5	27	6.8
40-49	234	13.9	49	12.3
50-59	442	26.3	102	25.6
60-69	415	24.7	105	26.3
70+	444	26.5	116	29.1
Male	923	55.0	206	51.6
White	1,148	68.4	270	67.7
Black/Af Am	480	28.6	109	27.3
Asian	34	2.0	17	4.3
Other	16	1.0	3	0.8
Hispanic	240	14.3	53	13.3
Hemodialysis	1,561	93.0	359	90.0

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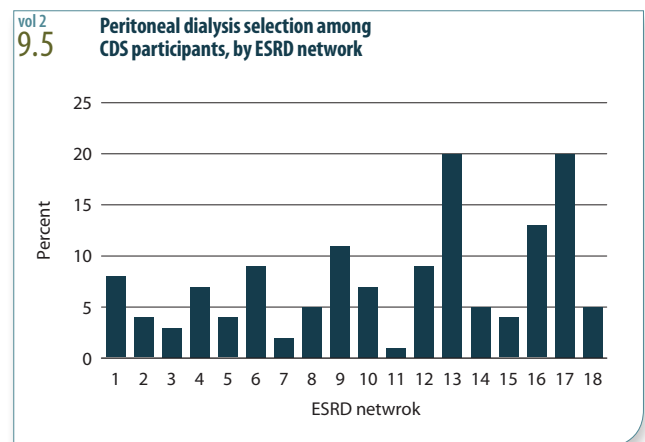
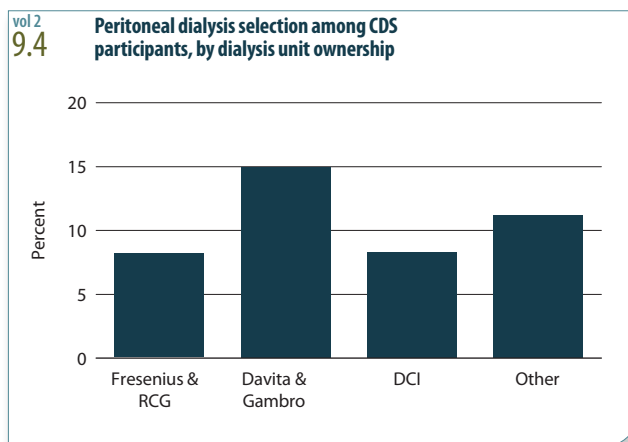
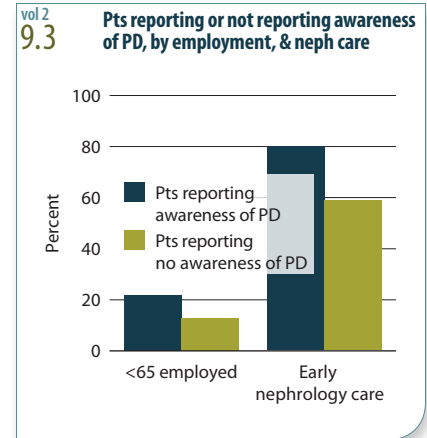
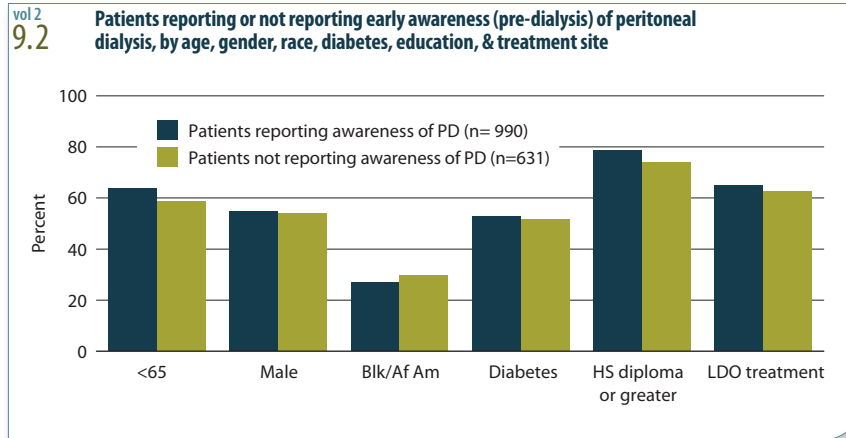
Sociodemographic characteristics of Comprehensive Dialysis Study participants

Patients reporting early (pre-dialysis) awareness of PD (n=990) and those not (n=631) were generally similar in age, gender, race, presence of diabetes, education level, and treatment in a facility owned by a large dialysis organization (LDO). Patients who said that PD had been discussed with them pre-dialysis, however, were more likely to be employed (among patients younger than 65) and to have received pre-dialysis nephrologist care.

Overall, 7 percent of CDS participants started on PD as their initial modality, and 99 percent of these individuals remained on this modality 90 days after the start of treatment. Patients

with early awareness of peritoneal dialysis, however, were more likely than those without it to start on the modality, at 11 versus 2 percent, respectively.

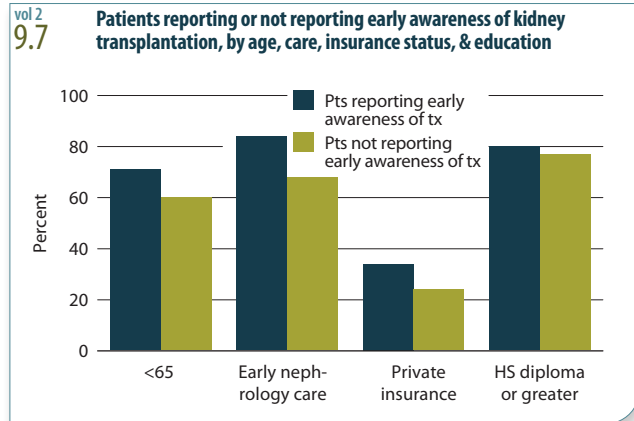
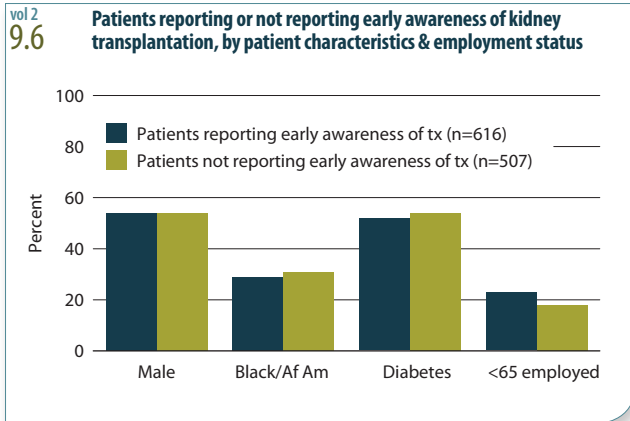
The proportions of patients initiating peritoneal dialysis in LDO and non-LDO clinics were similar, at 10.8 and 11.2 percent, respectively. And among the LDOs, DaVita had the highest proportion of patients initiating on PD, at 15 percent compared to 8.2–8.3 percent in units owned by Fresenius or DCI. » **Figures 9.2–4**; see page 443 for analytical methods. *Incident dialysis patients who started treatment June 1, 2005 to June 1, 2007.*



Although more use of PD might be expected in less populated areas that require patients to travel greater distances to a dialysis clinic, no association was found between increasing rurality of dialysis facility location and patients' selection of PD. Variation in PD use was, however, evident across ESRD Networks.

Previous research has shown that dialysis units in which patients are less likely to have received pre-dialysis nephrology care tend to be clustered geographically, and differences in the availability of pre-dialysis care may contribute to geographic variation in PD selection.

Geographic variation in pre-ESRD care may be related to inadequate dissemination of evidence-based practice guidelines and ambiguities in the state of clinical practice. Low detection rates of chronic kidney disease by primary care physicians and limited availability of nephrology manpower are additional possibilities. Geographic variation in availability of pre-ESRD care could be targeted by ESRD Networks for quality improvement initiatives. » **Figure 9.5**; see page 443 for analytical methods. *Incident dialysis patients who started treatment June 1, 2005 to June 1, 2007.*



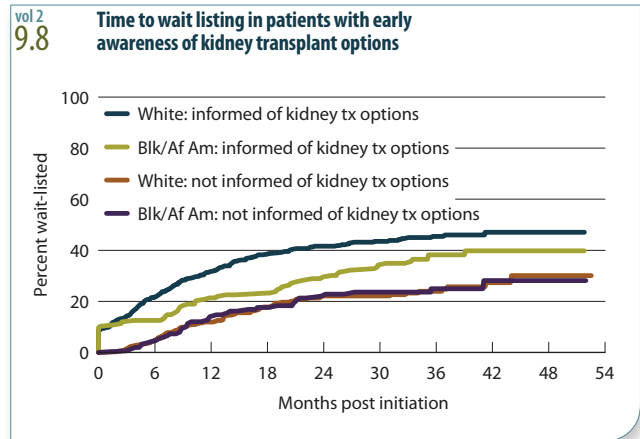
In order to focus on patients most likely to be eligible for transplantation, the CDS study group was restricted to 1,123 patients reported on the Medical Evidence form to be “informed of kidney transplant options.” Patients reported not informed because of being “medically unfit,” “unsuitable due to age,” etc. were not considered.

Among potentially eligible candidates for transplantation, patients who reported early (pre-dialysis) awareness of kidney transplantation (n=616) and those who did not (n=507) were generally similar in gender, race, diabetes, and employment status (among patients younger than 65). Thus, black/African American and white patients were equally likely to recall that kidney transplantation had been discussed with them prior to dialysis.

Patients who said that kidney transplantation had been discussed with them pre-dialysis were on average younger, more likely to have received pre-dialysis nephrology care, to have private health insurance, and to have a high school diploma or greater. » **Figures 9.6–7**; see page 443 for analytical methods. *Incident dialysis patients who started treatment June 1, 2005 to June 1, 2007.*

Examination of time to wait listing shows that both black/African American and white patients who had early exposure to information about kidney transplantation were more likely to be wait-listed compared with their same race peers who did not report this early exposure. At the same time, white patients were significantly more likely to be wait-listed than blacks/African Americans. The differential early discussion/race effects on wait listing were not explained by other patient characteristics, nor by geographic region of the country.

Being wait listed or receiving a deceased donor transplant within one year of ESRD initiation is a Healthy People 2010/2020 objective. Among blacks/African Americans, 21.1 percent who reported pre-dialysis discussion of kidney transplantation were wait-listed or transplanted within one year, compared to 13.8 percent who did not report that kidney transplantation was discussed with them pre-dialysis; among whites, the numbers were 31.3 and 11.5 percent, respectively. These data again demonstrate that early awareness of transplant was beneficial for both blacks/African Americans and whites, but that whites were more likely to experience early wait-listing or transplantation. » **Figure 9.8 & Table 9.c;** see page 443 for analytical methods. *Incident dialysis patients who started treatment June 1, 2005 to June 1, 2007.*

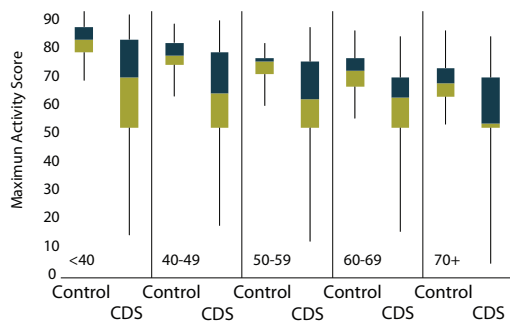


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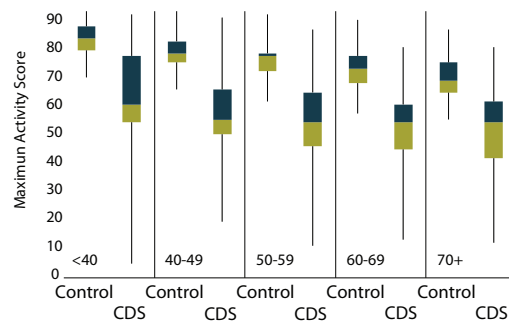
Patients wait-listed or who received a deceased donor kidney transplant within one year of ESRD initiation

	Black/Af Am pts. wait-listed/transplanted within one year	White pts wait-listed/transplanted within one year
Transplant options discussed pre dialysis	21.1%	31.3%
Transplant options not discussed pre dialysis	13.8%	11.5%

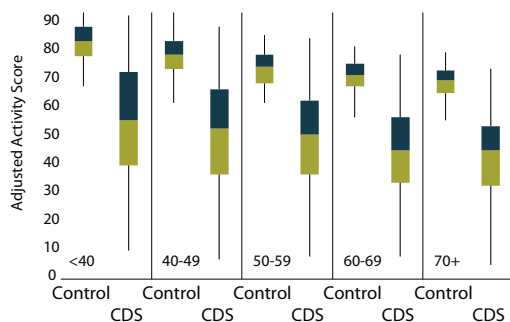
MAS: Males



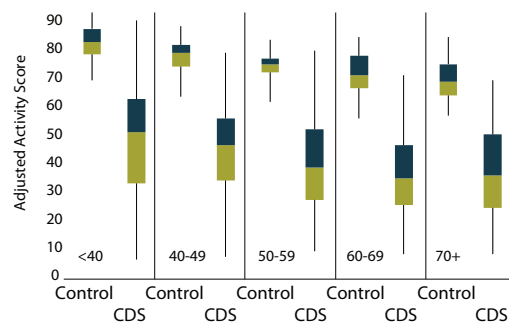
MAS: Females



AAS: Males



AAS: Females



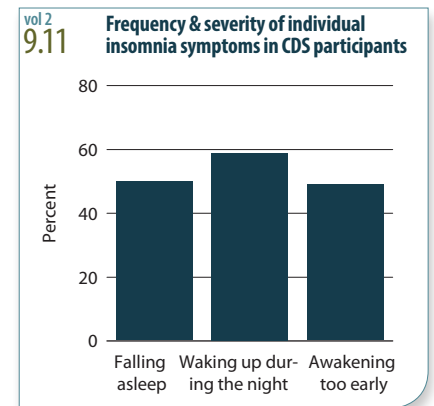
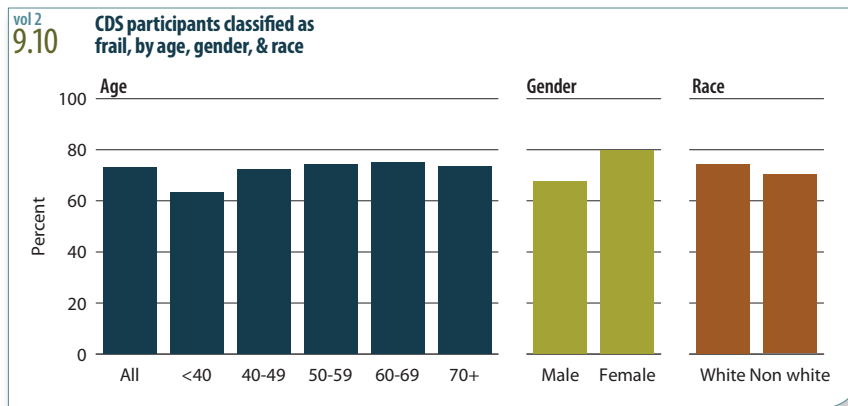
Here and in the next spread the Nutrition Special Studies Center presents data on physical activity (measured using the Human Activity Profile (HAP)), patient frailty (using data on physical activity level, self-reported physical functioning, and exhaustion), insomnia, restless legs syndrome (RLS), and depression. Data are also presented from a sub-study of the CDS, which provides information about usual dietary intake using the Block 2000 Brief Food Frequency Questionnaire.

CDS participants were asked in the HAP questionnaire to report whether they are “still doing,” have “stopped doing,” or “never did” 94 activities ranked according to estimated energy expenditure, and ranging from getting in and out of chairs or bed without assistance to running or jogging three miles in 30 minutes or less. Two scores are generated from the HAP, a Maximum Activity Score (MAS) and an Adjusted Activity Score (AAS). The MAS is the highest oxygen-demanding activity that the respondent still performs, and is indicative of the respondent’s current maximum activity level. The AAS is calculated by subtracting from the MAS the total number of activities that are less demanding than the MAS but that the respondent is no longer doing, and is reflective of an individual’s usual daily activity level.

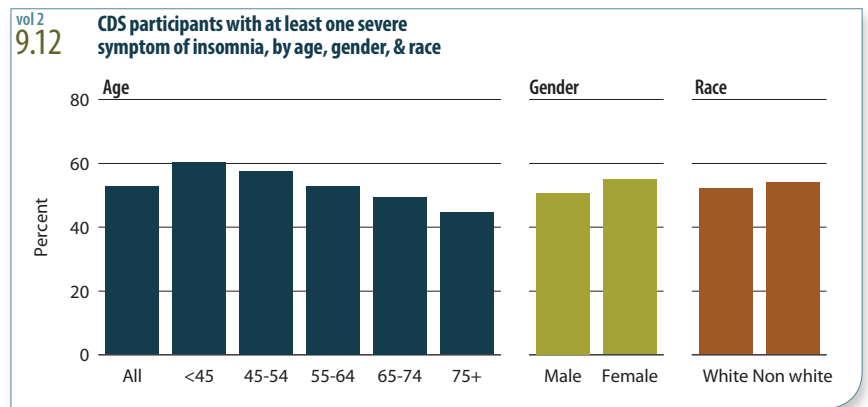
Among CDS participants, self-reported physical activity was extremely low when compared with control data from healthy individuals. The median maximum activity score (MAS) for male CDS participants in all age groups was considerably below the 25th percentile for healthy men, and for women the median MAS for CDS participants was consistently below the first percentile for healthy individuals. The adjusted activity score (AAS) of CDS participants, representative of usual daily activity, was even lower relative to control data, with the 75th percentile for men in all age groups below the 25th percentile for the general population, and the 75th percentile for women in the CDS below the first percentile at all ages. » **Figure 9.9**; see page 443 for analytical methods. *Incident dialysis patients who started treatment June 1, 2005 to June 1, 2007. The boxes represent the 25th to 75th percentiles with the line in the center indicating the 50th percentile. Lines above and below extend to the 99th and 1st percentile, respectively. In each figure, scores are shown by age group, beginning with age <40 and progressing by decade to age 70 & older. Within each age group, control data are represented on the left and CDS participants’ data are plotted on the right.*

Seventy-three percent of CDS participants were considered frail and even among participants younger than 40 years, the prevalence of frailty was 63 percent. As expected, women were more likely to be frail. There was little difference in the proportion of frail individuals based on age, a finding that differed from previous cohorts using slightly different definitions of frailty. Whites were slightly but not statistically more likely to be frail than non-white patients. » [Figure 9.10](#); see page 443 for analytical methods. *Incident dialysis patients who started treatment June 1, 2005 to June 1, 2007. A frailty phenotype was constructed using data on physical activity level, self-reported physical functioning, & exhaustion. One point was given for self-reported physical activity (from the HAP) in the lowest quintile of the general population based on age, one point for a Physical Function score on the SF-12 of <75, & one point for responding “a little of the time” or “none of the time” when asked how much of the time during the past four weeks they thought they had a lot of energy. Patients with two or more points were considered frail.*

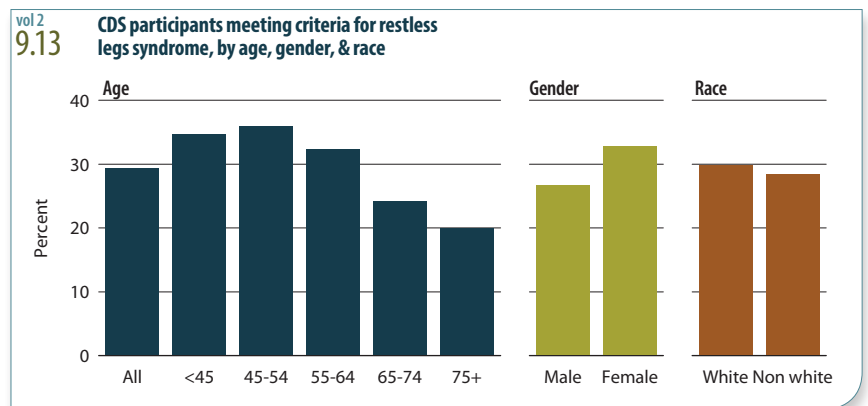
Approximately half of CDS respondents indicated at least moderate difficulty with each aspect of sleep quality — 50 percent having trouble falling asleep, 59 percent waking up during the night, and 49 percent awakening too early. » [Figure 9.11](#); see page 443 for analytical methods. *Incident dialysis patients who started treatment June 1, 2005 to June 1, 2007.*



Here we show the distribution of CDS participants with at least one severe symptom of insomnia all or most of the time. Differences based on gender and race were minor, but insomnia was significantly more common among younger than among older CDS participants. » [Figure 9.12](#); see page 443 for analytical methods. *Incident dialysis patients who started treatment June 1, 2005 to June 1, 2007.*

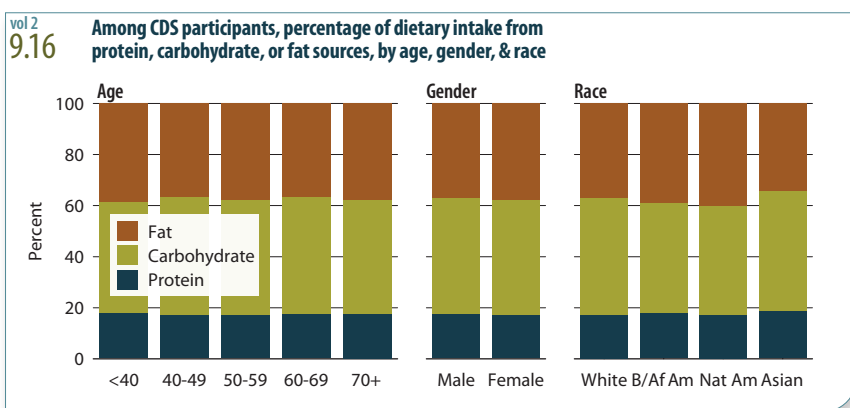
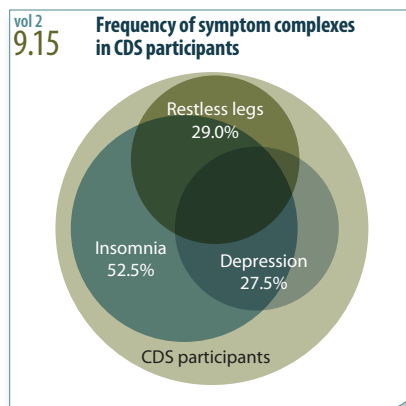
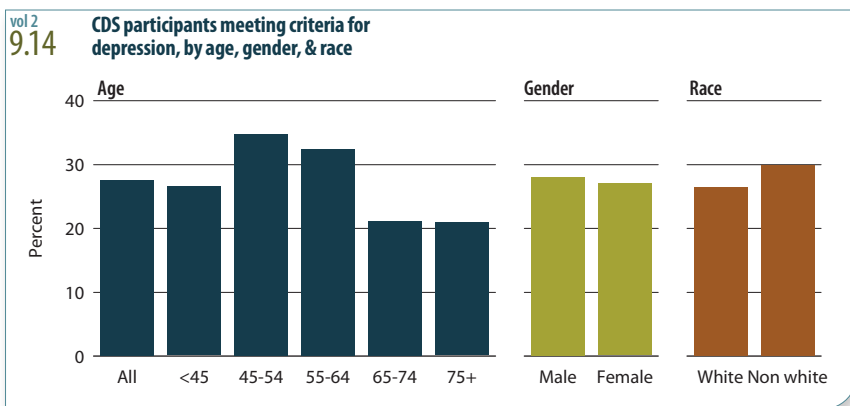


Overall, 29 percent of CDS respondents met the criteria for restless legs syndrome. There were differences in the prevalence of restless legs based on age and gender, with women and younger participants more likely to be affected. There were no significant differences in prevalence of restless legs syndrome based on race. » [Figure 9.13](#); see page 443 for analytical methods. *Incident dialysis patients who started treatment June 1, 2005 to June 1, 2007.*

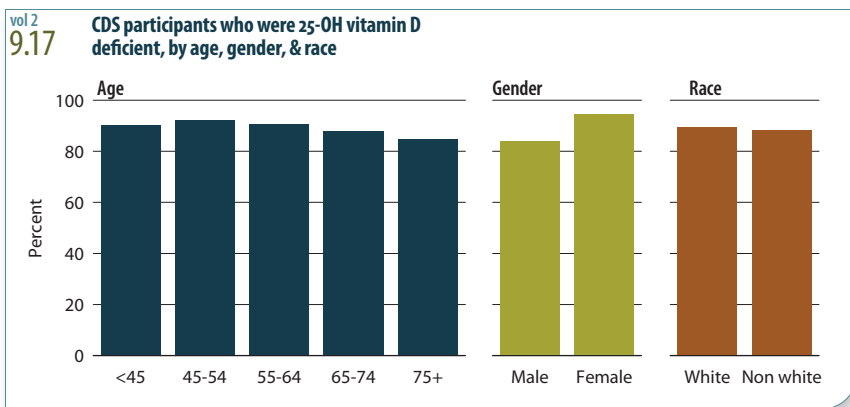


Twenty-seven percent of CDS participants met the criterion for depression (a score of 3 or greater on the two-item Patient Health Questionnaire-2), and as with restless legs, younger participants were more likely to be affected. There were, however, no clear differences based on gender or race. » [Figure 9.14](#); see page 443 for analytical methods. *Incident dialysis patients who started treatment June 1, 2005 to June 1, 2007.*

Eighty percent of patients with depression also reported insomnia, restless leg syndrome (RLS) or both; 70 percent of RLS sufferers also reported depression and/or insomnia; and 57 percent of patients with insomnia also reported depression and/or RLS. These results highlight the heavy burden of symptoms among patients with ESRD and the potential for interdependence among symptom complexes. » [Figure 9.15](#); see page 443 for analytical methods. *Incident dialysis patients who started treatment June 1, 2005 to June 1, 2007.*



On average, CDS participants derived 37.4 percent of their calories from fat, 45 percent from carbohydrates, and 17.6 percent from protein, a diet that is higher in fat than currently recommended ranges. Group differences based on age, gender, and race were small and statistically insignificant. » [Figure 9.16](#); see page 443 for analytical methods. *Incident dialysis patients who started treatment June 1, 2005 to June 1, 2007.*



Among all subgroups, 25-OH vitamin D levels were low. Eighty-nine percent of patients, for instance, were vitamin D deficient with concentrations of less than 20 ng/ml. Women were statistically more likely to be vitamin D deficient than men, but there were no significant differences based on age or race. » [Figure 9.17](#); see page 443 for analytical methods. *Incident dialysis patients who started treatment June 1, 2005 to June 1, 2007.*

EARLY AWARENESS OF PD & TRANSPLANT AS TREATMENT OPTIONS

patients reporting (n=990) early awareness (pre-dialysis) of peritoneal dialysis (percent; Figure 9.2)

» <65 · 64 » male · 55 » blk/Af Am · 27 » diabetes · 53 » high school education+ · 79 » treatment in LDO facility · 65

patients not reporting (n=631) early awareness (pre-dialysis) of peritoneal dialysis (percent; Figure 9.2)

» <65 · 59 » male · 54 » blk/Af Am · 30 » diabetes · 52 » high school education+ · 74 » treatment in LDO facility · 63

peritoneal dialysis selection among CDS participants, by dialysis unit ownership (percent; Figure 9.4)

» Fresenius/RCG · 8.2 » DaVita/Gambro · 15 » DCI · 8.3 » other · 11.2

HEALTH STATUS

CDS participants classified as frail (percent; Figure 9.10)

» all · 73.3 » age <40 · 63.4 » age 40–49 · 72.6 » age 50–59 · 74.6 » age 60–69 · 75.3 » age 70+ · 73.7

» male · 68.0 » female · 79.9

» white · 74.6 » non-white · 70.3

CDS participants with at least one severe symptom of insomnia (percent; Figure 9.12)

» all · 52.7 » age <45 · 60.4 » age 45–54 · 57.6 » age 55–64 · 53.0 » age 65–74 · 49.5 » age 75+ · 44.7

» male · 50.7 » female · 55.0

» white · 52.2 » non-white · 54.0

CDS participants meeting criteria for depression (percent; Figure 9.14)

» all · 27.6 » age <45 · 26.6 » age 45–54 · 34.7 » age 55–64 · 32.5 » age 65–74 · 21.2 » age 75+ · 21.0

» male · 28.0 » female · 27.0

» white · 26.5 » non-white · 30.0

CDS participants who were 25-OH vitamin D deficient (percent; Figure 9.17)

» age <45 · 90.0 » age 45–54 · 92.1 » age 55–64 · 90.4 » age 65–74 · 87.8 » age 75+ · 84.8

» male · 83.8 » female · 94.6

» white · 89.4 » non-white · 88.2