PEAK

Performance Excellence and Accountability in Kidney Care

FINAL REPORT

SEPTEMBER 2013

PREFACE

In December 2008, Kidney Care Partners (KCP) took an unprecedented step to conduct a voluntary, national goal-based quality improvement initiative, and in January 2009 KCP established improving survival for patients new to dialysis as the goal. At the time, available data indicated that overall survival rates for patients with end-stage renal disease (ESRD) had been improving, but by comparison the first-year mortality rate had remained relatively stagnant.

Publicly launched in June 2009 as the PEAK Campaign (Performance Excellence in Kidney Care), this multi-stakeholder initiative aimed to reduce first-year mortality by 20% by the end of 2012. Working with patients, clinicians, researchers and other experts in the kidney care community, KCP partnered with Brown University to monitor the data in consultation with a Data/Results Expert Panel. KCP also worked with Quality Partners of Rhode Island to manage the Expert Panels who identified both clinical and patient and family engagement best practices to improve survival rates. KCP greatly appreciates the significant time, effort, and expertise of the Expert Panel members, whose contributions were invaluable.

The Final Report that follows from Dr Shailender Swaminathan and Dr. Vincent Mor of Brown University reports the PEAK Campaign's results as of December 2012. The kidney care community's reduction in mortality represents a significant achievement, saving and extending the lives of thousands of patients with ESRD.

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Monitoring the Kidney Care Partners' PEAK Campaign to Reduce the 1-year Mortality Rates of Dialysis Patients: Final Report

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I. INTRODUCTION AND BACKGROUND

In January 2009, Kidney Care Partners (KCP) initiated a voluntary, community-based quality improvement initiative, the PEAK (Performance Excellence in Kidney Care) Campaign, with the goal of substantially reducing 1-year mortality among patients newly initiating dialysis. This initiative brought together patients, nephrologists, nephrology nurses, other health care professionals, senior leaders from dialysis organizations, researchers, representatives from manufacturers, and epidemiologists from the United States Renal Data System (USRDS). Relying upon evidence-based recommendations for patients initiating dialysis, PEAK reflected multiple quality improvement initiatives undertaken simultaneously by all the major End-Stage Renal Disease (ESRD) providers and professionals in the United States..

Brown University was awarded the contract to serve as the independent monitor of the 1-year mortality rates of patients newly entering dialysis since the initiation of the Campaign. In addition, Brown also was asked to provide information on 90-day mortality rates and, together with PEAK's Data/Results Technical Panel,[1] analyzed changes in several of the individual demographic and clinical characteristics that also might have impacted mortality rates. In this report, we summarize changes in associated mortality and treatment patterns associated with the initiation of PEAK.

II. METHODS

This section summarizes the data sources and methods we used to track the progress of the PEAK Campaign. Appendix A provides additional details.

1. Data Sources

The Renal Management Information System (REMIS) database is part of the data repository of the Centers for Medicare and Medicaid Services (CMS) and is widely used by USRDS in generating its annual reports. The data set contains several segments, but for our analyses we primarily used information from two of CMS' many data

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elements: (a) Medical Evidence Form (2728), and (b) Cause of Death Form (2746). The data from Form 2728 provides information on demographic and clinical characteristics of patients when they enter dialysis, while the data from the Form 2746 provides information on the dates of death. In addition, there are other sub-files within REMIS that contain date of death information, such as the Patient Master File.

In calculating the date of death, we used the *maximum date of death* that is recorded in any one of the sub-files of REMIS data. We also used the transplant datafile within REMIS to identify the date of kidney transplant, when applicable; this date influences the calculation of the mortality estimates. (Please see section II.5 below.)

2. Determination of Mortality Rates

We note that the literature has several different approaches to calculating and/or adjusting for 1-year mortality rates. After consulting with the Panel, we ultimately adopted the approach similar to that used by USRDS.

i. *1-year mortality rate per person-year*

As noted, the methodology we use is similar to that used by USRDS. Thus, for example, the 1-year rates were calculated using the following formula:

$$1 \text{ year rate} = \frac{\#\,\text{deaths in 1 - year after entering dialysis}}{\#\, of \;\; person\ years}$$

The use of this definition makes our rates sensitive to interventions/programs that may have a short-run impact on mortality. For example, if a particular intervention were to extend life/postpone death by two months, the estimated rate would be lower since now the denominator would increase.

<u>Censoring point</u>: We censor the information on all patients at either the date of death or the date of transplant.

$$\text{censoring point (date)=minimum(date of death, date of transplant)}$$

ii. ***90-day mortality rate per person year***

We follow a very similar methodology to that used for 1-year mortality. However, here we calculate the number of deaths in the first 90 days after dialysis initiation, and multiply the number by 4.05—a strategy that is consistent with that adopted by USRDS.

iii. ***1-year and 90-day (% dying)***

We also created a variable that represents an indicator variable if a patient dies within a pre-specified time span (i.e., 90 days or one year). In our regression analysis to create "adjusted" estimates, we used this variable as our outcome. Further details on our method to create "adjusted" estimates are provided below.

III. MONITORING CHANGES AND VARIATION IN MORTALITY, 90-DAY AND 1-YEAR

1. Changes in Case Mix Over Time

The focus of PEAK was to reduce mortality rates among those entering dialysis, but changes that occurred in the characteristics of patients prior to entering dialysis cannot, by definition, be affected by PEAK. We therefore examined trends in the demographic and clinical characteristics of the patients at the time they initiated dialysis. The results are presented in Table 1.

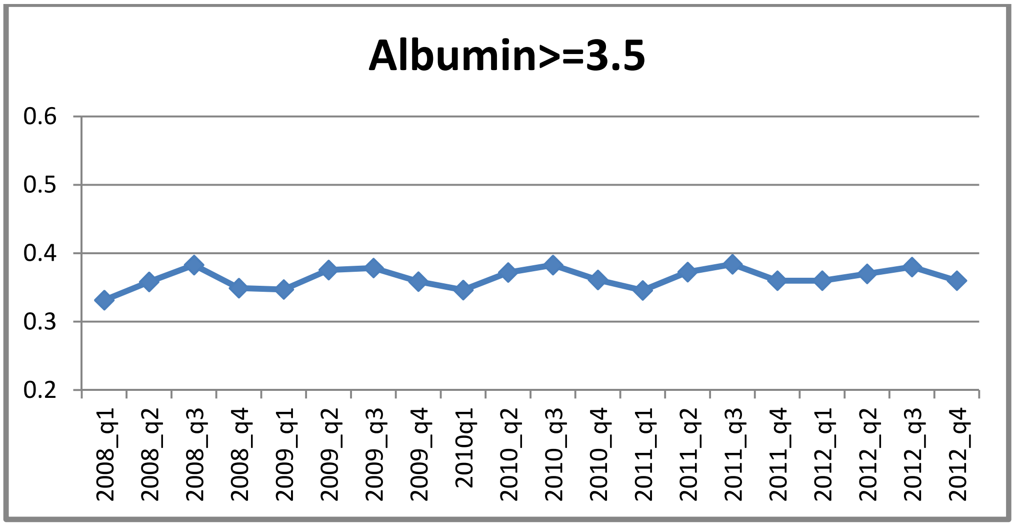
Table 1. Trends in Characteristics of Incident Cohort

Characteristics	2006	2007	2008	2009	2010	2011	2012
Male (%)	56	56	56	56	56	56	56
Age (%)							
<45	14	14	14	14	14	14	14
>=45&<=64	38	38	38	38	38	38	38
>=65&<=74	23	23	23	23	23	23	23
>75	25	25	25	25	25	25	25
White (%)	66	66	66	66	66	66	66
Black (%)	28	28	28	28	28	28	28
Other (%)	6	6	6	6	6	6	6
Diabetes Cause	44	44	44	44	44	44	44
Co-morbid conditions (%)							
Hypertension	40	40	40	40	40	40	40
Diabetes	46	46	46	46	46	46	46
Congestive Heart Failure	38	38	38	38	38	38	38
Ischemic Heart Disease	25	25	25	25	25	25	25

The data presented in Table 1 reveal there has been virtually no change in the demographic or clinical characteristics of the population initiating dialysis between 2006 and 2012.

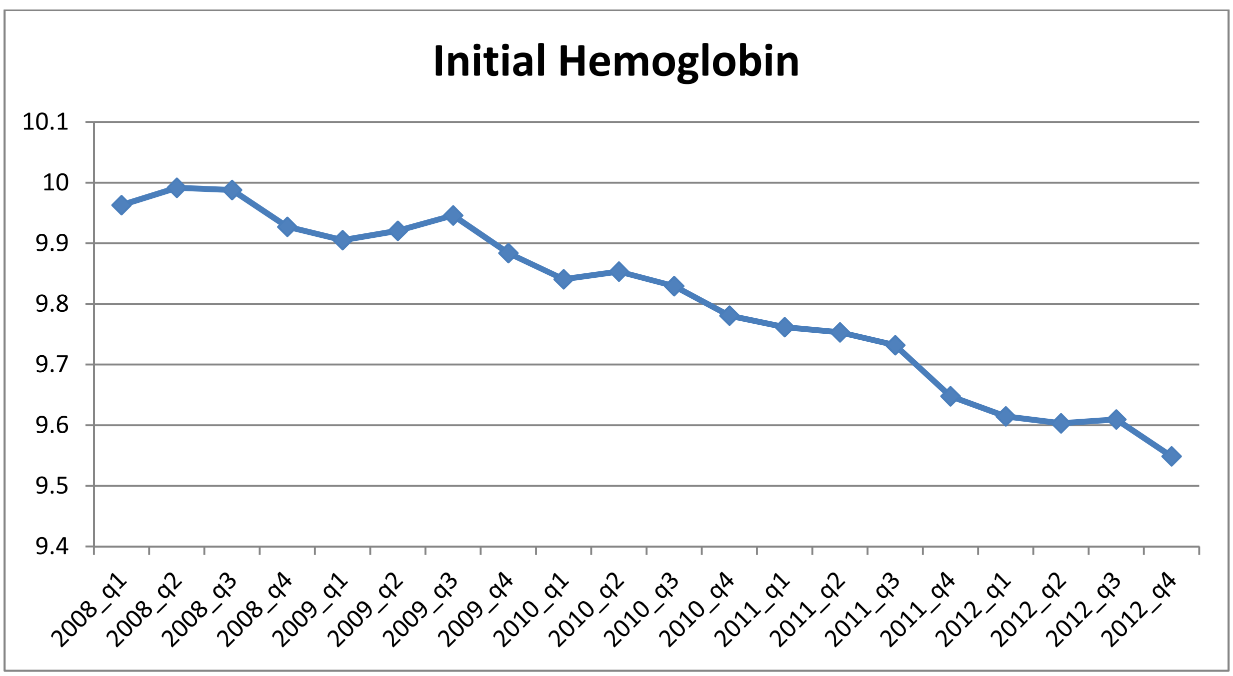
In Figure 1 below, we plot trends of patients' average laboratory values for patient albumin >=3.5 levels at the time of dialysis entry. These have remained remarkably similar over the course of the study.

Figure 1: Trends in Albumin >=3.5



In contrast to the relatively stable albumin levels, Figure 2 reveals a small, but steady, decline in baseline hemoglobin levels among new entrants to the ESRD program.

Figure 2: Initial Hemoglobin at Time of Entry



In Figure 3A, 3B, and 3C, we plot trends in creatinine values within age groups. Since creatinine is an important determinant of a patient's glomerular filtration rate (GFR), a measure of the kidney function of the patient that varies as a function of age, it is important to ensure that over the period of our study the proportion of individuals entering dialysis with elevated creatinine did not change within age group. (Higher values of serum creatinine correspond with worse kidney function.)

As can be seen, among patients entering dialysis who are under 65 years, the average creatinine level over time remained largely unchanged. However, for both groups of older patients, creatinine levels appeared to have increased some time towards the end of 2011—although for the oldest age group, the quarterly rates are fairly volatile, making it more difficult to determine whether the increase is a consistent trend.

Figure 3A: Trend in Mean Levels of Creatinine, 45-64 years

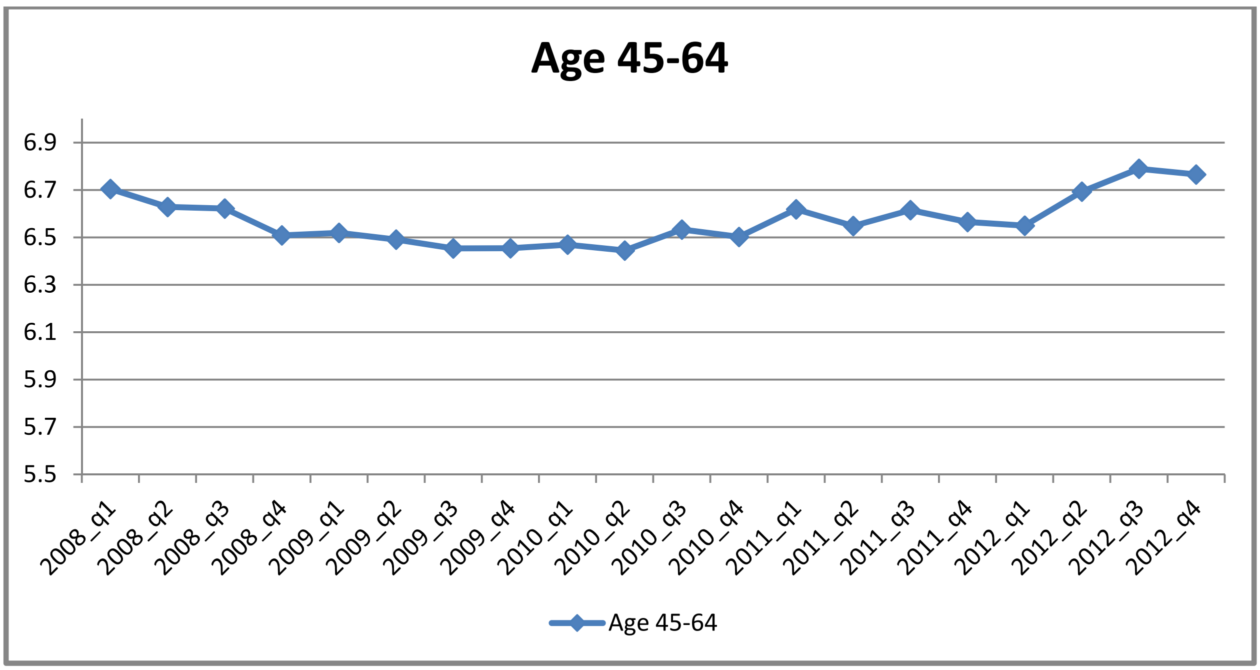


Figure 3B: Trend in Mean Levels of Creatinine, 65-74 years

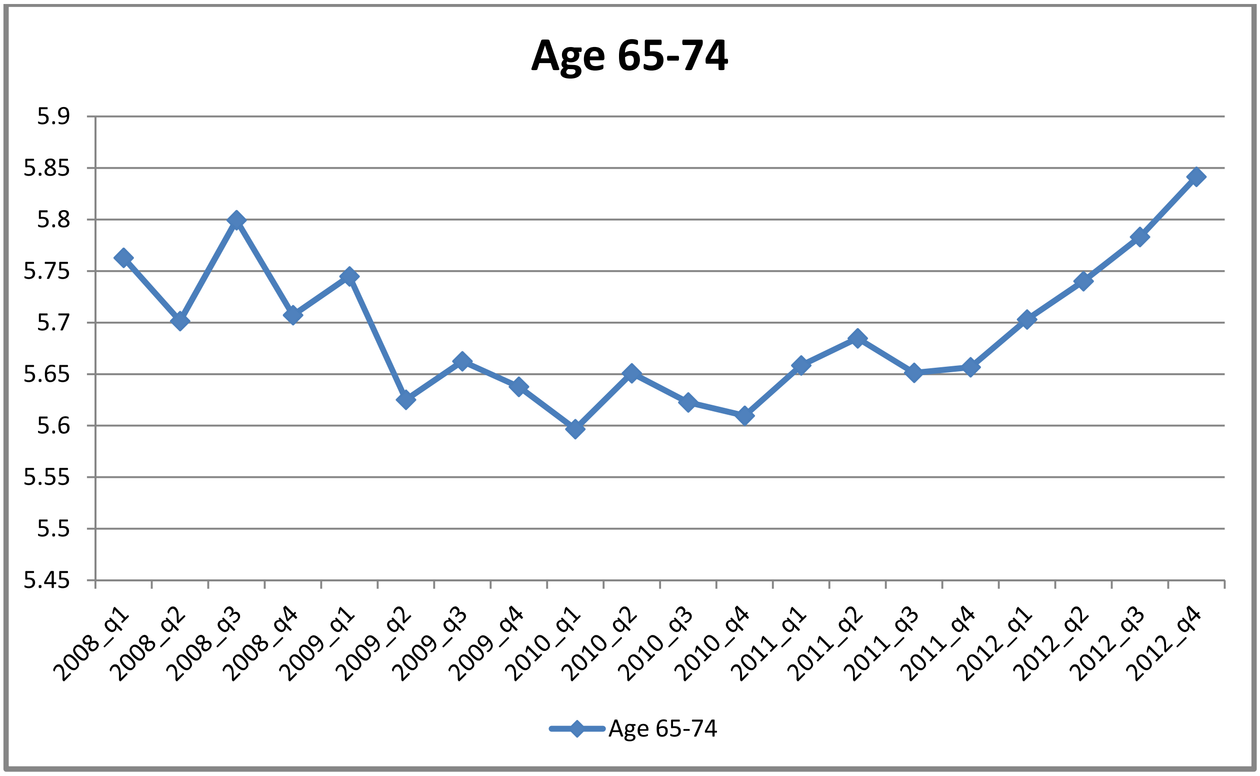
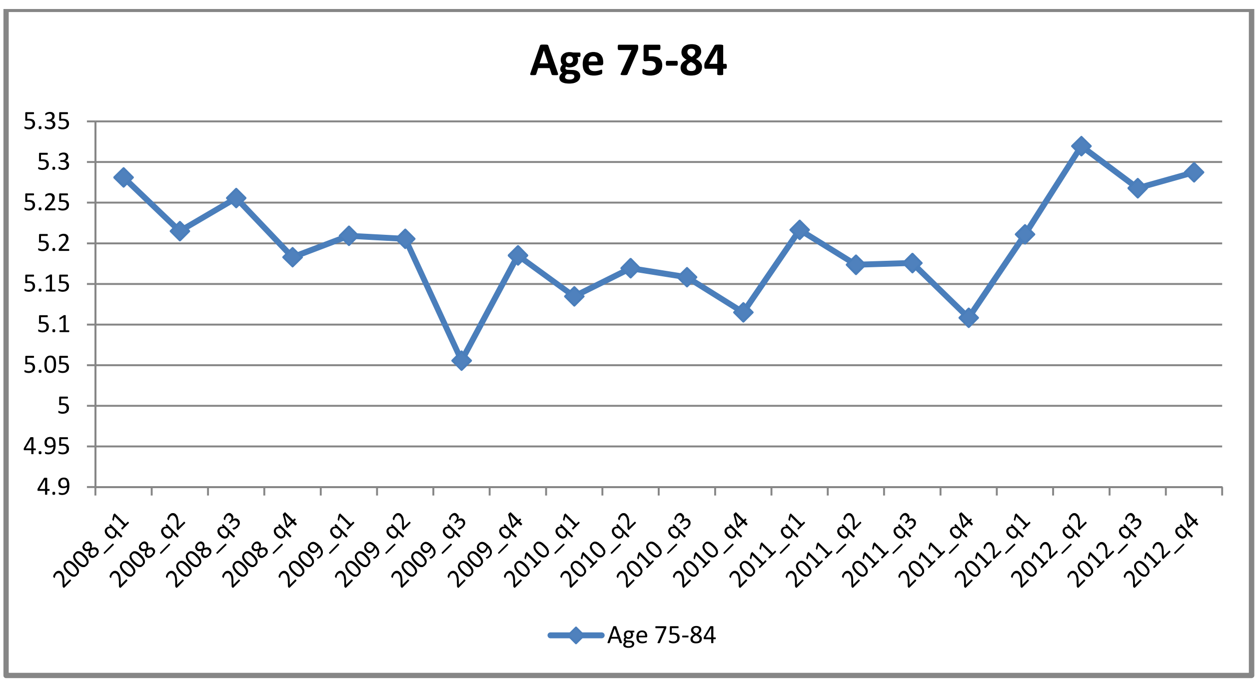


Figure 3C: Trend in Mean Levels of Creatinine, 75-84 years



The data on hemoglobin and creatinine reveal there are some changes in laboratory values that may be correlated with the health of the ESRD patient. While there has been virtually no change in albumin values, initial hemoglobin levels have declined. Data presented in Figure 3C suggests that creatinine values appear to be creeping up over the last couple of years, reflecting a slightly worse kidney function at the time of initiating dialysis, particularly among the elderly population (i.e., age 65-84), reversing an earlier period of declining trend.

2. Changes in Prescribed "Treatment"

The literature suggests that the use of catheters is associated with increased mortality relative to the use of fistulas for hemodialysis patients, although this conclusion is based on data from observational studies and not randomized clinical trials. Indeed, since by definition a catheter is the only option available when there is an immediate need for dialysis, it is also likely that those with a catheter at the time of initiation are sicker than those who have a fistula in place.

We plot trends in the use of catheters and fistulas at the time of initiation in Figures 4A, 4B, and 4C. In Figure 4D, we plot trends on whether the prescribed hemodialysis hours at initiation, as reported on the Form 2728, is 4 or more hours.

Figure 4A: Trend in Catheter Use at Dialysis Initiation (By Incident Quarter)

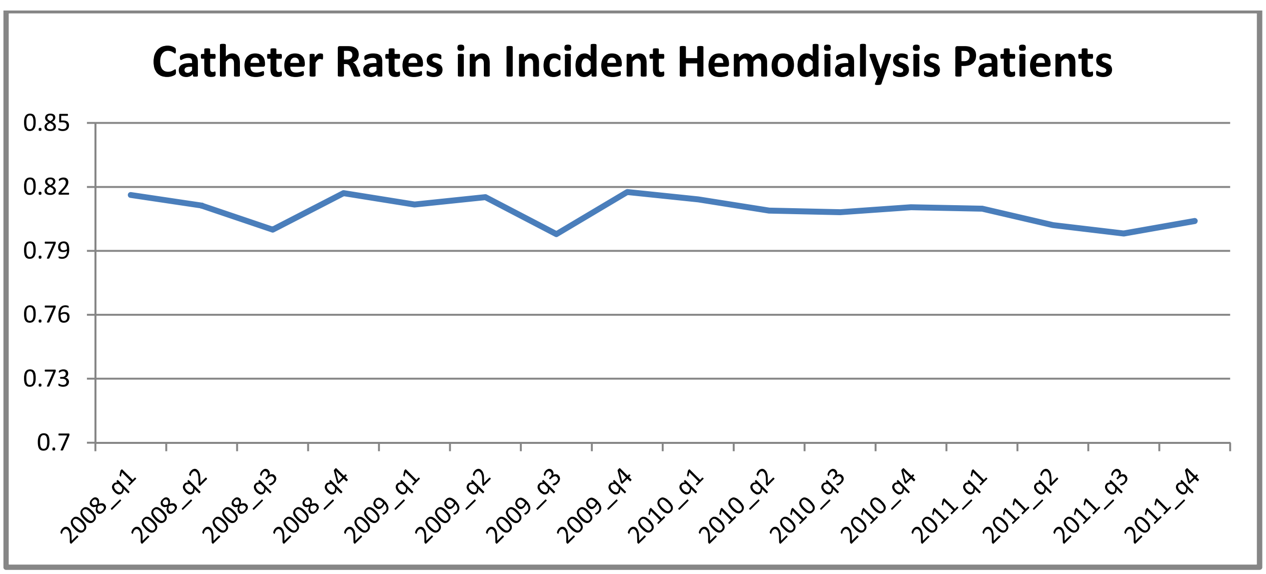


Figure 4B: Trend in Fistula or Graft Use at Dialysis Initiation(By Incident Quarter)

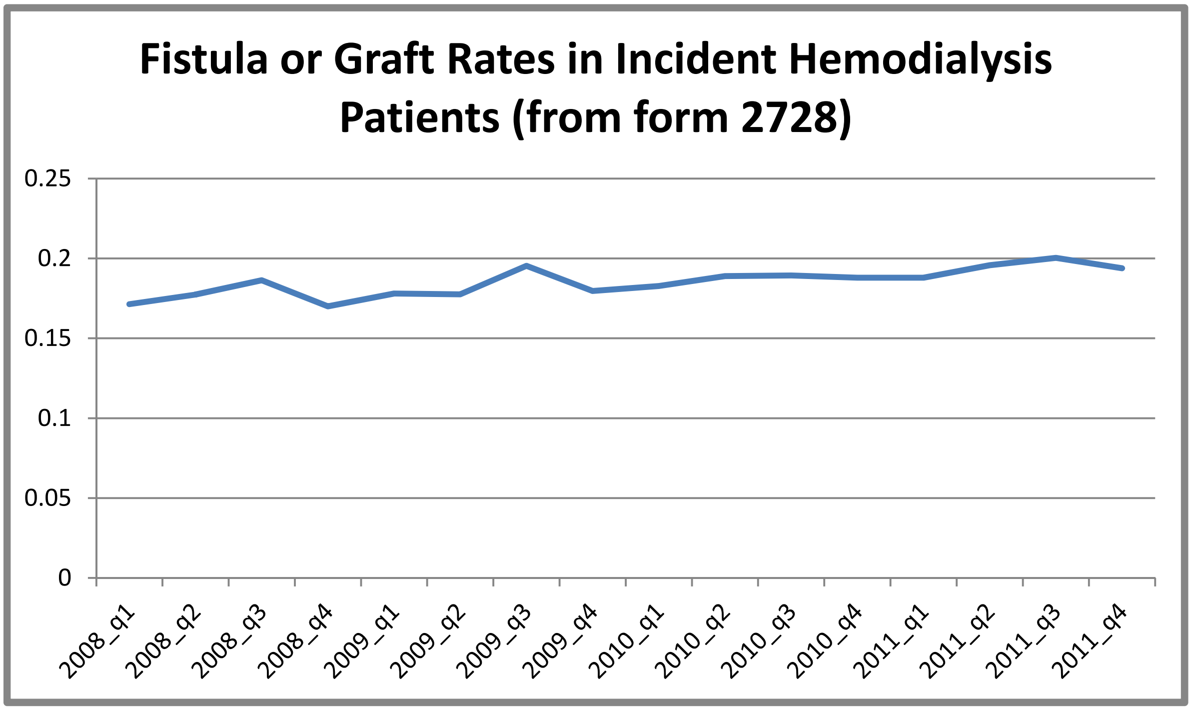


Figure 4C: Trend in Maturing Fistulas at Dialysis Initiation(By Incident Quarter)

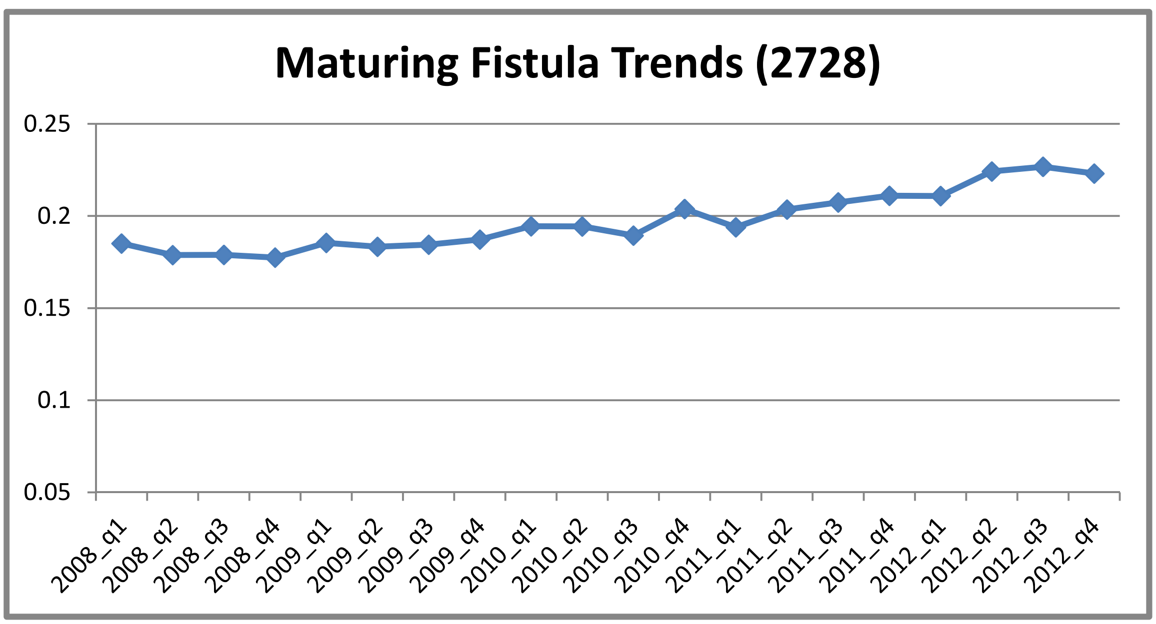


Figure 4D: Trend in Prescribed Hemodialysis Hours >= 4 at Dialysis Initiation (By Incident Quarter)

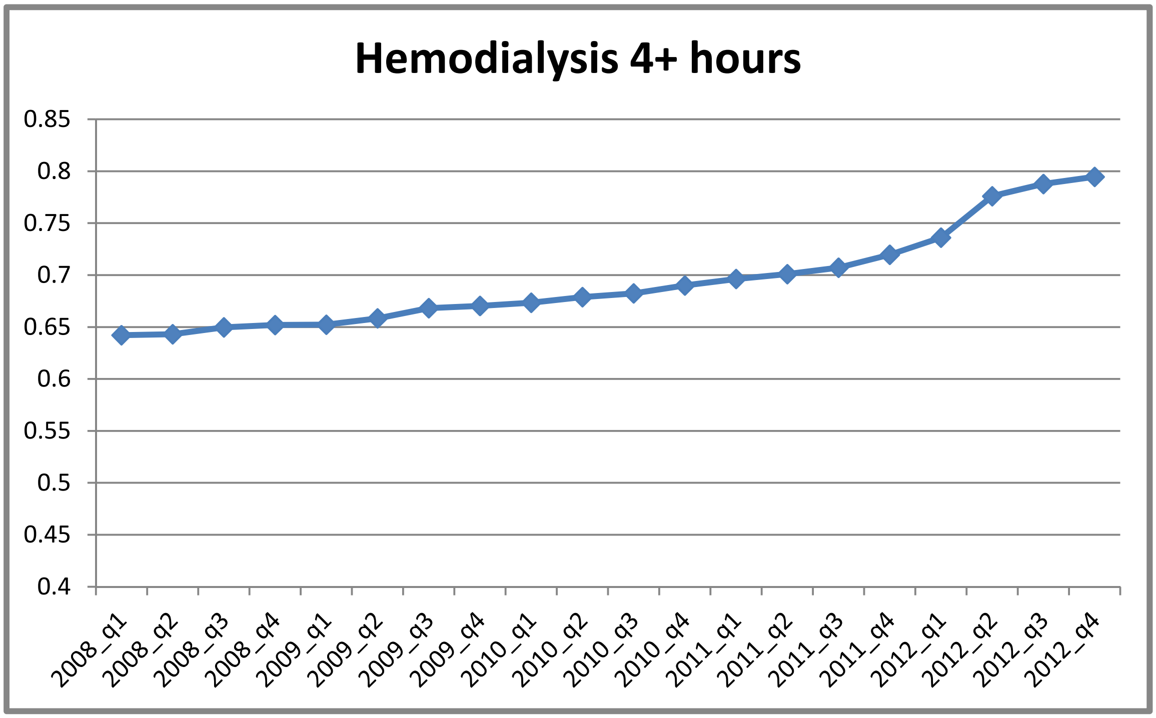


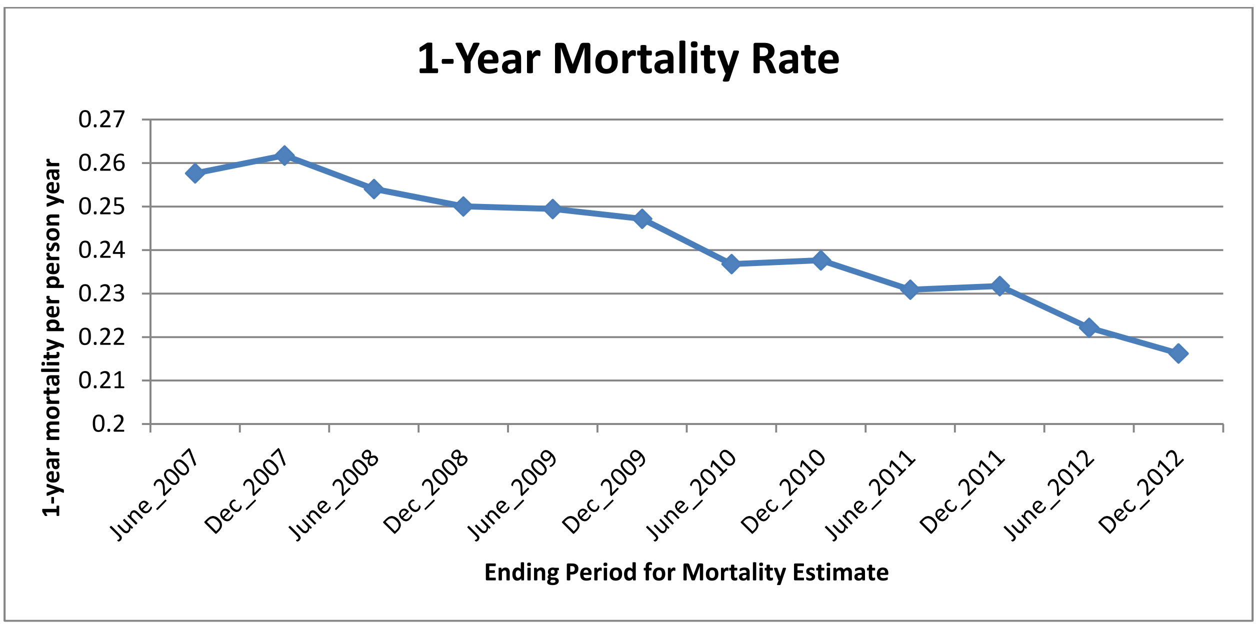
Figure 4A suggests there has not been much change in the use of catheters at the time of entry into the ESRD program. It is important to note that we do not have information on the use of catheters AFTER initiating dialysis, meaning that we cannot make any judgment about the use of catheters in prevalent dialysis patients. Indeed, beginning in the third quarter of 2011, there appears to be an uptick in the rate of maturing fistulas; raising the likelihood that the use of catheters may begin to decline in prevalent dialysis patients and earlier after dialysis initiation than before.

A striking trend is observed in Figure 4D, which reveals that the proportion of patients who are prescribed to have dialysis for 4 or more hours at dialysis initiation—as opposed to 3 hours—has been increasing, particularly in the last few years. Between 2008 and 2010 the proportion prescribed dialysis for at least 4 hours increased 10 percentage points; the rate of change seems to have spiked after that time, rising more than 5 percentage points in just one year.

3. Trends in Mortality Per Person Year

In Figures 5A and 5B, we plot the trend in 1-year mortality rates based on per person years. The Y-axis measures the mortality (deaths per person-years in 5A, and percent dying within 1-year in 5B), and the X-axis measures the date at which mortality is estimated based on successive 6-month incident cohorts. For example, the date December 2012 represents the mortality through the end of 2012 for the cohort that began dialysis between July 1, 2011 and December 31, 2011. We use an initial start date of January 2009, the time at which KCP approved the Campaign's focus on improving 1-year mortality rates. Based on this start date, **we estimate that through the end of 2012, there was a decline of about 13.6 percent in 1-year mortality rates.** (If we adopt the USRDS approach and use patient cohorts incident each year [as opposed to 6-months], the percent decline is similar [13.5 percent]).

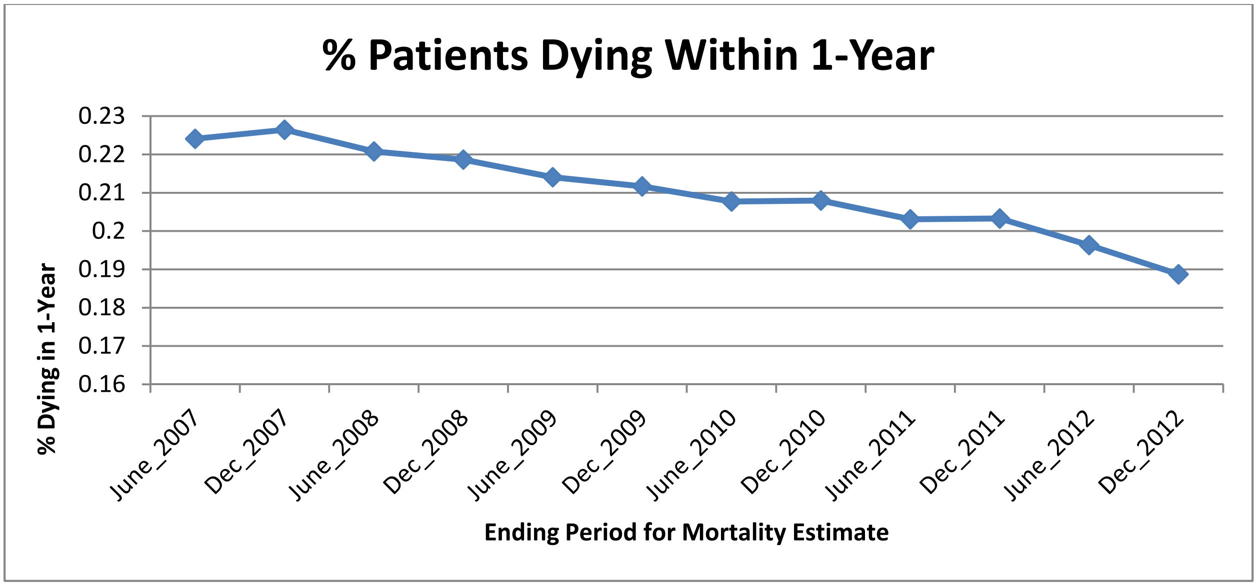
Figure 5A: Trend in 1-year Mortality Rate



We note that the decline in 1-year mortality varied across age groups. We note that this represents the "non-parametric" adjustment referred to in the methods section since we estimate the trends separately for each age group. The greatest decline of 14.7 percent occurred in the group of patients < 45 years old at the time of dialysis initiation, 14.2 percent for patients aged 45-64 years, 13. 5 percent for patients aged 65-74 years, and

12.9 percent for patients aged 75 years or older. We further note that this approach of providing separate estimates for each “cell” represents our non-parametric method for arriving at “adjusted” trends.

Figure 5B: Trend in Percent Dying Within 1 Year of Beginning Dialysis

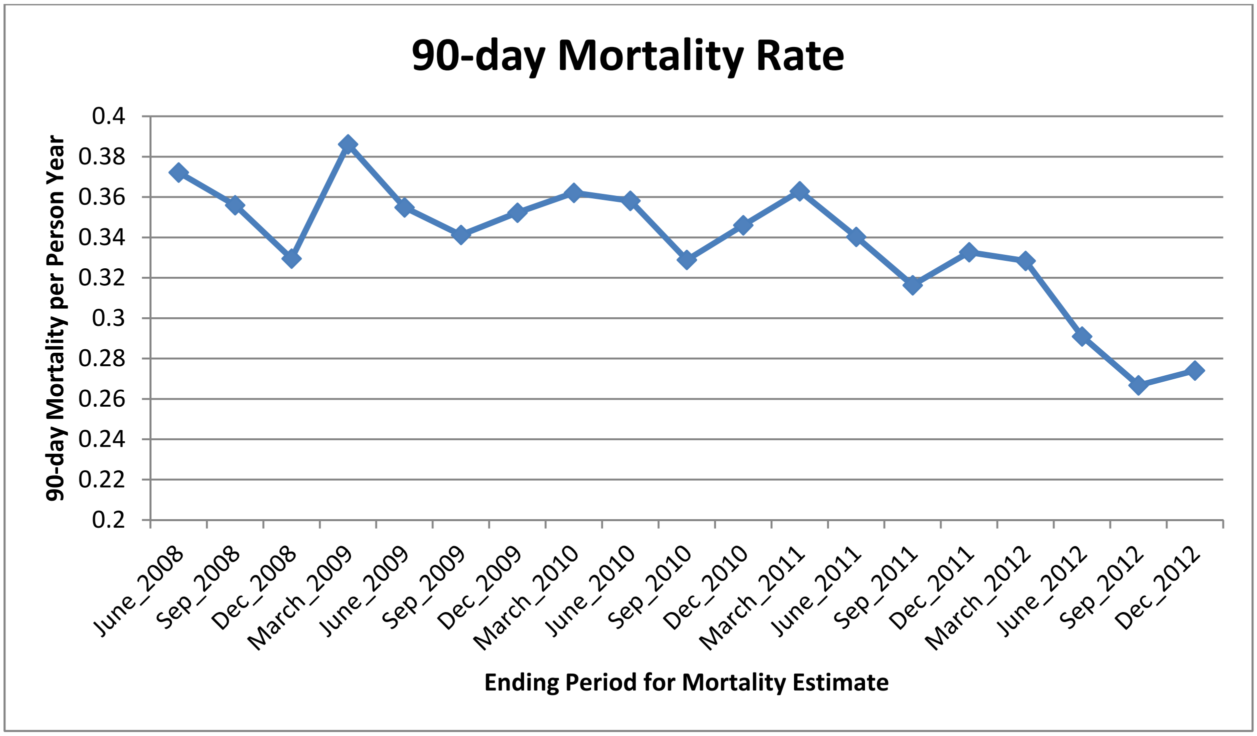


In figure 5B, we plot the data on the percent of patients dying within the first year of dialysis after adjusting for several demographic, clinical, and treatment characteristics at the time of initiation into dialysis. There is a 13.7 percent decline in this value since the beginning of the PEAK program.

90-day Mortality

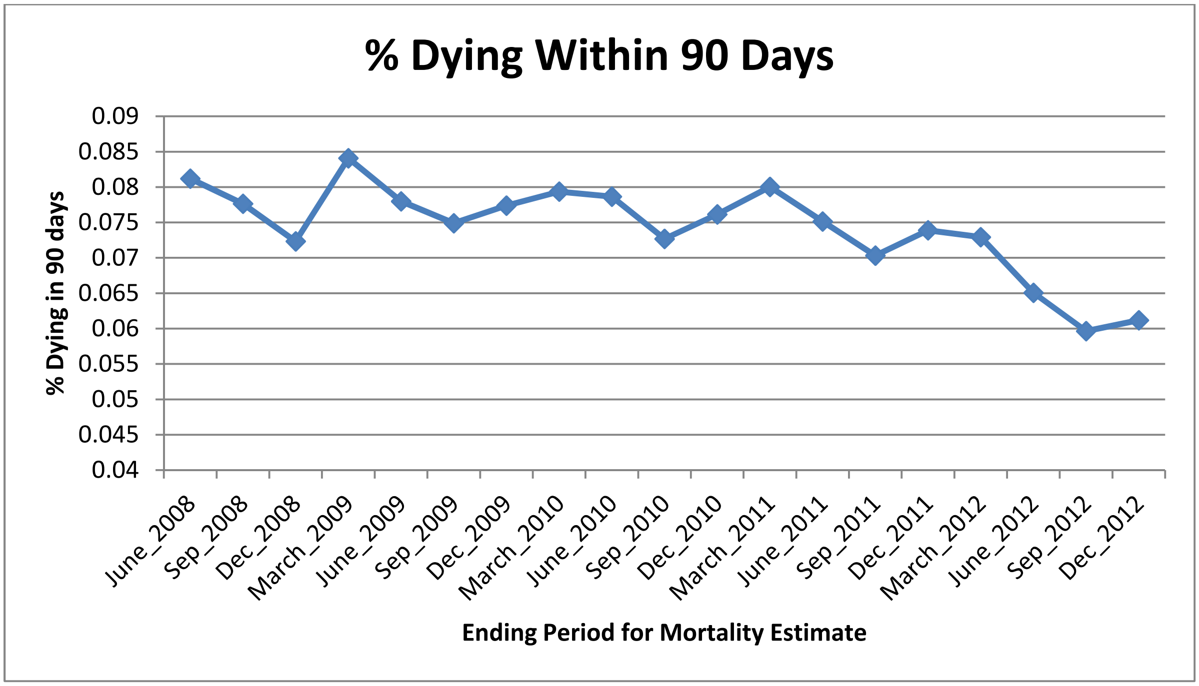
In Figure 6A, we present the trends in the 90-day mortality rate based on per person year. The decline in the rate is about 25 percent since the advent of the PEAK program.

Figure 6A: 90-day Mortality Rate per Person-Year



In Figure 6B, we present trends in the 90-day mortality (percent dying) for patients; early deaths among patient who initiate dialysis declined over the study period from around 8% of all new entrants to about 6% by the end of 2012.

Figure 6B: Trend in 90-day Mortality (% dying within 90 days)



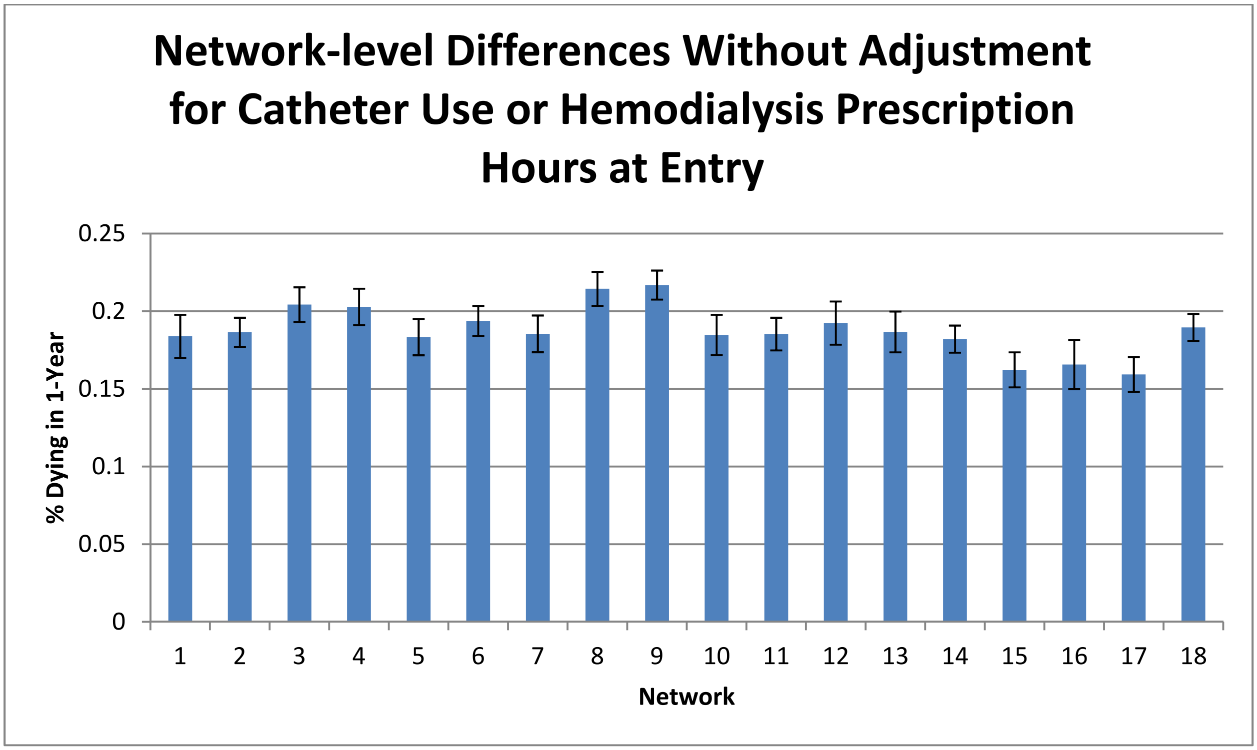
Overall, then Figure 6A reveals that the 90-day mortality rate (per person year) fell by about 25 percent since the beginning of PEAK. Figure 6B reveals that **the percent of patients dying within 90-days fell by about 22.5 percent since the beginning of PEAK** after adjusting for several demographic, clinical, and treatment characteristics at the time of initiation into dialysis. Furthermore, more than 60 percent of this decline in 90-day mortality occurred for incident cohorts on or after the first quarter of 2012, suggesting that the impact of PEAK may not have completed its impact on reductions in 1- year mortality, since the literature notes that, in general, survival at 90 days can be predictive of survival to one year.

IV. VARIATION BY NETWORK

1. Mortality Variation

Regional variations in the quality of health care delivery and in health outcomes have been documented in almost all facets of health and health care. Since CMS organizes ESRD patient care support and data collection into geographic Networks, we felt it may be important to examine the extent of any Network differences as they relate to 1-year mortality rates of dialysis patients.

Figure 7 A: 1-year Mortality Network-level Variations, Unadjusted for Catheter Use or Hemodialysis Prescription Hours (per person year)

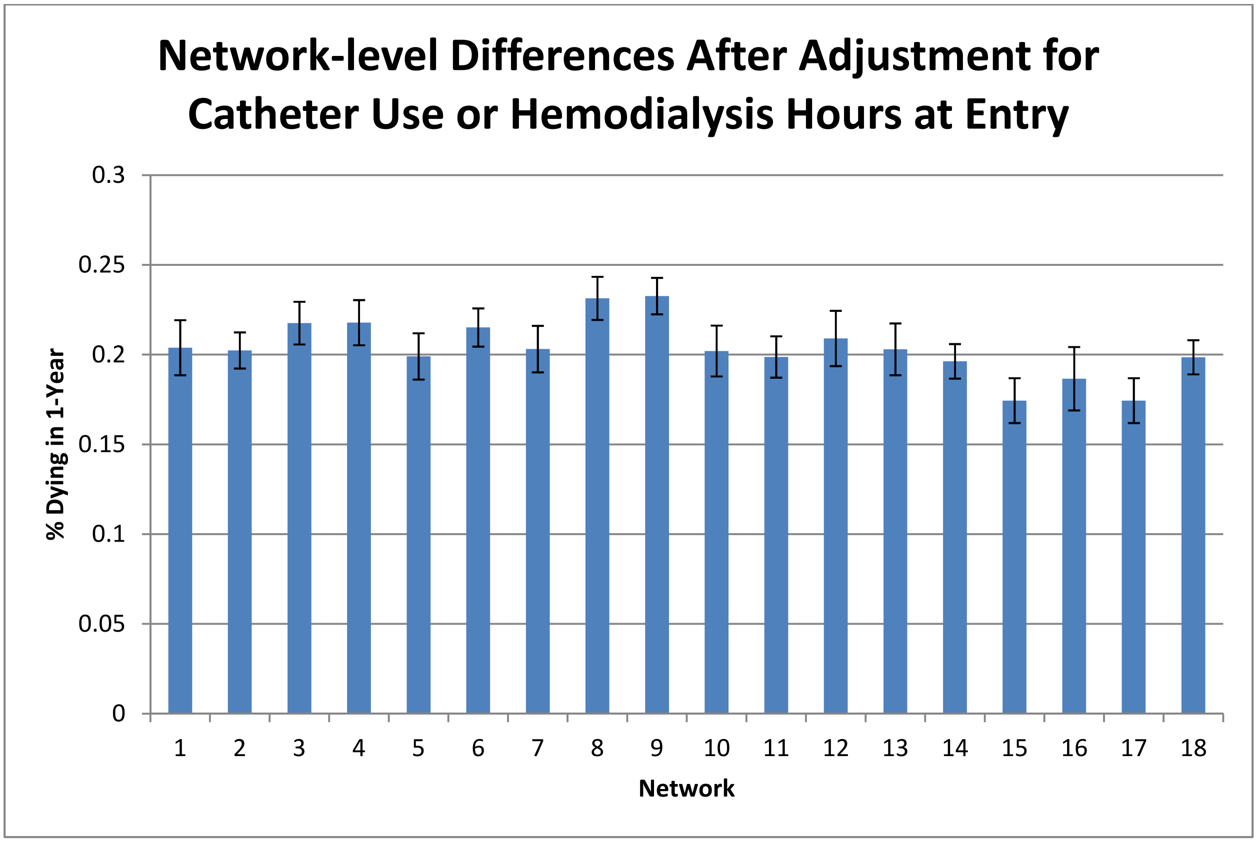


Note: Figure uses all patients that begin dialysis in calendar year 2011

In Figure 7A, we present Network-level differences in 1-year mortality rates adjusted for patient-level demographic and clinical characteristics, but NOT adjusted for any treatment-characteristics (i.e., whether or not the patient was prescribed hemodialysis treatment at initiation for 4 hours or more and catheter at dialysis initiation). In Figure 7B, we present the Network-level differences, but now adjusted for the treatment level factors of catheter at dialysis and prescribed hemodialysis at initiation of 4 hours or more. We observe that the Network-level differences in mortality remain even after adjusting for these treatment differences. If differences in treatment were the underlying reason for Network-level differences in mortality, we would expect that the observed Network-level differences in mortality would shrink substantially after adjustment. However, the differences persist.

Network-level differences may persist even after adjustment for clinical, and treatment characteristics because we have data that are measured at the point of initiation, and hence subject to substantial measurement error or changes in practice after patients are in treatment for a period of time. In any event, more research may be necessary to understand the causal drivers of mortality.

Figure 7 B: 1-year Mortality by Network Adjusted for Variations in Catheter Use and Hemodialysis Hours >=4 at Time of Initiating Dialysis



2. Network-level Variation in Treatment (Prior to and at Initiation of Dialysis)

Figures 8A, 8B, 8C, 8D, and 8E illustrate the extent of differences in case mix and treatment variables among Networks.

Figure 8A: Fraction of Patients with Albumin >=3.5 at Initiation, By Network

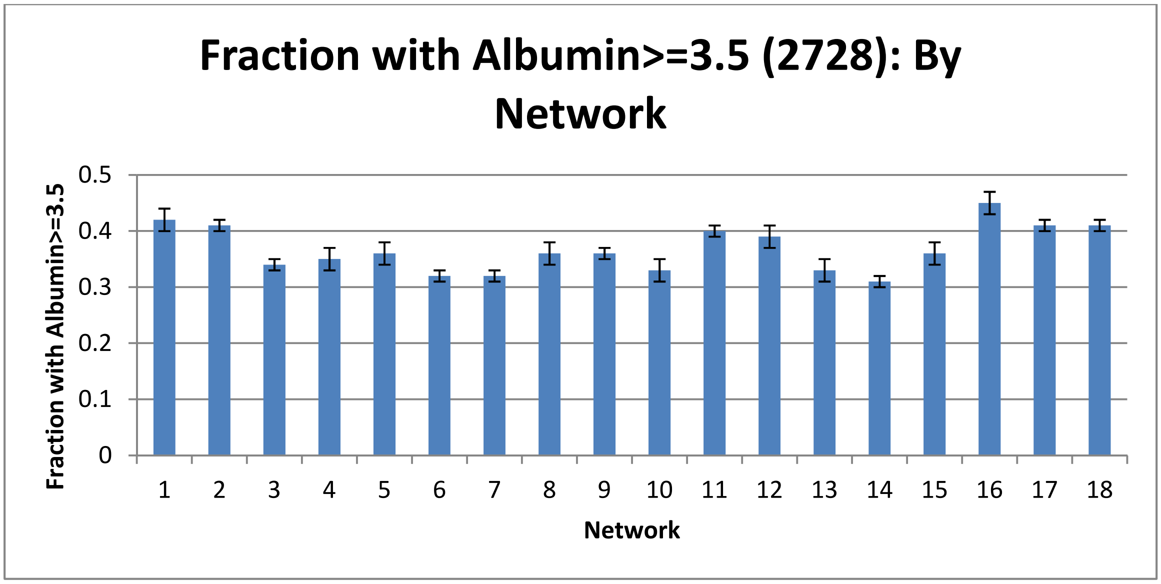


Figure 8B: Mean Hemoglobin at Initiation, By Network

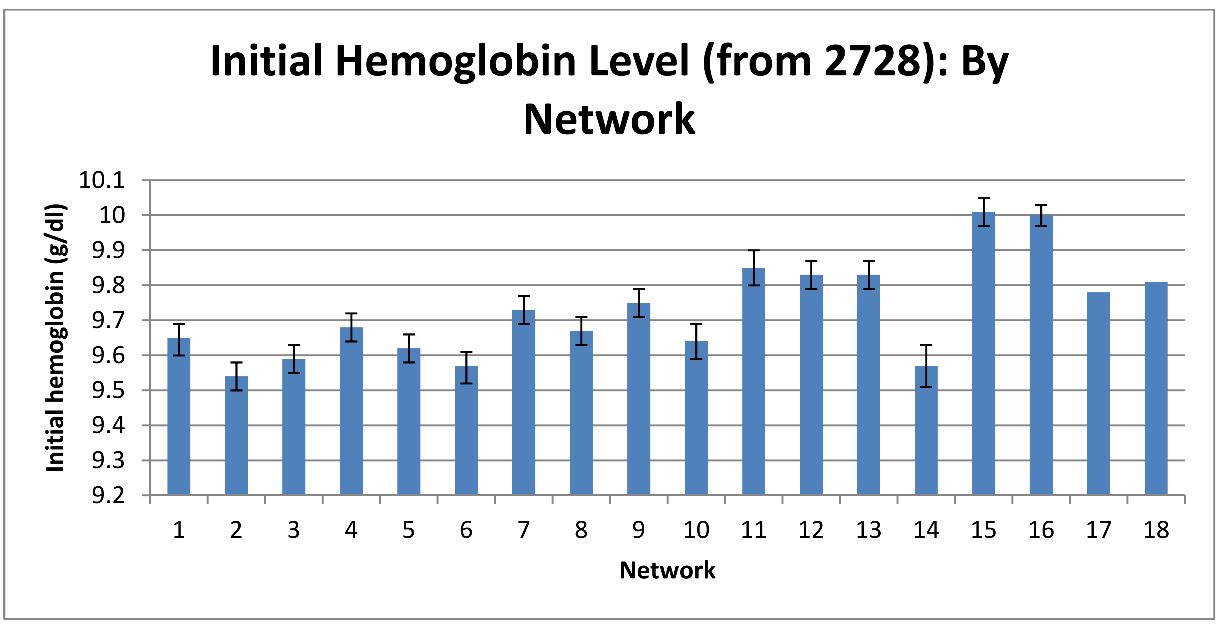


Figure 8C: Catheter at Dialysis Initiation, by Network

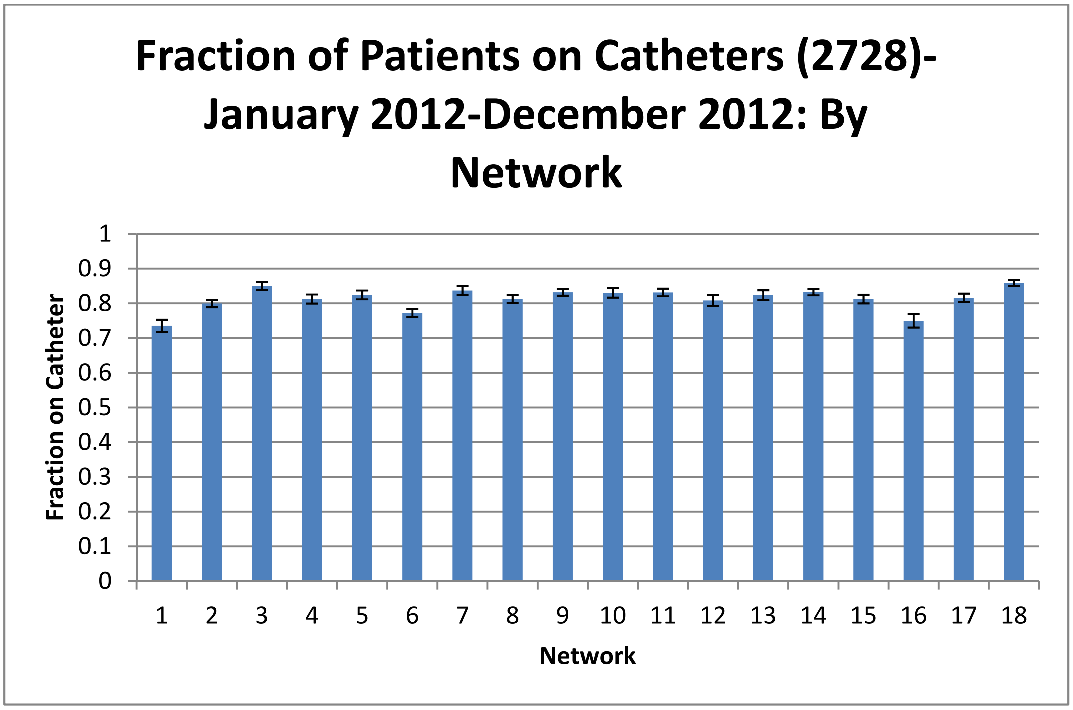


Figure 8D: Fistula or Graft at Dialysis Initiation, by Network

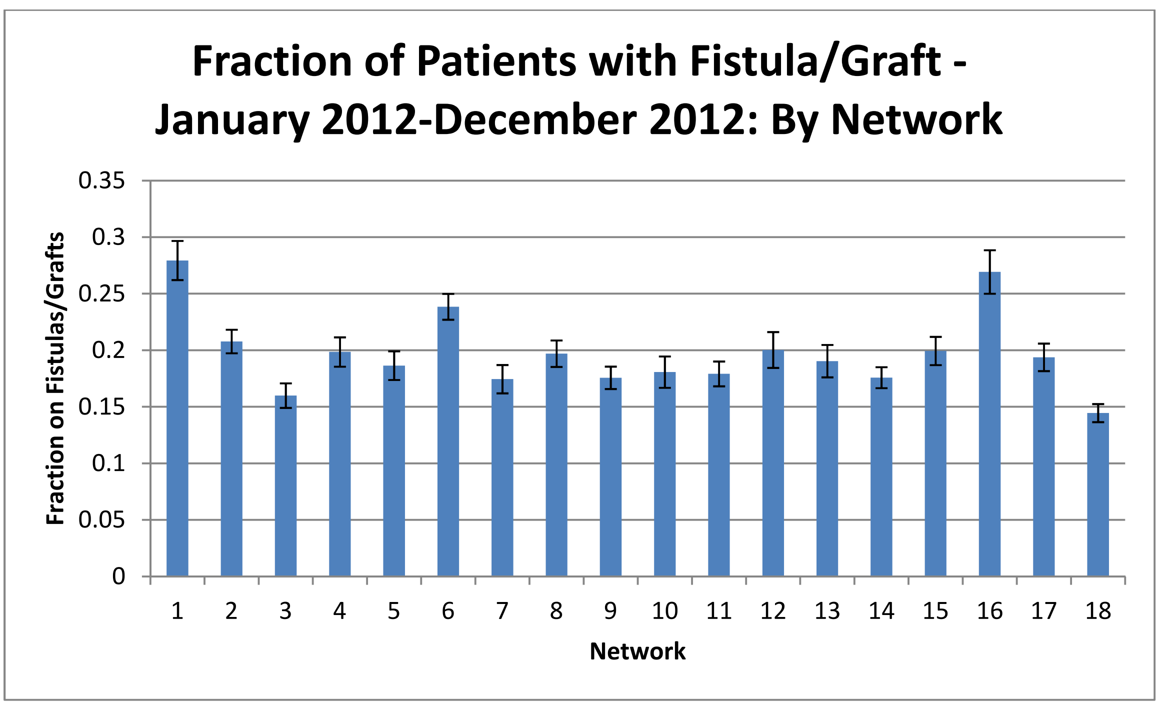
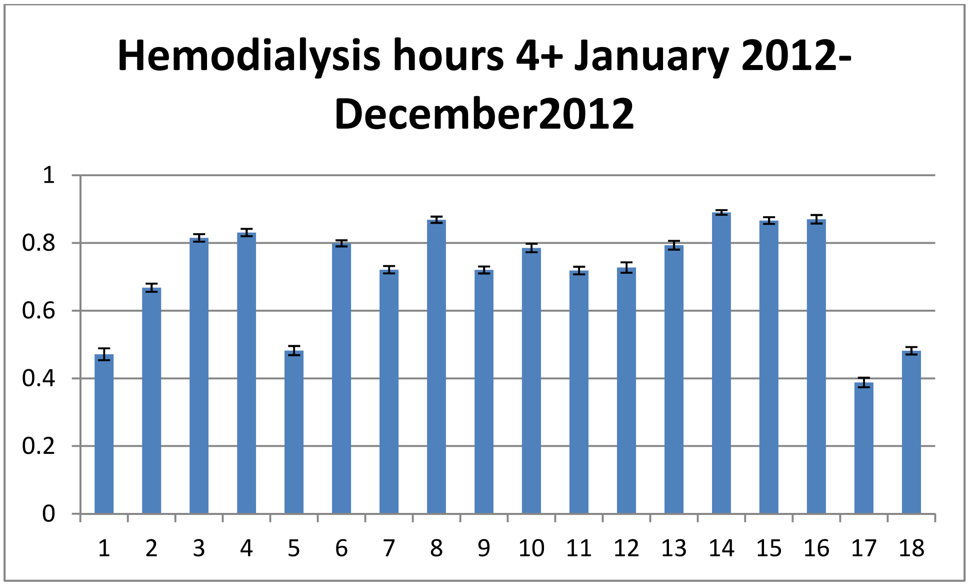


Figure 8E: Hemodialysis Prescripion >=4 Hours at Dialysis Initiation, by Network



The data in Figures 8A, 8B, 8C, 8D, and 8E suggest that there are substantial differences in among Networks in several clinical and treatment characteristics at the time of initiating dialysis.

V. SUMMARY and CONCLUSIONS

We have summarized our findings with regards to monitoring trends in 1-year and 90-day mortality rates. The PEAK program began in January 2009 with the goal of achieving a 20 percent reduction in 1-year mortality rates through the end of 2012. Over the course of our monitoring, we observe a reduction of 13.6 percent in the 1-year mortality rate, and a decline of 25 percent in 90-day mortality rate. We further note that more than 60 percent of the reduction in 90-day mortality occurred for cohorts' incident in 2012. Based upon the accelerating rate of improvement in 90-day mortality, we believe that a further reduction in one year mortality is likely to be reflected in the remaining quarters of 2013.

We tried to gauge the extent to which changes in the characteristics of the patients at initiation might have contributed to the declines observed in 1-year mortality rates. Overall, we find that the demographic characteristics and co-morbid conditions afflicting patients are fairly stable over time. Similarly, many of the other laboratory values at the time of initiating dialysis such as hemoglobin, albumin, and creatinine have not changed appreciably over time. It is therefore likely that many of the changes in mortality rates are attributable to changes in treatment AFTER the patients began dialysis. Our data are unable to identify what those treatments might be since we do not have access to any of the treatment variables past the point of entry. However, the nephrology community has identified several modifiable clinical and treatment characteristics that could lead to lower mortality rates (e.g., more hours on hemodialysis, less use of catheters or increased albumin levels). It is possible that, since the advent of the PEAK program, there was a change in one or more of these factors that, in turn, might have resulted in the decline in mortality rates.

In particular, we find it striking that the sharp decline in 90-day mortality rates beginning in 2012 correspond well with the uptick in the percent of patients with prescribed hours on hemodialysis of 4 or higher. Further, we expect that the decline in 90-day mortality rates in 2012 would be reflected in declines in 1-year mortality rates through the first half of 2013. Since we observe consistent variation by Network in the proportion of patients prescribed dialysis for 4 or more hours and this approach has been related to improved quality of care and survival, perhaps efforts to generalize treatment for four or more hours may eventually contribute to further reductions in 1- year mortality.

APPENDIX A

1. Differences between Data Used and the USRDS

During the first half of our monitoring efforts, we used information from the Social Security Death Master File (SSDMF). However, the SSDMF subsequently “dropped” a number of deaths because of contractual issues between the Social Security Administration and the States. This resulted in agreement among the Data Panel members that through the duration of our monitoring efforts, we must report mortality rates calculated solely on the basis of the information reported in the REMIS files. Importantly, it was determined that since PEAK was following improvement from a baseline and hence is relative, using only REMIS is a reasonable approach. We note that one way in which this approach could result in inaccurate estimates of trends is if the contribution of death records solely from the SSDMF changed appreciably over time. In our preliminary work on this, we confirmed that this is not the case, and hence believe the approach is reasonable.

We also note that the USRDS uses other data to generate its annual reports. In particular, it uses mortality data from the National Center for Health Statistics (NCHS), which is considered the most accurate source of death data. In addition, the USRDS allows the data to “age” before reporting on it—i.e., they allow almost a 2-year lag between the time of death and the time when information on that death is used in its analyses. Because of the nature of our monitoring, which required continuous updates, we were restricted to only using the deaths from the form 2746. However, we do allow the data to “age” six months, so while the information in this report is through the end of 2012, we are using the REMIS data through the 2nd quarter of 2013.

2. Determination of Incident Cohorts

We spent some time in thinking about the width of the incident cohorts (i.e., 3 months, 6 months, 1 year) that should be used in monitoring. Ultimately, the decision was influenced by our goal: to provide constant updates about the progress of PEAK. With this in mind, we arrived at a “width” of six months to track 1-year mortality rates, and a width of three months to track 90-day mortality rates.

An important part of tracking 1-year mortality rates is to determine the number of patients' that are incident in a given cohort. We used the variable "*datebegan:* available from the Form 2728 to find the number of patients incident in a given cohort. In addition, we found that this variable was missing in a few instances; for these patients' we used the date provided in the variable "*patsigndat*," which is the date when the physician signs a form confirming that the patient has begun dialysis. We feel comfortable using the *patsigndat*, since in more than 95 percent of the cases the two dates (*patsigndat and datebegan*) are exactly the same. (The USRDS strategy also primarily uses the variable *datebegan* to identify its incident cases. However, they likely bolster these data with other data from Medicare enrollment records.)

3. Comparison of Incident Numbers with USRDS

USRDS provided us with the total number of incident patients in its file for the years 2007 and 2008. Our incident numbers and that of the USRDS differ by 600 to 900 patients. We did not have any way of verifying the patients that do not match between our data and that of the USRDS, but the difference in incident numbers comprises roughly 0.6 percent of the total number of incident patients each year. We therefore believe that the differences in incident numbers between us and the USRDS do not influence the mortality trends we report here.

4. Deriving Adjusted Estimates

To the extent that changes in patient clinical or demographic characteristics over time confound the trends in mortality, it is useful to present trend estimates after adjusting for patient characteristics. We followed two methods to derive the adjusted estimates. First, we regression-adjust the mortality when the outcome is an indicator variable equal to 1 if the patient dies within a specified time-period (90 days or 1 year).

$$Y_{it} = \alpha_0 + \alpha_1^{'} x_i + \alpha_2 D_{t=2} + \alpha_3 D_{t=3} + ... \alpha_N D_{t=N} + u_{it}$$

In the above equation, Y_{it} is equal to 1 if individual i initiates dialysis in period t, and also dies within a given period (i.e., 1-year or 90-days) of beginning dialysis. The variable equals 0 otherwise. We estimate the above equation assuming a logit link function between the outcome, and the variable vector x_i is the set of individual demographic, clinical and treatment characteristics all measured at the time of entry into dialysis, while the D is a series of indicator variables for successive time periods when an individual initiates dialysis. Once we regression-adjust the outcomes, we present in our results the percent of patients dying in each period (derived using transformation of coefficients $\alpha_3 ....\alpha_N$).

In results where we present adjusted Network-level differences in mortality, we again use the similar equation using all incident patients in a particular year (e.g., 2011), and calculate 1-year differences in mortality. In this instance, we include Network-level indicator variables in the regression model, similar to the indicator variables for time period that we include in the equation above. This method represents a “parametric” adjustment, since it relies on the notion that we know the exact functional form that links the outcome and the independent variables.

We note that USRDS uses the Cox regression to “adjust” its estimates. The regression assumes that the variables “proportionally” shift the baseline hazard. Thus the shift in the hazard at, for example, 3 months due to being an African-American is the same as the shift in the hazard at 12 months; an assumption that is useful, but not completely necessary. However, an even greater complicating factor here was trying to derive adjusted estimates when the outcome variable is the number of deaths per person years. Note that here, deaths factor into both the numerator and the denominator, and the use of regressions to “adjust” estimates is more complicated.

An alternative we employed to arrive at “adjusted” estimates used more *non-parametric methods .* For example, we estimated the mortality rates separately by age group; implicitly this approach adjusts for mortality differences across age groups. This would involve estimating separate rates for each race, primary diagnosis and age-category cell. At the national level, this non-parametric approach can be used since the number of incident cases is often large (e.g., > 100,000).

As a final note, the trends in mortality include all patients on either hemodialysis or peritoneal dialysis. However, information on the use of catheters and/or fistulas is missing for patients on peritoneal dialysis. In the models that present trends in catheters and/or fistulas, the sample is restricted to patients on hemodialysis. In the regression models where mortality is the outcome, and where we “regression-adjust” for the use of catheters and/or fistulas (variable coded as 1 if catheter and 0 otherwise), we replace the missing catheter or fistula information for peritoneal patients with a value equal to 1. The regression model also includes a dummy variable that equals 1 if the patient is undergoing peritoneal dialysis.