**Attention: Below includes some supporting information and suggestions for your final project. You are encouraged to explore further on your own.**

**Motivations:**

* **2011 Medicare Prospective Payment System (PPS) Reform:** The reform introduced new incentives for healthcare providers to make Peritoneal Dialysis (PD) more widely available to patients with end-stage renal disease (ESRD).
* **Advantages of Peritoneal Dialysis (PD):** Unlike the more commonly used hemodialysis (HD), PD does not require patients to visit a dialysis center three times a week. Instead, patients can perform dialysis either overnight or continuously throughout the day, offering greater flexibility in scheduling and improving their overall quality of life.
* **Previous Research:** Studies (citation XX) have shown that the use of PD increased following the PPS reform. However, these studies have not addressed whether the demographic changes in the PD user population after the reform are linked to different health outcomes.
* **Study Objective:** This study aims to bridge that gap by providing scientific and statistical evidence using data from the United States Renal Data System (USRDS).
* **Research Focus:**
  + Compare mortality rates in two cohorts of incident ESRD patients before and after the PPS reform.
  + Examine trends in the adoption of different dialysis modalities and explore any interactions between these modalities before and after the reform.
* **Bonus (Extra Credit, 10%):**
  + Apply a Cox Proportional Hazards Model to calculate hazard ratios for these two cohorts.

1. **INTRODUCTION**

**Supporting Resources:**

* **Peritoneal Dialysis (PD) as an Alternative Treatment:**Peritoneal dialysis (PD) is an alternative treatment for patients with end-stage renal disease (ESRD). PD offers potential advantages in terms of improved quality of life and greater independence, while typically yielding similar clinical outcomes compared to in-center hemodialysis (HD) (Citations XX).
* **How PD Works:**  
  While traditional, in-center HD requires patients to visit a dialysis facility three times a week for blood filtration, PD enables patients to perform dialysis at home. After a catheter is surgically inserted into the abdomen, waste is filtered through the abdominal lining. Continuous Ambulatory PD (CAPD) involves inserting cleansing fluid into the abdomen for continuous filtration throughout the day. Automated PD (APD), typically done overnight, is performed with the help of a machine connected to the catheter (Citations XX).
* **PD Use in the U.S.:**Despite its advantages, the use of PD in the United States has lagged behind other countries with similar healthcare infrastructure, and its use was even declining prior to 2011 (Citations XX).
* **Impact of the 2011 PPS Reform:**  
  In 2011, this trend began to reverse following the introduction of a new Prospective Payment System (PPS) as part of Medicare reform (Citations XX). The PPS implemented a bundled payment system, where all costs associated with a dialysis session were combined into one fixed price. This price was set equally across all dialysis modalities, including both PD and HD (Citations XX).
* **Financial Incentives Under the PPS Reform:**  
  The overhead costs of PD are lower than those of HD, and as a result, providers can make a higher profit from offering PD under the new PPS structure compared to HD (Citations XX).
* **Impact on PD Availability and Uptake:**Initial analyses of the PPS reform indicate that it successfully increased both the availability and uptake of PD (Citations XX). In 2006, only 36% of dialysis facilities in the U.S. offered PD, and this figure rose to 38% by 2010, reaching 42% by 2013 (Citations XX).
* **Growth of PD Programs in Nonurban Areas:**  
  The initial increase in PD availability was concentrated primarily in nonurban facilities, which had more capacity to expand compared to urban facilities (Citations XX).
* **Uptake Among Medicare Beneficiaries:**Uptake of PD among Medicare beneficiaries also increased during this period. One study found that, after the reform, patients were more likely to start on PD or switch to PD from HD, while the rate of modality switches away from PD to HD decreased (Citations XX). Another study found that the increase in PD usage was consistent across different racial/ethnic groups, age groups, and both rural and urban areas (Citations XX).

1. **STUDY BACKGROUND**

**Supporting Resources:**

* **Comparing PD and HD:**  
  Numerous studies have outlined the potential advantages and disadvantages of Peritoneal Dialysis (PD) compared to Hemodialysis (HD) (Citations XX).
* **Quality of Life and Independence:**  
  Patients on PD often report a higher quality of life compared to those on HD. They experience greater independence, less disruption to their daily routines, and an increased ability to return to or maintain employment (Citations XX).
* **Flexibility of PD:**  
  Unlike in-center HD, which requires patients to travel to a facility three times a week, PD offers greater flexibility. PD can be performed at home, either continuously throughout the day or overnight while the patient sleeps (Citations XX).
* **Cost-Effectiveness and Health Benefits:**  
  PD has been associated with higher cost-effectiveness, a reduced risk of hospital-acquired infections, and better preservation of residual kidney function compared to HD (Citations XX).
* **Challenges of PD:**  
  Despite its advantages, PD has some drawbacks, including the need for a catheter, potential sleep disturbances, changes in daily routine, and a sensation of bloating due to the dialysis fluid (Citations XX).
* **Improvements in PD Outcomes:**  
  Early PD outcomes were less favorable compared to HD, but improvements in PD techniques and patient management have led to better outcomes in recent years (Citations XX).
* **Mortality Rates and PD vs. HD:**  
  Some recent studies have found no significant difference in mortality rates between PD and HD patients (Citations XX). However, other studies have identified differences in outcomes, particularly in the early stages of ESRD. For example, PD users tend to have a lower risk of death compared to HD users early in the disease course (Citations XX), though these differences often decrease as the disease progresses (Citations XX).
* **Factors Influencing Outcomes:**  
  Patient outcomes may depend on various factors, including age, diabetes status, and the presence of other comorbidities. For instance, diabetes patients may have worse outcomes on PD compared to non-diabetic patients (Citations XX).
* **Non-Medical Determinants of Dialysis Modality:**  
  The choice of dialysis modality is often influenced by non-medical factors, such as patient and physician preferences. Most patients are eligible for either HD or PD, but their choice may be guided by personal circumstances (Citations XX).
* **Education and Physician Involvement:**  
  A key factor in determining PD uptake is whether a patient has been properly educated about their options by their healthcare provider (Citations XX). Previous studies have found that many patients feel they did not receive adequate information to make an informed choice about their dialysis modality (Citations XX). Additionally, patients who have seen a nephrologist before starting dialysis are more likely to be well-informed about their options, as nephrologists typically have more expertise in this area (Citations XX).
* **Demographic Factors and PD Uptake:**  
  Studies have shown that PD users tend to be younger, more likely to be White, and less likely to have comorbidities compared to HD patients (Citations XX). Additionally, living alone may limit PD uptake due to the need for assistance with care, which is typically provided at dialysis centers for HD patients (Citations XX).
* **Switching Between Dialysis Modalities:**  
  Most switches between dialysis modalities are from PD to HD. The reasons for switching are varied, with infections being the most common cause, followed by cardiovascular issues like fluid overload. Other factors, such as abdominal surgery, pancreatitis, malnutrition, decreased mental capacity, or abdominal wall defects, may also contribute (Citations XX).
  + **Characteristics of Switchers:**  
    A study on PD-to-HD switchers found that these patients were more likely to have a higher BMI and serum creatinine at baseline. They were also less likely to be White and had lower residual urine output at both baseline and one year of follow-up (Citations XX). Interestingly, patients who lived farther from a dialysis center or had higher levels of education were less likely to switch modalities. More than 70% of switches occurred within the first two years of starting PD, with infections being the primary cause of the switch (Citations XX).
  + **HD to PD Switches:**  
    In contrast, switches from HD to PD tend to be driven more by personal preference or changes in the patient’s circumstances, although some medical reasons may also be involved. Common reasons for switching to PD include lack of awareness about PD as an option due to late referral, changes in caregiver preference, or issues with vascular access or hypotension associated with HD (Citations XX).
* **Impact of Switching from HD to PD on Mortality:**  
  Some studies have found that switching from HD to PD may be associated with a higher risk of mortality. This could be due to factors such as subclinical cardiac ischemia caused by the initial period on HD, unmeasurable variables related to the decision to start HD, or more rapid loss of residual kidney function following an initial HD start (Citations XX).
* **Outcomes of HD-to-PD Switchers:**  
  Other studies have reported worse outcomes for patients who switched from HD to PD compared to those who started on PD. This may be related to a higher burden of comorbidities and malnutrition in the switch population (Citations XX).
* **Comorbidities and PD Outcomes:**  
  Poorer outcomes in PD patients who switch from HD may be attributable to their comorbid conditions. Studies have found that these switchers are often at greater risk of complications, which may affect the success of their dialysis treatment (Citations XX).

**Research Goal and Question:**

The final goal of this project is to confirm the association between the PPS reform and the increased availability and uptake of PD, focusing on the impacts of this change rather than just its occurrence. Specifically, the study seeks to determine whether outcomes, particularly mortality, differed between PD users and HD users in the years following the reform, compared to before the reform. This will help assess the appropriateness of the policy changes.

Overall, the study aims to evaluate the effects of the PPS reform and explore the potential for broader use of PD to improve the quality of life for the Medicare ESRD population.

***Research Questions***

1. **Question 1:** Did mortality rates differ between incident cases of ESRD on PD before and after the reform period?
2. **Question 2:** Were the comparative mortality rates different between HD and PD users among incident cases of ESRD, both before and after the reform?
3. **METHODOLOGY**

Source of Data:

* Data for this study were extracted from the United States Renal Data System (USRDS), a comprehensive source for information on ESRD patients.
* The primary dataset for this study was sourced from institutional claims SAFs, which contain claims data from the CMS Renal Beneficiary and Utilization System (REBUS), providing detailed information on dialysis modality.
* This dialysis modality data was supplemented with demographic and comorbidity information from the Patient Core and Comorbidities SAFs within the CKD 5% files, which are derived from the 5% sample of the general Medicare Claims SAFs. These files include a patient master file, a payer sequence file, and multiple comorbidity files.

More specifically, the following files were used:

|  |  |
| --- | --- |
| **File** | **Information drawn from it for this project** |
| (From CKD 5% Core file): Ckd\_patient\_master\_file | Sex  Age  Death status  ESRD onset date  Race |
| (From 2013 ESRD file):  in\_clm\_2013  out\_clm\_2013  sn\_clm\_2013 | Dialysis modality for each claim  Hemoglobin  Hemotocrit |
| (From 2008-2012 ESRD files)  Inc20XXa  Inc20XXb | Same information as prior row, but the information that was spread across three files in the 2013 files was spread across two files for 2008-2012 |
| (From CKD 5% Core file, comorbidity information for the six years of the study):  Ckd\_co\_morbid\_08 - Ckd\_co\_morbid\_13 | Diabetes Status  Number of distinct comorbidities found in claims for each individual |

*Cohort Creation and Inclusion/Exclusion Criteria*

Using the data from these files, two cohorts were created: one consisting of incident ESRD cases with an ESRD onset date (from the CKD 5% Patient Core SAF) between January 1, 2008, and December 31, 2010, and the other comprising incident ESRD cases with an ESRD onset date between January 1, 2011, and December 31, 2013. These date ranges were selected to ensure a sufficient sample of individuals receiving dialysis care both before and after the 2011 reform, allowing enough time for the dialysis modalities to potentially impact mortality rates.

**Inclusion and Exclusion Criteria for Study Cohorts:**

The following inclusion and exclusion criteria were applied to select individuals for the study cohorts:

* **Demographic Data:** Individuals had to have a corresponding claim in the **Chronic Kidney Disease (CKD) Patient Master File SAF**, as this was the primary source for demographic information (e.g., sex, race) needed for the analysis.
* **Medicare Eligibility:** Only individuals in the **5% Medicare sample** were included in the study.
* **Prior CKD Care:** Participants had to be receiving Medicare coverage for **Chronic Kidney Disease (CKD)** prior to their ESRD onset date, with available ESRD onset information.
* **Incident ESRD Cases:** Only incident cases of ESRD were included in the study.
* **Missing Dialysis Modality Information:** Individuals without any dialysis modality listed in the claims data were excluded.
* **Incomplete Modality Information:** For individuals with missing or undetermined dialysis modality information in some claims, the most recent valid modality was carried forward for missing entries. This process resulted in the removal of **5,274** individuals out of **29,455** with ESRD onset dates during the study period.
* **Missing Comorbidity Data:** Individuals who did not have a record in the **CKD Core Comorbidities SAFs** were excluded, as it was assumed that all ESRD patients should have associated comorbidities. Missing comorbidity data might indicate incomplete records, leading to the removal of **60** individuals out of **24,181**.
* **Death and Modality Uncertainty:** Individuals who died and whose last claim date occurred more than six months before their death date were excluded, based on the assumption that a modality switch might have occurred during the final six months of the study period, making the final modality uncertain. This resulted in the removal of **479** individuals.

**Data Processing Workflow:**

A combination of merging and filtering was employed to obtain a sample that met the study criteria:

1. **Cohort Creation:**
   * Load the **Patient Core Master File** and filter it to include only individuals with ESRD onset dates between **2008 and 2013**.
   * Add a new variable for **cohort designation**:
     + ESRD onset between 2008-2010 = 0
     + ESRD onset between 2011-2013 = 1
2. **Claims Data Processing:**
   * Load and stack claims data for all six years, then perform the following initial cleanup steps:
     + **Remove duplicate records**.
     + **Exclude claims** that do not list any dialysis sessions (and thus no modality).
     + For claims that report dialysis sessions but have **missing or unknown modality**, fill in the modality field with the most recent available modality, sequentially by date, for each individual (identified by **USRDS\_ID**).
     + **Exclude individuals** who have dialysis sessions but no modality listed in any of their claims.
     + **Left join** the claims file with cohort information from the Patient Core file, ensuring no duplicates are retained after merging. Then, remove any claims from **cohort 0 (2008-2010)** that correspond to service dates after **December 31, 2010**.
3. **Comorbidity and Diabetes Status Variables:**
   * Stack all **Comorbidity Files** and create the following variables:
     + **Count distinct comorbidities** (ICD-9 codes) for each individual by using a **count function** based on the **USRDS\_ID**.
     + **Inner join** the distinct comorbidity count file with the filtered Patient Core file to add the number of distinct comorbidities as a variable. Exclude individuals with no comorbidities listed in the comorbidity files.
     + Create an indicator variable for **diabetes status** in the stacked comorbidities files using an "if, then" statement to identify ICD-9 codes associated with diabetes.
     + **Collapse** the diabetes indicator variable to one line per person by summing the number of “1”s for any diabetes-related ICD-9 codes. Replace any value greater than 0 with a “1” to create a file where each individual has a diabetes status of “1” if they had a diabetes-related code listed.
     + **Left join** the diabetes status indicator file with the Patient Core file to add diabetes status for each individual.
4. **Filtering Individuals Based on Death Date and Last Claim Date:**
   * To filter out individuals whose last claim date was not within six months of their death date (assuming they died), follow these steps:
     + **Order** the claims files by **USRDS\_ID** and **CLM\_THRU** date.
     + Create a column that identifies the **last claim date** for each individual.
     + **Left join** the Patient Core file with the claims file to import the last claim date column.
     + Calculate the number of **days between the death date** and the final claim date.
     + **Filter out** any rows where the difference between the last claim date and death date is greater than 180 days, after checking key study characteristics using **proc freq** to ensure no significant differences before and after filtering.

**Dialysis Modality Classification**

To classify individuals by dialysis modality, we developed a categorical variable that divides the sample into seven distinct groups based on their dialysis modality patterns during the study period:

1. **Peritoneal-Only Group**:  
   This group includes individuals who began the study period on **peritoneal dialysis (PD)** and remained on PD throughout. This status was assigned to individuals who only had claims listing PD modalities during the study period, even if they switched between different PD modalities. The PD modalities included in the analysis were **CAPD, CAPD training, CCPD, CCPD training, and other peritoneal**. For the purposes of this study, all these modalities were grouped under the PD category.
2. **HD-Only Group**:  
   This group consists of individuals who started the study period on **hemodialysis (HD)** and remained on HD throughout. Individuals in this group had claims with HD modalities listed throughout the study period, regardless of switching between different HD modalities. The HD modalities included were **center hemodialysis, center self-hemodialysis, and home hemodialysis**. These were all categorized as HD for the purpose of the study.
3. **Peritoneal Switcher Group**:  
   This group includes individuals who switched from HD to PD during the study period, but not in the final six months of their respective cohort's study period. For example, an individual who switched to PD in May 2010 and was part of the 2008-2010 cohort would be included in this group. Individuals in this group must have had at least six months of PD after switching from HD.
4. **HD Switcher Group**:  
   This group consists of individuals who switched from PD to HD during the study period, but not in the final six months of their cohort's study period. Individuals in this group must have had at least six months of HD after switching from PD.
5. **PD Late Switch Group**:  
   This group includes individuals who switched from HD to PD in the **last six months** of their study period. For instance, if an individual in the 2008-2010 cohort switched from HD to PD in September 2010, they would be included in this group.
6. **HD Late Switch Group**:  
   This group includes individuals who switched from PD to HD in the **final six months** of their study period.
7. **More Than One Switch Group**:  
   This group includes individuals who switched dialysis modalities **more than once** during the study period. This group was separated from the others to account for the complexity of multiple modality switches, as the effects of such switches on mortality may be difficult to isolate.

The method for obtaining these groups was roughly as follows:

* Identify lines where the claim modality switched:
  + - Use the lag function to create another variable that contains the dialysis modality indicator for the previous line in the document;
    - Compare the contents of each original modality indicator with the lag column and use an “if, then” function to classify the switch into one of three categories. Note, the original “RXCAT” dialysis modality variable is broken up into 9 categories; categories 1-4 are for HD, including center hemo (1), center self-hemo (2), home hemo (3) and hemo training (4); categories 5-9 are for PD, including Continuous Ambulatory PD (CAPD - 5), CAPD training (6), Continuous Cycling PD (CCPD - 7), CCPD training (8), and other peritoneal (9). The categories created in this step included:

0= either the two lines contained the same modality; or the line indicated a switch within either HD or PD modalities

(e.g. from center hemo (1) to home hemo (3));

1. = the line indicated a switch from a HD to a PD modality;

2 = the line indicated a switch from PD to HD.

* + - Since this process resulted in some lines being identified as a switch when really it was a switch in ID, a variable was created using lag(USRDS\_ID) and the contents of that variable were compared the contents of the USRDS\_ID column and the switch column to revert any “false” switches back to 0.
* Create a variable for the date of each switch by creating a column that reads in the CLM\_THRU variable if the switch column is not set to a value of 0.
* Create an indicator of only having been on hemo or only having been on PD the whole time (even including times when there was a switch within hemo or peritoneal broader categories, for example if someone switched from center hemo to home hemo);
* Create a list by USRDS\_ID that sums the contents of the switch column. Anyone with only zeros will have a sum of zero. Then make this list into an indicator variable by setting it to 0 for each individual if the contents of their sum is more than zero (indicating at least one meaningful switch between modalities hemo to peritoneal or peritoneal to hemo) and 1 if the contents of their sum is zero. Thus, “1” indicates that they didn’t switch or only switched within a broader peritoneal or HD modality.
* Add this indicator variable to the claims document, and then use the modality information in the claims document to identify whether the person was on HD or PD the whole time by creating two new indicator variables with an “if, then” statement.
* Identify people who have had more than one switch by counting the number of switch dates by individual and then using that information to create an indicator variable of having had more than one switch (multiswitch).
* Remove switch dates for individuals who have had more than one switch, then create variables to indicate if individuals had a switch date before the end date of their respective cohort (December 31, 2010 for cohort 0 and December 31, 2013 for cohort 1)
* Create indicators for the final four categories:
  + Switched once HD to peridialysis more than six months before the end date of their cohort;
  + Switched once HD to peri-dialysis less than six months before the end date of their cohort,
  + Switched once PD to HD more than six months before the end date of their cohort; and
  + Switched once PD to HD within six months of the end date of their cohort.
* Create a table with one line per participant and an indicator of which of the seven groups they fall into (for each indicator variable - one per category - sum the number of 1’s across all their claims in the claim file by USRDS\_ID, then reset the cells that are more than 1 to 1 for a 0-1 indicator variable).

**Method for Identifying Dialysis Modality Groups**

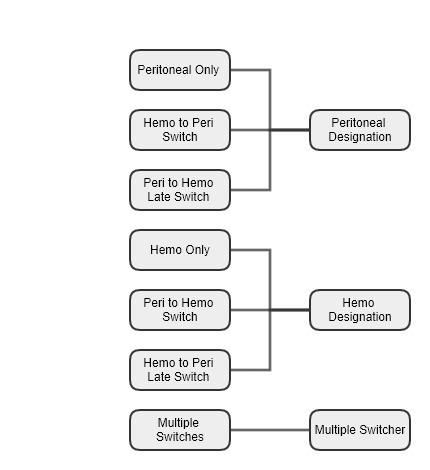
The process for assigning individuals to the modality groups involved several steps:

1. **Identify Lines Where Modality Switches Occurred:**
   * Use the **lag function** to create a new variable containing the dialysis modality from the previous line in the claims data.
   * Compare the current modality with the previous (lagged) modality using an "if-then" function to classify the switch into one of three categories:
     + **0** = No switch (either the two lines show the same modality, or both lines show a switch within the same modality category, e.g., from center hemo to home hemo).
     + **2** = Switch from **HD to PD**.
     + **3** = Switch from **PD to HD**.
   * The original **RXCAT** dialysis modality variable has 9 categories:
     + **HD categories**:
       - Center hemodialysis (1)
       - Center self-hemodialysis (2)
       - Home hemodialysis (3)
       - Hemodialysis training (4)
     + **PD categories**:
       - Continuous Ambulatory PD (CAPD, 5)
       - CAPD training (6)
       - Continuous Cycling PD (CCPD, 7)
       - CCPD training (8)
       - Other peritoneal dialysis (9)
2. **Handle False Switches:**
   * Some instances were identified as modality switches when, in fact, the ID had changed. To correct for this, a variable was created using **lag(USRDS\_ID)**, and the contents of the **USRDS\_ID** were compared with the switch column. Any “false” switches (resulting from ID changes) were reverted back to 0.
3. **Create a Variable for the Date of Each Switch:**
   * Create a **switch date** variable by extracting the **CLM\_THRU** date for lines where the switch column is not set to 0.
4. **Create an Indicator for Constant Modality (HD or PD):**
   * Identify individuals who remained on the same modality throughout the study period (even if they switched within the broader modality categories, such as from center hemo to home hemo). This indicator reflects whether someone was consistently on either HD or PD.
5. **Create a Switch Summary by USRDS\_ID:**
   * For each individual, **sum** the contents of the switch column. Individuals with a sum of **0** indicate no switch, while a sum greater than 0 indicates at least one modality switch.
   * Create a binary indicator variable based on this sum:
     + **0** for no switch or only switches within the same broader modality category (HD to HD or PD to PD).
     + **1** for individuals who switched between modalities (e.g., HD to PD or vice versa).
6. **Add the Switch Indicator to the Claims Document:**
   * Incorporate this new indicator variable into the claims file and use the modality information to determine whether the individual was on HD or PD for the entire study period.
   * Create two additional indicator variables to flag whether an individual stayed on HD or PD the entire time.
7. **Identify Individuals with More Than One Switch:**
   * **Count** the number of switch dates per individual, then create an indicator variable to flag individuals who had more than one switch (i.e., **multiswitch**).
8. **Remove Switch Dates for Individuals with Multiple Switches:**
   * For individuals with more than one switch, remove any switch dates, and create variables indicating whether the switch occurred **before** the end date of their cohort’s study period:
     + **Cohort 0**: December 31, 2010
     + **Cohort 1**: December 31, 2013
9. **Create Indicator Variables for the Four Categories of Switches:**
   * **HD to PD (more than six months before cohort end date)**.
   * **HD to PD (within six months of cohort end date)**.
   * **PD to HD (more than six months before cohort end date)**.
   * **PD to HD (within six months of cohort end date)**.
10. **Create a Summary Table:**
    * Create a table with one row per participant and an indicator of which of the seven groups they fall into.
    * For each indicator variable (one per group), **sum** the number of 1s across all claims for each individual, grouped by **USRDS\_ID**.
    * Reset any values greater than 1 to 1, resulting in a binary indicator variable.

At the end of this process, the following breakout of the sample into these groups was obtained:

|  |  |
| --- | --- |
| **Group Designation** | **Number of Individuals (Percent)** |
| Peritoneal Only | 957 (4.3%) |
| HD Only | 20,033 (89.6%) |
| Peritoneal to HD Switch | 304 (1.4%) |
| HD to Peritoneal Switch | 156 (0.7%) |
| Peritoneal to HD Late Switch | 73 (0.33%) |
| HD to Peritoneal Late Switch | 104 (0.47%) |
| Multiple Switches | 723 (3.2%) |
| **Total** | **22,350 (100%)[[1]](#footnote-1)** |

* After creating the modality groups, individuals were categorized into one of three groups: **PD User**, **HD User**, or **Multiple Switches**.
* To streamline the analysis, these categories were collapsed into a simpler format.
* The resulting categorical variable was merged with the patient core data using an inner join, yielding a final sample size of 21,863, consisting of 11,519 individuals from the 2008-2010 cohort and 10,344 individuals from the 2011-2013 cohort.
* The **PD User** designation included individuals in the "Peritoneal-only" group, those who switched from HD to PD at least six months prior to the end of their cohort's study period, and individuals who switched from PD to HD within the last six months of their cohort's study period.
* The **HD User** designation included the inverse categories (as detailed in the diagram below).
* The **Multiple Switches** group was kept separate due to the uncertainty in the relationship between their modality switches and outcomes.



*Potential Covariates*

* potential covariates: sex; race; age; number of comorbidities; diabetes status; average hemoglobin across available readings, and average hematocrit across available readings.
* The table below shows the method of creation of each variable, along with their source.

|  |  |  |
| --- | --- | --- |
| **Variable** | **Source** | **Method** |
| Sex | CKD 5% Patient Core SAF | Format and label variable; no other changes needed |
| Race | CKD 5% Patient Core SAF | Format and label variable; no other changes needed |
| Age at ESRD onset | CKD 5% Patient Core SAF | Find years between month and year of birth and ESRD onset date. Format and label variable. |
| Number of comorbidities | CKD 5% Core Morbidities SAFs from 2008-2013 (count of number of distinct comorbidities per 5PID) | See description of process in the Cohort Creation section above. Format and label variable. |
| Diabetes | CKD 5% Core Morbidities SAFs from 2008-2013 (individual had a code that matched an ICD-9 code for diabetes, Type I or Type II) | See description of process in the Cohort Creation section above. Format and label variable. |
| Average Hemoglobin | Institutional Claims ESRD files (average of as many readings as were available for a given individual) | Take average of available hemoglobin readings by individual in institutional claims SAFs and left join patient core set with the result. Format and label variable. |
| Average Hematocrit | Institutional Claims ESRD files (average of as many readings as were available for a given individual) | Take average of available hematocrit readings by individual in institutional claims SAFs and left join patient core set with the result. Format and label variable. |

Some information may catch your attention:

-The selection of potential covariates was guided by literature indicating that these factors may significantly influence both mortality rates and the choice of dialysis modality.

-Diabetes status, age, and comorbidities have consistently been identified in studies as key factors that modify the effect of dialysis modality on patient outcomes.

-Hemoglobin and hematocrit are both key indicators of iron levels in the body and are commonly low in patients with end-stage renal disease (ESRD), who frequently suffer -from anemia. Anemia in individuals with renal failure is primarily due to a deficiency in endogenous erythropoietin, a hormone essential for red blood cell production. This condition is associated with complications such as left ventricular hypertrophy.

-Renal failure-related anemia also increases the risk of cardiovascular morbidity and mortality.

-In ESRD patients, lower hemoglobin levels have been linked to higher mortality rates.

-Normal hemoglobin levels are generally considered to be above 12 g/dL for women and 13 g/dL for men.

-For ESRD patients, the National Kidney Foundation recommends a target hemoglobin level between 11 and 12 g/dL.

-Previous studies have found that hematocrit values between 30% and 36% are associated with a lower risk of mortality.

-Hematocrit measures the proportion of red blood cells in relation to the total blood cell count.

Note: You can check the finding below if you work on the bonus/extra credit using survival analysis.

Paradoxically, despite generally worse health outcomes for Black individuals across various health metrics, studies have shown that Black individuals undergoing dialysis tend to have longer survival rates compared to White individuals. This finding was confirmed in an observational study of 1,330,007 incident cases of ESRD using USRDS data collected between January 1, 1995, and September 28, 2009.

***Outcome Variables***

**Primary Outcome: Mortality (Yes/No)**  
The primary outcome, death (yes/no), is defined an indicator variable where patients with a recorded date of death be assigned a value of "1" and those without a recorded death date are assigned a value of "0." This process should be conducted after excluding death dates for individuals in the 2008-2010 cohort who died after their respective cohort end date.

**Follow-up Time (for Bonus/Extra Credit):**  
If you decide to work on the bonus/extra credit, the follow-up time for each individual was calculated as follows:

* **For individuals who did not die and whose last available claim date occurred within six months of their cohort end date** (December 31, 2010, for the 2008-2010 cohort and December 31, 2013, for the 2011-2013 cohort), follow-up time is calculated as the duration from their ESRD onset date to the cohort end date.
* **For individuals who did not die and whose last available claim date was before the final six months of their cohort end date**, follow-up time is calculated as the number of days between their last available claim date and their ESRD onset date.
* **For individuals who died**, follow-up time is calculated as the number of days between their ESRD onset date and their date of death (this calculation is performed after removing the death dates of individuals in the 2008-2010 cohort who died after the cohort end date).

**4. REPORT**

See more expectations for this final project in details in the project outline document.

1. **Data management in SAS**

See the project outline in detail

1. **Data Analysis in SAS**

See the project outline in detail

*Participant Characteristics*

Model-Building Process

Interpretation result findings based on the final Model

1. **DISCUSSION**

See the project outline document …

1. **APPENDIX**

You may separately have appendix in a separate document. Below is just suggestion.

1. SAS code files
   1. Master SAS
   2. Cohort Construction
   3. Final Formatting
   4. Descriptive Analysis
   5. Model Building
   6. Model Analysis
2. Analytic Data Set
3. Claims Data Set
4. SAS ODS Output (graphs, tables, model results)

**REFERENCES**

Below is a list of suggested references.

Bhamidipati V.R. Murthy, Donald A. Molony and Austin G. Stack

JASN March 2005, 16 (3) 782-790; DOI: <https://doi.org/10.1681/ASN.2004080627>

Boateng E.A., East L. (2011). The impact of dialysis modality on quality of life: a systematic review. *Journal of Renal Care* 37(4), 190–200.

Brown, E. A., Johansson, L., Farrington, K., Gallagher, H., Sensky, T., Gordon, F., ... & Hickson, M. (2010). Broadening Options for Long-term Dialysis in the Elderly (BOLDE): differences in quality of life on PD compared to haemodialysis for older patients. *Nephrology Dialysis Transplantation*, *25*(11), 3755-3763.

Byrne, Colene, Jerry Nedelman, and Robert G. Luke. "Race, socioeconomic status, and the development of end-stage renal disease." *American Journal of Kidney Diseases* 23.1 (1994): 16-22.

Ghaderian SB, Hayati F, Shayanpour S, Beladi Mousavi SS. Diabetes and end-stage renal disease; a review article on new concepts. *J Renal Inj Prev*. 2015;4(2):28-33. Published 2015 Jun 1. doi:10.12861/jrip.2015.07

Heaf, J. G., & Wehberg, S. (2014). Relative survival of PD and haemodialysis patients: effect of cohort and mode of dialysis initiation. *PLoS One*, *9*(3), e90119.

Hosmer, David, Lemeshow, Stanley and Sturdivant, Rodney (2013). Applied Logistic Regression. 3rd edition. Hoboken, New Jersey: John Wiley & Sons, Inc.

Kausz, A. T., Obrador, G. T., Arora, P., Ruthazer, R., Levey, A. S., & Pereira, B. J. (2000). Late initiation of dialysis among women and ethnic minorities in the United States. *Journal of the American Society of Nephrology*, *11*(12), 2351-2357.

Kucirka, L. M., Grams, M. E., Lessler, J., Hall, E. C., James, N., Massie, A. B., ... & Segev, D. L. (2011). Association of race and age with survival among patients undergoing dialysis. *Jama*, *306*(6), 620-626.

Li, S., & Collins, A. J. (2004). Association of hematocrit value with cardiovascular morbidity and mortality in incident HD patients. *Kidney international*, *65*(2), 626-633.

Liu, K. D., Himmelfarb, J., Paganini, E., Ikizler, T. A., Soroko, S. H., Mehta, R. L., & Chertow, G. M. (2006). Timing of initiation of dialysis in critically ill patients with acute kidney injury. *Clinical Journal of the American Society of Nephrology*, *1*(5), 915-919.

Lobbedez, T., Crand, A., Le Roy, F., Landru, I., Quéré, C., & Ryckelynck, J. P. (2005). Transfer from chronic haemodialysis to PD. *Nephrologie & therapeutique*, *1*(1), 38-43.

Mehrotra, R., Chiu, Y. W., Kalantar-Zadeh, K., Bargman, J., & Vonesh, E. (2011). Similar outcomes with HD and PD in patients with end-stage renal disease. *Archives of internal medicine*, *171*(2), 110-118.

National Kidney Foundation (2021). PD: what you need to know. Web page accessed 11.26.2021 at: <https://www.kidney.org/atoz/content/peritoneal>.

Nessim, S. J., Bargman, J. M., Jassal, S. V., Oliver, M. J., Na, Y., & Perl, J. (2015). The impact of transfer from HD on PD technique survival. *PD International*, *35*(3), 297-305.

Noshad, H., Sadreddini, S., Nezami, N., Salekzamani, Y., & Ardalan, M. R. (2009). Comparison of outcome and quality of life: haemodialysis versus peritoneal dialysis patients. *Singapore medical journal*, *50*(2), 185.

Ofsthun, N., Labrecque, J., Lacson, E., Keen, M., & Lazarus, J. M. (2003). The effects of higher hemoglobin levels on mortality and hospitalization in HD patients. *Kidney international*, *63*(5), 1908-1914.

Ritz E, Rychlik I, Locatelli F, Halimi S. End-stage renal failure in type 2 diabetes: A medical catastrophe of worldwide dimensions. Am J Kidney Dis. 1999;34:795–808.

Sloan, C. E., Coffman, C. J., Sanders, L. L., Maciejewski, M. L., Lee, S. Y. D., Hirth, R. A., & Wang, V. (2019). Trends in PD use in the United States after Medicare payment reform. *Clinical Journal of the American Society of Nephrology*, *14*(12), 1763-1772.

Sukul, N., Zhao, J., Fuller, D. S., Karaboyas, A., Bieber, B., Sloand, J. A., ... & Perl, J. (2019). Patient-reported advantages and disadvantages of PD: results from the PDOPPS. *BMC nephrology*, *20*(1), 1-10.

Turenne, M., Baker, R., Pearson, J., Cogan, C., Mukhopadhyay, P., & Cope, E. (2018). Payment reform and health disparities: Changes in dialysis modality under the new medicare dialysis payment system. *Health services research*, *53*(3), 1430-1457.

United States Renal Disease System (USRDS) (2010). Researcher’s Guide to the USRDS Database: 2010 ADR System.

Van Biesen, W., Dequidt, C., Vijt, D., Vanholder, R., & Lameire, N. (1998). Analysis of the reasons for transfers between HD and PD and their effect on survivals. *Advances in PD*, *14*, 90-94.

Vonesh, E. F., Snyder, J. J., Foley, R. N., & Collins, A. J. (2006). Mortality studies comparing PD and HD: what do they tell us?. *Kidney International*, *70*, S3-S11.

Wang, V., Coffman, C. J., Sanders, L. L., Lee, S. Y. D., Hirth, R. A., & Maciejewski, M. L. (2018). Medicare’s new prospective payment system on facility provision of PD. *Clinical Journal of the American Society of Nephrology*, *13*(12), 1833-1841.

Yang, W., Israni, R. K., Brunelli, S. M., Joffe, M. M., Fishbane, S., & Feldman, H. I. (2007). Hemoglobin variability and mortality in ESRD. *Journal of the American Society of Nephrology*, *18*(12), 3164-3170.

Zee, J., Zhao, J., Subramanian, L., Perry, E., Bryant, N., McCall, M., ... & Tentori, F. (2018). Perceptions about the dialysis modality decision process among PD and in-center HD patients. *BMC nephrology*, *19*(1), 1-10.

Zhang, X., Han, F., He, Q., Huang, H., Yin, X., Ge, J., & Chen, J. (2008). Outcomes and risk factors for mortality after transfer from HD to PD in uremic patients. *PD International*, *28*(3), 313-314.

1. Note that this is not the final sample size; this reflects the sample size before individuals whose death date was more than six months from their last modality claim information were removed. [↑](#footnote-ref-1)