

STATISTICAL ANALYSIS PLAN FOR
“Seasonal Differences in Home Dialysis Uptake and Initiating Dialysis in the Hospital”

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Cohort construction

- 1) Identify incident adults who started dialysis from 12/1/2007 – 11/30/2017
 - a. USA, no transplant or death in first 90 days, dialysis first modality
 - b. Has medical evidence form
 - c. Has Medicare AB 30 days prior to first date of dialysis
- 2) Create season/year variables based on the first date of dialysis
 - a. Season is winter, spring, summer, fall
 - b. For December, use the following year (i.e., we want 12/2012-2/2013 to be “winter of 2013”)
- 3) Outcomes:
 - a. Type of dialysis at start (home versus in-center), end of month 3, 6, 9, 12
 - i. Indicator for whether patient is alive by end of month 3, 6, 9, 12
 - b. Time until home dialysis
 - i. Indicator for whether patient used home dialysis
 - ii. Censor for transplant, death, day 360, or end of follow-up, whichever occurs soonest
 - c. Whether the patient had a hospitalization in the 14 days prior to first_se (include if first_se occurs during the hospitalization)
 - i. Categorize the hospitalization as acute infectious respiratory OR one of the following cardiac (myocardial infarction, stroke/TIA, arrhythmia, fluid overload) if either of the following is true:
 1. Any of the diagnosis codes has one of the following CCS: 1, 2, 3, 7, 97, 100, 108, 109, 112, 122, 123, 125, 131
 2. The principal diagnosis code is one of the following CCS: 101, 105, 106, 107, 129
 3. (We use CCS categories as constructed by AHRQ)
 - ii. Otherwise, the hospitalization is non-acute cardiac/infectious-respiratory
- 4) Covariates
 - a. Patient level
 - i. Age
 - ii. Sex
 - iii. Race
 - iv. Ethnicity
 - v. Whether patient is dual eligible
 - vi. Employment status
 - vii. Type of dialysis access at the start of dialysis
 - viii. Whether patient had a nephrologist prior to dialysis start
 - ix. Primary reason for ESRD
 - x. Comorbidities using the CMS 2728 Form
 - b. Facility characteristics
 - i. Profit status
 - ii. Chain vs. independent
 - iii. Size of facility (Number of patients)
 - iv. Staff : patient ratio
 - v. ESRD Network
 - c. Zipcode Characteristics

- i. Median income
 - ii. High school graduation rate
 - iii. % below poverty
 - d. Yearly level fixed effects (an indicator for each year as defined above)
- 5) Using multiple imputation (chained equations and ordinal logit) to impute missing characteristics. We use ordinal logit because all variables (including continuous ones) will be modeled as categorical variables.
 - a. Variables used for imputation: Covariates as above, type of dialysis at start, whether the patient had an acute cardiac/infectious-respiratory, or other hospitalization within 14 days of dialysis
 - b. 10 imputations
 - c. Recombine estimates using Rubin's rules

PLANNED ANALYSES

Table 1: Descriptive statistics (frequencies and percentages) of all covariates, stratified by season of dialysis start

Table 2: Descriptive statistics (frequencies and percentages) of each hospitalization type by season of year. Compute the ratio in frequency between winter and summer

Figure 1: Unadjusted seasonal differences in home dialysis and # of patients starting with a hospitalization

- A) Y axis: # of in-center patients, X axis: time; series: show patients who start with a hospitalization and patients who start without a hospitalization
- B) Y axis: # of home patients, X axis: time; series: show patients who start with a hospitalization and patients who start without a hospitalization
- C) Compute log rank test (p-value)

Figure 2: Differences in time to home dialysis uptake by season and by whether patients start with a hospitalization

- Kaplan-Meier curves, censoring for death, transplant, loss to follow-up (1 year maximum follow-up)
- A) By season of year
- B) By whether patients start with and without a hospitalization
- C) Compute log rank test (p-value) for A & B

Figure 3: Mortality by season of year

- Kaplan-Meier survival curves, censoring for loss to follow-up
- By season of year
- Compute log rank test (p-value)

Regressions (using multiple imputation). Robust standard errors for all models.

- A) Logits (each outcome is a different regression)
 - a. Outcome: home dialysis at start, months 3, 6, 9, 12
 - b. Exposure: season of year, whether hospitalized (and type of hospitalization)

- c. Covariates: as above
- B) Cox
 - a. Outcome: time to home dialysis (st set data)
 - b. Exposure: season of year, whether hospitalized (and type of hospitalization)
 - c. Covariates: as above
- C) Subgroup analyses
 - a. Repeat A and B but interact the exposures
 - b. For each of the subgroups, compute the following:
 - i. winter + winter##hospitalized
 - ii. hospitalized + winter##hospitalized
 - iii. Repeat for spring, fall
- D) Planned Sensitivity Analyses
 - a. Complete Case Analysis