

# Measure Methodology Report: Delay in Progression of Chronic Kidney Disease Measure

**Submitted By:**

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## Section 1: Introduction

### Overview of Project

The Centers for Medicare & Medicaid Services (CMS), through the Center for Medicare and Medicaid Innovation (Innovation Center), has contracted Yale New Haven Health Services Corporation—Center for Outcomes Research and Evaluation (CORE) to develop a Delay in Progression of Chronic Kidney Disease (CKD) Measure. Although this measure is intended for use in the Kidney Care Choices Model, a new voluntary payment model by the Innovation Center for nephrologists and CKD-focused providers of care, the measure was developed for possible use beyond the Kidney Care Choices Model.

The Delay in Progression of CKD Measure will assess the success of kidney care providers in delaying patients' progression from Stage 4 CKD to [End-Stage Renal Disease](#) (ESRD) requiring [chronic dialysis](#) initiation (also named maintenance dialysis). The measure includes adult patients with Stage 4 CKD who are not on chronic dialysis. CORE developed the detailed measure specifications to implement the measure concept, consistent with the approach to outcomes measurement set forth in the National Quality Forum (NQF) guidance for outcome measures<sup>1</sup> and aligning with CMS Measures Management System (MMS) Blueprint guidance<sup>2</sup>.

Please see [Section 5: Glossary](#) for definitions of key terms used in this report.

### Kidney Care Choices Model Background

The Kidney Care Choices Model is designed to test new ways of reimbursing care for Medicare patients with Late-Stage CKD and ESRD. The model will apply financial incentives for nephrologists and affiliated health care providers that elect to participate in this Model (referred to as “Model participants” throughout). Model participants manage Medicare beneficiaries (referred to as “patients” throughout) with Late-Stage CKD (defined as Stage 4 and 5 CKD), ESRD, including those who had kidney transplants. More information on the Kidney Care Choices Model can be found on their website:

<https://innovation.cms.gov/innovation-models/kidney-care-choices-kcc-model>.

This measure supports the goals of the Kidney Care Choices Model:

- Delay and improve initiation of dialysis for patients with Late-Stage CKD;
- Improve coordination of care between providers caring for patients with Late-Stage CKD and ESRD, which may reduce total cost of care;
- Increase the number of patients receiving kidney transplants; and
- Increase options for provider risk and payment to improve financial accountability.

The Kidney Care Choices Model plans to implement the Delay in Progression of CKD Measure as part of a set of quality measures that assess the quality of care that Kidney Care Choices Model participants deliver to their patients. This Delay in Progression of CKD Measure is being developed in conjunction with the Standardized Mortality Ratio for Late-Stage CKD and ESRD Measure, which is a re-specification of the National Quality Forum endorsed #0369 Standardized Mortality Ratio for Dialysis Facilities Measure. The mortality measure is being re-specified to assesses the mortality rate among the Kidney Care Choices Model beneficiaries, which is a wider group of patients than the Delay in Progression of CKD Measure. Both measures will likely assess the same Model participants in the Kidney Care Choices Model.

### Measure Intent: Delay in Progression of CKD as a Quality Indicator

The intent of the Delay in Progression of CKD Measure is to improve the care of patients with Stage 4 CKD by incentivizing health care providers to slow disease progression of CKD and delay the need for chronic dialysis or kidney transplants. Delaying the dependency on dialysis is important since people who need dialysis often cannot work, need to be hospitalized more often, and are at a higher risk of dying<sup>3,4</sup>. Dialysis can be delayed through improved care coordination, and patient lifestyle changes such as eating a healthy diet, avoiding or quitting smoking, and exercising regularly. Delaying dialysis gives patients a better quality of life and reduces healthcare costs<sup>3,4</sup>.

Evidence has shown that timely intervention to manage other chronic conditions that often occur with CKD, such as high blood pressure and blood sugar can delay the progression of CKD and dialysis dependence. Several studies have demonstrated that a greater delay in chronic dialysis is associated with both living longer and cost savings to patients and providers, in addition to an improved quality of life<sup>5,6,7</sup>. Therefore, we intend the Delay in Progression of CKD Measure to encourage providers to improve the quality of care and reduce out-of-pocket costs for patients with CKD and produce long-term savings for the healthcare system.

There are currently no national measures that assess or incentivize appropriate delay in CKD progression to chronic dialysis dependence. While dialysis can be life-prolonging for patients with kidney failure, chronic dialysis is not benign. Delaying dialysis initiation when possible can be beneficial for patients. Several studies show that an early start to dialysis does not reduce the risk of death or improve patients' quality of life<sup>8,9,10,11,12,13</sup>. In fact, there is some data to suggest that early initiation of dialysis may be harmful due to increased risk of infection, pain from dialysis procedures, and disruption in routines and functioning that results in psychosocial stress<sup>14,15,16</sup>. Adults have also been shown to experience loss of executive cognitive function which can interfere with normal daily functioning<sup>17</sup>.

### *Feasibility*

This measure uses Medicare claims data to identify the cohort and risk-adjustment variables. Information on ESRD requiring chronic dialysis, for assessing the measure outcome, is obtained from the Medicare Enrollment Data Base (EDB). A benefit of using claims data for the measure is that it will not create additional costs or burdens for providers. Prior research has demonstrated that administrative claims can be used to assess the quality of care delivered by individual or small clinician groups (for example, use of claims in the risk adjustment for the claims-based Hospital-wide Readmission Measure in the Value Modifier Program)<sup>18</sup>. These models have demonstrated consistent performance across years of claims data.

## **Section 2: Methods & Measure Specifications**

In the following section, we discuss the measure development process, including our approach, the measure specifications, the data sources used, and methods used for testing.

### Approach to Measure Development

CORE and the Innovation Center are collaborating to develop this measure. The approach and specifications are informed by input from: multiple clinical experts including nephrologists; statistical and methodological experts; and a Technical Expert Panel. We convened a diverse Technical Expert Panel in March 2020 that includes physicians, quality measure experts, patients, and patient advocates and caregivers, to solicit their input regarding measure intent and specifications. Technical Expert Panel

meetings were held on June 30, 2020, June 29, 2021, and July 18, 2022. Discussion included the specifications outlined in this report, risk adjustment, and testing results.

Our goal was to develop measure specifications suitable for the Kidney Care Choices Model that could also be adapted beyond this model for use in other payment programs.

This report includes current draft measure specifications along with testing results.

### Draft Measure Specifications

This outcome quality measure produces a risk-standardized score for nephrologists and other kidney care providers treating patients with Stage 4 CKD.

- The [measure cohort](#) includes Medicare Fee-For-Service (FFS) patients aged 18 years and older who have received a diagnosis of Stage 4 CKD and are not on chronic dialysis.
- Patients who reach the [measure outcome](#) are those who progress to chronic dialysis within the measurement year. Those that receive a kidney transplant (prior to chronic dialysis or within a month of ESRD enrollment) are not counted in the outcome.
- The [risk adjustment](#) model includes 43 age and clinical risk factors.
- The [performance score calculation](#) for providers utilize a time-to-event Cox proportional hazard model with frailty.

### Data Sources

For measure development and reliability testing, the **Progression Development Dataset** is being used. The Progression Development Dataset consists of Medicare fee-for-service (FFS) administrative claims and enrollment information from calendar years (CYs) 2017 through 2018 (January 1, 2017 – December 31, 2018) from CMS' Chronic Conditions Data Warehouse and CMS Virtual Research Data Center (CCW/VRDC) and the CMS integrated data repository (IDR). For risk adjustment model performance testing, the Progression Development Dataset is split into a Progression Development Sample and a Progression Validation Sample.

To establish data element validity, being the accuracy of a diagnosis of Stage 4 CKD from International Classification of Diseases, 10th revision (ICD-10) codes in Medicare FFS claims, CORE used two datasets derived from electronic health records (EHR), referred to as the **Progression EHR Dataset A** and **Progression EHR Dataset B**. CORE compared the accuracy of ICD-10 codes from claims compared with laboratory data (estimated glomerular filtration rate (eGFR) values) from the EHR (patients' medical records).

Progression EHR Dataset A was from a single health system and included all patients with any outpatient encounters from 2013-2019 with Stage 4 or 5 CKD ICD diagnosis code or had an eGFR lab value under 30 during an outpatient visit. Progression EHR Dataset B was from a larger, nation-wide non-profit healthcare system with data from July 2018 – December 2021 with Stage 4 CKD or an eGFR 15-29 from any outpatient encounters. Data for both datasets included demographic (such as age, sex, gender, race), creatinine/eGFR values, and claims history (comorbidities). Minor data cleaning was applied, including: encounters on the same day were combined as one; patients who only had one encounter

were removed; for encounters where patients only had creatinine, eGFR was calculated using the CKD-EPI 2009 equation<sup>1</sup>.

### Cohort Definition

The initial patient population was informed by the Kidney Care Choices Model intent to assess quality of care for Medicare FFS beneficiaries with Stage 4 CKD who are not dependent on dialysis. The intent was to capture the broadest possible cohort who receive care from nephrologists or other kidney care providers. Most inclusion criteria align with Kidney Care Choices Model requirements.

### *Inclusion*

Patients are eligible for inclusion in the measure if:

- Patient is enrolled in Medicare FFS Parts A and B for one full year prior to the performance year (calendar year) as well as the full performance year or until the date of death (in the performance year).
  - *Rationale:* Medicare FFS administrative claims will be used for measure calculation. Enrollment is required for the year prior to the performance year to ensure sufficient claims for the risk-adjustment model. Continuous enrollment during the performance year is required to ensure complete records for assessing patient outcomes.
- Patient is at least 18 years old at the start of the year prior to the performance year.
  - *Rationale:* Pediatric patients only receive Medicare coverage for ESRD requiring dialysis or due to transplantation.
- Patient has at least one occurrence of ICD-10 code N18.4: “CKD, Stage 4 (Severe)” in at least one claim during the performance year.
  - *Rationale:* This ICD-10 code establishes a diagnosis of Stage 4 CKD.
- Patient is not enrolled in ESRD (Medicare enrollment in ESRD or ESRD for Dialysis; this measure does not use ESRD for Transplant) at the time of their Stage 4 CKD diagnosis.
  - *Rationale:* The measure will not include patients who have already experienced the outcome of interest.
- Patient is not enrolled in hospice at the time of their Stage 4 CKD diagnosis.
  - *Rationale:* Patients in hospice care have complex medical needs and have an outcome rate unrelated to Model Participant decision-making or quality of care. The care goals and decisions of patients enrolled in hospice care likely differ from those who are not enrolled in hospice care.
- If patient had a prior kidney transplant, they are not eligible for the measure until one-year post transplant.
  - *Rationale:* Patients are more vulnerable post-transplant to renal injury and have more variable disease staging due to early rejection and other issues related to the procedure rather than to the nephrology care provided.

### *Exclusion*

The measure excludes patients with:

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<sup>1</sup> Equation can be accessed at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2763564/>



- Metastatic and advanced cancers, defined as specific cancer-related ICD-10 codes from an inpatient encounter. Patients are excluded if coded with advanced or metastatic cancer within one year prior to the earlier date of being attributed to a nephrology practice or having Stage 4 CKD in the measurement year based on an inpatient claim with specific ICD-10 codes from the following Condition Categories: CC8, CC10, CC12, CC177, CC178 (for full, refer to [Appendix A](#)).
  - *Rationale:* The measure excludes patients with metastatic and advanced cancers since the outcome (mortality) is not a reliable signal of care quality among these patients. Many patients in this population may be too ill for dialysis and have a high risk of mortality; thus, we find it inappropriate to attribute outcomes for these patients to their nephrologists' quality of care.

### Outcome Definition

The goal of the measure is to incentivize providers to delay progression to ESRD requiring chronic dialysis. The measure outcome is patients with Stage 4 CKD who have ESRD requiring chronic dialysis.

ESRD requiring chronic dialysis will be identified using Medicare beneficiary enrollment (coverage) data, which include start and end dates. We will consider enrollment in ESRD or ESRD for Dialysis.

### **Events Not Counted in the Outcome**

The outcome does not count the following events as an outcome of progression for patients who:

- Receive a kidney transplant prior to progression to chronic dialysis (or within one month of ESRD enrollment).
  - *Rationale:* This aligns with the goal to incentivize transplants. The specific codes are presented in [Table 1](#).
- Enroll in hospice prior to beginning ESRD enrollment.
  - *Rationale:* Patients in hospice care have complex medical needs and may have an outcome rate unrelated to Model Participant decision-making or quality of care. Hospice enrollment before dialysis initiation may be due to diseases unrelated to CKD such as a metastatic cancer. Appropriate referral to hospice care should be encouraged.
- Die prior to beginning ESRD enrollment during the measurement period.
  - *Rationale:* For patients who die with Stage 4 CKD before progressing to ESRD or chronic dialysis, the cause of death is likely related to diseases or conditions other than CKD, therefore it is unlikely that these patients are representative of the quality of care provided by a nephrologist.

*Table 1. Transplant Codes Not Counted in Measure Outcome, from Agency for Healthcare Research and Quality Clinical Classifications Software (AHRQ CCS) 105*

Code	Description of Code
OTY00Z0	Transplantation of Right Kidney, Allogeneic, Open Approach
OTY00Z1	Transplantation of Right Kidney, Syngeneic, Open Approach
OTY00Z2	Transplantation of Right Kidney, Zooplasic, Open Approach
OTY10Z0	Transplantation of Left Kidney, Allogeneic, Open Approach
OTY10Z1	Transplantation of Left Kidney, Syngeneic, Open Approach

Code	Description of Code
0TY10Z2	Transplantation of Left Kidney, Zooplastic, Open Approach
50360-50365	Kidney transplant
50380	Kidney transplant
S2065	Kidney transplant

### Attribution

This measure is developed across a national set of nephrology practices. CORE attributed patients to providers using similar methods as the Kidney Care Choices Model alignment. Patient alignment during measure implementation will be completed by the Kidney Care Choices Model. We represented the nephrology practice by their tax identification numbers. For measurement purposes, beneficiaries are attributed to the provider who has the highest number of evaluation and management (E&M) claims for visits with the beneficiary.

To identify the nephrology practice responsible for patient care, we attribute patients to providers based on having at least two encounters with that provider. Specifically, we first identified all the nephrology practices that provided any nephrology specialty services (with specialty code 39) during the performance year. We then identified the eligible patient visits with those nephrology practices by specific Healthcare Common Procedure Coding System (HCPCS) codes prescribed by the Kidney Care Choices Model, listed in [Table 2](#), eligible E&M services<sup>19</sup>. If a patient visited multiple practices that provide specialty care, the patient is attributed, 1) to the practice that provided most of the services to the patient; or if there is a tie, 2) to the practice that billed the most for those services; or there is still a tie, 3) the practice who provided the most recent service; or if there is still a tie, 4) a random selected practice.

*Table 2. E&M HCPCS Codes Identifying Providers Who Delivered Nephrology Specialty Services*

Service	CPT /HCPCS Codes
Office/Outpatient Visit E/M	99201-99205 99211-99215
Prolonged E/M	99354-99355
Transitional Care Management Services	99495-99496
Advance Care Planning	99497-99498
Welcome to Medicare and Annual Wellness Visits	G0402, G0438, G0439
Chronic Care Management Services	99490

Patients enter the cohort and begin being contributing at-risk time with the following parameters:

- The patient enters the measure at “t<sub>0</sub>” or “time zero,” which begins when the beneficiary is both attributed to a nephrology practice (see [Attribution](#)) and has a confirmed diagnosis of Stage 4 CKD. Beneficiaries are required to have at least one Stage 4 CKD claim during the measurement year. For attribution, beneficiaries are required to have two visits with the same nephrology practice with at least one occurring in the measurement year. The first attributed visit can occur in the prior year. The t<sub>0</sub> is the last date among: 1) the start of the measurement year (if continuing care from the prior year); 2) the start of the attribution to the provider (after at least two encounters); or, 3) the start of the CKD Stage 4 (one or more claims).

The patient will stop contributing at-risk time - (no longer eligible for the outcome) if they:

- Enroll in Medicare hospice;
- Die;
- Have a kidney transplant prior to or within one month of initiation of maintenance dialysis (using Medicare ESRD or ESRD- Dialysis enrollment data); or
- Enroll in Medicare ESRD, indicating an outcome event.

### Approach to Risk Adjustment

In this section, we describe the conceptual basis for risk adjustment, our rationale for candidate variables including consideration of clinical and social risk factors, and our approach to selecting final variables from the candidate variables. CORE developed the risk model by using variables from claims.

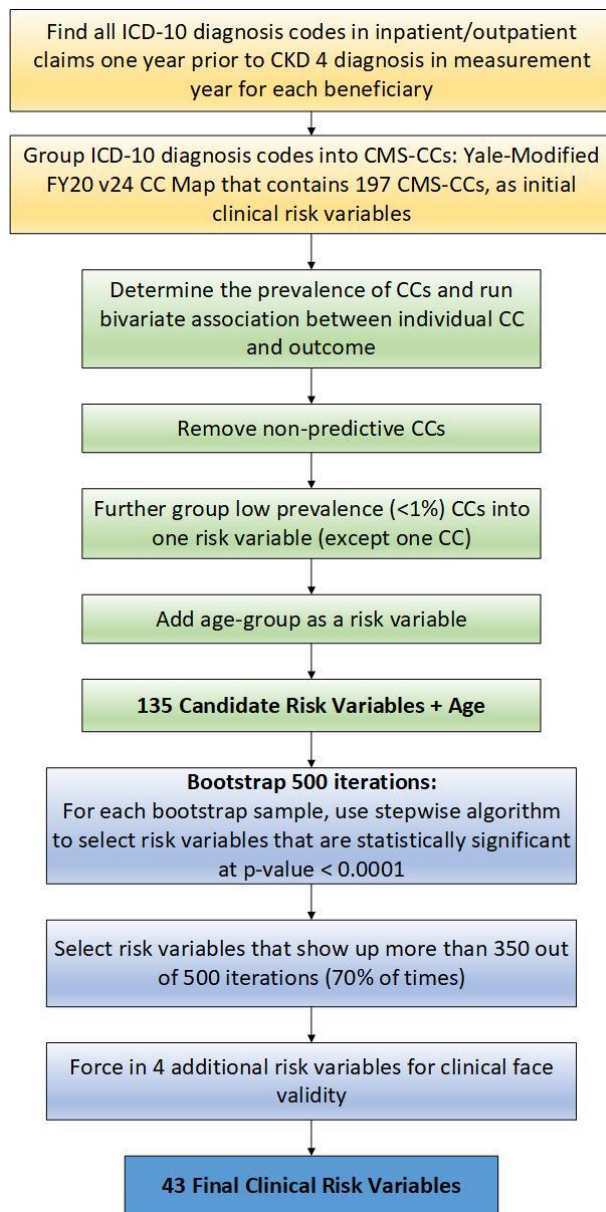
The goal of risk adjustment is to account for differences among nephrologists in patient demographic and clinical characteristics. The measure incorporates risk adjustment to account for factors that are associated with the outcome, vary across providers, and are unrelated to quality of care, so that measure scores reflect true differences in quality of care. Accounting for case-mix differences is important because it recognizes that some providers care for older, sicker patients who have anticipated higher progression rates. Through the risk-adjustment modeling, a higher expected outcome rate is set for providers who care for patients with certain risk factors. We identified potential candidate risk factors using a focused literature search, clinical experts' input, and empirical analysis. We used logistic regression with a binary outcome to select risk variables for final models.

### *Candidate Clinical and Demographic Risk Variables*

We considered age and medical history (comorbidities/frailty) as candidate variables.

- Comorbidities for inclusion in risk adjustment were identified through inpatient and outpatient administrative claims during the twelve months prior to entering the cohort.
- We used Yale-Modified FY20 v24 CC Map that contains 197 CMS condition categories (CMS-CCs), based on publicly available CMS-CCs, to group ICD-10 diagnosis codes into CMS-CCs as candidate clinical risk factors.

Figure 1. Risk Variable Selection Flowchart for CKD Progression Measure



Above is a flowchart depicting the process of selecting clinical risk variables for the model. To select candidate clinical variables (yellow and green boxes in flowchart):

- We examined all condition categories (CMS-CCs).
- Examined frequencies and bivariate associations with outcome (including odds ratios) of all CMS-CCs.
- CMS-CCs that were not statistically significant were removed, unless deemed clinically relevant to the outcome by expert nephrologists (ex: cancer-related CC). Statistical significance was defined by having a p-value less than 0.05 (23 CC removed).
- CMS-CCs with low frequency (<1% of cohort) were grouped into one variable, except for CC1 HIV/AIDS (35 CC grouped).

- CC132 Kidney Transplant Status was split into two: CC132Z ICD-10-CM codes beginning with 'Z' (codes indicating general aftercare or status); and CC132T ICD-10-CM codes beginning with 'T' (codes indicative of a kidney failure or complication).

This resulted in 135 candidate risk variables, in [Appendix A](#).

### *Final Risk Variable Selection*

We selected the final set of risk variables using bootstrap methods (blue boxes in flowchart, above) using logistic regression from the candidate variables:

- 500 random samples were generated with replacement.
- For each of the 500 samples, a logistic regression model (binary outcome) was selected by using backward selection approach.
- All variables significant at  $p < 0.0001$  were retained in each final bootstrap risk model. For each variable, we note its % retained in the 500 bootstrap models.
- We then selected all variables that were retained in the model which are above 70% threshold (cut-off). The threshold was based on clinical and statistical evaluation to have a clinically meaningful, statistically robust, and parsimonious risk model.
  - Low frequency CC variable was removed. This group was very heterogeneous; removing aligns with many other measures that excluded prior to bootstrap results.
  - Three additional CCs were included that were below the 70% cutoff, for face validity per our expert nephrologists (Dialysis Status [CC134]; Diabetes without Complication [CC19]; and Cirrhosis of Liver [CC28]).
  - Proteinuria identified by ICD-10 code (R80.9) was included as a risk variable; Proteinuria is within the CC 179 Minor Symptoms, Signs, Findings, which fell below the 70% cutoff. Adding the whole condition category is not as predictive as adding a specific variable, therefore, only the ICD-10 code for proteinuria has been added. We included the Proteinuria code as a separate variable based on input from nephrologists regarding its clinical relevance and importance for face validity.

There are 43 final risk variables, shown in [Table 5](#). We evaluated the performance of the model in Cox model with the selected risk factors.

### *Candidate Social Risk Variables*

A patient's progression to dialysis is likely influenced by their social risk factors (SRFs). Kidney care providers have the ability to partially or fully address these SRFs and mitigate the impact on progression. We considered whether to adjust for SRF using a comprehensive approach that evaluates the following:

1. Conceptual influence of SRFs on measure outcome (and provider role)
2. Feasibility of utilizing meaningful SRFs in available data
3. Empiric testing of SRFs for inclusion in the measure risk models

As a starting principle, a [recent ASPE report](#) recommends against SRF adjustment for outcome measures in public reporting and for careful consideration of adjustment in measure programs or payment models.

The conceptual relationship, or potential causal pathways by which these possible social risk factors influence the risk of progression to dialysis are varied and complex. Some social risk factors may, for instance, influence the patient's ability to manage self-care such as following dietary recommendations. However, the best quality care should slow progression for all patient groups, especially if tailored to a particular patient's situation and preferences. Therefore, the conceptual rationale for risk-adjustment is limited.

We first compiled initial list of SRFs to consider, using the National Academies of Sciences, Engineering, and Medicine (NASEM) report framework which categorized social risk factors into the four domains:

- Socioeconomic position;
- Race, ethnicity (not social risk factors but proxy for the social risk factor of exposure to systemic racism), and cultural factors;
- Social relationships; and
- Residential and community context

Second, we identified candidate SRFs for analyses, based on:

- Internal hypotheses regarding the relationships between the SRF to progression for patients with CKD;
- Potential / perceived ability of a kidney care provider to mitigate the SRF; and
- Data availability and feasibility, including level of analysis (availability of patient-level or area-level data).

Among candidate SRFs, we identified the corresponding variable from different data sources and linked them to the test dataset based on the related beneficiary information. The candidate social risk variables considered are listed in [Table 3](#), which includes social risk factors from Medicare FFS claims including dual eligibility for Medicare and Medicaid, Agency for Healthcare Research and Quality (AHRQ) socioeconomic status (SES) index, and being an urban resident.

*Table 3. Candidate Social Risk Factors*

Variable	Description	Data level
Dual-eligible	Dual-eligible for Medicare and Medicaid vs. Medicare-only (ref)	Beneficiary
Race	Each race vs. White race (ref). Note: Medicare administrative claims data are not a reliable source for accurate race information except for Black race, as noted in the literature. Included here as above to explore general impact using available data	Beneficiary
AHRQ SES index	Socioeconomic status indicator (higher score = less social risk)	Zip code
Urban resident	Residence in metro area county (ref) vs. non-metro county (suburban and rural are considered non-urban)	County

Methods for testing each social risk factor included examining the distribution of SRFs, bivariate (unadjusted) relationships of SRFs with progression, risk adjusted relationships, and risk model performance when incorporating SRFs including impact on provider performance scores.

### *Risk Model Performance*

CORE computed summary statistics to assess model performance: calibration (a measure of over-fitting), discrimination in terms of predictive ability, and discrimination in terms of c-statistic (see below).

Over-fitting refers to the phenomenon in which a model describes the relationship between predictive variables and outcome well in the Development Sample but fails to provide valid predictions in new patients as those in the Validation Sample. So, a model without over-fitting is desirable. CORE calculates one set of statistics, with two parameters, for over-fitting using the Validation Sample and models built with the Development Sample:  $\gamma_0$  and  $\gamma_1$ . If the  $\gamma_0$  in the Validation Sample is close to zero and the  $\gamma_1$  is close to one, then there is little evidence of over-fitting.

Discrimination in predictive ability measures the ability to distinguish high-risk subjects from low-risk subjects. It is desirable to see a large difference of observed outcome rates between the lowest decile and highest decile ranked by predicted probabilities.

The c-statistic is a summary score of how accurately a statistical model can distinguish between a patient with and without an outcome. For binary outcomes, the c-statistic is identical to the area under the Receiver Operator Curve (ROC). For time to event outcomes, we examined the Harrel's C-statistic, a concordance statistic that can be considered as a generalization of C-statistic for binary outcome.

A c-statistic of 0.50 indicates random prediction, implying all patient risk factors are useless. A c-statistic of 1.0 indicates perfect prediction, implying patients' outcomes can be predicted completely by their risk factors. While a higher c-statistic is desirable, we do not want to maximize it by adjusting for factors that should not be adjusted for.

### Measure Score Calculation and Testing

The measure score is a risk-standardized progression ratio, defined as the ratio of:

- The number of progression events that were predicted for eligible patients seen by provider given their case mix, provider quality, and length of time patients were observed in the cohort; over
- The number of progression events that would be expected given the patient case mix in the cohort, an average providers' quality, and length of time patients were observed in the cohort.

The measure outcome is a time-to-event outcome, which calculates the time from Stage 4 CKD to ESRD requiring chronic dialysis. Specifically, the start time (at-risk time) from each beneficiary is calculated when the beneficiary becomes eligible in the measurement period (see [Attribution](#)) until the earliest time of either: date of the first observed enrollment dates of either Medicare ESRD or ESRD-Dialysis (outcome); enrollment in Medicare hospice or death date; first date of patient receiving a kidney transplant (can be within first month of enrolling in ESRD); or the end of the performance year. The event of interest is enrolling in ESRD or ESRD-Dialysis.

The outcome, or events in the numerator, are progression events. Some patient events are ‘censored’ from being counted as an outcome: a kidney transplant before ESRD enrollment (or within one month); enrollment in Medicare hospice; or death before ESRD enrollment. These patients have their time included in the denominator from time zero (cohort eligibility) until the time they have censored event stated above. Once they have a censored event, they stop contributing at-risk time to the denominator, as they are no longer eligible for the outcome of ESRD requiring chronic dialysis.

#### Measure Score Calculation Details

Assume that the hazard function of an event for patient  $i$  serviced by provider  $j$ , with a vector of risk factors  $\mathbf{X}_{ij}$  is defined as a frailty model under the proportional hazard framework:

$$h_{ii}(t_{ii}) = w_j h_0(t_{ii}) \exp(\mathbf{X}_{ii}\boldsymbol{\beta}),$$

where the  $w_j$  is the frailty for each provider  $j$ .

So, for the patient  $ij$ , the predicted probability of progression at time  $t$  as cumulative hazard at the time  $t_{ij}$ <sup>20</sup> is

$$P_{ij} = H_{ij}(t_{ij}) = \int_0^{t_{ij}} w_j h_0(t) \exp(\mathbf{X}_{ij}\boldsymbol{\beta}) dt = w_j \exp(\mathbf{X}_{ij}\boldsymbol{\beta}) \int_0^{t_{ij}} h_0(t) dt = w_j \exp(\mathbf{X}_{ij}\boldsymbol{\beta}) H_0(t_{ij})$$

Correspondingly, the expected probability of progression is defined, by setting  $w_j = 1$ , as:

$$E_{ij} = \exp(\mathbf{X}_{ij}\boldsymbol{\beta}) H_0(t_{ij})$$

Thus, the risk standardized ratio (RSR) for progression in a frailty model for provider  $j$  will be the frailty estimation  $w_j$ , since RSR

---


$$= \frac{\text{predicted number of events}}{\text{expected number of events}} = \frac{\sum_{i=1}^{n_j} P_{ij}}{\sum_{i=1}^{n_j} E_{ij}} = \frac{w_j \sum_{i=1}^{n_j} \exp(\mathbf{X}_{ij}\boldsymbol{\beta}) H_0(t_{ij})}{\sum_{i=1}^{n_j} \exp(\mathbf{X}_{ij}\boldsymbol{\beta}) H_0(t_{ij})} = w_j$$

Where  $n_j$  is the number of patients seeing provider  $j$ .

We used the lognormal distribution for frailty, i.e.  $\log(w_j) \sim N(0, \vartheta)$ , where median  $(w_j) = 1$ .

The confidence interval for  $\text{RSR}_j$  (i.e. frailty) is a direct output from estimation software.

The final measure score, Risk Standardized Incidence Rate (RSIR), is calculated as  $\text{RSIR} = \text{RSCKDPR} * \text{IR}$ ,

where  $\text{IR}$  is the national incidence rate calculated as number of progression events in the measurement year divided by total patient years times 100.

#### Measure Score Variation

CORE examined the extent of RSR variation across providers using summary statistics: mean, standard deviation, median, interquartile range.



## Reliability

For **data element reliability**, this measure will use routinely submitted claims data to identify the measure's cohort, risk-adjustment variables, and outcome. Using claims data imposes no costs on providers and eliminates provider burden, which is important since providers have limited time to dedicate to reporting. Prior research has demonstrated that administrative claims can be used to assess the quality of care delivered by individual or small clinician groups (for example, use of claims in the risk adjustment model for the claims-based Hospital-Wide Readmission Measure in the Value Modifier Program). These risk models have demonstrated consistent performance across years of claims data. CMS claims are regularly audited which further supports their validity in measure development. For more information on the audit process, please refer to the following resource:

<https://www.cms.gov/files/document/2020-program-audit-process-overview.pdf>.

For **measure score reliability** we calculated signal-to-noise reliability scores for nephrologists. We used the formula for signal-to-noise reliability presented by Adams et al. to calculate individual clinician-level and TIN-level reliability scores<sup>20</sup>. To estimate the overall signal and noise, we first calculated the ICC for the Model Participant,  $j$ , using the estimates of between-entity variance  $\tau^2$  and the formula for intraclass correlation coefficient (ICC) presented by Shrout and Fleiss<sup>21</sup>. Specifically, the signal-to-noise reliability score for Model Participant,  $j$ ,  $R_j$  is calculated as:

$$R_j = \frac{n_j ICC}{1 + (n_j - 1) ICC}$$

while

$$ICC = \frac{\tau^2}{\tau^2 + \pi^2 / 6\gamma^2}$$

$n_j$  is the number of beneficiaries for the nephrologist  $j$ ,  $\tau^2$  is the between agency variance in a Weibull model with lognormal frailty that used to approximate the Cox model with lognormal frailty specified above and represent the signal, and  $\pi^2 / 6\gamma^2$  represents the noise and  $\gamma$  is the shape parameter of the Weibull distribution.

$R_j$  ranges from 0 to 1.0. The higher the score, the higher the reliability. Also, we can see that the reliability of agency measure score will vary depending on the number of beneficiary encounters. Entities with higher volume will tend to have more reliable scores, while those with lower volume will tend to have less reliable scores.

## Validity

For **data element validity**, we tested the Stage 4 CKD data element (ICD-10 code N18.4) using two different datasets containing EHR data: Progression EHR Dataset A and Progression EHR Dataset B. More details are in the [Data Sources](#) section. Both datasets compared the accuracy of ICD-10 claims diagnoses of Stage 4 CKD with laboratory data (eGFR values) from patients' medical records. For each encounter with a Stage 4 CKD diagnosis (claim), we defined a positive 'match' if the patient had an eGFR of 15-29 within 6-month (180 days) prior, or 30-days after diagnosis. The timeframe was based on clinical

guidelines that a stable patient with Stage 4 CKD should see their provider every 3-6 months. Matching looks forward to account for labs ordered during the patient visit but drawn and resulted weeks later.

For **measure score validity**, CORE developed this measure in consultation with national guidelines for publicly reported outcome measures and consulted with experts in healthcare delivery, payment reform, and clinical delivery. Measure score validity was conducted through TEP engagement for face validity. To conduct face validity, a standardized Qualtrics survey was sent to all participating TEP members with the following questions intended to assess how stakeholders felt about the validity of the measure.

CORE evaluated the options for empiric validity testing by correlating the measure score against existing quality measures in the Merit-Based Incentive Payment System (MIPS) and in the CMS Dialysis Compare Program, but found the providers to be too dissimilar to CORE's measure to be meaningful for validity assessment.

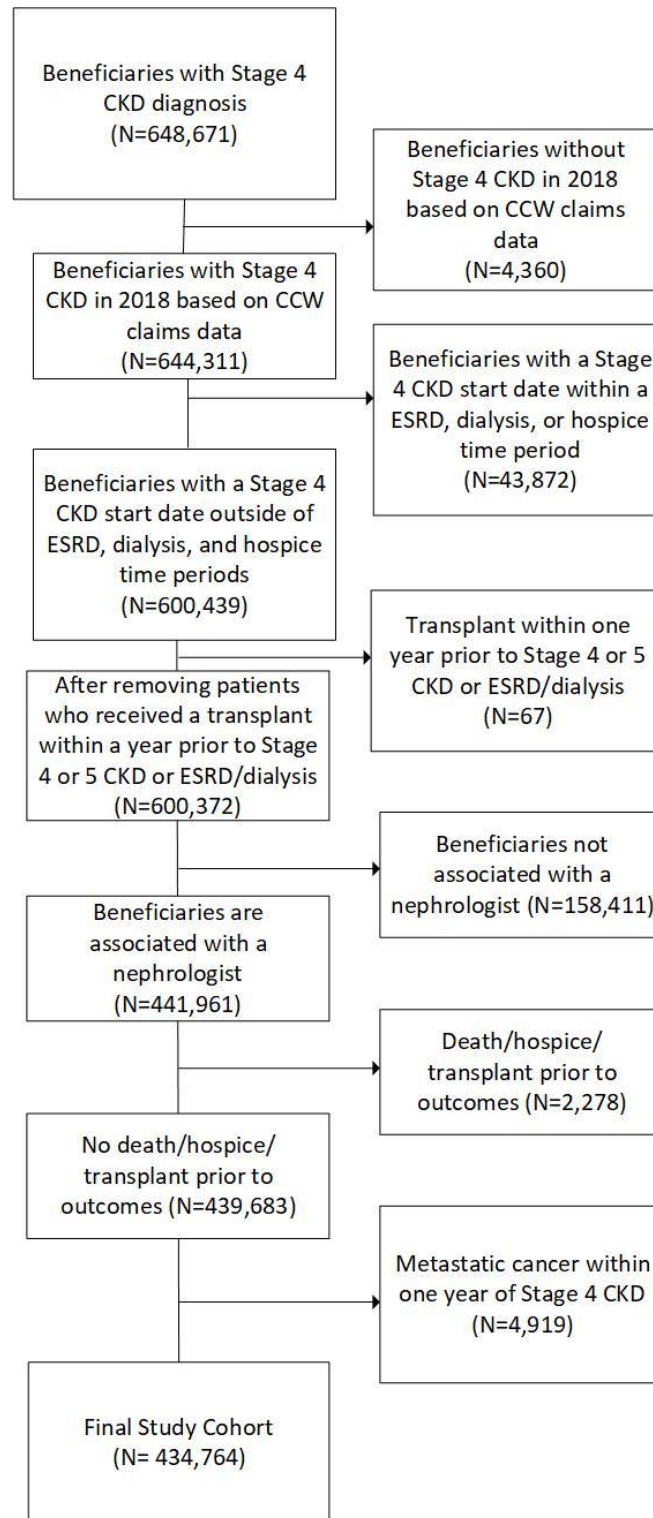
### Section 3: Results

Details on data sources for the results are outlined in [Data Sources Section](#) above, and each analysis is labeled by dataset, below.

#### Measure Cohort

[Figure 2](#) below shows the cohort flowchart, with the number of patients remaining in the cohort and the number being excluded shown in the offshoots. Beginning with 648,671 patients with a Stage 4 CKD claim in the measurement period (2018), the cohort was then restricted to those without a Stage 4 claim in 2018 based on CCW claims data, leaving 644,311 patients. After cleaning the data to ensure that the Stage 4 CKD start date is valid (not in a period of hospice, ESRD, or dialysis), the cohort was further restricted to patients who had not received a transplant within 12 months of Stage 4 or 5 CKD or progression to ESRD/dialysis, leaving 600,372 patients. Patients were then attributed to a nephrologist, resulting in 441,961 patients left in the cohort. After removing hospice prior to an outcome or death prior to the patient's time zero (the time at which the patient is established as having Stage 4 disease and being attributed to a nephrologist), the cohort was further reduced to 439,683. After removing the beneficiaries with metastatic cancer within one-year prior the entering the cohort, the final study cohort in the Progression Development Dataset consists of 434,764 beneficiaries.

Figure 2. Progression Development Dataset Measure Study Cohort Flowchart



Details on patient demographics of the Progression Development Dataset are presented in [Table 4](#). Patients in the cohort have a mean age of 75.9 years with a standard deviation of 10.2 years (minimum 18, maximum 109) and the majority are female and White race. 16.5% of patients in the cohort are also

dual enrolled in Medicare and Medicaid, which is expected with a Medicare measure that is inclusive of patients 18 years and older. This is in part because Medicare patients between 18 and 64 are often enrolled in both Medicare and Medicaid.

*Table 4. Patient Characteristics, Progression Development Dataset (N=434,764)*

Characteristic	#	%
Total Beneficiaries	434,764	100.00
Age in the measure year (2017)	-	-
Mean (SD)	75.9	10.2
Minimum, Maximum	18	109
Q2 (IQR)	76	13
Gender	-	-
Male	208,029	47.85
Female	226,735	52.15
Race	-	-
Unknown	3,201	0.74
White	348,283	80.11
Black	57,179	13.15
Other	7,142	1.64
Asian	8,214	1.89
Hispanic	7,604	1.75
North America Native	3,141	0.72
Dual in 2018	-	-
No	362,861	83.46
Yes	71,903	16.54

### Final Risk Variable Selection

The final 43 risk variables with frequencies, estimates, and hazard ratios (HR) with 95% confidence interval (similar interpretation to odds ratio) using Cox Proportional Hazard Model with Frailty Regression Model are listed in [Table 5](#), below.

*Table 5. Parameter Estimates for Final Risk Variables Using Cox Proportional Hazard Model with Frailty Regression Model, Progression Development Dataset (N= 434,764 Patients)*

Risk Variable	(%)	Parameter Estimates (Standard Error)	Hazard Ratio (LHR- UHR)
Age: Mean (SD)	75.86 (10.23)	-0.032 (0.001)	0.969 (0.967-0.970)
Proteinuria (ICD-10 DX Code R80.9)	22.58	0.353 (0.015)	1.423 (1.381-1.466)
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock (CC2)	10.08	-0.256 (0.024)	0.774 (0.738-0.811)
Diabetes with Chronic Complications (CC18)	55.77	0.312 (0.024)	1.365 (1.302-1.433)

<b>Risk Variable</b>	<b>(%)</b>	<b>Parameter Estimates (Standard Error)</b>	<b>Hazard Ratio (LHR- UHR)</b>
Diabetes without Complication (CC19)	56.55	0.088 (0.024)	1.092 (1.042-1.145)
Morbid Obesity (CC22)	13.78	-0.088 (0.019)	0.916 (0.882-0.952)
Other Significant Endocrine and Metabolic Disorders (CC23)	35.94	0.147 (0.015)	1.158 (1.125-1.192)
Disorders of Fluid/Electrolyte/Acid-Base Balance (CC24)	51.23	0.179 (0.017)	1.196 (1.157-1.235)
Cirrhosis of Liver (CC28)	2.69	0.101 (0.038)	1.106 (1.026-1.191)
Chronic Hepatitis (CC29)	1.40	0.264 (0.044)	1.302 (1.196-1.418)
Rheumatoid Arthritis and Inflammatory Connective Tissue Disease (CC40)	11.24	-0.130 (0.023)	0.878 (0.839-0.919)
Osteoarthritis of Hip or Knee (CC42)	17.99	-0.114 (0.020)	0.892 (0.858-0.928)
Osteoporosis and Other Bone/Cartilage Disorders (CC43)	24.81	-0.129 (0.017)	0.879 (0.849-0.909)
Iron Deficiency and Other/Unspecified Anemias and Blood Disease (CC49)	71.63	0.438 (0.021)	1.55 (1.487-1.615)
Dementia Without Complication (CC52)	12.10	-0.276 (0.027)	0.759 (0.719-0.800)
Major Depressive, Bipolar, and Paranoid Disorders (CC59)	11.15	-0.142 (0.024)	0.867 (0.828-0.909)
Other Psychiatric Disorders (CC63)	19.07	-0.135 (0.019)	0.873 (0.841-0.907)
Congestive Heart Failure (CC85)	48.08	0.173 (0.017)	1.189 (1.150-1.230)
Angina Pectoris (CC88)	11.20	-0.119 (0.023)	0.888 (0.849-0.928)
Coronary Atherosclerosis/Other Chronic Ischemic Heart Disease (CC89)	49.35	0.047 (0.016)	1.048 (1.015-1.082)
Hypertension (CC95)	94.91	0.253 (0.040)	1.288 (1.191-1.394)
Specified Heart Arrhythmias (CC96)	36.78	-0.185 (0.017)	0.831 (0.804-0.859)
Other and Unspecified Heart Disease (CC98)	27.58	0.117 (0.017)	1.125 (1.088-1.163)
Other Circulatory Disease (CC109)	30.57	-0.091 (0.016)	0.913 (0.884-0.942)
Pleural Effusion/Pneumothorax (CC117)	15.58	0.245 (0.020)	1.278 (1.229-1.328)
Proliferative Diabetic Retinopathy and Vitreous Hemorrhage (CC122)	1.30	0.168 (0.042)	1.183 (1.089-1.285)
Diabetic and Other Vascular Retinopathies (CC123)	7.50	0.140 (0.024)	1.151 (1.097-1.207)
Kidney Transplant Status: ICD-10-CM codes beginning with 'Z' (CC132Z; includes Z4822 Encounter for aftercare following kidney transplant; and Z940 Kidney transplant status)	2.48	-0.242 (0.032)	0.785 (0.738-0.836)
Dialysis Status (CC134)	3.08	0.283 (0.023)	1.328 (1.268-1.39)
Acute Renal Failure (CC135)	43.62	0.255 (0.017)	1.291 (1.247-1.336)
Chronic Kidney Disease, Stage 5 (CC136)	14.56	1.264 (0.016)	3.538 (3.429-3.651)
Chronic Kidney Disease, Severe (Stage 4) (CC137)	92.87	-0.094 (0.038)	0.911 (0.844-0.982)
Chronic Kidney Disease, Moderate (Stage 3) (CC138)	73.73	-0.399 (0.016)	0.671 (0.651-0.692)
Chronic Kidney Disease, Mild or Unspecified (Stages 1-2 or Unspecified) (CC139)	83.01	0.188 (0.025)	1.206 (1.148-1.268)
Unspecified Renal Failure (CC140)	10.27	0.223 (0.019)	1.249 (1.204-1.297)
Nephritis (CC141)	5.77	0.320 (0.022)	1.377 (1.319-1.437)

Risk Variable	(%)	Parameter Estimates (Standard Error)	Hazard Ratio (LHR- UHR)
Urinary Tract Infection (CC144)	33.73	-0.154 (0.016)	0.857 (0.831-0.884)
Other Urinary Tract Disorders (CC145)	46.19	0.128 (0.015)	1.137 (1.104-1.171)
Other Female Genital Disorders (CC148)	5.24	-0.202 (0.034)	0.817 (0.765-0.873)
Male Genital Disorders (CC149)	22.68	0.085 (0.017)	1.088 (1.053-1.125)
Complications of Specified Implanted Device or Graft (CC176)	5.20	0.176 (0.025)	1.192 (1.135-1.253)
Other Complications of Medical Care (CC177)	8.65	-0.141 (0.024)	0.868 (0.828-0.91)
Alcohol/Cannabis Use or Use Disorder, Mild or Uncomplicated; Non-Psychoactive Substance Abuse; Nicotine Dependence (CC203)	10.11	0.113 (0.021)	1.12 (1.076-1.166)

CC = condition category (groups of ICD-10 codes); LHR = lower hazard ratio; UHR = upper hazard ratio

### Candidate Social Risk Factor Results

Candidate SRFs were tested using a bivariate association between each variable and the outcome (“unadjusted”) in [Table 6](#), and the multivariate association that includes each variable along with full condition-based risk model to assess how the risk factor impacts the overall model predictive ability (“adjusted”) in [Table 7](#). AHRQ SES scores were used as quartiles with the top quartile (highest economic status) as the reference variable.

- Dual eligibility: Unadjusted hazard ratio shows non-dual eligible patients having a lower risk of progressing to the outcome compared to those who are dual eligible; however, once adjusted for other factors, non-dual eligible patients become slightly *more likely* to progress to the outcome. This suggests that the increased risk of progressing to dialysis associated with dual eligibility is entirely explained by greater co-morbidity among dual eligible beneficiaries.
- AHRQ SES Index: Although having lower economic status is associated with the outcome of progression in the unadjusted model, once adjusted for co-morbidities, there is no significant relationship.
- Urban: Patients living outside urban areas (non-urban) have slightly lower risk of progression to the outcome.

Additionally, the original measure score c-statistic (Receiver Operating Characteristic/ROC) with the **full risk model (with no SRF)** is **0.792**; including any variable in the model does not improve overall predictive ability.

*Table 6. Bivariate Associations Using Cox Proportional Hazard Regression Models Between SRF (Parameter) and Outcome (Progression), Progression Development Dataset (N= 434,764)*

Parameter	Frequency	Unadjusted	
		Estimate (Standard Error)	Hazard Ratio (95% confidence interval)
Dual Eligibility	15%	ref	ref
Non-Dual (Medicare-only)	85%	-0.39 (0.02)	0.68 (0.66-0.70)
AHRQ SES quartile 1	22%	0.23 (0.02)	1.25 (1.21-1.30)

Parameter	Frequency	Unadjusted	
		Estimate (Standard Error)	Hazard Ratio (95% confidence interval)
(Lowest economic status)			
AHRQ SES quartile 2	23%	0.09 (0.02)	1.10 (1.06-1.14)
AHRQ SES quartile 3	23%	0.05 (0.02)	1.05 (1.01-1.09)
AHRQ SES quartile 4 (highest economic status)	32%	ref	ref
Non-Urban	21%	-0.04 (0.02)	0.96 (0.93-1.00)
Urban	79%	ref	ref

*Table 7. Multivariate Association with Risk Model (43 Clinical Factors, Including Age) and SRF, Progression Development Dataset (N= 434,764)*

Parameter	Estimate (Standard Error)	Hazard Ratio (95% confidence interval)	C-Statistic	Interpretation
Non-Dual (Medicare-only)	0.06 (0.02)	1.06 (1.02-1.10)	0.792	Non-Dual eligible patients slightly more likely to progress
AHRQ SES Score: Not Top Quartile	-0.02 (0.02)	0.98 (0.95-1.01)	0.792	Lower socioeconomic status not significantly associated with progression
Non-urban	-0.04 (0.02)	0.96 (0.93-0.99)	0.792	Non-Urban patients slightly less likely to progress

Finally, we looked at the provider performance among all providers stratified with their proportion of patients with given social risk factors (from a nationwide cohort) in the figures below.

- For each SRF, we divided the providers into deciles based on % of SRFs of each provider.
- Distribution of Risk Standardized Incidence Rate (RSIR) are similar across all deciles (indicates there is no need for further adjustment for SRFs)

Figure 3. RSIR Across Deciles of Providers based on percent of Dual-Eligible Patients, Progression Development Dataset (N= 434,764)

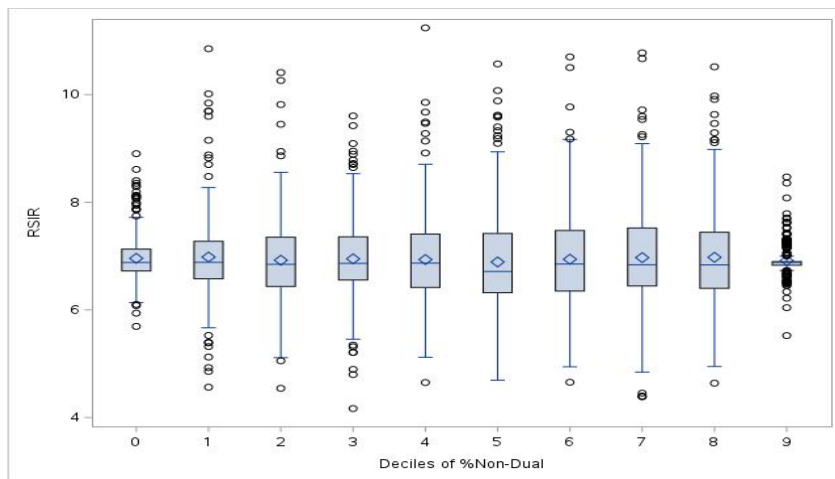
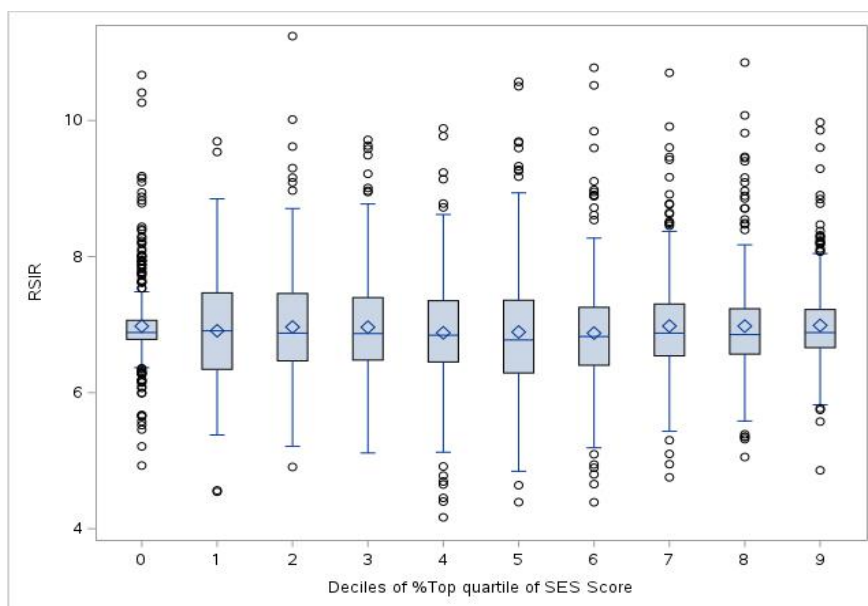


Figure 4. RSIR Across Deciles of Providers based on percent of patients with top quartile AHRQ SES Scores, Progression Development Dataset (N= 434,764)



Overall, the variables do not improve the model and do not have a large impact on provider scores. Differences may best be addressed through provider quality of care. No SRFs were added to the final risk model.

### Risk Model Performance

The Harrel's C-statistic, evaluating the risk model using Cox proportional hazard model, is 0.792.

Results in [Table 8](#) include summary statistics to assess model performance used logistic regression: calibration (a measure of over-fitting), discrimination in terms of predictive ability, and discrimination in terms of c-statistic.



The c-statistic indicated strong model discrimination across the development and validation model. There was agreement in model performance between the development and validation datasets. Discrimination in predictive ability measures the ability to distinguish high-risk subjects from low-risk subjects. We observed a big difference between the observed outcome rates of the lowest and highest decile defined by predicted outcome rates.

*Table 8. Risk Model Performance, Progression Development Dataset (N=434,764)*

Model Performance Statistic	Development Sample	Validation Sample
Number of Patients	217,382	217,382
Progression Delay Rate	4.714	4.745
Calibration ( $\gamma_0, \gamma_1$ )	(0, 1)	(-0.026, 0.987)
Discrimination- Predictive ability (lowest decile %- highest decile %)	(0.4%, 20.8%)	(0.4%, 20.4%)
C-statistic	0.800	0.798

### Measure Score Calculation Results

Below, measure score variation, reliability, and validity are presented and discussed.

#### Measure Score Variation

Examination of provider-level results in [Table 9](#) below, include measure scores for all nephrologists and those with at least 25 patients, along with their summary statistics such as mean (SD), median (IQR), and the minimum (min) and maximum (max). We are using 25 as an example minimum case count, which aligns with CMS publicly reported outcome measures.

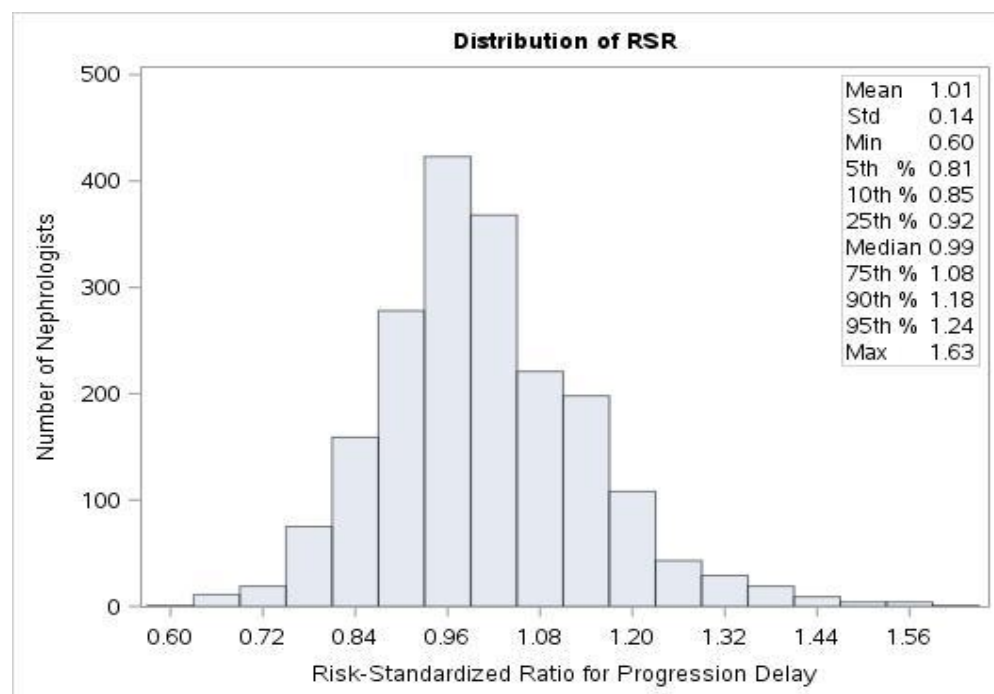
As shown by these distributions of the performance score, there was a substantial gap in performance with the range from 0.604-1.629 for providers with 25 or more patients, with the progression risk standardized ratio varying across providers.

[Figure 5](#) visually depicts the distribution of the risk standardized rate (RSR) across providers with 25 or more patients, showing that measure performance is reasonably evenly distributed amongst providers.

*Table 9. Measure Performance Statistics for All Providers and Providers with 25 or More Patients, Progression Development Dataset (N=434,764)*

Statistics	All Providers (N=2,854)	Providers with 25 + Patients (N=1,970)
Mean (SD)	1.007 (0.117)	1.007 (0.136)
Median (IQR)	0.996 (0.948-1.056)	0.993 (0.922-1.083)
Range (min-max)	(0.604 - 1.629)	(0.604-1.629)

Figure 5. Distribution of RSR Across Providers with 25 or more Patients, Progression Development Dataset (N= 434,764)



## Reliability

[Table 10](#) below shows summary statistics of the signal-to-noise measure score reliability among all providers and those with 25 or more cases, such as the mean, standard deviation, median, inter-quartile ranges, minimum and maximum.

The variation between entities ('signal') comprises the total variation ('noise' and 'signal') in the outcome; signal-to-noise is a statistic from 0-1, where closer to one is interpreted as having more of a quality signal than noise. Looking at the median, even among all nephrologists, at least half of the providers have a reliability over 0.6, and of those with at least 25 cases, at least half have a reliability of 0.8. This represents strong "acceptable" reliability.

Table 10. Signal-to-Noise Reliability Results, Progression Development Dataset (N=434,764)

Description	N Providers	Mean	STD	Median	Q1	Q3	Min	Max
Among All Nephrologists	2,854	0.614	0.293	0.696	0.375	0.872	0.036	0.991
Among Nephrologists with at least 25 cases	1,970	0.787	0.141	0.821	0.681	0.909	0.484	0.991

## Validity

**Data element validity** used two different datasets. Neither dataset contained identifying provider information, so analyses were conducted at the patient-level. The Progression EHR Dataset A, which

included 7,599 patients, is described further below in [Table 11](#). The Progression EHR Dataset B included 10,198 patients, described in [Table 12](#).

Progression EHR Dataset B had a larger cohort, with more hospitals and more patients. Patients in Progression EHR Dataset B were on average younger than those in Progression EHR Dataset A. Since Dataset B had a larger volume of patients, there were higher absolute counts of risk variable outcomes compared to Progression EHR Dataset A, but no variable was drastically underrepresented. Some risk factors were less represented in Progression EHR Dataset A than would be expected in a larger dataset.

*Table 11. Patient Demographics, Progression EHR Dataset A Cohort, 7,599 Patients (2013-2019)*

<b>Total Patients</b>	<b>N</b>	<b>%</b>
All	7,599	100.00
Age	-	-
Mean, Standard Deviation	72.81	15.40
Minimum, Maximum	20	109
Median, IQR	74	21
Gender	-	-
Male	3,858	50.77
Female	3,741	49.23
Race	-	-
American Indian or Alaska Native	19	0.25
Asian	119	1.57
Black or African American	1,796	23.63
Native Hawaiian	2	0.03
Native Hawaiian or Other Pacific Islander	11	0.14
Patient Refused	68	0.89
White or Caucasian	5,073	66.76
Other	135	1.78
Other Pacific Islander	2	0.03
Other/Not Listed	351	4.62
Unknown	22	0.29

*Table 12. Patient Demographics, Progression EHR Dataset B Cohort, 10,198 Patients*

<b>Total Patients</b>	<b>N</b>	<b>%</b>
All	10,198	100.00
Age	-	-
Mean, Standard Deviation	72.16	13.09
Minimum, Maximum	18	103
Median, IQR	73	17
Gender	-	-
Male	4,574	44.85
Female	5,624	55.15

Race	-	-
American Indian or Alaska Native	92	0.90
Asian	138	1.35
Black or African American	2,140	20.98
Native Hawaiian or Other Pacific Islander	18	0.18
Other/Not Listed	770	7.55
White or Caucasian	7,040	69.03

As outlined in the Methods section, CORE defined a match of the Stage 4 CKD diagnosis to the eGFR as when a patient had an eGFR of 15-29 within 6-month (180 days) prior, or 30-days after diagnosis. In the Progression EHR Dataset A the match rate, was 82% at the patient-year level (any encounter with a match within the calendar year). Additional analysis showed the match rate within 15-days prior (or +30 days) to be 78.5%. In The Progression EHR Dataset B, the match rate was 83% at the encounter-level (every encounter was included).

We interpret these match rates to show adequate data element validity. There were many limitations with this dataset. Some laboratory data may be captured outside of this EHR system. Additionally, patients often fluctuate between stages, so eGFR in the clinical chart and codes from administrative claims are not expected to be perfectly matched. Despite these limitations, this analysis shows that for most patients identified as Stage 4 CKD in claims/condition coding, a relevant and timely measure of eGFR confirmed this staging to be correct. The data element for ESRD is derived from Medicare enrollment status which is audited by CMS and considered to be reliable and valid.

**Measure score validity** testing was completed using a vote of face validity. A Qualtrics standardized survey was sent to all 15 TEP members. The below responses include 12 out of the 15 members.

The first question asked was “Do you believe this measure (claims-based) can be used to distinguish provider quality among nephrologists with Stage 4 CKD?”. Possible responses ranged from “strongly agree” to “strongly disagree” and members were asked to justify their responses. There were twelve members who responded to the question. **66% of TEP members agreed somewhat or strongly that the Progression of CKD Measure can be used to distinguish provider quality (8 out of 12).**

The breakdown of responses are shown below:

Response	Number of Responses
Strongly Agree	4
Somewhat Agree	4
Somewhat Disagree	3
Strongly Disagree	1

The second question asked was “Would you support the use of this claims-based measure for implementation in a voluntary payment model?” 75% of TEP members agreed somewhat or strongly that the Progression of CKD Measure can be used in a voluntary payment model (9 out of 12).

The breakdown of responses are shown below:

Response	Number of Responses
Strongly Support	2
Somewhat Support	7
Somewhat Do Not Support	1
Strongly Do Not Support	2

TEP members additionally indicated their preference for the Innovation Center to move towards developing a measure that incorporates eGFR, for a more precise picture of patient severity. These results support the face validity of the measure and its inclusion in voluntary payment model(s).

## **Section 4: Summary**

CORE developed and tested an outcome measure for assessing the success of kidney care providers in delaying patients' progression from Stage 4 CKD to ESRD requiring chronic dialysis. The primary goal of the Progression Measure is to improve the care of patients with Stage 4 CKD through the incentivization of providers to slow disease progression and delay initiation of dialysis or kidney transplant. Input from clinical experts, statistical and methodological experts, and a TEP was used in developing the measure approach and specifications. This measure was developed using Medicare claims data for identification of the cohort and risk adjustment variables.

The final measure risk adjustment model included 43 risk variables from claims. Testing the inclusion of SRFs in the multivariate ('adjusted') model did not improve the risk model, indicating that differences in SRFs are likely best addressed through provider quality of care as opposed to risk adjustment. The c-statistic from the risk model was 0.792, and indicated strong model discrimination. Results also showed a strong median signal-to-noise reliability statistic ranging from 0.696-0.821.

The Stage 4 CKD variable (ICD-10 code N18.4) was validated twice using datasets containing EHR data, from various size health systems, with high matching rates. One health system found data element validity match rate of 82%, and the other health system had a match rate of 83%. CORE considers the Stage 4 CKD variable from claims valid, even considering the limitations of the datasets.

The TEP believed the measure distinguished between provider quality and supported use of the measure in a voluntary payment program such as the Kidney Care Choices Model (face validity).

CORE supports use of Delay in Progression of Chronic Kidney Disease Measure this claims measure for implementation, as well as a potential future measure which incorporates the use of EHR data.

## Section 5: Glossary

**Beneficiary Enrollment (Coverage) Data:** A dataset that is used for determination of the outcome of chronic dialysis and/or ESRD. It determines a patient's coverage for these benefits, not by individual ICD-10 codes. We expect these data points to be accurate because they are audited and have payment implications. These data include specific time periods of ESRD coverage and of chronic dialysis (with start and end dates) and are more accurate than individual claims (ICD-10 codes) billed for these as procedures.

**Chronic Dialysis / Renal Replacement Therapy:** When your kidneys are no longer cleaning the blood adequately, chronic dialysis involves a machine that cleans the blood on behalf of the kidneys. Dialysis helps remove waste, salt, and extra water; keeps a safe level of certain chemicals and nutrients in your blood; and helps control blood pressure. Although dialysis does some of the work of healthy kidneys, it does not cure CKD. Without a kidney transplant, people with ESRD need to have dialysis treatments permanently to survive.<sup>4</sup>

**Chronic Kidney Disease (CKD):** Gradual loss of kidney function over many years. If left untreated, CKD can lead to ESRD.

**Cohort:** The group of patients included in the measure, eligible for the outcome.

**End-Stage Renal Disease (ESRD):** ESRD is the most severe stage of CKD, requiring either chronic dialysis or a kidney transplant for the patient to survive.<sup>3</sup> Some patients may also choose more conservative, palliative care, and enroll in hospice.

**Kidney Care Choices Model:** An Innovation Center Model that uses financial incentives to encourage providers to better manage care of Medicare patients with Stage 4 and 5 CKD and ESRD.

**Outcome:** Result of care, or endpoint in care (for example, what happens to the patient) specific to this quality measure. In this measure, the outcome is defined as CKD progression to ESRD requiring initiation of chronic dialysis. ESRD with a kidney transplant is not considered in the measure outcome, as this is encouraged.

**Medicare Fee-for-Service (FFS):** A system of health care payment in which a provider is paid for each service they perform. These individuals have Medicare Part A and Part B healthcare coverage.

**Progression Development Dataset:** The data that is being used to develop the measure, based on claims from CY 2017-2018.

**Progression EHR Dataset:** Data used specifically to test the stage 4 CKD data element used to define the measure cohort. Data obtained from single health system, using CY 2013-2019.

**Risk Adjustment:** Statistical model within a measure that accounts for how sick patients are so that providers can be fairly compared to each other, even if one provider takes care of patients who are sicker. The risk-adjustment model intends to "adjust for" factors so that differences in performance on the measure are due to quality of care, rather than patient and provider characteristics. The goal of risk adjustment is to make the comparison of providers fairer and more meaningful.

## Section 6: Appendix A

Table A13. CKD Progression Measure Candidate Risk Variables

CC Description	CC Number
Age	NA
Low frequency CCs	NA
HIV/AIDS	1
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	2
Other Infectious Diseases	7
Metastatic Cancer and Acute Leukemia	8
Lung and Other Severe Cancers	9
Lymphoma and Other Cancers	10
Colorectal, Bladder, and Other Cancers	11
Breast, Prostate, and Other Cancers and Tumors	12
Other Digestive and Urinary Neoplasms	14
Other Neoplasms	15
Benign Neoplasms of Skin, Breast, Eye	16
Diabetes with Acute Complications	17
Diabetes with Chronic Complications	18
Diabetes without Complication	19
Protein-Calorie Malnutrition	21
Morbid Obesity	22
Other Significant Endocrine and Metabolic Disorders	23
Disorders of Fluid/Electrolyte/Acid-Base Balance	24
Disorders of Lipoid Metabolism	25
Other Endocrine/Metabolic/Nutritional Disorders	26
End-Stage Liver Disease	27
Cirrhosis of Liver	28
Chronic Hepatitis	29
Other Hepatitis and Liver Disease	31
Gallbladder and Biliary Tract Disorders	32
Intestinal Obstruction/Perforation	33
Peptic Ulcer, Hemorrhage, Other Specified Gastrointestinal Disorders	36
Other Gastrointestinal Disorders	38
Bone/Joint/Muscle Infections/Necrosis	39
Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	40
Disorders of the Vertebrae and Spinal Discs	41
Osteoarthritis of Hip or Knee	42
Osteoporosis and Other Bone/Cartilage Disorders	43
Other Musculoskeletal and Connective Tissue Disorders	45



CC Description	CC Number
Severe Hematological Disorders	46
Disorders of Immunity	47
Coagulation Defects and Other Specified Hematological Disorders	48
Iron Deficiency and Other/Unspecified Anemias and Blood Disease	49
Delirium and Encephalopathy	50
Dementia With Complications	51
Dementia Without Complication	52
Nonpsychotic Organic Brain Syndromes/Conditions	53
Substance Use Disorder, Moderate/Severe, or Substance Use with Complications	55
Schizophrenia	57
Major Depressive, Bipolar, and Paranoid Disorders	59
Depression	61
Anxiety Disorders	62
Other Psychiatric Disorders	63
Spinal Cord Disorders/Injuries	72
Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	75
Parkinson's and Huntington's Diseases	78
Seizure Disorders and Convulsions	79
Polyneuropathy, Mononeuropathy, and Other Neurological Conditions/Injuries	81
Cardio-Respiratory Failure and Shock	84
Congestive Heart Failure	85
Acute Myocardial Infarction	86
Unstable Angina and Other Acute Ischemic Heart Disease	87
Angina Pectoris	88
Coronary Atherosclerosis/Other Chronic Ischemic Heart Disease	89
Heart Infection/Inflammation, Except Rheumatic	90
Valvular and Rheumatic Heart Disease	91
Other Congenital Heart/Circulatory Disease	93
Hypertensive Heart Disease	94
Hypertension	95
Specified Heart Arrhythmias	96
Other Heart Rhythm and Conduction Disorders	97
Other and Unspecified Heart Disease	98
Intracranial Hemorrhage	99
Ischemic or Unspecified Stroke	100
Precerebral Arterial Occlusion and Transient Cerebral Ischemia	101
Cerebrovascular Atherosclerosis, Aneurysm, and Other Disease	102
Hemiplegia/Hemiparesis	103
Late Effects of Cerebrovascular Disease, Except Paralysis	105

<b>CC Description</b>	<b>CC Number</b>
Atherosclerosis of the Extremities with Ulceration or Gangrene	106
Vascular Disease with Complications	107
Vascular Disease	108
Other Circulatory Disease	109
Chronic Obstructive Pulmonary Disease	111
Fibrosis of Lung and Other Chronic Lung Disorders	112
Asthma	113
Aspiration and Specified Bacterial Pneumonias	114
Pneumococcal Pneumonia, Empyema, Lung Abscess	115
Viral and Unspecified Pneumonia, Pleurisy	116
Pleural Effusion/Pneumothorax	117
Other Respiratory Disorders	118
Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	122
Diabetic and Other Vascular Retinopathies	123
Exudative Macular Degeneration	124
Other Retinal Disorders	125
Glaucoma	126
Other Eye Disorders	128
Hearing Loss	130
Kidney Transplant Status: ICD-10-CM codes beginning with 'T'	132T
Kidney Transplant Status: ICD-10-CM codes beginning with 'Z'	132Z
Dialysis Status	134
Acute Renal Failure	135
Chronic Kidney Disease, Stage 5	136
Chronic Kidney Disease, Severe (Stage 4)	137
Chronic Kidney Disease, Moderate (Stage 3)	138
Chronic Kidney Disease, Mild or Unspecified (Stages 1-2 or Unspecified)	139
Unspecified Renal Failure	140
Nephritis	141
Urinary Obstruction and Retention	142
Urinary Incontinence	143
Urinary Tract Infection	144
Other Urinary Tract Disorders	145
Pelvic Inflammatory Disease and Other Specified Female Genital Disorders	147
Other Female Genital Disorders	148
Male Genital Disorders	149
Pressure Ulcer of Skin with Full Thickness Skin Loss	158
Pressure Ulcer of Skin with Partial Thickness Skin Loss	159
Pressure Pre-Ulcer Skin Changes or Unspecified Stage	160

<b>CC Description</b>	<b>CC Number</b>
Chronic Ulcer of Skin, Except Pressure	161
Cellulitis, Local Skin Infection	164
Other Dermatological Disorders	165
Vertebral Fractures without Spinal Cord Injury	169
Internal Injuries	172
Other Injuries	174
Poisonings and Allergic and Inflammatory Reactions	175
Complications of Specified Implanted Device or Graft	176
Other Complications of Medical Care	177
Major Symptoms, Abnormalities	178
Minor Symptoms, Signs, Findings, modified	179
Major Organ Transplant or Replacement Status	186
Other Organ Transplant Status/Replacement	187
Artificial Openings for Feeding or Elimination	188
Amputation Status, Lower Limb/Amputation Complications	189
Post-Surgical States/Aftercare/Elective	191
Chemotherapy	193
History of Disease	196
Supplemental Oxygen	197
Patient Lifts, Power Operated Vehicles, Beds	199
Alcohol/Cannabis Use or Use Disorder, Mild or Uncomplicated; Non-Psychoactive Substance Abuse; Nicotine Dependence	203

## Section 7: References

- <sup>1</sup> National Quality Forum. 2019. Measure Evaluation Criteria and Guidance for Evaluating Measures for Endorsement. [http://www.qualityforum.org/docs/measure\\_evaluation\\_criterias.aspx](http://www.qualityforum.org/docs/measure_evaluation_criterias.aspx)
- <sup>2</sup> Centers for Medicare and Medicaid Services <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf>
- <sup>3</sup> Chen T, Lee VW, Harris DC. When to initiate dialysis for end-stage kidney disease: evidence and challenges. *Med J Aust.* 2018;209(6):275-279.
- <sup>4</sup> Dabrowska-Bender M, Dykowska G, Zuk W, Milewska M, Staniszewska A. The impact on quality of life of dialysis patients with renal insufficiency. *Patient Prefer Adherence.* 2018;12:577-583.
- <sup>5</sup> Rosansky SJ, Eggers P, Jackson K, Glasscock R, Clark WF. Early start of hemodialysis may be harmful. *Arch Intern Med.* 2011;171(5):396-403.
- <sup>6</sup> Trivedi HS, Pang MM, Campbell A, Saab P. Slowing the progression of chronic renal failure: economic benefits and patients' perspectives. *Am J Kidney Dis.* 2002;39(4):721-729.
- <sup>7</sup> Wright S, Klausner D, Baird B, et al. Timing of dialysis initiation and survival in ESRD. *Clin J Am Soc Nephrol.* 2010;5(10):1828-1835.
- <sup>8</sup> Ku E, McCulloch CE, Johansen KL. Starting Renal Replacement Therapy: Is It About Time? *American Journal of Nephrology.* 2019;50(2):144-151.
- <sup>9</sup> Chen T, Lee VW, Harris DC. When to initiate dialysis for end-stage kidney disease: evidence and challenges. *The Medical Journal of Australia.* 2018;209(6):275-279.
- <sup>10</sup> O'Hare AM, Wong SP, Yu MK, et al. Trends in the Timing and Clinical Context of Maintenance Dialysis Initiation. *Journal of the American Society of Nephrology.* 2015;26(8):1975-1981.
- <sup>11</sup> Crews DC, Scialla JJ, Boulware LE, et al. Comparative Effectiveness of Early Versus Conventional Timing of Dialysis Initiation in Advanced CKD. 2014;63(5):806-815.
- <sup>12</sup> Rosansky SJ, Cancarini G, Clark WF, et al. Dialysis Initiation: What's the Rush? *Seminars in Dialysis.* 2013;26(6):650-657.
- <sup>13</sup> Cooper BA, Branley P, Bulfone L, et al. A Randomized, Controlled Trial of Early versus Late Initiation of Dialysis. *New England Journal of Medicine.* 2010;363(7):609-619.
- <sup>14</sup> Ku E, McCulloch CE, Johansen KL. Starting Renal Replacement Therapy: Is It About Time? *American Journal of Nephrology.* 2019;50(2):144-151.
- <sup>15</sup> Susantitaphong P, Altamimi S, Ashkar M, et al. GFR at Initiation of Dialysis and Mortality in CKD: A Meta-analysis. *American Journal of Kidney Diseases.* 2012;59(6):829-840.
- <sup>16</sup> Rosansky SJ, Eggers P, Jackson K, Glasscock R, Clark WF. Early Start of Hemodialysis May Be Harmful. *Archives of Internal Medicine.* 2011;171(5).
- <sup>17</sup> Kurella Tamura M, Vittinghoff E, Hsu CY, et al. Loss of executive function after dialysis initiation in adults with chronic kidney disease. *Kidney Int.* 2017;91(4):948-953.
- <sup>18</sup> Ash, A.S., Posner, M.A., Speckman, J., Franco, S., Yacht, A.C. and Bramwell, L. (2003), Using Claims Data to Examine Mortality Trends Following Hospitalization for Heart Attack in Medicare. *Health Services Research*, 38: 1253-1262. doi:10.1111/1475-6773.00175
- <sup>19</sup> Request for Applications (RFA): Kidney Care Choices (KCC) Model. 2019. Centers for Medicare & Medicaid Services (CMS), Center for Medicare and Medicaid Innovation (CMMI). <https://innovation.cms.gov/files/x/kcc-rfa.pdf>
- <sup>20</sup> G. Berry. The Analysis of Mortality by the Subject-Years Method. *Biometrics* 1983, 39(1) pp. 173-184
- <sup>21</sup> Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE). Risk-Standardized Acute Admission Rates for Patients with Multiple Chronic Conditions Measure Technical Report, September 29, 2014

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<sup>22</sup> Shrout PE, Fleiss JL. Intraclass correlations: uses in assessing rater reliability. *Psychological bulletin*. 1979;86(2):420. 35. Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics*. 1977:159-174.