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Rima Pai Date

Association of a maximum ultrafiltration rate policy with intermediate outcomes in a prevalent underserved population undergoing hemodialysis

By

Rima Pai

Degree to be awarded: MPH

Global Epidemiology

_____

Dr. Laura Plantinga

Faculty Thesis Advisor

Association of a maximum ultrafiltration rate policy with intermediate outcomes in a prevalent underserved population undergoing hemodialysis

By

Rima Pai

Bachelor of Medicine and Bachelor of Surgery

Maharashtra University of Health Sciences

2013

Faculty Thesis Advisor: Dr. Laura Plantinga, PhD, ScM

An abstract of a thesis submitted to the Faculty of the Rollins School of Public Health of Emory University in partial fulfillment of the requirements for the degree of Master of Public Health in Global Epidemiology 2020

Abstract

Association of a maximum ultrafiltration rate policy with intermediate outcomes in a prevalent underserved population undergoing hemodialysis

By Rima Pai

Introduction: Recent observational studies have shown an association between higher ultrafiltration (UF) rates and increased mortality among individuals receiving maintenance hemodialysis (HD). Here, we leveraged a local rollout of a maximal UF policy to assess the association of maximum UF rate policy at the clinic level with intermediate patient outcomes, particularly blood pressure, among a prevalent underserved population undergoing HD.

Methods: We conducted a retrospective cohort study of data collected from 2,353 in center-HD patients treated at 23 not-for-profit dialysis facilities in Georgia and North Carolina at and after the rollout of a local UF rate policy (4/30/12). Patients were followed for 180 days for patient systolic and diastolic blood pressure outcomes [post-dialysis sitting systolic blood pressure (SBP) and diastolic blood pressure (DBP) and the lowest SBP and DBP recorded during the dialysis session (lowest intra-dialytic SBP and DBP)]. Using generalized estimating equations modeling, we examined the linear association between the presence of a UF rate policy at the treating clinic (12/23 clinics) and patients' mean blood pressure values.

Results: In crude analyses, the presence vs. absence of a UF rate policy was associated with 5.3 mmHg (95% CI (-7.1, -3.4)) higher post-dialysis SBP, 1.6 mmHg (95% CI (-3.8, 0.7)) higher post-dialysis DBP, and 3.3 mmHg (95% CI (-4.9, -1.7)) lower intradialytic SBP; the difference in lowest intradialytic DBP was <1 mmHg (95% CI (-2.4, 0.7)). In a fully adjusted model, presence vs. absence of UF rate policy was associated with 2.3 mmHg lower post-dialysis SBP (95% CI (-4.8, 0.3)), 2.2 mmHg higher post-dialysis DBP (95 % CI (1.0, 3.4)), 0.4 mmHg lower average lowest intradialytic SBP (95% CI (-2.8, 2.1)) and 2.5 mmHg higher lowest intra-dialytic DBP (95% CI (1.4, 3.6)).

Conclusion: In general, we found that the presence of a maximum UF policy at the dialysis clinic was not independently associated with patient blood pressure outcomes in a prevalent underserved population undergoing HD. Further studies are needed to identify how UF policies are implemented and how they ultimately affect morbidity and mortality among HD patients.

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Author

Rima Pai

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CHAPTER I: LITERATURE REVIEW

End-stage renal disease (ESRD) is a medical condition in which a person's kidneys cease functioning, leading to the need for a regular course of long-term dialysis or a kidney transplant to maintain life (1). ESRD diagnosis generally occurs when kidney functionality is below ~10% of the normal capacity for filtration (1). Kidney disease, including ESRD, ranks among the top 10 causes of death in the United States (2). Social Security-eligible ESRD patients are entitled to Medicare coverage, regardless of age or disability. Benefits based on ESRD are for all covered services, not only those related to the kidney failure condition (3). Per the United States Renal Data System (USRDS) annual data report, in 2017, there were 124,500 newly reported cases of ESRD; the unadjusted (crude) incidence rate was 370.2 per million/year in the US population. The number of prevalent ESRD cases has continued to rise by about 20,000 cases per year (4). On December 31, 2017, there were 746,557 prevalent cases of ESRD; the crude prevalence (proportion) was 2,204 per million in the US population (4). As per the USRDS annual report from 2017, the incident rate of ESRD cases is higher among males by 415.1 per million population compared with 256.6 for females (4). Prevalence and incidence are even higher among minority and underserved populations. The prevalence of recognized ESRD among black patients was higher than that among white patients in the Medicare population (5, 6). This is reflected in part by the incidence rate of ESRD which affects US minorities from 1.5 to nearly 4.0 times more than age-adjusted non-Hispanic white counterparts, with black populations suffering from the highest rates (5, 6).

Additionally, overall mortality rates among ESRD patients on dialysis are higher than the general population who are covered by Medicare (4). Recent improvements in pre-ESRD care and dialysis-related complications in the last 16 years have led to the leveling of life-expectancy rates (7). In 2017, adjusted mortality rates for ESRD and dialysis patients were 134 and 165 per 1,000 patient-years (4). By dialysis modality, mortality rates were 167 for hemodialysis (HD) patients and 156 for peritoneal dialysis patients, per 1,000 patient-years (4).

As the major payer for ESRD services, the Centers for Medicare & Medicaid Services (CMS) plays an active role in monitoring dialysis quality and attempts to motivate performance improvement through public reporting of results and ratings (4, 8, 9, 10). As a further incentive to enhance dialysis quality, CMS imposes financial penalties on underperforming facilities defined through its ESRD Quality Inventive Program (QIP) (4, 8, 9, 10). This program uses measures of quality to derive a "total performance score" that is intended to be an aggregate reflection of a facility's quality performance. Based on this result, facilities may lose between 0% and 2% of Medicare payments (4, 8, 9, 10). On January 1, 2012, the first-ever mandatory federal pay-for-performance program was launched: the ESRD-QIP. An initial goal of the QIP was to ensure adequate resource utilization (4, 8, 9, 10).

Associations between mortality and cardiovascular disease, the dose of dialysis, and diabetes are well-studied (11). Poor volume control can exacerbate hypertension and its many detrimental effects on the cardiovascular system (11, 12). Although higher interdialytic weight gain (IDWG) has been associated with better nutritional status, it can predispose to volume overload and other cardiometabolic complications (13). Moreover,

those patients with excessive IDWG tend to have higher ultrafiltration (UF) rates, which means a faster rate of volume removal during HD, potentially resulting in a higher frequency of intradialytic hypotension episodes (13, 14). Observational studies looking at the association of high UF rates among patients on regular HD have shown that high UF rates are independently associated with increased mortality among HD patients (13, 14, 15). Furthermore, Flythe et al. have shown in multiple studies that rapid ultrafiltration rates are associated with adverse outcomes among patients on HD (13, 14, 15). For patients with ESRD, treatments such as HD help with maintaining volume and electrolyte balance with each session lasting for 3-4 hours almost three times a week (1). Over the last several years, more observational data supporting an association between higher ultrafiltration UF rates and increased mortality among individuals receiving maintenance hemodialysis have accumulated (12, 13). If the fluid is removed too quickly, resulting in a high UF rate (13, 14), the patient may experience immediate side effects such as debilitating fatigue (14, 15). Based only on this observational evidence, a new performance measure regarding the maximum amount of fluid that can be removed during a treatment (13 ml/kg of dry weight per hour) was added to the ESRD-QIP in 2016 (4).

To determine whether this performance measure actually improves patient outcomes, the examination of proximal outcomes (prior to mortality) is needed. Particularly, examining whether blood pressures are improved is important because UF rates determine volume extraction and often excess fluid removal can lead to hypotension and cardiovascular instability (16, 17, 18). Also, it is important to know whether rolling out a policy will actually change patient UF rates. Furthermore, changes in UF rates

might involve provider adjustments to target weights and modifications to volume goals, in addition to increasing dialysis duration, to achieve lower UF rates per the ESRD-QIP.

In anticipation of this change to the ESRD-QIP, in 2012, some (but not all) of the dialysis facilities managed by Health Systems Management (HSM; manager of Emory and Wake Forest dialysis facilities) instituted a maximal UF rate policy, whereby patients whose UF rates were ≥13 mL/kg/h were scheduled for longer sessions and/or additional sessions per week so that UF rates would remain <13 mL/kg/h. Furthermore, there is no evidence that the presence of a policy at a clinic lowers patients' UF rates or other related variables, such as weight gain between dialysis sessions due to fluid (IDWG) or patient's target "dry" weight (weight when all excess fluid is removed by hemodialysis). This is important, given that a national policy is being rolled out as part of the ESRD-QIP but such changes may require that dialysis clinics have the flexibility to schedule extra time or sessions, which may not be possible due to time, space, or personnel limitations. In this study, we will leverage the natural experiment of the rollout of a local policy within HSM-managed clinics to determine the association of the presence of a maximal UF rate policy at the clinic with patient blood pressure. Secondarily, we will estimate the effect of the policy on potential mediators, including actual UF rates, IDWG, and patient dry or target weight.

CHAPTER II: MANUSCRIPT

Association of a maximum ultrafiltration rate policy with intermediate outcomes in a prevalent underserved population undergoing hemodialysis

Rima Pai[1], Laura Plantinga[1]

[1] Emory University, Rollins School of Public Health, Atlanta, Georgia

Abstract

Introduction: Recent observational studies have shown an association between higher ultrafiltration (UF) rates and increased mortality among individuals receiving maintenance hemodialysis (HD). Here, we leveraged a local rollout of a maximal UF policy to assess the association of maximum UF rate policy at the clinic level with intermediate patient outcomes, particularly blood pressure, among a prevalent underserved population undergoing HD.

Methods: We conducted a retrospective cohort study of data collected from 2,353 in center-HD patients treated at 23 not-for-profit dialysis facilities in Georgia and North Carolina at and after the rollout of a local UF rate policy (4/30/12). Patients were followed for 180 days for patient systolic and diastolic blood pressure outcomes [post-dialysis sitting systolic blood pressure (SBP) and diastolic blood pressure (DBP) and the lowest SBP and DBP recorded during the dialysis session (lowest intra-dialytic SBP and DBP)]. Using generalized estimating equations modeling, we examined the linear association between the presence of a UF rate policy at the treating clinic (12/23 clinics) and patients' mean blood pressure values.

Results: In crude analyses, the presence vs. absence of a UF rate policy was associated with 5.3 mmHg (95% CI (-7.1, -3.4)) higher post-dialysis SBP, 1.6 mmHg (95% CI (-3.8,

0.7)) higher post-dialysis DBP, and 3.3 mmHg (95% CI (-4.9, -1.7)) lower intradialytic SBP; the difference in lowest intradialytic DBP was <1 mmHg (95% CI (-2.4, 0.7)). In a fully adjusted model, presence vs. absence of UF rate policy was associated with 2.3 mmHg lower post-dialysis SBP (95% CI (-4.8, 0.3)), 2.2 mmHg higher post-dialysis DBP (95% CI (1.0, 3.4)), 0.4 mmHg lower average lowest intradialytic SBP (95% CI (-2.8, 2.1)) and 2.5 mmHg higher lowest intra-dialytic DBP (95% CI (1.4, 3.6)).

Conclusion: In general, we found that the presence of a maximum UF policy at the dialysis clinic was not independently associated with patient blood pressure outcomes in a prevalent underserved population undergoing HD. Further studies are needed to identify how UF policies are implemented and how they ultimately affect morbidity and mortality among HD patients.

Introduction

As the major payer for End-Stage Renal Disease (ESRD) services, the Centers for Medicare & Medicaid Services (CMS) plays an active role in monitoring dialysis quality and attempts to motivate performance improvement through public reporting of results and ratings (4, 8, 9, 10). As a further incentive to enhance dialysis quality, CMS imposes financial penalties on underperforming facilities defined through its ESRD Quality Inventive Program (QIP) (4, 8, 9, 10). This program uses measures of quality to derive a "total performance score" that is intended to be an aggregate reflection of a facility's quality performance. Based on this result, facilities may lose between 0% and 2% of Medicare payments (4, 8, 9, 10). On January 1, 2012, the first-ever mandatory federal pay-for-performance program was launched: the ESRD-QIP, which disincentivizes US dialysis facilities for providing less-than-optimal care by reducing Medicare

reimbursements for poor performance facilities. An initial goal of the ESRD-QIP was to ensure adequate resource utilization (4, 8, 9, 10). Flythe et al. have shown in multiple studies that rapid ultrafiltration (UF) rates are associated with adverse outcomes among patients on HD (10, 14). Such evidence has led to the recent addition to the ESRD-QIP of a maximum amount of fluid that can be removed during a treatment (13 ml/kg of dry weight per hour) (4, 13, 14).

In anticipation of this change to the ESRD-QIP, in 2012, some (but not all) of the dialysis facilities managed by Health Systems Management (HSM; manager of Emory and Wake Forest dialysis facilities) instituted a maximal UF rate policy, whereby patients whose UF rates were ≥13 mL/kg/h were scheduled for longer sessions and/or additional sessions per week so that UF rates would remain <13 mL/kg/h. To the best of our knowledge, currently, no study has examined at the association of a maximum UF rate policy with intermediate outcomes in a prevalent underserved population undergoing HD. Furthermore, there is no evidence that the presence of a policy at a clinic affects patients' UF rates or other related variables, such as weight gain between dialysis sessions due to fluid [interdialytic weight gain (IDWG)] or patient's target "dry" weight (weight when all excess fluid is removed by hemodialysis). This is important, given that a national policy is being rolled out as part of the ESRD-QIP but such changes may require that dialysis clinics have the flexibility to schedule extra time or sessions, which may not be possible due to time, space, or personnel limitations. In this study, we leveraged the natural experiment of the rollout of a policy within some, but not all, HSM-managed clinics to examine the association of the presence of a maximal UF rate policy at the clinic with patients blood pressure values. Secondarily, we aimed to estimate the effect of the policy

on potential mediators, including actual UF rates, IDWG, and patient dry or target weight.

Methods

Study Design

Data were obtained from the electronic medical record (EMR) for a prevalent cohort of 17,548 patients receiving HD at 23 not-for-profit dialysis facilities (Emory Dialysis and Wake Forest Dialysis, which share management) from January 2010 through December 2018. The UF rate policy was rolled out at selected facilities on April 30, 2012. To compare blood pressure among patients treated at facilities that implemented the policy versus facilities that did not, we limited the study data to the period between 45 days pre-policy roll-out and 210 days post-policy roll-out **(Figure 1**). From the policy roll-out date, a 30-day lag period was included before the 180-day follow-up for blood pressure outcomes (**Figure 1**), to allow time for dialysis facilities to make treatment changes related to the UF rate policy. Patients were included if they were age 18 years or older and received in-center HD during the entire study period (N=4442). Exclusion criteria included the occurrence of death (n=737), dialysis modality change (n=90), receipt of nocturnal dialysis (dialysis duration of greater than 4 hours; n=29), or kidney transplantation (n=22) during the study period; lack of facility-level data (n=10); and missing covariate data (n=1201), leaving 2353 in the analytic cohort (**Figure 2**). The Emory Institutional Review Board approved the study, with a waiver of informed consent.

Study Variables

Exposure. The exposure of interest in this study was the UF rate policy rolled out at 12 of the 23 clinics on 4/30/12. The policy mandated that if the patient's weight gain necessitates fluid removal greater than the maximum allowed per hour, it was essential for the patient to run extra time, in addition to the regularly prescribed treatment time. As needed, the treatment time was extended, in increments of 15 minutes for a total of up to 1 hour. Per the policy, the maximum amount of fluid that could be removed during an HD session was 13 ml/kg of dry weight per hour. This would ensure that the appropriate target weights were achieved while preventing too-rapid removal of excess fluid. Patients were assigned as the "presence of policy" if they were treated at a facility that implemented this policy and as the "absence of policy" if they were treated at one of the other facilities.

Outcomes. The outcomes of interest were the mean blood pressures of the patients, specifically, the systolic blood pressure (SBP) and diastolic blood pressure (DBP) taken in the seated position after the dialysis session (post-dialysis sitting SBP and DBP) and the lowest SBP and DBP recorded during the dialysis session (lowest intra-dialytic SBP and DBP). Implausible values were removed (<80 mm Hg or >250 mm Hg for SBP; <40 mm Hg or >120 mm Hg for DBP), and the mean value for each of the outcomes over the follow-up period (**Figure 2**) was assigned to each patient.

Intermediate outcomes. Patient UF rate normalized to body weight (ml/kg/h) was calculated as follows: inter-dialytic weight gain (IDWG) (kg)/post-HD weight (kg)/

prescribed session duration (h) for each HD treatment, with 1 kg assumed to represent 1000 ml of fluid. IDWG was defined as the pre-dialysis weight (kg) - post-dialysis weight (kg) from the previous session. Target or dry weight was the target post-dialysis weight noted in the dialysis orders. Implausible values for the weight (=0 kg or >160 kg), IDWG (<0 kg or >10 kg), and UF rates (>20 ml/kg/h) were removed before the mean of values over the follow-up period (**Figure 2**) was assigned to each patient.

Other variables. Demographics were recorded upon admission to the dialysis facility. Patient age for this cohort was calculated at the time of policy rolled out [(4/30/2012 - date of birth)/365.25]. Patient race was categorized as black versus other (white, Asian, or Native American). Comorbid conditions were captured in the problem lists and classified and grouped using the classifications used on the Centers for Medicare & Medicaid (CMS)-2728 form [diabetes mellitus, hypertension, peripheral vascular disease (including amputations), and atherosclerotic cardiovascular disease (including myocardial infarction, congestive heart failure, arrhythmia, and stroke)]. The assigned primary cause of ESRD was recorded by clinic personnel at the start of treatment in the facility and was categorized as diabetes, hypertension, glomerulonephritis, and others. Patient labs (albumin, potassium, hemoglobin, and phosphate) were measured monthly for patients at these facilities. Unless otherwise indicated, all variables reflect the mean of all values in the baseline period (**Figure 2**).

Statistical Analyses

Baseline patient characteristics were described across presence and absence of policy groups as counts and proportions for categorical variables and as means ± standard deviations for continuous variables; chi-square test for categorical variables and t test for continuous variables were used to estimate p-values, to determine whether characteristics were associated with the exposure. Univariate linear regression was used to explore the associations of the characteristics with the outcomes. To evaluate the associations between the exposure, outcomes, and intermediate outcomes/potential mediators (**Figure 3**), we conducted several analyses. For the primary association of interest, between UF rate policy and blood pressure outcomes, we conducted linear regression. Multivariable adjustment for *a priori* confounders found to be associated with both exposure and outcome was performed. Generalized estimating equations (GEE) modeling was to account for the multiple measurements (baseline and post-policy rollout) and clustering of patients within facilities. Analyses for the association of policy with intermediate outcomes (UF rate, IDWG, and dry weight) were conducted similarly. Analyses of the primary association (between policy and blood pressure), adjusted for intermediate outcomes, was also performed to assess the effect of these potential mediators on the associations. Participants with missing values for the UF rate, race, blood pressure, and laboratory variables were excluded from the analytic cohort **(Figure 2**). Analyses were performed using SAS version 9.4 (SAS Institute Inc, Cary, NC).

Results

Cohort Characteristics

Table 1 displays cohort characteristics of the analytic cohort overall and across patients treated at facilities presence vs. absence policy. Patients in facilities without the policy group were, on average, younger, and more likely to be male, black, and have comorbid hypertension and cardiovascular diseases as compared to policy group (**Table 1**). At baseline, UF rates were higher in the absence of a policy group (8.4 mL/kg/h) than in the presence of a policy group (7.6 mL/kg/h). Patients in the facilities without the policy had higher lowest intradialytic SBP and DBP, higher post-dialysis sitting SBP and DBP, and more prevalent hypertension as a cause of ESRD at baseline. Diabetes mellitus, as both a comorbid condition and as the primary assigned cause of ESRD, was more common in the patients treated at the facilities with vs. without the policy. Laboratory values were similar across the two groups.

There was a negative relationship between age and all four blood pressure outcomes, such that older age was associated with lower blood pressure (**Table 2**). Female vs. male sex was associated with lower blood pressure: lowest intradialytic SBP (β= -2.9; 95% CI (-4.4, -1.5)), lowest intradialytic DBP (β= -4.0; 95% CI (-4.9, -3.1)) and average post-dialysis sitting DBP (β= -2.8; 95% CI (-3.7, -2.0)). Black vs. other race was associated with 3 mmHg higher average lowest intradialytic SBP, 3.9 mmHg higher average intradialytic session DBP, 3.2 mmHg higher average post-dialysis sitting SBP, and 4.8 mmHg higher post-dialysis sitting DBP. The UF rate had no effect on the average lowest intradialytic SBP, average lowest intradialytic DBP, and average post-dialysis sitting DBP mmHg. Higher UF rates were not associated with lower average post-dialysis sitting SBP (β= -0.1; 95 % CI (-0.3, 0.3)). Presence vs. absence of peripheral vascular disease as a comorbid condition was associated with 4.5 mmHg lower average lowest

intradialytic SBP, 3.9 mmHg lower intradialytic DBP, 2.1 mmHg lower average post-dialysis sitting SBP, and 3.0 mmHg lower post-dialysis sitting DBP. Diabetes (β=5.1; 95 % CI (2.7, 7.5)) and hypertension (β=6.0; 95 % CI (3.5, 8.5)) as a cause of ESRD were associated with the highest differences in post-dialysis sitting SBP as compared to other blood pressure outcomes. For laboratory characteristics, statistically significant differences in blood pressure outcomes were only seen for hemoglobin and albumin (DBP only). Overall, every 1 g/dl higher hemoglobin was associated with 1-2 mmHg lower average intradialytic SBP, average intradialytic DBP, and average post-dialysis sitting SBP, and post-dialysis sitting DBP.

Primary Analysis: Association between UF Rate Policy at Facility and Patient Blood Pressure

In crude analyses, the presence vs. absence of a UF rate policy was associated with 5.3 mmHg higher post-dialysis SBP, 1.6 mmHg higher post-dialysis DBP, and 3.3 mmHg lowest intradialytic SBP; differences in intradialytic DBP were <1 mmHg (Model 1). Model 4 is a fully adjusted model with demographics and clinical characteristics showing the difference between blood pressure outcomes for presence vs. absence of policy. UF rate policy was associated with 2.3 mmHg lower post-dialysis SBP (95 % CI (-4.8, 0.3)), 2.2 mmHg higher post-dialysis DBP (95 % CI (1.0, 3.4)), 0.4 mmHg lower average lowest intradialytic SBP (95 % CI (-2.8, 2.1)) and 2.5 mmHg higher lowest intra-dialytic DBP (95% CI (1.4, 3.6)) (**Table 3**).

Secondary Outcomes Analyses

Higher UF rates (per ml/kg/h) were negatively associated (β= -0.7; 95 % CI (-1.2, -0.1)) with the presence vs. absence of a UF rate policy. The IDWG was, on average, 1.6 kg higher among the policy versus no policy group. The crude target weight was, on average, higher by 1.25 kg among policy versus no policy group. Results after adjustment for the same confounders in the primary analysis showed similar results (**Table 4**). The addition of each potential mediator (UF rate, IDWG, and target weight) to the fully adjusted primary analysis, resulted in statistically significant differences in all four blood pressure outcomes by the presence of a clinic UF rate policy. The association of facilities with presence of policy vs. absence of policy with blood pressure, after adjusting for a potential mediator by UF rate, shows that the average lowest intra-dialytic SBP is 0.3 mmHg lower, 2.3 mmHg lower average post-dialysis sitting SBP, 2.2 mmHg higher average post-dialysis sitting DBP and 2.6 mmHg higher for average lowest intra-dialytic DBP for presence vs. absence of policy clinics (**Table 5**). The association for the presence of policy vs. absence of policy with blood pressure, after adjusting for a potential mediator by IDWG, shows that the average lowest intra-dialytic SBP is 2.2 mmHg higher, 0.5 mmHg higher average post-dialysis sitting SBP, 3.2 mmHg higher average post-dialysis sitting DBP and 3.4 mmHg higher for average lowest intra-dialytic DBP for presence vs. absence of policy clinics (**Table 5**). For UF rate policy and its association with blood pressure, after adjusting for a potential mediator by target weight, shows that the average lowest intra-dialytic SBP is 3.8 mmHg higher, 1.1 mmHg higher average post-dialysis sitting SBP, 3.9 mmHg higher average post-dialysis sitting DBP and 5.1 mmHg higher for average lowest intra-dialytic DBP for presence vs. absence of policy clinics (**Table 5**).

Discussion:

The objective of this study was to examine the association of a maximum UF rate policy with intermediate outcomes in a prevalent underserved population undergoing HD. While we found that the presence of the policy was associated with blood pressure in crude analyses, after adjustment for potential confounders, the presence of UF rate policy was not consistently or independently associated with these outcomes. We found that with potential mediator analysis of target weight, UF rate, and IDWG that their effect on UF rate policy and blood pressure was bigger, and they were positively associated with higher blood pressure outcomes. Furthermore, adjusting for UF rate policy we found that the presence of a maximum UF policy at the dialysis clinic was not independently associated with patient blood pressure outcomes in a prevalent underserved population undergoing HD.

These findings can be due to possibly overall no effect of ESRD-QIP policy or potentially UF rates were not lower enough as the effects were minimal as suggested by our secondary analysis. Some potential factors for which more evidence is needed is whether the facilities were able to implement this policy to all HD patients or changes in the UF rate were made based on the total performance scoring system. The providers could be adjusting target weight to make the UF rates appear lower but leaving too much fluid on consequently leading to no effect on blood pressure. Also, conducting longer dialysis sessions at facilities and chronic volume expansion which all play a critical role in IDWG which affects the intradialytic blood pressure control. Patients presenting with fluid gains requiring UF rates above the threshold would require the extension of HD or

additional HD treatments. Patients declining longer HD treatment time would have UF rates capped, leaving them above their prescribed target weights at the end of their HD session. While it is plausible that the possible consequence of extended longer HD treatment time would lead to patients limiting their IDWG, it is equally plausible that UF rate needs would remain unchanged and therefore patients declining longer HD treatment time would become volume-expanded. As a result, we need a rigorous investigation to gather evidence on the effect of UF rate thresholds on volume status, fluid-related hospitalizations, and other cardiovascular outcomes when the threshold of 13 mL/kg/h has been adopted to reduce UF-related risk.

Here, we found that clinics with the local policy had target weights that were on average 1.2 kg higher than those in the clinics with an absence of policy, which potentially again reflects the difference in healthcare provider approaches at these facilities. However, it may also represent an attempt to achieve UF rate targets without additional or longer sessions, or in patients in whom these measures were not sufficient to achieve policy. These differences, and failure to remove adequate fluid due to overestimated target weights, can lead to repeated hospital admissions among HD patients burdening the healthcare system (19).

Multiple mechanisms exist that affect the UF rate and outcomes associated with higher vs. lower UF rates have been proposed. In contrast, one study suggests UF rate is not a part of the mechanistic path leading to changes in blood pressure (20, 21). Thus, UF rate and blood pressure changes are not likely causally related but associated through a set of intermediate determinants (such as IDWG and target weight) (20, 21, 22). Our

results further support that the UF rate, IDWG, and target weight are on the causal pathway for intermediate blood pressure outcomes (**Figure 3**).

Furthermore, patients among the underserved populations have socio-economic influences that interactively and dynamically affect the access to quality care for ESRD and HD sessions (6). Expanding upon the current work and adjusting for socioeconomic factors, future studies should focus on identifying a definitive pathway linking UF rate policy to long-term blood pressure effects and cardiovascular outcomes among these underserved communities as well.

There are several strengths to this study. We were able to leverage a natural experiment to examine the effect of UF rate policy on outcomes. Also, we had sufficient follow-up (180 days) to allow for the gradual adoption of the policy. Our cohort represents a significantly underserved population in the US and therefore contributes to the potential reduction in disparities among ESRD populations. This study benefits from its large sample size may be generalizable to other, similar HD patient populations.

One of the surprising findings among this cohort noted was there is a negative relationship between age and all four blood pressure outcomes. Usually, older age is associated with higher blood pressure among the general population (17). However, in HD patients who are undergoing at least thrice weekly dialysis, this negative association can be attributed to multifactorial causes. Due to the dynamic nature of fluid and electrolyte balance among HD patients, particularly older age groups have more unstable relationships with cardiovascular, blood pressure outcomes, and aging combined with existing or worsening comorbidities (17). Other studies conducted among HD patients possibly explain this where pre and post-HD blood pressures are considered imprecise

and estimates of blood pressure (17, 18). Another observation seen among this cohort was the presence of peripheral vascular disease and atherosclerotic cardiovascular diseases to be lower among HD patients which could be possibly explained by the lack of quality of documented via inconsistent problem list from electronic medical records.

However, this study also limitations. One limitation of this study is the potential survival bias in the prevalent cohort of HD patients. These patients must survive 45 days before and 210 days after the policy period, and patients who died may have been differentially affected by the UF rate policy. Additionally, exclusions based on kidney transplantation status and switching modalities of treatment other than in-center HD may lead to other types of selection bias. There is also potential misclassification of data as it was collected primarily for clinical purposes and not research. The intervention was not randomized, and individual and available facility characteristics to account for confounding were limited. Also, other unmeasured confounders at the patient and clinic levels likely exist and cannot be ruled out.

In conclusion, we found no evidence of an independent effect of UF rate policy on blood pressure outcomes among HD patients admitted to 23 not-for-profit dialysis facilities. Additionally, more evidence among underserved populations and policy implications at other dialysis facilities across the United States will provide more information regarding how the national UF rate policy is being implemented and how it is affecting multiple patient outcomes.

Table 1: Characteristics of in-center hemodialysis patients treated in 23 not-for-profit dialysis facilities in GA and NC, USA, at ultrafiltration policy rollout (April 30, 2012)

Characteristic	Overall (N=2353)	Patients Treated at Facilities: Absence of Policy (N=1176)	Patients Treated at Facilities: Presence of Policy (N=1177)	P
Demographics				
Mean (SD) age, in years	60 (15.0)	58.1 (14.4)	62 (15.3)	<.0001
Female, *n* (%)	1058 (45.0)	563 (47.9)	495 (42.1)	0.005
Black, *n* (%)	1605 (68.2)	1020 (86.7)	585 (49.7)	<.0001
Clinical Characteristics				
Mean (SD) ultrafiltration rate, ml/kg/h	8.0 (2.9)	8.4 (3.1)	7.6 (2.7)	<0.0001
Mean (SD) lowest intra-dialytic SBP, mmHg	117.9 (17.7)	119 (18.2)	116.3 (17.0)	<0.0001
Mean (SD) lowest intra-dialytic DBP, mmHg	61.9 (11.0)	62.3 (11.4)	61.6 (10.6)	0.2
Mean (SD) post-dialysis sitting SBP, mmHg	138.3 (19.0)	141.7 (20.1)	135.0 (19.4)	<0.0001
Mean (SD) post-dialysis sitting DBP, mmHg	73.9 (10.7)	74.5 (11.1)	73.3 (10.2)	0.006
Co-Morbid Conditions				
Diabetes, *n* (%)	1034 (43.9)	473 (40.2)	561 (47.7)	0.0003
Hypertension, *n* (%)	1590 (67.6)	829 (70.5)	761 (64.7)	0.003
Peripheral vascular disease, *n* (%)	363 (15.4)	116 (9.9)	247 (21.0)	<0.0001
Atherosclerotic cardiovascular disease, *n* (%)	1936 (82.3)	973 (82.7)	963 (81.8)	0.6
Cause of End-Stage Renal Disease				
Diabetes, *n* (%)	880 (37.4)	325 (27.6)	555 (47.2)	<0.0001
Hypertension, *n* (%)	918 (39.0)	660 (56.1)	258 (21.9)	
Glomerulonephritis, *n* (%)	236 (10.0)	86 (7.3)	150 (12.7)	
Other, *n* (%)	319 (13.6)	105 (8.9)	214 (18.2)	
Lab Characteristics				
Mean (SD) hemoglobin, g/dl	10.7 (1.1)	10.6 (1.1)	10.8 (1.1)	<0.0001
Mean (SD) serum albumin, g/dl	3.8 (0.4)	3.8 (0.4)	3.7 (0.4)	<0.0001
Mean (SD) serum phosphorus, mg/dl	5.2 (1.4)	5.1 (1.3)	5.2 (1.5)	0. 5
Mean (SD) serum potassium, mEq/l	4.5 (0.6)	4.5 (0.5)	4.5 (0.6)	0.03

Abbreviations: DBP, diastolic blood pressure; SBP, systolic blood pressure.

Table 2: Crude associations of the outcomes (blood pressures) with characteristics of in-center hemodialysis patients treated in 23 not-for-profit dialysis facilities in GA and NC, USA, at ultrafiltration policy rollout (April 30, 2012)

	β (95% CI), representing the difference in mmHg for:			
Characteristic	**Lowest intradialytic SBP**	**Lowest intradialytic DBP**	**Post-dialysis sitting SBP**	**Post-dialysis sitting DBP**
Demographics				
Age, per year	-0.2 (-0.3, -0.2)	-0.4 (-0.4, -0.4)	-0.1 (-0.1, 0.1)	-0.3 (-0.4, -0.3)
Female vs. male	-2.9 (-4.4, -1.5)	-4.0 (-4.9, -3.1)	0.3 (-1.3, 1.9)	-2.8 (-3.7, -2.0)
Black vs, other race	3.0 (1.4, 4.7)	3.9 (2.9, 4.9)	3.2 (1.4, 5.0)	4.8 (3.8, 5.8)
Clinical Characteristics				
UF rate, per ml/kg/h	0.2 (-0.1, 0.5)	0.5 (0.4, 0.7)	-0.1 (-0.3, 0.3)	0.4 (0.2, 0.5)
Co-Morbid Conditions (all vs. not)				
Diabetes	0.1 (-1.4, 1.6)	-3.1 (-3.9, -2.2)	2.3 (0.7, 3.8)	-2.4 (-3.3, -1.5)
Hypertension	0.8 (-0.8, 2.4)	0.4 (-0.6, 1.4)	1.7 (-0.1, 3.3)	0.7 (-0.3, 1.6)
Peripheral vascular disease	-4.5 (-6.5, -2.5)	-3.9 (-5.2, -2.7)	-2.1 (-4.2, 0.2)	-3.0 (-4.2, -1.8)
Atherosclerotic cardiovascular disease	-3.1 (-5, -1.3)	-1.9 (-3.1, -0.8)	-2.1 (-4.1, -0.1)	-1.1 (-2.2, 0.1)
Cause of End-Stage Renal Disease				
Diabetes	1.8 (-0.5, 4.1)	-3.0 (-4.4, -1.6)	5.1 (2.7, 7.5)	-2.3 (-3.7, -1.0)
Hypertension	3.5 (1.2, 5.8)	1.4 (-0.2, 2.8)	6.0 (3.5, 8.5)	2.4 (1.0, 3.8)
Glomerulonephritis	1.5 (-1.6, 4.5)	2.9 (1.1, 4.7)	0.7 (-2.5, 3.9)	2.2 (0.5, 4.0)
Other	Ref	Ref	Ref	Ref
Lab Characteristics				
Hemoglobin, per g/dl	-2.7 (-3.4, -2.1)	-1.0 (-1.4, -0.6)	-2.8 (-3.5, -2.2)	-0.8 (-1.2, -0.5)
Serum albumin, per g/dl	1.2 (-0.7, 3.1)	2.4 (1.3, 3.5)	-1.3 (-3.2, 0.7)	1.3 (0.2, 2.4)
Serum phosphorus, per mg/dl	0.2 (-0.4, 0.7)	1.0 (0.7, 1.3)	-0.3 (-0.9,0.3)	0.9 (0.6, 1.2)
Serum potassium, per mEq/l	-0.4 (-1.7, 1.0)	0.7 (-0.2, 1.5)	-1.0 (-2.4, 0.4)	0.4 (-0.5, 1.2)

Abbreviations: UF, ultrafiltration; DBP, diastolic blood pressure; SBP, systolic blood pressure.

Table 3: Associations of ultrafiltration rate policy at treating facility with blood pressure outcomes of in-center hemodialysis patients across 23 dialysis facilities in GA and NC, USA

Model:	β (95% CI), representing the difference in mmHg (policy vs. no policy) for:			
	Lowest intradialytic SBP	**Lowest intradialytic DBP**	**Post-dialysis sitting SBP**	**Post-dialysis sitting DBP**
Model 1: Unadjusted	-3.3 (-4.9, -1.7)	-0.9 (-2.4, 0.7)	-5.3 (-7.1, -3.4)	-1.6 (-3.8, 0.7)
Model 2: Model 1 + demographics	-1.7 (-4.0, 0.6)	1.6 (0.6, 2.5)	-3.8 (-6.2, -1.4)	1.3 (-0.1, 2.5)
Model 3: Model 2 + clinical characteristics	-0.5 (-3.5, 2.6)	2.7 (1.4, 3.9)	-2.6 (-5.5, 0.4)	2.4 (1.3, 3.5)
Model 4: Model 3 + labs	-0.4 (-2.8, 2.1)	2.5 (1.4, 3.6)	-2.3 (-4.8, 0.3)	2.2 (1.0, 3.4)

Abbreviations: DBP, diastolic blood pressure; SBP, systolic blood pressure. Demographics = age, sex, race; clinical characteristics = comorbid conditions (diabetes mellitus, hypertension, peripheral vascular disease, atherosclerotic cardiovascular disease), cause of end-stage renal disease; labs = hemoglobin, albumin, potassium, phosphorus.

Table 4: Associations between ultrafiltration rate policy and potential mediators among in-center hemodialysis patients across 23 dialysis facilities in GA and NC, USA

Model	β (95% CI), representing the difference in mmHg (presence of policy vs. absence of policy) for:		
	UF rate, per ml/kg/h	**IDWG, kg**	**Target weight, kg**
Unadjusted	-0.7 (-1.2, -0.1)	1.6 (0.5, 2.6)	1.3 (1.2, 1.4)
Adjusted*	-0.6 (-1.2, 0.1)	1.6 (0.5, 2.7)	1.2 (1.1, 1.4)

Abbreviations: UF, ultrafiltration; IDWG; interdialytic weight gain. *Adjusted for demographics = age, sex, race; clinical characteristics = comorbid conditions (diabetes mellitus, hypertension, peripheral vascular disease, atherosclerotic cardiovascular disease), cause of end-stage renal disease; labs = hemoglobin, albumin, potassium, phosphorus.

Table 5: Associations of ultrafiltration rate policy, adjusted* for potential mediators, at treating facility with blood pressure outcomes of in-center hemodialysis patients across 23 dialysis facilities in GA and NC, USA

Additionally, adjusting for:	β (95% CI), representing the difference in mmHg (presence of policy vs. absence of policy) for:			
	Lowest intradialytic SBP	**Lowest intradialytic DBP**	**Post-dialysis sitting SBP**	**Post-dialysis sitting DBP**
UF rate, per ml/kg/h	-0.3 (-2.7, 2.1)	2.6 (1.5, 3.7)	-2.3 (-4.8, 0.3)	2.2 (1.1, 3.4)
IDWG, kg	2.2 (-2.3, 6.6)	3.4 (1.8, 5.0)	0.5 (-3.8, 4.7)	3.2 (1.9, 4.4)
Target weight, kg	3.8 (-1.9, 9.3)	5.1 (2.3, 7.9)	1.1 (-4.0, 6.0)	3.9 (2.2, 5.6)

Abbreviations: DBP, diastolic blood pressure; SBP, systolic blood pressure; UF, ultrafiltration; IDWG, Interdialytic Weight Gain. *Adjusted for Demographics = age, sex, race; clinical characteristics = comorbid conditions (diabetes mellitus, hypertension, peripheral vascular disease, atherosclerotic cardiovascular disease), cause of end-stage renal disease; labs = hemoglobin, albumin, potassium, phosphorus.

Figure 1: Study design schematic showing the baseline and follow-up periods relative to the rollout of the policy. Abbreviations: UF, ultrafiltration; HD, hemodialysis.

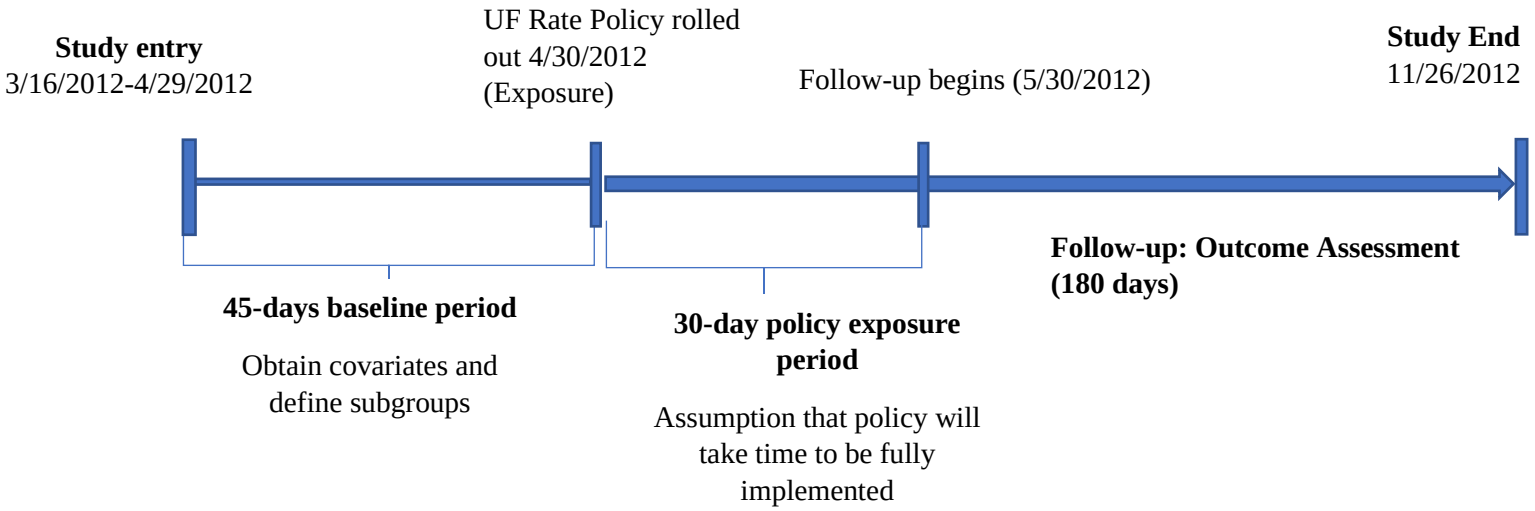
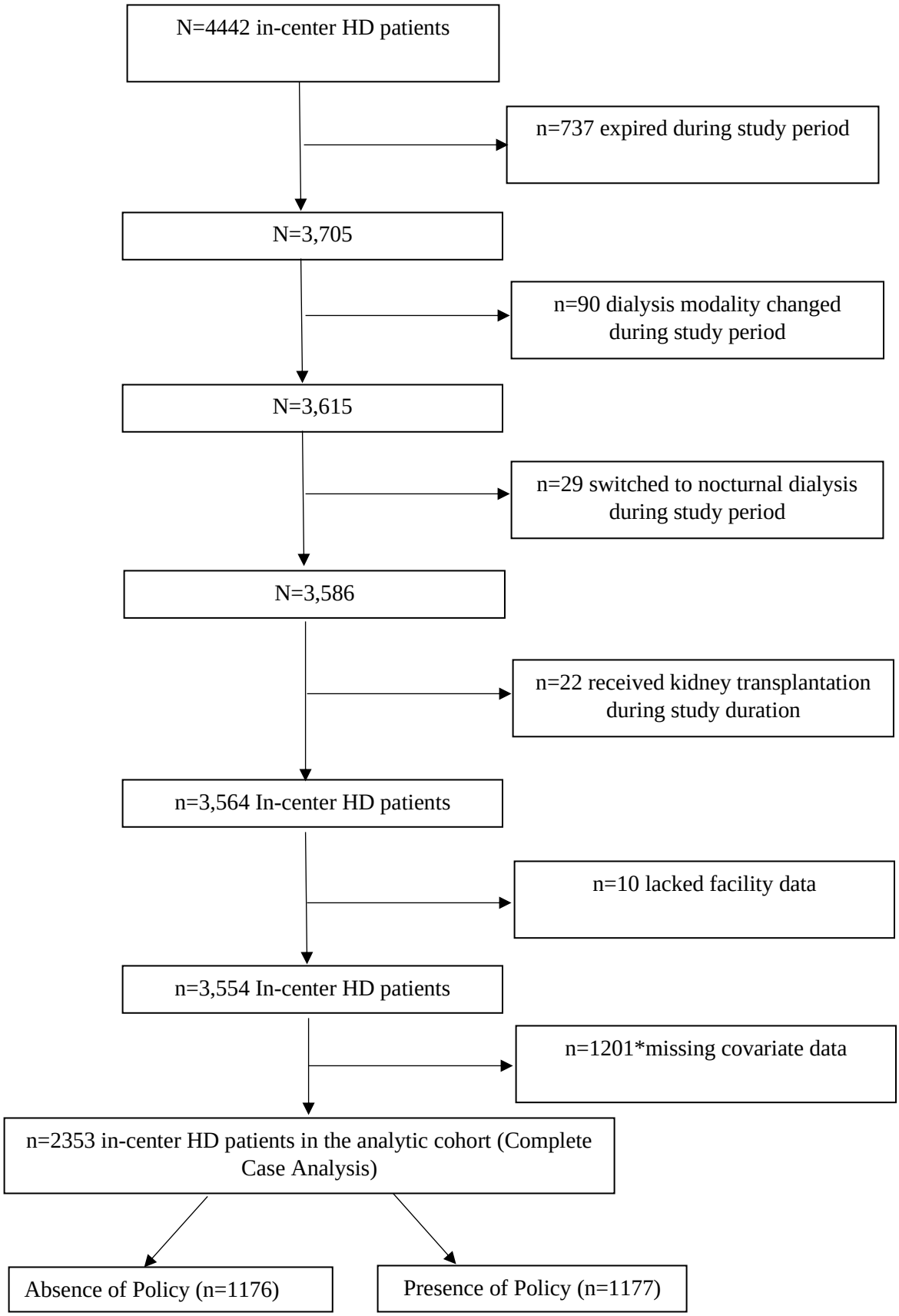
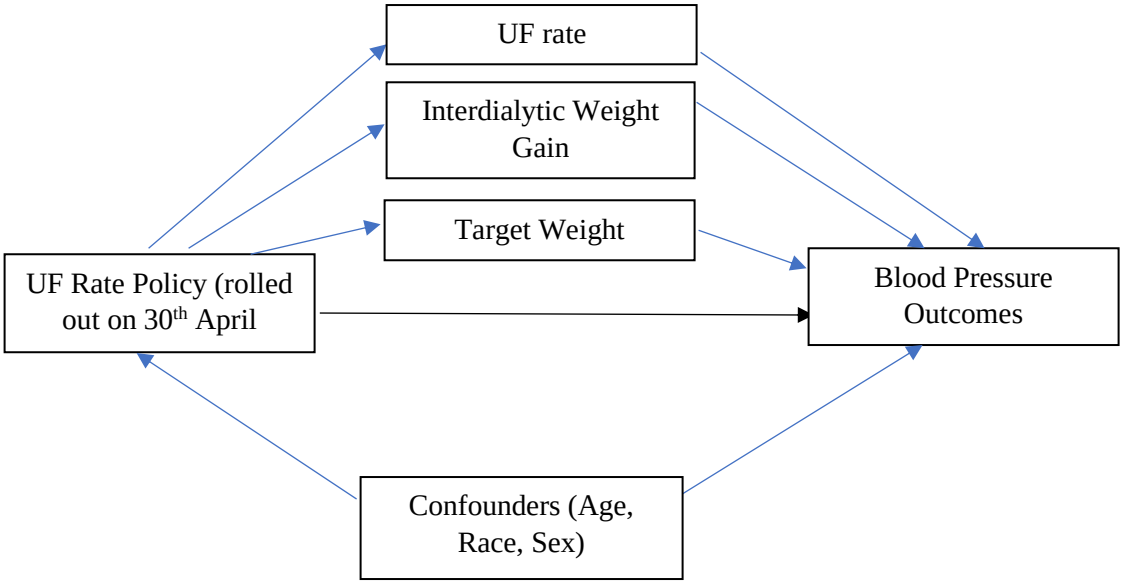


Figure 2: Flow diagram of the selection of the in-center hemodialysis cohort. HD, hemodialysis.



Abbreviations: DBP, diastolic blood pressure; SBP, systolic blood pressure. *Missing covariate data [*n* (%)]: race(black): 424 (11.9); ultrafiltration rate [183 (5.2)]; lowest intradialytic SBP: [364 (10.2)]; lowest intradialytic DBP: 364 (10.2%); post-dialysis sitting SBP: 183 (5.2%); post-dialysis sitting DBP: 183 (5.2%); hemoglobin: 494 (13.9); albumin: 472 (13.3); phosphorus: 499 (14.0); potassium: 500 (14.1).

Figure 3: Directed acyclic graph (DAG) showing hypothesized associations between the exposure, outcomes, and potential mediators. UF, ultrafiltration.



CHAPTER III: IMPLICATIONS

Summary

ESRD is common among U.S. populations. The burden on the healthcare system due to patients on HD cannot be understated. There exist pathways that establish a linkage among UF rate, IDWG, and target weight that determine the dialysis session time and several dialysis sessions among the HD patients (19, 20, 21). Despite the recent ESRD-QIP guidelines that address the maximum UF rate policy, the long-term consequences of the effects of policy on intermediate outcomes remain unclear. Here, we examined the association of maximum ultrafiltration (UF) rate policy at the clinic level with intermediate outcomes, particularly blood pressure, among the prevalent underserved population undergoing hemodialysis.

In crude analyses, the presence vs. absence of a UF rate policy was associated with 5.3 mmHg (95 % CI (-7.1, -3.4)) higher post-dialysis SBP, 1.6 mmHg (95 % CI (-3.8, 0.7)) higher post-dialysis DBP, and 3.3 mmHg (95 % CI (-4.9, -1.7)) lower intradialytic SBP; the difference in lowest intradialytic DBP was <1 mmHg (95 % CI (-2.4, 0.7)). In a fully adjusted model, presence vs. absence of UF rate policy was associated with 2.3 mmHg lower post-dialysis SBP (95 % CI (-4.8, 0.3)), 2.2 mmHg higher post-dialysis DBP (95 % CI (1.0, 3.4)), 0.4 mmHg lower average lowest intradialytic SBP (95 % CI (-2.8, 2.1)) and 2.5 mmHg higher lowest intra-dialytic DBP (95% CI (1.4, 3.6)).

In general, we found that the presence of a maximum UF policy at the dialysis clinic was not independently associated with patient blood pressure outcomes in a prevalent underserved population undergoing HD. Further studies are needed to identify

how UF policies are implemented and how they ultimately affect morbidity and mortality among HD patients.

Public Health Implications

High-quality HD treatment in ESRD is critical for improved short- and long-term morbidity and mortality outcomes. Our findings suggest that a UF rate policy, which is based on primarily observational evidence thus far, may not be associated with differences in intermediate outcomes, which might subsequently affect cardiovascular events or mortality. Furthermore, our data suggest that a clinic-level UF rate policy may have little effect on patients' UF rates. This evidence supports the need for intervention assessment at the clinic, healthcare provider, and patient levels. This will require examining how the HD sessions are conducted, with regards to volume calculated (UF volume goals), target weight adjustments made by providers, and IDWGs of patients between dialysis sessions. Thus, a multipronged approach to assess this policy is needed. Considering the high prevalence of adverse outcomes among dialysis patients, we now need to build evidence on the plausible mediators of the observed association between lower UF rates and its protective effects from adverse outcomes.

Possible Future Directions

Although multiple mechanistic pathways linking UF rate, target weight, and IDWG, along with pre-existing comorbidities, among HD patients exist, the precise mechanism and lack of standardized scoring approaches by healthcare providers to implement the QIP policy-based guidelines are not well-known. Furthermore, the lack of

studies among the facilities to look at the effect of the ESRD-QIP policy among is needed to look at proximal outcomes (prior to mortality) as well as long-term morbidities and change is the course of mortality rates among HD patients. Thus, future studies should identify how these extra sessions and extended time for HD per policy change the association between various components of quality of care and HD to further develop the most effective strategy to prevent and control the problem of high UF rates and their sequelae, including morbidity and mortality, among HD patients.

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APPENDICES

Form Approved
OMB No. 0938-0046

END STAGE RENAL DISEASE MEDICAL EVIDENCE REPORT MEDICARE ENTITLEMENT AND/OR PATIENT REGISTRATION

A. COMPLETE FOR ALL ESRD PATIENTS *Check one:* ☐ Initial ☐ Re-entitlement ☐ Supplemental

1. Name *(Last, First, Middle Initial)*

2. Medicare Beneficiary Identifier or Social Security Number

3. Date of Birth *(mm/dd/yyyy)*

4. Patient Mailing Address *(Include City, State and Zip)*

5. Phone Number *(including area code)*

6. Sex
☐ Male ☐ Female

7. Ethnicity
☐ Not Hispanic or Latino ☐ Hispanic or Latino (Complete Item 9)

8. Country/Area of Origin or Ancestry

9. Race *(Check all that apply)*
☐ White
☐ Black or African American
☐ American Indian/Alaska Native
☐ Asian
☐ Native Hawaiian or Other Pacific Islander*
☐ Other
Print Name of Enrolled/Principal Tribe _____

10. Is patient applying for ESRD Medicare coverage?
☐ Yes ☐ No

11. Current Medical Coverage *(Check all that apply)*
☐ Medicaid ☐ Medicare ☐ Employer Group Health Insurance
☐ VA ☐ Medicare Advantage ☐ Other ☐ None

12. Height
INCHES _____ OR
CENTIMETERS _____

13. Dry Weight
POUNDS _____ OR
KILOGRAMS _____

14. Primary Cause of Renal Failure *(Use code from back of form)*

15. Employment Status *(6 mos prior and current status)*

Prior	Current	
☐	☐	Unemployed
☐	☐	Employed Full Time
☐	☐	Employed Part Time
☐	☐	Homemaker
☐	☐	Retired due to Age/Preference
☐	☐	Retired (Disability)
☐	☐	Medical Leave of Absence
☐	☐	Student

16. Co-Morbid Conditions *(Check all that apply currently and/or during last 10 years)* *See instructions

a. ☐ Congestive heart failure
b. ☐ Atherosclerotic heart disease ASHD
c. ☐ Other cardiac disease
d. ☐ Cerebrovascular disease, CVA, TIA*
e. ☐ Peripheral vascular disease*
f. ☐ History of hypertension
g. ☐ Amputation
h. ☐ Diabetes, currently on insulin
i. ☐ Diabetes, on oral medications
j. ☐ Diabetes, without medications
k. ☐ Diabetic retinopathy
l. ☐ Chronic obstructive pulmonary disease
m. ☐ Tobacco use (current smoker)
n. ☐ Malignant neoplasm, Cancer
o. ☐ Toxic nephropathy
p. ☐ Alcohol dependence
q. ☐ Drug dependence*
r. ☐ Inability to ambulate
s. ☐ Inability to transfer
t. ☐ Needs assistance with daily activities
u. ☐ Institutionalized
☐ 1. Assisted Living
☐ 2. Nursing Home
☐ 3. Other Institution
v. ☐ Non-renal congenital abnormality
w. ☐ None

17. Prior to ESRD therapy:

a. Did patient receive exogenous erythropoetin or equivalent? ☐ Yes ☐ No ☐ Unknown If Yes, answer: ☐ <6 months ☐ 6-12 months ☐ >12 months
b. Was patient under care of a nephrologist? ☐ Yes ☐ No ☐ Unknown If Yes, answer: ☐ <6 months ☐ 6-12 months ☐ >12 months
c. Was patient under care of kidney dietitian? ☐ Yes ☐ No ☐ Unknown If Yes, answer: ☐ <6 months ☐ 6-12 months ☐ >12 months
d. What access was used on first outpatient dialysis: ☐ AVF ☐ Graft ☐ Catheter ☐ Other
If not AVF, then: Is maturing AVF present? ☐ Yes ☐ No
Is maturing graft present? ☐ Yes ☐ No

18. Laboratory Values Within **45** Days Prior to the Most Recent ESRD Episode. (Lipid Profile within 1 Year of Most Recent ESRD Episode).

LABORATORY TEST	VALUE	DATE	LABORATORY TEST	VALUE	DATE
a.1. Serum Albumin (g/dl)	___.___		d. HbA1c	___ ___.___%	
a.2. Serum Albumin Lower Limit	___.___		e. Lipid Profile TC	___ ___ ___	
a.3. Lab Method Used (BCG or BCP)			LDL	___ ___ ___	
b. Serum Creatinine (mg/dl)	___ ___.___		HDL	___ ___	
c. Hemoglobin (g/dl)	___ ___.___		TG	___ ___ ___ ___	

B. COMPLETE FOR ALL ESRD PATIENTS IN DIALYSIS TREATMENT

19. Name of Dialysis Facility

20. Medicare Provider Number *(for item 19)*

21. Primary Dialysis Setting
☐ Home ☐ Dialysis Facility ☐ SNF/Long Term Care Facility

22. Primary Type of Dialysis
☐ Hemodialysis (Sessions per week____/hours per session____)
☐ CAPD ☐ CCPD ☐ Other

23. Date Regular Chronic Dialysis Began *(mm/dd/yyyy)*

24. Date Patient Started Chronic Dialysis at Current Facility *(mm/dd/yyyy)*

25. Has patient been informed of kidney transplant options?
☐ Yes ☐ No

26. If patient NOT informed of transplant options, please check all that apply:
☐ Patient declined information
☐ Patient has not been assessed
☐ Patient is not eligible medically
☐ Other

C. COMPLETE FOR ALL KIDNEY TRANSPLANT PATIENTS

27. Date of Transplant *(mm/dd/yyyy)*	28. Name of Transplant Hospital	29. Medicare Provider Number for Item 28

Date patient was admitted as an inpatient to a hospital in preparation for, or anticipation of, a kidney transplant prior to the date of actual transplantation.

30. Enter Date *(mm/dd/yyyy)*	31. Name of Preparation Hospital	32. Medicare Provider number for Item 31

33. Current Status of Transplant *(if functioning, skip items 36 and 37)*	34. Type of Donor:
☐ Functioning ☐ Non-Functioning	☐ Deceased ☐ Living Related ☐ Living Unrelated
35. If Non-Functioning, Date of Return to Regular Dialysis *(mm/dd/yyyy)*	36. Current Dialysis Treatment Site
	☐ Home ☐ Dialysis Facility ☐ SNF/Long Term Care Facility

D. COMPLETE FOR ALL ESRD SELF-DIALYSIS TRAINING PATIENTS (MEDICARE APPLICANTS ONLY)

37. Name of Training Provider	38. Medicare Provider Number of Training Provider (for Item 37)
39. Date Training Began *(mm/dd/yyyy)*	40. Type of Training ☐ Hemodialysis a. ☐ Home b. ☐ In Center ☐ CAPD ☐ CCPD ☐ Other
41. This Patient is Expected to Complete *(or has completed)* Training and will Self-dialyze on a Regular Basis. ☐ Yes ☐ No	42. Date When Patient Completed, or is Expected to Complete, Training *(mm/dd/yyyy)*

I certify that the above self-dialysis training information is correct and is based on consideration of all pertinent medical, psychological, and sociological factors as reflected in records kept by this training facility.

43. Printed Name and Signature of Physician personally familiar with the patient's training			44. UPIN or NPI of Physician in Item 43
a.) Printed Name	b.) Signature	c.) Date *(mm/dd/yyyy)*	

E. PHYSICIAN IDENTIFICATION

45. Attending Physician *(Print)*	46. Physician's Phone No. *(include Area Code)*	47. UPIN or NPI of Physician in Item 45

PHYSICIAN ATTESTATION

I certify, under penalty of perjury, that the information on this form is correct to the best of my knowledge and belief. Based on diagnostic tests and laboratory findings, I further certify that this patient has reached the stage of renal impairment that appears irreversible and permanent and requires a regular course of dialysis or kidney transplant to maintain life. I understand that this information is intended for use in establishing the patient's entitlement to Medicare benefits and that any falsification, misrepresentation, or concealment of essential information may subject me to fine, imprisonment, civil penalty, or other civil sanctions under applicable Federal laws.

48. Attending Physician's Signature of Attestation *(Same as Item 45)*	49. Date *(mm/dd/yyyy)*
50. Physician Recertification Signature	51. Date *(mm/dd/yyyy)*

52. Remarks

F. OBTAIN SIGNATURE FROM PATIENT

I hereby authorize any physician, hospital, agency, or other organization to disclose any medical records or other information about my medical condition to the Department of Health and Human Services for purposes of reviewing my application for Medicare entitlement under the Social Security Act and/or for scientific research.

53. Signature of Patient *(Signature by mark must be witnessed.)*	54. Date *(mm/dd/yyyy)*

G. PRIVACY STATEMENT

The collection of this information is authorized by Section 226A of the Social Security Act. The information provided will be used to determine if an individual is entitled to Medicare under the End Stage Renal Disease provisions of the law. The information will be maintained in system No. 09-700520, "End Stage Renal Disease Program Management and Medical Information System (ESRD PMMIS)", published in the Federal Register, Vol. 67, No. 116, June 17, 2002, pages 41244-41250 or as updated and republished. Collection of your Social Security number is authorized by Executive Order 9397. Furnishing the information on this form is voluntary, but failure to do so may result in denial of Medicare benefits. Information from the ESRD PMMIS may be given to a congressional office in response to an inquiry from the congressional office made at the request of the individual; an individual or organization for research, demonstration, evaluation, or epidemiologic project related to the prevention of disease or disability, or the restoration or maintenance of health. Additional disclosures may be found in the Federal Register notice cited above. You should be aware that P.L.100-503, the Computer Matching and Privacy Protection Act of 1988, permits the government to verify information by way of computer matches.

LIST OF PRIMARY CAUSES OF RENAL DISEASE

Item 14. Primary Cause of Renal Failure should be completed by the attending physician from the list below. Enter the ICD-10-CM code to indicate the primary cause of end stage renal disease. If there are several probable causes of renal failure, choose one as primary. **An ICD-10-CM code is effective as of October 1, 2015.**

ICD-10	DESCRIPTION
DIABETES	
E10.22	Type 1 diabetes mellitus with diabetic chronic kidney disease
E10.29	Type 1 diabetes mellitus with other diabetic kidney complication
E11.22	Type 2 diabetes mellitus with diabetic chronic kidney disease
E11.29	Type 2 diabetes mellitus with other diabetic kidney complication
GLOMERULONEPHRITIS	
N00.8	Acute nephritic syndrome with other morphologic changes
N01.9	Rapidly progressive nephritic syndrome with unspecified morphologic changes
N02.8	Recurrent and persistent hematuria with other morphologic changes
N03.0	Chronic nephritic syndrome with minor glomerular abnormality
N03.1	Chronic nephritic syndrome with focal and segmental glomerular lesions
N03.2	Chronic nephritic syndrome with diffuse membranous glomerulonephritis
N03.3	Chronic nephritic syndrome with diffuse mesangial proliferative glomerulonephritis
N03.4	Chronic nephritic syndrome with diffuse endocapillary proliferative glomerulonephritis
N03.5	Chronic nephritic syndrome with diffuse mesangiocapillary glomerulonephritis
N03.6	Chronic nephritic syndrome with dense deposit disease
N03.7	Chronic nephritic syndrome with diffuse crescentic glomerulonephritis
N03.8	Chronic nephritic syndrome with other morphologic changes
N03.9	Chronic nephritic syndrome with unspecified morphologic changes
N04.0	Nephrotic syndrome with minor glomerular abnormality
N04.1	Nephrotic syndrome with focal and segmental glomerular lesions
N04.2	Nephrotic syndrome with diffuse membranous glomerulonephritis
N04.3	Nephrotic syndrome with diffuse mesangial proliferative glomerulonephritis
N04.4	Nephrotic syndrome with diffuse endocapillary proliferative glomerulonephritis
N04.5	Nephrotic syndrome with diffuse mesangiocapillary glomerulonephritis
N04.6	Nephrotic syndrome with dense deposit disease
N04.7	Nephrotic syndrome with diffuse crescentic glomerulonephritis
N04.8	Nephrotic syndrome with other morphologic changes
N04.9	Nephrotic syndrome with unspecified morphologic changes
N05.9	Unspecified nephritic syndrome with unspecified morphologic changes
N07.0	Hereditary nephropathy, not elsewhere classified with minor glomerular abnormality
SECONDARY GLOMERULONEPHRITIS/VASCULITIS	
D59.3	Hemolytic-uremic syndrome
D69.0	Allergic purpura
I77.89	Other specified disorders of arteries and arterioles
M31.0	Hypersensitivity angiitis
M31.1	Thrombotic microangiopathy
M31.31	Wegener's granulomatosis with renal involvement
M31.7	Microscopic polyangiitis
M32.0	Drug-induced systemic lupus erythematosus
M32.10	Systemic lupus erythematosus, organ or system involvement unspecified
M32.14	Glomerular disease in systemic lupus erythematosus
M32.15	Tubulo-interstitial nephropathy in systemic lupus erythematosus
M34.89	Other systemic sclerosis
INTERSTITIAL NEPHRITIS/PYELONEPHRITIS	
N10	Acute tubulo-interstitial nephritis
N11.9	Chronic tubulo-interstitial nephritis, unspecified
N13.70	Vesicoureteral-reflux, unspecified
N13.8	Other obstructive and reflux uropathy 2
TRANSPLANT COMPLICATIONS	
T86.00	Unspecified complication of bone marrow transplant
T86.10	Unspecified complication of kidney transplant
T86.20	Unspecified complication of heart transplant
T86.40	Unspecified complication of liver transplant
T86.819	Unspecified complication of lung transplant
T86.859	Unspecified complication of intestine transplant
T86.899	Unspecified complication of other transplanted tissue

LIST OF PRIMARY CAUSES OF RENAL DISEASE

Item 14. Primary Cause of Renal Failure should be completed by the attending physician from the list below. Enter the ICD-10-CM code to indicate the primary cause of end stage renal disease. If there are several probable causes of renal failure, choose one as primary. **An ICD-10-CM code is effective as of October 1, 2015.**

ICD-10	DESCRIPTION
HYPERTENSION/LARGE VESSEL DISEASE	
I12.9	Hypertensive chronic kidney disease with stage 1through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I15.0	Renovascular hypertension
I15.8	Other secondary hypertension
I75.81	Atheroembolism of kidney
CYSTIC/HEREDITARY/CONGENITAL/OTHER DISEASES	
E72.04	Cystinosis
E72.53	Hyperoxaluria
E75.21	Fabry (-Anderson) disease
N07.8	Hereditary nephropathy, not elsewhere classified with other morphologic lesions
N31.9	Neuromuscular dysfunction of bladder, unspecified
Q56.0	Hermaphroditism, not elsewhere classified
Q60.2	Renal agenesis, unspecified
Q61.19	Other polycystic kidney, infantile type
Q61.2	Polycystic kidney, adult type
Q61.4	Renal dysplasia
Q61.5	Medullary cystic kidney
Q61.8	Other cystic kidney diseases
Q62.11	Congenital occlusion of ureteropelvic junction
Q62.12	Congenital occlusion of ureterovesical orifice
Q63.8	Other specified congenital malformations of kidney
Q64.2	Congenital posterior urethral valves
Q79.4	Prune belly syndrome
Q85.1	Tuberous sclerosis
Q86.8	Other congenital malformation syndromes due to known exogenous causes
Q87.1	Congenital malformation syndromes predominantly associated with short stature
Q87.81	Alport syndrome
NEOPLASMS/TUMORS	
C64.9	Malignant neoplasm of unspecified kidney, except renal pelvis
C80.1	Malignant (primary) neoplasm, unspecified
C85.93	Non-Hodgkin lymphoma, unspecified, intra-abdominal lymph nodes
C88.2	Heavy chain disease
C90.00	Multiple myeloma not having achieved remission
D30.9	Benign neoplasm of urinary organ, unspecified
D41.00	Neoplasm of uncertain behavior of unspecified kidney
D41.9	Neoplasm of uncertain behavior of unspecified urinary organ
E85.9	Amyloidosis, unspecified
N05.8	Unspecified nephritic syndrome with other morphologic changes
DISORDERS OF MINERAL METABOLISM	
E83.52	Hypercalcemia
GENITOURINARY SYSTEM	
A18.10	Tuberculosis of genitourinary system, unspecified
N28.9	Disorder of kidney and ureter, unspecified
ACUTE KIDNEY FAILURE	
N17.0	Acute kidney failure with tubular necrosis
N17.1	Acute kidney failure with acute cortical necrosis
N17.9	Acute kidney failure, unspecified
MISCELLANEOUS CONDITIONS	
B20	Human immunodeficiency virus [HIV] disease
D57.1	Sickle-cell disease without crisis
D57.3	Sickle cell trait
I50.9	Heart failure, unspecified
K76.7	Hepatorenal syndrome
M10.30	Gout due to renal impairment, unspecified site
N14.0	Analgesic nephropathy
N14.1	Nephropathy induced by other drugs, medicaments and biological substances
N14.3	Nephropathy induced by heavy metals
N20.0	Calculus of kidney
N25.89	Other disorders resulting from impaired renal tubular function
N26.9	Renal sclerosis, unspecified
N28.0	Ischemia and infarction of kidney
N28.89	Other specified disorders of kidney and ureter
O90.4	Postpartum acute kidney failure
S37.009A	Unspecified injury of unspecified kidney, initial encounter
Z90.5	Acquired Absence of Kidney

INSTRUCTIONS FOR COMPLETION OF END STAGE RENAL DISEASE MEDICAL EVIDENCE REPORT MEDICARE ENTITLEMENT AND/OR PATIENT REGISTRATION

For whom should this form be completed:

This form **SHOULD NOT** be completed for those patients who are in acute renal failure. Acute renal failure is a condition in which kidney function can be expected to recover after a short period of dialysis, i.e., several weeks or months.

This form **MUST BE** completed within 45 days for **ALL** patients beginning any of the following:

Check the appropriate block that identifies the reason for submission of this form.

Initial

For all patients who initially receive a kidney transplant instead of a course of dialysis.

For patients for whom a regular course of dialysis has been prescribed by a physician because they have reached that stage of renal impairment that a kidney transplant or regular course of dialysis is necessary to maintain life. The first date of a regular course of dialysis is the date this prescription is implemented whether as an inpatient of a hospital, an outpatient in a dialysis center or facility, or a home patient. The form should be completed for all patients in this category even if the patient dies within this time period.

Re-entitlement

For beneficiaries who have already been entitled to ESRD Medicare benefits and those benefits were terminated because their coverage stopped 3 years post transplant but now are again applying for Medicare ESRD benefits because they returned to dialysis or received another kidney transplant.

For beneficiaries who stopped dialysis for more than 12 months, have had their Medicare ESRD benefits terminated and now returned to dialysis or received a kidney transplant. These patients will be reapplying for Medicare ESRD benefits.

Supplemental

Patient has received a transplant or trained for self-care dialysis within the first 3 months of the first date of dialysis and initial form was submitted.

All items except as follows: To be completed by the attending physician, head nurse, or social worker involved in this patient's treatment of renal disease.

Items 14, 16-17, 25-26, 48-49: To be completed by the attending physician.
Item 43: To be signed by the attending physician or the physician familiar with the patient's self-care dialysis training.
Items 53 and 54: To be signed and dated by the patient.

1. Enter the patient's legal name (Last, first, middle initial). Name should appear exactly the same as it appears on patient's social security or Medicare card.
2. If the patient is covered by Medicare, enter his/her Medicare Beneficiary Identifier as it appears on his/her Medicare card. If the patient has not yet been assigned a Medicare Beneficiary Identifier, enter the Social Security Number as it appears on his/her Social Security Card. **Only enter the Social Security Number if the patient does not have a Medicare Beneficiary Identifier**.
3. Enter patient's date of birth (2-digit Month, Day, and 4-digit Year). Example 07/25/1950.
4. Enter the patient's mailing address (number and street or post office box number, city, state, and ZIP code.)
5. Enter the patient's home area code and telephone number.
6. Check the appropriate block to identify sex.
7. Check the appropriate block to identify ethnicity. Definitions of the ethnicity categories for Federal statistics are as follows:

   Not Hispanic or Latino—A person of culture or origin not described below, regardless of race.

   Hispanic or Latino—A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin regardless of race. Please complete Item 9 and provide the country, area of origin, or ancestry to which the patient claims to belong.
8. Country/Area of origin or ancestry—Complete if information is available or if directed to do so in question 9.
9. Check the appropriate block(s) to identify race. The 1997 OMB standards permit the reporting of more than one race. An individual's response to the race question is based upon self-identification.

   Definitions of the racial categories for Federal statistics are as follows:

   White—A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

   Black or African American—A person having origins in any of the Black racial groups of Africa.

   American Indian/Alaska Native—A person having origins in any of the original peoples of North and South America (including Central America) and who maintains tribal affiliation or community attachment.

   Asian—A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.

   Native Hawaiian or Other Pacific Islander—AA person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

   Other Race—For respondents unable to identify with any of these five race categories
10. Check the appropriate yes or no block to indicate if patient is applying for ESRD Medicare. **Note: Even though a person may already be entitled to general Medicare coverage, he/she should reapply for ESRD Medicare coverage.**

DISTRIBUTION OF COPIES:

- **To the Applicant:** Forward the hard copy of this form with original signatures to the Social Security office servicing the claim.
- **To the Dialysis Facility:** Complete the form in Crown Web or maintain a copy with signature's in the patient file.

11. Check **all** the blocks that apply to this patient's current medical insurance status.

    Medicaid—Patient is currently receiving State Medicaid benefits.

    Medicare—Patient is currently entitled to Federal Medicare benefits.

    Employer Group Health Insurance—Patient receives medical benefits through an employee health plan that covers employees, former employees, or the families of employees or former employees.

    VA—Patient is receiving medical care from a Department of Veterans Affairs facility.

    Medicare Advantage—Patient is receiving medical benefits under a Medicare Advantage organization.

    Other Medical Insurance—Patient is receiving medical benefits under a health insurance plan that is not Medicare, Medicaid, Department of Veterans Affairs, HMO/M+C organization, nor an employer group health insurance plan. Examples of other medical insurance are Railroad Retirement and CHAMPUS beneficiaries.

    None—Patient has no medical insurance plan.

12. Enter the patient's most recent recorded height in inches **OR** centimeters at time form is being completed. If entering height in centimeters, round to the nearest centimeter. Estimate or use last known height for those unable to be measured. (Example of inches - 62. DO NOT PUT 5'2") NOTE: For amputee patients, enter height prior to amputation.

13. Enter the patient's most recent recorded dry weight in pounds **OR** kilograms at time form is being completed. If entering weight in kilograms, round to the nearest kilogram.

NOTE: For amputee patients, enter actual dry weight.

14. Primary Cause of Renal Failure should be determined by the attending physician using the appropriate ICD-10-CM code. Enter the ICD-10-CM code from page 3 or 4 of form to indicate the primary cause of end stage renal disease. If there are several probable causes of renal failure, choose one as primary. An ICD-10-CM code is effective as of October 1, 2015. These are the only acceptable causes of end stage renal disease.

15. Check the first box to indicate employment status 6 months prior to renal failure and the second box to indicate current employment status. **Check only one box for each time period**. If patient is under 6 years of age, leave blank.

16. **To be completed by the attending physician**. Check all co-morbid conditions that apply.

    ***Cerebrovascular Disease** includes history of stroke/ cerebrovascular accident (CVA) and transient ischemic attack (TIA).

    ***Peripheral Vascular Disease** includes absent foot pulses, prior typical claudication, amputations for vascular disease, gangrene and aortic aneurysm.

    ***Drug dependence** means dependent on illicit drugs.

17. Prior to ESRD therapy, check the appropriate box to indicate whether the patient received Exogenous erythropoetin (EPO) or equivalent, was under the care of a nephrologist and/or was under the care of a kidney dietitian. Provide vascular access information as to the type of access used (Arterio-Venous Fistula (AVF), graft, catheter (including port device) or other type of access) when the patient first received outpatient dialysis. If an AVF access was not used, was a maturing AVF or graft present?

NOTE: For those patients re-entering the Medicare program after benefits were terminated, Items 18a thru 18c should contain initial laboratory values within 45 days prior to the most recent ESRD episode. Lipid profiles and HbA1c should be within 1 year of the most recent ESRD episode. Some tests may not be required for patients under 21 years of age.

18a1. Enter the serum albumin value (g/dl) and date test was taken. This value and date must be within 45 days prior to first dialysis treatment or kidney transplant.

18a2. Enter the lower limit of the normal range for serum albumin from the laboratory which performed the serum albumin test entered in 19a1.

18a3. Enter the serum albumin lab method used (BCG or BCP).

18b. Enter the serum creatinine value (mg/dl) and date test was taken. **THIS FIELD MUST BE COMPLETED.** Value must be within 45 days prior to first dialysis treatment or kidney transplant.

18c. Enter the hemoglobin value (g/dl) and date test was taken. This value and date must be within 45 days prior to the first dialysis treatment or kidney transplant.

18d. Enter the HbA1c value and the date the test was taken. The date must be within 1 year prior to the first dialysis treatment or kidney transplant.

18e. Enter the Lipid Profile values and date test was taken. These values: TC–Total Cholesterol; LDL–LDL Cholesterol; HDL–HDL Cholesterol; TG–Triglycerides, and date must be within 1 year prior to the first dialysis treatment or kidney transplant.

19. Enter the name of the dialysis facility where patient is currently receiving care and who is completing this form for patient.

20. Enter the 6-digit Medicare identification code of the dialysis facility in item 19.

21. If the person is receiving a regular course of dialysis treatment, check the appropriate **anticipated long-term treatment setting** at the time this form is being completed.

22. If the patient is, or was, on regular dialysis, **check the anticipated long-term primary type of dialysis**: Hemodialysis, (enter the number of sessions prescribed per week and the hours that were prescribed for each session), CAPD (Continuous Ambulatory Peritoneal Dialysis) and CCPD (Continuous Cycling Peritoneal Dialysis), or Other. **Check only one block**. NOTE: Other has been placed on this form to be used only to report IPD (Intermittent Peritoneal Dialysis) and any new method of dialysis that may be developed prior to the renewal of this form by Office of Management and Budget.

23. Enter the date (month, day, year) that a "regular course of chronic dialysis" began. The beginning of the course of dialysis is counted from the beginning of regularly scheduled dialysis necessary for the treatment of end stage renal disease (ESRD) regardless of the dialysis setting. The date of the first dialysis treatment after the physician has determined that this patient has ESRD and has written a prescription for a "regular course of dialysis" is the "Date Regular Chronic Dialysis Began" regardless of whether this prescription was implemented in a hospital/ inpatient, outpatient, or home setting and regardless of any acute treatments received prior to the implementation of the prescription.

NOTE: For these purposes, end stage renal disease means irreversible damage to a person's kidneys so severely affecting his/her ability to remove or adjust blood wastes that in order to maintain life he or she must have either a course of dialysis or a kidney transplant to maintain life.

If re-entering the Medicare program, enter beginning date of the current ESRD episode. Note in Remarks, Item 52, that patient is restarting dialysis.

24. Enter date patient started chronic dialysis at current facility of dialysis services. In cases where patient transferred to current dialysis facility, this date will be after the date in Item 24.

25. Enter whether the patient has been informed of their options for receiving a kidney transplant.

26. If the patient has not been informed of their options (answered "no" to Item 25), then enter all reasons why a kidney transplant was not an option for this patient at this time.

27. Enter the date(s) of the patient's kidney transplant(s). If reentering the Medicare program, enter current transplant date.

28. Enter the name of the hospital where the patient received a kidney transplant on the date in Item 27.

29. Enter the 6-digit Medicare identification code of the hospital in Item 28 where the patient received a kidney transplant on the date entered in Item 27.

30. Enter date patient was admitted as an inpatient to a hospital in preparation for, or anticipation of, a kidney transplant prior to the date of the actual transplantation. This includes hospitalization for transplant workup in order to place the patient on a transplant waiting list.

31. Enter the name of the hospital where patient was admitted as an inpatient in preparation for, or anticipation of, a kidney transplant prior to the date of the actual transplantation.

32. Enter the 6-digit Medicare identification number for hospital in Item 31.

33. Check the appropriate functioning or non-functioning block.

34. Enter the type of kidney transplant organ donor, Deceased, Living Related or Living Unrelated, that was provided to the patient.

35. If transplant is nonfunctioning, enter date patient returned to a regular course of dialysis. If patient did not stop dialysis post transplant, enter transplant date.

36. If applicable, check where patient is receiving dialysis treatment following transplant rejection. A nursing home or skilled nursing facility is considered as home setting.

Self-dialysis Training Patients (Medicare Applicants Only)
Normally, Medicare entitlement begins with the third month after the month a patient begins a regular course of dialysis treatment. This 3-month qualifying period may be waived if a patient begins a self-dialysis training program in a **Medicare approved training facility** and is expected to self-dialyze after the completion of the training program. Please complete items 37-42 if the patient has entered into a self-dialysis training program. Items 37-42 must be completed if the patient is applying for a Medicare waiver of the 3-month qualifying period for dialysis benefits based on participation in a self-care dialysis training program.

37. Enter the name of the provider furnishing self-care dialysis training.

38. Enter the 6-digit Medicare identification number for the training provider in Item 32.

39. Enter the date self-dialysis training began.

40. Check the appropriate block which describes the type of self-care dialysis training the patient began. If the patient trained for hemodialysis, enter whether the training was to perform dialysis in the home setting or in the facility (in center). If the patient trained for IPD (Intermittent Peritoneal Dialysis), report as Other.

41. Check the appropriate block as to whether or not the physician certifies that the patient is expected to complete the training successfully and self-dialyze on a regular basis.

42. Enter date patient completed or is expected to complete self-dialysis training.

43. Enter printed name and signature of the attending physician or the physician familiar with the patient's self-care dialysis training.

44. Enter the National Provider Identifier (NPI) or the Unique Physician Identification Number (UPIN) of physician in Item 43. (See Item 47 for explanation of UPIN.)

45. Enter the name of the physician who is supervising the patient's renal treatment at the time this form is completed.

46. Enter the area code and telephone number of the physician who is supervising the patient's renal treatment at the time this form is completed.

47. Enter the National Provider Identifier (NPI) or the Unique Physician Identification Number (UPIN) of physician in Item 45

A system of physician identifiers is mandated by Section 9202 of the Consolidated Omnibus Budget Reconciliation Act of 1985. It requires a unique identifier for each physician who provides services for which Medicare payment is made. An identifier is assigned to each physician regardless of his or her practice configuration. The UPIN is established in a national Registry of Medicare Physician Identification and Eligibility Records (MPIER). Transamerica Occidental Life Insurance Company is the Registry Carrier that establishes and maintains the national registry of physicians receiving Part B Medicare payment. Its address is: UPIN Registry, Transamerica Occidental Life, P.O. Box 2575, Los Angeles, CA 90051-0575.

The NPI is established by the NPI Enumerator located in Fargo, North Dakota. The NPI Enumerator may be contacted by:

Phone: (800)465-3203 or TTY (800)692-2326.
Email: customerservice@npienumerator.com.
Mail: NPI Enumerator, P.O. Box 6059, Fargo, ND 58108-6059.

48. To be signed by the physician supervising the patient's kidney treatment. Signature of physician identified in Item 45. A stamped signature is unacceptable.

49. Enter date physician signed this form.

50. To be signed by the physician who is currently following the patient. If the patient had decided initially not to file an application for Medicare, the physician will be re-certifying that the patient is end stage renal, based on the same medical evidence, by signing the copy of the CMS-2728 that was originally submitted and returned to the provider. If you do not have a copy of the original CMS-2728 on file, complete a new form.

51. The date physician re-certified and signed the form.

52. This remarks section may be used for any necessary comments by either the physician, patient, ESRD Network or social security field office.

53. The patient's signature authorizing the release of information to the Department of Health and Human Services must be secured here. **If the patient is unable to sign the form, it should be signed by a relative, a person assuming responsibility for the patient or by a survivor**.

54. The date patient signed form.