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COVID-19 and Dialysis: What's Past Is Prologue

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In late February 2020, the United States had its first reported coronavirus disease 2019 (COVID-19) death, a nursing home resident in the Seattle, Washington area who had been receiving outpatient dialysis.[1] Since then, multiple studies have shown that maintenance dialysis patients are a vulnerable population in the COVID-19 pandemic, with very high rates of hospitalization and mortality, likely related to limited ability to physically distance as well as a high burden of comorbid conditions.[2]

Related article, 100537

The pandemic has upended the US health care system; early measures to conserve health care resources have since yielded to critical staffing shortages in a vastly changed working landscape. Against this backdrop, dialysis care has been evolving constantly to meet each new crisis of the pandemic. Within this context, the Centers for Medicare & Medicaid Services (CMS) is now grappling with how to account for the impact of COVID-19 on dialysis care in the US given that Medicare, either through fee-for-service or via Medicare Advantage, serves as the primary insurer for the majority of patients receiving maintenance dialysis. Accordingly, CMS is considering various approaches to adjust for COVID-19 in the quality metrics it uses to incentivize high-quality dialysis care in the End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP).

In this issue of *Kidney Medicine*, Ding and colleagues[3] developed a model using data from Medicare patients receiving maintenance dialysis to account for hospitalizations in the context of the turmoil faced by the health care system throughout 2020 and beyond. This model serves 2 purposes. First, its pragmatic purpose is to inform CMS-led discussions about how to appropriately adjust for the impact of COVID-19 on the quality metrics used to evaluate dialysis facilities through the ESRD QIP. Specifically, the authors address the Standardized Hospitalization Ratio, which CMS defines as the ratio of the number of observed versus expected hospitalizations, risk-adjusted for patient case mix and excluding patients new to dialysis or to the dialysis facility as well as those withdrawing from dialysis.[4] Because COVID-19 had such uneven geographic and temporal distribution, a methodology to adjust for the variable impact of COVID-19 is needed to maximize the likelihood for a fair distribution of ESRD QIP penalties for quality of care. Second, in the course of analyzing these data, the investigators developed a time-dependent model of individuals' hospitalization and mortality risks as they progress through the course of COVID-19. Namely, hospitalization and mortality risks are vastly increased in Stage 1, defined by the authors as the first 10 days after a COVID-19 diagnosis, and, although attenuated thereafter, the increased hospitalization risk relative to those without COVID-19 persists well beyond the initial period. Although their analyses were limited to 2020, this approach and its utilization in quality measures may be applicable throughout the COVID-19 era and beyond.

In June 2022, CMS published the Calendar Year (CY) 2023 ESRD Prospective Payment System Proposed Rule (CMS-1768-P).[5] In this, CMS proposed suppressing the Standardized Hospitalization Ratio along with multiple other clinical measures in the ESRD QIP, including the Standardized Readmission Ratio, the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems, the Long-Term Catheter Rate, the Percentage of Prevalent Patients Waitlisted, and Dialysis Adequacy, for CY 2021/payment year (PY) 2023. This follows the 2022 ESRD Prospective Payment System Final Rule where performance on the Standardized Hospitalization Ratio, Standardized Readmission Ratio, In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems, and Long-Term Catheter Rate for CY 2020 was also suppressed in the setting of the COVID-19 public health emergency and, additionally, dialysis facility payment reductions under the ESRD QIP were suspended.[6] Importantly, measure suppression served 2 purposes: (1) avoiding penalizing dialysis facilities for the impact of the COVID-19 public health emergency on provision of dialysis care in 2020; and (2) accounting for questionable data quality received by CMS in 2020 because of a transition from CROWNWeb to the new ESRD Quality Reporting System.[6] Notably, both the 2022 Final Rule, released in November 2021, and the 2023 Proposed Rule, released in July 2022, propose using data from CY 2019 to determine baseline performance standards that will inform quality thresholds for both CY 2021/PY 2023 and CY 2022/PY 2024 rather than using data from CY 2020/PY 2022.

Given the enormous impact of COVID-19 on hospitalization rates among maintenance dialysis patients, assessment of dialysis facility quality measures during and after 2020 must account for the disruptions in care resulting from the pandemic. Recognizing this, CMS has proposed a COVID-19 patient level adjustment for the Standardized Hospitalization Ratio and Standardized Readmission Ratio based on the work by Ding and colleagues[3]; however, this would not be incorporated until CY 2023/PY 2025 and fails to address the issue of what data should serve as a baseline for current quality comparisons. Given the impact of the pandemic on health care in 2020 and beyond, using unadjusted CY 2019 data for this purpose is inappropriate, as would be using CY 2020 data because of its aforementioned limitations. One potential approach is to

simulate the impact of COVID-19 on pre-COVID data, such as through incorporation of a time-varying regional COVID-19 hospitalization adjustment to facility data from calendar year 2019. Other potential solutions include using CY 2021 data as a new baseline and continuing the suppression of quality performance data reporting and penalties through CY 2021. Ultimately, quality measures are only as useful as their ability to meaningfully measure the care that is provided, and appropriately accounting for the ongoing impact of COVID-19 is critical to measuring quality going forward.

At the individual patient level, the work by Ding et al[3] traces over time the increased risk for hospitalization and mortality among dialysis patients with or recently recovered from COVID-19. The strong association between COVID-19 and hospitalization during the first 10 days after diagnosis reflects the pandemic's early course. In particular, the initial spring 2020 COVID-19 surge was characterized by low testing availability and limited medical knowledge of this new disease. As a result, most COVID-19 cases were diagnosed on presentation to the hospital, when the clinical picture had already progressed to severe COVID-19. The late presentation in the setting of limited available therapies further accounts for the high mortality rate associated with COVID-19, approximately 20% among maintenance dialysis patients.[2] Notably, many maintenance dialysis patients died after prolonged hospitalizations, and the high mortality rate even after the first 10 days (designated as "COVID2" in this study) may reflect the typical clinical course of severe COVID-19.[7,8]

Critically, Ding and colleagues[3] also show that, among maintenance dialysis patients, the association between COVID-19 status and increased risk of hospitalization persists well beyond the initial acute periods. This continued increase in risk may represent deconditioning during the acute illness, particularly during hospitalization. Not only did patients with COVID-19 experience lengthy admissions in 2020, many also had prolonged periods of ventilator dependence and associated immobility.[9] Because of a high burden of comorbid conditions, most patients receiving maintenance dialysis require greater time and support to recover from a prolonged admission; in the meantime, hospital-acquired frailty increases their vulnerability to future illness and complications,[10] even after recovery from COVID-19 itself.

Prevention of severe COVID-associated disease is critical to reducing the short and longer term risk of hospitalization among maintenance dialysis patients. Although these patients comprise a high risk population, as of September 2022, the vaccination guidelines of the Centers for Disease Control and Prevention remain ambiguous for patients with advanced chronic kidney disease, acknowledging that they are at increased risk for poor outcomes but not specifically recommending a 3-dose primary series over a 2-dose series as they do for patients receiving immunosuppressive medications.[11] As of late August 2022, 38% of maintenance dialysis patients have not yet received a third vaccine dose.[12] Given the exceptionally high risk of hospitalization and mortality among maintenance dialysis patients with COVID-19 and the ready availability of vaccines, it is critical that all maintenance dialysis patients receive sufficient vaccination, preferably with a 3-dose primary mRNA vaccine series followed by all applicable boosters, including a bivalent booster. The findings in this study and in other similar studies strongly support widespread vaccination of the dialysis population; consideration should be made to adding COVID-19 vaccination status as an ESRD QIP reporting measure.

In addition, the findings in this study suggest a need for greater postdischarge support for maintenance dialysis patients. These patients often have limited mobility and rely on shared transportation. Their high comorbidity burden requires appointments with multiple specialists in addition to thrice-weekly in-center hemodialysis for most or home dialysis for some. The time and energy needed by patients and their families to coordinate all of this care leaves little reserve to manage an acute illness like COVID-19, and, as suggested by Ding and colleagues,[3] they continue to require greater support after COVID-19 recovery.

The COVID-19 pandemic has indelibly changed the health care landscape, and CMS is developing methodologies to account for this upheaval in its evaluation of dialysis facilities via the ESRD QIP. Importantly, the overarching goal remains unchanged—incentivizing high-quality dialysis care. To this end, vaccines are a critical tool to reduce COVID-19 related hospitalizations and death. In recommending and facilitating broad vaccination, including a 2- to 3-dose primary series and boosters, the nephrology community can provide better patient care, aligning with the ESRD QIP's structure of metrics and incentives and helping establish a new quality baseline. Ultimately, we hope to establish a new normal that can serve as a foundation for future quality improvement efforts.

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