



April 17, 2023

Karen Hacker, MD, MPH

Director

National Center for Chronic Disease Prevention and Health Promotion

Centers for Disease Control and Prevention

1600 Clifton Road, Atlanta, GA 30329

Dear Dr. Hacker,

I am writing on behalf of Kidney Care Partners (KCP) to provide a set of consensus-based recommendations that an expert panel and the Steering Committee of the Kidney Care Quality Alliance (KCQA)¹ developed related to the fielding of the NHSN Bloodstream Infection (BSI) measure that is included in the Medicare End Stage Renal Disease (ESRD) Quality Incentive Program (QIP). KCP believes that if CDC were to adopt these recommendations and CMS supported their implementation in the ESRD QIP, then many of the concerns raised by the community about the reliability and validity of the measure would be addressed. We would welcome the opportunity to meet with you virtually to discuss how these suggestions could be incorporated in the near future. KCP views improving the NHSN BSI measure as critically important to improving patient safety and antimicrobial stewardship, which are two goals we know that the CDC and CMS share.

The Kidney Care Quality Alliance (KCQA) was created in 2005 as a quasi-independent sister organization to KCP. The primary purpose of KCQA is to develop dialysis-facility level performance measures specifically for use in federal ESRD quality programs such as the ESRD QIP, Five-Star Program, and now the ETC and KCC innovation models. Its mission is to develop dialysis facility-level performance measures that are evidence-based, empirically sound, and community-supported; that appropriately address social risk and health inequities; and that effectively meet the unique needs of dialysis patients, providers, other members of the kidney care community, and federal policymakers. KCQA is guided by a Steering Committee and has a broad-based membership of leading stakeholders in kidney care. Technical experts from the community are invited to participate in expert panels that develop the specifications of candidate measures.

KCQA's successes in helping shape the ESRD quality agenda are well-documented; since its inception, we have received National Quality Forum (NQF) endorsement for seven of ten measures developed to date on topics ranging from hemodialysis vascular access, immunization, patient education, fluid management, and medication reconciliation. Other measures were used by NQF to materially refine and improve competing measures through

¹A list of the expert work group panel and the Steering Committee are available in Appendix A.

its Consensus Development Process. A number of KCQA's measures have now been formally incorporated into the QIP and Five-Star.

I. Background

KCP has raised concerns about the reliability and validity of the BSI measure since its inception in the ESRD QIP. The CDC's research shows that the measure is not a valid representation of the care provided. Knowing the importance of this measure, the KCQA convened an expert panel to review the measure and offer solutions to the validity problem so that the QIP can include a measure that is meaningful for patients, caregivers, and health care professions in addressing blood stream infections.

Patient and patient advocates, as well as health care professionals, have raised concerns that the current measure produced results that can mislead patients and caregivers into believing a facility is performing better or worse than it actually is. Given the understandable importance that patients place on a facility's ability to manage blood stream infections, a measure that fails to accurately represent the facility's performance deprives patients of their ability to make informed health care decisions and may obscure social disparities. It also unfairly penalizes facilities that diligently pursue and report the hospital infection data necessary for a full picture of infection rates.

The KCP supports the recommendations identified through the KCQA. While they may not address every potential issue, we believe that these changes will improve the ability of facilities to report blood stream infections and lead to results that more accurately reflect the actual performance of each dialysis facility. This step will not only help patients and caregivers make better decisions, but it will also improve CDC's ability to achieve the goals it has established for tracking BSIs in the dialysis setting.

II. Recommendations

The KCQA has identified the following set of concerns and provided specific recommendations to resolve each concern.

- Concern: CDC requires the numerator and denominator data for acute kidney injury (AKI) infections to be reported separately from ESRD infections, and this results in inaccurate data and provider burden.
 - Recommendation: CDC to apply logic in its system to distinguish between AKI and ESRD infections rather than have the facilities report this information.

- Concern: Monthly Reporting Plan required before data can be entered into NHSN by the dialysis facilities, and this can have negative implications on a facility's quality improvement program scores.
 - Recommendation: Eliminate this requirement.
- Concern: Facilities must complete the Annual Outpatient Dialysis Center Practices Survey by April 30 of each year in order to submit data to NHSN. This survey is long and burdensome.
 - Recommendation: Establish a Technical Expert Panel (TEP) to streamline the survey instrument and eliminate the requirement to complete the survey before submitting data.
- Concern: Current processes require reporting of infections in all vascular accesses even if not used for dialysis; this leads to inaccurate reporting (both under- and over-reporting).
 - Recommendation: Facility to report all accesses and CDC to apply risk stratification via system logic.
- Concern: The 21-day rule requires at least 21 days between infection events for the second event to be reported separately, and this leads to both under- and over-reporting.
 - Recommendation: Allow facilities to report all events and have the CDC apply the 21-day rule using system logic.
- Concern: If a positive culture is drawn in a hospital, the dialysis facility is still responsible for reporting these cultures. There is confusion regarding the existing "one calendar day after admission" specification and it is burdensome for dialysis facility staff to try to track down the blood culture from the hospital or laboratory.
 - Recommendation: Eliminate the requirement for dialysis facilities to report positive cultures drawn in the hospital and have CDC's system apply an attribution logic to attribute these findings to the appropriate dialysis facility. We propose to modify the specifications to address the one-calendar-day confusion.

III. Conclusion

KCP appreciates the efforts the CDC has undertaken to try to address BSI in the dialysis setting. Reducing BSI is a priority for KCP and the entire kidney care community. We encourage the CDC to adopt the recommendations set forth by the KCQA and supported by KCP to address at least some of the reliability and validity concerns identified by the kidney care community with the current implementation practices. Our counsel in Washington, Kathy Lester, will be in touch to request a virtual meeting to discuss these recommendations. In the meantime, if you have questions about the KCQA's

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recommendations, please feel free to contact her directly. She can be reached at klester@lesterhealthlaw.com or 202-534-1773.

Sincerely,

A handwritten signature in black ink, appearing to read 'John Butler', with a stylized flourish extending to the right.

John Butler

Chairman

cc: Michelle Schreiber, M.D., Deputy Director for Quality & Value; Director Quality Measurement & Value-Based Incentives Group
Tamyra Garcia, Deputy Director Quality Measurement & Value-Based Incentives Group
Reid Kiser, Director, Division of Quality Measurement
Vinitha Meyyur, Deputy Director, Division of Quality Measurement

Appendix: KCP Members

Akebia Therapeutics, Inc.
American Kidney Fund, Inc.
American Nephrology Nurses Association
American Society of Nephrology
American Society of Pediatric Nephrology
Ardelyx
AstraZeneca
Atlantic Dialysis Management Services, LLC
Baxter International, Inc.
Cara Therapeutics, Inc.
Centers for Dialysis Care
CorMedix Inc.
CSL Vifor
DaVita, Inc.
Dialysis Patient Citizens, Inc.
DialyzeDirect
Fresenius Medical Care North America
GlaxoSmithKline
Greenfield Health Systems
Kidney Care Council
North American Transplant Coordinators Organization
Nephrology Nursing Certification Commission
Renal Healthcare Association
Renal Physicians Association
Renal Support Network
Rogosin Institute
Satellite Healthcare, Inc.
U.S. Renal Care, Inc.