

Kidney Health Initiative ESKD Data Standards Project

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The end-stage kidney disease (ESKD) Data Standards Project was launched by the Kidney Health Initiative (KHI) with the goal of standardizing dialysis-related measurements for research use. KHI is a public-private partnership between the American Society of Nephrology, US Food and Drug Administration, and organizations with an interest in kidney disease. KHI promotes safe and effective patient-centered therapies for people with kidney disease. In 2018, KHI established a workgroup with expertise in nephrology, nursing, quality management, ESKD data, organizational management, and clinical research. The workgroup identified 5 topic areas and 8 specific measures for the development of standards on the basis of the existing ESKD Measurement Specification Manual published by the Centers for Medicare & Medicaid Services. The topic areas were ultrafiltration rate, vascular access, dialysis small solute clearance (3 data standards), hospitalization (2 data standards), and mortality. The research standards were approved by the workgroup, reviewed by external reviewers, and opened to public comment. The data standards attempt to achieve balance between brevity and completeness in the face of knowledge gaps. The ESKD Data Standards are publicly available on the KHI website (<https://khi.asn-online.org/projects/project.aspx?ID=78>).

Complete author and article information provided before references.

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Kidney Med. 4(8):100495. Published online May 27, 2022.

doi: 10.1016/j.xkme.2022.100495

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KIDNEY HEALTH INITIATIVE END-STAGE KIDNEY DISEASE DATA STANDARDS PROJECT

The Kidney Health Initiative (KHI) launched the end-stage kidney disease (ESKD) Data Standards Project with the goal of standardizing dialysis-related measurements for research use. The project was motivated by recognition of the central importance of data and measurement for successful delivery of dialysis. Dialysis providers and researchers seek to quantify multiple aspects of treatment, such as dialysis dose, ultrafiltration rate, and mortality rate. Accurate measurement underlies many interrelated activities, including research, education, patient care, quality management, and regulatory compliance. Data from multiple sources frequently populate the data registries used to generate new dialysis-related research. Stakeholders, including the Global Chief Medical Officers of the multinational dialysis service providers, expressed concerns about the relative lack of standardization of registry data originating from different sources.¹

KHI, a public-private partnership between the American Society of Nephrology, the US Food and Drug Administration, and over 100 companies and organizations in the kidney community, is focused on catalyzing the development of safe and effective patient-centered therapies for people with kidney disease.² Twice a year, KHI solicits project ideas from the membership to convene multidisciplinary stakeholders for precompetitive work that will address barriers to this development. Through a partnership with the Clinical Data Interchange Standards Consortium, data standards in solid organ transplantation and diabetic kidney diseases were published as official Clinical Data Interchange Standards Consortium Therapeutic User Guides.^{3,4} In addition to the Global Chief Medical Officers,

KHI leadership had expressed interest in a KHI project focused on ESKD data standards. The project was endorsed in February 2018 and launched with a broad charge to develop dialysis measurement standards that support interoperability, comparability, and maximal predictive value across the interrelated dialysis activities.

KHI solicited project volunteers from the dialysis community via the standard KHI Call for Workgroup (<https://khi.asn-online.org/projects/workgroups.aspx>). In November 2018, KHI assembled a workgroup of 12 members (reduced to 9 through attrition) and support staff. The complete list of KHI workgroup members is available on the KHI website.⁵ The group represented multiple stakeholders, including academic institutions, dialysis organizations, and research organizations with expertise in nephrology, nursing, quality management, ESKD data, organizational management, and clinical research. The group was asked to define a core ESKD patient dataset by starting with the existing ESKD Measurement Specification Manual published by the Centers for Medicare & Medicaid Services.⁶ The workgroup was given latitude to determine key steps and deliverables, including specific measurement standards, group approval process, presentation format, dissemination plan, and other strategic and operational issues. In December 2018, the workgroup prioritized the top 5 areas for the data standards: volume removal, vascular access, small solute clearance, hospitalization, and mortality.

Project members conducted regular virtual meetings. The initial meetings were used to establish organizational principles that ultimately developed the standard template for the data standards. Several underlying principles

emerged. The workgroup confirmed the initial focus on standardized measures for research purposes as opposed to overlapping but distinct activities such as clinical management and quality assurances. The workgroup decided to produce relatively brief, focused data standard documents that would serve as a reference for most research-based data collection efforts. The standards would be particularly helpful to new dialysis researchers and may improve the comparability of findings. The project team decided against creating a detailed treatise on each measure. Rather, the data standards seek to summarize the current state of measurement for research purposes. Knowledgeable researchers may have valid reasons for deviating from some standards. The workgroup recognized that data standards may change over time and require periodic updates. Although the data standards project was initially conceived as a global effort, it became apparent that using the Centers for Medicare & Medicaid Services Measurement Manual directed the project toward measurements and standards that were not necessarily applicable to all regions. However, this effort could be

used to inform other data standardization efforts around the world.

The workgroup identified 5 topic areas and 8 specific measures for the development of measurement standards (Table 1). To develop a standardized approach to specifications, the committee developed an outline for each data standard that included the following elements: description, rationale, data source(s), required and derived data elements, calculation method, exclusions, additional desirable data elements to collect, additional considerations, acronyms, and references. The 8 data standards were assigned to a total of 5 subgroups, with each subgroup consisting of 2-3 committee members. The subgroups addressed the following topic areas: ultrafiltration rate, vascular access, dialysis small solute clearance (3 data standards), hospitalization (2 data standards), and mortality. Each subgroup was responsible for the initial drafting of the assigned data standard(s). After initial drafting, the data standards were presented and discussed by the full committee and subsequently underwent further revisions and full committee review and approval.

Table 1. Selected ESKD Data Standards

Topic Area	Data Standard	Required Data Elements
UFR	Single treatment net UFR	<ul style="list-style-type: none"> • Predialysis and postdialysis weight (kg) • Delivered treatment time (min)
Vascular access	HD vascular access	<ul style="list-style-type: none"> • Vascular access type and location used during HD treatment • Presence and location of maturing vascular access, if applicable • Presence and location of central venous catheter not in use, if applicable
Small solute clearance	Weekly urea Kt/V for PD	<ul style="list-style-type: none"> • Collection time (min) and volume (mL) for PD fluid • Urea concentration of collected PD fluid (mg/dL) • Collection time (min) and volume (mL) for urine • Urea concentration of collected urine (mg/dL) • Plasma urea concentration (mg/dL) • Estimated dry weight (kg) • Height (cm), sex, and age (y)
Small solute clearance	spKt/V and eKt/V	<ul style="list-style-type: none"> • Predialysis and postdialysis weight (kg) • Predialysis and postdialysis BUN (mg/dL) • Delivered treatment time (min)
Small solute clearance	Standard weekly urea Kt/V for HD	<ul style="list-style-type: none"> • eKt/V • Urea distribution volume (L) • Delivered treatment time (min) • Number of hemodialysis treatments in a week • Weekly ultrafiltration volume (L) • Residual kidney function (mL/min)
Hospitalization	Hospital admission	<ul style="list-style-type: none"> • Acute care hospital admission(s) and discharge(s) dates • Start date and end date of follow-up time • Cause of end of follow-up
Hospitalization	Hospital readmission	<ul style="list-style-type: none"> • Acute care hospital admission(s) and discharge(s) dates • Start date and end date of follow-up time • Cause of end of follow-up • Time period after hospital discharge where subsequent hospitalization is defined as a readmission • Vital status at the time of hospital discharge
Mortality	Mortality	<ul style="list-style-type: none"> • Vital status during observation period • Start date and end date of follow-up time • Types of censoring events, if applicable

Note: Detailed data specifications, including derived data elements, calculation methods, and important considerations, are available on the KHI website.⁵
Abbreviations: BUN, Blood urea nitrogen; eKt/V, equilibrated urea Kt/V; ESKD, end-stage kidney disease; HD, hemodialysis, PD, peritoneal dialysis; spKt/V, single-pool urea Kt/V; UFR, ultrafiltration rate.

Table 2. KHI Project Timeline

Date	Activity
Fall 2017	Project submitted to KHI for membership review and comment KHI review and selection
February 2018	KHI Board of Directors endorsed project for initiation
June 2018	KHI Call for Workgroup applications
July-September 2018	Co-chairs confirmed and workgroup selected
November 2018	First workgroup meeting
November-December 2018	Measure prioritization
January-March 2019	Creation of standardized approach
March-October 2019	Subgroup meetings and drafting of data standards Subgroup presentations and discussion with full committee Full committee review and approval
December 2019-July 2020	Committee work paused by KHI because of COVID-19 and KHI staffing
August-September 2020	Initial external expert review
October 2020-January 2021	Revisions to data standards on the basis of external expert review
November 2020	Development of a dissemination plan and survey for public comment
March-April 2021	Public comment period
May 2021	Review of public comments
May-June 2021	Revisions and finalization of standards

Abbreviations: COVID-19, Coronavirus disease 2019; KHI, Kidney Health Initiative.

The data standards then underwent initial external review by individuals with expertise in nephrology, epidemiology, biostatistics, and/or clinical research. The external review provided the basis for further discussion and revisions to the data standards before dissemination for public comment. To obtain public comment, KHI posted the data standards on their website and disseminated the data standards to all KHI members, Chief Medical Officers of dialysis organizations, and other individuals identified by the committee or a member of the current or former KHI Board of Directors. The comments provided during the public comment period were reviewed by the committee, and further revisions, as applicable, were undertaken. An overview of the approximate timeline of activities is shown in Table 2. The final ESKD Data Standards (<https://khi.asn-online.org/projects/project.aspx?ID=78>) are publicly available on the KHI website.⁵ The final documents represent consensus approval by the full workgroup.

The challenges and limitations include the long process of developing the KHI Data Standards; the KHI directive to use the Centers for Medicare & Medicaid Services Measurement Manual as the basis for selecting data standards, resulting in a limited range of topics and the absence of patient-reported outcomes; achieving the optimal balance between brevity and completeness; reconciling the desire

for standardization against gaps in knowledge; competing commitments because of the coronavirus disease 2019 pandemic; and the absence of a future process for updating the data standards.

In conclusion, the KHI ESKD Data Standards provide an overview of key research considerations for select measures relevant to research in populations with kidney failure receiving maintenance dialysis. The data standards were developed by a broad range of experts and were refined on the basis of public comment and feedback. The data standards are publicly available to the community and support ongoing efforts to advance research in kidney disease.

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Support: This work was supported by the Kidney Health Initiative (KHI), a public-private partnership between the American Society of Nephrology, US Food and Drug Administration, and more than 100 member organizations and companies to enhance patient safety and foster innovation in kidney disease. KHI funds were used to defray costs incurred during the conduct of this project, including project management support, which was expertly provided by Grace Squillaci and the American Society of Nephrology staff members. There was no honorarium, or other financial support, provided to the KHI workgroup members. The authors of this paper had final review authority and are fully responsible for its content. KHI makes every effort to avoid actual, potential, or perceived conflicts of interest that may arise as a result of industry relationships or personal interests among the members of the workgroup. More information on KHI, the workgroup, or the conflict-of-interest policy can be found at www.kidneyhealthinitiative.org.

Financial Disclosure: Dr Dalrymple is employed by Fresenius Medical Care and her spouse is employed by Kaiser Permanente; Dr Dalrymple has share options in Fresenius Medical Care and owns stock in GE, and her spouse has shares in The Permanente Medical Group and owned stock in GE, CVS, and Bayer in the last 36 months. Dr Dalrymple serves on the Kidney Medicine Editorial Board, NQF Renal Standing Committee (co-chair), and the KCQA Steering Committee. Dr Young is employed by Arbor Research Collaborative for Health. His effort is partially supported by contracts from the Centers for Medicare & Medicaid Services

and by the Dialysis Outcomes & Practice Patterns Study, which is supported by multiple nonprofit, governmental, and private sector sources (www.ArborResearch.org/Support/FundingSources.aspx). Dr Farag is employed by and has ownership interest in Goldfinch Bio, Inc has and received honoraria from Harvard Medical School. Dr Fischer is employed by the University of Illinois Hospital and Health Sciences Center, Department of Veterans Affairs, and serves on the National Kidney Foundation of Illinois Scientific Advisory Board and Executive Committee. Author Hamilton is employed by and has ownership interest in Fresenius Medical Care. Author Hussein is employed by Satellite Healthcare. Dr Lacson Jr is employed by Dialysis Clinic, Inc. Dr Lacson has no conflicts of interest to disclose. Dr Ofsthun is employed by and has share options in Fresenius Medical Care. Dr Tentori is employed by DaVita Clinical Research and serves on the Ardelyx Medical Advisory Board. Author West is employed by the American Society of Nephrology.

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Peer Review: Received November 29, 2021. Evaluated by 2 external peer reviewers, with direct editorial input from an Associate Editor, who served as Acting Editor-in-Chief. Accepted in revised form April 1, 2022. The involvement of an Acting Editor-

in-Chief was to comply with Kidney Medicine's procedures for potential conflicts of interest for editors, described in the Information for Authors & Journal Policies.

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