CBE ID

1423

Title

Minimum spKt/V for Pediatric Hemodialysis Patients

Project

Management of Acute Events, Chronic Disease, Surgery, and Behavioral Health

Endorsement Status

Endorsed with Conditions

E&M Committee Rationale/Justification

When the measure returns for maintenance (5 years), the measure developer should have:

- Aligned with any forthcoming CBE polices around pediatric population measures;
- Explored meaningfulness with patients/parents/caregivers that have direct lived experience in this measure area; and
- Explored the potential for risk adjustment based on patient age.

Is Under Review

No

Next Maintenance Cycle

Fall 2029

Previous Endorsement Cycle

Fall 2024

Initial Endorsement

Tue, 08/16/2011 - 11:35

Steward

Centers for Medicare & Medicaid Services

1.0 New or Maintenance

Maintenance

1.1 Measure Structure

Single Measure

1.3 Electronic Clinical Quality Measure (eCQM)

No

1.6 Measure Description

Percentage of patient months for all pediatric (<18 years old) in-center hemodialysis patients in which the delivered dose of hemodialysis (calculated from the last measurement of the month using the UKM or Daugirdas II formula) was spKt/V >= 1.2.

1.7 Composite Measure

No

1.7 Measure Type

Intermediate Outcome

1.8 Level of Analysis

Facility

1.9 Care Setting

Other

1.9b Other Care Setting

Dialysis Facility

1.10 Measure Rationale

In considering target spKt/V, the pediatric population should receive at least a spKt/V of 1.2, which is the minimum requirement for the adult population in order to allow for the increased nutritional needs of children. Analysis of CPM data further support this cut-off since adolescents with spKt/V below 1.2 were found to have significantly increased risk of hospitalization as compared to those with spKt/V of 1.2-1.4.

1.13 Data Dictionary

Not attached. I attest that all information will be provided where codes and/or value sets are needed (1.14a - 1.15c).

1.13a Attach Data Dictionary

1423_Data_Dictionary.xlsx

1.14 Numerator

Number of patient months from the denominator in which the delivered dose of hemodialysis (calculated from the last measurement of the month using the UKM or Daugirdas II formula) was spKt/V >= 1.2.

1.14a Numerator Details

Months with spKt/V >=1.2 are counted in the numerator. Eligible spKt/V values are those >=1.2 during the reporting month. The last spKt/V value reported (from any facility), not including missing, expired, out-of-range, and not performed, is selected when multiple values are reported in the month. EQRS is the primary data source for obtaining Kt/V values, supplemented by Medicare claims when values are missing or out-of-range.

Missing, expired, out-of-range, and not performed are not counted as achieving the minimum spKt/V threshold.

1.15 Denominator

To be included in the denominator for a particular month, a patient must be on hemodialysis for the entire month, must be <18 years old at the beginning of the month, must have had ESRD for greater than 90 days at the beginning of the month, must be on thrice weekly in-center hemodialysis during the month, and must be assigned to that facility for the entire month.

1.15a Denominator Details

A treatment history file is the data source for the denominator calculation used for the analyses supporting this submission. This file provides a complete history of the status, location, and dialysis treatment modality of an ESRD patient from the date of the first ESRD service until the patient dies or the data collection cutoff date is reached. For each patient, a new record is created each time he/she changes facility or treatment modality. Each record represents a time period associated with a specific modality and dialysis facility. EQRS is the primary basis for placing patients at dialysis facilities and dialysis claims are used as an additional source of information in certain situations. Information regarding first ESRD service date, death, and transplant is obtained from EQRS(including the CMS Medical Evidence Form (Form CMS-2728) and the Death Notification Form (Form CMS-2746)) and Medicare claims, as well as the Organ Procurement and Transplant Network (OPTN).

1.15b Denominator Exclusions

Exclusions that are implicit in the denominator definition include:

1. Patients on home hemodialysis
2. Patients on peritoneal dialysis
3. Adult patients (>=18 years old)
4. Patients on ESRD less than 91 days
5. Patients not on thrice weekly dialysis
6. Patients not assigned to the facility for the entire month

There are no additional exclusions for this measure.

1.15c Denominator Exclusions Details

There are no additional or explicit exclusions beyond what is embedded in the denominator's definition.

1.15d Age Group

Children (0-17 years)

1.16 Type of Score

Rate/proportion

1.17 Measure Score Interpretation

Better performance = Higher score

1.18 Calculation of Measure Score

Denominator:

For the reporting month, patients are included in the denominator if:

- Patient modality is indicated as Hemodialysis during the entire month (in-center)
- Patient is dialyzing thrice weekly during the month
- Patient age as of the beginning of the reporting month is less than 18 years
- Patient has had ESRD for greater than 90 days at the beginning of the month

- Patient is assigned to the facility for the entire month

Numerator:

For the reporting month, patient months from the denominator are also included in the numerator if they have a spKt/V >=1.2. The last spKt/V value reported (from any facility), not including missing, expired, out-of-range, and not performed, is selected when multiple values are reported in the month.

To obtain the measure score, the numerator is divided by the denominator to produce a rate of patients who meet the measure criteria.

1.19 Measure Stratification Details

The measure is not stratified.

1.20 Types of Data Sources

Claims Data, Registries

1.25 Data Source Details

For the analyses supporting this submission, the measure is calculated using EQRS as the primary data source for the Kt/V values used to determine the numerator. If a patient's Kt/V data are

missing in EQRS, Kt/V values from Medicare claims are used as an additional source for obtaining that information.

EQRS is the primary basis for placing patients at dialysis facilities and dialysis claims are used as an additional source. Information regarding first ESRD service date, death, age and incident comorbidities adjustments and transplant is obtained from EQRS (including the CMS Medical Evidence Form (Form CMS-2728) and the Death Notification Form (Form CMS-2746)) and Medicare claims, as well as the Organ Procurement and Transplant Network (OPTN) and the Social Security Death Master File.

1.26 Minimum Sample Size

Public reporting of this measure on DFCC or in the ESRD QIP would be restricted to facilities with at least 11 eligible patients for the measure to comply with restrictions on reporting of potentially patient identifiable information related to small cell size. We have applied this restriction to all the reliability and validity testing reported here.

2.1 Attach Logic Model

1423_Importance_Logic Model_508.pdf

2.2 Evidence of Measure Importance

The primary source of evidence for this measure is the KDOQI guidelines for pediatric hemodialysis prescription and adequacy. The guideline states:

“8.3.1 Children should receive at least the delivered dialysis dose as recommended for the adult population. (A)”

Clinical Practice Guidelines for Hemodialysis Adequacy: KDOQI Guideline 8. Pediatric Hemodialysis Prescription and Adequacy: 2006.

http://www2.kidney.org/professionals/KDOQI/guideline_upHD_PD_VA/hd_guid...

KDOQI CPG 8.3.1 rating strength grade is ‘A’. The recommendation for Grade A guidelines states ‘It is strongly recommended that clinicians routinely follow the guideline for eligible patients. There is strong evidence that the practice improves health outcomes.’

In addition to the above guideline, the 2009 clinical pediatric dialysis adequacy TEP conducted a literature search, where we retrieved a total of 190 articles using several sources.

- First, we retrieved 79 articles using a PubMed search of articles with human subjects, published in English since January 1, 2005. The search terms were: [(pediatric OR pediatrics

OR children) and (dialysis OR hemodialysis OR peritoneal dialysis) and (adequacy OR "dialysis dose" OR "dose monitoring" OR "residual renal function" OR "urea clearance" OR "solute clearance" OR "phosphate clearance" OR "amino acid clearance" OR "folate clearance" OR "Kt/V" OR "peritoneal equilibration test" OR ("ultrafiltration" and peritoneal)) and NOT (cvvhd OR "continuous veno venous" OR transplant OR "kidney transplant" OR transplantation)].

- Second, we reviewed 61 citations from the Kidney Disease Outcomes Quality Initiative Guidelines on pediatric peritoneal dialysis and hemodialysis. Third, we reviewed the tables of contents of the journal Pediatric Nephrology and retrieved two articles from early on-line publishing that had not yet been included in PubMed. Finally, we reviewed the citations in 14 articles previously identified; this found an additional 65 articles for review. Duplicate articles were excluded.
- A total of 124 articles were found to be relevant for measure development. Four pieces of evidence listed below [1-4] were determined to be relevant to this specific measure.

An additional literature search was conducted in May 2014 and additional evidence has been added to the list of citations [5-8].

1. Lowrie EG, et al. Effect of the hemodialysis prescription of patient morbidity: report from the National Cooperative Dialysis Study. N Engl J Med 305:1176–1181, 1981.
2. Owen WF Jr, et al. The urea reduction ratio and serum albumin concentration as predictors of mortality in patients undergoing hemodialysis. N Engl J Med 329:1001–1006, 1993.
3. Gorman G, et al. Clinical outcomes and dialysis adequacy in adolescent hemodialysis patients. Am Journal Kidney Dis; 47: 285-93, 2006.
4. Fischbach M, et al. Intensified and daily hemodialysis in children might improve statural growth. Pediatr Nephrol 21:1746–1752, 2006.
5. Daugirdas JT. Dialysis dosing for chronic hemodialysis: beyond Kt/V. Semin Dial. 2014 Mar;27(2):98-107.
6. Kaur A, Davenport A. Hemodialysis for infants, children, and adolescents. Hemodial Int. 2014 Apr 14. doi: 10.1111/hdi.12163. [Epub ahead of print]
7. Dunne N, Campbell M, Fitzpatrick M, Callery P. Comparison of Kt/V and urea reduction ratio in measuring dialysis adequacy in paediatric haemodialysis in England.J Ren Care. 2014 Jun;40(2):117-24. doi: 10.1111/jorc.12059. Epub 2014 Mar 20.
8. Cadnapaphornchai MA, Teitelbaum I. Strategies for the preservation of residual renal function in pediatric dialysis patients. Pediatr Nephrol. 2014 May;29(5):825-36; quiz 832. doi: 10.1007/s00467-013-2554-0. Epub 2013 Jul 19.

An additional literature search was performed for the Fall 2024 maintenance review but no relevant publications were identified.

2.4 Performance Gap

Among the 15 facilities that have at least 11 eligible patients, we generated the following statistics of their performance scores (based on the patient month) using the January – December 2022

EQRS and Medicare claims data: mean=85.4% (SD=16.8%); min=41.7%; max=100.0%. Mean scores by decile are shown in Table 1 below. These results indicate that, on average, facilities are meeting the Kt/V guidelines in 85.4% of pediatric HD patients.

Note about Table 1: Deciles were defined differently between Tables 1 and 2. In Table 1, facilities are grouped and ranked according to ascending performance score. In Table 2, ranking is calculated on the basis of ascending facility size.

Table 1. Performance Scores by Decile

Performance Gap

	Overall	Minimum	Decile_1	Decile_2	Decile_3	Decile_4	Decile_5	Decile_6	Decile_7	Decile_8	Decile_9	Decile_10	Maximum
Mean Performance Score	85.42%	41.67%	64.27%	76.92%	86.91%	89.92%	91.81%	95.23%	97.47%	98.85%	100%	100%	100%
N of Entities	15	1	1	2	1	2	1	2	2	1	1	2	2
N of Persons / Encounters / Episodes	220	15	15	27	14	33	21	26	36	11	13	24	24

2.6 Meaningfulness to Target Population

In response to the question, we provide two examples:

- Direct evidence: when CMS held a Star Ratings TEP (comprised of approximately equal numbers of providers and patients) to discuss the fate of Kt/V inclusion in the Star Ratings composite reported on DFCC, the patients overwhelmingly voted to retain Kt/V as one important determinant of quality care in the dialysis facilities. Many individually expressed a high degree of comfort in being able to see the Kt/V monthly, to be reassured that at least that component of their dialysis treatments was at or above a minimum standard.
- Indirect evidence: most US dialysis patients achieve a Kt/V above 1.2 (HD) and 1.7 (PD). This achievement requires the cooperation of the patient, as they MUST provide consent for the length of treatment and other ordered dialysis parameters involved in achieving these targets. It is well documented in the literature that shortened dialysis treatments, for example, often result in lower Kt/V results. Thus, implicit consent from the patient, a member of the CMS-defined Interdisciplinary Team responsible for dialysis plan of care, is required to complete dialysis as ordered by the provider and executed by the interdisciplinary dialysis team.

3.1 Contributions Towards Closing Care Gaps

We are not providing a response to this optional question.

4.1 Feasibility Assessment

Data collection is accomplished primarily via EQRS, a web-based and electronic batch submission platform maintained and operated by CMS contractors, supplemented by Medicare claims.

Publicly reported measures like this one are reviewed on a regular basis by dialysis facility providers and rare instances of inaccurate or missing data are present (based on comments received during facility previews).

4.3 Feasibility Informed Final Measure

No changes were made.

4.4 Proprietary Information

Not a proprietary measure and no proprietary components

5.1.1 Data Used for Testing

For the Fall 2024 maintenance submission, calendar year 2022 EQRS and Medicare claims data were used.

5.1.2 Differences in Data

For the Fall 2024 maintenance submission, 15 facilities that had at least 11 eligible patients during January 2022 – December 2022 were included in the analyses. Public reporting of this measure on DFCC or in the ESRD QIP would be restricted to facilities with at least 11 eligible patients for the measure to comply with restrictions on reporting of potentially patient identifiable information related to small cell size. We have applied this restriction to all the reliability and validity testing reported here.

5.1.3 Characteristics of Measured Entities

For the Fall 2024 maintenance submission, 15 facilities that had at least 11 eligible patients during January 2022 – December 2022 were included in the analyses. Public reporting of this measure on DFCC or in the ESRD QIP would be restricted to facilities with at least 11 eligible patients for the measure to comply with restrictions on reporting of potentially patient identifiable information related to small cell size. We have applied this restriction to all the reliability and validity testing reported here.

5.1.4 Characteristics of Units of the Eligible Population

For the Fall 2024 maintenance submission, 218 pediatric hemodialysis dialysis patients were included. Out of all included patients, 100.0% were aged < 18, 48.6% were female, 2.3% were Native American, 3.7% were Asian, 0.5% were Pacific Islander, 43.1% were Black, 49.5% were White, 0.9% were Other/Multi-Racial, and 26.2% were Hispanic. Please note, the number of patients listed here may not match the total number of patients in Tables 1 and 2 due to patients being counted multiple times if they switched providers during the year.

5.2.1 Level(s) of Reliability Testing Conducted

Accountable entity level (i.e., measure score) (e.g., signal-to-noise analysis)

5.2.2 Method(s) of Reliability Testing

We used January 2022 – December 2022 EQRS and Medicare claims data to calculate the inter-unit reliability (IUR) for the overall 12 months, minimum, maximum, and within each decile to assess the reliability of this measure. The inter-unit reliability (IUR) measures the proportion of the measure variability that is attributable to the between-facility variance. The yearly based IUR was estimated using a bootstrap approach, which uses a resampling scheme to estimate the within facility variation that cannot be directly estimated by ANOVA. We note that the method for calculating the IUR was developed for measures that are approximately normally distributed across facilities. Since this measure is not normally distributed, the IUR value should be interpreted with some caution.

5.2.3 Reliability Testing Results

For the Fall 2024 maintenance submission, the annual IUR=0.873 across 12 reporting months, which suggests 87% of variation in the measure is attributed to between facility variations.

Note about Table 2: Deciles were defined differently between Tables 1 and 2. In Table 1, facilities are grouped and ranked according to ascending performance score. In Table 2, ranking is calculated on the basis of ascending facility size.

5.2.4 Interpretation of Reliability Results

For the Fall 2024 maintenance submission, the IUR again suggests this measure is reliable. However, since the distribution of performance scores is skewed, the IUR value should be interpreted with some caution.

Table 2. Accountable Entity Level Reliability Testing Results by Denominator, Target Population Size

Accountable Entity-Level Reliability Testing Results

	Overall	Minimum	Decile_1	Decile_2	Decile_3	Decile_4	Decile_5	Decile_6	Decile_7	Decile_8	Decile_9	Decile_10	Maximum
Reliability	0.873	0.838	0.838	0.849	0.849	0.859	0.859	0.864	0.872	0.876	0.902	0.919	0.919
Mean Performance Score	85.42%	97.47%	97.47%	96.99%	100.00%	82.95%	91.30%	76.89%	59.59%	86.84%	88.45%	96.48%	96.48%
N of Entities	15	1	1	2	1	2	1	2	2	1	2	1	1
N of Persons / Encounters / Episodes	220	11	11	24	12	26	13	27	29	15	39	24	24

5.3.1 Level(s) of Validity Testing Conducted

Person or encounter level (i.e., data element) (e.g., sensitivity and specificity)

5.3.1a Why Testing Not Conducted

Validity testing could not be conducted due to small patient population.

5.3.3 Method(s) of Validity Testing

Data elements in EQRS for quality measures that are used in value-based purchasing undergo regular validity testing to ensure accuracy and results are publicly reported. This process involves a medical record review from 300 randomly selected dialysis facilities with up to 10 patients from each facility also being randomly selected. A total of 24 data elements were most recently reviewed from April – June 2023. A nurse review team compares these data elements from the patients chart to what is reported in EQRS. Patient-level data elements include: date of birth, date regular dialysis began, admission and discharge date to facility, type of dialysis treatment and date of death. Quality measure data elements include: Kt/V for hemodialysis, date of Kt/V collection, method used to calculate Kt/V, and modality type.

5.3.4 Validity Testing Results

Results of this analysis are notable for the following:

- 96.5% correct matches with 1.6% of entries in either EQRS (0.2%) or Medical Records (1.4%) containing missing information.
- 1.9% incorrect matches
- Date elements showed error rates ranging from 0-2.3%

5.3.5 Interpretation of Validity Results

This analysis reveals a high degree of validity for the key data elements used in the measure. Additional details can be found at: https://qualitynet.cms.gov/esrd/data-validation#tab2

5.3.2 Type of Accountable Entity Level Validity Testing Conducted (derived)

Not applicable/accountable entity level validity testing not conducted

5.3.2a Why Testing Not Conducted (derived)

Validity testing could not be conducted due to small patient population.

5.4.1 Methods Used to Address Risk Factors

No risk adjustment or stratification

6.1.1 Current Status

In use

6.1.3 Current Use(s)

Public Reporting, Payment Program

6.1.3 Program Details

Name of the program and sponsor
Dialysis Facility Care Compare
URL of the program
http://www.medicare.gov/
Purpose of the program
Dialysis Facility Care Compare helps patients find detailed information about Medicare-certified dialysis facilities. They can compare the services and the quality of care that facilities provide.
Geographic area and percentage of accountable entities and patients included
United States
Applicable level of analysis and care setting

All Medicare-certified dialysis facilities who are eligible for the measure, and have at least 11 patients (due to public reporting requirements).

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Name of the program and sponsor
ESRD QIP
URL of the program
http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/...
Purpose of the program
The ESRD QIP will reduce payments to ESRD facilities that do not meet or exceed certain performance standards. The measure was added to the program for PY2015. In PY2019, the QIP began reporting a comprehensive Kt/V measure, for which this the data used i
Geographic area and percentage of accountable entities and patients included
United States
Applicable level of analysis and care setting

All Medicare-certified dialysis facilities who are eligible for the measure, and have at least 11 patients (due to public reporting requirements).

6.2.1 Actions of Measured Entities to Improve Performance

Most U.S. chronic dialysis facilities perform quite well on both the hemodialysis Kt/V as well as the PD Kt/V metric. Given this performance, most dialysis facilities are not required to “do more” in order to avoid flagging as underperforming. The greatest utility of the Kt/V measure is as a minimum standard to provide ongoing information about the effectiveness of small solute clearance, one technical outcome of dialysis treatments that contributes to the overall assessment of dialysis success. As the ISPD Guidelines for PD adequacy point out, it is not the only metric that should be used to assess dialysis adequacy, but one important minimum standard for assessment of one aspect of the therapy. In addition to providing this minimum dialytic clearance of small metabolic solutes, the dialysis facility has multiple other aspects of holistic care to monitor and address for optimal dialysis care. Unfortunately, quality metrics that assess these components of dialysis adequacy are either in development, or not yet available based on the current standards of the underlying scientific evidence.

6.2.2 Feedback on Measure Performance

We reviewed the comments and questions submitted during the DFC preview periods that have taken place since the last maintenance (2019-present). Outside of questions about facility-specific results (such as questioning the Kt/V value on record for a particular patient), we receive a handful of questions each preview period regarding the measure specifications, such as the determination of thrice weekly dialysis.

Note that since UM-KECC is not the contractor responsible for the ESRD Quality Incentive Program, we do not have access to the detailed comments/requested that are submitted during the annual preview period for that program.

Since PY 2019, the ESRD QIP has been reporting a combined Kt/V measure in order to allow for more reporting of data for pediatric and peritoneal dialysis patients. Most of the recent comments addressed in the rule have to do with that decision, and a desire to return to reporting the four measures separately. The ESRD QIP NPRM for PYX includes a proposal to return to the four separate measures.

For DFCC, feedback can be provided any time through contacting the dialysisdata.org helpdesk. Preview periods allow for specific times for facilities review and comment on measure calculations, and provide an opportunity to request a patient list.

For the ESRD QIP, feedback can be provided any time through contacting the QIP helpdesk. Preview periods allow for specific times for facilities review and comment on measure calculations. Comments can also be submitted in response to the Notice of Proposed Rulemaking for each QIP payment year.

6.2.3 Consideration of Measure Feedback

The measure specifications have not been revised since the last maintenance cycle in 2019. Feedback received during DFCC preview periods has resulted in more detailed and accurate documentation available to the public, primarily via the ESRD Measures Manual and the Guide to the Quarterly Dialysis Facility Reports.

6.2.4 Progress on Improvement

The following table reports the performance scores for this measure at the yearly level for 2015 - 2022. This analysis suggests an early increase in performance followed by a period of decline for the measure as implemented on DFCC, however these trends are based on small numbers of facilities and will, therefore, exhibit more variability. Calendar year 2020 was not reported due to

CMS's COVID Extraordinary Circumstances Exception (ECE) data policy that restricted the use of EQRS clinical data from a portion of that year.

Year 2015: N = 17 Mean = 88.0%, Std Dev =8.6%, Min = 71.3%, Max = 100.0%

Year 2016: N = 14, Mean =90.3%, Std Dev = 7.8%, Min = 74.8%, Max = 100.0%

Year 2017: N = 14, Mean = 95.2%, Std Dev = 4.6%, Min = 85.4%, Max = 100.0%

Year 2018: N = 18, Mean = 92.2%, Std Dev = 7.7%, Min = 73.6%, Max = 100.0%

Year 2019: N = 14, Mean = 92.5%, Std Dev = 6.5%, Min = 75.7%, Max = 100.0%

Year 2021: N = 11, Mean = 88.8%, Std Dev = 12.2%, Min = 63.5%, Max = 100.0%

Year 2022: N = 15, Mean = 85.4%, Std Dev = 16.8%, Min = 41.7%, Max = 100.0%

6.2.5 Unexpected Findings

We have not been notified of documented unintended impacts on patients as a result of measure implementation.

Developer POC email

jmsto@med.umich.edu

Measure Developer POC

Jennifer Sardone
University of Michigan
Ann Arbor, MI
United States

The measure developer is different from the measure steward

Yes

Steward Address

Wil Agbenyikey
Woodlawn, MD
United States

Steward Organization

Centers for Medicare & Medicaid Services

Steward Organization URL

https://www.cms.gov/

Steward POC email

wilfred.agbenyikey@cms.hhs.gov