
CBE ID

1425

Title

Measurement of nPCR 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 policies around pediatric population measures; and
- Explored meaningfulness with patients/parents/caregivers that have direct lived experience in this measure area.

Is Under Review

No

Next Maintenance Cycle

Fall 2029

Previous Endorsement Cycle

Fall 2024

Initial Endorsement

Tue, 08/16/2011 - 11:48

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 of pediatric (< 18 years old) in-center hemodialysis patients

(irrespective of frequency of dialysis) with documented monthly nPCR measurements.

1.7 Composite Measure

No

1.7 Measure Type

Process

1.8 Level of Analysis

Facility

1.9 Care Setting

Other

1.9b Other Care Setting

Dialysis Facility

1.10 Measure Rationale

For in-center hemodialysis patients, nPCR provides an estimate of dietary protein intake, which has been shown to provide additional information to spKt/V. Studies have shown that in adolescent patients who achieved target spKt/V levels, nPCR was associated with nutritional status. Furthermore, there is evidence that nPCR < 1 gram/kg/day is predictive of malnutrition and sustained weight loss among adolescent patients.

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

[1425_Data_Dictionary.xlsx](#)

1.14 Numerator

Number of patient months in the denominator with monthly nPCR measurements.

1.14a Numerator Details

The number of patients in the study month where (1) the nPCR value and the date the nPCR value was collected are reported or (2) the following 7 components used to calculate nPCR are reported (BUN pre-dialysis, BUN post-dialysis, pre-dialysis weight, pre-dialysis weight unit of measure, post-dialysis weight, post-dialysis weight unit of measure, delivered minutes of BUN hemodialysis session), and the date of collection.

Note: Interdialytic time is also needed to calculate nPCR; however, EQRS currently does not allow collection of that data element therefore the measure does not require reporting of this variable.

1.15 Denominator

Number of all patient months for pediatric (less than 18 years old) in-center hemodialysis patients (irrespective of frequency of dialysis).

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 adult patients (greater than or equal to 18 years of age), all patients who have not been in the facility for the entire reporting month, and all home hemodialysis and peritoneal dialysis patients. 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

To be included in the denominator for a particular month, the patient must be on in-center hemodialysis for the entire month, must be < 18 years old at the beginning of the month, and must be assigned to that facility for the entire month. An individual patient may contribute up to 12 patient-months per year.

The numerator counts the number of patients in the study month where (1) the nPCR value and the date the nPCR value was collected are reported or (2) the components that allow calculation of nPCR are reported (BUN pre-dialysis, BUN post-dialysis, pre-dialysis weight, pre-dialysis weight unit of measure, post-dialysis weight, post-dialysis weight unit of measure, delivered minutes of BUN hemodialysis Session and the date of collection).

Note: Interdialytic time is also needed to calculate nPCR; however, EQRS currently does not allow collection of that data element, therefore the measure does not require reporting of that variable.

1.18a Attach measure score calculation diagram

[1425_Flowchart_508.pdf](#)

1.19 Measure Stratification Details

The measure is not stratified.

1.20 Types of Data Sources

Claims Data, Registries

1.25 Data Source Details

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 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

[1425_Importance_Logic Model_508.pdf](#)

2.2 Evidence of Measure Importance

The primary source of evidence for this measure is the KDOQI Clinical Practice Guidelines and

Clinical Practice Recommendations for 2006 Updates: Hemodialysis Adequacy, Peritoneal Dialysis Adequacy and Vascular Access.

The guideline states:

“8.2.2 Assessment of nutrition status is an essential component of HD adequacy measurement. nPCR should be measured monthly by using either formal urea kinetic modeling or algebraic approximation. (B)

2008 KDOQI CPR RECOMMENDATION 1: EVALUATION OF GROWTH AND NUTRITIONAL STATUS

1.1 The nutritional status and growth of all children with CKD stages 2 to 5 and 5D should be evaluated on a periodic basis. (A)

1.2 The following parameters of nutritional status and growth should be considered in combination for

evaluation in children with CKD stages 2 to 5 and 5D. (B)

1. Dietary intake (3-day diet record or three 24-hour dietary recalls)
2. Length- or height-for-age percentile or standard deviation score(SDS)
3. Length or height velocity-for-age percentile or SDS
4. Estimated dry weight and weight-for-age percentile or SDS
5. BMI-for-height-age percentile or SDS
6. Head circumference-for-age percentile or SDS (=3 years old only)

Normalized protein catabolic rate (nPCR) in hemodialyzed adolescents with CKD stage 5D.”

National Kidney Foundation. KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for 2006 Updates: Hemodialysis Adequacy, Peritoneal Dialysis Adequacy and Vascular Access. Am J Kidney Dis 48:S1-S322, 2006 (suppl 1).

http://www.kidney.org/PROFESSIONALS/kdoqi/guideline_upHD_PD_VA/index.htm

The 2006 KDOQI Guideline 8.2.2 rating strength grade is 'B'. The recommendation for Grade B guidelines states 'It is recommended that clinicians routinely follow the guideline for eligible patients. There is moderate to strong evidence that the practice improves health outcomes.'

In May 2014, an additional literature search was performed. A recent comprehensive review on the subject [4] is included in the citations below as a result of that search. This review continues to be supportive of the concept of monitoring nPCR as part of evaluation of Protein Energy Wasting (PEW) in children/adolescents on dialysis.

1. Goldstein, Baronette, et al. nPCR assessment and IDPN treatment of malnutrition in pediatric hemodialysis patients. *Pediatric Nephrology* (2002) 17:531-534.
2. Orellana P, Juarez-Congelosi M, Goldstein SL. Intradialytic parenteral nutrition treatment and biochemical marker assessment for malnutrition in adolescent maintenance hemodialysis patients. *J Ren Nutrition* 2005 Jul;15(3):312-7.
3. Juarez-Congelosi M, Orellana P, Goldstein SL: Normalized protein catabolic rate versus serum albumin as a nutrition status marker in pediatric patients receiving hemodialysis. *J Ren Nutr* 17:269-274, 2007.
4. Mastrangelo A, Paglialonga F, Edefonti A. Assessment of nutritional status in children with chronic kidney disease and on dialysis. *Pediatr Nephrol*. 2014 Aug;29(8):1349-58. doi: 10.1007/s00467-013-2612-7. Epub 2013 Sep 5.

An additional literature search was performed for the Fall 2024 cycle and no additional relevant publications were identified to support the measure. ISPD Guidelines did not address adequacy in children.

2.4 Performance Gap

After applying all exclusion criteria, we evaluated the nPCR performance scores for all dialysis facilities that had at least 11 patients in 2022 (n=23). The nPCR varies considerably across this small group of facilities, largely due to poor performance within the bottom quartile. The mean value of nPCR was 0.87 (i.e. 87% of pediatric patients had documented monthly nPCR measurements). The interquartile range (Q3-Q1) is around 0.13, with the bottom quartile of facilities having 85% or less of pediatric patients with documented nPCR measurements versus the top quartile of facilities having 98% or more of their patients with documented measurements. These are the following statistics of performance: Mean (SD) = 87% (20%), Min = 12%, 25th percentile = 85%, 50th percentile = 97%, 75th percentile = 98%, Max = 100%.

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	0.873	0.119	0.359	0.647	0.839	0.915	0.952	0.976	0.982	0.984	0.990	1.000	1.000
N of Entities	23	1	2	2	3	2	2	3	2	3	3	1	3
N of Persons / Encounters / Episodes	384	17	36	31	65	37	25	42	24	67	40	17	67

2.6 Meaningfulness to Target Population

Direct Evidence: due to the small number of pediatric patients, and sensitivity to their privacy, we have never collected patient level data on the perception of this measure. In addition, we are not aware of peer-reviewed literature that reports on pediatric dialysis patients' perception of the meaningfulness of the measure.

Indirect Evidence: A kidney dietician is required to be available in all Medicare-certified dialysis clinics. This is particularly important for pediatric patients whose growth is monitored closely. Maintaining adequate protein intake, while being mindful of other minerals such as calcium and phosphorus, are critical for pediatric patients to achieve optimal growth. Therefore, a metric to track protein intake is meaningful to patients who want to achieve normal stature.

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 via EQRS, a web-based and electronic batch submission platform maintained and operated by CMS contractors. 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 preview).

4.3 Feasibility Informed Final Measure

No changes were made

4.4 Proprietary Information

Not a proprietary measure and no proprietary components

4.4a Fees, Licensing, or Other Requirements

N/A

5.1.1 Data Used for Testing

Calendar year 2022 data derived from a combination of EQRS and Medicare Claims Data.

5.1.2 Differences in Data

We excluded three facilities from reliability testing for which there were no calculated nPCR values in 2022. Because calculation of nPCR requires interdialytic time, which is not currently reported in EQRS, we are unable to calculate nPCR for these facilities.

5.1.3 Characteristics of Measured Entities

The measured entities used in testing and analysis include reported nPCR or the necessary data elements needed for calculation of nPCR. There are 384 in-center hemodialysis (ICH) pediatric patients from 23 dialysis facilities that have had at least 11 eligible pediatric patients across all regions of the United States.

Public reporting of this measure on DFC or in the ESRD QIP would be restricted to facilities with at least 11 eligible patients in order 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.

Facilities vary in size and include anywhere from 11 to 32 eligible ICH pediatric patients.

5.1.4 Characteristics of Units of the Eligible Population

In 2022, there were 384 pediatric patients in total, after applying exclusion criteria (i.e., those at small facilities and those older than 18 years). Among them, 46.8% of patients were female, 55.8% were White, 37.0% were Black, 2.12% were Native American/Alaskan Native, 3.7% were Asian/Pacific Islander, 1.3% were Other/Multi-racial, and 30.4% 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

January 2022 – December 2022 EQRS data were used to calculate the inter-unit reliability (IUR)

for the overall 12 months to assess the reliability of this measure. The NQF-recommended approach for determining measure reliability is a one-way analysis of variance (ANOVA), in which the between and within facility variation in the measure is determined. 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

The overall IUR was 0.952, which indicates that about 95.2% of the variation in the measure can be attributed to the between facility differences and 4.8% to the within facility variation.

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

The IUR 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	0.952	0.9333	0.933	0.938	0.942	0.946	0.950	0.953	0.955	0.961	0.965	0.974	0.976
Mean Performance Score	0.873	96.948	96.948	98.653	98.058	97.649	82.578	79.863	84.783	52.150	91.896	88.178	98.374
N of Entities	23	3	3	2	1	3	2	2	4	2	2	2	1
N of Persons / Encounters / Episodes	384	33	33	24	13	42	30	32	68	39	44	59	32

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 was not performed due to the small size of the pediatric 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. Although the nPCR value is not one of the data elements directly validated as part of this process, some of the data elements that would be used to calculate nPCR are validated such as patient weight and session duration. Other 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. While the urea nitrogen levels are also not directly validated as part of this process, other laboratory values (calcium, phosphorus) are directly validated and findings should be similar across all laboratory values given the automated process used by most dialysis facilities.

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 was not performed due to the small size of the pediatric 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

6.1.3 Program Details

Name of the program and sponsor

Dialysis Facility Care Compare

URL of the program

<https://www.medicare.gov>

Purpose of the program

DFCC 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 that 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

In order for facilities to improve performance on this measure, they must increase collection and reporting of the nPCR value or the data elements necessary to calculate an nPCR value on a monthly basis. Given that these data elements are known and monitored during each dialysis session, and the requirement is only to report one of these each month, it is felt that collecting and reporting these is not difficult to achieve.

6.2.2 Feedback on Measure Performance

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.

6.2.3 Consideration of Measure Feedback

We reviewed the comments and questions submitted during the DFCC preview periods that have taken place since the original maintenance (2016-present). We have received only a handful of clarification questions since the measure was added to DFCC, likely due to the very small number of facilities that receive a measure score.

6.2.4 Progress on Improvement

Given that small scale observational studies have shown an association between nPCR and nutritional status among malnourished adolescent patients who achieved target spKt/V levels, we would expect that public reporting of this measure may engage facilities to better monitor the nutrition status of their pediatric patients. With the exception of the most current year, the mean and min values have been steadily increasing since this measure's inception. 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.

CY 2017: N = 29, Mean = 76.64%, Std Dev = 32.46%, Min = 0.0%, Max = 99.32%

CY 2018: N = 26, Mean = 78.40%, Std Dev = 25.36%, Min = 0.0%, Max = 100.0%

CY 2019: N = 31, Mean = 90.24%, Std Dev = 13.59%, Min = 37.33%, Max = 100.0%

CY 2021: N = 18, Mean = 92.24%, Std Dev = 10.95%, Min = 57.66%, Max = 100.0%

CY 2022: N = 23, Mean = 87.29%, Std Dev = 20.48%, Min = 11.88%, Max = 100.0%

6.2.5 Unexpected Findings

None that we are aware of.

Developer POC email

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Measure Developer POC

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The measure developer is different from the measure steward

Yes

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Steward Organization

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Steward Organization URL

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