Print

Measure Comment Report for End Stage Renal Disease

1463: Standardized Hospitalization Ratio for Admissions
Comment By
Name: Dr. Ellen Schwalenstocker, PhD, MBA
Organization: National Association of Children's Hospitals and Related Institutions

Date - Time: Apr 22, 2011 - 05:55 PM

Comments

We received a comment from a member hospital noting that hospializations are not under the control of ESRD's, but should be minimized. This hospital noted that the measure should take into consideration reasons for admission as these reasons may be unrelated to ESRD/dialysis and that the ratio should take into consideration only preventable issues resulting in hospitalization. NACHRI agrees that it is important to monitor the risk of unintended consequences, including discouraging hospitalization of patients in need of it.

1425: Measurement of nPCR for Pediatric Hemodialysis Patients
Comment By
Name: Dr. Ellen Schwalenstocker, PhD, MBA
Organization: National Association of Children's Hospitals and Related Institutions

Date - Time: Apr 22, 2011 - 05:50 PM

Comments

We received one comment from a member hospital that this measure should be applied to adolescents only as "the value has not been standardized for younger patients."

Comments on the general draft report
Comment By
Name: Dr. Ellen Schwalenstocker, PhD, MBA
Organization: National Association of Children's Hospitals and Related Institutions

Date - Time: Apr 22, 2011 - 05:46 PM

Comments

On behalf of the National Association of Children's Hospitals and Related Institutions, thank you for the opportunity to comment on the proposed measure. We are pleased that the National Quality Forum included a focus on pediatric measures and agree with the comments by the Children's Hospital Boston regarding the need to look at pediatric-specific needs and etiology in developing measures. Comments we received were generally supportive of the measures.

Comments on measures not recommended
Comment By
Name: Randel E. Richner, BSN, MPH
Organization: Neocure Group

Date - Time: Apr 22, 2011 - 04:44 PM

Comments

Neocure understands the importance of the NQF recommended measures as both a means to improve the quality of care delivered to ESRD patients and as the potential basis for CMS policy decisions. We concur with the 11 endorsed measures, however,

we would like to offer perspective on the importance of additional measures:

Measure 1427- Adult Dialysis Patients - Serum Phosphorus Greater Than 6 mg/dl

We support this measure for public reporting and payment, and we recommend this measure be endorsed. We believe high serum phosphorus to be an important biomarker for monitoring. In particular, dialysis regimens that include longer and more frequent hemodialysis treatments are able to reduce the serum phosphorus levels without the introduction of additional medications. One goal of dialysis therapy should be to return patients to pre-dialysis lab levels as often as possible and an aggresive metric is needed to support this.

Measure 1439- Utilization of High Ultrafiltration(UF) Rate for Fluid Removal

We believe this measure to be particularly relevant considering the repeated supporting studies linking high UF to reduced mortality. While 15 ml/kg/hr may not be the definitive standard for measurement, we believe having a pre-defined metric, at least for reporting purposes, to be important in further understanding the relationship between fluid overload and patient outcomes as well as a step towards improving patient survival.

1460: National Healthcare Safety Network (NHSN) Bloodstream Infection Measure
Comment By
Name: Ms. Carmella Bocchino, MBA, RN
Organization: America's Health Insurance Plans

Date - Time: Apr 22, 2011 - 01:52 PM

Comments

We applaud NQF's leadership in working with CDC and CMS to develop a single measure on bloodstream infections for the ESRD patient population. Given the important safety initiative introduced by the Department of Health and Human Services' (HHS), the "Partnership for Patients," AHIP encourages NQF to continuing working with the developers to endorse measures for infections, such as CLABSI, and ensure that the measures are inclusive of all patient populations.

1463: Standardized Hospitalization Ratio for Admissions
Comment By
Name: Ms. Carmella Bocchino, MBA, RN
Organization: America's Health Insurance Plans

Date - Time: Apr 22, 2011 - 01:51 PM

Comments

AHIP supports this measure, as developing a standardized hospital ratio for the admission of ESRD patients, is an important aspect of coordinating care, reducing hospital admissions and understanding the quality of care for this vulnerable patient population.

Comments on the general draft report
Comment By
Name: Ms. Carmella Bocchino, MBA, RN
Organization: America's Health Insurance Plans

Date - Time: Apr 22, 2011 - 01:50 PM

Comments

Thank you for the opportunity to provide comments on the NQF National Voluntary Consensus Standards for End Stage Renal Disease (ESRD) draft report. We support NQF's efforts to put forth supplemental measures that seek to enhance and continuously improve the quality of care delivered to ESRD patients.

AHIP supports the 11 measures recommended by NQF for endorsement, and believes they are clinically appropriate and represent a starting point for measuring quality of care for ESRD patients. However, the usability of these measures to health plans may be limited. Several of these measures require clinical data extraction by dialysis facilities for submission to CMS using a web-based submission process. A similar data infrastructure for dialysis facilities to submit such data to all private payers currently does not exist. It would therefore be helpful for the measure developer to clarify if the data for these measures is derived from all-payers or just Medicare patients. If the measures are intended to reflect all-payer data and were publicly reported, private payers could use these measures to assess quality care to ESRD patients.

Comments on the general draft report

Comment By
Name: Dr. Dale Lupu, PhD
Organization: American Academy of Hospice and Palliative Medicine

On Behalf Of
Name: Ron Crossno, MD, President
Organization: American Academy of Hospice & Palliative Medicine

Date - Time: Apr 22, 2011 - 01:15 PM

Comments

The American Academy of Hospice and Palliative Medicine supports the eleven new measures, particularly noting that they are a step forward because they include pediatric patients in measures of dialysis adequacy and complications. However, even with these new measures, the list of NQF-endorsed measures for ESRD is still lacking in measures that robustly address the palliative care needs of ESRD patients as outlined in current guidelines.[i] We strongly recommend that NQF note this gap and develop a strategy for addressing it in future work.

None of the 11 recommended measures address any essential domains of palliative care (e.g. quality of life, advance care planning, symptom assessment or management, or bereavement support.) Extended comments submitted by AAHPM by email further outline domains of palliative care that need to be addressed by additional quality measures. We strongly recommend that future work include measures addressing the palliative care aspects of the applicable ESRD guidelines and by applicable to the pediatric population.

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[i]Renal Physicians Association (RPA). Shared decision-making in the appropriate initiation of withdrawal from dialysis. 2nd ed. Rockville (MD): Renal Physicians Association (RPA); 2010 Oct.

1463: Standardized Hospitalization Ratio for Admissions

Comment By
Name: Ms. Amy Beckrich
Organization: Renal Physicians Association

On Behalf Of
Name: Robert Blaser
Organization: Renal Physicians Association

Date - Time: Apr 22, 2011 - 11:12 AM

Comments

There is insufficient clarity for this measure. For example, it is unclear whether a comorbidity index would be calculated, and by what method, or whether it would be age adjusted. Also it is unclear whether this can be reported by indicating “yes or no” for various comorbidities from the 2728 form.

1460: National Healthcare Safety Network (NHSN) Bloodstream Infection Measure

Comment By
Name: Ms. Amy Beckrich
Organization: Renal Physicians Association

On Behalf Of
Name: Robert Blaser
Organization: Renal Physicians Association

Date - Time: Apr 22, 2011 - 11:11 AM

Comments

From the dialysis standpoint, what is most important are dialysis (access) related infections, whereas this measure is looking at all positive blood cultures. The reality, however, is that the rate of non-dialysis access associated infections will likely be much smaller than the number of access-associated infections, and specifying what an access-related infections is would be very difficult – in particular since bacteremia due to endocarditis or osteomyelitis might be indirectly related to access infection.

1454: Proportion of patients with hypercalcemia

Comment By
Name: Ms. Amy Beckrich
Organization: Renal Physicians Association

On Behalf Of
Name: Robert Blaser
Organization: Renal Physicians Association

Date - Time: Apr 22, 2011 - 11:10 AM

Comments

1. It is not clear from the specifications that blood should be drawn for this measure prior to start of dialysis.
2. For PD patients, the language should be changed from "at facility" to "by outpatient facility…"

1438: Periodic Assessment of Post-Dialysis Weight by Nephrologists

Comment By
Name: Ms. Amy Beckrich
Organization: Renal Physicians Association

On Behalf Of
Name: Robert Blaser
Organization: Renal Physicians Association

Date - Time: Apr 22, 2011 - 11:08 AM

Comments

1. We agree with the time limited status to determine whether this measure will result in improved ECF control, hospitalizations for cardiac causes, etc.
2. We believe that this measure is not sufficiently robust—"receiving a new post dialysis weight" will not be likely to improve patient outcomes because it does not assure that a proper, correct, or appropriate change has occurred (e.g., a patient with obvious ECF expansion crashes recurrently during dialysis so the dry weight is increased).
3. There is a high burden without ability for electronic submission.
4. We agree with committee's suggestion to include "… irrespective of change or not."

1433: Use of Iron Therapy for Pediatric Patients

Comment By
Name: Ms. Amy Beckrich
Organization: Renal Physicians Association

On Behalf Of
Name: Robert Blaser
Organization: Renal Physicians Association

Date - Time: Apr 22, 2011 - 11:07 AM

Comments

1. The language in the exclusions stating: "PD patients not in facility …" should be replaced with "PD patients not followed by the facility …"
2. The measure does not imply appropriate frequency for measuring % sat and ferritin or appropriate interval after IV iron for re-measurement.
3. We agree with the time-limited status for this measure.

1430: Lower Limit of Hemoglobin for Pediatric Patients

Comment By
Name: Ms. Amy Beckrich
Organization: Renal Physicians Association

On Behalf Of
Name: Robert Blaser
Organization: Renal Physicians Association

Date - Time: Apr 22, 2011 - 11:06 AM

Comments

1. Peritoneal dialysis patients should be included.
2. We agree that patients with sickle cell anemia should be excluded.

1460: National Healthcare Safety Network (NHSN) Bloodstream Infection Measure

Comment By
Name: Ms. Denise Graham
Organization: Association for Professionals in Infection Control and Epidemiology

On Behalf Of
Name: Denise Graham
Organization: APIC

Date - Time: Apr 22, 2011 - 11:05 AM

Comments

The Association for Professionals in Infection Control and Epidemiology (APIC) support the Steering Committee's recommendation that the Centers for Medicare and Medicaid Services (CMS) and Centers for Disease Control and Prevention (CDC) collaborate on one measure so that facilities can submit data once and be included in both systems. CMS will require dialysis facilities to submit data to the CMS CROWNweb data system. The CDC National Health Safety Network data collection requires much of the same information that is required by CMS CROWNweb. By creating one measure, duplication of collection efforts will be reduced. The measure submitted to NQF by NHSN - 1460 NHSN Bloodstream infection is best suited for collaboration with CMS CROWNweb. This candidate consensus standard was recommended for endorsement by the Steering Committee. Other measures did not meet NQF criteria for endorsement.

1424: Monthly Hemoglobin Measurement for Pediatric Patients

Comment By
Name: Ms. Amy Beckrich
Organization: Renal Physicians Association

On Behalf Of
Name: Robert Blaser
Organization: Renal Physicians Association

Date - Time: Apr 22, 2011 - 11:03 AM

Comments

1. The title of measure should specify both hemodialysis and peritoneal dialysis.
2. Exclusion criteria: "Not in facility …" statements do not capture home patients, who may never be in the facility. Rather, the phrase should be changed for home dialysis patients to read "followed by the facility for entire month."

Comments on the general draft report

Comment By
Name: Ms. Denise Graham
Organization: Association for Professionals in Infection Control and Epidemiology

On Behalf Of
Name: Denise Graham
Organization: APIC

Date - Time: Apr 22, 2011 - 11:02 AM

Comments

CDC's Vital Signs of March 1, 2011 (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6008a4.htm?s_cid=mm6008a4_w). To capsulize, in 2009 an estimated 37,000 CLABSIs occurred among patients receiving outpatient hemodialysis. The substantial number of infections occurring especially in outpatient hemodialysis centers reveals an important area for expanded prevention efforts. Continued success in CLABSI prevention will require increased adherence to current CLABSI prevention recommendations, development and implementation of additional prevention strategies, and the ongoing collection and analysis of data, including specific microbiologic information. To prevent CLABSIs in hemodialysis patients, efforts to reduce central

line use for hemodialysis and improve the maintenance of central lines should be expanded. APIC agrees that the lower the proportion of patients in whom a central line is placed for hemodialysis the better the chances are for minimizing infectious complications. While we understand that NQF is not accepting new measures at this time, a future metric might be the percentage of new patients who agree to receive a fistula for dialysis versus a central line.

1425: Measurement of nPCR for Pediatric Hemodialysis Patients

Comment By
Name: Ms. Amy Beckrich
Organization: Renal Physicians Association

On Behalf Of
Name: Robert Blaser
Organization: Renal Physicians Association

Date - Time: Apr 22, 2011 - 11:01 AM

Comments

1. We agree with time limited requirement because measure is untested and evidence lacking.
2. We disagree with "irrespective of frequency" because nPCR is based on interdialytic interval and therefore frequency of dialysis should be considered.

1423: Minimum spKt/V for Pediatric Hemodialysis Patients

Comment By
Name: Ms. Amy Beckrich
Organization: Renal Physicians Association

On Behalf Of
Name: Robert Blaser
Organization: Renal Physicians Association

Date - Time: Apr 22, 2011 - 10:59 AM

Comments

Adequacy measures should take frequency of dialysis into account using a new standard based on weekly KT/V, and should be blended with adult adequacy measures.

1421: Method of Adequacy Measurement for Pediatric Hemodialysis Patients

Comment By
Name: Ms. Amy Beckrich
Organization: Renal Physicians Association

On Behalf Of
Name: Robert Blaser
Organization: Renal Physicians Association

Date - Time: Apr 22, 2011 - 10:58 AM

Comments

Adequacy measures should take frequency of dialysis into account, using a new standard based on weekly KT/V, and should be blended with adult adequacy measures.

1418: Frequency of Adequacy Measurement for Pediatric Hemodialysis Patients

Comment By
Name: Ms. Amy Beckrich
Organization: Renal Physicians Association

On Behalf Of
Name: Robert Blaser
Organization: Renal Physicians Association

Date - Time: Apr 22, 2011 - 10:57 AM

Comments

Home hemodialysis patients should be included in the measure.

Comments on the general draft report

Comment By

On Behalf Of

Name: Ms. Amy Beckrich
Organization: Renal Physicians Association

Name: Robert Blaser
Organization: Renal Physicians Association

Date - Time: Apr 22, 2011 - 10:56 AM

Comments

Thank you for the opportunity to comment on the National Quality Forum's (NQF) draft document, *National Voluntary Consensus Standards for End Stage Renal Disease (ESRD) 2010: A Consensus Report*. The Renal Physicians Association (RPA) is the professional organization of nephrologists whose goals are to ensure optimal care under the highest standards of medical practice for patients with renal disease and related disorders. RPA acts as the national representative for physicians engaged in the study and management of patients with renal disease.

Comments on measures not recommended
Comment By
Name: Ms. Nina A. Rauscher, MS, RN, CPHQ
Organization: Children's Hospital Boston - Program for Patient Safety & Quality

Date - Time: Apr 22, 2011 - 10:22 AM

Comments

For Measure 1431 (Measurement of iron stores for pediatric patients) which was not endorsed, Children's Hospital Boston agrees with this decision. We believe that the endorsed measure 1433 regarding use of iron therapy and the other two endorsed anemia measures 1424 and 1430 that set a lower limit for hemoglobin for pediatric patients would be better quality measures of anemia therapy in children.

1425: Measurement of nPCR for Pediatric Hemodialysis Patients
Comment By
Name: Ms. Nina A. Rauscher, MS, RN, CPHQ
Organization: Children's Hospital Boston - Program for Patient Safety & Quality

Date - Time: Apr 22, 2011 - 10:17 AM

Comments

We would support the measure requiring assessment of nPCR for pediatric hemodialysis patients. We would point out, however, that nPCR needs to be interpreted in the context of the child's dietary protein intake and the child's growth rate to make conclusions about nutritional adequacy. For instance, the nPCR may indeed be less than the typical target of nPCR>1 in growing children receiving adequate nutrition who are in an anabolic state.

The rationale as written also now contains a typographical error and repeats the word improved twice: "Its use can result in improved improved long-term outcomes . . ."

1433: Use of Iron Therapy for Pediatric Patients
Comment By
Name: Ms. Nina A. Rauscher, MS, RN, CPHQ
Organization: Children's Hospital Boston - Program for Patient Safety & Quality

Date - Time: Apr 22, 2011 - 10:15 AM

Comments

Children's Hospital Boston supports this measure. We would additionally emphasize that children are at particular risk of adverse effects on growth and cognitive development with anemia, sequelae that do not pertain as importantly to adults. As a result, there needs to be special care taken in any anemia measure to make sure that data specifically from children be considered in formulating measures applying to children.

1430: Lower Limit of Hemoglobin for Pediatric Patients
Comment By
Name: Ms. Nina A. Rauscher, MS, RN, CPHQ
Organization: Children's Hospital Boston - Program for Patient Safety & Quality

Date - Time: Apr 22, 2011 - 10:15 AM

Comments

Children's Hospital Boston supports this measure. We would additionally emphasize that children are at particular risk of adverse effects on growth and cognitive development with anemia, sequelae that do not pertain as importantly to adults. As a result, there needs to be special care taken in any anemia measure to make sure that data specifically from children be considered in formulating measures applying to children.

1424: Monthly Hemoglobin Measurement for Pediatric Patients
Comment By
Name: Ms. Nina A. Rauscher, MS, RN, CPHQ
Organization: Children's Hospital Boston - Program for Patient Safety & Quality

Date - Time: Apr 22, 2011 - 10:14 AM

Comments

Children's Hospital Boston supports this measure. We would additionally emphasize that children are at particular risk of adverse effects on growth and cognitive development with anemia, sequelae that do not pertain as importantly to adults. As a result, there needs to be special care taken in any anemia measure to make sure that data specifically from children be considered in formulating measures applying to children.

1423: Minimum spKt/V for Pediatric Hemodialysis Patients
Comment By
Name: Ms. Nina A. Rauscher, MS, RN, CPHQ
Organization: Children's Hospital Boston - Program for Patient Safety & Quality

Date - Time: Apr 22, 2011 - 10:10 AM

Comments

We support the measure as now written.

1421: Method of Adequacy Measurement for Pediatric Hemodialysis Patients
Comment By
Name: Ms. Nina A. Rauscher, MS, RN, CPHQ
Organization: Children's Hospital Boston - Program for Patient Safety & Quality

Date - Time: Apr 22, 2011 - 10:10 AM

Comments

We support the measure as now written.

1418: Frequency of Adequacy Measurement for Pediatric Hemodialysis Patients
Comment By
Name: Ms. Nina A. Rauscher, MS, RN, CPHQ
Organization: Children's Hospital Boston - Program for Patient Safety & Quality

Date - Time: Apr 22, 2011 - 10:10 AM

Comments

We support the measure as now written.

Comments on the general draft report
Comment By
Name: Ms. Nina A. Rauscher, MS, RN, CPHQ
Organization: Children's Hospital Boston - Program for Patient Safety & Quality

Date - Time: Apr 22, 2011 - 10:05 AM

Comments

Children's Hospital Boston is pleased to comment on this draft report and its 8 specific measures pertaining to children.

We are especially pleased to see draft measures that are specific to pediatric ESRD patients and would urge that ESRD measures for children continue to be developed and implemented separately than measures for adults. The pediatric population with ESRD differs significantly from the adult population in etiology of ESRD, in issues of access to specialty care, in respect to the importance of ongoing growth and development, and in associated co-morbidities. Children with ESRD form a unique population and children on dialysis need measures that pertain to their specific needs to insure quality care.

Children on dialysis are much more likely than their adult colleagues to do home dialysis, generally using peritoneal dialysis. We would urge that as future measures be developed that there also be focus on this group of children with ESRD.

Please note: On page 3 of the Background section it is now written: "More than 360,000 patients are on dialysis, 7,200 of which are pediatric patients." This statement is incorrect and needs to be amended in the final report. There are 7,200 pediatric patients with ESRD, but the majority of them have been treated with transplantation and are not dialysis patients. According to the 2008 USRDS data, there are just over 2000 children on dialysis.

1430: Lower Limit of Hemoglobin for Pediatric Patients
Comment By
Name: Ms. Kathryn Schubert
Organization: American Society of Pediatric Nephrology

Date - Time: Apr 22, 2011 - 09:39 AM

Comments

The American Society of Pedaitric Nephrology supports this measure.

1424: Monthly Hemoglobin Measurement for Pediatric Patients
Comment By
Name: Ms. Kathryn Schubert
Organization: American Society of Pediatric Nephrology

Date - Time: Apr 22, 2011 - 09:39 AM

Comments

The American Society of Pedaitric Nephrology supports this measure.

1433: Use of Iron Therapy for Pediatric Patients

Comment By
Name: Ms. Kathryn Schubert
Organization: American Society of Pediatric Nephrology

Date - Time: Apr 22, 2011 - 09:39 AM

Comments

The American Society of Pedaitric Nephrology supports this measure.

1425: Measurement of nPCR for Pediatric Hemodialysis Patients
Comment By
Name: Ms. Kathryn Schubert
Organization: American Society of Pediatric Nephrology

Date - Time: Apr 22, 2011 - 09:38 AM

Comments

The American Society of Pediatric Nephrology suggests that measures 1425 only be applied to adolescents > 12 years of age since the available evidence suggests that a normalized protein catabolic rate <1 gram/kg/day is predictive of sustained weight loss only in adolescent patients receiving maintenance hemodialysis.

1423: Minimum spKt/V for Pediatric Hemodialysis Patients
Comment By
Name: Ms. Kathryn Schubert
Organization: American Society of Pediatric Nephrology

Date - Time: Apr 22, 2011 - 09:37 AM

Comments

The American Society of Pediatric Nephrology supports this measure.

1421: Method of Adequacy Measurement for Pediatric Hemodialysis Patients
Comment By
Name: Ms. Kathryn Schubert
Organization: American Society of Pediatric Nephrology

Date - Time: Apr 22, 2011 - 09:37 AM

Comments

The American Society of Pediatric Nephrology supports this measure.

1418: Frequency of Adequacy Measurement for Pediatric Hemodialysis Patients
Comment By
Name: Ms. Kathryn Schubert
Organization: American Society of Pediatric Nephrology

Date - Time: Apr 22, 2011 - 09:36 AM

Comments

The American Society of Pediatric Nephrology supports this measure.

Comments on the general draft report
Comment By
Name: Ms. Kathryn Schubert
Organization: American Society of Pediatric Nephrology

On Behalf Of
Name: Kathryn Schubert
Organization: American Society of Pediatric Nephrology

Date - Time: Apr 22, 2011 - 09:35 AM

Comments

The American Society of Pediatric Nephrology (ASPN) appreciates the opportunity to comment.

The ASPN urges measure developers to begin work on measures that could be applied to home dialysis patients in the pediatric patient population. There is a much greater proportion of children on home dialysis than adults, and not having measures for this group would unfairly exclude pediatric patients and providers.

Additionally, pediatric measures should continue to be developed and implemented separately from adult measures. The pediatric population is unique and especially vulnerable. Separate measures would account for unique aspects of pediatric dialysis.

Finally, there appears to be an error in the draft report on page 3. There are not 7,200 pediatric dialysis patients. According to the latest USRDS report in 2008 there were 7,200 prevalent pediatric ESRD patients; of those about 5,100 had transplants, 1,250 were on HD and 850 were on PD. The correct total of pediatric dialysis patients is 2,100. The ASPN asks that this be corrected.

1438: Periodic Assessment of Post-Dialysis Weight by Nephrologists
Comment By
Name: Ms. Maureen Dailey, DNSc, RN
Organization: American Nurses Association

Date - Time: Apr 22, 2011 - 09:34 AM

Comments

The American Nurses Association (ANA) submits the following comments:

The intent of the standard is an actual assessment of the patient's dry weight to improve individualized care management. While the intent is good, the proposed method of measurement could create an undue burden for the renal care team. This may precipitate unintended consequences, such as work around behaviors, in order to meet the standard. Alternatively, a requirement of periodic dry weight assessment documentation in the health record may be more efficient and effective standard.

Comments on the general draft report
Comment By
Name: Ms. Christine Chen
Organization: Pacific Business Group on Health

Date - Time: Apr 21, 2011 - 05:21 PM

Comments

The Pacific Business Group on Health (PBGH) appreciates the opportunity to comment on these measures evaluated by the ESRD steering committee. We are very disappointed in the absence of outcome measures and the emphasis on process measures, many of which we fear will fall into the category of "check-the-box" measures. We are also concerned that this represents a movement away from high-value measures.

Comments on measures not recommended
Comment By
Name: Julie Black

Organization: Kidney Care Partners

Date - Time: Apr 21, 2011 - 04:47 PM

Comments

In addition to the measures recommended by NQF, KCP offers the following comments on two measures not recommended and strongly encourages their reconsideration: "Serum Phosphorus Greater Than 6 mg/dl" and "Avoidance of Iron Therapy in Iron Overload". Specifically, we recommend that these measures be advanced for voting as voluntary consensus standards.

NQF1429 Avoidance of Iron Therapy in Iron Overload (CMS): KCP supports this measure for public reporting only, and we recommend this measure be advanced to the voting phase. Again, given implementation of the bundled payment system, we believe this is an appropriate measure to evaluate quality of care for ESRD patients.

Comments on measures not recommended
Comment By
Name: Julie Black
Organization: Kidney Care Partners

Date - Time: Apr 21, 2011 - 04:47 PM

Comments

In addition to the measures recommended by NQF, KCP offers the following comments on two measures not recommended and strongly encourages their reconsideration: "Serum Phosphorus Greater Than 6 mg/dl" and "Avoidance of Iron Therapy in Iron Overload". Specifically, we recommend that these measures be advanced for voting as voluntary consensus standards.

NQF 1427 Adult Dialysis Patients - Serum Phosphorus Greater Than 6 mg/dl (Genzyme): KCP supports this measure for public reporting and payment, and we recommend this measure be advanced to the voting phase. We believe high serum phosphorus is a biomarker that is important to monitor. In addition, with the implementation of the bundled payment system (in particular the forthcoming inclusion of oral medications in the bundle), measures that can assess appropriate treatment/undertreatment are central to evaluate quality of care for ESRD patients.

1433: Use of Iron Therapy for Pediatric Patients
Comment By
Name: Julie Black
Organization: Kidney Care Partners

Date - Time: Apr 21, 2011 - 04:45 PM

Comments

KCP supports this measure for public reporting and payment.

1430: Lower Limit of Hemoglobin for Pediatric Patients
Comment By
Name: Julie Black
Organization: Kidney Care Partners

Date - Time: Apr 21, 2011 - 04:44 PM

Comments

KCP supports this measure for public reporting and payment.

1424: Monthly Hemoglobin Measurement for Pediatric Patients
Comment By
Name: Julie Black
Organization: Kidney Care Partners

Date - Time: Apr 21, 2011 - 04:43 PM

Comments

KCP supports this measure for public reporting and payment.

1425: Measurement of nPCR for Pediatric Hemodialysis Patients
Comment By
Name: Julie Black
Organization: Kidney Care Partners

Date - Time: Apr 21, 2011 - 04:41 PM

Comments

KCP supports this measure for public reporting and payment.

1423: Minimum spKt/V for Pediatric Hemodialysis Patients
Comment By
Name: Julie Black
Organization: Kidney Care Partners

Date - Time: Apr 21, 2011 - 04:40 PM

Comments

KCP supports this measure for public reporting and payment.

1421: Method of Adequacy Measurement for Pediatric Hemodialysis Patients
Comment By
Name: Julie Black
Organization: Kidney Care Partners

Date - Time: Apr 21, 2011 - 04:39 PM

Comments

KCP supports this measure for public reporting and payment.

1418: Frequency of Adequacy Measurement for Pediatric Hemodialysis Patients
Comment By
Name: Julie Black
Organization: Kidney Care Partners

Date - Time: Apr 21, 2011 - 04:38 PM

Comments

KCP supports this measure for public reporting and payment.

1463: Standardized Hospitalization Ratio for Admissions
Comment By
Name: Julie Black
Organization: Kidney Care Partners

Date - Time: Apr 21, 2011 - 04:37 PM

Comments

KCP recognizes the important area this measure addresses and supports it for public reporting only, subject to certain modifications. As the measure is currently specified, it encompasses all admissions. KCP recommends the specifications be modified to "Risk-adjusted standardized hospitalization ratio *for dialysis access-related infections and fluid overload,*" with the numerator and denominator limited to the appropriate DRGs for dialysis access-related infections and fluid overload. In addition to this recommended change, we note that the measure developer, CMS, needs to provide greater transparency of methodology—in particular clarity with respect to the denominator of "expected" hospitalizations.

1438: Periodic Assessment of Post-Dialysis Weight by Nephrologists
Comment By
Name: Julie Black
Organization: Kidney Care Partners

Date - Time: Apr 21, 2011 - 04:35 PM

Comments

KCP recognizes the important area this measure addresses, but does not support this measure at the facility level. KCP believes this aspect of care should be assessed at the clinician level. KCP also notes that the specifications require a "prescription," and recommends this be modified to an "assessment," as indicated in the description—a *new* prescription may not be necessary after the assessment. By "assessment," we mean documentation in the medical record/CROWNWeb that the assessment was done and either a new prescription was written or one was not required. We also note that the denominator is specified as "Number of patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis (HD)." We note this measure is also appropriate for home hemodialysis and peritoneal dialysis patients.

1460: National Healthcare Safety Network (NHSN) Bloodstream Infection Measure
Comment By
Name: Julie Black
Organization: Kidney Care Partners

Date - Time: Apr 21, 2011 - 04:34 PM

Comments

KCP supports this measure for public reporting only.

1454: Proportion of patients with hypercalcemia
Comment By
Name: Julie Black
Organization: Kidney Care Partners

Date - Time: Apr 21, 2011 - 04:32 PM

Comments

Mineral and Bone Disorder measures are specifically noted in MIPPA as an important area for quality measurement. KCP supports this measure for public reporting and payment. We also recommend that future development of measure for a lower limit for serum calcium be pursued.

Comments on the general draft report
Comment By
Name: Julie Black
Organization: Kidney Care Partners

Date - Time: Apr 21, 2011 - 04:28 PM

Comments

Again, thank you for undertaking this important project; we appreciate the opportunity to provide KCP's consensus comments. Please do not hesitate to contact us if you have any questions.

Abbott Laboratories; Affymax; American Kidney Fund; American Nephrology Nurses' Association; American Renal Associates, Inc.; American Society of Diagnostic and Interventional Nephrology; American Society of Nephrology; Amgen; Baxter Healthcare Corporation; Board of Nephrology Examiners and Technology; California Dialysis Council; Centers for Dialysis Care; DaVita, Inc.; Dialysis Patient Citizens; Fresenius Medical Care North America; Fresenius Medical Care Renal Therapies Group; Genzyme; Kidney Care Council; Mitsubishi Tanabe Pharma America; National Kidney Foundation; National Renal Administrators Association; Nephrology Nursing Certification Commission; Northwest Kidney Centers; NxStage Medical; Renal Support Network; Renal Ventures Management, LLC; sanofi-aventis; Satellite Healthcare; U.S. Renal Care; Watson Pharma, Inc.

Comments on the general draft report
Comment By
Name: Julie Black
Organization: Kidney Care Partners

Date - Time: Apr 21, 2011 - 04:28 PM

Comments

The NQF report recommends 11 measures be endorsed as national voluntary consensus standards. Our understanding is that NQF endorsement historically has been for the purposes of public reporting and internal quality improvement. As an operating premise, however, KCP has assumed that endorsement means the Centers for Medicare and Medicaid Services (CMS) may use a measure in the Quality Incentive Program (QIP)—i.e., for payment/value-based purchasing. And while CMS states it will use rulemaking to implement measures for the QIP, for purposes of clarity we have stated KCP's support for each measure in the context of intended use.

Comments on the general draft report
Comment By
Name: Julie Black
Organization: Kidney Care Partners

Date - Time: Apr 21, 2011 - 04:27 PM

Comments

Thank you for the opportunity to comment on the National Quality Forum's (NQF) draft document, *National Voluntary Consensus Standards for End Stage Renal Disease (ESRD) 2010: A Consensus Report*. Kidney Care Partners (KCP) is an alliance of members of the kidney care community that includes the full spectrum of stakeholders related to dialysis care—patient advocates, dialysis care professionals, dialysis providers, researchers, and manufacturers and suppliers—organized to advance policies that improve the quality of care for individuals with both chronic kidney disease and ESRD. We greatly appreciate NQF undertaking this important work and commend the significant contributions of the Steering Committee and NQF staff.

Comments on the general draft report
Comment By
Name: Mr. John Agos
Organization: Sanofi-Aventis

Date - Time: Apr 21, 2011 - 02:51 PM

Comments

reference for comments #5

[1] Coyne DW, Kapoian T, Suki W, et al. Ferric gluconate is highly efficacious in anemic hemodialysis patients with high serum ferritin and low transferrin saturation: results of the Dialysis Patients' Response to IV Iron with Elevated Ferritin (DRIVE) Study. J Am Soc Nephrol 2007; 18:975

[1] Kapoian T, O'Mara NB, Singh AK, et al. Ferric gluconate reduces epoetin requirements in hemodialysis patients with elevated ferritin. J Am Soc Nephrol. 2008;19:372-379

[1] Phrommintikul A, Haas SJ, Elsik M, Klum H: Mortality and target haemoglobin concentrations in anemia patients with chronic kidney disease treated with erythropoietin: A meta-analysis. Lancet 369: 381–388, 2007.

[1] Singh AK, Szczech L, Tang KL, Barnhart H, Sapp S, Wolfson M, Reddan, CHOIR Investigators: Correction of anemia with epoetin alfa in chronic kidney disease. N Engl J Med 355: 2085–2098,2006.

[1] K/DOQI Clinical practice guidelines and clinical practice recommendations for anemia in chronic kidney disease. Am J Kidney Dis 2006; 47(Suppl 3):S1.

Comments on the general draft report
Comment By
Name: Mr. John Agos
Organization: Sanofi-Aventis

Date - Time: Apr 21, 2011 - 02:50 PM

Comments

comment 4 of 4

Given that clinical guidelines have significant influence on clinical practice and when tied to incentives have the potential to change patient outcomes, this highlights the need for further research into the clinical benefits of wider adoption of this alternative treatment strategy, i.e., treating up to 1200 ng/ml.

In conclusion, sanofi-aventis fully supports this project and looks forward to seeing the development, endorsement, and use of additional performance measures in the ESRD space as tools to promote improvements in patient-centered care.

Sincerely,
Akbar Akbary MD
Sr. Director Medical Affairs

Comments on the general draft report
Comment By
Name: Mr. John Agos
Organization: Sanofi-Aventis

Date - Time: Apr 21, 2011 - 02:49 PM

Comments

comment 3 of 3

In addition, from the DRIVE study there is evidence to support clinical benefits and safety of intravenous (IV) iron therapy in anemic hemodialysis patients with serum ferritin between 500 ng/ml and 1200 ng/ml and transferring saturation (TSAT) below <25%[1]. As an extension of DRIVE, the DRIVE-II study found that epoetin requirements were reduced in patients who received iron during DRIVE while they remained the same for the control (no iron therapy) group[1]. The outcome of DRIVE-II has significant implications because lower utilization of epoetin is associated with a lower risk of adverse events such as strokes and cardiovascular events[2][3]. However, current National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines specify a serum ferritin of 500 ng/ml as the threshold above which iron therapy decisions should be made after evaluating the patient's clinical status and the results of additional tests such as TSAT and hemoglobin[4].

Sincerely,
Akbar Akbary MD
Sr. Director Medical Affairs

[

Comments on the general draft report
Comment By
Name: Mr. John Agos
Organization: Sanofi-Aventis

Date - Time: Apr 21, 2011 - 02:47 PM

Comments

comment # 2 of 3

Although NQF has already endorsed 25 measures through its 2008 National Voluntary Consensus Standards for ESRD project, we believe significant gaps remain, specifically with respect to iron deficiency anemia and the use of iron therapy. Therefore we, take this opportunity to highlight the need for further research into the treatment of iron deficiency anemia in ESRD patients undergoing hemodialysis. For example, with regards to a measure that was not recommended for endorsement namely, 'Avoidance of Iron Therapy in Iron Overload' (1429), a reason given by the committee for not recommending the measure was that definitions of iron overload are not evidence-based. While the measure developer selected 1200 ng/ml as the threshold above which iron should not be administered, there is little published evidence to support this threshold. This calls for broader research into appropriate markers for determining the adequacy of iron therapy in the context of overall clinical benefit and safety.

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[1] Coyne DW, Kapoian T, Suki W, et al. Ferric gluconate is highly efficacious in anemic hemodialysis patients with high serum ferritin and low transferrin saturation: results of the Dialysis Patients' Response to IV Iron with Elevated Ferritin (DRIVE) Study. J Am Soc Nephrol 2007; 18:975

Comments on the general draft report
Comment By
Name: Mr. John Agos

Organization: Sanofi-Aventis

Date - Time: Apr 21, 2011 - 02:45 PM

Comments

Comment #1 of three comments

On behalf of sanofi-aventis, we are pleased to respond to National Quality Forum's (NQF) call for comments on the project: National Voluntary Consensus Standards for End-Stage Renal Disease (ESRD). We acknowledge the impact of ESRD on patients and families as well as the overall burden on society. We therefore support efforts by NQF in the use of consensus standards to drive significant improvements in the care received by pediatric and adult patients with ESRD. In particular, sanofi-aventis recognizes the need to increase the number of standards focusing on the pediatric population, a theme which is reflected in the choice of seven of the eleven proposed quality measures recommended by the steering committee. Overall, sanofi-aventis applauds continuing efforts by NQF to influence the quality of care for patients with ESRD and we look forward to being fully engaged with the upcoming endorsement maintenance cycle project for renal disease.

1460: National Healthcare Safety Network (NHSN) Bloodstream Infection Measure
Comment By
Name: Ms. Gaye Fortner
Organization: HealthCare 21 Business Coalition

Date - Time: Apr 21, 2011 - 10:09 AM

Comments

I support endorsement of this measure, and believe it will add greatly to the current portfolio of measures designed to improve patient safety and reduce harmful and costly infection rates, particularly for the most vulnerable patients undergoing dialysis.

1423: Minimum spKt/V for Pediatric Hemodialysis Patients
Comment By
Name: Ms. Gaye Fortner
Organization: HealthCare 21 Business Coalition

Date - Time: Apr 21, 2011 - 10:09 AM

Comments

Measures that capture laboratory data on a continuous scale, rather than in binary form (e.g., above or below a threshold value) that is tied to guidelines or opinions and subject to change are better. This distinction is particularly important in this case, since the evidence does not fully support the value of 1.2 as the ideal spKt/V level for pediatric patients. Unless this measure could be modified to allow for continuous lab value data collection, I cannot support it.

1421: Method of Adequacy Measurement for Pediatric Hemodialysis Patients
Comment By
Name: Ms. Gaye Fortner
Organization: HealthCare 21 Business Coalition

Date - Time: Apr 21, 2011 - 10:07 AM

Comments

The draft report and supporting material do not make a strong case for the importance of this measure, which only looks at the method used to collect data on dialysis adequacy. The materials included for review do not provide enough information on a) to what extent dialysis centers are not using the "preferred" methods of UKM or Daugirdas II to collect the adequacy data; or b) why using alternative methods would negatively affect patients. Without this information it is hard to make the

case for why consumers or purchasers would support this measure.

1424: Monthly Hemoglobin Measurement for Pediatric Patients
Comment By
Name: Ms. Gaye Fortner
Organization: HealthCare 21 Business Coalition

Date - Time: Apr 21, 2011 - 10:01 AM

Comments

This measure will only provide information on whether the dialysis center recorded a patient's spKt/V, nPCR, and hemoglobin values each month. It does not provide information on whether these data are being used in a way that will improve dialysis treatment. Therefore I do not think that this measure meets the standard for importance or usability. While measuring these values frequently comprises important process steps in the care of ESRD patients, having measures only of the frequency -and not the data themselves - is setting the bar particularly low.

1425: Measurement of nPCR for Pediatric Hemodialysis Patients
Comment By
Name: Ms. Gaye Fortner
Organization: HealthCare 21 Business Coalition

Date - Time: Apr 21, 2011 - 10:00 AM

Comments

This measure will only provide information on whether the dialysis center recorded a patient's spKt/V, nPCR, and hemoglobin values each month. It does not provide information on whether these data are being used in a way that will improve dialysis treatment. Therefore I do not think that this measure meets the standard for importance or usability. While measuring these values frequently comprises important process steps in the care of ESRD patients, having measures only of the frequency -and not the data themselves - is setting the bar particularly low.

1418: Frequency of Adequacy Measurement for Pediatric Hemodialysis Patients
Comment By
Name: Ms. Gaye Fortner
Organization: HealthCare 21 Business Coalition

Date - Time: Apr 21, 2011 - 10:00 AM

Comments

This measure will only provide information on whether the dialysis center recorded a patient's spKt/V, nPCR, and hemoglobin values each month. It does not provide information on whether these data are being used in a way that will improve dialysis treatment. Therefore I do not think that this measure meets the standard for importance or usability. While measuring these values frequently comprises important process steps in the care of ESRD patients, having measures only of the frequency -and not the data themselves - is setting the bar particularly low.

Comments on the general draft report
Comment By
Name: Dr. Thomas James, III, MD
Organization: Humana Inc.

Date - Time: Apr 21, 2011 - 06:45 AM

Comments

Aside from NQF #1463 Standardized hospitalization ratio, the other measures have clinical utility but cannot be captured using claims data sets. Because these will necessarily be reported through more manual mechanisms, it may be useful to prioritize those ESRD measures and use the ones of greater importance to clincial outcomes rather than the entire set when evaluating effectiveness of care

1463: Standardized Hospitalization Ratio for Admissions
Comment By
Name: Dr. Thomas James, III, MD
Organization: Humana Inc.

Date - Time: Apr 21, 2011 - 06:36 AM

Comments

Health plans will need the exact definitions of "risk adjustment" in order to calculate this particular measure. It is the only one of the ESRD measures that can be derived from claims data. We would look to the developer to publish the elements to be included in the numerator, denominator and in the exclusions. With that information this will become an important measure and one that could be widely caluclated using health plan data.

1460: National Healthcare Safety Network (NHSN) Bloodstream Infection Measure
Comment By
Name: Ms. Bonnie L. Freshly, MEd
Organization: The National Forum of ESRD Networks

Date - Time: Apr 20, 2011 - 02:07 PM

Comments

One reviewer offers:

1. Interpretation of measure is unclear. Is it good or bad if there is a low rate of positive cultures? Is it a measure of proper blood culture drawing, handling, transporting, etc. in addition to correlating blood culture positivity with access type? Suppose blood cultures were obtained in every patient, every week as "surviellance." Without a specified indication (fever, erythema and drainage at insertion site, etc), this measure does not inform clinical or beneficiary decison making.
2. Measure might be more useful if it included a stratification for positive blood cultures/total blood cultures or total number of blood cultures obtained per patient-months.

A second reviewer disagreed and commented:

1. Since we start by knowing nothing about our access infection rates, or how they compare to other facilities', I'd argue that the raw rate (stratified by access type) is very valuable information, that collecting the blood culture information is challenging enough, and that requiring the addition of the clinical information suggested by the first reviewer would put the enterprise back several years.
2. It's number of positive blood cultures per unit time, not number of positive blood cultures per number of blood cultures performed per unit time.

1463: Standardized Hospitalization Ratio for Admissions
Comment By
Name: Ms. Bonnie L. Freshly, MEd
Organization: The National Forum of ESRD Networks

Date - Time: Apr 20, 2011 - 01:42 PM

Comments

1. Will comorbidity index be calculated? By what method? Charlson? Age adjusted? Or is this merely "yes or no" for various comorbidities from the 2728 form?

1454: Proportion of patients with hypercalcemia
Comment By
Name: Ms. Bonnie L. Freshly, MEd
Organization: The National Forum of ESRD Networks

Date - Time: Apr 20, 2011 - 01:35 PM

Comments

1. Could not find in specs that blood should be drawn for this measure prior to start of dialysis.
2. For PD patients change "at facility" to "by outpatient facility…"

1438: Periodic Assessment of Post-Dialysis Weight by Nephrologists
Comment By
Name: Ms. Bonnie L. Freshly, MEd
Organization: The National Forum of ESRD Networks

Date - Time: Apr 20, 2011 - 01:33 PM

Comments

1. Agree with time limited status to determine whether this measure will result in improved ECF control, hospitalizations for cardiac causes, etc.
2. This is a weak measure – "receiving a new post dialysis weight" will not be likely to improve patient outcomes because it does not assure that a proper, correct, or appropriate change has occurred (e.g., a patient with obvious ECF expansion crashes recurrently during dialysis so the dry weight is increased).
3. Hi burden without ability for electronic submission.
4. Agree with committee's suggestion to include "… irrespective of change or not."

1433: Use of Iron Therapy for Pediatric Patients
Comment By
Name: Ms. Bonnie L. Freshly, MEd
Organization: The National Forum of ESRD Networks

Date - Time: Apr 20, 2011 - 01:19 PM

Comments

1. Replace in exclusions: "PD patients not in facility …" with "PD patients not followed by the facility …"
2. Does not imply appropriate frequency for measuring % sat and ferritin or appropriate interval after IV iron for re-measurement.
3. Agree with time-limited status.

1424: Monthly Hemoglobin Measurement for Pediatric Patients
Comment By
Name: Ms. Bonnie L. Freshly, MEd
Organization: The National Forum of ESRD Networks

Date - Time: Apr 20, 2011 - 01:17 PM

Comments

1. Title of measure should specify both HD and PD.
2. Exclusion criteria: "Not in facility …" statements do not capture home patients, who may never be in the facility. Rather, the phrase should be changed for home dialysis patients to read "followed by the facility for entire month."

1425: Measurement of nPCR for Pediatric Hemodialysis Patients
Comment By
Name: Ms. Bonnie L. Freshly, MEd
Organization: The National Forum of ESRD Networks

Date - Time: Apr 20, 2011 - 01:16 PM

Comments

1. Agree with time limited requirement because measure is untested and evidence lacking.
2. Disagree with "irrespective of frequency" because nPCR is based on interdialytic interval and therefore frequency of dialysis should ne considered.
3. What method for nPCR calculation? Will 24 hr urine collections be required? When?

1424: Monthly Hemoglobin Measurement for Pediatric Patients
Comment By
Name: Ms. Bonnie L. Freshly, MEd
Organization: The National Forum of ESRD Networks

Date - Time: Apr 20, 2011 - 01:15 PM

Comments

1. Title of measure should specify both HD and PD.
2. Exclusion criteria: "Not in facility …" statements do not capture home patients, who may never be in the facility. Rather, the phrase should be changed for home dialysis patients to read "followed by the facility for entire month."

1433: Use of Iron Therapy for Pediatric Patients
Comment By
Name: Ms. Bonnie L. Freshly, MEd
Organization: The National Forum of ESRD Networks

Date - Time: Apr 20, 2011 - 01:13 PM

Comments

1. Replace in exclusions: "PD patients not in facility …" with "PD patients not followed by the facility …"
2. Does not imply appropriate frequency for measuring % sat and ferritin or appropriate interval after IV iron for re-measurement.
3. Agree with time-limited status.

1433: Use of Iron Therapy for Pediatric Patients
Comment By
Name: Ms. Bonnie L. Freshly, MEd
Organization: The National Forum of ESRD Networks

Date - Time: Apr 20, 2011 - 01:11 PM

Comments

1. PD patients should be included
2. Agree that patients with sickle cell anemia should be excluded.

1430: Lower Limit of Hemoglobin for Pediatric Patients
Comment By
Name: Ms. Bonnie L. Freshly, MEd
Organization: The National Forum of ESRD Networks

Date - Time: Apr 20, 2011 - 01:08 PM

Comments

1. PD patients should be included
2. Agree that patients with sickle cell anemia should be excluded.

1424: Monthly Hemoglobin Measurement for Pediatric Patients
Comment By
Name: Ms. Bonnie L. Freshly, MEd
Organization: The National Forum of ESRD Networks

Date - Time: Apr 20, 2011 - 01:05 PM

Comments

1. Title of measure should specify both HD and PD.
2. Exclusion criteria: "Not in facility …" statements do not capture home patients, who may never be in the facility. Rather, the phrase should be changed for home dialysis patients to read "followed by the facility for entire month."

1423: Minimum spKt/V for Pediatric Hemodialysis Patients
Comment By
Name: Ms. Bonnie L. Freshly, MEd
Organization: The National Forum of ESRD Networks

Date - Time: Apr 20, 2011 - 01:04 PM

Comments

1. Home hemodialysis patients should be included.
2. Adequacy measures should take frequency of dialysis into account – need a new standard based on weekly KT?V – should be blended with adult adequacy measures.

Comments on the general draft report
Comment By
Name: Ms. Rabia Khan, MPH
Organization: Centers for Medicare and Medicaid Services

Date - Time: Apr 20, 2011 - 09:41 AM

Comments

Sodium Profiling Practice (1434)

In the United States, a significant proportion of HD patients are repeatedly subjected to the practice of sodium profiling in dialysis facilities to ensure stability of the HD session. While the practice tends to achieve this aim, it exposes the patient to a high time averaged dialysate sodium concentration of 140-145mEq/L in the process, even though the intent is to lower the serum sodium by the end of the treatment (Flanigan 2000, Levin 2001). Sodium loading during dialysis militates against sodium restriction by the patient during the interdialytic interval. Elimination of this practice over time in the vast majority of HD patients will prevent this repetitive sodium loading which has the potential for cumulative harm in the form of excessive thirst, excessive interdialytic weight gains, hypertension, with worsening left ventricular hypertrophy, heart failure, etc., and counteracts the beneficial effects of dietary sodium reduction by the patient. The recent European best practice guidelines (2009) do not recommend the use of sodium profiling for these reasons. The KDOQI (2006) panel had also cautioned against the potential deleterious effects of this practice. **We therefore strongly urge the NQF to reconsider the endorsement of this measure.** Feasibility for both Measure 1434 and 1435 is high and widespread implementation, along with measure 1432 is likely to reduce exposure to excessive sodium load during dialysis sessions.

Comments on the general draft report
Comment By
Name: Ms. Rabia Khan, MPH
Organization: Centers for Medicare and Medicaid Services

Date - Time: Apr 20, 2011 - 09:40 AM

Comments

1435: Lowering of dietary sodium intake as envisaged by dietary restriction of sodium in measure 1432, would not serve its intended purpose in management of overhydrated dialysis patients if during the dialysis procedure itself patients were to receive repeated exposure to sodium concentrations ranging typically from 140-145mEq/L in the dialysate or subjected to 'sodium profiling' with high time averaged dialysate sodium concentration of 140-145mEq/L (Flanigan, 2000, Levin, 2001, Davenport, 2006) thereby resulting in significant sodium gain that induces thirst and excessive interdialytic weight gain and volume induced hypertension, warranting high rates of ultrafiltration at the next dialysis session thereby leading to a vicious cycle underlying the high cardiovascular mortality observed in this patient population. These arguments have been well articulated in a recent in-depth review of a number of clinical studies that support the reduction in average dialysate sodium to <138mEq/L (Santos and Piexoto, 2008). This measure is likely to be high impact because it has the potential to lower the net sodium gain by dialysis patients during dialysis treatments and would supplement measure 1432. Feasibility for both Measure 1434 and 1435 is high and widespread implementation is likely to reduce exposure to excessive sodium load during dialysis sessions. **We therefore strongly urge the NQF to reconsider the endorsement of this measure along with measures 1432 and 1434.**

Comments on the general draft report
Comment By

Name: Ms. Rabia Khan, MPH
Organization: Centers for Medicare and Medicaid Services

Date - Time: Apr 20, 2011 - 09:33 AM

Comments

On behalf of Dr. Michael Rapp:

Dietary sodium restriction to at least K/DOQI recommended levels (and lower if tolerated in individual patients) is fundamental to the management of hypertension and improving the almost universally volume expanded state in dialysis patients (Bibbins-Domingo 2010; Frieden & Briss 2010; Smith-Spangler, et al. 2010, Appel & Anderson 2010; Kayikcioglu 2009).**In our view, therefore it would be considered one of the best practices that should be diligently and urgently implemented by all dialysis facilities. This measure is similar in principle to the measure requiring the periodic assessment of post-dialysis weight by nephrologist endorsed by the NQF and consistent with K/DOQI guidelines for periodic dietary counseling and focuses on the need to provide counseling with regard to lowering of sodium intake for dialysis patients. Widespread implementation of this measure should be feasible and potentially high impact, thus leading to better patient outcomes. We therefore strongly urge the NQF to reconsider this measure for endorsement.**

1438: Periodic Assessment of Post-Dialysis Weight by Nephrologists
Comment By
Name: Ms. Rabia Khan, MPH
Organization: Centers for Medicare and Medicaid Services

Date - Time: Apr 20, 2011 - 09:31 AM

Comments

On behalf of Dr. Michael Rapp:

We commend the NQF Steering Committee for recognizing the importance of this topic area in general and specifically for recommending this important measure for endorsement. Formal requirement for periodic assessment of post dialysis weight is likely to raise awareness of the importance of periodic formal assessment of target post-dialysis weight in the dialysis community and focus the attention of the treating nephrologist as well as other personnel in the dialysis units to the regular documentation of this field. Currently, while nephrologists realize its clinical importance, there is the likelihood of significant variation in the rigor with which they seek to optimize their post dialysis weight prescription on a periodic basis. It is ultimately this diligence that is likely to pay dividends in terms of improving the achievement of optimal state of hydration that is so crucial to improving patient outcomes.

Comments on the general draft report
Comment By
Name: Ms. Rabia Khan, MPH
Organization: Centers for Medicare and Medicaid Services

Date - Time: Apr 19, 2011 - 03:37 PM

Comments

On behalf of Dr. Michael Rapp:

In general, the focus on IV iron use is important because prudent use of IV iron improves management of anemia and encourages optimum utilization of pharmacologic and laboratory resources. More specifically, this measure is intended to minimize the potential harm of excess iron administration to dialysis patients. The ferritin limit of 1200 ng/mL is supported by a series of observational studies which demonstrate no safety signal for patients with serum ferritin values up to that level. The safety of ferritin >1200 ng/mL has not been evaluated. At the same time, we recognize limitations of the evidence and that some practitioners may choose to not dose IV iron to patients with ferritin of 500 to 1200 ng/mL. For this reason, the measure does not evaluate IV iron dosing in the 500 to 1200 ng/mL ferritin range.

Comments on the general draft report
Comment By
Name: Ms. Rabia Khan, MPH
Organization: Centers for Medicare and Medicaid Services

Date - Time: Apr 19, 2011 - 03:37 PM

Comments

On behalf of Dr. Michael Rapp:

The measure focus is important because prudent use of IV iron when indicated in dialysis patients improves management of anemia by lowering the dose of ESA needed to maintain the Hgb in the target range. The cut-point of 100 ng/mL was chosen because this is a level below which there is clear consensus about iron deficiency for all dialysis patients receiving an ESA, i.e. the need for IV iron therapy to optimize Hgb response to ESA dosing. This is conservative cupoint because, in practice, many providers give replacement IV iron to HD patients with ferritin <200 ng/mL. The TSAT cut-point of 50% was chosen because TSAT <20% should not be used independently to determine iron deficiency, due to high within-subject and between-assay variability and the effect of inflammation on lowering TSAT levels. On the other hand, iron is typically withheld for TSAT >50% due to concerns about iron overload. We recognize that very few patients have both ferritin <100 ng/mL and TSAT >50%.

Comments on the general draft report
Comment By
Name: Ms. Rabia Khan, MPH
Organization: Centers for Medicare and Medicaid Services

Date - Time: Apr 19, 2011 - 03:36 PM

Comments

On behalf of Dr. Michael Rapp:

Assessment of Iron Stores

The measure focus is important because assessment of iron stores improves the management of anemia by facilitating the prudent use of IV iron, lowering the dose of erythropoietin stimulating agent (ESA) needed to maintain the hemoglobin in the target range, lessening the risk and potential harm of excess iron administration, and encouraging optimum utilization of pharmacologic and laboratory resources. **The proposed measure was intended to replace the prior CPM (**CROWNWeb Phase III Anemia Management CPM IIa) based on the following rationale: (1) measuring ferrtin and TSAT on the same day is consistent with current practice, as 99% measured within one month were measured on the same day in CROWNWeb test data,; (2) measuring serum ferritin and TSAT for all patients (rather than patients with Hgb<11) is consistent with the trend to utilize rational iron dosing strategies to limit to ESA therapy overall; while patients with near-normal Hgb levels without long-term ESA use would not benefit from ferritin/TSAT monitoring, this applies to <2% of dialysis patients; (3) dropping the use of reticulocyte hemoglobin content (CHr) as an alternative to TSAT levels is consistent with current practice, as 0.2% of patients had CHr but not TSAT values in CROWNWeb test data.

1460: National Healthcare Safety Network (NHSN) Bloodstream Infection Measure
Comment By
Name: Ms. Rabia Khan, MPH
Organization: Centers for Medicare and Medicaid Services

Date - Time: Apr 19, 2011 - 03:35 PM

Comments

On behalf of Dr. Michael Rapp:

The NQF and its steering committee later recommended that CMS and CDC collaborate on an infection measure. As a result, both agencies now plan to use the CDC-submitted bloodstream infection measure (1460) because it can calculated based on either CDC's NHSN data or CMS's CROWNWeb data.

A CMS Clinical Technical Expert Panel (C-TEP) provided the basis for the CMS infection measures. This panel proposed a collection of infection measures within the construct of an overarching quality-monitoring program that minimized data collection burden. The NQF steering committee's recommendation of one infection measure for endorsement is an important piece of this program; however, we feel it is important not to lose sight of the broader infection program. As the CMS CROWNWeb data collection begins, revised or additional quality measures that incorporate elements from the proposed suite measure (e. g., extension to PD catheter-related infections; clarify how bacteremia and access-related bacteremia are defined/attributed) into the CDC measure.
C-TEP and D-TEP Meeting Synthesis Report:http://www.cms.gov/CPMProject/Downloads/ESRD2010TechnicalExpertPanelReport.pdf

1425: Measurement of nPCR for Pediatric Hemodialysis Patients
Comment By
Name: Ms. Rabia Khan, MPH
Organization: Centers for Medicare and Medicaid Services

Date - Time: Apr 19, 2011 - 03:33 PM

Comments

On behalf of Dr. Michael Rapp:

In the pediatric population, the assessment of dialysis adequacy requires an evaluation of both small solute clearance and nutritional status in order to promote growth and visceral weight gain. Whereas there are several potentialmeasures of nutritional status, these are outside the scope of HD adequacy measures with the exception of nPCR a value that is a fundamental component of and already readily available from urea kinetics.

nPCR provides an estimate of dietary protein intake and has been shown to provide additional information to spKt/V. In malnourished adolescent patients who achieved target spKt/V levels, nPCR, but not serum albumin, was associated with nutritional status. In adolescent patients, nPCR levels <1 gram/kg/day were found to be an earlier and more sensitive marker than serum albumin levels in predicting malnutrition and sustained weight loss.

We would like to note that the denominator of this measure has a typographical error and this should be revised to include all pediatric in-center hemodialysis patients (rather than patients with an nPCR measure).

1423: Minimum spKt/V for Pediatric Hemodialysis Patients
Comment By
Name: Ms. Rabia Khan, MPH
Organization: Centers for Medicare and Medicaid Services

Date - Time: Apr 19, 2011 - 03:31 PM

Comments

On behalf of Dr. Michael Rapp:

In considering target spKt/V, the pediatric population should receive at least an 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 a significantly increased risk of hospitalization as compared to those with spKt/V of 1.2-1.4. Whereas a higher target Kt/V may be necessary in the pediatric population given the increased dietary needs to ensure growth, there is insufficient evidence to support increasing target Kt/V based on hospitalization rates and mortality. A proportion of pediatric patients receive a dialysis dose below the target adult spKt/V suggesting that even with this target, there is room for improvement in quality of care.

This proposed measure differs from the corresponding adult adequacy measure in that this includes patients on 4x/week dialysis. Analysis of 2007 claims data suggests that in 5.6% of pediatric patient-weeks, dialysis sessions occurred 4x/week. There were 3 or 4 dialysis sessions in approximately 88% of patient-weeks. Based on these results it is evident that by restricting the denominator to HD patients receiving dialysis 3 or 4 times weekly, the measure will be applicable to most pediatric HD patients.

1421: Method of Adequacy Measurement for Pediatric Hemodialysis Patients
Comment By
Name: Ms. Rabia Khan, MPH
Organization: Centers for Medicare and Medicaid Services

Date - Time: Apr 19, 2011 - 11:18 AM

Comments

On behalf of Dr. Michael Rapp:

Various methods for estimating urea clearance (Kt/V) were considered. The second generation natural logarithmic formula (Daugirdas II formula) has been shown to approximate Kt/V obtained from formal urea kinetic modeling. Data from a single-center pediatric study showed that calculation of spKt/V using urea kinetic monitoring (UKM) or Daugirdas II was reliable. The use of an equilibrated two-compartment model eKt/V was also evaluated. Although eKt/V has some advantage over spKt/V in that it takes into account urea rebound, data suggest a low rate of spKt/V and eKt/V discordance (defined as spKt/V > 0.2 higher than eKt/V). The use of standard Kt/V was considered but not accepted due to potential difficulty in interpreting this metric as it is currently not widely used in patients receiving less than 5 times weekly HD. Surface area normalized Kt/V was also considered but not included in the measure because this has not been studied in the pediatric population, and the implications of its use including the need for more frequent and intensified dialysis may not be feasible. The use of spKt/V as calculated using formal urea kinetic modeling or the Daugirdas II formula is consistent with clinical practice guidelines in the pediatric population, as well as with the clinical performance measures in the adult population.

1418: Frequency of Adequacy Measurement for Pediatric Hemodialysis Patients
Comment By
Name: Ms. Rabia Khan, MPH
Organization: Centers for Medicare and Medicaid Services

Date - Time: Apr 19, 2011 - 11:16 AM

Comments

On behalf of Dr. Michael Rapp:

In the adult population, outcome studies have shown an association between dose of HD in terms of small solute removal and clinical outcomes. However, no equivalent large scale clinical trials have been conducted in the pediatric HD population. Smaller observational studies support the association between delivered HD dose and patient outcomes including the potential for improved growth with intensive HD regimens.

Since pediatric patients are in a growth phase, a minimum of monthly evaluation of HD adequacy is critical to ensure timely dose adjustment as needed. A performance gap currently exists- analysis of 2007 CPM data demonstrate that during the 3 month study period, dialysis adequacy using spKt/V was not measured at any time in 20% of pediatric patients. For all of these reasons, monthly measurement of HD adequacy is a highly important measure in the pediatric population.

The Committee raised a question regarding the use of stdKt/V. However, because of potential difficulty in interpreting this metric as it is currently not widely used in patients receiving <5x/week HD, this is currently not feasible to implement. Furthermore, analysis of 2007 claims data (N=312 patients with first Medicare dialysis claim on or before January 1, 2007) suggest that in only 1% of pediatric patient-weeks, dialysis sessions occurred five or more times per week.

1433: Use of Iron Therapy for Pediatric Patients
Comment By
Name: Ms. Rabia Khan, MPH
Organization: Centers for Medicare and Medicaid Services

Date - Time: Apr 19, 2011 - 11:14 AM

Comments

On behalf of Dr. Michael Rapp:

Iron deficiency is a leading cause of non-response to ESA therapy, and several studies demonstrate the effectiveness of oral or IV iron in correcting iron deficiency in the pediatric population.

The Committee notes a concern that a potential unintended consequence of this measure may be an overuse of iron therapy. We believe that the appropriate response to the initiation of iron therapy is evaluating clinical response and repeating the measurement of iron stores. We will address this further in our testing plan for this measure.

1430: Lower Limit of Hemoglobin for Pediatric Patients
Comment By
Name: Ms. Rabia Khan, MPH
Organization: Centers for Medicare and Medicaid Services

Date - Time: Apr 19, 2011 - 11:13 AM

Comments

On behalf of Dr. Michael Rapp:

Evidence suggests that among CKD pediatric patients, anemia is associated with adverse outcomes. A significant performance gap also exists, as an analysis of CPM data demonstrated that 16% of pediatric patients had mean hemoglobin levels <10g/dL in 2007.

There were two conditions that the Committee had given us prior to endorsement of this measure. The first requested the exclusion of patients with sickle cell anemia (SC). On discussion with our Technical Expert Panel, we agreed with the Committee, however, due to data limitations, that the diagnosis of SC disease may not be available for exclusion. We therefore recommended that the exclusion of SC patients be implemented as a measure maintenance step as soon as data for this diagnosis are available.

The second condition proposed the use of persistently low Hb levels for 3 months rather than the original measure of a mean level of Hb<10g/dL. We believe that using the mean may be more appropriate because 1)using persistently low levels reduces the measure sensitivity, 2) studies as well as existing policies utilize mean levels, and 3) using a persistently low level may delay an appropriate clinical response.

1424: Monthly Hemoglobin Measurement for Pediatric Patients
Comment By
Name: Ms. Rabia Khan, MPH
Organization: Centers for Medicare and Medicaid Services

Date - Time: Apr 19, 2011 - 11:11 AM

Comments

On behalf of Dr. Michael Rapp:

Anemia is associated with increased mortality risk and hospitalizations in CKD pediatric patients. Staples et al analyzed stage II-V predialysis CKD patients and found that anemic children were 55% more likely to be hospitalized compared to non-anemic children.

Warady and Ho studied pediatric hemodialysis (HD) and peritoneal dialysis (PD) patients at the initiation of dialysis and showed that 68% of patients were anemic (hematocrit<33%), and that anemia was associated with a 55% increase in mortality risk. An increased risk of mortality with lower hemoglobin levels was also observed in adolescent HD patients (Amaral et al). These studies demonstrate the importance of managing anemia, including routine measurement of hemoglobin levels, in the pediatric ESRD population.

A significant performance gap in measurement of hemoglobin levels currently exists. Analysis of the 2008 CPM project, in which hemoglobin data were collected over a 6 month period (October 2007 through March 2008), indicated that 29% of pediatric ESRD patients had fewer than three hemoglobin values, with 11% (N=81) missing hemoglobin in all six study months. These data support the clinical importance of developing a measure that ensures regular monitoring of hemoglobin values.

Comments on the general draft report

Comment By
Name: Ms. Rabia Khan, MPH
Organization: Centers for Medicare and Medicaid Services

On Behalf Of
Name: Michael Rapp
Organization: CMS

Date - Time: Apr 18, 2011 - 03:19 PM

Comments

Monthly Hemoglobin Measurement for Pediatric Patients

Anemia is associated with increased mortality risk and hospitalizations in CKD pediatric patients. Staples et al analyzed stage II-V predialysis CKD patients and found that anemic children were 55% more likely to be hospitalized compared to non-anemic children. Warady and Ho studied pediatric hemodialysis (HD) and peritoneal dialysis (PD) patients at the initiation of dialysis and showed that 68% of patients were anemic (hematocrit<33%), and that anemia was associated with a 55% increase in mortality risk. An increased risk of mortality with lower hemoglobin levels was also observed in adolescent HD patients (Amaral et al). These studies demonstrate the importance of managing anemia, including routine measurement of hemoglobin levels, in the pediatric ESRD population.

A significant performance gap in measurement of hemoglobin levels currently exists. Analysis of the 2008 CPM project, in which hemoglobin data were collected over a 6 month period (October 2007 through March 2008), indicated that 29% of pediatric ESRD patients had fewer than three hemoglobin values, with 11% (N=81) missing hemoglobin in all six study months. These data support the clinical importance of developing a measure that ensures regular monitoring of hemoglobin values.

Comments on the general draft report

Comment By
Name: Ms. Rabia Khan, MPH
Organization: Centers for Medicare and Medicaid Services

On Behalf Of
Name: Michael Rapp
Organization: CMS

Date - Time: Apr 18, 2011 - 03:10 PM

Comments

Measure of Iron Stores for Pediatric Patients

The use of ESAs and iron supplementation are effective therapies for correcting anemia in children with ESRD. However, erythropoietin therapy will not result in an increase in hemoglobin if iron stores are deficient. As such, assessment of iron stores is important to ensure success of anemia management.

The Committee's primary reason for not endorsing this measure is because "obtaining a laboratory value is not proximal to desired outcomes". We understand the committee's reason; however, we believe that it would be important to measure iron stores when hemoglobin levels are low, so that an appropriate clinical response can be initiated. This is consistent with the Committee's approach to another measure that was recommended for endorsement- Measure 1418 (Frequency of adequacy measurement for pediatric patients). In addition, our analysis of pediatric patients demonstrates that at the facility level, only 80% of facilities had all patients meeting this measurement requirement. These suggest a significant performance gap with opportunity

for improvement. Nevertheless, we will work on revising this measure for future consideration by the NQF.

Comments on the general draft report

Comment By
Name: Ms. Rabia Khan, MPH
Organization: Centers for Medicare and Medicaid Services

On Behalf Of
Name: Michael Rapp
Organization: CMS

Date - Time: Apr 18, 2011 - 03:08 PM

Comments

Standardized Hospitalization Ratio for Days

We would like to reiterate that our validity testing for the NQF form shows that SHR Days is significantly correlated with important facility practices and outcomes. SHR Days is significantly correlated with the Standardized Mortality Ratio (SMR) over a 2006-2008 cohort (r=0.45). Additionally, SHR Days is negatively correlated with % of patients in the facility with AV Fistula in each of the 3 years (r≈-0.20) so that higher values of SHR Days are associated with lower usage of AV Fistulas. Obversely, SHR Days is positively correlated with catheter use (r≈0.20). The SHR is also correlated in appropriate ways with other quality measures such as % of patients with URR≥65% and % of patients with Hemoglobin 10-12.

We would like to stress that SHR Days is a similar measure, as both use the same methodology. However, SHR Admissions captures the number of hospitalizations, while SHR Days is a reflection of the duration and disease burden of such hospitalizations. Together the measures serve as a concise summary of a facility's experience with hospitalizations. On its own SHR Days is a natural measure of the extent of usage of hospital resources by a facility's dialysis patients and might also be viewed as a measure relating to quality of life of the patients themselves.

1463: Standardized Hospitalization Ratio for Admissions

Comment By
Name: Ms. Rabia Khan, MPH
Organization: Centers for Medicare and Medicaid Services

On Behalf Of
Name: Michael Rapp
Organization: CMS

Date - Time: Apr 18, 2011 - 03:07 PM

Comments

Hospitalization rates are an important indicator of patient morbidity and quality of life. On average, dialysis patients are admitted to the hospital twice a year and spend an average of 13 days in the hospital per year. Hospitalizations account for approximately 35% of total Medicare expenditures for ESRD patients. Measures of the frequency of hospitalization can help control escalating medical costs, and identify potential problems.

SHR Admissions is significantly correlated with important facility practices and outcomes. For example, SHR Admissions is significantly correlated with the Standardized Mortality Ratio (SMR), % of patients in the facility with AV Fistula, % of patients in the facility using a catheter, % of patients treated with URR≥65% and % of patients with Hemoglobin 10-12.
Hospitalization measures have been in use in the Dialysis Facility Reports (DFRs) since 1995. The DFRs are used by the dialysis facilities and ESRD Networks for quality improvement, and by ESRD state surveyors for monitoring and surveillance.

Comments on the general draft report

Comment By
Name: Ms. Rabia Khan, MPH
Organization: Centers for Medicare and Medicaid Services

On Behalf Of
Name: Michael Rapp
Organization: CMS

Date - Time: Apr 18, 2011 - 03:05 PM

Comments

Proportion of Patients With Hypophoshatemia

NQF #1461

We would like to emphasize the importance of serum phosphorus as a marker of poor health and/or inadequate therapeutic decisions among patients with ESRD. Observational studies showed a consistent adverse association of low serum phosphorus with all-cause mortality. The basic science supports a pathological role of low serum phosphorus & intracellular phosphate depletion in disturbed cellular function. Low pre-dialysis serum phosphorus concentrations (e.g.<2.5mg/dL) will result in interdialytic phosporus levels recognized as deleterious in the general population. Hypophosphatemia among patients with ESRD may be a marker of malnutrition or other morbid conditions. Patients who are undergoing more intensive dialysis (nocturnal or daily hemodialysis) may experience hypophosphatemia as a result of the dialysis modality. The etiology of the hypophosphatemia should be determined. In patients who are malnourished or have other morbid conditions, therapy should be directed to reverse the underlying condition. Patients undergoing more intensive dialysis may require dietary or other forms of phosphate supplementation. Given the importance of low serum phosphorus as a modifiable risk factor for poor outcomes, as new evidence becomes available we will revisit this topic as a potential clinical practice measure for future consideration.

1454: Proportion of patients with hypercalcemia

Comment By
Name: Ms. Rabia Khan, MPH
Organization: Centers for Medicare and Medicaid Services

On Behalf Of
Name: Michael Rapp
Organization: CMS

Date - Time: Apr 18, 2011 - 03:03 PM

Comments

There is strong evidence supporting the association between serum calcium levels and adverse outcomes among patients with end-stage renal disease. Results of observational cohort studies show a consistent adverse association of hypercalcemia with cardiovascular events and all-cause mortality. Clinical data demonstrate the association of increased serum calcium with vascular and valvular calcifications. The basic science also supports a pathological role of high calcium in promoting soft tissue and vascular calcification. Although there are no interventional studies demonstrating the benefit of correcting hypercalcemia, elevated calcium levels are likely to place the patient at increased risk of poor outcomes. The clinical practice measure will be calculated as the proportion of facility patients with 3-month rolling average of total serum calcium greater than 10.2 mg/dL, a level consistent with both the KDOQI and KDIGO guidelines. Implementation of this quality indicator will facilitate identification of patients who may have a higher risk of cardiovascular events.

1460: National Healthcare Safety Network (NHSN) Bloodstream Infection Measure

Comment By
Name: Ms. Tanya Alteras, MPP
Organization: National Partnership for Women & Families

On Behalf Of
Name: Tanya Alteras
Organization: Consumer-Purchaser Disclosure Project

Date - Time: Apr 15, 2011 - 05:28 PM

Comments

The Consumer-Purchaser Disclosure Project fully supports this measure, and believes that having this information on infection rates for dialysis patients is essential to improving patient safety for this population.

1421: Method of Adequacy Measurement for Pediatric Hemodialysis Patients

Comment By
Name: Ms. Tanya Alteras, MPP
Organization: National Partnership for Women & Families

On Behalf Of
Name: Tanya Alteras
Organization: Consumer-Purchaser Disclosure Project

Date - Time: Apr 15, 2011 - 05:27 PM

Comments

On behalf of the Consumer-Purchaser Disclosure Project, we have serious concerns about whether this measure is meaningful enough to warrant endorsement by NQF. It was not clear from the draft report or from the measure specifications form why having information on the method of measurement is going to have a direct connection to quality improvement. We also do not think

this information would be useful by consumers for decision-making purposes, and do not think this measure meets the high standards set by NQF.

Comments on the general draft report
Comment By
Name: Ms. Tanya Alteras, MPP
Organization: National Partnership for Women & Families

On Behalf Of
Name: Tanya Alteras
Organization: Consumer-Purchaser Disclosure Project

Date - Time: Apr 15, 2011 - 05:25 PM

Comments

The Consumer-Purchaser Disclosure Project appreciates the opportunity to comment on this set of ESRD measures, and appreciates that the National Quality Forum has identified this condition as an area for which additional measures of quality are critical. We are generally in favor of the 11 measures recommended for endorsement by the steering committee. We ask that NQF and CMS strongly consider the possibility of creating a composite measure that includes the various pediatric measures relating to spKt/V, nPCR, and hemoglobin. The measures as current specified would not necessarily be useful to patients, but as a composite measure, we believe that patients and their families would have a much easier time understanding and using the information on whether a dialysis center is providing high quality care.

Comments on the general draft report
Comment By
Name: Ms. Lori Hartwell
Organization: Renal Support Network

Date - Time: Apr 15, 2011 - 05:11 PM

Comments

RSN hopes that this is only the beginning for adult dialysis patients. More measures are critically important, to ensure patients receive quality care when CMS bundles oral drugs with no IV equivalents. We also would find it crucial to be sure we haven't overlooked any measures that involve variables that may be great predictors of outcomes, but are as yet unproven, such as C reactive protein. We think it would be valuable to design measures that can validate the demonstrated improved outcomes related to longer and more frequent dialysis treatments, which currently are not measured routinely or even appropriately. Finally, from a patient perspective, it is most important to assess our experience of treatment. How we feel during and after treatment not only is clearly related to outcomes and quality of life, but it gets at the very heart of compliance issues. What patient would want to continue treatment who is in misery during treatment, experiencing crashing, cramping and nausea, or who is virtually completely fatigued following treatment, only to recover sufficiently in time to go to the next treatment? These are the questions that need to be addressed in any future proposed measures, and will help to shore up the quality in dialysis care, protect patients' safety and provide for improving outcomes to drive practice.

We appreciate the opportunity to comment on these endorsed measures and would be happy to provide any further information should you require it.

Comments on the general draft report
Comment By
Name: Ms. Lori Hartwell
Organization: Renal Support Network

Date - Time: Apr 15, 2011 - 05:10 PM

Comments

Adult Measures

RSN also supports the four proposed measures for adult patients as significant improvements upon the two anemia markers and the URR dialysis adequacy measure that will be initially implemented. This is a beginning point, and we would expect that these

measures will evolve in both strength and complexity to best address fully the impact and quality of care. So we support the following proposed and endorsed measures for adult patients:

- NQF 1454 Upper Limit for Total Uncorrected Serum Calcium: Being > 10.2 mg/dL on average for three months
- NQF 1460 National Healthcare Safety Network Bloodstream Infection Measure: Being the number of HD patients with positive blood cultures/100 HD patient months
- NQF Standardized Hospitalization Ratio for Admissions: Being the number of patient hospitalizations vs. the number that would be expected by a risk assessment and national rates
- NQF 1438 Periodic assessment of Post Dialysis Weight by Nephrologists: Being the percentage of patients who have documented as received a post-dialysis weight assessment

Comments on the general draft report
Comment By
Name: Ms. Lori Hartwell
Organization: Renal Support Network

Date - Time: Apr 15, 2011 - 05:08 PM

Comments

Pediatric Measures

RSN supports each of the measures endorsed for pediatric patients, especially understanding that there has been very little guidance previously for the provision of care for these very vulnerable patients. We expect that the work of pediatric nephrologists will be markedly better in terms of having clearer parameters for outcomes through these endorsed measures, and can only imagine how this may improve the health and longevity of these patients. So we support the following measures as proposed and endorsed:

- NQF 1418 Frequency of HD Adequacy Measurement for Pediatric Patients: Being Monthly
- NQF 1421 Method of HD Adequacy Measurement for Pediatric Patients: Being spKt/V
- NQF 1423 Minimum spKt/V for Pediatric Patients: Being spKt/V >=1.2
- NQF 1425 Measurement of nPCR for Pediatric HD Patients: Being a monthly assessment of normalized protein catabolic rate to assess dietary protein
- NQF 1424 Monthly Hemoglobin Measurement for Pediatric Patients (HD and PD): Being Monthly and done at the end of the month
- NQF 1430 Lower Limit of Hemoglobin for Pediatric Patients (HD and PD): Being <10g/dL for 3 months, irrespective of ESA use
- NQF 1433 Iron Therapy for Pediatric Patients (HD and PD): Being a Hgb of 11 g/dL, with simultaneous serum ferratin concentration <100ng/ml and TSAT<20% who received iron within 3 months

Comments on the general draft report
Comment By
Name: Ms. Lori Hartwell
Organization: Renal Support Network

Date - Time: Apr 15, 2011 - 05:08 PM

Comments

Kidney disease is a complex illness, and the provision of dialysis care requires a delicate balance between treatment parameters and the individual status of each patient. It needs to be well and carefully monitored in terms of each of the major areas examined by the NQF: fluid management, dialysis adequacy, bone and mineral disorder management, infection control, and anemia management, differentially for both pediatric and adult patients. We also understand these measures to be subsequent to the initial markers of care implemented, to improve upon those measures and more thoroughly evaluate the best predictors and assessors of what makes good care.

RSN knows that no metrics have existed in this way before, and understands that ultimately CMS will use them not so much as a policing mechanism, but as financial incentives for improving quality of care for people on dialysis. We are pleased to be able to

offer feedback below.

Comments on the general draft report
Comment By
Name: Ms. Lori Hartwell
Organization: Renal Support Network

Date - Time: Apr 15, 2011 - 05:05 PM

Comments

I am writing as the President and Founder of Renal Support Network(RSN), a patient-focused, patient-run organization dedicated to helping improve the quality of life for kidney patients by educating and empowering them, to thank you for the opportunity to comment on the Endorsed Quality Measures for the End Stage Renal Disease Project 2010, as referenced above. On behalf of the thousands of renal patient advocates of RSN, I am grateful that the National Quality Forum has undertaken such a thorough examination of the 44 original proposed measures and endorsed 11 of those for recommendation for use by the Centers for Medicare and Medicaid Services ESRD program.

Measuring the quality of care received in dialysis is the single most important factor from the patient's perspective in determining the course of that care, and helping to protect our lives and our health, provide for good treatment outcomes, and to live full and productive lives. Patients rely both on how we feel, during treatment and after, and on the reported clinical values that help to show how well our treatment is working for us, and to safeguard us from unintended consequences of that treatment.

Comments on the general draft report
Comment By
Name: deborah k. williams
Organization: genetech

Date - Time: Apr 15, 2011 - 03:20 PM

Comments

The most common complications resulting in catheter dysfunction and, thus, replacement are thrombosis and infection.[1] Although no measures were proposed pertaining to the prevention of catheter-related infections, we suggest that NQF call for additional research to be conducted in this area. The incidence of catheter-related infections is not known, but an estimated 250,000 health care–onset bloodstream infections (BSI) occurred in the United States in 2002, resulting in 130,000 deaths.

Genentech also believes that thrombosis—which causes roughly 30–40 percent of catheter dysfunctio[2]—should be incorporated into NQF's quality program. As an example, the rate of central venous catheter thrombosis ranges from 4.0 to 5.5 episodes per 1000 days. This can result in missed dialysis sessions, costly catheter replacement, and potential hospitalizations, adding to the economic burden of the disease. We strongly encourage NQF to further examine this area for future measure development. Susan M. Begelman, M.D., F.A.C.C., Genentech

Comments on measures not recommended
Comment By
Name: deborah k. williams
Organization: genetech

Date - Time: Apr 15, 2011 - 03:06 PM

Comments

Support:

- 1477 NHSN Intravenous (IV) Antibiotic Start Measure
- 1456 Bacteremia (rate)
- 1457 Access-related Bacteremia (rate)

None of the 11 measures proposed address antibiotic use within the dialysis center. The initiation of antibiotics within the first two days more often affects patients who have catheters and have a higher risk of infection. The CDC's intravenous antibiotic start measure has not be used in dialysis facilities, and presents an opportunity to measure an important area in the relevant setting of care.

Re. the number of hemodialysis patients with positive bloodstream infections, this rate alone does not provide enough information to make serious quality advancements. The inclusion of measures for access-related bacteremia would provide a much better target for improved patient outcomes.

Endorsement of these measures, even in time-limited status, would help address key questions concerning their validity, usability, and feasibility. Continued field testing of the measures would solidify whether these measures could serve as a proxy for infection, as well as generate the data needed (with a larger sample size) to demonstrate the scientific acceptability of the measure properties. by Susan M. Begelman, M.D., F.A.C.C.,Associate, Genentech:

1460: National Healthcare Safety Network (NHSN) Bloodstream Infection Measure
Comment By
Name: deborah k. williams
Organization: genetech

Date - Time: Apr 15, 2011 - 02:55 PM

Comments

Susan M. Begelman, M.D., F.A.C.C., Associate Group Medical Director, US Medical Affairs, Genentech: .[1] Several measures pertaining to infection were submitted, one of which—1460 National Healthcare Safety Network (NHSN) Bloodstream Infection Measure, proposed by the Centers for Disease Control and Prevention (CDC)—has been recommended by the Steering Committee.

Genentech further supports the Steering Committee's recommendation to endorse this measure

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[1] Develter W et al., "Survival and Complications of Indwelling Venous Catheters for Permanent Use in Hemodialysis Patients," *Artif Organs* 29, no. 5 (2005): 399–405.

1463: Standardized Hospitalization Ratio for Admissions
Comment By
Name: deborah k. williams
Organization: genetech

Date - Time: Apr 15, 2011 - 02:51 PM

Comments

Susan M. Begelman, M.D., F.A.C.C.

Associate Group Medical Director

US Medical Affairs, Genentech

As NQF notes, the survival of ESRD patients depends upon the quality of care given. Reducing hospitalizations of ESRD patients undergoing dialysis is an important step toward this end. Two measures pertaining to hospitalization rates were submitted for consideration, one of which—1463 Standardized Hospitalization Ratio for Admissions, proposed by the Centers for Medicare & Medicaid Services (CMS)—has been recommended by the Steering Committee. Genentech strongly supports the Steering Committee's recommendation. Due to the fact that cardiovascular and infectious hospitalizations rates have increased substantially among ESRD patients undergoing dialysis in recent years,[2] coupled with the fact that increased hospitalization rates are a proxy outcome for deteriorating health status, this is an important area to measure with significant room for improvement.

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[2] Collins AJ et al., "The State of Chronic Kidney Disease, ESRD, and Morbidity and Mortality in the first Year of Dialysis," *Clin J Am Soc Nephrol* 4, suppl. 1 (2009): S5–S11.

1463: Standardized Hospitalization Ratio for Admissions

Comment By
Name: Cathleen OKeefe
Organization: Fresenius Medical Care

On Behalf Of
Name: Raymond Hakim, MD, PhD
Organization: Fresenius Medical Care

Date - Time: Apr 15, 2011 - 02:48 PM

Comments

We support use of this measure, consistent with a standardized method used by USRDS or alternatively, if different, by Arbor Research Foundation. We request that the panel fully examine the methodology that goes into the calculation of expected hospitalization rate.

We further request for information on the following questions:

1. What are the strengths and weaknesses of the method?
2. Is it necessary to include race and ethnicity?
3. How are hospital readmissions for the same conditions within 30 days treated and coded?
4. Do you need to impute missing data and how can it bias results?
5. At what level of facility size (number of patients treated) does the measure become unstable?

We also urge the panel to consider recommending that proponents of the measure explore the potential of a limited SHR, specific to conditions that are directly actionable from a dialysis perspective, such as:

a. Hospitalization for fluid overload, including congestive heart failure, or acute pulmonary edema; and/or
b. Hospitalization for bloodstream infections or sepsis; with the caveat that the definition and documentation for these types of hospitalizations appropriately standardized across hospitals.

1460: National Healthcare Safety Network (NHSN) Bloodstream Infection Measure

Comment By
Name: Cathleen OKeefe
Organization: Fresenius Medical Care

On Behalf Of
Name: Raymond Hakim, MD, PhD
Organization: Fresenius Medical Care

Date - Time: Apr 15, 2011 - 02:43 PM

Comments

We support the measure as approved but request consideration of a complementary measure leveled towards hospitals to improve transition of care. Placement of a permanent vascular access in a hospitalized dialysis patient - Unless the nephrologist determines that a patient is not a candidate for placement of a permanent vascular access, prior to a hospital discharge all ESRD patients with a central venous catheter must have either undergone, or be scheduled for a work-up for the placement of a permanent AV fistula or AV graft. The work-up must include vessel mapping and placement of the fistula prior to discharge. **Coordination-of-care for ESRD patient population** would ensure *proper transitional care* and hospital discharge and transfer of ESRD patients to the outpatient dialysis facility. This coordination, including *timely referral*, would encourage communication of best practices to prevent re-hospitalization, and would serve to prevent/reduce costly catheter-related infections. Hospitals should be required to provide a discharge summary of the patient's hospitalization to the patient's nephrologist and designated dialysis facility. Such summary should include, at a minimum, the dialysis prescription during hospitalization, a complete medication record during hospitalization, vascular access care, and a complete list of all diagnoses present during the hospitalization and at discharge.

1454: Proportion of patients with hypercalcemia

Comment By
Name: Cathleen OKeefe
Organization: Fresenius Medical Care

On Behalf Of
Name: Raymond Hakim, MD, PhD
Organization: Fresenius Medical Care

Date - Time: Apr 15, 2011 - 02:23 PM

Comments

We support the measure as approved but would like to bring into the panel's consideration the following:

1. Calcium is a tightly regulated cation, and simply looking at the upper limit for "long-term" risk misses the potential acute consequences of sustained hypocalcemia. Low serum calcium is a risk factor for sudden cardiac death. A greater proportion of patients have low serum calcium than high. For patient safety, we recommend that a lower limit of serum calcium be incorporated as well to create a target range of 8.4-10.2 mg/dL.
2. We also recommend that the panel reconsiders NQF 1427 for adult hemodialysis patients that will track the proportion of patients with serum phosphorus levels >6 mg/dL. The level of evidence supporting increased risk for patients associated with having sustained levels beyond this threshold is similar if not better than those used to support a high calcium threshold. Furthermore, there is a potentiating effect associated with a combination of high serum phosphorus and a high serum calcium whereby phosphorus predisposes vascular smooth muscle cells to undergo calcification, leading to vascular stiffness and increased morbidity and mortality.

1438: Periodic Assessment of Post-Dialysis Weight by Nephrologists

Comment By
Name: Cathleen OKeefe
Organization: Fresenius Medical Care

On Behalf Of
Name: Raymond Hakim, MD, PhD
Organization: Fresenius Medical Care

Date - Time: Apr 15, 2011 - 02:02 PM

Comments

We agree with the measure with no specific requirement to prescribe a change in target weight, as long as an assessment of dry weight by physical examination was made and documented by the physician. We recommend that a similar rrequirement should be put in place for home patients, whether on hemodialysis or peritoneal dialysis, consistent with their scheduled MCP visit. The measure can be revisited with adoption of new ways to more accurately determine dry weight and/or body composition.

1433: Use of Iron Therapy for Pediatric Patients

Comment By
Name: mazen arar
Organization:

Date - Time: Apr 15, 2011 - 11:52 AM

Comments

The elemnts for reporting iron therapy in this measure requires that the dialysis patient has a hemoglubin less than 11, ferritin less than 100, and transferrin saturation less than 20%. First, there is discrepancy in the level of hemoglubin that represent anemia in children in this measure compaired to measure #1430 that define anemia as hemoglubin less than 10. The hemoglubin target is 10-12. There is no evidence that anemia in children should be different than adults. Second, meeting the other two criteria to start iron therapy is likely to exclude some patients with iron deficiency. It may be better to start iron therapy if either transferrin saturation is less than 20% and ferritin is less than 500 or ferritin is less than 100 and transferrin saturation is less than 50%. Accepting higher ferrin level when transferrin saturation is less than 20% takes in consideration that ferritin elevation is a response to inflamation.

1438: Periodic Assessment of Post-Dialysis Weight by Nephrologists
Comment By
Name: mazen arar
Organization:

Date - Time: Apr 15, 2011 - 11:06 AM

Comments

I strongly agree with the measure of periodic assessment of post-dialysis weight by nephrologists. Documentation of of monthly new post-dialysis weight is vital and likely will insure quality of care especially in pediatrics. Dry weight in children can change rapidly. It will not only monitor nutrition status but also the growth rate especially in infants. I agree with the clarification by adding the phrase 'irrespective of whether or not a change in post-dial;ysis weight prescription was made.'

Comments on measures not recommended
Comment By
Name: Dolph Chianchiano
Organization: National Kidney Foundation

Date - Time: Apr 14, 2011 - 05:57 PM

Comments

Serum Phosphorus (P) Upper Limit.2003 KDOQI guideline target ranges aren't supported by high-quality evidence. Also, nutrition and patient compliance affect P levels. Nonetheless,from a patient safety perspective, there is evidence linking hyperphosphatemia to poor outcomes. In addition, there are concerns that financial incentives in the ESRD Prospective Payment System (PPS) may affect clinical decisions. A conservative target (e.g. P greater than or equal to 7.0 mg/dL, in each of 3 consecutive months) might be a place to start.

Iron Overload - is also a safety measure in a PPS environment and should be reconsidered. We don't know the exact tradeoff between more iron and less ESA but hemoglobin response to additional iron is lower at higher ferritin levels. With little evidence for a specific upper ferritin limit, a measure for trends in ferritin may be of some value.

Infection Measure(s): Shifting Locus of Care - Dialysis units can screen patients with blood cultures and treat many infections with antibiotics. However, with a PPS, they will have incentives to send all infected and potentially infected patients to hospital emergency departments for evaluation and care. This may negatively affect patient outcomes. NKF recommends that NQF communicate to CMS the need to develop a methodology for monitoring and evaluating shifts in locus of care for dialysis patients which are attributable to economic considerations rather than clinical discretion.

Comments on measures not recommended
Comment By
Name: Dr. Jose A. Menoyo
Organization: Genzyme Corporation

Date - Time: Apr 14, 2011 - 05:35 PM

Comments

Genzyme is disappointed that the NQF Committee decided not to endorse the **Measure #1427-Serum Phosphorus Greater Than 6.0mg/dl.** The NKF Mineral Metabolism Guidelines has established specific targets for serum phosphorus. Recently, KDIGO published guidelines that recommended targeting a phosphorus level towards normal. These guidelines reiterate that a high serum phosphorus level is a strong predictor of mortality.The community has utilized these guidelines to guide the care of dialysis. Studies have reported consistently that the achievement of these targets is associated with lower mortality. Additional evidence, like DOPPS, consistently demonstrates that serum phosphorus >6.0mg/dL is strongly associated with adverse outcomes and mortality. In adjusted facility-level models, a higher percentage of patients in phosphorus categories ≥6.0mg/dL was associated with higher risk for all-cause and cardiovascular mortality. The results from this study can be viewed as a valid representation to discriminate performance and assess outcomes. In a recent review of the literature, Palmer also found an association with higher serum levels and mortality in CKD patients. Genzyme as the steward of **Measure #1427** believes that CMS lacks both essential performance measures and protections for patients in the ESRD bundled payment system regarding bone and mineral disease. For this reason we strongly encourage the NQF committee to reconsider the endorsement of **Measure #1427.**

1460: National Healthcare Safety Network (NHSN) Bloodstream Infection Measure
Comment By
Name: Robert S. Brown, MD
Organization: Beth Israel Deaconess Medical Center

Date - Time: Apr 14, 2011 - 12:19 PM

Comments

Decreasing bloodstream infections remains an important means to decrease morbidity and mortality in dialysis patients. The ESRD community is working to decrease the proportion of central venous catheters in dialysis patients and now that there are the means to lower the rate of bacteremic events in patients that still require catheters for vascular access, this measure is a quality goal we can all support.

Robert S. Brown, MD

1463: Standardized Hospitalization Ratio for Admissions
Comment By
Name: Robert S. Brown, MD
Organization: Beth Israel Deaconess Medical Center

Date - Time: Apr 14, 2011 - 12:13 PM

Comments

While hospitalization rate is a very important parameter, there is no data to support a contention that high or low rates represent better or worse quality of care, just more costly care of ill patients. Unless the measure is modified to examine specific diagnoses of the hospitalizations that might be affected by dialysis interventions, such as CHF from fluid volume overload, hyperkalemia, or complications of the dialysis procedure, this goal should not be accepted. Moreover, the goal may have the unintended consequences of dialysis units not sending patients to hospitals that require medical care.

Robert S Brown, MD

Comments on the general draft report
Comment By
Name: Dr. Allen R. Nissenson, MD
Organization: DaVita Inc.

Date - Time: Apr 14, 2011 - 12:03 PM

Comments

DaVita is committed to the relentless pursuit of quality. We therefore are supportive of the recommendations of the NQF in this area with the exceptions and requested clarifications listed above. As we have outlined the SHR measure methodology requires peer

review or external, third party validation before it can be considered as a performance metric. Next, the NHSN BSI measure should be used as it is superior to any claims based measure using V8 and V9 modifier code. . Lastly, and most importantly, the NQF needs to reconvene its expert committee to endorse the submitted phosphorous measure. With the inclusion of oral drugs in the bundled payment system in 2014, there is now question that CMS will be forced to implement such a measure. That measure will be implemented with or without NQF endorsement, but we urge the NQF to consider this inevitability in its deliberations and approve the current measure. We are supportive of the processes that lead to the development of these measures with one notable exception. Measures need to be subjected to data feasibility BEFORE submission the NQF. Without this needed step, the NQF will receive a large number of measures unsuitable for use as was the case in this cycle of measure development and review. CMS and NQF need to work collaboratively to ensure that this does not happen again.

1454: Proportion of patients with hypercalcemia
Comment By
Name: Dr. Allen R. Nissenson, MD
Organization: DaVita Inc.

Date - Time: Apr 14, 2011 - 12:01 PM

Comments
DaVita is supportive of the proposed hypercalcemia metric. We believe that the recommendation is consistent with the prevailing community standard and the literature, and as such offer no supplemental comments

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1438: Periodic Assessment of Post-Dialysis Weight by Nephrologists
Comment By
Name: Dr. Allen R. Nissenson, MD
Organization: DaVita Inc.

Date - Time: Apr 14, 2011 - 12:00 PM

Comments

We agree that fluid related overload is a preventable condition that requires a metric. As such, the periodic assessment of post dialysis weight by nephrologists is a reasonable measure. The data is available in electronic health records today and thus meets the data feasibility criteria. However, paralleling our discussion around the strength of evidence for the phosphorous measure, we are not aware of any data, either prospective or retrospective which supports the validity of this measure.

1463: Standardized Hospitalization Ratio for Admissions
Comment By
Name: Dr. Allen R. Nissenson, MD
Organization: DaVita Inc.

Date - Time: Apr 14, 2011 - 11:59 AM

Comments

Hospitalization rate reflects a combination of factors. Thus, unlike in the hospital setting, quality in the dialysis unit may not be directly reflected in the admission rate for that facility. The currently proposed measure seeks to create a ratio of the actual hospitalization rates to a predicted hospitalization rate using only claims based data. While such reporting has been disclosed through the Dialysis Facility (DFC) and Dialysis Facility Report (DFR) process, there has been limited disclosure around the mathematical equations for the predicted hospitalization rate that drives this metric. To date, the predicted hospitalization equation and methodology has not been subject to peer review or validation despite its use today. The approach used for the ESRD SHR and SMR contrasts sharply with the peer reviewed process used for the predicted hospitalization rate used for the SHR ratio for hospitals. (Krumholtz, Circ Cardiovasc Qual Outcomes, March 2011) We urge the NQF to recommend a peer review and validation process for the SHR metric prior to implementation. Further, it is inevitable that the detailed clinical information available via CROWNWeb can only strengthen the predictive power of any modeling. Therefore, NQF may wish to ask the measure developers to consider this richer data set for modeling purposes before needlessly settling on the claims based data only

1454: Proportion of patients with hypercalcemia
Comment By
Name: Robert S. Brown, MD
Organization: Beth Israel Deaconess Medical Center

Date - Time: Apr 14, 2011 - 11:55 AM

Comments

While not opposed to the assessment of the proportion of ESRD patients with hypercalcemia, as defined by this measure, as a reasonable goal, one might question the wisdom of accepting such a surrogate marker as a true quality parameter. One, the data for setting the 10.2 mg/dL level is weak to begin with, and two, the rationale that the proportion of patients with calcium levels over 10.2 represent poor quality care is uncertain. Even if the NQF premise that this measure does represent drug toxicity is accepted, the role of control of hyperphosphatemia with calcium-containing phosphate binders when patients can't afford the more costly alternatives remains uncertain. Is it better to have a calcium level over 10.2 mg/dL or a phosphate level over 6 mg/dL? Some patients cannot achieve both at a price that they can pay. Therefore, since this question remains unanswered, I would suggest that the hypercalcemia quality parameter should be deferred until medication insurance coverage for oral phosphate binders is included in the bundle, presumably in 2014. An alternative might be to formulate a more inclusive surrogate marker goal for assessing bone mineral metabolism utilizing both calcium and phosphate levels.

Robert S. Brown, MD

Comments on measures not recommended
Comment By
Name: Dr. Allen R. Nissenson, MD
Organization: DaVita Inc.

Date - Time: Apr 14, 2011 - 11:54 AM

Comments

While a phosphorous measure was submitted for consideration (percentage of patients with phosphorus less than 6 mg/dl), this was rejected by the committee. The rationale for this rejection seemed to be the validity of having such a measure or not and the lack of strong, direct evidence supporting the importance of such a mesasure. This may make sense from an academic perspective, but not from a policy perspective. Oral medications affecting serum phosphorous will be included in the bundle by January 2014. CMS included anemia metrics when ESAs were included in the bundle. Following this logic, a phosphorous metric be desired when phosphorus binders are included. In a recent GAO report, CMS has already said it will likely move forward with a non NQF endorsed metric for phosphorus for this very reason. Therefore, we urge the NQF to reconvene its committee to discuss and debate not if a measure is appropriate (as that is a foregone conclusion) but rather approve the existing measure. The level of evidence supporting a phosphorous measure such as less than 6 mg/dl is observational and retrospective. So too are the data supporting many of the other measures listed for ESRD. The NQF panel should be able to have such a discussion and make a recommendation that will serve as an NQF endorsed recommendation for CMS's inevitable future CPM.

1460: National Healthcare Safety Network (NHSN) Bloodstream Infection Measure
Comment By
Name: Dr. Allen R. Nissenson, MD
Organization: DaVita Inc.

Date - Time: Apr 14, 2011 - 11:50 AM

Comments

We support the NHSN BSI Measure as the recommended by the committee. Using this metric stratified by vascular access type will provide a meaningful metric to support HAI efforts. This metric is superior in terms of sensitivity and specificity the currently claims based V8/V9 measures.

1438: Periodic Assessment of Post-Dialysis Weight by Nephrologists
Comment By
Name: Robert S. Brown, MD
Organization: Beth Israel Deaconess Medical Center

Date - Time: Apr 14, 2011 - 11:24 AM

Comments

The periodic assessment of post-dialysis weights in the care of dialysis patients is an important quality assessment. However, the proportion of patients that receive "new" post-dialysis weight prescriptions each month is not. The decision to maintain "new" in this measure was an incorrect one, unless you add the phrase, "irrespective of whether or not a change in post-dialysis weight prescription is made" to remove the ambiguity. As a nephrologist for over 40 years and a medical director of 2 dialysis units, I can assure the NQF that otherwise this parameter will associate primarily with the proportion of new patients (< 90 days) that a dialysis unit has. It is in that period of time that the post-dialysis weight needs the most adjustment and a "new" weight is ordered. Thereafter, one would hope that the patient is close to "dry" weight and will need less monthly adjustments of weight. So it is clear that the proportion of patients receiving "new" post-dialysis weights cannot serve as a quality parameter, but prescribed post-dialysis weights can.

Comments on measures not recommended
Comment By
Name: Mr. Hrant Jamgochian
Organization: Dialysis Patient Citizens

On Behalf Of
Name: Nancy Scott
Organization: Dialysis Patient Citizens

Date - Time: Apr 11, 2011 - 05:44 PM

Comments

We thank the steering committee for its work on the ESRD measures submitted and are particularly pleased the committee makeup included dialysis patients who can attest to their experience with the delivery of quality care. This consumer perspective is of great importance, as all patients should be actively engaged with health care decisions both when it comes to their own health decisions and when it comes to policy matters that influence care delivery.

Comments on measures not recommended
Comment By
Name: Mr. Hrant Jamgochian
Organization: Dialysis Patient Citizens

On Behalf Of
Name: Nancy Scott
Organization: Dialysis Patient Citizens

Date - Time: Apr 11, 2011 - 05:44 PM

Comments

We are respectful of the challenges in applying and finding data and research to support the impact that outcome measures have on mortality and co-morbidities, but believe where data and research are lacking that deference to widely used clinical practices, shown to cause no harm to patients, should be considered until more definitive scientific data becomes available. Since Medicare has moved to a bundled reimbursement for dialysis care, it is important that quality measures are in place to ensure patients receive optimal care. We believe a safer route to ensure patients continue to receive proper treatment is to endorse the serum phosphorus levels below 6mg/dl measure, which is clearly an established standard of care and shows no evidence of causing harm to patients. Since the steering committee could not come to a consensus on this measure, we suggested as an alternative to a full three-year endorsement, it may be appropriate to endorse it as time-limited allowing more research to be conducted. Not endorsing the measure could send the signal that this measure is not of clinical importance and may have negative consequences for patient care.

Comments on measures not recommended

Comment By
Name: Mr. Hrant Jamgochian
Organization: Dialysis Patient Citizens

On Behalf Of
Name: Nancy Scott
Organization: Dialysis Patient Citizens

Date - Time: Apr 11, 2011 - 05:43 PM

Comments

While in general we are supportive of the measures the steering committee is recommending, we are particularly concerned the Committee did not include **measure 1427 Adult Dialysis Patients - Serum Phosphorus Greater Than 6 mg/dl**. As mentioned under our comments for the upper serum calcium measure, bone and mineral measures are important to evaluating patients' health. Regulating patients' bone and mineral metabolism is vital to preventing co-morbidities such as increased bone fractures, cardiovascular complications, calcification of arteries and parathyroidectomies. Dialysis does not adequately remove phosphorus from the blood, and phosphorus levels cannot be completely controlled by diet alone because, in order to maintain proper albumin, patients must eat plenty of protein. Phosphorus is commonly found in most sources of protein, and for this reason, patients are routinely prescribed phosphorus binders to remove excessive levels of phosphorus.

Comments on the general draft report

Comment By
Name: Mr. Hrant Jamgochian
Organization: Dialysis Patient Citizens

On Behalf Of
Name: Nancy Scott
Organization: Dialysis Patient Citizens

Date - Time: Apr 11, 2011 - 05:09 PM

Comments

We thank the steering committee for its work on the ESRD measures submitted and are particularly pleased the committee makeup included dialysis patients who can attest to their experience with the delivery of quality care. This consumer perspective is of great importance, as all patients should be actively engaged with health care decisions both when it comes to their own health decisions and when it comes to policy matters that influence care delivery.

Comments on the general draft report

Comment By
Name: Mr. Hrant Jamgochian
Organization: Dialysis Patient Citizens

On Behalf Of
Name: Nancy Scott
Organization: Dialysis Patient Citizens

Date - Time: Apr 11, 2011 - 05:09 PM

Comments

We are respectful of the challenges in applying and finding data and research to support the impact that outcome measures have on mortality and co-morbidities, but believe where data and research are lacking that deference to widely used clinical practices, shown to cause no harm to patients, should be considered until more definitive scientific data becomes available. Since Medicare has moved to a bundled reimbursement for dialysis care, it is important that quality measures are in place to ensure patients receive optimal care. We believe a safer route to ensure patients continue to receive proper treatment is to endorse the serum phosphorus levels below 6mg/dl measure, which is clearly an established standard of care and shows no evidence of causing harm to patients. Since the steering committee could not come to a consensus on this measure, we suggested as an alternative to a full three-year endorsement, it may be appropriate to endorse it as time-limited allowing more research to be conducted. Not endorsing the measure could send the signal that this measure is not of clinical importance and may have negative consequences for patient care.

Comments on the general draft report

Comment By
Name: Mr. Hrant Jamgochian
Organization: Dialysis Patient Citizens

On Behalf Of
Name: Nancy Scott
Organization: Dialysis Patient Citizens

Date - Time: Apr 11, 2011 - 05:08 PM

Comments

While in general we are supportive of the measures the steering committee is recommending, we are particularly concerned the Committee did not include **measure 1427 Adult Dialysis Patients - Serum Phosphorus Greater Than 6 mg/dl**. As mentioned under our comments for the upper serum calcium measure, bone and mineral measures are important to evaluating patients' health. Regulating patients' bone and mineral metabolism is vital to preventing co-morbidities such as increased bone fractures, cardiovascular complications, calcification of arteries and parathyroidectomies. Dialysis does not adequately remove phosphorus from the blood, and phosphorus levels cannot be completely controlled by diet alone because, in order to maintain proper albumin, patients must eat plenty of protein. Phosphorus is commonly found in most sources of protein, and for this reason, patients are routinely prescribed phosphorus binders to remove excessive levels of phosphorus.

1463: Standardized Hospitalization Ratio for Admissions

Comment By
Name: Mr. Hrant Jamgochian
Organization: Dialysis Patient Citizens

On Behalf Of
Name: Nancy Scott
Organization: Dialysis Patient Citizens

Date - Time: Apr 11, 2011 - 04:36 PM

Comments

While we are supportive of this measure we feel it is important to note that dialysis facilities currently do not provide the totality of patients' care, and there are factors not currently treated at the dialysis facility that could lead to hospitalization of the patient. We feel this measure should be modified to measure hospitalizations related to the outcomes of dialysis treatment.

1460: National Healthcare Safety Network (NHSN) Bloodstream Infection Measure

Comment By
Name: Mr. Hrant Jamgochian
Organization: Dialysis Patient Citizens

On Behalf Of
Name: Nancy Scott
Organization: Dialysis Patient Citizens

Date - Time: Apr 11, 2011 - 04:34 PM

Comments

Infections are the second leading cause of death in dialysis patients falling just slightly behind cardiovascular disease. We strongly support the Steering Committee's recommendation for endorsement and believe this is a crucial measure to be included in the future years of the QIP.

1454: Proportion of patients with hypercalcemia

Comment By
Name: Mr. Hrant Jamgochian
Organization: Dialysis Patient Citizens

On Behalf Of
Name: Nancy Scott
Organization: Dialysis Patient Citizens

Date - Time: Apr 11, 2011 - 04:32 PM

Comments

Bone and mineral measures are extremely critical to dialysis patients. Patients are currently measured on these areas and in many cases receive not only the lab results, but also a separate progress report educating them on how well they are doing in keeping their calcium and phosphorus at appropriate levels. We recognize this is a measure that not only requires proper care delivery, but also education for patients, as they have a role in managing bone and mineral metabolism through maintaining proper diet and medication adherence. DPC supports the upper limit for serum calcium because we recognize high levels of

calcium can cause calcification of arteries and other cardiovascular complications for dialysis patients. Additionally, we believe with the payment changes under the Medicare program for ESRD and medications being moved into a bundled payment system, this measure is of particular importance and should be included in the QIP to ensure patients receive optimal quality care.

Comments on the general draft report
Comment By
Name: Mr. Hrant Jamgochian
Organization: Dialysis Patient Citizens

On Behalf Of
Name: Nancy Scott
Organization: Dialysis Patient Citizens

Date - Time: Apr 11, 2011 - 04:31 PM

Comments

Dialysis Patient Citizens (DPC) is pleased to provide comments. As America's largest dialysis patient organization, DPC seeks to ensure that the patient's point of view is heard and considered by policy makers on a wide variety of issues so continued progress may be made in the quality of care and life for dialysis patients. We are pleased that Congress and the Centers for Medicare and Medicaid Services (CMS) have taken steps to develop a Quality Incentive Program (QIP) that seeks to align incentives with patient outcomes. We believe that the quality measures included in this program should, above all, be patient-centered, reflective of health outcomes for all dialysis patients regardless of the treatment modality they choose (i.e. in-center hemodialysis, home hemodialysis and peritoneal dialysis) and target levels that will ensure patients do not just meet adequate standards, but can live good quality lives. We know that a diagnosis of End Stage Renal Disease (ESRD) does not mean the end of life; it simply means the end of kidney function. With proper health care and self-management, dialysis patients can lead long, productive lives. An NQF endorsement is important to the decision making at CMS in regards to the selection of future measures for the QIP. It is with this frame of mind that we respectfully issue the following comments on this NQF report.

1460: National Healthcare Safety Network (NHSN) Bloodstream Infection Measure
Comment By
Name: Caprice Vanderkolk, RN, MS, BC-CNA
Organization: SSM Healthcare of WI

Date - Time: Apr 11, 2011 - 03:58 PM

Comments

I agree and can support these recommendations

Comments on the general draft report
Comment By
Name: Dr. Michael J. Schuh, MBA, PharmD, BS
Organization: Mayo Clinic Jacksonville

Date - Time: Mar 31, 2011 - 10:26 AM

Comments

A decrease in infection rates and issues with pharmacologic treatments can be assisted by having pharmacists involved in the process as physician extenders. Pharmacists are uniquely qualified to understand infection control and have the pharmacokinetic and pharmacologic training to assist with many of the cited medication problems to help hold down hospitalizations. Pharmacist help with management and monitoring coupled with reimbursement under Medicare Part B as providers partnering with physician led overall management of the patient in a collaborative setting would help decrease hospitalizations in patients with ESRD just as it has in other collaborative settings.

Michael J. Schuh, PharmD, MBA

Clinical Pharmacist and NQF Advisory Panel Member

Comments on the general draft report
Comment By
Name: Ms. Lauren Agoratus
Organization:

Date - Time: Mar 30, 2011 - 09:47 AM

Comments

I didn't see any measures on preventing antimicrobial resistance in hospitalized children as recommended by the CDC. One of the largest sources of infection associated with increased morbidity/morality is the inappropriate use of catheters. This type of measure should be recommended for pediatric patients with ESRD.

Comments on measures not recommended
Comment By
Name: Ms. Lauren Agoratus
Organization:

Date - Time: Mar 30, 2011 - 09:38 AM

Comments

I also disagree that the measure on hypophosphatemia not be recommended. So often the focus is on hyperphosphatemia and the need for calcium binders when in actuality mineral level measurement must be balanced within a normal range. Hypophosphatamia is associated with increased morbidity/mortality and measure 1461 should be recommended.

Comments on measures not recommended
Comment By
Name: Ms. Lauren Agoratus
Organization:

Date - Time: Mar 30, 2011 - 09:30 AM

Comments

I disagree that the dietary sodium reduction advice should not be recommended. I would also recommend that protein intake be considered. Both sodium and protein intake influence the course of ESRD and may prolong or prevent the need for dialysis/transplant. Dietary sodium/protein intake are both cost effective and result in better health outcomes. With the current focus on patient centered medical homes and shared-decision making, measure 1432 should be revised to included protein and recommended.

1433: Use of Iron Therapy for Pediatric Patients
Comment By
Name: Ms. Lauren Agoratus
Organization:

Date - Time: Mar 30, 2011 - 09:19 AM

Comments

I strongly support this recommendation on iron therapy for pediatric patients. Again, I would recommend that this be extended to stage 3/4, not just dialysis patients. This measure is also extremely important as anemia is associated with increased morbidity/mortality.

1430: Lower Limit of Hemoglobin for Pediatric Patients

Comment By
Name: Ms. Lauren Agoratus
Organization:

Date - Time: Mar 30, 2011 - 09:16 AM

Comments

I also support the lower limit of hemoglobin for pediatric patients equal/greater than 3 mos. with Hb less than 10. Again, I would extend this to stage 3 and 4, not just dialysis patients due to the increased risks to morbidity/mortality mentioned under measure 1424.

1424: Monthly Hemoglobin Measurement for Pediatric Patients
Comment By
Name: Ms. Lauren Agoratus
Organization:

Date - Time: Mar 30, 2011 - 09:10 AM

Comments

I strongly support monthly hemoglobin measurement for pediatric patients. In fact I would extend this beyond dialysis patients to stage 3 and 4 pediatric patients. I agree that reliability has been established for Hb equal/greater than 9. This measure is extremely important as Hemoglobin affects morbidity/mortality rates in ESRD.