Print

Measure Comment Report for End Stage Renal Disease

1460: National Healthcare Safety Network (NHSN) Bloodstream Infection Measure
Comment By
Name: Ms. Tanya Alteras, MPP
Organization: National Partnership for Women & Families

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

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

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

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

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

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

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.

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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.

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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.