

Memo

- TO: Infectious Disease Steering Committee
- FR: Reva Winkler, Senior Director Alexis Morgan, Senior Project Manager
- SU: Infectious Disease Endorsement Maintenance: Post-Comment Call to Discuss Member and Public Comments
- DA: November 6, 2012

The Infectious Disease Steering Committee will meet via conference call on Friday, November 9. The purpose of this call is to:

- Review and discuss comments received during the Member and Public Comment period.
- Provide input on responses to comments.
- Determine whether reconsideration of any measures or other courses of action is warranted.

Steering Committee Action:

- 1. Review this briefing memo, which includes comment themes and proposed responses.
- 2. Review the individual comments received during the public and member comment period and proposed responses. (Excel spreadsheet included in the meeting materials has been sorted by measure. Filters have also been applied to the spreadsheet so that custom filters can be applied by submitter, member council, etc.).
- 3. Be prepared to provide feedback and input on proposed comment responses.

Conference Call: Friday, November 9, 12-2pm ET

Please use the following information to access the conference call line and webinar:

Dial-in Number: 1-888-799-5160 Confirmation Code: 58067136 Event Title: Infectious Disease Steering Committee – Post Comment Conference Call

Webinar: Register at <u>http://nqf.commpartners.com/se/Rd/Mt.aspx?841511</u> All Committee and speaker phone lines will be open. Please place your phone on mute when not speaking. Please do not place your phone on hold during the call.

Attachments

- Agenda with dial-information
- Comment table (excel spreadsheet)

• Letters from AMA-PCPI and HIV Medicine Association (their comments are also in the comment table)

NQF received 54 comments on the draft report from 8 public and NQF members. In order to facilitate discussion, many of the comments have been categorized into major themes, although several other comments outside of the major thematic categories also were received and may require discussion by the Committee. Where possible, NQF staff have proposed draft responses for the Committee to consider. The major themes of the comments and issues identified for Committee discussion are listed below. All comments and proposed responses are subject to discussion. Please refer to the comment table (excel spreadsheet) to view all of the comments that we received. This comment table contains the commenter's name, as well as the comment, associated measure, and draft responses for the Committee's consideration.

Major Themes

The vast majority of comments reflect support for the recommended measures. Several major themes were identified in the comments:

- 1. General issues applicable to the measures under consideration
- 2. Utility of the medical visit measures
- 3. Disagree with measures recommended
- 4. Disagree with measures not recommended
- 5. Additional areas for measure development
- 6. Comments on measure specifications referred to developers

Theme 1: General Issues Applicable to the Measures under Consideration

Use of the Measure in Current Programs

Description: Comments suggest that the Committee should take into consideration metrics that have been accepted by other federal agencies, for example CMS's Medicare and Medicaid "meaningful use" incentive programs for adoption and utilization of electronic health records. Specifically, measures 0403 and 0407, which are currently not recommended by the committee for continued endorsement, are included in the final Stage II EHR "Meaningful Use" rule. It is unclear whether discontinuation of NQF endorsement of these measures will invalidate their use for CMS purposes.

Stratification for Disparities

Description: Several commenters recommend that all HIV measures include stratification of disparity data. Known disparities in HIV care do exist and should be reflected in the measures so that the medical community and patients can address these disparities.

Measure Specific Comments

Theme 2: Utility of the Medical Visit Measures

2079: Medical visit frequency

Description: The Committee is asked to revisit measures 0403 and 2079. A commenter notes that although NQF measure 0403 was not re-endorsed, from a practical standpoint it makes more sense than the variation of this metric (measure 2079) which was recommended. The fact that measure 0403 is based on CPT II coding should not have ruled it out, because both the Veteran's Administration and Kaiser Permanente have demonstrated on a large scale that this measure can be captured electronically. In addition, the 12-month medical visit frequency utilized in measure 0403 is consistent with the time period captured in all the other HIV metrics, whereas measure 2079 relies on a 24-month frequency. The comment questions the rationale and practicality of using a 24-month timeframe, given that the patient population being measured may shift considerably within a 24-month window, and considering that the same 24-month outcome could be captured by looking at measure 0403 serially, over time; how measure 2079 could be reported as the denominator would be different every six months; and measure 2079 was tested only in HIV-specific clinical settings (Ryan White clinics) and may not be as applicable in other clinical settings. (HIV Medicine Association)

<u>ACTION ITEM</u>: After review and discussion of the comments on the medical visit measures, does the Committee wish to change their evaluation of any of the criteria or overall recommendations for measures 2079, 2080 or 0403? Should measures 2079 and 2080 be paired?

2080: Gap in medical visits

Description: The commenter is concerned that this measure will not yield sufficiently helpful new information to justify the additional administrative burden it would entail. (HIV Medicine Association)

Another commenter indicates that this process measure captures an event that has a high correlation with health outcomes. Patients who are not retained in care are less likely to receive or adhere to appropriate therapies and therefore have shorter survival times. Rather than competing with 2079, 2080 compliments 2079 because of the difference in patient populations, time frames, and intent of the measures. Measures 2080 and 2079 should be paired so that they are reported together. (National Partnership for Women and Families)

Theme 3: Disagree with Measures Recommended

2082: HIV viral load suppression

Description: The Committee is asked to reconsider measure 2082 and the rejected measure 0407. Measure 2082 captures the percentage of **all** HIV-diagnosed patients that have achieved RNA control in a given 12 month period, whereas the measure 0407, which was not recommended, captures viral control within a six-month window from the start of treatment for patients on anti-retroviral therapy. The commenter suggests that adoption of measure 2082 will penalize providers that have higher numbers of long-term non-progressors in their patient populations, and that the measure does not account for clinical judgment and patient choices not to begin antiretroviral therapy (ART) for various reasons. Also, if all patients with an HIV diagnosis are presumed to be on ART, then there is no need for Measure 2083 (Prescription of anti-retroviral therapy). (HIV Medicine Association)

This is the sole outcome measure of this infectious disease endorsement measure set. There is a strong correlation between the reduction of viral loads and that of morbidity, mortality, and HIV transmission, which makes this measure beneficial not only to individual patients but to populations as well as transmission of the virus is reduced. Data for this measure should be stratified by race, ethnicity, gender, and age when it is publically reported so as to build a capacity to identify disparities in a nationally standardized, meaningful fashion Development e-specification is encouraged. (National Partnership for Women and Families)

2083: Prescription of HIV antiretroviral therapy

Description: The Committee is asked to reconsider measure 2083 and measure 0406, which is currently not recommended. There will be the same difficulty in operationalizing measure 2083 that is occurring with attempts to update measure 0406 such that it comports with current clinical practice guidelines. The metric should capture and define prescription of "potent" ART, and should exclude ART combinations that are contraindicated. (HIV Medicine Association)

The commenter does not support this measure because it does not capture whether the ARV therapy was received by or had an effect on the patient. Though it is important to have measures that capture the effects of ARV therapy on HIV+ patients, this documentation measure falls short of meeting the needs of the affected population. (National Partnership for Women and Families)

0404 HIV/AIDS: CD4 cell count or percentage performed

Description: A commenter says this is effectively a proxy measure for patient retention (something that is better captured by measures specifically designed for this purpose such as measures 2079 and 2082). This measure captures provider-patient contact to a greater extent than it provides meaningful information on the effectiveness of Antiretroviral (ARV) therapy or the health of the patient. Rather longitudinal tracking of the levels to assess whether improvement is occurring (i.e. outcomes), this measure accounts only for whether a count test

was performed. Measures of viral load suppression (such as measure 2082) have become more relevant indicators of outcomes than measures of CD4 levels. (National Partnership for Women and Families)

Another commenter recommends including whether the patient received the results of the tests. Knowledge of personal CD4 count and/or percentage is a helpful tool for patients to understand their own disease. Simply measuring that the test was performed does not indicate that the patient or the physician discussed the result. (National Quality Center Consumer Advisory Committee)

<u>ACTION ITEM</u>: After review of and discussion of the comments, does the Committee wish to change their evaluation of any of the criteria or overall recommendation for measures 2082, 2083 and 0404?

Theme 4: Disagree with Measures not Recommended

0298: Central line bundle compliance

Description: A commenter advises that this important healthcare-associated infection (HAI) prevention measure - process may directly lead to the desired outcome of infection prevention. The process components within this measure establish a means of direct accountability and empower all caregivers to serve an active role in prevention and monitoring. (Highmark, Inc.)

<u>Proposed Committee Response</u>: The measure developer advised the Steering Committee that this measure has not been tested for reliability and validity. As a result the Committee agreed that the measure does not meet NQF criteria for endorsement.

0400: Hepatitis C: Hepatitis B vaccination

Description: CDC encourages the continued paired measurement of Hepatitis B vaccination AND Hepatitis A vaccination among those with Hepatitis C because even 1 dose provides appreciative protection, although CDC agrees that documentation of full schedule immunization is (as the committee noted) very difficult at this time.

The developer states that research has found a lower superinfection with Hepatitis B in vaccinated patients there have been three systematic reviews that demonstrate much higher risk of hepatocellular carcinoma when co-infected with both Hepatitis B and Hepatitis C, above the additional effects of one on top of the other. CDC data shows that 30%-55% of patients are protected after one vaccination, 75% of patients are protected after 2 shots, and the third shot is essentially the booster and can be administered at any time. However, we disagree with the

SC in that we believe that a 50% antibody reduction from just one shot is a sufficient improvement. (AMA PCPI)

0393: Testing for chronic hepatitis C – Confirmation of hepatitis C viremia

Description: The Committee determined that the criteria for evidence were not met; however, a few Steering Committee members discussed the indirect evidence linking the process to the outcome. Additional information provided by the Work Group included a meta-analysis of 31 studies that found a consistent overall estimate of 15 to 20 percent of people who become infected with acute Hepatitis C will clear the virus. The absence of confirmatory viral testing may then leave these 15 to 20 percent of patients with the mistaken belief that they have chronic Hepatitis C, subjecting these patients to unnecessary anxiety and other harms. The remaining viral positive patients could benefit from the additional counseling for their own and for transmission risk, as mentioned by SC members, namely avoiding alcohol, getting vaccinated, and providing counseling regarding transmission and remaining engaged in care. Thus, this test is critically important in differentiating whether or not people have resolved infection or are currently infected with HCV, regardless of whether antiviral treatment is contemplated. (AMA PCPI)

0397 Hepatitis C: Antiviral treatment prescribed

Description: The Committee discussed that a reasonable action for many patients and providers is to wait before initiating therapy until newer and beneficial treatments are available (estimated 18-36 months) that might be more benign. The newer, oral regimens will likely move treatment into an infectious disease realm rather than waiting until it is a significant liver disease. However, in the meantime, of all of the proposed measures, our Hepatitis C Expert Work Group believes that this is the one measure that would have the largest impact on outcomes. Currently, Hepatitis C is overall an undertreated disease. This is not fully reflected in the current performance measure because of the opportunity for numerous appropriate exclusions due to absolute or relative contraindications associated with recommended therapies. Currently recommended treatments. (AMA PCPI)

0401 Hepatitis C: Counseling regarding risk of alcohol consumption

Description: CDC disagrees with not recommending this measure. Such counseling is included in the recent CDC recommendations addressing Hepatitis C screening (Recommendations for the Identification of Chronic Hepatitis C Virus Infection Among Persons Born During 1945–1965 August 17, 2012 / 61(RR04);1-18).

<u>ACTION ITEM</u>: After review and discussion of the comments, does the Committee wish to change their evaluation of any of the criteria and overall recommendation for measures 0400, 0393, 0397 or 0401?

Theme 5: Additional Areas for Measure Development

Description: Several comments included suggestions for additional gaps in measure development:

Lack of outcome measures or follow-up for screening tests

Commenters are frustrated by the overabundance of process measures in this set and measures would be more meaningful to consumers if they captured outcomes. The many screening measures in particular make no note of the results of the screening tests or of any follow-up for tests with a positive indication. In future measure development measures should account for results where data is available and collection is feasible.

Screening for STIs

In addition to the screening for specific STIs captured in measure 0409 consideration should also be given to screening for HPV.

Theme 6: Comments on measure specifications referred to the developer

Description: Several comments address the measure specifications such as suggesting revisions to titles to clarify the intent of the measure; the need for stratification by disparities; including review of test results with the patient; or additional exclusionary criteria. These comments have been forwarded to the measure developers for their response. The developer responses have been included in the final comment spreadsheet. Committee members are encouraged to identify any comments or responses for discussion by the entire group.