

May 16, 2012

Stephen Lutz, MD
Chair, Cancer Endorsement Maintenance Steering Committee
National Quality Forum
1030 15th Street NW
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Dear Dr. Lutz:

On behalf of the American Academy of Dermatology (AAD), the American Medical Association (AMA) convened Physician Consortium for Performance Improvement® (PCPI™), and the National Committee for Quality Assurance (NCQA), we are writing to provide you with some additional information and our perspectives as you seek public comment on the endorsement recommendations of National Quality Forum's (NQF) Cancer Endorsement Maintenance Steering Committee (SC). We appreciate the large task before the Committee and short timeframe for discussion. However, we believe additional dialogue with the SC is essential to demonstrate the value and reliability of a measure, NQF #0562 Overutilization of Imaging Studies in Melanoma, that has initially not been recommended for endorsement, in order to accomplish our mutual goal of improving the quality of care provided to cancer patients.

Brief Introduction

The National Priorities Partnership has identified overuse as a National Priority, which aims to eliminate overuse while ensuring the delivery of appropriate care. The Overutilization of Imaging Studies in Melanoma measure focuses on the process of identifying signs and/or symptoms prior to ordering imaging for a melanoma patient, and aims to prevent overuse of imaging in localized melanoma patients. The measure is related to improved outcomes, including reduction of radiation exposure and patient anxiety, and also focuses on cost reduction. The measure was recently updated, based on changes in evidence-based guidelines. The current version of the measure was reviewed and approved by the AMA-PCPI membership, including an additional review by the American Society of Clinical Oncology (ASCO).

1) SC Assessment of Evidence supporting the Overutilization of Imaging Studies in Melanoma measure:

The original vote by the SC indicated that the requirement for evidence was not met. However, the measure was updated and constructed based on the updated evidence-based guidelines from the National Comprehensive Cancer Network (NCCN) and AAD. The AAD guideline recommendation states that in asymptomatic patients with localized cutaneous melanoma of any thickness, baseline blood tests and imaging studies are generally not recommended and should only be performed as clinically indicated for suspicious signs and symptoms¹. The NCCN 2012 guideline based its recommendations for imaging studies on the patient's stage of disease, stating that routine cross-sectional imaging (CT, PET, MRI) is not recommended for patients with localized melanoma. For patients with stage IA melanoma, this is consistent with the National Institutes of Health guideline. For patients with stage IB to IIC, this recommendation is based on the very low yield of detection of subclinical disease. In patients with stage IIB-IIC, chest x-ray is optional. In any patient with localized melanoma, cross-sectional imaging should only be used to investigate specific signs or symptoms.²

In summary, our measure is designed to discourage clinicians from ordering unnecessary and/or inappropriate imaging for patients with a current diagnosis of stage 0-IIc melanoma and patients with a history of melanoma without signs or symptoms. The measure is clearly supported by clinical practice guidelines, and therefore, meets the evidence criteria.

2) SC assessment of Scientific Acceptability of the Overutilization of Imaging Studies in Melanoma measure

During the in-person meeting and subsequent review of the measure, the Steering Committee noted several concerns regarding the reliability of the measure as currently specified. The original submission of the measure, however, included a detailed signal-to-noise ratio analysis, which demonstrates the reliability of the measure. According to the NQF's modified measure evaluation criteria, "Examples of reliability testing for data elements include, but are not limited to: inter-rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item scales; test-retest for survey items. Reliability testing of the measure score addresses precision of measurement (e.g., signal-to-noise).³" Therefore, the signal-to-noise ratio analysis clearly meets the NQF reliability testing requirements.

Reliability was measured as the ratio of signal to noise. The signal in this case is the proportion of the variability in measured performance that can be explained by real differences in physician performance.

Reliability is the ratio of the physician-to-physician variance divided by the sum of the physician-to-physician variance plus the error variance specific to a physician. A reliability of zero implies that all the variability in a measure is attributable to measurement error. A reliability of one implies that all the variability is attributable to real differences in physician performance.

Reliability is estimated at two different points, at the minimum number of quality reporting events for the measure and at the mean number of quality reporting events per physician. For this measure, the minimum number of quality reporting events required to be included in this analysis is 10 events. The sample for this measure was taken from the American Academy of Dermatology (AAD) registry, used for PQRS reporting. Given the structure of the PQRS program, a physician may choose to submit or not submit to PQRS. Since these data contain results on a large number of physicians, limiting the reliability analysis to only those physicians who are participating in the program will eliminate the bias introduced by the inclusion of physicians who are in the data but are not submitting claims to PQRS.

The total number of physicians reporting on this measure is 467. Of those, 298 met the minimum number of quality reporting events for inclusion in the reliability analysis. For this measure 63.81 percent of physicians are included in the analysis, and the average number of quality reporting events for physicians included is 40.56 for a total of 12,087 events. The average number of quality reporting events for the remaining 36.19 percent of physicians who aren't included is 3.89 for a total of 658 events.

For this measure, the reliability at the minimum level of quality reporting events (i.e. 10 quality events) was .8098. The reliability at the average number of quality reporting events was .9453

This measure has high reliability when evaluated at both the minimum level of quality reporting events and at the average number of quality events.

Data analyses were conducted by using SAS/STAT software, version 8.2 (SAS Institute, Cary, North Carolina).

Despite the analysis results and conclusion that the measure has high reliability, the committee requested additional data analyses, with regards to the two patient populations being captured separately (patients with a history of melanoma and patients presenting with a new occurrence of melanoma). On day 2 of the in-person meeting, the AMA-PCPI Measure Testing staff presented the SC with additional data, in order to exhibit the reliability of the measure with new diagnosis patients and patients with a history of melanoma being captured separately. This data was also taken from the American Academy of Dermatology registry, used for PQRS reporting.

**Please note that the data is presented below at the data element level*

New (Current) Diagnosis

% Agreement; Kappa Statistic (95% CI)
Overall - 88.89%; 0.4706 (0.000-1.000)
Denominator - 88.89%; 0.4545 (0.000-1.000)
Numerator - 88.89%; 0.4545 (0.000-1.000)
Exception - 100%; kappa is noncalculable*

*This is an example of the limitation of the Kappa statistic. While the agreement can be 90% or greater, if one classification category dominates, kappa can be significantly reduced. (<http://www.ajronline.org/cgi/content/full/184/5/1391>)

Existing Diagnosis (History of Melanoma)

% Agreement; Kappa Statistic (95% CI)
Overall - 74.59%; 0.4143 (0.2362-0.5924)
Denominator - 76.23%; 0.4460 (0.2699-0.6221)
Numerator - 76.23%; 0.4460 (0.2699-0.6221)
Exception - 74.59%; 0.3983 (0.2154-0.5812)

Based on this data analysis, it is clear that the overall agreement rates are very high amongst the measure elements and the kappa statistics are within 95% confidence interval for both new diagnosis and existing diagnosis patients.

Therefore, we respectfully request that the CSAC reconsider the potential endorsement of this measure, for which we have demonstrated reliability, via several different types of data analyses.

3) SC concern that patients with recurrent Melanoma will not be restaged and would, therefore, not be eligible to receive imaging studies

Several members of the Steering Committee expressed concern that patients with recurrent disease would not be restaged at the time of recurrence, and as a result, these patients may not receive the appropriate care (which may require imaging). This measure focuses on localized melanoma patients only. This is demonstrated in the measure language, as the measure is specified to capture patients “*without signs or symptoms suggesting systemic spread.*” The Melanoma Work Group agrees that a patient with signs or symptoms *should* have imaging tests performed. Therefore, all patients that have a melanoma recurrence, indicating metastatic disease

would display signs or symptoms and would not be captured in this measure, so they absolutely would receive the appropriate imaging.

We appreciate your time and thoughtful consideration of our perspectives, at this stage in the measure review process and we would be happy to discuss these issues further with you, in the near future.

Sincerely,



Dirk Elston, MD



Raj Behal, MD, MPH

Co-Chairs of the AAD/PCPI/NCQA Work Group for Melanoma

Enclosure

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References:

¹ American Academy of Dermatology (AAD). Guidelines of Care for the Management of Primary Cutaneous Melanoma. <http://www.aad.org/education-and-quality-care/clinical-guidelines/current-and-upcoming-guidelines/current-guidelines-and-guidelines-in-development>. Accessed May 4, 2011.

² National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Melanoma. 2011. Available at: www.nccn.org.

³ National Quality Forum. Guidance for Measure Testing and Evaluating Scientific Acceptability of Measure Properties. Accessed at: <http://www.qualityforum.org/Search.aspx?keyword=testing+requirements> on May, 9, 2012.

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