NATIONAL QUALITY FORUM

Memo

TO: NQF Members

FR: NQF Staff

RE: Voting Draft Report: *NQF-Endorsed Measures for Cardiovascular Conditions*

DA: March 24, 2015

Background

Cardiovascular disease is the leading cause of death for men and women in the United States. It accounts for approximately $312.6 billion in health care expenditures annually. Coronary heart disease (CHD) accounts for 1 of every 6 deaths in the United States.[1] Hypertension—a major risk factor for heart disease, stroke, and kidney disease—affects 1 in 3 Americans, with an estimated annual cost of $156 billion in medical costs, lost productivity, and premature deaths.[2]

NQF's portfolio cardiovascular measures is one of the largest and most long-standing with measures in the topic areas of primary prevention and screening, coronary artery disease (CAD) or ischemic heart disease (IHD), heart attacks (AMI), percutaneous coronary intervention (PCI), cardiac rehabilitation, cardiac imaging, high blood pressure, heart failure, rhythm disorders and ICDs. Due to the large number of cardiovascular measures, maintenance review of endorsed measures and consideration of new measures is taking place over several phases in 2014-2015.

In phase 2 of the Cardiovascular Project, the 22-member Cardiovascular Standing Committee met during a two-day in-person meeting to evaluate 16 measures: 8 new measures and 8 measures undergoing maintenance of endorsement review against NQF's standard evaluation criteria. Of the 16 measures under consideration, 8 were recommended for endorsement, 1 was withdrawn for consideration, 4 were not recommended for endorsement, and 3 were deferred by the Standing Committee to be voted on after the Post Comment Call on March 18, 2015. After the Post Comment Call, the Committee voted to recommend the 3 deferred measures for NQF Endorsement.

Post-Comment Period Conference Call

The Cardiovascular Standing Committee held their 2014 Cardiovascular Phase 2 Post-Comment Period conference call on March 18, 2015 with two purposes: 1) Evaluate three appropriate use measures deferred for reconsideration from the in person meeting; and 2) Review, discuss and provide feedback on member and public comments received for the Phase 2 Cardiovascular measures, and determine if any measures warranted further reconsideration based on Committee, developer, member and public responses.

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[1] Lloyd-Jones D, Adams RJ, Brown TM, et al., Heart disease and stroke statistics—2013 update: a report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee , Circulation, 2013;127:e6-e10.

[2] "HHS Secretary Sebelius Statement on National High Blood Pressure Education Month." U.S. Department of Health & Human Services (HHS), 2 May 2012. Available at http://www.hhs.gov/news/press/2012pres/05/20120502a.html. Last accessed October 2013.

Reconsideration of Cardiovascular Phase 2 Measures

Measures for appropriate use of procedures and medical technologies are becoming more common and reflect multi-stakeholder interest in assessing appropriate use of healthcare services. NQF's Importance Criteria states the evidence for measures that focus on inappropriate use should include "a systematic assessment and grading of the quality, quantity, and consistency of the body of evidence that the measured process does not lead to a desired health outcome." Therefore the evidence for appropriate/inappropriate use measures should primarily focus on the lack of effectiveness or benefit of the test or procedure to patients. During the Cardiovascular Phase 2 In-Person Meeting on December 4-5, 2014, three appropriate use cardiac imaging measures were scheduled for Standing Committee review. These measures utilized appropriate use criteria (AUC) described by the developer as the "when to do" and "how often to do" a given procedure in the context of scientific evidence, the health care environment, the patient's profile and a physician's judgment. The AUC are designed to examine the use of diagnostic and therapeutic procedures to support efficient use of medical resources, while also providing patients with quality, appropriate care. While the Committee found the evidence for the AUC acceptable and generally favored the underpinnings of the three measures, the Standing Committee requested additional clinical evidence supporting each measure, and reconsidered the three measures listed below at the Post-Comment Period Call on March 18, 2015. No pre- or post-evaluation comments were received for these three measures. The Committee recommendations accompany each measure, with voting held remotely following the meeting.

- 0670: Cardiac stress imaging not meeting appropriate use criteria: Preoperative evaluation in low risk surgery patients *(recommended by the Committee after the Post Comment Call on March 18, 2015)*
- 0671: Cardiac stress imaging not meeting appropriate use criteria: Routine testing after percutaneous coronary intervention (PCI) *(recommended by the Committee after the Post Comment Call on March 18, 2015)*
- 0672: Cardiac stress imaging not meeting appropriate use criteria: Testing in asymptomatic, low risk patients *(recommended by the Committee after the Post Comment Call on March 18, 2015)*

Comments Received

NQF solicits comments on measures undergoing review in various ways and at various times throughout the evaluation process. First, NQF solicits comments on endorsed measures on an ongoing basis through the Quality Positioning System (QPS). Second, NQF solicits member and public comments prior to the evaluation of the measures via an online tool located on the project webpage. Third, NQF opens a 30-day comment period to both members and the public after measures have been evaluated by the full committee and once a report of the proceedings has been drafted. To further hear the voice of the measurement stakeholders, NQF includes open public commenting during in person meetings and conference calls.

Pre-evaluation comments

The pre-evaluation comment period was open from October 21, 2014 to November 10, 2014 for all 16 measures under review. No pre-evaluation comments were received for these measures.

Post-evaluation comments

The Draft Report went out for Public and Member comment from January 28, 2015 to February 27, 2015. During this commenting period, NQF received 31 comments from 5 member organizations enumerated below, as well as comments from 5 members of the general public:

Consumers – 0	Professional – 1
Purchasers – 0	Health Plans – 2
Providers – 0	QMRI – 0
Supplier and Industry – 2	Public & Community Health – 0

See the post-evaluation comment table for all comments received, as well as developer and Committee comments for each comment. Also available for review are the revisions to the *NQF-Endorsed Measures for Cardiovascular Conditions 2014-2015: Phase 2 Draft Technical Report for Voting* with identified with red-lined changes on the project page. (Note: Typographical errors and grammatical changes have not been red-lined, to assist in reading.)

Comments and their Disposition

4 major themes were identified in the post-evaluation comments, as follows:

1. Updated Guidelines Implications
2. Burden of paper record measures
3. Recommendations for improved measures
4. Recommendation for continued effort in developing and advancing directives measures

Theme 1 - Updated Guidelines Implications

There were several comments requesting revisions to the following measures that were impacted by the updated 2014 AHA/ACC/HRS Guidelines for Management of Patients with Atrial Fibrillations recommending developers use CHA2DS2-VASc as the risk assessment tool of choice instead of CHADS2, which is no longer recommended by the Updated Guidelines.

- 1525: Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy *(recommended by the Committee)*
- 1524: Atrial Fibrillation: Assessment of Thromboembolic Risk Factors (CHADS2) *(not recommended by the Committee)*

Developer Response: The reason why this measure does not include the CHA2DS2-VASc was that the NQF deadline for measure submission (December 23, 2013) did not align with the updated Atrial Fibrillation guidelines were not yet released. As a result, modifications to the measure could not be made, and tested utilizing the NQF evaluation criteria in time for the measure review. The reason we cannot modify this measure to include CHA2DS2-VASc during the NQF endorsement process is twofold. NQF requires that measures tested given the existing measure specification. Given that at the time of submission the guideline had not yet been released, the measure reflected the previous guideline recommendations of CHADS2, as well as the testing data provided to NQF that shows that the measure is feasible, reliable, and valid. Second, as measure developers we try to ensure an open process to providing feedback on all measures included in a measure set. Therefore, we have not only a peer review process, but also an open comment period where we encourage the public to comment on our draft measure set prior to it being finalized. We would provide such a process even for changes such

as changes CHADS2 to CHA2DS2-VASc. We are in the process of convening the writing committee and do plan to look at replacing CHADS2 with CHA2DS2-VASc.

Committee Response: Thank for your comment. The developer can consider these suggestions for future iterations of the measure. The Committee encourages the developer to include the most recent guidelines along with the testing necessary to meet the NQF evaluation criteria.

Based on the developer's responses and comments provided during the Post-Comment Period Call, the Committee agreed to uphold their recommendations and no further actions are required.

Theme 2 - Burden of paper record measures

Commenters emphasized their concerns with endorsing paper medical records as it can be a potential burden for end users. Potential burden comments were raised pertaining to the following measures:

- 2438: Beta-Blocker Therapy (i.e., Bisoprolol, Carvedilol, or Sustained-Release Metoprolol Succinate) for LVSD Prescribed at Discharge *(recommended by the Committee)*

Developer Response: Thank you for your comment. The designated setting for this measure is: Hospital/Acute Care Facility and this measure was not intended to be a claims based measure, nor do hospitals have access to pharmacy claims. The measure requires: documentation that bisoprolol, carvedilol, or sustained-release metoprolol succinate was prescribed at discharge. With consideration of burden of abstraction, the Hospital/Acute Care Facility has the flexibility in using a number of available sources in order to abstract this information. These sources include but are not limited to: Medication Administration Record (MAR), Discharge Summary, Discharge Instruction Sheet, Nursing Notes, Progress Notes, Physician Orders, Physician's Notes, Transfer Sheet, and Medication Reconciliation Form.

This measure was developed and tested prior to implementation and has been in use for over a year by programs who have been awarded Advanced Certification in Heart Failure. The Joint Commission has not received feedback respecting undue burden of data abstraction for this measure.

- 2439: Post-Discharge Appointment for Heart Failure Patients *(recommended by the Committee)*

Developer Response: The designated setting for this measure is: Hospital/Acute Care Facility, and it was not developed for use by health plans. Additionally, this measure was not intended to be a claims based measure. The Joint Commission develops performance measures based upon Attributes of Performance Measures and Associated Evaluation Criteria. One of these attributes requires that the measure is: Under Provider Control - refers to the extent to which the provider has the ability to influence the processes and/or outcomes being measured.

During the Post-Comment Period Call, the developer reiterated their response provided for 2438: Beta-Blocker Therapy (i.e., Bisoprolol, Carvedilol, or Sustained-Release Metoprolol Succinate) for LVSD Prescribed at Discharge in relation to this measure. They additionally stated no comments related to the "burden of data collection" have been received by the developer during the piloting of the measures, nor within the year of measure implementation.

- 2443: Post-Discharge Evaluation for Heart Failure Patients *(recommended by the Committee)*

Developer Response: Thank you for your comment. The designated setting for this measure is: Hospital/Acute Care Facility with a focus on patients admitted to the hospital for heart failure. Therefore, it does include those patients who entered the inpatient setting via the observation unit or Emergency Department. With respect to the burden of abstraction, the Hospital/Acute

Care Facility has the flexibility in using data sources that are not a part of the inpatient medical record as this information would be captured after the patient is discharged. The data sources include but are not limited to: home health forms, logs from follow-up phone calls, or other logs that record follow-up information. This measure was developed and tested prior to implementation and has been in use for over a year by programs who have been awarded Advanced Certification in Heart Failure. The Joint Commission has not received feedback respecting undue burden of data abstraction for this measure. The measure is specified to capture patients only with a principal discharge diagnosis of Heart Failure. There are exclusions considered for the following: Patients who had a left ventricular assistive device (LVAD) or heart transplant procedure during hospital stay, patients with comfort measures only, and patients enrolled in a clinical trial.

Committee Response: The Committee recognizes the commenters' concerns with paper medical records and its potential burden to the end users. However, the Committee agreed during the in-person meeting the data collection methods are based on the program the measures are used, and that they are feasible for implementation.

Based on the developer's responses and comments provided during the Post-Comment Period Call, the Committee agreed to uphold their recommendations and no further actions are required.

Theme 3- Recommendations for improved measures

There were several submitted comments requesting revisions to measures to capture more meaningful information:

- 0543: Adherence to Statin Therapy for Individuals with Cardiovascular Disease *(withdrawn for consideration)*
    - a recommendation to include "at least moderate or high intensity" statin in the measure description
    - a recommendation to define therapeutic treatment level in measure description
    - a recommendation to include or acknowledge the use of non-statins for cardiac care prevention (for statin intolerance)
    - questions related to patient dosing, outcomes and socio-demographic concerns with the data collection methodology

Developer Action: Immediately prior to the Post-Comment Period Call, NQF staff was notified by the developer will no longer be maintaining the measure as it is not being utilized in the CMS Quality and Resource Use Report (QRUR).

Committee Response: Thank you for your comment. As the measure developer will no longer maintaining the measure and the measure will be withdrawn from further consideration, no further Committee comments are required.

- 1525: Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy (recommended by the Committee)
    - a recommendation to include "at risk" for thromboembolism
    - a recommendation to consider the role or impact of percutaneous closure devices
    - a recommendation to include patients preference or refusal

Developer Response: Measure #1525 does include both medical and patient reason exceptions for not prescribing warfarin OR another oral anticoagulant drug that is FDA approved for the prevention of thromboembolism. Patient reason exceptions include economic, social, and/or religious impediments, noncompliance, patient refusal, other patient reason. Given the

importance in engaging consumers in their care decisions, we believe in some instances the patients may choose not to have a prescription issued by the physician.

The developer also stated during the Post-Comment Period Call, they will consider the "at risk" and "the role or impact of percutaneous closure devices" with their measures workgroup for the next round of measure updates. They also stated patient preference or refusal is currently specified as a measure exception.

Committee Response: Thank you for your comment. Although some Committee members raised concerns regarding the exclusion for patient refusals, the Committee recommended the measure for continued endorsement.

- 2440: Care Transition Record Transmitted *(not recommended by the Committee)*
    - recommends transmission of records within 24 hours (not 7 days)

Developer Response: During the Post-Comment Period Call, the developer stated they did not wish to provide a response as the measure was not recommended by the Committee.

Based on the developers' responses and comments provided during the Post-Comment Period Call, the Committee agreed to uphold their recommendations and no further actions are required.

Theme 4 - Recommendation for further development of advanced care/ directives measures

Several comments were received from health plans regarding advance directives for end-of-life care. The commenters emphasized the importance of measuring advance directives as it is essential in addressing the quality of life and cost issues with end-of-life care. Moreover, commenters highlighted that continued effort to develop Advance Directive measures should be a priority. Comments were received for the following measures:

- 2441: Discussion of Advance Directives/Advance Care Planning *(not recommended by the Committee)*
- 2442: Advance Directive Executed *(not recommended by the Committee)*

Developer Response: During the Post-Comment Period Call, the developer stated they did not wish to provide a response as the measure was not recommended by the Committee.

Committee Response: Thank you for your comment. The Committee questioned the qualifications of the healthcare worker assessing patients' end-of-life preferences, stating is should not be "passed off" function, rather one who is appropriately trained, cares about the patient and has a focal role in their care. The Committee discussed the potential psychological unintended consequences as it only focuses on one-time discussions. As part of our portfolio of endorsed measures, *0326: Advance Care Plan* addresses documentation of a discussion regarding advance care plan or surrogate decision maker documentation for patients 65 and older regardless of diagnosis in the ambulatory, home health, hospice, acute care facility, post-acute/long term care inpatient rehab and nursing facilities.

Based on the developer's responses and comments provided during the Post-Comment Period Call, the Committee agreed to uphold their recommendations and no further actions are required.

Measure Specific Comments

Measure specific comments were received for the following measures:

- 2461: In-Person Evaluation Following Implantation of a Cardiovascular Implantable Electronic Device (CIED) *(recommended by the Committee)*

One commenter recommended that the time frame for follow-up visits to be stratified, “We recommend that the range of in-person follow up visits be stratified by time (e.g. 2-7 weeks; 8-12 weeks) since the time frame for the in-person evaluation is fairly broad, ranging from 2 through 12 weeks.”

Developer Response: As noted in the measure submission application, appropriate device programming can have an impact on patient outcomes following CIED implantation. Intermediate outcomes include optimizing cardiac device function to meet the patient’s clinical needs, along with detection and treatment of arrhythmias. Health outcomes include improving the patient’s quality of life. For example, optimizing ICD programming may reduce unnecessary device therapy and could potentially reduce mortality (as suggested by MADIT-RIT).”It has also been recently demonstrated that follow-up within 2-12 weeks after CIED placement is independently associated with improved survival at 1 year.” (Hess 2013) In addition, the HRS/EHRA expert consensus on the monitoring of cardiovascular implantable electronic devices (CIEDs): description of techniques, indications, personnel, frequency and ethical considerations states that device interrogations should continue every 3-6 months after the initial outpatient face-to-face visit that occurs within the first 2-12 weeks post-implantation. Heart Rhythm. 2008;5(6):907-925. The timeframe for the performance measure should align with the timeframe specified in the clinical evidence and the consensus statement and should not be further delineated or stratified.

Committee Response: Thank you for your comment, the Committee recognizes the commenters' recommendation. The developer may consider these suggestions for future iterations of the measure.

Based on the developer’s responses and comments provided during the Post-Comment Period Call, the Committee agreed to uphold their recommendations and no further actions are required.

- 2474: Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation *(recommended by the Committee)*

One commenter questioned the Committee’s decision with respect to the performance gap of this measure, “Due to the continued need for patient safety and continued quality concerns we understand the consideration of this measure. However, the performance rates associated with this measure is already high. We encourage the Committee to discuss revisions to this measure and/or the "value add" of this measure.”

Developer Response: During the Post-Comment Period Call, the developer stated recent evidence with limited data demonstrates varying performance gaps based on the characteristics of the institution performing the cardiac ablation, as well as the population.

Committee Response: Thank you for your comment. The Committee reviewed this issue of performance gap at the in-person meeting and agreed that although the performance rates were low across literature reviews, cardiac tamponade is critical to patient safety in cardiovascular care.

Based on the developer’s responses and comments provided during the Post-Comment Period Call, the Committee agreed to uphold their recommendations and no further actions are required.

NQF Member Voting

Information for electronic voting has been sent to NQF Member organization primary contacts. Accompanying comments must be submitted via the online voting tool.

Please note that voting concludes on April 7, 2015 at 6:00 pm ET – no exceptions.