NATIONAL QUALITY FORUM
Driving measurable health improvements together

Memo

June 23, 2020

To: Cardiovascular Standing Committee

From: NQF staff

Re: Post-comment web meeting to discuss public comments received and NQF member expression of support

COVID-19 Updates

Considering the recent COVID-19 global pandemic, many organizations needed to focus their attention on the public health crisis. In order to provide greater flexibility for stakeholders and continue the important work in quality measurement, the National Quality Forum (NQF) extended commenting periods and adjusted measure endorsement timelines for the Fall 2019 cycle.

Commenting periods for all measures evaluated in the Fall 2019 cycle were extended from 30 days to 60 days. Based on the comments received during this 60-day extended commenting period, measures entered one of two tracks:

Track 1: Measures Continuing in Fall 2019 Cycle
Measures that did not receive public comments or only received comments in support of the Standing Committees' recommendations will be reviewed by the CSAC on July 28 – 29.

- **Exceptions**
  Exceptions were granted to measures if non-supportive comments received during the extended post-comment period were similar to those received during the pre-evaluation meeting period and have already been adjudicated by the respective Standing Committees during the measure evaluation Fall 2019 meetings.

Track 2: Measures Deferred to Spring 2020 Cycle
Fall 2019 measures requiring further action or discussion from a Standing Committee were deferred to the Spring 2020 cycle. This includes measures where consensus was not reached or those that require a response to public comments received. Measures undergoing maintenance review will retain endorsement during that time. Track 2 measures will be reviewed during the CSAC's meeting in November.

During the Cardiovascular post-comment web meeting on June 30, the Cardiovascular Standing Committee will be reviewing Fall 2019 measures assigned to Track 2. A complete list of Track 1 measures can be found in Appendix B.

Purpose of the Call

The Cardiovascular Standing Committee will meet via web meeting on June 30, 2020 from 8:30-5 pm ET. The purpose of this call is to:

- Review and discuss comments received during the post-evaluation public and member comment period;
- Provide input on proposed responses to the post-evaluation comments;
- Review and discuss NQF members' expression of support of the measures under consideration; and
- Determine whether reconsideration of any measures or other courses of action are warranted.

Standing Committee Actions

1. Review this briefing memo and draft report.
2. Review and consider the full text of all comments received and the proposed responses to the post-evaluation comments
3. Review the NQF members' expressions of support of the submitted measures.
4. Be prepared to provide feedback and input on proposed post-evaluation comment responses.

Conference Call Information

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

Dial-In: 800-768-2983
Access Code: 7445915
Web link: https://core.callinfo.com/callme/?ap=8007682983&ac=7445915&role=p&mode=ad

Background

Cardiovascular disease (CVD) is a significant burden in the United States, leading to approximately one in four deaths per year.[1] Considering the effect of CVD, measures that assess clinical care performance and patient outcomes are critical to reducing the negative impacts of CVD.

The measures in the Cardiovascular portfolio have been grouped into various conditions, diseases, or procedures related to cardiovascular health. These topic areas include primary prevention and screening, coronary artery disease (CAD), ischemic vascular disease (IVD), acute myocardial infarction (AMI), cardiac catheterization, percutaneous catheterization intervention (PCI), heart failure (HF), rhythm disorders, implantable cardioverter-defibrillators (ICDs), cardiac imaging, cardiac rehabilitation, and high blood pressure.

On February 6, 2020, NQF convened a multistakeholder Standing Committee composed of 22 individuals met in person to review seven measures— one new measure and six maintenance measures—against NQF's standard evaluation criteria. Four measures were recommended for endorsement; the Committee did not recommend three measures for endorsement.

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 during a 16-week comment period via an online tool on the project webpage.

Post-evaluation Comments

The draft report was posted on the project webpage for public and NQF member comment March 18, 2020 for 60 calendar days. During this commenting period, NQF received two comments from two member organizations:

Member Council	# of Member Organizations Who Commented
Health Professional	1
Public/Community Health Agency	1

We have included all comments that we received in the comment table (Excel spreadsheet) posted to the Committee SharePoint site. This comment table contains the commenter's name, comment, associated measure, topic (if applicable), and—for the post-evaluation comments—draft responses (including measure steward/developer responses) for the Committee's consideration. Please review this table in advance of the meeting and consider the individual comments received and the proposed responses to each.

We have also included all comments that we received in Appendix A. Please note measure stewards/developers were asked to respond where appropriate. Where possible, NQF staff has proposed draft responses for the Committee to consider.

Comments and Their Disposition

Measure-Specific Comments

0018 Controlling High Blood Pressure

The commenter stated that the definition of blood pressure (BP) control in measure 0018 does not align with the American Academy of Family Physician's (AAFP) clinical guidelines, specifically the recommendation of a goal SBP < 150 mmHg and goal DBP < 90 mmHg in the general population aged ≥ 60 years. In addition, the commenter expressed concern that self-monitoring and reporting of blood pressure by the patient is not allowed in the proposed measure. The commenter also suggested using blood pressure readings taken over time as this may be more reliable than the point reading used for this measure.

Measure Steward/Developer Response:

To be added once provided.

Proposed Committee Response:

Thank you for your comments. The Committee will review these comments during its deliberations on the Post-Comment Call scheduled on June 30, 2020.

Action Item:

The Committee will discuss the blood pressure goals during the Post-Comment Meeting.

3534 30 Day All-cause Risk Standardized Mortality Odds Ratio following Transcatheter Aortic Valve Replacement (TAVR)

The commenter was supportive of this measure and had suggestions for future improvements and areas to consider for additional measure development around aortic stenosis (AS). In particular:

- Disease-specific quality measures for AS, regardless of treatment modality
- Patient-centered quality measures that reflect demonstrated patient priorities for outcomes
- Quality measures supporting timely diagnosis and treatment for all patients requiring future treatment of AS

Measure Steward/Developer Response:
No developer response required.

Proposed Committee Response:
Thank you for your comments.

Action Item:
No Committee action required

NQF Member Expression of Support

Throughout the 16-week continuous public commenting period, NQF members had the opportunity to express their support ("support" or "do not support") for each measure submitted for endorsement consideration to inform the Committee's recommendations. No NQF members provided their expressions of support.

Appendix A: Comment Received for Fall 2019 measures

Comment 1:

0018 Controlling High Blood Pressure

Date Submitted: Apr 13, 2020

Comment by:
American Academy of Family Physicians

On Behalf Of
American Academy of Family Physicians

ID# 8304 :
Controlling high blood pressure in patients with hypertension is a more complex issue than what this performance measures allows. The very simplistic approach to controlling blood pressure is not consistent with American Academy of Family Physicians' (AAFP) clinical guidelines: https://www.aafp.org/patient-care/clinical-recommendations/all/highbloodpressure.html which are based on the the 2014 Evidence-Based Guidelines for the Management of High Blood Pressure in Adults, developed by panel members appointed to the Eighth Joint National Committee (JNC 8). The following are key recommendations from JNC 8), some of which are not considered or are contradicted in the proposed measure:

- In the general population aged ≥ 60 years, initiate pharmacologic treatment to lower blood pressure (BP) at systolic blood pressure (SBP) ≥ 150 mmHg or diastolic blood pressure (DBP) ≥ 90 mmHg to a goal SBP < 150 mmHg and goal DBP < 90 mmHg.
- In the general population < 60 years, initiate pharmacologic treatment to lower BP at SBP ≥ 140 mmHg or DBP ≥ 90 mmHg to a goal SBP < 140 mmHg and goal DBP < 90 mmHg.
- In the population aged ≥ 18 and < 70 years with chronic kidney disease (CKD), initiate pharmacologic treatment to lower BP at SBP ≥ 140 mmHg or DBP ≥ 90 mmHg and treat to goal SBP < 140 mmHg and goal DBP < 90 mmHg. Initial (or add-on) antihypertensive treatment should include an angiotensin-converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB) to improve kidney outcomes, regardless of race.
- In the population aged ≥ 18 years with diabetes, initiate pharmacologic treatment to lower BP at SBP ≥ 140 mmHg or DBP ≥ 90 mmHg and treat to a goal SBP < 140 mmHg and goal DBP < 90 mmHg.
- In the general nonblack population, including those with diabetes, initial antihypertensive treatment should include a thiazide-type diuretic, calcium channel blocker (CCB), ACEI, or ARB.
- In the general black population, including those with diabetes, initial antihypertensive treatment should include a thiazide-type diuretic or CCB.
- The main objective of hypertension treatment is to attain and maintain goal BP. If goal BP is not reached within a month of treatment, increase the dose of the initial drug or add a second drug from one of the recommended classes (thiazide-type diuretic, CCB, ACEI, or ARB). Continue to assess BP and adjust the treatment regimen until goal BP is reached, adding a third drug if needed. Do not use an ACEI and an ARB together in the same patient. If goal BP cannot be reached using the recommended drug classes because of a contraindication or the need to use more than 3 drugs to reach goal, antihypertensive drugs from other classes can be used.

- Consider referral to a hypertension specialist for patients in whom goal BP cannot be attained or for complicated patients.

In addition, we are concerned that self-monitoring and reporting of blood pressure by the patient is not allowed in the proposed measure. Patients play an increasingly important role in their care and should be allowed to assume responsibility for blood pressure monitoring. Blood pressure readings taken over time may be more reliable than one reading taken at the most recent office visit, which is the value used for this measure.

Comment 2:

3534 30 Day All-cause Risk Standardized Mortality Odds Ratio following Transcatheter Aortic Valve Replacement (TAVR)

Date Submitted: May 24, 2020
Comment by

Edwards Lifesciences
Dr. Gregory Daniel
SPI
gregwdaniel@gmail.com

ID #8361 :
Dear Cardiovascular Standing Committee,

Edwards Lifesciences is the global leader in the science of structural heart disease and hemodynamic monitoring. Our technologies address patient populations in which there are significant unmet clinical needs, such as structural heart disease, heart valve disease and advanced monitoring of the critically ill. At Edwards Lifesciences, we are passionate about helping patients and have a sincere interest in ensuring patients have access to life-saving medical technologies and services that promote a high quality of care.

Edwards Lifesciences supports the development of quality measures for patients requiring treatment for Aortic Stenosis (AS). We believe this measure is a commendable first step toward supporting better outcomes in this population, including reduced 30-day mortality. We support NQF endorsement of the proposed measure.

However, Edwards believes there are opportunities for improvement with future measure development for AS in the following areas:

- Disease-specific quality measures for AS, regardless of treatment modality
- Patient-centered quality measures that reflect demonstrated patient priorities for outcomes
- Quality measures supporting timely diagnosis and treatment for all patients requiring future treatment of AS

Edwards Lifesciences supports the development of quality measures aimed at quantifying and supporting improved patient outcomes from TAVR and believes the 30 Day All-cause Risk Standardized Mortality Odds Ratio following Transcatheter Aortic Valve Replacement (NQF#3534) is a commendable first step toward incentivizing a healthcare system based on better patient outcomes and value over

volume. Thirty-day mortality is an important outcome widely considered in the evaluation of quality of care delivered by providers and cardiac programs.

Common measures should be developed across treatments for AS

Edwards believes in continually measuring and improving care for all AS patients who require aortic valve replacement, regardless of whether a patient receives surgical aortic valve replacement (SAVR) or TAVR. Edwards believes future quality measure development (by the American College of Cardiology or other groups) should consider exploring development of a common set of quality measures to simplify tracking and improving outcomes for all patients receiving aortic valve replacement. Edwards welcomes future opportunities to collaborate on such measure development.

Having separate quality measures for each treatment modality could further contribute toward disparities in treatment outcomes. Analyses of Medicare data revealed that SAVR in-hospital mortality rates could be as much as twice as high as those for TAVR programs. The same data also revealed unadjusted SAVR in-hospital mortality was lower at programs offering both TAVR and SAVR, as compared with SAVR-only facilities (4.4% vs. 6.7%, $p<0.001$).[1] This difference in mortality outcomes between procedures highlights the need to compare mortality outcomes across all aortic valve replacement (AVR) procedures, since many AS patients may be clinically eligible to receive either TAVR or SAVR. Although a quality measure currently exists for SAVR mortality, the mortality measure utilizes different data sources and methodology than the TAVR mortality measure currently under consideration, making a comparison between each measure inappropriate due to a lack of consistent methods for adjustment. We believe a quality measure aimed at improvement in mortality outcomes is beneficial; however, this measure should accommodate a broader, condition-level perspective that supports improved mortality outcomes across all patients requiring AVR.

Patient-centered quality measures should reflect patient priorities

Although the measurement of mortality outcomes is crucial, additional measures either in composite or individually, are needed to more fully reflect the full effects of a therapy on patients' emotional, physical, functional, and mental wellbeing, particularly among elderly populations.[2] Edwards believes it is important to utilize measures that reflect the outcomes patients prioritize as being important to them. Studies on the patient perspective demonstrate that the consideration of outcomes such as a patient's treatment goals, preferences and the measurement of quality of life (QOL) and functional status are important to providing patient-centered care and should be reinforced by the development of patient-centric quality measures. For example, patients who have severe AS, heart failure, and/or are elderly may value improvements in symptoms, functional status, and QoL more than improvements in longevity.[3],[4] A retrospective study conducted at the Dartmouth-Hitchcock Medical Center sought to understand these goals in a population who were inoperable or at high risk for surgery and underwent TAVR between June 2012 and August 2014. Before the intervention, patients were asked, "What do you hope to accomplish by having your valve replaced?". The ability to do a specific activity was the most frequently reported goal (48% of patients), followed by maintaining independence, reducing/eliminating pain or symptoms, and staying alive. The authors noted that elicitation of such preferences is paramount to the ongoing movement towards increased patient-centered care, and that various members of the Heart Team can be successful in assessing these preferences.

Another study evaluated patient preferences for TAVR or SAVR using a quantitative benefit-risk assessment.[5]Patient responses were elicited in terms of their preferences for the performance of TAVR and SAVR on a number of different attributes: type of procedure (e.g., invasiveness), 30-day

mortality rates, 30-day disabling non-fatal stroke rates, dependence, need for new pacemaker, need for dialysis, and time over which the procedure has been proven to work. The respondents' valuation of reduced procedural invasiveness, quicker time to normal QoL, as well as lower mortality associated with TAVR offset their valuation of the time over which SAVR has been proven to work.

Quality measures are needed for the diagnosis and surveillance of AS

Active surveillance and timely diagnosis of AS is critical to receiving effective, life-saving treatment for AS patients and a critical area for significant quality improvement. Therefore, future quality measure development that drives improvements in timely diagnosis and surveillance of AS should be a priority for measure development stewards, such as ACC or others. Currently, most published literature on the management of AS focuses on options for valve replacement and symptom management once a patient is diagnosed.[6] However, many AS patients do not undergo timely surveillance of their symptoms.[7] Without surveillance, identification, and treatment of AS, the condition can progress and cause heart failure, stroke, blood clots, and other consequences. Without a valve replacement, nearly half of patients with severe AS do not live beyond an average of two years after symptoms begin.[8] Providers do play a role in missed AS diagnoses across health care settings. One study reported that more than 40% of heart murmurs, a potential first sign of AS, went undetected by primary care clinicians.[9] This lack of awareness and recognition persists even when patients are diagnosed with severe forms of AS. For example, literature reports that 30-40% of patients with severe AS seen by a primary care physician are not referred for surgical consideration due to lack of knowledge of the prognosis and misconceptions about surgical risk.11 Another study found that 1/3 of severe AS patients are symptomatic, but do not receive an aortic valve replacement.[10] Given these gaps, along with the dire consequences if patients remain untreated, measuring quality by evaluating provider adherence to clinical guidelines on the management of AS should be prioritized.

For example, the American Heart Association and ACC have published guidelines for Heart Valve Disease (HVD), including AS.[11] These guidelines recognize that timely Transthoracic Echocardiograms (TTEs) are essential to monitoring the progression of HVD, specifically to evaluate the presence/absence of symptoms, severity of HVD, and change in heart rhythm or other factors. However, a 2010 retrospective analysis of TTE surveillance found that a significant number of HVD patients received echocardiograms outside of the guideline recommendations.[12] The goal of surveilling HVD patients through timely TTEs is to ensure patients receive valve replacements before their condition exacerbates and becomes potentially lethal. A quality measure aligned to clinical guidelines and focused on the timely TTE assessment would help address the current gap in diagnosis and treatment for HVD patients.

Priority must be placed on ensuring timely patient access to high-quality care, so that clinicians can provide all people with heart valve disease with the therapy that is right for them. Often, the primary risk facing severe AS patients is not treatment complications, but the risk of not receiving treatment at all. Edwards believes appropriate, timely and equal access to all treatment options for AS, whether surgical or transcatheter, is essential to ensuring high-quality care and reducing the mortality for patients in need.

All references available upon request.

Sincerely,
Gregory Daniel, PhD, MPH
Head, US Healthcare Policy
Edwards Lifesciences
202-615-0318

Appendix B: Fall 2019 Track 1 Measures

The following measures did not receive public comments or only received comments in support of the Standing Committees' recommendations and will be reviewed by the CSAC on July 28 – 29:

- 0071 Persistence of Beta-Blocker Treatment After a Heart Attack (American College of Cardiology)
- 0670 Cardiac stress imaging not meeting appropriate use criteria: Preoperative evaluation in low risk surgery patients (American College of Cardiology)
- 0671 Cardiac stress imaging not meeting appropriate use criteria: Routine testing after percutaneous coronary intervention (PCI) (American College of Cardiology)
- 0672 Cardiac stress imaging not meeting appropriate use criteria: Testing in asymptomatic, low risk patients (American College of Cardiology)
- 0965 Discharge Medications (ACE/ARB and beta blockers) in Eligible ICD/CRT-D Implant Patients (American College of Cardiology)
- 3534 30 Day All-cause Risk Standardized Mortality Odds Ratio following Transcatheter Aortic Valve Replacement (TAVR) (American College of Cardiology)