

- TO: Consensus Standards Approval Committee (CSAC)
- FR: NQF Staff
- RE: Cardiovascular Measures Phase 2, Member Voting Results
- DA: April 8, 2015

The CSAC will review recommendations from the *Cardiovascular Measures, Phase 2* project at its April 8, 2015 in-person meeting.

This memo includes a summary of the project, recommended measures, and themes identified from and responses to the public and member comments.

Member voting on these recommended measures will end on April 7, 2015 at 6pm ET.

Accompanying this memo are the following documents:

- 1. <u>Cardiovascular Phase 2 Draft Report</u>. The draft report has been updated to reflect the changes made following Standing Committee discussion of public and member comments. The complete draft report and supplemental materials are available on the <u>project page</u>.
- 2. <u>Comment table</u>. Staff has identified themes within the comments received. This table lists 31 comments received along with the NQF/Standing Committee and measure developer responses.

CSAC ACTION REQUIRED

Pursuant to the CDP, the CSAC may consider approval of 11 candidate consensus standards.

Cardiovascular Measures Recommended for Endorsement:

- <u>0090 Emergency Medicine: 12-Lead Electrocardiogram (ECG) Performed for Non-Traumatic</u> <u>Chest Pain (eMeasure)</u>
- <u>0715 Standardized adverse event ratio for children < 18 years of age undergoing cardiac</u> <u>catheterization</u>
- <u>1525 Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy</u>
- <u>2438</u> Beta-Blocker Therapy (i.e., Bisoprolol, Carvedilol, or Sustained-Release Metoprolol Succinate) for LVSD Prescribed at Discharge
- <u>2439 Post-Discharge Appointment for Heart Failure Patients</u>
- <u>2443 Post-Discharge Evaluation for Heart Failure Patients</u>
- <u>2461 In-Person Evaluation Following Implantation of a Cardiovascular Implantable Electronic</u> <u>Device (CIED)</u>
- 2474 Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation
- <u>0670 Cardiac stress imaging not meeting appropriate use criteria: Preoperative evaluation in low</u> <u>risk surgery patients</u>
- <u>0671 Cardiac stress imaging not meeting appropriate use criteria: Routine testing after</u> percutaneous coronary intervention (PCI)



• <u>0672 Cardiac stress imaging not meeting appropriate use criteria: Testing in asymptomatic, low</u> <u>risk patients</u>

Cardiovascular Measures Not Recommended

- <u>1524 Atrial Fibrillation: Assessment of Thromboembolic Risk Factors (CHADS2)</u>
- <u>2440 Care Transition Record Transmitted</u>
- 2441 Discussion of Advance Directives/Advance Care Planning
- 2442 Advance Directive Executed

Cardiovascular Measure Withdrawn from Consideration by the developer

• 0543 Adherence to Statin Therapy for Individuals with Cardiovascular Disease

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 <u>Cardiovascular Standing Committee</u> 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, 11 were recommended for endorsement, with 3 of these measures' endorsement recommendation deferred for reconsideration by the Standing Committee until the Post Comment Call on March 18, 2015. Four measures were not recommended for endorsement. One measure was withdrawn for consideration during the measure evaluation process, and 5 others were withdrawn prior to measure evaluation by the measure stewards.

DRAFT REPORT

The Cardiovascular Phase 2 Draft Report presents the results of the evaluation of 16 measures considered under the CDP. Eleven measures were recommended for endorsement as voluntary consensus standards suitable for accountability and quality improvement while four were not

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.



recommended and one was withdrawn from consideration by the measure developer. The measures were evaluated against the 2013 version of the <u>measure evaluation criteria</u>.

	MAINTENANCE	NEW	TOTAL
Measures considered	8	8	16
Withdrawn from consideration	6	N/A	6
Recommended	8	3	11
Not recommended	1	3	4
Reasons not	Importance – 1	Importance – 1	N/A
Recommended	Scientific Acceptability – 1	Competing Measure – 1	

COMMENTS AND THEIR DISPOSITION

NQF received 31 comments pertaining to the general draft report and to the measures under consideration from 10 organizations, 5 of which are member organizations, as well as individual commenters.

<u>A table of comments</u> submitted during the comment period, with the responses to each comment and the actions taken by the Standing Committee and measure developers, is posted to the <u>Cardiovascular</u> <u>Project Page</u> under the Public and Member Comment section.

Comment Themes and Committee Responses

For Post Comment Call Meeting, the Standing Committee reviewed all received comments. The comments related to measure specifications were forwarded to the measure developers, who were invited to respond. During the Post Comment Call, the Standing Committee discussion was focused on comment themes or topic areas with the most significant and recurring issues. They also discussed measure-specific comments for 2 measures.

The 4 major themes identified from the post-evaluation comments were:

- 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 affected by the updated 2014 AHA/ACC/HRS Guidelines for Management of Patients with Atrial Fibrillations. Commenters recommended 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 that had not yet been released. As a result, modifications to the measure could not be made 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 are tested based on 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 should 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. Additionally, the developers stated that during the measure's implementation and pilot testing, they did not receive any comments in regards to the "burden of data collection" for this measure.

• 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 followup 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 inperson meeting that 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 recommendation for endorsement 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)
 - \circ $\,$ a recommendation to include "at least moderate or high intensity" statin in the measure description



- o 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: Prior to the Post-Comment Period Call, NQF staff was notified that 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 be maintaining the measure therefore 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)
 - o a recommendation to include "at risk" for thromboembolism
 - a recommendation to consider the role or impact of percutaneous closure devices
 - o 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 these measures were 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.

NQF MEMBER VOTING RESULTS

NQF Member Voting on the Cardiovascular Phase 2 measures closes at 6pm ET on April 7, 2015. Voting results will be sent as an addendum to this memo and will be presented to CSAC for consideration during the in-person meeting on April 8, 2015.

REMOVE ENDORSEMENT OF MEASURES

Ten measures previously endorsed by NQF have not been re-submitted, withdrawn from maintenance of endorsement, or not recommended for continued endorsement:

Measure	Description	Reason for removal of
		endorsement
0092 Aspirin at Arrival of AMI	Percentage of patients, regardless of age, with an emergency department discharge diagnosis of acute myocardial infarction (AMI) who had documentation of receiving aspirin within 24 hours before emergency department arrival or during emergency department stay.	Developer decided not to submit the measure based on programmatic use in the current claims and registry format.



Measure	Description	Reason for removal of
		endorsement
0543 Adherence to Statin	This measure identifies patients	Developer will no longer be
Therapy for Individuals with	age 18 or older who started lipid-	maintaining the measure as it is
Coronary Artery Disease	lowering medication during the	not being utilized in the CMS
	measurement year and had a lipid	Quality and Resource Use Report
	panel checked within 3 months	(QRUR).
	after starting drug therapy.	
0569 Adherence to Lipid-	To ensure that members who are	Developer will not be maintaining
lowering medication	taking statins to treat	the measure.
	hyperlipidemia filled sufficient	
	medication to have at least 80%	
	coverage during the measurement	
	year.	
0639 Statin Prescribed at	Percent of acute myocardial	Developer will not be maintaining
Discharge	infarction (AMI) patients who are	the measure.
	prescribed a statin at hospital	
	discharge.	
1524 Atrial Fibrillation:	Percentage of patients aged 18	This measure did not meet the
Assessment of	years and older with a diagnosis of	Scientific Acceptability criteria and
Ihromboembolic Risk Factors	nonvalvular atrial fibrillation (AF)	was not recommended for
(CHADS2)	or atrial flutter in whom	endorsement
	assessment of all the specified	
	thromboembolic risk factors using	
	the CHADS2 risk criteria is	
1FF2 Plead Pressure	The percentage of adelescents 12	Douglapar desided to rotire the
Screening by age 13	the percentage of adolescents 15	measure due to underutilization
Screening by age 15	pressure screening with results	
	during the measurement year or	
	the year prior to the measurement	
	vear	
1553 Blood Pressure	The percentage of adolescents 18	Developer decided to retire the
Screening by age 18	vears of age who had a blood	measure due to underutilization.
	pressure screening with results	
	during the measurement or the	
	year prior to the measurement	
	year.	
2440 Care Transition Record	A care transition record is	This measure did not meet the
Transmitted	transmitted to a next level of care	Importance criteria and was not
	provider within 7 days of discharge	recommended for endorsement.
2441 Discussion of Advance	Patients who have documentation	The Committee decided to
Directives/Advance Care	in the medical record of a one-	remove their recommendation of
Planning	time discussion of advance	endorsement for Measure #2440,
	directives/advance care planning	as measure #0648 was
	with a healthcare provider.	determined to be "best in class"



Measure	Description	Reason for removal of
		endorsement
		and will remain endorsed within
		the Care Coordination portfolio.
2442 Advance Directive	Patients who have documentation	This measure did not meet the
Executed	in the medical record that an	Importance criteria and was not
	advance directive was executed.	recommended for endorsement.

Appendix A-Measure Evaluation Summary Tables for Recommended Measures

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LEGEND: Y = Yes; N = No; H = High; M = Moderate; L = Low; I = Insufficient

0090 Emergency Medicine: 12-Lead Electrocardiogram (ECG) Performed for Non-Traumatic Chest Pain (eMeasure)
Submission Specifications
Description: Percentage of patients aged 40 years and older with an emergency department discharge diagnosis of non-traumatic chest pain who had a 12-lead electrocardiogram (ECG) performed
Numerator Statement: Patients who had a 12-Lead ECG performed
Denominator Statement: All patients aged 40 years and older with an emergency department discharge diagnosis of non-traumatic chest pain
Exclusions: Medical reasons for not performing a 12-lead ECG
Patient reasons for not performing a 12-lead ECG
Adjustment/Stratification:
Level of Analysis: Clinician : Group/Practice
Setting of Care: Hospital/Acute Care Facility, Other
Type of Measure: Process
Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record
Measure Steward: American Medical Association - Physician Consortium for Performance Improvement (AMA- PCPI)
STANDING COMMITTEE MEETING [12/04/2014-12/05/2014]
1. Importance to Measure and Report: The measure meets the Importance criteria
(1a. Evidence, 1b. Performance Gap, 1c. High Impact)
1a. Evidence: H-10; M-6; L-1; I-0; IE-0; 1b. Performance Gap: H-0; M-10; L-7; I-0; 1c. Impact: H-1; M-8; L-8; I-0
Rationale:
 The Committee agreed that the evidence presented from the summary of two clinical practice guidelines, 1) 2013 ACCF/AHA Guidelines for the Management of ST-Elevation Myocardial Infarction and 2) ACCF/AHA Task Force on Practice Guidelines Class I recommendation and from additional recent research studies is sufficient.
• The developer provided electronic clinical data from 2010 PQRS claims data from 69, 602 providers with 97.05% aggregate performance rate and 95.16% mean performance rate. The 25th percentile is 96.55%. which the Committee agreed does not leave much room for improvement.



- The developer noted that the performance data may be skewed upward as it is from a voluntary reporting program and could imply that most of the participants who are reporting are already performing well on this type of care.
- Some Committee members questioned the priority of this measure as it identifies only missed myocardial infarction (MI) patients at discharge. Considering the improvements in MI care within the past few years, the missed MI rate being captured is low.
 - The developer highlighted the importance of chest pain as it is a very high prevalent issue and if an MI is missed, the consequences can be severe and costly.
- The Committee did not come to consensus with both performance gaps (58.8%) and priorities (52.9%) in the gray zone.

 Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u> (2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)
 Reliability: H-3; M-14; L-0; I-0; 2b. Validity: H-11; M-6; L-0; I-0 <u>Rationale</u>:

- The Committee agreed the specifications presented were clearly defined and consistent with the evidence. The eMeasure specifications capture the data elements and measure logic needed for the automated measure calculation. The developer value sets and the applicable ICD-9 and ICD-10 codes. The developer submitted the appropriate eMeasure documentation, except the "eMeasure XML" due to anticipated updates and unavailability of the Measure Authoring Tool (MAT). The developer agreed to submit the missing documentation in the 1st quarter of 2015.
- Reliability testing was performed at the data element level with data abstracted from one EHR in 2010 and tested at both the individual and group levels of analysis, with data from one urban academic center in a large Midwestern city in 50 charts in 3416 eligible patients. Kappa reliability testing was conducted on critical data elements in the measure, the results of the testing found 100% agreement for the numerator and exceptions and 94% agreement for the denominator (kappa score was not provided).
- The developer submitted the appropriate eMeasure documentation, except the "eMeasure XML" due to anticipated updates and unavailability of the Measure Authoring Tool (MAT). The developer agreed to submit the missing documentation in the 1st quarter of 2015.
- Empiric reliability testing on the data element level counts for empiric validity testing. Validity testing was also with a systematic assessment of face validity of performance scores using an ACEP (Quality and Performance Committee 2013-2014) expert panel. The results indicated the majority of the expert panel was in agreement that the measure's performance score could be used to distinguish good and poor quality. Additionally kappa validity testing conducted showed a score of 1.00 indicates the measure exceptions demonstrate almost perfect agreement.

3. Feasibility: H-5; M-11; L-1; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented) <u>Rationale</u>:

• Data for the eMeasure was abstracted from one EHR with an eMeasure feasibility score provided on the



testing site. Overall, the Committee agreed the measure is moderately feasible.
4. Use and Usability: H-1; M-14; L-1; I-1
(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)
Rationale:
• The measure is currently not publicly reported although the developer stated it would be submitted for public reporting and maintenance of certification programs. Additionally the claims and registry complements to this measure that were not included for the endorsement submission, were included in PQRS and in professional certification/recognition with the American Board of Emergency Physicians.
5. Related and Competing Measures
 This measure is related to facility-level measure NQF #0289 Median Time to ECG. Median time from emergency department arrival to ECG (performed in the ED prior to transfer) for acute myocardial infarction (AMI) or Chest Pain patients (with Probable Cardiac Chest Pain).
Ine committee agreed there is minimal overlap between the two measures.
Standing Committee Recommendation for Endorsement: Y-15; N-2
6. Public and Member Comment[03/24/15-04/07/15]
 Comments received showed general support for this measure. However, commenters highlighted that there is still a performance gap with timely EKGs in sub-populations.
 "Despite some concerns of a performance gap from the standing committee, there are still many eligible professionals not reporting on this measure and the current literature reveals some inequalities in the timing of EKG received by sex and minority status, further demonstrating the importance of this measure maintaining endorsement."
Committee Response:
 While the Committee recognized the narrow window for improvement and considered the voluntary reporting programs that could skew the data, the Committee agrees with the commenter, that this measure should continue to be part of the Cardiovascular portfolio.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X
8. Board of Directors Vote: Y-X; N-X

9. Appeals

1525 Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy

Submission | Specifications

Description: Percentage of patients aged 18 years and older with a diagnosis of nonvalvular atrial fibrillation (AF) or atrial flutter whose assessment of the specified thromboembolic risk factors indicate one or more high-risk factors or more than one moderate risk factor, as determined by CHADS2 risk stratification, who are prescribed warfarin OR another oral anticoagulant drug that is FDA approved for the prevention of thromboembolism Numerator Statement: Patients who are prescribed warfarin OR another oral anticoagulant drug that is FDA approved for the prevention of thromboembolism Approved for the prevention of thromboembolism for the prevention for the prevention of thromboembolism for the prevention for the prevention

Denominator Statement: All patients aged 18 years and older with a diagnosis of nonvalvular atrial fibrillation (AF) or atrial flutter whose assessment of the specified thromboembolic risk factors indicate one or more high-risk factors or more than one moderate risk factor, as determined by CHADS2 risk stratification



Exclusions: Denominator Exclusions:

- Patients with mitral stenosis or prosthetic heart valves
- Patients with transient or reversible causes of AF (eg, pneumonia, hyperthyroidism, pregnancy, cardiac surgery)

Denominator Exceptions:

Documentation of medical reason(s) for not prescribing warfarin OR another oral anticoagulant drug that is FDA approved for the prevention of thromboembolism (eg, allergy, risk of bleeding, other medical reason) Documentation of patient reason(s) for not prescribing warfarin OR another oral anticoagulant drug that is FDA approved for the prevention of thromboembolism (eg, economic, social, and/or religious impediments, noncompliance, patient refusal, other patient reason)

Adjustment/Stratification:

Level of Analysis: Clinician : Individual

Setting of Care: Ambulatory Care : Clinician Office/Clinic

Type of Measure: Process

Data Source: Electronic Clinical Data : Registry

Measure Steward: American College of Cardiology

STANDING COMMITTEE MEETING [12/04/2014-12/05/2014]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap, 1c. High Impact)

1a. Evidence: H-16; M-2; L-0; I-0; IE-0; 1b. Performance Gap: H-17; M-0; L-0; I-0; 1c. Impact: H-17; M-0; L-0; I-0 Rationale:

- The Committee agreed that there is strong evidence to support the use of chronic anticoagulation therapy in the prevention of thromboembolism/ stroke and the reduction of stroke morbidity and mortality rates from two Clinical Practice Guidelines 1) ACCF/AHA/HRS 2013 Guideline and 2) the ACCP 2012 Guideline studies.
- Data presented by the developer showed significant variability in the use of oral anticoagulation for the prevention of thromboembolism with the overall mean performance rate for 2011 and 2012 at 57.2% and 59.4% respectively. Committee members concluded there is a strong performance gap and opportunity for improvement.
- The Committee agreed the measure is disparities sensitive with the data suggesting at risk populations (women, older patients, African Americans and those with low income) are less likely to be treated with warfarin.
- Atrial fibrillation is a prevalent disease associated with high morbidity, mortality and cost.

 Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u> (2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)
 Reliability: H-8; M-8; L-1; I-0 2b. Validity: H-3; M-14; L-0; I-0 <u>Rationale</u>:

- The Committee determined that the measure specifications are clearly defined and consistent with the evidence presented, noting that all codes necessary to calculate the measure are present.
- The Committee concluded the test sample was adequate with a sample size of 225,446 patients with



atrial fibrillation/flutter in the PINNACLE registry for CY2012. Reliability testing was conducted at the performance measure score level. For the performance measure level, the developer conducted a signal-to-noise reliability test with an overall score of 0.99.

- Face validity was assessed by various experts serving on ACC and AHA committees to establish agreement that the measure's performance score could be used to distinguish quality. The majority (88.2%) of these experts either agreed or strongly agreed that the measure's performance score could be used to distinguish quality. Moreover the developers elicited content validity assessments from the development workgroup members, from a public comment process, and other various review and approval processes.
- Overall, the Committee agreed that exclusions are consistent with the evidence provided. However, one Committee member raised concerns with the exclusions of the measure such as religious preference, patient preference and compliance, suggesting it could be a potential threat to validity. With further discussion, the Committee came to a consensus that this exception is acceptable as patient refusal to anticoagulants is common in the field.

3. Feasibility: H-5; M-12; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)Rationale:

• Overall, the Committee agreed the measure was feasible to implement. Some raised concerns with the feasibility of extracting some data elements (i.e. mitral stenosis, economic, social, religious issues, and noncompliance) via EMRs.

4. Use and Usability: H-7; M-10; L-0; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)

Rationale:

- This measure is currently publicly reported in PQRS and in professional certification and recognition in ACC's Cardiology Practice Improvement Pathway (CPIP)/Bridges to Excellence (BTE). This measure will also be included in the 2014 PQRS Qualified Clinical Data Registry as part of the PINNACLE registry.
- Concerns were raised regarding the use and access to the PINNACLE Registry as not all providers use the registry.

5. Related and Competing Measures

- This measure directly is related to:
- 1524: Assessment of Thromboembolic Risk Factors (CHADS2)
- 0241 : Stroke and Stroke Rehabilitation: Anticoagulant Therapy Prescribed for Atrial Fibrillation (AF) at Discharge
- 0436 : STK-03: Anticoagulation Therapy for Atrial Fibrillation/Flutter The Committee discussed that although these measures address the same focus, the target populations are slightly different, justifying the need for both measures

Standing Committee Recommendation for Endorsement: Y-17; N-0

- 6. Public and Member Comment [03/24/15-04/07/15]Comments Received:
 - The comments received for this measure had three major themes:
 - A request to include all "at risk" atrial fibrillation (AF) patients in the numerator statement.
 - A request to use CHA2DS2 VASc instead of CHADS2, according to the 2014 AHA/ACC/HRS Guideline for the Management of Patients with Atrial Fibrillation



• Addressing the exclusion of patients who refuse treatment Developer Response:

• We are in the process of convening the writing committee to update the entire atrial fibrillation measure set, and will share with them your feedback regarding "at risk" versus high risk.

As noted in our comment for 1525, 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 that had not yet been 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 to update our atrial fibrillation measure set and do plan to look at replacing CHADS2 with CHA2DS2-VASc. With regards to considering the role or non-role of percutaneous, we will share your feedback with the writing committee as they review this measure and start the process of updating the entire measure set. Thank you again for your comment.

• 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.

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.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X

- 8. Board of Directors Vote: Y-X; N-X
- 9. Appeals

2461 In-Person Evaluation Following Implantation of a Cardiovascular Implantable Electronic Device (CIED)

Submission | Specifications

Description: Proportion of adult patients with a new CIED with an in-person evaluation within 2 to 12 weeks following implantation.

Numerator Statement: This measures assess the number of patients from the denominator with an in-person evaluation within 2-12 weeks following implantation. For the purposes of this measure, an "in-person evaluation" is defined as an in-person interrogation device evaluation either with or without iterative adjustment, as clinically indicated. The in-person evaluation can be provided by any trained physician or Clinically Employed Allied Professional (CEAP) in a designated CIED follow-up clinic, medical institution, or physician office.

Denominator Statement: All Medicare FFS patients with implantation of a new CIED during the reporting period. CIEDs encompassed for this measure are the following devices:

• Pacemakers (PMs)



- Implantable Cardioverter Defibrillators (ICDs)
- Cardiac resynchronization devices (CRTs)

Exclusions: Exclude patients with any of the following diagnoses/conditions:

- Patients with Implantable Loop Recorders or Implantable Cardiovascular Monitors.
- Patients with pulse generator exchange only.
- Patients with prior CIED implantation.
- Patient preference for other or no treatment.

Adjustment/Stratification:

Level of Analysis: Clinician : Individual

Setting of Care: Ambulatory Care : Clinician Office/Clinic, Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Administrative claims

Measure Steward: Heart Rhythm Society

STANDING COMMITTEE MEETING [12/04/2014-12/05/2014]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap, 1c. High Impact)

1a. Evidence: H-6; M-10; L-0; I-0; IE-0; 1b. Performance Gap: H-13; M-3; L-0; I-0; 1c. Impact: H-11; M-5; L-0; I-0 Rationale:

- Evidence provided by the developer includes a clinical practice guideline, an Expert Consensus Statement by the Heart Rhythm Society & European Heart Rhythm Association, and additional publications that support the recommendation of patients with newly implanted devices should have an in-person followup appointment 2-12 weeks from implantation, and yearly in-person evaluations from the time of implantation.
- Using data from the Ingenix (now OptumInsight) anonymized database of claims information, the developer highlights various performance gaps in follow up evaluations for newly implanted CIEDs with only 42.4% having had an initial in-person visit within 2 to 12 weeks. Additionally data provided illustrates only 19.62% receiving recommended follow up evaluation, with performance rates ranging from 14.07-27.27%.
- The Committee acknowledged the measure to be disparities sensitive with minorities having lower incidence for follow up visits.
- Approximately 200,000 Americans now receive a CIED annually, representing a substantial number of patients with implantable cardiac device, and a NQS priority, the Committee acknowledged this is a high priority.



 Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u> (2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)
 Reliability: H-8; M-8; L-0; I-0; 2b. Validity: H-12; M-4; L-0; I-0 <u>Rationale</u>:

- The data source is from both administrative and electronic clinical data and is specified at the clinician level of analysis. Overall, the Committee determined that the measure specifications were precise, noting that all codes necessary to calculate the measure were present and the specifications were consistent with the evidence presented.
- Some Committee members raised concerns with the measure's exclusion of patients with prior CIED implants as those patients are still vulnerable to complications. The developer explained that this helps to minimize the variability.
- Reliability testing was conducted at the data element level using data derived from administrative claims.
- Validity testing was conducted at the data element level comparing data from administrative claims to patient charts, results of this testing indicate sensitivities in the 95-100% range; specificities in the 92-93% range; positive predictive values were greater than 89% and negative predictive values were greater than 91%.

3. Feasibility: H-5; M-11; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented) Rationale:

• Overall the Committee agreed the measure is feasible to implement as it is collected through electronic administrative claims.

4. Use and Usability: H-5; M-11; L-0; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)

Rationale:

- Although the measure is currently not publicly reported, it has been submitted to CMS for public reporting and payment programs for 2015.
- The Committee acknowledged the measure demonstrates usability toward achieving the goal of high quality, efficient healthcare for individuals or populations.

5. Related and Competing Measures

No related or competing measures noted.

Standing Committee Recommendation for Endorsement: Y-16; N-0

6. Public and Member Comment [03/24/15-04/07/15]

- The comment received requested that the range of in-person follow up visits be stratified by time. Developer response:
- As noted in the measure submission application, appropriate device programming can 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:
 The developer may consider these suggestions for future iterations of the measure.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

2474 Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation	
Submission Specifications	
Description: Rate of cardiac tamponade and/or pericardiocentesis following atrial fibrillation (AF) ablation. Numerator Statement: The number of patients from the denominator with cardiac tamponade and/or pericardiocentesis occurring within 30 days following atrial fibrillation ablation.	
Denominator Statement: All patients aged 18 years and older with atrial fibrillation ablation performed during the reporting period.	
Exclusions: No exclusions.	
Adjustment/Stratification:	
Level of Analysis: Facility, Clinician : Individual	
Setting of Care: Ambulatory Care : Clinician Office/Clinic, Hospital/Acute Care Facility	
Type of Measure: Outcome	
Data Source: Administrative claims	
Measure Steward: Heart Rhythm Society	
STANDING COMMITTEE MEETING [12/04/2014-12/05/2014]	
1. Importance to Measure and Report: The measure meets the Importance criteria	
(1a. Evidence, 1b. Performance Gap, 1c. High Impact)	
1a. Evidence: 16-Y; 1-N; 1b. Performance Gap: H-1; M-8; L-6; I-2; 1c. Impact: H-2; M-9; L-4; I-1	
Rationale:	
• The Committee acknowledged the importance of this outcome measure, noting the correlation between the health outcomes to processes of care.	
• One Committee member questioned whether there is an alternative to ablation. The developer acknowledged an alternative of the use of medication therapy and discussed on the two approaches, highlighting that although there are other alternatives, ablation is the last effective option for this patient	

• The mean performance rate ranges from 1.2-2.4% reported across literature reviews. Some Committee members interpreted the results as moderate due to low incidence rates, while others did not view this as

group.



an opportunity for improvement.

The agreed with the high severity impact of the measure. However, the Committee noted the low prevalence of cardiac tamponade and/or pericardiocentesis with the incidence of cardiac tamponade at 2 cases per 10,000 population in the United States.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria (2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity) 2a. Reliability: H-6; M-9; L-1; I-0; 2b. Validity: H-1; M-10; L-4; I-1 Rationale:

- The Committee found the measure specifications to be clearly defined. The data source is specified as • administrative claims various levels of analysis (individual clinician, and hospital/facility/agency).
- Reliability testing was conducted at the performance measure score level through beta-binomial model measuring signal-to-noise ratio for individual clinicians and facilities, and the results demonstrated high reliability analysis, which the Committee stated was sufficient.
- Face validity was assessed by an expert committee review during the measure development phase and agreed that the measure was valid as specified.
- Empiric validity testing was conducted at the performance measure score level to minimize variability by setting (i.e., provider level data vs. hospital level data).

3. Feasibility: H-9; M-7; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

The Committee agreed the measure is feasible for implementation as data elements are routinely generated and obtained through administrative data claims; additionally there are electronic forms readily available.

4. Use and Usability: H-7; M-9; L-0; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)

Rationale:

The measure is currently publicly reported in PQRS since 2015. The Committee encourages the use of this measure to better understand the trends for quality improvement initiatives.

5. Related and Competing Measures

No related or competing measures noted.

Standing Committee Recommendation for Endorsement: Y-13; N-3

6. Public and Member Comment [03/24/15-04/07/15]

- The comment received raised the issue of a lack in performance gap and did not agree with the Committee's recommendation to endorse this measure.
- The committee reviewed the performance gap issue and agreed that although the performance rates were low across literature reviews, cardiac tamponade is critical to patient safety in cardiovascular



care.

- 7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X
- 8. Board of Directors Vote: Y-X; N-X
- 9. Appeals

0715 Standardized adverse event ratio for children < 18 years of age undergoing cardiac catheterization

Submission | Specifications

Description: Ratio of observed to expected clinically important adverse events, risk-adjusted using the Catheterization for Congenital Heart Disease Adjustment for Risk Method (CHARM)

Numerator Statement: Number of diagnostic and interventional cardiac catheterization cases for children < 18 years of age resulting in a clinically important adverse event, performed by an institution performing at least 50 cases per year in pediatric patients < 18 years of age.

Denominator Statement: Number of diagnostic and interventional cardiac catheterization cases for children < 18 years of age, performed by an institution performing at least 50 cases per year in pediatric patients < 18 years of age.

Exclusions: Primary electrophysiology cases, ablation cases, pericardiocentesis only, thoracentesis only.

Adjustment/Stratification:

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Outcome

Data Source: Electronic Clinical Data, Paper Medical Records, Electronic Clinical Data : Registry

Measure Steward: Boston Children's Hospital

STANDING COMMITTEE MEETING [12/04/2014-12/05/2014]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap, 1c. High Impact)

1a. Evidence: 15-Y; 1-N; 1b. Performance Gap: H-2; M-12; L-0; I-1; 1c. Impact: H-10; M-6; L-0; I-0 Rationale:

- The Committee agreed that there is evidence to support the correlation between the occurrence of adverse clinical outcomes during a cardiac catheterization, which result in harm or potential patient injury and require assessment of causality to focus improvement efforts.
- Observed adverse event rates from eight pediatric hospitals used in testing are included with rates from these facilities ranging from 1.71% to 7.86%, however it was not clear whether these rates reflect primarily moderate or severe events.
- Congenital heart disease is a leading cause of morbidity/mortality, affecting 1% of infants. Cardiac catheterization has become a common quote interventional procedure with therapeutic goals complementing surgical strategies helping to eliminate the need for surgery.

 Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u> (2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)
 Reliability: H-2; M-11; L-2; I-1 2b. Validity: H-4; M-11; L-0; I-1 <u>Rationale</u>:



- A sample of 3,359 pediatric patients from 11 pediatric hospitals with a total of 784 cases were abstracted from EHRs and paper records entered into the database registry. The Committee agreed that the specifications were detailed and consistent with the evidence presented.
- Reliability testing was assessed using a statistical risk model using three risk factors included in the specifications (procedure type risk group, number of indicators of hemodynamic vulnerability, and age. The c-statistic reported for the risk-adjustment model was 0.72.
- The data element validity testing indicates that 85% of the 149 adverse events included in the medical record were captured in the registry.

3. Feasibility: H-6; M-9; L-0; I-1(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

• The Committee agreed the measure is feasible to implement, as all of the data elements are used in electronic sources.

4. Use and Usability: H-5; M-10; L-1; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)

Rationale:

- The Committee noted that the measure is currently being used internally for quality improvement in the Congenital Cardiac Catheterization Project on Outcomes-Quality Improvement (C3PO-QI) program.
- The developer stated they would like to include in future public reporting though concrete plans are not in place. They are, however, tracking on the progress of participating institutions and providing reporting to participants.

5. Related and Competing Measures

• No related or competing measures noted.

Standing Committee Recommendation for Endorsement: Y-15; N-1

6. Public and Member Comment [03/24/15-04/07/15]

- The comment received showed support for this measure.
- 7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X
- 8. Board of Directors Vote: Y-X; N-X
- 9. Appeals

2438 Beta-Blocker Therapy (i.e., Bisoprolol, Carvedilol, or Sustained-Release Metoprolol Succinate) for LVSD Prescribed at Discharge

Submission | Specifications

Description: Proportion of heart failure patients age18 and older with LVSD for whom beta-blocker therapy (i.e., bisoprolol, carvedilol, or sustained-release metoprolol succinate) is prescribed at discharge. For purposes of this measure, LVSD is defined as chart documentation of a left ventricular ejection fraction (LVEF) less than 40% or a narrative description of left ventricular systolic (LVS) function consistent with moderate or severe systolic dysfunction.



Numerator Statement: Patients who are prescribed bisoprolol, carvedilol, or sustained-release metoprolol succinate for LVSD at hospital discharge.

Denominator Statement: Heart failure patients with current or prior documentation of left ventricular ejection fraction (LVSD) < 40%.

Exclusions: Excluded Populations:

- Patients who had a left ventricular assistive device (LVAD) or heart transplant procedure during hospital stay (ICD-9-CM procedure code for LVAD and heart transplant as defined in Appendix A, Table 2.2)
- Patients less than 18 years of age
- Patients who have a Length of Stay greater than 120 days
- Patients with Comfort Measures Only documented
- Patients enrolled in a Clinical Trial
- Patients discharged to another hospital
- Patients who left against medical advice
- Patients who expired
- Patients discharged to home for hospice care
- Patients discharged to a healthcare facility for hospice care
- Patients with a documented Reason for No Bisoprolol, Carvedilol, or Sustained-Release Metoprolol Succinate Prescribed for LVSD at Discharge

Adjustment/Stratification:

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data : Electronic Health Record, Paper Medical Records

Measure Steward: The Joint Commission

STANDING COMMITTEE MEETING [12/04/2014-12/05/2014]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap, 1c. High Impact)

1a. Evidence: H-4; M-11; L-1; I-0; IE-0; 1b. Performance Gap: H-7; M-11; L-0; I-1; 1c. Impact: H-11; M-7; L-1; I-0 Rationale:

- Evidence provided by the developer included four large randomized trials indicating that using one of three specific beta blocker drugs (Bisoprolol, Carvedilol, or Sustained-Release Metoprolol Succinate) reduces morbidity and mortality for patients with heart failure by 27-34%.
- Although guidelines from the ACCF/AHA was classified as a Class 1 recommendation, it was emphasized by the Committee that this evidence does not support the prescription of the three specific beta blockers at the time of discharge but rather the benefits of these drugs are for long-term therapy and compliance.
- During pilot testing in nine sites (878 patients), the performance rates varied from 61.5 100%, displaying an opportunity for improvement.
- Approximately 5.1 million patients have heart failure with a 20% lifetime risk of developing heart failure, making it a national health priority.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u> (2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: H-2; M-13; L-3; I-1; 2b. Validity: H-2; M-11; L-5; I-1

Rationale:

• Empiric validity testing was performed for both the data elements and the measure score, however did



not show statistical significance as a result of small sample sizes.

Developers provided the % agreement and Kappa scores for three data elements: Bisoprolol, Carvedilol, or Sustained-Release Metoprolol Succinate Prescribed for LVSD at Discharge (88.55%; 0.72); LVSD < 40% (70.15%; 0.77); Reason for No Bisoprolol, Carvedilol, or Sustained-Release Metoprolol Succinate Prescribed for LVSD at Discharge (84.58%; 0.33), showing fair to substantial agreement

3. Feasibility: H-1; M-11; L-6; I-1

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

• The Committee agreed the measure is feasible for implementation, however voiced concerns that using data elements from paper medical records can contribute to administrative and cost burdens.

4. Use and Usability: H-2; M-9; L-8; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)

Rationale:

• This new process measure is one of six HF measures from TJC Advanced Certification in Heart Failure (ACHF) program starting in 2014, with approximately 70-80 facilities participating as of the time of the meeting. The measure data elements are also part of the GWTG HF data collection tool.

5. Related and Competing Measures

• N/A

Standing Committee Recommendation for Endorsement: Y-17; N-2

6. Public and Member Comment [03/24/15-04/07/15]

• The comments received for this measure included an overall theme to consider the burden of data collection.

Developer Response:

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.

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.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals



2439 Post-Discharge Appointment for Heart Failure Patients

Submission | Specifications

Description: Patients for whom a follow-up appointment, including location, date, and time, for an office or home health visit for management of heart failure was scheduled within 7 days post-discharge and documented. Numerator Statement: Patients for whom a follow-up appointment, including location, date, and time, for an office or home health visit for management of heart failure was scheduled within 7 days post-discharge and documented.

Denominator Statement: All heart failure patients discharged from a hospital inpatient setting to home or home care.

Exclusions: Excluded Populations:

- Patients who had a left ventricular assistive device (LVAD) or heart transplant procedure during hospital stay (ICD-9-CM procedure code for LVAD and heart transplant as defined in Appendix A, Table 2.2)
- Patients less than 18 years of age
- Patient who have a Length of Stay greater than 120 days
- Patients with Comfort Measures Only documented
- Patients enrolled in a Clinical Trial
- Patients discharged to locations other than home, home care, or law enforcement
- Patients with a documented Reason for No Post-Discharge Appointment Within 7 Days

Adjustment/Stratification:

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data : Electronic Health Record, Paper Medical Records

Measure Steward: The Joint Commission

STANDING COMMITTEE MEETING [12/04/2014-12/05/2014]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap, 1c. High Impact)

1a. Evidence: H-0; M-4; L-4; I-3; IE-6; 1b. Performance Gap: H-3; M-12; L-2; I-0; 1c. Impact: H-11; M-4; L-2; I-0

Rationale:

- The Committee agreed that the evidence presented from a systematic review of two clinical practice guidelines, 1) 2013 ACCF/AHA: Scheduling an early follow-up visit (within 7 to 14 days) and early telephone follow-up (within 3 days) of hospital discharge is reasonable and 2) 2010 HFSA: Plans for post-discharge management (scale present in home, visiting nurse or telephone follow up generally no longer than 3 days after discharge) demonstrate evidence to support post-op evaluation performed. However, no evidence is presented to clearly demonstrate how an appointment scheduled is related to patient outcomes.
- Based on the data presented from two studies in 2005-2007, results demonstrate that 19.6% of patients hospitalized for heart failure were hospitalized within 30 days of discharge. It was noted by the Committee that there was no associated bill for an outpatient visit for 52% of the patients who were rehospitalized within 30 days after discharge for heart failure.
- Approximately 5.1 million Americans are currently suffering from heart failure. The impact of heart failure increases with age, rising from approximately 20 per 1,000 individuals 65 to 69 years of age to more than



80 per 1,000 individuals among those over 85 years of age, thus making this measure a high priority.

Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>
 (2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: H-0; M-13; L-3; I-1; 2b. Validity: H-0; M-12; L-5; I-0

Rationale:

- The Committee determined that the measure specifications were precise, noting that the all codes necessary to calculate the measure were present and the specifications were consistent with the evidence presented
- Empiric reliability testing was performed at the data element level using data from nine hospitals submitted for 878 inpatient records. Inter-rater reliability was assessed with two different abstractions compared to the medical record. The % agreement scores (82.1% and 96.2%) and Kappa scores (0.63 and 0.43) for two data elements are reported, showing moderate or substantial agreement.
- Empiric validity of the measure score was assessed correlating the results with other heart failure transition measures of performance. Due to the small sample sizes, none of the correlations reached statistical significance.

3. Feasibility: H-1; M-15; L-1; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

• Overall the Committee agreed the measure is feasible as it uses defined elements in electronic sources and paper records.

4. Use and Usability: H-4; M-11; L-2; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)

Rationale:

• This new process measure is one of six HF measures from TJC Advanced Certification in Heart Failure (ACHF) program starting in 2014, with approximately 70-80 facilities participating as of the time of the meeting. The measure data elements are also part of the GWTG HF data collection tool.

5. Related and Competing Measures

This measure is directly related with NQF # 2455 Heart Failure: Post-discharge Appointment for Heart Failure Patients (measure reviewed during the Cardiovascular Phase 1 project)

- Generally, the Committee agreed that these measures are similar but noted key differences in the timing of the appointment and the exclusions. Committee members strongly emphasized the importance of a quality measure that assessed whether a patient had a post-discharge rather than an appointment scheduled. The developers will request that their Cardiovascular Writing Committee and technical Advisory Panel (TAP) modify the measure to incorporate the visit concept, or add an additional measure accounting for an actual patient visit.
- Both measures NQF# 2439 and NQF# 2455 include patients admitted as inpatients from observation. However, the measure steward clarified NQF# 2439 does not incorporate observation patients discharged as outpatients as they are often difficult to identify as a group due to billing constraints. NQF# 2455 does include discharge observation patients. NQF #2439 also has denominator exclusions, which are standardized across the ACHF measure set.
- As both measures are newly implemented, #2439 implemented in CY2014 and #2455 receiving



endorsement in Phase 1 of the project, the Committee could not come to consensus on a superior measure without reported implementation data, and both measure were recommended for endorsement.

Standing Committee Recommendation for Endorsement: Y-12; N-6

6. Public and Member Comment [03/24/15-04/07/15]

- There were two main themes to the comments received for this measure:
 - The burden of data collection
 - o Emphasis on care coordination and outcome measurement

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.
- The criterion for this attribute is that the measure addresses processes or outcomes over which the health care organization has responsibility, substantial control, and the ability to effect change. Given that designated setting for this measure is Hospital/Acute Care Facility, it is within provider control to secure an appointment for follow-up care within 7 days of discharge. The Hospital/Acute Care Facility however would have no control over patient attendance for the appointment. Therefore this would be an unreasonable burden to place on a hospital/Acute Care Facility for performance measurement. With respect to this measure being utilized for other conditions, it was developed and tested for use specifically for heart failure patients. Expansion to other clinical conditions would require further testing in those populations.

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.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

2443 Post-Discharge Evaluation for Heart Failure Patients

Submission | Specifications

Description: Patients who receive a re-evaluation for symptoms worsening and treatment compliance by a program team member within 72 hours after inpatient discharge.

Numerator Statement: Patients who have a documented re-evaluation conducted via phone call or home visit within 72 hours after discharge.

Denominator Statement: All heart failure patients discharged from a hospital inpatient setting to home or home care AND patients leaving against medical advice (AMA).

Exclusions: Excluded Populations:



- Patients who had a left ventricular assistive device (LVAD) or heart transplant procedure during hospital stay (ICD-9-CM procedure code for LVAD and heart transplant as defined in Appendix A, Table 2.2)
- Patients less than 18 years of age
- Patient who have a Length of Stay greater than 120 days
- Patients with Comfort Measures Only documented
- Patients enrolled in a Clinical Trial
- Patients discharged to locations other than home, home care or law enforcement.

Adjustment/Stratification:

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data : Electronic Health Record, Paper Medical Records

Measure Steward: The Joint Commission

STANDING COMMITTEE MEETING [12/04/2014-12/05/2014]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap, 1c. High Impact)

1a. Evidence: H-1; M-5; L-1; I-0; IE-7; 1b. Performance Gap: H-11; M-3; L-0; I-0; 1c. Impact: H-13; M-1; L-0; I-0 Rationale:

- The Committee raised concerns on the lack of evidence provided, but agreed the practical application of this measure is beneficial to patient outcomes. The 2012 Cochran review of 25 clinical trials where posthospital early follow-up was discussed as being relevant, although not originally cited. While the cited study only analyzed a 7 day reevaluation, the recommendation to reevaluate within 3 days is aligned the two cited guidelines from ACCF/AHA and HFSA.
- The Committee agreed that the results of the measure developer's pilot study demonstrated a significant performance gap of 38% compliance with the indicator.
- With a 20% lifetime risk rate of developing heart failure, and its correlation to high costs and morbidity, the Committee deemed this to be a high priority.

 Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u> (2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)
 Reliability: H-2; M-12; L-0; I-0; 2b. Validity: H-1; M-9; L-3; I-1 <u>Rationale</u>:

- The Committee determined that the measure specifications were precise, noting that all codes necessary to calculate the measure were present and the specifications were consistent with the evidence presented.
- Empiric reliability testing was performed at the data element level using data from nine hospitals and 878 inpatient records. Re-abstraction was provided for one data element, Post-Discharge Evaluation Conducted within 72 Hours: which resulted in a 95% agreement rate and a Kappa score of 0.75, indicating



suboptimal reliability.

• Empiric validity testing showed an overall adherence rate of 9.5%. This measure was positively correlated with post-discharge appointments for heart failure patients, not proven statistically significant. However, the Committee agreed the validity provided was adequate.

3. Feasibility: H-2; M-11; L-1; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented) <u>Rationale</u>:

• The Committee agreed the measure is feasible to implement. However, concerns were raised over the ability to capture telephone follow-up. The cost was estimated to be \$10.34 to abstract the data for each measure, depending on the level of personnel, by either electronic or paper charts. Developer also mentioned plans to develop this into an e-measure.

4. Use and Usability: H-4; M-10; L-0; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)

Rationale:

• This new process measure is one of six HF measures from TJC Advanced Certification in Heart Failure (ACHF) program starting in 2014, with approximately 70-80 facilities participating as of the time of the meeting. The measure data elements are also part of the GWTG HF data collection tool.

5. Related and Competing Measures

This measure is related to:

- 2438 Beta-Blocker Therapy (i.e., Bisoprolol, Carvedilol, or Sustained-Release Metoprolol Succinate) for LVSD Prescribed at Discharge;
- 2439 Post-Discharge Appointment for Heart Failure Patients;
- 2440 Care Transition Record Transmitted;
- 2441 Discussion of Advance Directives/Advance Care Planning;
- 2442 Advance Directive Executed.

Standing Committee Recommendation for Endorsement: Y-14; N-0

6. Public and Member Comment [03/24/15-04/07/15]

• The comment received for this measure raised the issues the burden of chart review and capturing patients treated through observation stays or in the emergency department.

Developers Response:

• 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 agrees that effective care coordination and outcome measures are critical components to improving care transitions for cardiovascular patients. Thank you for your comment.
- 7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

0670 Cardiac stress imaging not meeting appropriate use criteria: Preoperative evaluation in low risk surgery patients
Submission Specifications
Description: Percentage of stress SPECT MPI, stress echo, CCTA, or CMR performed in low risk surgery patients for preoperative evaluation
Numerator Statement: Number of stress SPECT MPI, stress echo, CCTA, or CMR performed in low risk surgery patients as a part of the preoperative evaluation
Denominator Statement: Number of stress SPECT MPI, stress echo, CCTA, and CMR performed
Exclusions: None.
Adjustment/Stratification:
Level of Analysis: Facility, Clinician : Group/Practice
Setting of Care: Ambulatory Care : Clinician Office/Clinic, Imaging Facility
Type of Measure: Efficiency
Data Source: Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry
Measure Steward: American College of Cardiology
STANDING COMMITTEE MEETING [12/04/2014-12/05/2014 3/23/2015]
1. Importance to Measure and Report: The measure meets the Importance criteria
(1a. Evidence: 1b. Performance Gap, 1c. High Priority)
1a. Evidence: H-1 0; M-12 7; L-2 9; I-1; IE-0 1; 1b. Performance Gap: H-3; M-7; L-6; I-0 X 1c. High Priority: H-4; M-9 ; L-3 ; I-0
Rationale:
 This imagining facility level process measure assesses whether cardiac stress imaging (by stress SPECT MPI, stress echo, CCTA, or CMR) was performed preoperatively in low risk surgery patients, a population in which the evidence does not recommended.

• This measure is one of three similar measures from this developer (#0670, #0671 and #0672). The developer define appropriate use criteria (AUC) as "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, stating the criteria 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.

- The developer references the evidence-based RAND Delphi process or the RAND Appropriateness Method (RAM) for AUC for use of cardiovascular procedures, detailing over-use and under-use characteristic. AUC provide practical tools to measure this variability and to look at utilization patterns. The criteria 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.
- Although the Committee found evidence for AUC or RAM sufficient, favored the underpinnings of the measure, and believed it supported the tenets the NQS Triple Aim, the evidence for cardiac stress imaging preoperatively in low risk surgery patients was not summarized. An updated submission from the developer was submitted to the Standing Committee for review at the Post Comment Call on March 18, 2015. Below includes highlighted discussions from the meeting:
- The 2014 ACC/AHA Guideline on Perioperative Cardiovascular Evaluation and Management of Patients Undergoing Noncardiac Surgery: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and multiple other studies in a systematic review of the clinical evidence supporting the measure, and additional studies on the use of AUC in determining appropriateness for cardiac imaging were summarized.
- Evidence on performance gaps demonstrated between 2% and 17% of cardiac imaging tests are performed preoperatively in asymptomatic patients having low risk surgeries, which the evidence does not recommend. Multiple studies using the RAND AUC for determining appropriateness of cardiac imaging were also provided.
- The Committee accepted the evidence stating that patient outcomes are not improved for patients receiving cardiac imaging prior to low risk surgeries versus those who do not.
- The committee discussed low performance gaps in newer data, yet older data does provide performance gaps, though they also reported the newer studies could not collect the reason the patient was having the study, which may increase reported performance gaps.
- The committee agreed this measure meets a high priority, as tests are costly and contribute to costly downstream effects.

2. Scientific Acceptability of Measure Properties:

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity) 2a. Reliability: H-4; M-12; L-0; I-0 2b. Validity: H-5; M-11; L-0; I-0

Rationale:

- The measure performance is calculated using clearly defined administrative data on the facility level of analysis from ACC's FOCUS Clinical Registry.
- Reliability testing was performed using inter-rater reliability testing in a mid-western acute care hospital in 298 patient records detailed kappa of 0.72 which is as "substantial agreement" or acceptable reliability. The Committee reported they would prefer more recent testing than the 2005 data provided.
- Validity specifications were consistent with the evidence. Empiric evidence for AUC showed no difference with or without testing. No threats are evident and data is not risk adjusted.
- The developer recommended the use of data collection prospectively. Also, they have not identified



issues related to missing data elements.

3. Feasibility: H-3; M-13; L-0; I-0

(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)

Rationale:

• The committee agreed that reasonable data sources are used in this measure by the registry or paper records are routinely generated with reasonable abstraction efforts. There was agreement that the information was acceptable.

4. Use and Usability: H-3; M-12; L-1; I-0

(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh evidence of unintended negative consequences)

Rationale:

- The developer stated the measure is used in the PQRS, FOCUS- ACC lab accreditation, quality improvement and utilization management
- The committee noted that coordinated reporting efforts would be necessary.

5. Related and Competing Measures

- 0669, 0671 and 0672.
- The developer demonstrated variability between the 3 measures, based on patient populations, including provider and institutional size of referring entities and referrals for cardiac imaging tests.

Standing Committee Recommendation for Endorsement: Y-13; N-3

6. Public and Member Comment

• There were no comments received for this measure.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

0671 Cardiac stress imaging not meeting appropriate use criteria: Routine testing after percutaneous coronary intervention (PCI)

Submission | Specifications

Description: Percentage of all stress SPECT MPI, stress echo, CCTA and CMR performed routinely after PCI, with reference to timing of test after PCI and symptom status.

Numerator Statement: Number of stress SPECT MPI, stress echo, CCTA and CMR performed in asymptomatic patients within 2 years of the most recent PCI

Denominator Statement: Number of stress SPECT MPI, stress echo, CCTA and CMR performed

Exclusions: None

Adjustment/Stratification:

Level of Analysis: Facility, Clinician : Group/Practice

Setting of Care: Ambulatory Care : Clinician Office/Clinic, Imaging Facility

Type of Measure: Efficiency



Data Source: Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry Measure Steward: American College of Cardiology

STANDING COMMITTEE MEETING [12/04/2014-12/05/2014 3/23/2015]

1. Importance to Measure and Report:

(1a. Evidence, 1b. Performance Gap, 1c. High Impact)

1a. Evidence: H-1; M-13; L-2; I-0; IE-0; 1b. Performance Gap: H-4; M-11; L-1; I-0; 1c. Impact: H-3; M-11; L-2; I-0 Rationale:

- This imagining level focused process measure assesses whether cardiac stress imaging (by stress SPECT MPI, stress echo, CCTA, or CMR) was performed routinely (within 2 years) in asymptomatic patients after percutaneous coronary intervention (PCI), a population in which the evidence does not recommended.
- This measure is one of three similar measures from this developer (#0670, #0671, and #0672). The Committee initiated a discussion on evidence and favored the underpinnings of the three measures, and believed it supports the tenets the NQS Triple Aim, though evidence questions for routine cardiac stress imaging within 2 years of PCI persisted. An updated submission from the developer was provided for Committee review at the Post Comment Call on March 18, 2015. Below includes highlighted discussions from the meeting:
- The 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS Guideline for the Diagnosis and Management of Patients with Stable Ischemic Heart Disease and multiple other studies in a systematic review of the clinical evidence supporting the measure, and additional studies on the use of AUC in determining appropriateness for cardiac imaging were summarized.
- Select Committee members questioned if patients with left main stenting and incomplete revascularization during the PCI were included in the denominator, 2 populations where cardiac imaging would be appropriate within 2 years after PCI in asymptomatic patients. The developer confirmed the FOCUS data collection tool captures information on patients with the 2 findings, and they are not included in the measure denominator.
- The Committee accepted the evidence stating that patient outcomes are not improved when cardiac imaging is performed for asymptomatic patients within 2 years of PCI versus patients without cardiac imaging during that time.
- Significant performance gaps demonstrating performance gaps in up to one half of asymptomatic patients undergoing cardiac imaging within 24 months PCI in patients from 2005-2013 from various urban and rural settings and patient populations, with varying results based on facility referral characteristics (e.g., cardiologist referrals affiliated with cardiovascular procedure and surgical facilities versus primary care referrals).
- The committee agreed that the measure developer indicated the necessary performance gap because this is an NQS priority area, tests are expensive and can lead to risky procedures, with significant downstream effects..

2. Scientific Acceptability of Measure Properties:

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: H-4; M-11; L-1; I-0; 2b. Validity: H-4; M-10; L-1; I-1

Rationale:

• Select Committee members questioned the measure denominator, stating they would prefer the measure



calculate performance with only the patients as defined for assessing the numerator activity, rather than all cardiac imaging completed at the facility though they recognized the constraints of registry collected data. The developer stated modification to the denominator would also represent challenges in benchmarking performance across facilities due to varying facility characteristics, and that local quality improvement activities are based on facility-specific performance.

- Inter-rater reliability testing was performed using data from 298 patients from the Mayo Clinic. The developer reported substantial agreement with a of kappa=0.72 for stress echocardiography
- The developers report that "in the inappropriate group, there were no statistically significant differences in major adverse coronary event rates between subjects with abnormal versus normal [imaging test]."
- The committee questioned the degree individuals tested were truly asymptomatic, but did not see any threats to validity.
- The Committee stated the specifications are consistent with the evidence, and empiric validity testing of the measure score evaluated the appropriate use score and the predictive value of SPECT MPI cardiac imaging test. This testing compared clinical outcomes for patients classified as having an appropriate or inappropriate stress imaging test and found no statistically significant differences in major adverse coronary events between the 2 groups.

3. Feasibility: H-4; M-12; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented) <u>Rationale</u>:

- Select Committee members raised the question of ACC's Registry cost to end users and the developer reported all data collection tools are open access without restriction or fee.
- The committee agreed that reasonable data sources are used in this measure by the registry or paper records are routinely generated with reasonable abstraction efforts. There was agreement that the information was acceptable.

4. Use and Usability: H-4; M-10; L-2; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)

Rationale:

- The developer stated the measure is used in the PQRS, FOCUS- ACC lab accreditation, quality improvement and utilization management.
- Public reporting is anticipated in 2017 as a mandate by CMS. 5% of outliers will need preauthorization.
- No unintended consequences are reported. On a national scale, elimination of 3-5% of unnecessary imaging in post PCI patients would result in significant savings without compromise of quality and patient outcome the data presented.

5. Related and Competing Measures

• The developer demonstrated variability between the 3 measures, based on patient populations, including provider and institutional size of referring entities and referrals for cardiac imaging tests.

Standing Committee Recommendation for Endorsement: Y-13; N-3



6. Public and Member Comment

• There were no comments received for this measure.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X

- 8. Board of Directors Vote: Y-X; N-X
- 9. Appeals

0672 Cardiac stress imaging not meeting appropriate use criteria: Testing in asymptomatic, low risk patients

Submission | Specifications

Description: Percentage of all stress SPECT MPI, stress echo, CCTA, and CMR performed in asymptomatic, low CHD risk patients for initial detection and risk assessment

Numerator Statement: Number of stress SPECT MPI, stress echo, CCTA, and CMR performed for asymptomatic, low CHD risk patients for initial detection and risk assessment*

Denominator Statement: Number of stress SPECT MPI, stress echo, CCTA, and CMR performed

Exclusions: None

Adjustment/Stratification:

Level of Analysis: Facility, Clinician : Group/Practice

Setting of Care: Ambulatory Care : Clinician Office/Clinic, Imaging Facility

Type of Measure: Efficiency

Data Source: Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry Measure Steward: American College of Cardiology

STANDING COMMITTEE MEETING [12/04/2014-3/23/2015]

1. Importance to Measure and Report:

(1a. Evidence, 1b. Performance Gap, 1c. High Impact)

1a. Evidence: H-1; M-12; L-3; I-X; IE-X; 1b. Performance Gap: H-3; M-10; L-3; I-0; 1c. Impact: H-4; M-10; L-1; I-1 <u>Rationale</u>:

- This imagining facility level process measure assesses whether cardiac stress imaging (by stress SPECT MPI, stress echo, CCTA, or CMR) was performed in asymptomatic, low risk patients, a population in which the evidence does not recommended.
- This measure is one of three similar measures from this developer (#0670, #0671, and #0672, though the measure was not discussed at the in-person meeting. The Committee favored the underpinnings of the the measure, believed it supported the tenets the NQS Triple Aim. Although the Committee accepted the evidence for AUC or RAM, favored the underpinnings of the measure, and believed it supported the tenets the NQS Triple Aim, the evidence for cardiac stress imaging preoperatively in low risk surgery patients was not summarized. An updated submission from the developer was submitted to the Committee for review at the Post Comment Call on March 18, 2015. Below includes highlighted discussions from the meeting:
- The 2010 ACCF/AHA Guideline for Assessment of Cardiovascular Risk in Asymptomatic Adults: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guideline, multiple other studies in a systematic review of the clinical evidence supporting the measure, and additional studies on the use of AUC in determining appropriateness for cardiac imaging were summarized.
- The Committee accepted the evidence stating that patient outcomes are not improved for asymptomatic,



low risk patients receiving cardiac imaging versus those who do not.

• Significant performance gaps were identified in patients from 2005-2013 in various urban and rural settings and patient populations, with varying results based on facility referral characteristics (e.g., cardiologist referrals affiliated with cardiovascular procedure and surgical facilities versus primary care referrals).

2. Scientific Acceptability of Measure Properties:

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity) 2a. Reliability: H-3; M-11; L-2; I-0; 2b. Validity: H-4; M-10; L-2; I-0

Rationale:

- Select Committee members questioned if patients with left main stenting and incomplete revascularization during the PCI were included in the denominator, 2 populations where cardiac imaging would be appropriate within 2 years after PCI in asymptomatic patients. The developer confirmed the FOCUS data collection tool captures information on patients with the 2 findings, and they are not included in the measure denominator.
- Reliability testing was conducted using data from 298 patients from the Mayo Clinic (Rochester, MN) in 2005. Reliability testing at the data element level was conducted, the developer reported the "agreement kappa=0.72 for stress echocardiography."
- The developer conducted empiric validity testing of the measure score to study the "relationship between appropriate use score and predictive value of SPECT MPI" by comparing the clinical outcome of patients classified as having an appropriate or inappropriate stress imaging test. The developers reported that "in the inappropriate group, there were no statistically significant differences in major adverse coronary event rates between subjects with abnormal versus normal [imaging test]."

3. Feasibility: H-4; M-11; L-0; I-1

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented) Rationale:

- Select Committee members raised the question of ACC's Registry cost to end users and the developer reported all data collection tools are open access without restriction or fee.
- The committee agreed that reasonable data sources are used in this measure by the registry or paper records are routinely generated with reasonable abstraction efforts. There was agreement that the information was acceptable.

4. Use and Usability: H-3; M-11; L-2; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)

Rationale:

• The developer stated the measure is currently being used in the following programs: PQRS, FOCUS-ACC/lab accreditation and IAC- lab accreditation, additionally the developer highlighted no unintended consequences were identified.

5. Related and Competing Measures OR



• The Committee acknowledged that although there were related measures, no competing measures were identified.

Standing Committee Recommendation for Endorsement: Y-14; N-2

- 6. Public and Member Comment
- There were no comments received for this measure.
- 7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals