TO: Consensus Standards Approval Committee (CSAC)

FR: NQF Cardiovascular Project Team

RE: Cardiovascular Project Phase 2, Follow-Up of CSAC Requested Cardiovascular Standing Committee Discussion

DA: May 12, 2015

In response to the CSAC's request, the *Cardiovascular Standing (CV) Committee* reconvened on April 20, 2015 via web meeting. This memo provides a summary of the CV Standing Committee's discussion and subsequent actions taken for:

- Three (3) recommended measures addressing patient reason exclusion criteria; and
- Two (2) not recommended measures addressing advanced care planning for heart failure (HF) patients.

Following the meeting, the CV Standing Committee decided to uphold its original recommendations for each of the five (5) measures with no changes or additional recommendations.

CSAC ACTION REQUIRED

The CSAC will review the following discussion summaries and recommendations from the *CV Standing Committee* during its May 12, 2015 conference call.

Pursuant to the Consensus Development Process (CDP), the CSAC may consider approval of five (5) candidate consensus standards.

- Measure # 0090: Emergency Medicine: 12-Lead Electrocardiogram (ECG) Performed for Non-Traumatic Chest Pain (eMeasure)
- Measure # 1525: Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy
- Measure # 2461: In-Person Evaluation Following Implantation of a Cardiovascular Implantable Electronic Device (CIED)
- Measure # 2441: Discussion of Advance Directives/Advance Care Planning
- Measure # 2442: Advance Directive Executed

Detailed measure information of the Committee discussion can be found within the Measure Evaluation Summary Tables.

Background

The Consensus Standards Advisory Committee (CSAC) reviewed the CV Standing Committee recommendations for fifteen measures during their in-person meeting on April 8, 2015. Following the review of these recommendations, CSAC requested that the CV Standing Committee reconvene to further discuss five of the fifteen measures reviewed within the Cardiovascular Phase 2 project.

CSAC Patient Reason Exclusions Discussion

- *Measure # 0090: Emergency Medicine: 12-Lead Electrocardiogram (ECG) Performed for Non-Traumatic Chest Pain (eMeasure) (PCPI/ACEP)*
- *Measure # 1525: Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy (ACCF)*
- *Measure # 2461: In-Person Evaluation Following Implantation of a Cardiovascular Implantable Electronic Device (CIED) (HRS)*

The CSAC raised concerns that the patient reason exclusions, which include concepts for patient preference and patient refusal, are too broad as defined within measures # 0090, 1525 and 2461. The application of these definitions may allow for a large number of patients to be inappropriately excluded from the measure. Some CSAC members emphasized a preference for either the removal of all patient reason exclusions, or the narrowing of patient reasons exclusions to only those that are applicable to the specific measures. Other CSAC members were concerned that removal of patient reasons would result in measure performance below 100%, and could negatively impact providers. Additionally, the CSAC further discussed the respective burdens to vendors and providers with implementing and documenting extensive patient reason exclusions.

In contrast, some CSAC members emphasized that the inclusion of broadly defined patient reason exclusions would be patient centric, and that all reasons a patient might refuse or decline treatment should be incorporated within the measure. The CSAC also discussed the potential of stratifying and separately calculating performance for patient reason exclusions.

The CSAC unanimously voted to have the CV Standing Committee reconvene to reconsider their recommendations to endorse measures # 0090, 1525 and 2461, in consideration of the CSAC discussion.

Summary of Further CV Standing Committee Actions Requested by CSAC

The following summary for the reconvened CV Standing Committee includes the Standing Committee discussion from its April 20, 2015 conference call, along with measure developer responses, and Standing Committee voting options and results for measures # 0090, 1525 and 2461.

Standing Committee Discussion:

- To further understand the impacts of patient reason exclusions, the Standing Committee requested the developers provide patient reason-specific use data, and patient outcomes data for measures with included and excluded patient-specific reasons. All three developers reported the inability to capture patient reason-specific data in their respective processes. In the absence of additional data for review, the Standing Committee utilized the summary of the CSAC requests, developer submissions, its previous recommendations, and Standing Committee and developer discussion and responses during the conference call to consider the CSAC requests.
- The Standing Committee reviewed the following discussion points in favor of maintaining broadly defined patient reason exclusions:
    - The impact of patient reason exclusions on patient outcomes is currently unknown; therefore modifications should not be made until more evidence or data is available.

  - The restriction of patient reason exclusions could be perceived as not supporting patient choice in care decisions, nor does it recognize all the circumstances why a patient may decline treatment.
  - Recent evidence suggests that provider communication skills often assist patients in overcoming barriers to treatment, and encourage discussions of risk versus benefits of treatment and shared-decision making.
  - Broadly defined patient reason exclusions are more appropriate for use in accountability and pay for performance programs.
- A few Standing Committee members disagreed with broadly defined patient reasons stating exclusions should be measure-specific and represent care specific to the measure and that broadly defined patient reasons may increase patient risks of negative outcomes without care.
- Having no additional evidence or data, the Standing Committee did not vote for the developers to modify their measures, but rather upheld its endorsement recommendation to maintain broadly defined patient reason exclusions for each of the three measures.

Measure Developer Responses:

During the Standing Committee call, the measure developers offered the following responses to the Standing Committee discussion.

- **Measure # 0090: Emergency Medicine: 12-Lead Electrocardiogram (ECG) Performed for Non-Traumatic Chest Pain (eMeasure) (PCPI/ACEP)**
  - Patient reason data was not available for Standing Committee review; however the developer stated the use of patient reasons, as well as medical and system reasons, is based from a long-standing, tested approach allowing for patient-centric application, especially in vulnerable patients, where the provider should not be penalized unfairly due to population characteristics. The developer also stated the patient reasons are harmonized across all PCPI measures, allowing for systematic implementation, rather than redefining patient reasons for each developed measure.
  - If requested, the measure developer agreed to address the use of patient reasons in its measure development and maintenance activities, though they also stated they would not make measure-specific modifications to the patient, medical and system reason definitions.

- **Measure # 1525: Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy (ACCF)**
  - The measure developer did not have data to demonstrate the use of the patient reasons, and stated prior to any measure modifications they would prefer to look at the impact of the patient reasons across the entire set of applicable measures.
  - The measure developer stated that economic, social, and/or religious impediments, noncompliance, patient refusal, other patient reason data elements are captured in the PINNACLE Registry data collection, and are not measure specific.
  - If requested, the measure developer agreed to discuss the application of patient reason exceptions within measure development and maintenance activities, though they stated they are not considering modifying the individual data elements for each patient, medical and system exceptions.

- **Measure # 2461: In-Person Evaluation Following Implantation of a Cardiovascular Implantable Electronic Device (CIED) (HRS)**
    - The measure developer stated the use of patient reason measure exclusions permits the patient to opt out of care, especially as follow up is not solely impacted by the provider or facility. It was also stated that the same reasons for including patients who voluntarily scheduled CIED placement, could be a similar motivation to exclude emergent or urgent CIED placement patients.
    - Patient refusal exceptions data was not available for the Committee to review.
    - If requested, the measure developer agreed to discuss the application of patient reason exceptions within measure development and maintenance activities, though they stated they are not considering modifying the individual data elements for each patient, medical and system exceptions.

STANDING COMMITTEE VOTING OPTIONS AND RESULTS:

Voting results and rationale from the Standing Committee reflect previous discussion and viewpoints from the post-CSAC call on April 20, 2015. A total of 19 CV Standing Committee voted out of 22 CV Standing Committee members. The Standing Committee upheld its recommendation to endorse all three measures with broadly defined patient reason exclusions. Voting results are provided below.

Measure # 0090: Emergency Medicine: 12-Lead Electrocardiogram (ECG) Performed for Non-Traumatic Chest Pain (eMeasure) (PCPI/ACEP):

Uphold previous Standing Committee decision: recommend measure 0090 for endorsement without modifications to measure	• 15 Votes; ***passes***
Uphold previous Standing Committee decision with the request for developers to modify measure 0090 to eliminate and/or exclude all patient reason exclusions in measure 0090	• 4 Votes
Reverse the previous Standing Committee decision: Do not recommend measure 0090 for endorsement	• 0 Votes

Measure # 1525: Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy (ACCF):

Uphold previous Standing Committee decision: recommend measure 1525 for endorsement without modifications to measure	• 14 Votes; ***passes***
Uphold previous Standing Committee decision with the request for developers to modify measure 1525 to eliminate and/or exclude all patient reason exclusions in measure 1525	• 5 Votes
Reverse the previous Standing Committee decision: Do not recommend measure 1525 for endorsement	• 0 Votes

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

Uphold previous Standing Committee decision: recommend measure 2461for endorsement without modifications to measure	• 13 Votes; ***passes***
Uphold previous Standing Committee decision with the request for developers to modify measure 2461 to eliminate and/or exclude all patient reason exclusions in measure 2461	• 6 Votes
Reverse the previous Standing Committee decision: Do not recommend measure 2461 for endorsement	• 0 Votes

CSAC Advance Care Planning for Heart Failure Discussion

- *Measure # 2441: Discussion of Advance Directives/Advance Care Planning(TJC)*
- *Measure # 2442: Advance Directive Executed (TJC)*

The CSAC discussed the concept of advanced care planning for heart failure patients for two (2) measures (# 2441 and # 2442) that were not recommended by the CV Standing Committee based on the *Importance* criteria. CSAC stated the concepts of advance directives and surrogate decisions making for advance care planning are of vital importance to all patients, and that a significant measure gap exists within NQF's portfolio for HF patients 18 years and older in all settings related to advance directives.

As measures # 2441 and # 2442 were not recommended for endorsement by the Standing Committee, based on the measure evaluation process, both measures were not evaluated alongside relating and competing measures. The CSAC members discussed the related endorsed measure # 0326 Advance Care Planning (developed by NCQA, part of NQF's Care Coordination project).

The CSAC unanimously voted to have the CV Standing Committee reconvene to reconsider their recommendations to not endorse measures # 2441 and 2442, in consideration of the CSAC discussion.

Summary of Further CV Standing Committee Actions Requested by CSAC

The following summary for the reconvened CV Standing Committee includes the Standing Committee discussion from its April 20, 2015 conference call, along with measure developer responses, and Standing Committee voting options and results for measures # 2441 and 2442.

Standing Committee Discussion:

- Although the Committee acknowledged the strong need for advance care planning patients with HF, the Standing Committee still believed its previous reasoning for not recommending both measures still exists, as the *Importance* criteria was not met for either measure.
    - # 2441 was not recommended for endorsement as it did not pass on the Importance: Performance Gap criteria. Based on the Standing Committee's original recommendation not to endorse the measure, they found the performance data provided was dated, missing patient input, and did not differentiate between documentation of the presence of advance directives/advance care planning and discussions by healthcare providers

about advance directives/advance care planning. Committee members acknowledged that while advance directives are an important aspect to consider for patient-focused care, the evidence provided by the developers that such discussions can influence outcome in heart failure was not present.
    - # 2442 was not recommended for endorsement as it did not pass on the Importance: Evidence. Based on the Standing Committee's original recommendation not to endorse the measure as scarce evidence on the relationship of the executed advance directive documentation options and patient outcomes was provided, the Standing Committee questioned the ability of the measure to improve performance.
- The Standing Committee briefly discussed level of analysis, patient population, and timing of advance care planning for measures # 2441 and 2442, as well as measure # 0326 Advance Care Planning.
    - Measures # 2441 and 2442 are acute care facility-level measures for HF patients 18 years and older. Measure # 2441 assesses an unspecified one-time only advance care planning event that may not be related to HF care.
    - Measure # 0326 is a clinician-level measure used in a wide variety of settings, it is limited to patients 65 years and older irrespective of diagnosis, and it assesses an advance care planning event within 12 months of care.
- The Standing Committee did not extensively discuss measure # 0326 as the measure is assigned to the Care Coordination CDP project. Without in-depth familiarity with the measure, the Standing Committee did not consider it within its purview to request CSAC guide the developer of # 0326 to modify the measure to include facility-level reporting and modify the age of the patient population to patients 18 years and older.
- Without additional evidence or empirical data on the impact to patient outcomes, the Standing Committee upheld their recommendation not to endorse measures # 2441 and 2442.

Measure Developer Responses:

During the Standing Committee call, the measure developers offered the following responses to the Standing Committee discussion.

- **Measure # 2441: Discussion of Advance Directives/Advance Care Planning (TJC)**
- **Measure # 2442: Advance Directive Executed (TJC)**
    - The measure developer stated both measures # 2441 and 2442 were initially condensed into a single measure but were split into two measures in order to provide two levels of performance.
    - Minimal evidence exists for advance care planning, especially related to HF patients, as these measures are an attempt to further the understanding of potential gaps in care for this population.

STANDING COMMITTEE VOTING OPTIONS AND RESULTS:

Voting results and rationale from the Standing Committee reflect previous discussion and viewpoints from the post-CSAC call on April 20, 2015. A total of 19 CV Standing Committee voted out of 22 CV Standing Committee members. The Standing Committee voting results are provided below for each measure. The Standing Committee upheld its original decision to not recommend both measures.

Measure # 2441: Discussion of Advance Directives/Advance Care Planning (TJC):

Uphold previous Standing Committee decision: do not recommend measure 2441 for endorsement	• 14 Votes; ***passes***
Uphold previous Standing Committee decision: do not recommend measure 2441 for endorsement, and recommend CSAC requests the measure developer of measure 0326 (Advance Care Planning) modify the measure to include patients 18 years and older and to include facility-level reporting	• 4 Votes
Reverse the previous Standing Committee decision: Recommend measure 2441 for endorsement	• 1 Vote

Measure # 2442: Advance Directive Executed (TJC):

Uphold previous Standing Committee decision: do not recommend measure 2442 for endorsement	• 13 Votes; ***passes***
Uphold previous Standing Committee decision: do not recommend measure 2442 for endorsement, and recommend CSAC requests the measure developer of measure 0326 (Advance Care Planning) modify the measure to include patients 18 years and older and to include facility-level reporting	• 4 Votes
Reverse the previous Standing Committee decision: Recommend measure 2442 for endorsement	• 2 Votes

Appendix A: Measure Evaluation Summary Tables

NOTE: The tables below were provided to the CSAC on April 8, 2015 to serve as a reference point for measure specification information for three patient reason and 2 advance care planning measures.

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

Patient Reason Measures

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. • One Committee member was concerned that the measure does not address importance of detecting a STEMI patient rather only to not performing an ECG in a patient with non-traumatic chest pain. • 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% leaving which the Committee agreed does not leave much room for improvement. o 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.

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-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)
<u>Rationale</u>:

- 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).
- The 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

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.

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-8; M-8; L-1; I-0 2b. Validity: H-3; M-14; L-0; I-0

Rationale:

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

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-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)

<u>Rationale</u>:

- 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)

<u>Rationale</u>:

- 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

Advance Care Planning Measures

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

2441 Discussion of Advance Directives/Advance Care Planning

Submission | Specifications

Description: Patients who have documentation in the medical record of a one-time discussion of advance directives/advance care planning with a healthcare provider.

Numerator Statement: Patients who have documentation in the medical record of a one-time discussion of advance directives/advance care planning with a healthcare provider

Denominator Statement: All heart failure patients.

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 discharged to another hospital
- Patients discharged to home for hospice care
- Patients discharged to a health care facility for hospice care
- Patients who expire

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 does not meet the Importance criteria**

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

1a. Evidence: H-1; M-0; L-3**; I-6;** IE-8; 1b. Performance Gap: H-1; M-4; L-4; I-8 1c. High Priority: Y-X; N-X;

Rationale:

- The developer referenced five studies and provided a diagram to support the execution of how advanced directives can lead to "Decreased anxiety for patients/caregivers regarding end-of-life decision making" and "Coordinated end-of-life care." However, no systematic review of the evidence was presented.
- 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. Some Committee members were concerned the measure may lead to psychological unintended consequences as it only focuses on one-time discussions.
- Select Committee members stated this measure is additionally appropriate for the pediatric population, and questioned the list of measure exclusions (specifically LVAD and comfort-care patients), while others questioned the limited denominator of the measure to HF-only patients.
- The Committee questioned the appropriateness of all HF patients in the denominator, specifically those with EF ≥ 40%, and questioned the relevance of a one-time discussion as patients wished change over time, especially after an acute hospitalization.
- Committee members acknowledged that while advanced directives is an important aspect to consider for patient-focused care, the evidence provided by the developers that such discussions can influence outcome in heart failure is not present. The Committee did not reach consensus on evidence.
- As a new measure, there are no direct data for performance. However, the developer provided data from a 2004 study that shows less than 50% of patients had an advanced directive in their medical record. Moreover, a pilot testing done at nine hospitals revealed a rate of 66.6%.
- The Committee found the data provided by the developer to be dated, missing patient input and questioned whether 100% performance was an appropriate goal for the measure. The measure did not pass on performance gap criteria.

2. Scientific Acceptability of Measure Properties:

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

2a. Reliability: H-X; M-X; L-X; I-X 2b. Validity: H-X; M-X; L-X; I-X

Rationale:

- N/A

3. Feasibility: H-X; M-X; L-X; I-X

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

Rationale:

- N/A

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

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

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-X; N-X

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

Comments Received:

- One comment received agreed with the Committee recommendation to not endorse this measure.
- One comment received did not support the Committee recommendation to not endorse this measure.

Committee response:

- 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. Additionally, during in-person meeting, there were several concerns raised regarding the lack of direct evidence relating process of care of executing an advanced directive to improved outcome in 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

2442 Advance Directive Executed

Submission | Specifications

Description: Patients who have documentation in the medical record that an advance directive was executed.

Numerator Statement: Patients who have documentation in the medical record that an advance directive was executed.

Denominator Statement: All heart failure patients.

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 discharged to another hospital
- Patients discharged to home for hospice care
- Patients discharged to a health care facility for hospice care
- Patients who expire

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 does not meet the Importance criteria**

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

1a. Evidence: H-0; M-1; L-7**; I-7;** IE-2; 1b. Performance Gap: H-X; M-X; L-X; I-X 1c. High Priority: Y-X; N-X;

Rationale:

- No systematic review was provided, however several citations highlighted the importance of initiating advance directives leads to favorable patient outcomes, and decreased anxiety for patients/caregivers regarding end-of-life decision making and coordinated end-of-life care.
- The Committee stated several concerns that there is no direct evidence relating process of care of executing an advanced directive with improved care.

2. Scientific Acceptability of Measure Properties:

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

2a. Reliability: H-X; M-X; L-X; I-X 2b. Validity: H-X; M-X; L-X; I-X

Rationale:

- N/A

3. Feasibility: H-X; M-X; L-X; I-X

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

Rationale:

- N/A

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

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

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-X; N-X

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

Comments received:

- The two comments received for this measure disagreed with the Committee's recommendation to not endorse this measure. The comments highlighted the cost of end-of-life care and capturing patient wishes as reasons why an advance directive is important

Committee Response:

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