HEART RHYTHM SOCIETY  
Comments and proposed actions for HRS-3.2 and HRS-4.2

BACKGROUND
To prepare the field of electrophysiology for the transition to value-based purchasing, HRS opted to proactively undertake development of appropriate performance measures to assess heart rhythm care. The Initiative commenced with the convening of the Society’s Quality Improvement (QI) Subcommittee to conduct an environmental scan of existing salient performance measures, to prioritize important clinical focus areas for heart rhythm care, and to identify performance measure gaps. In December 2010, HRS created the Measure Development Task Force (MDTF) to develop specifications for the measures identified by the QI Subcommittee, including the data source(s), unit of analysis, inclusions, exclusions, inclusions, and risk adjustment. The two physician-level measures developed and recommended by the MDTF for advancement to testing are:

- HRS-3: Implantable Cardioverter-Defibrillator (ICD) Complications Rate
- HRS-4: In-Person Evaluation Following Implantation of a Cardiovascular Implantable Electronic Device (CIED)

These two measures were posted on the HRS website for public review and comment from April 25 to May 27, and two 2-hour focus groups were convened during the HRS Annual Meeting on May 4 to educate members on the measure development initiative and to solicit feedback from HRS physician members on the measures.

COMMENTS AND THEIR DISPOSITION
HRS received a total of 290 public comments on the measures from 36 individuals and 20 organizations. (Note: Most commenters submitted multiple comments.) A synthesis of major concerns highlighted during the review period and proposed responses and actions are reviewed in the following sections.

HRS-3.2: Implantable Cardioverter-Defibrillator (ICD) Complications Rate
A total of 164 comments from 35 individuals and 18 organizations were received for HRS-3.2. Comments were categorized as follows: 24 general comments; 39 related to measure intent; 64 on the measure specifications; 29 on potential barriers; and 8 proposing solutions to identified issues.

Small Numbers and Patient Confidentiality
Some reviewers expressed concern about the use of this measure at the physician level, as many providers will not have enough eligible patients to create a stable annual rate. Another suggested that since complications tend to be rare events, including physicians with small numbers might inevitably compromise patient confidentiality. Reviewers suggested that the MDTF incorporate into the specifications a minimum number of denominator patients under which a provider’s score should be suppressed (i.e., not reported).

Response: The measure utilizes a hierarchical logistic regression risk model, which takes into account differences in sample sizes across providers. Additionally, small numbers is an issue of measure implementation that is addressed by the implementing organization rather than the measure developer. Patient confidentiality is a valid concern and the Quality Improvement
Subcommittee may wish to generally discuss the issue to assess whether the Society wishes to officially opine on the matter given it will not be unique to this measure.

Risk Model and Complications Included/Not Included
Several comments related to aspects of the risk model or specific complications—what was included and why, what was excluded and why. A few commenters remarked that the risk model is overly complex, and one suggested that it is incomprehensible to providers and thus, is not transparent. One requested clarification on how the risk variables were selected, and another on how outliers will be defined. One commenter suggested using creatinine clearance as a measure of renal function rather than BUN, two advised that gender should not be included among the risk variables as the National Quality Forum (NQF) recommends against this, and two urged that use of anticoagulants/antiplatelets and steroids be included in the risk variables, as use of these medications are linked to increased numbers of complications and poorer outcomes.

Response: The measure uses a hierarchical risk model, which requires a complex algorithm. The model was selected for the measure because of its ability to recognize that there are sources of variation among patients and between providers (i.e., patients are "nested" by physician). Hierarchical models are particularly attractive for publicly reported outcome measures because they more accurately account for clusters of patients within providers, are more likely to produce standard errors with the appropriate degrees of freedom for independent variables, and are less likely to falsely categorize a provider as an outlier than linear models.

The risk model was developed and tested by Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation for the Centers for Medicare and Medicaid Services (CMS) Hospital Risk-Standardized Complication Rate Following Implantation of ICD Measure, which is the hospital-level corollary of this physician-level measure, which has been endorsed by NQF. Yale sought to develop a model that included key variables that were clinically relevant and based on a strong association with complications. To select candidate variables, a team of clinicians began with a review of the variables from the National Cardiovascular Data Registry (NCDR) ICD database and modified the final variable list as appropriate for a complication measure. They did not consider as candidate variables those that one would not want to adjust for in a quality measure, such as potential complications, certain patient demographics (e.g., race, socioeconomic status), and patients’ admission path or discharged status. Variables were also considered ineligible if there were particularly vulnerable to gaming or were deemed to lack clinical relevance. A total of 30 variables were determined to be appropriate for consideration. Logistic regression with stepwise selection (entry p<0.10; retention with p<0.05) was used for variable selection, and the direction and magnitude of the regression coefficients was assessed. This resulted in a final risk-adjusted complication model that included the 13 variables presented in the measure specifications table.

Given the complexity of the model, but the need to maintain harmonization with the corollary hospital measure, no action at this time is recommended regarding changes to the model. We recommend relevant recommendations be provided to NCDR and/or Dr. Jeptha Curtis, as appropriate, as informational items for future consideration when the risk model/specifications are updated.

As well, to maintain harmonization with the hospital measure, no changes to the list of
complications are recommended at this time. We recommend relevant recommendations be provided to Dr. Jeptha Curtis, as appropriate, as informational items for future consideration when the specifications are updated. HRS will consider them in future iterations of the measure. HRS will provide a link to access *Hospital Risk-Standardized Complication Rate Following Implantation of ICD Measure*, in order to reference specific details of the research design. HRS staff will seek information from NQF to inquire about its criteria relating to the inclusion of gender as a risk factor in logistic regression models.

Additionally, given the complexity of the measure, it is recommended that the Society develop educational plans/materials for members that provide a “plain English” description of the model, complications encompassed, and process used to develop it.

**Use of the NCDR as a Data Source**

Some commenters voiced concern about use of the NCDR as a data source, opining that the registry is fraught with errors and that data accuracy depends on the clinical knowledge base of the individual entering the information (e.g., nurse versus medical aide). One commenter noted that while the original NCDR registry was targeted at primary prevention patients, some implanting centers still have a significant population of patients implanted based on secondary indications; these patients typically have other co-morbid conditions that are not represented in the risk variables that might impact performance. The commenter requested that the MDTF give consideration to how these patients may contribute to the complication rate.

**Response:** Measure development is limited by available data sources. Currently, use of the NCDR is the only viable way to collect much of the information necessary for this measure. The MDTF recognized that the endorsement of this and the hospital-level corollary could serve as an impetus for more careful and cleaner data submission to the NCDR by providers. Regarding the comment on secondary prevention patients, the commenter did not specify what additional comorbidities he believes should be incorporated into the risk model. Current risk variables cover a wide range of comorbidities, including heart failure status, history of prior coronary artery bypass graft, chronic lung disease, renal failure/dialysis, atrioventricular conduction aberrations, hypotension, and BUN and sodium abnormalities.

No specific action is recommended with respect to the specifications, but the MDTF and the Society should be mindful of concerns about NCDR.

**Concerns about Gaming**

One commenter discouraged using complication rates as performance measures for value-based purchasing as they might encourage some physicians to 'game' the system and could ultimately harm patients. For example, some physicians might delay performing a clinically indicated pericardiocentesis until after 30 days so as to avoid being penalized for a complication.

**Response:** No specific action is recommended. We note that gaming of the system is a valid concern with performance measurement. We acknowledge the potential downstream unintended consequences of implementing this measure (e.g., impact patient selection). However, the MDTF noted that the mission of the responsible physician under value-based purchasing systems does not change from the standard medical ethics tenets. Such value-based purchasing initiatives will employ methods (e.g., auditing) to monitor physician. Avoidance of gaming any system, maintaining clinical competency, and consistent provision of quality care in
a patient-centered manner remains the standard for success. The MDTF concluded that implementation of this measure will generate important data that will ultimately improve patient care.

Suggestions on Coding
Several commenters supplied suggestions to improve the accuracy of the codes included in the Code Key.

Response: While the codes were directly translated from the corresponding CMS hospital-level measure, the HRS staff and the Consultants reviewed all codes to determine if they can be modified to improve precision (see Appendix A).

HRS-4.2: In-Person Evaluation Following Implantation of a Cardiovascular Implantable Electronic Device (CIED)
A total of 126 comments from 33 individuals were received for HRS-4.2. Comments were categorized as follows: 21 general comments; 35 related to measure intent; 28 on the measure specifications; 31 on potential barriers; and 11 proposing solutions to identified issues. In general, significantly more concerns were expressed regarding HRS-4.2 than HRS-3.2. A summary of these concerns is presented in the following sections.

Measure Intent and Link to Outcomes
Numerous commenters voiced a lack of understanding of the measure intent, some noting that there is currently no peer-reviewed evidence that an in-person evaluation following device implant ultimately improves patient outcomes.

Response: For aspects of care for which there is little or no peer-reviewed evidence to provide guidance, NQF reports that the process that is the focus of measurement should be deemed by expert consensus to have benefits to patients that outweigh potential risks. Accordingly, this measure was developed to reflect the guidance provided in the HRS/EHRA Expert Consensus on the Monitoring of Cardiovascular Implantable Electronic Devices (CIEDs): Description of Techniques, Indications, Personnel, Frequency, and Ethical Considerations document released in April 2008. The statement summarizes the opinion of the writing group members based on their own experience in treating patients, as well as a review of the literature, CIED manufacturers, and governmental reimbursement and regulatory bodies who are involved in the care of patients with CIEDs. Additionally, the measure will be presented to NQF as a “care coordination” measure, a topic that has been identified by NQF’s National Priorities Partnership as one of eight priority areas with the greatest potential to eradicate disparities, reduce harm, and remove waste from the American health care system.

It appears that membership education on the guidance, as well as the intent and scope of the measure, should be considered by the Society.

Small Numbers, Patient Confidentiality, and Outliers
As with HRS-3.2, some reviewers expressed concern about the use of this measure at the physician level. Many providers may not have enough eligible patients to create a stable annual rate, and including such physicians in the measure might inevitably compromise patient confidentiality. It was recommended that the MDTF incorporate into the specifications a minimum number of denominator patients under which a provider’s score should be
suppressed (i.e., not reported). Concerns regarding how outliers will be defined were also voiced.

Response: Defining adequate sample size and outliers is an issue of measure implementation that is addressed by the implementing organization(s) based on the baseline performance of its physicians rather than by the measure developer. Patient confidentiality is a valid concern and the Quality Improvement Subcommittee may wish to generally discuss the issue to assess whether the Society wishes to officially opine on the matter given that it is not unique to this measure.

Eligible Providers and the Definition of “Evaluation”
Many commenters questioned whether the measure requires that follow-up specifically be performed by the implanting physician, and urged that evaluations by other physicians (e.g., the referring cardiologist) and by mid-level providers also be considered valid for numerator inclusion. Others requested that the term “evaluation” be more clearly defined, and that the specifications provide explicit expectations for the visit’s content.

Response: In accordance with the HRS consensus document, the MDTF agreed that the follow-up 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. Thus, no changes to address comments recommending expansion are recommended.

Regarding the definition of an evaluation, we note that the Code Key contains a detailed list of eligible visit codes. However, the HRS staff and Consultants reviewed the numerator specifications and made suggested revisions to more clearly convey (1) which providers can perform the follow-up evaluation, and (2) the required content of the visit.

Patient Refusal Exclusion
A number of commenters remarked that the exclusion for patient refusal of treatment is unclear. Clarification was requested regarding whether the exclusion encompasses patient refusal of a follow-up evaluation, and if so, how this information can be reliably captured using administrative claims data. Additionally, allowing providers to code for patient refusal of treatment creates a significant “loophole” that will make the measure highly susceptible to gaming.

Response: Gaming of the system is a valid concern with performance measurement, but the MDTF discussed that it is the mission of the responsible physician to adhere to the tenets of standard medical ethics. Avoidance of gaming any system, maintaining clinical competency, and consistent provision of quality care in a patient-centered manner remains the standard for success. However, we note that both the Focus Group and several MDTF members expressed similar concerns, and we recommend that the exclusion remain as it does not compromise the measure. This serves as additional opportunity to educate physicians about performance measures. Physicians should be made aware that 100 percent compliance is not the threshold for this measure as there is no method of mitigating patient refusal.

Measure Timeframe and Reimbursement
Several commenters questioned the 2 to 12 week timeframe of the measure, noting that many physicians routinely see their patients as early as one week post-implant and as late as 90 days, both of which fall outside the limits of the numerator. It was suggested that the acceptable
timeframe be expanded to accommodate such practices, particularly given that there is not convincing evidence of better outcomes when patients are seen within the parameters defined by the measure. Concern also was raised that since the 90-day global period prohibits physicians from billing for a follow-up visit until after 12 weeks, the measure timeframe should be expanded.

Response: No changes to the specifications are recommended. Again, the MDTF agreed that the measure must adhere to the HRS consensus document, which recommends that the initial follow-up evaluation occur within 72 hours of implantation and the second evaluation within 2 to 12 weeks. Similarly, the MDTF discussed the issue of physicians waiting to conduct the follow-up so as to bill for the visit versus conducting it within the global payment period. The MDTF acknowledged that physician education of both the guidance and appropriate coding to indicate a visit occurred (to receive credit), despite the lack of a claim for payment. We note that in testing the measure, the MDTF has recommended the protocol assess the degree to which in-person follow-up occurs within 90 days and just outside that period.

Remote Monitoring
Several commenters questioned why remote device monitoring is not included in the measure specifications. One commenter opined that remote evaluations might become the norm as technology advances, and that a quality measure establishing in-person-only follow-up might fail to accommodate future trends.

Response: No changes recommended. The MDTF agreed the specifications must adhere to the HRS consensus document, which recommends that the 2 to 12 week follow-up evaluation for patients with pacemakers, ICDs, and cardiac resynchronization therapies occur in person. The initial in-person follow-up visit provides vital clinical information which can provide the basis for future courses of therapy. Subsequent evaluations can occur remotely. The commenter’s concerns regarding changing trends is valid, but we note that if the measure is endorsed and future iterations of the consensus statement are in fact modified to accommodate remote monitoring, NQF allows for ad hoc reviews/updates of performance measures when there are changes in the supporting evidence base.

Attribution
One commenter raised the issue of attribution, noting that the implanting physician has little control of scheduling and follow-up reminders, and no control when follow-up is scheduled with another provider. A couple of other comments questioned attribution to the operator if the patient either preferred to be seen by the referring cardiologist or if, because of geographic separation, the in-person evaluation was best conducted by another physician.

Response: No changes recommended. The MDTF’s deliberations acknowledged that ensuring appropriate follow-up is at times difficult, but agreed that this was an important measure of care coordination—a topic that has been identified by NQF’s National Priorities Partnership as one of eight priority areas with the greatest potential to eradicate disparities, reduce harm, and remove waste from the American health care system. The MDTF believed that this measure will promote coordination of care between providers in instances when the patient cannot follow up with the implanting physician and will ultimately improve patient care.
We note that with respect to the issue of geographic distance, the testing approach will be to assess, to the extent feasible, whether rural patients/practices appear to be correlated with significantly poorer performance.

**Suggestions on Coding**

Several commenters supplied suggestions to improve the accuracy of the codes included in the Code Key.

*Response:* The HRS staff and the Consultants reviewed all codes to determine if they can be modified to improve precision (see Appendix A).
Appendix A: RECOMMENDED REVISIONS FOR HRS-3 AND HRS-4

Based on the input received during the public comment period and the Focus Group sessions, and on subsequent discussions with the MDTF, several revisions have been made to the HRS performance measures, as summarized in this document. Revisions are categorized as pertaining to the numerator, denominator, or exclusions, by measure. All coding and language revisions will be evaluated for feasibility and precision during field-testing.

HRS-3: ICD COMPLICATIONS RATE

Numerator
Suggestions for an additional numerator code and an expansion of some of the existing codes were offered in the public comments:

- ICD-9-CM 996.0 (mechanical complication of cardiac device implant and graft) requires a 5th digit to address specific ICD devices. The following ICD-9-CM codes have consequently been identified:
  - 996.00 — mechanical complications of unspecified cardiac device implant and graft;
  - 996.04 — mechanical complication of automatic implantable cardiac defibrillator; and
  - 996.09 — other mechanical complication of cardiac device implant and graft.
- ICD-9-CM 996.72 (other complications due to other cardiac device implant and graft) is applicable to defibrillator devices and was identified as a potentially appropriate addition to the ‘mechanical complications’ numerator category.

As these codes are not included in the CMS corollary hospital-level measure, HRS will review these comments with the measure Yale to assess whether, how, and when they should be incorporated.

Exclusions
While the CMS measure excludes patients with prior ICDs from the denominator, a code for the exclusion was not provided in the microspecifications. HRS has identified an ICD-9-CM code for ‘patients with prior ICD implantation’ (V45.02), and will discuss with Yale how patients with prior implants were identified in the CMS measure during field-testing and whether this code should be incorporated into future iterations of the measures or whether it was in fact used and is missing from the CMS table due to an oversight.
HRS-4: IN-PERSON EVALUATION FOLLOWING CIED IMPLANTATION

Denominator

• Since only patients with implantation of a new CIED are included in the denominator population, an exclusion for patients with prior CIED implant has been added to the measure specifications for clarity.

• Codes for isolated pulse generator exchanges (e.g., CPT 33240) have been removed from the denominator to reflect the fact that these patients are excluded from the measure.

• Codes for insertion of temporary devices (i.e., CPT Codes 33210 and 33211) were removed from the denominator, as the intent of the measure is to capture only patients with permanent CIEDs.

Exclusions

• Both the Focus Group and public commenters expressed significant concern about the potential for gaming with the “patient preference for no or other treatment” exclusion. However, as the exclusion was deemed important by the MDTF, ICD-9-CM code V62.6 will remain in the specifications and will be field-tested to determine whether the exclusion is feasible and appropriate.

• ICD-9 and CPT codes indicating a revision, replacement, or upgrade of a previous device have been added to the list of exclusion codes to reflect that the measure applies only to patients with implantation of a new CIED.

Numerator

• During the Focus Group discussion, a participant suggested that the numerator for this measure could be accurately captured using only administrative data, eliminating the need for manual chart review. Specifically, the participant suggested that the initial follow-up visit should be a programming evaluation consisting of an interrogation plus iterative testing of the device. Relevant codes include:

  o Three codes each for in person programming device evaluation with iterative adjustment for pacers and defibrillators (one code each for single, dual, and multiple lead systems).

  o One code each for in person interrogation device evaluation for pacers and defibrillators.

The numerator verbiage and the Code Key have been revised accordingly.

• Public commenters requested clarification on what types of medical professionals can perform the follow-up evaluation. The numerator verbiage has thus been revised to indicate that, in accordance with the HRS/EHRS Expert Consensus on the Monitoring of Cardiovascular Implantable Electronic Devices document, the follow-up evaluation can be provide by any trained physician or Clinically Employed Allied Professional (CEAP) in a designated CIED follow-up clinic, medical institution, or physician office.