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Measuring Quality in Electrophysiology

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Abstract

The evolving healthcare environment demands optimally measured quality of care. Performance measures are increasingly being used for quality improvement, public reporting, and reimbursement determinations. The National Quality Forum has created rigorous criteria for the evaluation of potential performance measures across medical fields. The Heart Rhythm Society has championed the development of four separate EP specific performance measures: implantable cardioverter defibrillator complication rate, cardiac tamponade and/or pericardiocentesis following atrial fibrillation ablation, infection within 180 days of a cardiac implantable electronic device implantation, replacement, or revision, and in-person evaluation following a cardiac implantable electronic device implantation. National registries serve a key role in developing performance measures and facilitating quality improvement, particularly as they provide improved granularity and accuracy of data compared with administrative claims data. All performance measures demand continued reassessment as technology and performance gaps change and as unintended consequences may arise.

Cardiac electrophysiology (EP) is an exciting, technology-driven field that has changed immensely in the last decade. Scientific advances in pacing, defibrillation, mapping, and ablation have given electrophysiologists unprecedented abilities to perform minimally invasive life changing procedures in patients on a daily basis. The tremendous opportunities associated with technologic advances come with associated responsibilities to ensure that procedural techniques, catheter designs, and devices/leads result in high quality care for patients. Therefore, approaches to measuring and reporting quality and performance in electrophysiology are being recognized by many as critically important. Indeed, performance measurement for the purpose of quality improvement has become a national top priority in the current health care environment. This is evidenced by the National Quality Strategy's emphasis on the need to measure performance using consistent, nationally endorsed measures, in order to provide information that is timely, actionable and meaningful to both providers and patients[1].

A key challenge in quality measurement is defining quality. The Institute of Medicine broadly defines quality as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." The Institute of Medicine further describes quality care as care that is "safe, effective, patient-centered, timely, efficient, and equitable.[2]" The

Institute of Medicine's broad definition of quality represents an important conceptual framework that should be applied when attempting to define – and measure – the quality of different types of care[2].

Performance measures are essential in today's healthcare system as they can serve different purposes related to quality improvement, public reporting, and re-imbursement determinations. While the use of performance measures can be controversial and occasionally dreaded by some, if used appropriately, these measures can improve the quality of patient care as well as their outcomes. It is expected that patients will increasingly use these metrics to select physicians, and payers are already using these metrics to determine payment for services. Although the procedural nature of EP makes the field ripe for the development of performance measures, few EP-specific measures have been developed. This article will review the current state of quality assessment in EP and offer ideas regarding changes in quality assessment in the future. It is hoped that this overview will lead to increased interest and engagement in the process of performance measurement and quality improvement across the EP subspecialty.

Performance measures versus quality metrics

The process of quality measurement can serve a wide variety of purposes; therefore, it is essential to ensure that the measurement process is designed to meet the specific need. Quality metrics and performance measures are two common ways to assess quality of care. Although quality metrics and performance measures attempt to quantify an aspect of care that is associated with higher quality, increased satisfaction, or increased effectiveness, they are meant to serve distinctly different roles. A “quality metric” generally refers to a tool that can quantify quality for *internal* use within an institution or organization. For example, an electrophysiology group may choose to measure rates of vascular access site complications to understand technical competence and need for internal education and quality improvement initiatives. Data associated with a quality metric may not be appropriate for the purpose of public reporting or augmenting re-imbursement.

A performance measure is a tool that is used to quantify quality for the purposes of objectively communicating details of quality of care to one or more *external* entities. A long-standing and well accepted performance measure has been the use of antibiotics within one hour of a surgical procedure as a means to reduce the risk of a post-procedural infection. The Physician Quality Reporting System (PQRS) adopted use of pre-procedure antibiotics as a performance measure and re-imbursement can be augmented based on meeting this standard. Because the reporting of performance measures can impact reimbursement and public opinion, they must be held to a higher standard than quality metrics. It is important to note that performance measures are usually suitable for use as internal performance standards although the reverse does not necessarily hold true. For example, although vascular access site complications can be important for internal tracking and quality improvement (with a goal of a zero percent complication rate), public disclosure of these rates would not be appropriate until there is an agreed upon definition of an acceptable risk-adjusted rate of complications.

Thus, a quality metric refers to tool for *internal* use (e.g. internal quality improvement) and a performance measure refers to a tool for *external* use (e.g. public reporting, reimbursement determinations).

Developing appropriate performance measures

The National Quality Forum (NQF) has developed rigorous criteria to evaluate potential performance measures [3]. Each candidate criterion is evaluated in a systematic and sequential manner. If an initial criterion is not met, subsequent criteria may not be evaluated. First, candidate measures are assessed to ensure that the measure is evidence-based and addresses an important performance gap including disparities in care when applicable. Second, measures are evaluated on reliability by determining if the measure data elements can be replicated and can produce the same results the vast majority of the time when assessed in the same population in the same time period and/or that the measure score is precise enough to elucidate differences in performance across providers. Third, measures are assessed on validity by determining whether the measure data elements are correct and/or the measure score correctly reflects the quality of care provided and adequately identifies differences in quality. For outcome measures, it is important to consider the need for risk-adjustment and if deemed appropriate, it is important to demonstrate the ability to perform evidence-based risk-adjustment. Next, the feasibility of large scale performance measure data acquisition is assessed. This step involves identifying if the necessary data are able to be captured in a manner that would not impose an undue burden on the treating physician. Data that are routinely documented in electronic health records, billing records, or in national registries are often amenable for use as performance measures. After feasibility of data collection is confirmed, candidate performance measures are assessed for “usability” to ensure that both accountability and performance improvement will advance the goal of promoting high-quality and efficient healthcare. Finally, proposed performance measures that meet all of the aforementioned criteria are examined for substantial overlap with performance measures that are currently endorsed or in-development.

The NQF is an organization that covers all medical disciplines and defines criteria for performance measures (as per above), convenes working groups to foster quality improvement, ensures performance information is publicly available, and evaluates performance measures in an ongoing fashion. Each performance measure endorsed by the NQF is championed and maintained by a steward organization. Within electrophysiology, the two current stewards are the Heart Rhythm Society and the American College of Cardiology. Notably, measures need not be endorsed by the NQF to be included in PQRS.

In the field of cardiology, a number of established performance measures have been developed. Current well accepted performance measures include the use of beta blockers and angiotensin converting enzyme inhibitors (ACEi) or angiotensin receptor blockers (ARB) in patients with heart failure and a reduced ejection fraction. These performance measures are excellent examples of measures that comply with all the NQF standards [3]. Use of these medications in patients with heart failure with reduced ejection fraction is supported by numerous randomized clinical trials [4–7] and meets the important need to reduce morbidity and mortality in heart failure. The measurement of use or non-use of these medications can

be accomplished through queries of electronic health records or relevant registries such as the NCDR ICD Registry and GWTG-HF to mention a couple. Finally, these performance measures are certainly “usable.” Indeed, these measures have been in use for years and are being publicly reported through PQRS [8].

Performance measures in EP

Recently, a number of EP specific performance measures have been developed by the Heart Rhythm Society. The development of EP specific measures has been driven by a variety of factors, including the desire to improve quality of care and changes to the PQRS program which, in 2015, transitioned from an incentive based program to penalty based program. Specifically, 2017 reimbursements will be discounted by 2% if quality standards are not met and reported to CMS for 2015 [9]. For these reasons, the Heart Rhythm Society wanted to ensure that practicing electrophysiologists have EP-specific performance measures to report on.

The Heart Rhythm Society has developed four separate performance measures: ICD complication rate (PQRS # 348), cardiac tamponade and/or pericardiocentesis following atrial fibrillation ablation (PQRS #392), infection within 180 days of a cardiac implantable electronic device (CIED) implantation, replacement, or revision (PQRS #393), and in-person evaluation following CIED. All of these measures, except for in-person evaluation following CIED implantation, are approved for use as part of PQRS. The Heart Rhythm Society is encouraging reporting of rates of in-person evaluation after CIED implantation in anticipation of this measure becoming available for use for the PQRS program in the future. Of note, the NQF has endorsed the performance measures on cardiac tamponade and/or pericardiocentesis following atrial fibrillation ablation and on in-person evaluation following CIED implantation.

There are a number of additional established performance measures that are relevant to EP practice and included in the current PQRS program. These measures include the use of evidence based medications for heart failure (ACE or ARB therapy and beta blocker therapy for left ventricular systolic dysfunction), use of peri-procedural antibiotics, and anticoagulation for patients with atrial fibrillation. See Table 1 for a list of PQRS performance measures relevant to the practice of cardiac electrophysiology. Practicing electrophysiologists can, as individuals or groups, choose to report on any of these performance measures.

Current methods for reporting performance measures to PQRS for individuals include using Medicare Part B claims, a qualified PQRS registry, a direct electronic health record (using a certified technology), a qualified clinical data registry, or a data submission vendor. Group practices may submit data to PQRS using a qualified PQRS registry, direct electronic health record, web interface, data submission vendor, or a Medicare certified survey vendor. In the future, e-measures will likely be an important mechanism for reporting.

Role of registries in performance measure development and quality improvement

National registries serve a key role in developing performance measures and facilitating quality improvement. Registries provide much improved granularity and accuracy of data compared with administrative claims data. Registries not only have important clinical data elements that cannot be found in administrative claims data, but they usually also have important variables needed for risk adjustment of outcome measures. The NCDR Cath-PCI Registry has been used for the development of several performance measures related to percutaneous coronary intervention. Likewise, the National Cardiovascular Data Registry (NCDR) ICD Registry has had the capacity to drive quality measurement and by extension, quality improvement. A recent study from the NCDR ICD Registry developed a risk score to predict in-hospital adverse events following ICD implantation using a cohort of over 230,000 patients implanted with an ICD during portions of 2010 and 2011 [10]. The authors created a risk score where one or more points are assigned for each patient or procedural characteristics associated with an in-hospital complication. This risk score can be used to compare observed versus projected complication rates and as a method for benchmarking an institution's complication rates. Based on this robust analysis, a performance measure on post-implant ICD complication rates has been included in the PQRS program (PQRS 348). Another study from the NCDR ICD Registry reported rates and predictors of CIED infection within 6 months of device implantation in a population of over 200,000 patients [11]. Results from this study have been incorporated into a PQRS performance measure (PQRS 393).

One challenge peculiar to electrophysiologists is the paucity of EP-specific registries. This challenge can be mitigated by the use of electronic medical records. In fact, NQF has been encouraging the development of e-measures that are likely best used in electronic health records. While the optimal process for developing and testing e-measures is yet to be determined, there is immense potential for e-measures to revolutionize the implementation of performance measures in clinical practice.

Notwithstanding the immense potential value in e-measures, national registries will likely continue to play a major role in quality assessment and quality improvement in the future. The AHA's Get With The Guidelines AF will capture information on the care of a large number of AF outpatients across the country and create opportunities for the development of quality measures and improvement [12]. The NCDR has recently announced the creation of two new EP specific registries: a left atrial appendage occlusion registry which will launch in late 2015 and an AF ablation registry which will launch in early 2016. These registries, like the ICD Registry, will likely provide a wealth of knowledge that will allow for improvements in care delivery and facilitate quality measurement and improvement.

Developing, monitoring and modifying performance measures

The development and maintenance of quality measures should be a dynamic and iterative process. New measures should constantly be sought out, and established measures should continually be evaluated for relevance, impact, and unintended consequences. Performance

measure developers should make every effort to study the impact of existing performance measures and capture data on improvement, remaining performance gaps, disparities in care, and unintended consequences. If major improvements are achieved and gaps are no longer demonstrated, then measures should be retired. If unintended consequences are observed, then modifications to the measures should be considered.

The “Door to Balloon” (D2B) for STEMI patients is an excellent example of a performance measure associated with improvements in care and a host of unanticipated consequences throughout its lifecycle [13]. After D2B time became a publically reported performance measure that linked to Medicare reimbursement, national D2B times dropped dramatically from a median of 96 minutes in 2005 to a median of 64 minutes in 2010 [14]. Decreases in D2B times were associated with an increase in reported system and patient related delays that effectively excluded the associated procedures, raising concerns that some were cheating the system to optimize re-imbursement and publically reported numbers [15]. Also concerning is that in the relentless pursuit of a quick D2B time, some cardiologists were forgoing the adoption of radial artery access in favor of femoral access, despite mounting data suggesting that radial artery catheterization may be superior even if associated with a slight increase in D2B time [16]. There is now minimal distinguishable variation in performance between hospitals; as such, Medicare will no longer make payment decisions based on D2B times although times will still be publically reported.

Strong candidate performance measures should typically be based on society guidelines and should be associated with equally strong recommendation and level of evidence (i.e. class 1A recommendations.) Based on mounting data [17–20] and published [21] and drafted [22] guideline recommendations, remote monitoring usage and innovative ICD programming to avoid unnecessary shocks may be well suited for future performance measures.

Relevance of existing performance measures is particularly important in the field of EP as the science and the technology are evolving rapidly, and certain measures may quickly become irrelevant or may need to be modified to reflect more current state of clinical practice. The subcutaneous ICD is an excellent example of an important and disruptive technology that may require development of new measures or amendments to existing performance measures. For example, the PQRS approved performance measure for in-hospital complications after ICD implantation [10] was developed using data on transvenous ICD systems. Certain data elements for this measure like pneumothorax, venous thrombosis, and cardiac perforation are irrelevant to subcutaneous ICDs. Therefore, the existing performance measure could not be used for the subcutaneous ICD, and as a result, a new performance measure on complications of subcutaneous ICDs will likely be needed. Another example is the current performance measure related to 6 month infection after device implantation [15]. During development, this measure was tested using infection rates associated with transvenous ICDs. Rates of infection related to subcutaneous ICDs are likely lower. Therefore, the current performance measure on device infection will likely need to be retested on subcutaneous ICDs, amended and resubmitted to NQF for endorsement.

The leadless pacemaker represents another technology that will require special consideration. If performance measures related to pacemaker implantation are ever

developed, a nuanced approach to specifications of the measures will be needed to ensure that differences across device types (leadless vs. not) are accounted for.

Measuring Quality in a Changing Reimbursement Landscape

Although the importance of and methods for measuring quality in electrophysiology are becoming more clearly established, the way in which this information will be incorporated into payment determinations (particularly Medicare) will likely be ever changing. The Medicare Access and CHIP Reauthorization Act (MACRA) was passed by Congress in April 2015[23]. Broadly, MACRA will repeal the sustainable growth rate method of reimbursement and combine existing quality assessment programs (including PQRS) into the Merit-Based Incentive Payment System (MIPS). MACRA will result in sweeping changes by reducing payments based on quantity of care in favor of reimbursing for quality of care. Thus, performance measurement will continue to grow in importance for the foreseeable future.

Conclusions

Performance measures are important tools for measuring quality of care. Use and reporting of performance measures will be demanded by patients and payers alike who will increasingly base physician selection and reimbursement decisions, respectively, on performance measurement. Performance measures will be used increasingly by physicians and hospitals to achieve quality improvement, particularly as alternative reimbursement models (e.g. accountable care organizations) gain traction. High quality performance measures require an intense vetting process to ensure that performance measures are: evidence-based, associated with important performance gaps, reliable, valid, feasible, and usable. Registries and electronic health records are better platforms for developing and implementing performance measures than administrative claims data. Therefore, more efforts and resources should be devoted to optimizing the use of registries and electronic health records for performance measures. All performance measures demand continued reassessment as technology and performance gaps change. Finally, the Heart Rhythm Society should continue to take a leading role in the development of performance measures to ensure that experts in the field of electrophysiology (and not other key stakeholders) are in control of such an important developing aspect of the field.

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Table 1

Performance measures included in the current Physician Quality Reporting System (PQRS) performance measures relevant to the practice of cardiac electrophysiology.

	Endorsing Agency and Measure Number if Applicable			
Measure Title	CMS	NQF	PQRS	Measure Descriptions
HF: ACE or ARB Therapy for Left Ventricular Systolic Dysfunction	135v3	0081	005	Percentage of patients aged 18 years and older with a diagnosis of HF with a current or prior left ventricular ejection fraction < 40% who were prescribed ACE inhibitor or ARB therapy either within a 12 month period when seen in the outpatient setting OR at each hospital discharge
HF: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction	144v3	0083	008	Percentage of patients aged 18 years and older with a diagnosis of HF with a current or prior left ventricular ejection fraction < 40% who were prescribed beta-blocker therapy either within a 12 month period when seen in the outpatient setting OR at each hospital discharge
Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin	N/A	0268	021	Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis
Stroke and Stroke Rehabilitation: Anticoagulant Therapy Prescribed for AF at Discharge	N/A	0241	033	Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or transient ischemic attack with documented permanent, persistent, or paroxysmal AF who were prescribed an anticoagulant at discharge
AF and Atrial Flutter: Chronic Anticoagulation Therapy	N/A	1525	326	Percentage of patients aged 18 years and older with a diagnosis of nonvalvular 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
HRS-3: ICD Complications Rate	N/A	N/A	348	Patients with physician-specific risk-standardized rates of procedural complications following the first time implantation of an ICD
HRS-12: Cardiac Tamponade and/or Pericardiocentesis Following AF Ablation	N/A	N/A	392	Rate of cardiac tamponade and/or pericardiocentesis following AF ablation
HRS-9: Infection within 180 Days of CIED Implantation, Replacement, or Revision	N/A	N/A	393	Infection rate following CIED device implantation, replacement, or revision

Table adapted from the Centers for Medicare and Medicaid's Physician Quality Reporting System 2015 Measure List[8]

ACE = angiotensin converting enzyme inhibitor, AF = atrial fibrillation ARB = angiotensin receptor blocker, CMS = Centers for Medicare and Medicaid Services, CIED = cardiac implantable electronic device, HF = heart failure, ICD = implantable cardioverter defibrillator, NQF = National Quality Forum, PQRS = Physician Quality Reporting System