

ACC/AHA/STS Statement on the Future of Registries and the Performance Measurement Enterprise

A Report of the American College of Cardiology/American Heart Association Task Force on Performance Measures and The Society of Thoracic Surgeons

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1. Background

This document was commissioned to provide a perspective on clinical registries; to identify specific future opportunities for registries to comprise an informatics infrastructure for quality and efficiency measures that are used for accountability; and to propose a model for a future state characterized by an increasingly close inter-relationship between registries and performance measure development. Specifically, this statement

focuses on how registries and performance measures are intertwined and how registries will become even more crucial with increasing focus on different types of measures, including process measures, risk-adjusted outcome measures, and resource use measures, that can be used by patients and purchasers. The writing committee anticipates that this statement will prove valuable to providers, payers, patients, policy makers, and other interested stakeholders.

1.1. Disclosures of Relationships With Industry

Every effort is made to avoid actual, potential, or perceived conflicts of interest that may arise as a result of relationships with industry or other entities. The work of the Writing Committee was supported exclusively by the American College of Cardiology (ACC) and the American Heart Association (AHA), in collaboration with The Society of Thoracic Surgeons (STS), without commercial support. The Writing Committee members volunteered their time. All members of the Writing Committee, as well as those selected to serve as peer reviewers of this document, were required to disclose all current relationships and those existing within the 12 months before the initiation of the project. It was also required that the Writing Committee co-chairs and at least 50% of the Writing Committee have no relevant relationships with industry or other entities. Author and peer reviewer relationships with industry and other entities relevant to the document are included in Appendixes A and B. Additionally, to ensure complete transparency, the writing committee members' comprehensive disclosure information, including RWI not relevant to the present document, is available as an [online supplement](#).

1.2. Clinical Registries and Quality Measurement in Cardiovascular Disease

Among the substantial changes in delivery of medicine over the past decades, 2 parallel developments are particularly noticeable: 1) an increasing emphasis on measuring and improving the quality and efficiency of medical care; and 2) the proliferation of clinical registries designed to understand care and outcomes in “real-world” medical settings. Although there is general consensus on the value of registries in improving quality of care, it is important to note that submitting data to registries is associated with a real cost to medical centers and practices. In some cases, data collection for registries duplicates reporting requirements for state and national initiatives, requiring institutional “champions” of registries to advocate for securing additional funding to support registry efforts.

Recently, registry operations and the development of quality measures for the purpose of accountability (referred to as “performance measures” according to the ACC/AHA Task Force on Performance Measures) have converged substantially. The development of quality metrics in cardiovascular disease has accelerated significantly since the early 1990s, when the Cooperative Cardiovascular Project, a national effort led by the Health Care Financing Administration (now the Centers for Medicare and Medicaid Services [CMS]), was initiated to measure the quality of care for Medicare beneficiaries with acute myocardial infarction.¹ Since that time, other payers, governmental agencies, and professional organizations

have become involved, greatly expanding the reach of quality performance measurement for cardiovascular disease.

The landscape of cardiovascular quality measurement has become increasingly complex because of several simultaneous developments. Legislative mandates are realigning payment incentives away from fee-for-service structures to reimbursement for the delivery of quality care.² The requirements for the endorsement of performance measures by the National Quality Forum (NQF)—an organization that develops and applies measurement standards—have expanded.³ Payers and healthcare consumers demand more meaningful and comprehensive measures to characterize outcomes, quality, safety, efficiency of care, and the patient experience. Additionally, the rapid deployment of electronic health records (EHRs) has been accompanied by increasing interest in quality measures that can be extracted from data collected during routine care. The confluence of these factors has expanded both the promise and the challenge of performance measurement.

Cardiovascular registries, which have a track record of supporting clinical quality improvement,^{4–11} are recognized as a potential solution to many of these emerging challenges. For example, the American Taxpayer Relief Act of 2012¹² gave providers the option of satisfying the requirements of the Physician Quality Reporting System (PQRS)¹³ by participating in qualifying registries. This legislation also required an examination by the Government Accountability Office of potential expanding roles for clinical registries. The resulting report recommended that the US Department of Health and Human Services require, as a condition of qualification, that registries demonstrate improvements in quality and efficiency.¹⁴ In 2013, the CMS introduced the concept of qualified clinical data registries¹⁵ into the PQRS program. The PQRS program established stringent requirements for registry designation but also made it possible for qualified registries to develop their own performance metrics on the basis of clinically enriched data. In addition, the CMS has partnered with national cardiovascular registries to develop robust measures of patient outcomes.¹⁶ These various efforts represent an evolution in the nexus of clinical registry data and performance measurement.

2. Introduction

2.1. What Is a Clinical Registry?

A clinical registry is an observational database focused on a clinical condition, procedure, therapy, or population. Data are collected systematically for specified scientific, clinical, or policy purposes. There are no mandated approaches to therapy in clinical registries (as opposed to registries associated with randomized controlled trials), and clinical registries have relatively broad inclusion criteria and few exclusion criteria.^{17,18} The National Committee on Vital and Health Statistics defines a registry as “an organized system for the collection, storage, retrieval, analysis, and dissemination of information on individual persons who have either a particular disease, a condition (eg, a risk factor) that predisposes [them] to the occurrence of a health-related event, or prior exposure to substances (or circumstances) known or suspected to cause adverse health effects.”¹⁹ The focus of clinical registries is on capturing data

that reflect “real-world” clinical practice in large, representative patient populations. Well-designed and well-executed clinical registries provide insights into patient characteristics, comorbid conditions, patterns of care, quality of care, safety, clinical outcomes, and comparative effectiveness.^{17–19} Clinical registries play an increasingly important role in gauging appropriate healthcare delivery, including:

- Measuring appropriateness of care and disparities in the delivery of care;
- Serving as public health surveillance systems;
- Supporting and measuring the effectiveness of quality improvement;
- Evaluating factors that influence prognosis and quality of life;
- Assessing healthcare effectiveness and safety; and
- Improving clinical outcomes, patient care experience, and patient-reported outcomes for a variety of conditions, including many cardiovascular diseases.^{17,18,20–23}

Over time, registries can also provide important information for patients’ decision making about their care and can facilitate more effective payment and incentive strategies.

Clinical registries can be classified on the basis of the defining characteristics of the patient population enrolled—for example, patients who have had a procedure, therapy, or encounter; patients with a particular disease; and patients in a demographic group, including but not limited to race, age, and sex.¹⁷ Registries can also be categorized by function, such as whether the registry is used for quality measurement, to provide feedback to clinicians for quality improvement, for clinical research, or to fulfill multiple functions. Clinical registries can be either prospective or retrospective in design and are developed and operated by many types of entities, including professional societies, researchers, research consortia, nonprofit organizations, government agencies (eg, the National Institutes of Health), and industry.^{17,18}

Clinical registries have well-defined purposes, and data are systematically collected in a way designed to meet these purposes.^{17,18} Clinical registries capture data elements with standardized, granular, and consistent data definitions and data standards.^{18,24} Historically, data have been entered into clinical registries via medical record abstraction and case report forms, although some registries, such as the National Cardiovascular Data Registry’s (NCDR’s) ambulatory registry (PINNACLE)²⁵ and TGA (The Guideline Advantage)^{26,27} (AHA/American Stroke Association’s collaboration with the American Cancer Society and the American Diabetes Association through the Preventive Health Partnership), extract electronic data directly from the EHR.

Clinical registries are generally observational rather than interventional, in that the care provided and recorded in the registry is determined by clinical evidence and judgment rather than dictated by a study protocol. Clinical registries usually do not contain claims, administrative data, resource utilization, or pharmacy records, but they may integrate data from or be linked to such data sources.^{17–19} Registries may also be dynamic; some are designed to modify the behavior of participants by providing timely feedback about process and outcomes of care to foster active quality improvement intervention.

2.2. The Role of Clinical Registries

Clinical registries represent a foundational tool in the cycle of developing evidence for best medical practices, measuring the outcomes of these care processes, providing actionable feedback to clinicians, and improving quality of care and outcomes. These activities span the domains of patient care, research, and teaching, as well as quality improvement and research, with the boundaries between these domains sometimes presenting ethical and regulatory challenges.²⁸

Clinical registries can be used as a platform for developing evidence for best medical practices and performing comparative-effectiveness research. The National Institutes of Health–funded ASCERT (ACC–STS collaboration on the Comparative Effectiveness of Revascularization sTrategies) trial and the Agency for Healthcare Research and Quality–funded COMPARE-HF (Compare the Effects of Coreg CR and Coreg IR on HF in Subjects with Stable Chronic HF) trial exemplify this approach.^{29,30} Randomized trials are considered the criterion standard for comparative effectiveness but historically have been extremely expensive and have recruited restricted patient populations, sometimes resulting in problematic generalizability. Recent efforts have examined the possibility of using clinical registries as a platform for conducting pragmatic clinical trials,^{31,32} potentially accomplishing the dual objectives of decreasing trial costs while simultaneously increasing the generalizability of the results.

Clinical registries are optimal tools for measuring the outcomes of care processes, although special effort may be necessary to ascertain nonfatal outcomes. Properly measuring clinical outcomes requires standardized clinical nomenclature, uniform standards for defining and collecting data elements, strategies to adjust for the complexity of patients, techniques to verify the completeness and accuracy of data, and longitudinal data collection.^{21,33–36} All of these features would exist in an ideal clinical registry, which would also have the potential for collaboration across medical and surgical subspecialties and across settings of care, as a means of tracking outcomes.

Clinical registries can provide practitioners with accurate and timely feedback about their own outcomes, which are benchmarked against regional, national, or even international aggregate data^{21,37–44}; however, the ultimate goal is not measurement, but rather improved quality of care and outcomes. Clinical registries have been used to create standardized measures of quality that have been endorsed by multiple professional medical societies and the NQF. Compliance with registry-based measures and the public reporting of these measures may lead to improvements in the overall quality of care delivered.^{21,45–49}

2.3. Registries and Electronic Health Records

The penetration of clinical practice by EHRs has increased rapidly since the introduction of the federal EHR financial incentive program in the Health Information Technology for Economic and Clinical Health Act of 2009.^{50,51} Concomitant with payment incentives, the federal Office of the National Coordinator created mandatory “meaningful use criteria” that must be met by EHRs before they qualify for financial incentives. The financial incentives are managed by the CMS at the hospital and physician level.⁵² Among several objectives, meaningful use criteria are meant to ensure that EHRs capture

data in ways that allow the data to be analyzed, reported as performance measures, and ultimately used to improve care. A few large EHR vendors captured a substantial proportion of the growing EHR market and are accumulating data entered by many clinicians in numerous hospitals.⁵³ Additionally, several companies provide analytic services to assist health systems and physicians with their raw EHR data.^{54–56} These companies provide performance information by using internally generated measures and benchmark performance on the basis of data from all of their clients. Finally, the CMS offers physicians the ability to use “a qualified clinical data registry”¹⁵ as a reporting option for the PQRS program.¹³ A qualified clinical data registry is a CMS-approved entity that collects medical or clinical data for a subset of measures and can report data on these measures to the physician for PQRS reporting purposes.

Some believe that EHR data will ultimately replace registries as the premier sources of clinical information in real-world settings; however, there are key differences between EHRs and registries that have important implications for the roles that each can play in evidence generation, public reporting, and quality improvement.

Governance

The governance structures of registries vary according to their purpose and the entities that operate them. Those operated by researchers are usually governed by the founding investigators, whereas industry-funded registries often remain under the control of their sponsoring companies. Specialty society registries are typically governed by the membership of a particular society, although joint specialty sponsorship is an increasingly important variant (eg, the STS/ACC TVT [Transcatheter Valve Therapy] Registry).⁷ They may also include registry “customers” and patient representatives.^{5,6,57}

Data Specifications and Entry

Data entry into dedicated clinical registries is typically accomplished by trained abstractors who abstract information from the clinical record in accordance with specific definitions and enter it into the registry via case report forms.^{5–7,10,57} The result is that registries contain highly reliable and valid information. However, data in EHRs are captured in the process of patient care by physicians and other members of the clinical team for purposes other than analysis and reporting. These clinicians might not use explicit, standardized definitions when documenting patient care. This lack of standardization makes it more difficult to: 1) allow for comparison and data aggregation of EHR data among providers; and 2) use data from EHRs for national and international comparisons and for accountability purposes. Some of the data, such as diagnosis and treatment codes, are collected and used primarily for billing and insurance purposes. Although efforts have been undertaken to establish common data models for EHR data, these models are not yet in widespread use.^{58,59}

Data Quality

Registries generally have processes in place to ensure data quality. For example, processes such as those implemented by the STS National Database,⁶ the GWGTG (Get With The Guidelines) Registry,⁶⁰ and the NCDR⁶¹ include ongoing training of abstractors and data audit. The STS National Database

contracts with an external organization to conduct random audits of 10% of its participant sites annually.³⁴ In 2013, nearly 100 000 individual data elements were audited, with an exceptional overall accuracy rate of 96.6%. In contrast, EHR data are generally not subject to formal audit. The quality of EHR data is usually addressed through *post hoc* “data scrubbing” and evaluation, through which data that are likely erroneous are removed from further analysis. Registries should continue to make concerted efforts to improve data quality so as to strengthen the validity of the data collected.

2.4. The Continuing Utility of Clinical Registries in an Era of Electronic Health Records

Despite the growth of EHRs and EHR-derived databases, clinical registries will continue to play an increasingly important role in measuring healthcare outcomes, appropriateness of care, and disparities in the delivery of care, and will serve as the basis for clinical and comparative-effectiveness research. EHR data have important limitations with regard to key cardiovascular data elements. For example, contraindications to therapy and other critical data elements might not be captured in discrete and hence analyzable fields. Studies suggest that caution should be exercised in using EHRs for quality monitoring,⁶² and some studies suggest that the use of EHRs per se has not resulted in better quality of care or outcomes.^{63–65} In contrast, clinical registries have well-documented efficacy as instruments for surveillance; supporting and measuring effectiveness of quality improvement; evaluating factors that influence prognosis and quality of life; assessing healthcare effectiveness and safety; and improving clinical outcomes for heart disease, stroke, and other diseases.^{17,18,20–23} Thus, clinical registries remain essential and well-validated methods for measuring and improving performance.

The future will likely involve some degree of integration of EHR and administrative data sources with registry data. Many registries track patients for only a short period of time after an initial event, although registries are increasingly trying to follow patients for longer periods of time,⁶⁶ as is the case with the REACH (Reduction of Atherothrombosis for Continued Health) registry,^{67–69} TGA,^{26,27} and PINNACLE.⁷⁰ EHR and administrative data could facilitate longitudinal patient follow-up and documentation of nonclinical outcomes, such as resource use. Registries, in turn, could bring the discipline of common data models and of systematic, structured data definitions and data quality to EHR-derived data. This would enable valid performance comparisons among providers, as well as the creation of large, patient-centered datasets that track individuals across diseases and procedures and over time. In the future, registries could also be used as platforms for multicenter, randomized clinical trials.^{31,32} Registries hold the potential to become data network hubs linking clinical, claims, and EHR data and could also link to patient-generated data (eg, symptoms, health status, and other patient-reported data). This will enhance capabilities in the conduct of comparative-effectiveness research, safety surveillance, and clinical quality improvement, as well as in providing meaningful feedback to clinicians on their performance.

3. Unrealized Opportunities to Leverage Clinical Registries for Performance Measurement

3.1. Limited Intersections of Clinical Registries and Performance Measure Development

Among professional societies and organizations that have developed clinical registries, there is wide variation in the degree to which these registries are integrated with the organizations’ corresponding performance measurement initiatives. Registry operations and performance measurement are increasingly complex, technically sophisticated activities that require specialized skills, and the synergy between them may not always be appreciated by external stakeholders.

Registries collect protected health information and thus must adhere to privacy and informed-consent regulations. Registry stewards must also engage in contractual relationships with database participants, data warehouses and analytical centers, vendors, and third parties, with whom data may be shared under specific circumstances. Registry operations are supervised by paid staff and volunteers who oversee a complex array of database functions, including data element specifications, data security, privacy, data harvests, data quality checks and audit, feedback reports to participants, and data manager support.

Performance measurement is also technical and requires a combination of clinical and statistical knowledge about matters such as risk adjustment.^{33,38–40,71–78} Even after measures are developed, they must be pilot-tested and then, ideally, submitted to organizations such as the NQF for endorsement. The submission process requires demonstration of importance, evidence base, scientific acceptability, usability, and feasibility, all of which entail specific technical knowledge and sophisticated analytics.⁷⁹ Ultimately, measures may be reported publicly in a scientifically credible yet consumer-friendly format, with such “report cards” potentially having significant implications for reputation, referrals, and reimbursement.

If one accepts that clinical registries are a highly reliable clinical data source, the close interaction between registry and performance activities is obvious. As the requirements for endorsement of quality measures for the purposes of public reporting have changed, the relationships between registries and performance measurement activities within professional organizations have also evolved. For example, in the past, performance measures developed by the ACC and AHA emanated from the ACC/AHA Task Force on Performance Measures. Performance measurement was viewed as distinct from registry operations and had its own full-time and volunteer staff. Typically, the topics chosen for performance measurement reflected cardiovascular conditions and procedures with perceived gaps in care, as well as the clinical interests of constituencies within the organization. ACC/AHA task force work groups were challenged in assessing issues of measure implementation. Measure implementation has been assisted by registries, including the PINNACLE Registry and TGA, both of which were developed as means of putting ambulatory performance measures into practice.

As the requirements for measurement endorsement have grown to include measures that not only have strong evidence

but also have been tested for validity and feasibility of implementation, this model of exclusively work group–driven measurement development has become less practical. For example, GWTG and some NCDR registries have developed comprehensive sets of quality metrics, yet the development, validation, and oversight of those measures have been conducted largely independently of the ACC/AHA Task Force on Performance Measures. Increasingly, measures have begun to emanate directly from the registries because implementation and validation are integral to registry operations. As the model for measure development within the professional organizations evolves, it will be important to ensure that the process includes the appropriate methodological support to guarantee the validity and reliability of measures.

At the other end of the spectrum, organizations such as the STS have historically included the “downstream” by-products of clinical registry data (eg, performance measurement, public reporting, quality improvement) as part of their database portfolio. Indeed, performance measurement is the focus of the STS Quality Measurement Task Force within the larger STS National Database structure. Some Quality Measurement Task Force members have methodological expertise in provider profiling (eg, statisticians with a special interest in provider profiling). Other surgeon members serve in a variety of database activities and have helped to design database elements that are used to construct performance measures. Involvement of statisticians, other profiling experts, and clinical surgeons, as well as highly competent staff, ensures that measures derived from registries are scientifically sound and clinically valid. Measures are thereby well designed to both meet the requirements of organizations such as the NQF and be acceptable to the surgeons being measured. In fact, all end users should be involved in the design and development process, especially consumers and payers, with their input incorporated from the beginning.

3.2. Challenges and Barriers to Better Integration of Registries and Performance Measure Development

To develop optimal performance measures on the basis of clinical registry data, professional societies and other organizations will first have to overcome the barriers to implementing and maintaining their own clinical data registries. As evidenced by substantial gaps in the disciplines covered by healthcare registries, there are significant barriers to starting a new registry. These include the need for dedicated full-time staff, software vendors, data warehouses, and analytical centers. In addition, registries must generally rely on a cadre of committed volunteer physician leaders who develop and periodically revise data elements and oversee registry operations. In the early stages of registry implementation, when participation levels are lower, fixed costs may exceed revenues, and societies must be willing to view these early losses as an investment in the future. Government or commercial support for both nascent and established registries would be invaluable. As participation levels grow, clinical registries can become self-sustaining.

Other practical issues are also a challenge to more widespread implementation of registries and their use in developing performance measures. For example, with the exception of a few

areas, such as cardiovascular medicine and surgery, little effort has been made to standardize data element definitions across registries. This lack of standardization can produce confusion, with postoperative kidney failure potentially meaning 1 thing for a patient having heart surgery and quite another for patients having neurosurgery or orthopedic surgery. Additionally, lack of standardization creates barriers to moving beyond the narrow focus of procedure- or diagnosis-specific registries to more broad-based, linked registries that embrace the entire spectrum of care experienced by most patients. Widely accepted data quality standards are also lacking, despite the fact that such standards are 1 of the most important features of any registry. Any registry that does not have regular external audit programs demonstrating high accuracy, such as those used in the STS National Database^{29,34} and NCDR registries,^{61,70} should not be the basis for performance measures.

Together, the time frame required for data collection and the nature of the outcomes collected constitute another barrier to more effective use of registries. Currently, most clinical registries collect clinical data during the period of hospitalization or within 30 days after discharge; however, stakeholders increasingly want information on longer-term outcomes (eg, survival, late complications, readmissions, reinterventions, and functional status), as well as nonclinical data, such as total costs. These data are difficult and prohibitively expensive for registries to collect primarily, but they can often be obtained by linking clinical registries to claims sources, such as those available from the government (eg, Medicare Provider Analysis and Review) and industry. As noted previously, integration of EHR data into registries or ambulatory registries such as PINNACLE, which extracts data from EHRs rather than requiring data abstraction,⁷⁰ would be alternative approaches to the challenge of longitudinal patient tracking.

Finally, the growth of EHRs is both a challenge and an opportunity with regard to the potential use of clinical registries for performance measure development. The largest single cost to hospitals for clinical registries is that of data management personnel. Registry stewards consider the expertise and dedication of these individuals to be crucial aspects of registry operations, and they are a major reason why registry data are more accurate and granular than claims data; however, as hospitals increasingly use EHRs, they understandably would prefer to automatically extract some registry data elements directly from EHRs rather than having to enter them manually. For some data, such as laboratory results, dates of service, and demographics, automatic extraction is feasible; however, extraction from EHRs of many of the more detailed elements in clinical registries will require the personnel administering these 2 data sources to work collaboratively on structured data element definitions or to blend electronic data abstraction with manual abstraction of nonextractable concepts. It will be essential to ensure that these data elements are collected by EHRs with the same rigorous attention to detail as displayed by clinical registries.

4. Envisioning the Future State of Registries

4.1. Why the Profession Should Define Quality Care

The explosion of clinical registries over the past decade was catalyzed both by the need to test the feasibility of measuring

and implementing performance measures and by a national focus on evidence-based medicine. Even with the growth in the number of registries, there are still broad clinical areas and specific procedures for which registries do not currently exist but would be highly beneficial. Today, registries not only report a site's performance but can also quantify site variations in performance. Because registries collect data from a broad spectrum of providers, timely feedback reports provide a means for hospitals and individual clinicians to evaluate their performance against local, regional, or national benchmarks for excellence, thus stimulating further improvement.

More recent advances in linking registry data to Medicare and insurance claims have transformed registries into dynamic entities with the ability to not only assess but also inform the development of new performance measures.^{80,81} Patients, clinicians, and stakeholders are increasingly focused on clinical outcomes (and variations in outcomes across sites) as the key markers of quality of care. The structure adopted by many contemporary registries (longitudinal vital status and readmission information; platform for feedback to clinicians, sites, and physician champions) offers substantial advantages over other modalities of data collection and positions them as entities that can both measure and help define high-quality care.

4.2. Addressing the Current Challenges

Nonstandard terminology and financial and knowledge barriers have prevented many professional societies and organizations from developing clinical registries and many hospitals from implementing them. These challenges may seem overwhelming, but some have been successfully addressed at local and regional levels and within specific specialties. Broad dissemination of the lessons learned from these successes, augmented by creative thinking, can lead to new and improved clinical registries.

Standardization of data elements facilitates the linking of registries within and across specialties. Although the International Classification of Diseases–9 and –10 codes provide a common language, they often do not provide the specificity and clinical granularity necessary for many quality initiatives. Therefore, more detailed terminology and definitions need to be developed. For example, the International Pediatric and Congenital Cardiac Code provides a detailed, standard nomenclature for diagnoses and procedures that is used by databases developed by multiple societies and organizations serving the population with congenital cardiac disease. These include the European Society Association for Cardio-Thoracic Surgery, Association for European Pediatric Cardiology, STS, ACC, and Virtual Pediatric Intensive Care Unit.⁸² Similar common nomenclatures for other diseases will support the development of new databases because these nomenclatures can be imported rather than developed *de novo*, and linking of databases will be facilitated by providing common terms and definitions. In addition, the adoption of such nomenclatures into administrative databases, such as the inclusion of the International Pediatric and Congenital Cardiac Code in International Classification of Diseases–11, will allow the strengths of administrative data to be better used for quality improvement. The collection of long-term patient data, including both data on patient experience of care

and patient-reported outcomes, is complex and costly, yet is increasingly important. The linking of clinical registries to administrative databases is a valuable approach that could be more useful if nomenclature were shared. Linking registries to claims data and other longitudinal data sources, such as EHRs, enables the creation of datasets of patients with chronic diseases that can be followed over many years, supporting the development of population-based measures and measures of care processes.⁸³

Cost is a barrier to the development and implementation of clinical registries. Although there is an initial cost to societies and organizations, clinical registries can become self-sustaining over time. All parties that benefit from analyses of registry data should provide the financial support required for registry development and ongoing operations. This includes payers, who should provide both direct and financial support to registries and to hospitals and clinicians who participate in recognized registries, thus making participation economically feasible. The reimbursement system should reward physician and hospital practices that improve patient care and manage cost appropriately. Success stories need to be shared to encourage those contemplating the development of registries. Because hospitals may be reluctant to implement new registries in a time of aggressive cost containment, the role of registries in clinical care improvement and the subsequent financial benefit should be emphasized. One example of such work is the Virginia Cardiac Surgery Quality Initiative.⁸⁴ This voluntary consortium of 17 hospitals and 13 cardiac surgical practices in Virginia not only identified quality improvement opportunities and tracked patient outcomes, but also found opportunities for cost containment, such as improved patient outcomes and decreased resource utilization associated with the implementation of a blood conservation guideline.⁸⁵ From 2006 to 2011, cardiac surgery practices that participated in the Virginia Cardiac Surgery Quality Initiative and Anthem Blue Cross Blue Shield received augmented payments and contracted rates that were on the basis of adherence to clinical and process metrics derived from performance measures from the STS Adult Cardiac Surgery Database. Similar experiences in Michigan were funded by Blue Cross Blue Shield of Michigan and more than paid for their investment.^{86,87} The Michigan Society of Thoracic and Cardiovascular Surgeons Quality Collaborative is a voluntary data and quality collaborative that uses the STS Adult Cardiac Surgery Database.⁸⁶ This pay-for-participation model is funded partially by Blue Cross and Blue Shield of Michigan. The opportunities provided for cost containment, as well as financial incentive programs supported by payers, can help defray the cost of implementing and maintaining clinical registries.

Clinical registries should interface with EHRs when possible. Because data collection is time consuming and costly, any opportunity to reduce effort and cost while maintaining data quality should be pursued. The standardization of data elements will enable the linking of registries with EHRs and allow for automated extraction of some data elements from the patient's record for the purposes of longitudinal follow-up and performance measure calculation. This will minimize manual data entry requirements and adverse effects on clinical workflow.

The use of EHRs has resulted in an emphasis on administrative and billing practices, through which EHR data are often obtained. Less attention has been paid to how clinical registries and quality initiatives can help improve care for patients by tracking data across payers and identifying areas for which care can be improved.

Both newly developing and more mature registries should share with and learn from each other. The National Quality Registry Network (NQRN),⁸⁸ formed by the American Medical Association–convened Physician Consortium for Performance Improvement, was established for this purpose. The NQRN is a voluntary network of private and public stakeholders that is intended to develop and improve clinical registries for quality initiatives. The ACC and the STS participate in the NQRN, which provides a venue for collaborative learning with other specialty societies that have developed registries, such as the American Academy of Orthopedic Surgeons,⁸⁹ the American Gastroenterological Association,⁹⁰ and the American Urological Association.⁹¹

The NQRN is intended to facilitate knowledge sharing between those who have mature registries and those in the development phase. Because the NQRN is a multi-stakeholder organization, end users of registries will have considerable input. Because the NQRN brings together registry stewards such as professional societies and registry users (including hospitals, insurance companies, and the federal government), issues such as public reporting, potential business models, and mutually beneficial registry content can be discussed. Additionally, patients, family caregivers, and consumers can also be involved in this discussion. Through mentoring and providing a forum to share templates, the NQRN plans to assist emerging registries, develop data and quality standards for all registries to ensure interoperability, help design sustainable business models, identify areas where registry data can be applied to quality initiatives, and work toward the extraction of some registry data from EHRs.

4.3. Role of Clinical Registry Infrastructure/Registries in Performance Measure Development

4.3.1. Identifying Gaps in Care and New Areas for Performance Measure Development

Clinical registries are at the center of the cycle of quality improvement, as depicted in Figure 1.⁹²

Clinical registries can inform guidelines and performance measure development by showing where contemporary patterns of care are not consistent with existing evidence-based recommendations. To have value as a performance measure, a treatment should be evidence based and linked to patient outcomes; additionally, there should be gaps in current usage. Conversely, clinical registries can also help demonstrate that it is time to sunset an existing performance measure if utilization of the treatment approaches 100%.

Additionally, registries can play important roles in addressing gaps in care related to healthcare disparities. The ACC and AHA have identified the evaluation of healthcare disparities involving racial and ethnic minorities, women, the elderly, individuals with multiple comorbidities, and individuals with congenital heart conditions as an important focus for

applying registry data.⁷² Registries have indeed proved useful in quantifying differences in care and clinical outcomes in various subpopulations, providing clinicians and other stakeholders with the necessary data infrastructure for using performance measures in evaluating efforts to correct identified disparities.^{93–99}

Beyond establishing the community need for a performance measure, clinical registries can assist in the technical development and optimization of a performance measure.⁷¹ Registries can demonstrate how various definitions for numerators and denominators, as well as exclusions, affect the performance measure. They can also help in evaluating whether the measure can be collected consistently across various sites and settings. Validation of a measure's reproducibility is necessary before a performance measure can be recommended for benchmarking provider performance. Additionally, clinical registries can help in evaluating how feasible it is for providers to collect a performance measure in routine clinical practice. Such feasibility testing includes assessing whether the measure can be collected routinely and with reasonable effort and cost. In fact, the NQF now requires evaluation of measure reproducibility, validity, and feasibility within a clinical registry or across multiple sites before a measure may be considered for their national performance measure recommendation. Inclusion of a performance measure within a clinical registry therefore provides not only an excellent means of developing and evaluating a new performance measure, but also an ongoing mechanism for continued refinement. Of vital importance, clinical registries can be used to evaluate the process–outcome link for process-based performance measures. When no such association is found, those measures of processes that do not directly improve outcomes can be considered for retirement or can be revised.^{100,101} Registry data have also been used to develop and validate robust risk-adjustment models to report outcomes measures that account for case mix.^{29,38–40,102–104}

4.3.2. Informing the Development of the Next Generation of Performance Measures: More Focused on Outcomes and Symptom Management and Based on Real-World Data

Increasingly, public and governmental agencies are requesting that performance measures focus more on patient clinical outcomes and patient-reported symptoms, physical function, and quality of life.^{71,72,105} Current registries typically collect information on patients' symptoms, but these assessments

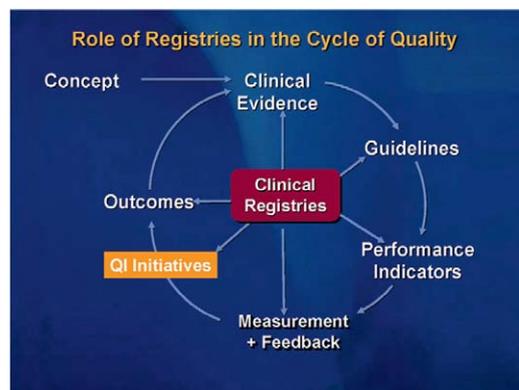


Figure 1. The Role of Registries in the Cycle of Quality. Adapted from Califf et al.⁹² QI = quality improvement.

are often not collected directly from the patient, nor do they use standardized instruments or methods. Clinical registries must adapt to collect patient-centric performance measures. The development of novel electronic tools for collecting standardized, patient-reported outcomes will assist this process. Capturing patient-generated data may also facilitate better communication between patients and clinicians and greater patient/family engagement in the care process.

Clinical registries typically collect clinical outcomes (complications, death) in a cross-sectional manner (eg, in hospital or over a period of 30 days), but there is growing value in understanding longer-term patient outcomes. Collection of longitudinal outcomes by clinical registries has been facilitated by linking these traditional databases with claims information^{28,29,80,81} and other outpatient clinical registries.

To be interpreted meaningfully, outcome-based performance measures should be adjusted for potential differences in the types of patients treated by various providers. Specifically, it is important to determine the degree to which any differences in outcomes seen among providers are due to true differences in care quality rather than differences in patient characteristics. Clinical registries can be a means of accurately collecting data on patient demographics, socioeconomic status, disease severity, and concomitant comorbid illness. Adjustment for socioeconomic status is now being studied by the NQF for certain measures, such as readmission, that are affected by factors that are not entirely within the control of the hospital and could affect outcomes.¹⁰⁶ Additionally, the data contained in large registries provide an adequate sample size for developing and validating the statistical models required for risk adjustment of performance measures.

4.3.3. Publicly Reporting Measure Results

For the first 30 years of their existence, most society-based clinical registries were used to generate confidential feedback for providers; however, in 2002, the CMS implemented the "Hospital Compare" web site, which provided the public with hospital-level process and outcome performance measure data for multiple common conditions.¹⁰⁷ This, along with some state and payer initiatives, ushered in the era of public provider reporting. In 2010, the STS began to voluntarily publish coronary artery bypass graft procedure performance measure data in *Consumer Reports* and on the STS web site.¹⁰⁸ Within the first 3 years of the initiation of the program, nearly one-half of STS participant hospitals had agreed to share their data publicly via this mechanism.¹⁰⁹ Similarly, the ACC has published a health policy statement defining 6 core principles of public reporting and has initiated a pilot program for voluntary, hospital-level public reporting.¹⁰⁵

4.4. Continuing Role for Performance Measure Developers

Developers of performance measures will continue to play an important role in creating methodology, identifying writing committees, and obtaining peer review and endorsement for their measures. Criteria for acceptable performance measures, such as those published by the ACC and the AHA,^{71,72,110-113} describe how candidate measures are selected, developed, and used (eg, for public reporting or internal quality improvement).

Only those guideline recommendations that are valid, actionable, measurable, and of acceptable value (eg, cost-effective care), should be considered as the basis for public reporting and pay-for-performance measures. If developers believe a measure does not meet all of these criteria, they will recommend that it be used for quality improvement only,¹¹² at least initially.

Developers may continue to submit their measures to an endorsing body such as the NQF. Endorsement often requires that developers provide evidence that a gap in care exists, that the data for the measure can be obtained, and that the measure can be reported back to providers. Developers may also seek to have measures adopted by federal, state, or private payers without having these measures endorsed by an entity such as the NQF. For example, numerous measures used in the Qualified Clinical Data Registry for PQRS reporting are not currently endorsed by the NQF but were determined by the CMS to be important for determining physician performance. Ultimately, developers of performance measures will rely on registries to provide these data on the existence of gaps in care and evidence that the performance measure can be calculated and presented to the relevant stakeholders.

Once developed, a performance measure will need to be maintained by developers through periodic reviews of published data and guidelines to ensure that the measure remains relevant to clinical practice. Developers will need to demonstrate to clinicians and administrators: 1) that the measure has value; and 2) that the measure has led to an improvement in care and patient outcomes. A measure developer may solicit public comment and, through this mechanism, try to secure feedback from patients, consumer organizations, and payers on new or revised versions of measures. Registries will play an important role in documenting any change in practice or outcome after the implementation of a new measure.

Developers of performance measures will also be expected to promote their measures to health systems (eg, hospital networks) and payers (eg, CMS). Measure developers may also seek to work with consumer organizations on how best to educate consumers about why the measures are important to consumers. Fortunately, such measure-promotion efforts will be synergistic with registry-promotion activities. Through advocacy for wider measure adoption, developers can simultaneously promote use of their performance measures and the registries that report those measures, thereby furthering the goals of patient-centered care.

5. Summary

The futures of registries and performance measurement are intertwined. The worldwide role of registries as tools to capture and analyze data will increase, and the parallel demand for performance measures will result in preferential use of these data because they are more credible and widely accepted than other sources and can be more fully risk adjusted. The nexus of clinical registries and performance measures will become even more important as risk-adjusted outcomes data are used for high-stakes applications, such as public report cards, preferred provider networks, and reimbursement. When feasible, limitations of clinical registries, such as their data collection burden, must be mitigated by automatic extraction of some data elements from

EHRs. This will be possible only for those variables for which the integrity of clinical registry content will not be compromised by automatic EHR data extraction. Similarly, the value of clinical registries, the data of which historically have been limited to short-term outcomes, will be enhanced through linkages with other data sources, such as claims data. Sources such as claims data can provide information on long-term outcomes, resource use, rehospitalizations, and reinterventions. These linkages will require methods for identifying patients across data sources. Also needed is clarification by the federal government of Common Rule and Health Insurance Portability and Accountability Act regulations, because lack of clarity in these rules sometimes dissuades providers from submitting data.

By measuring and reporting registry performance to clinicians, individual sites, and integrated healthcare networks, as well as publicly reporting when appropriate, registries will be able to influence care profoundly. This will include iterative changes occurring as a result of routine, nationally benchmarked feedback reports, as well as randomized clinical trials embedded into ongoing registries, such as the TASTE (Thrombus Aspiration in ST-Elevation myocardial infarction) trial, which was performed in the Swedish Coronary Angiography and Angioplasty Registry,^{31,32} and the SAFE PCI for Women (Study of Access Site for Enhancement of PCI for Women) study, which used the NCDR's CathPCI Registry.¹¹⁴ Measuring and reporting registry performance data would facilitate the empirical determination of specific process-improvement strategies that result in improved patient-centered outcomes. As clinical registries cover progressively more of the healthcare landscape and are supplemented by additional data from EHRs, claims databases, and other data sources (eg, industry databases, patient-reported information from personal health records and websites ["big data"]), we will benefit from insights into real-world practice that have not yet been possible, ultimately improving healthcare delivery and patient outcomes.

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KEY WORDS: AHA Scientific Statements ■ health policy and outcome research
■ quality indicators ■ registries

Appendix A. Author Listing of Relationships With Industry and Other Entities (Relevant)-ACC/AHA/STS Statement on the Future of Registries and the Performance Measurement Enterprise

Name	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Deepak L. Bhatt, Chair	Brigham and Women's Hospital, Harvard Medical School	<ul style="list-style-type: none"> • DCRI: Bristol-Myers Squibb/Pfizer • DCRI: Eli Lilly • DCRI: Novartis* 	None	None	None	<ul style="list-style-type: none"> • DCRI: Data Safety Monitoring Board† 	None
Joseph P. Drozda, Jr., Co-Chair	Mercy Health—Director, Outcomes Research	None	None	None	None	None	None
David M. Shahian, Co-Chair	Massachusetts General Hospital—Director of Research, Center for Quality and Safety	None	None	None	None	None	None
Paul S. Chan	Mid America Heart Institute—Assistant Professor of Cardiology	None	None	None	None	None	None
Gregg C. Fonarow	Ahmanson-UCLA Cardiomyopathy Center—Director, Division of Cardiology	None	None	None	None	None	None
Paul A. Heidenreich	Stanford VA Palo Alto Health Care System—Professor of Medicine	None	None	None	None	None	None
Jeffrey P. Jacobs	Cardiac Surgical Associates	None	None	None	None	None	None
Frederick A. Masoudi	University of Colorado at Denver—Professor of Medicine, Division of Cardiology	None	None	None	None	None	None
Eric D. Peterson	Duke Clinical Research Institute—Professor of Medicine	None	None	None	None	<ul style="list-style-type: none"> • DCRI† 	None
Karl F. Welke	Children's Hospital of Illinois	None	None	None	None	None	None

This table represents the relationships of committee members with industry and other entities that were determined to be relevant to this document. These relationships were reviewed and updated in conjunction with all meetings and/or conference calls of the writing committee during the document development process. The table does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of ≥5% of the voting stock or share of the business entity, or ownership of ≥\$10 000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted.

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*Significant (>\$10 000) relationship.

†DCRI has numerous grants and contracts sponsored by industry. These include the following: Aastrom Biosciences,* Abbott,* Abiomed,* Acom Cardiovascular,* Adolor Corp.,* Advanced Cardiovascular Systems,* Advanced Stent Technologies,* Adynxx,* Ajinomoto,* Allergan,* Amgen,* Alnylam Pharma,* Alpharma,* Amylin Pharmaceuticals,* Anadys,* Anesiva,* Angel Medical Systems,* ANGES MG,* Angiometrix,* APT Nidus Center,* ASCA Biopharma,* Astellas Pharma,* Asklepios,* AstraZeneca,* Atritech,* Attention Therapeutics,* Aventis,* Baxter,* Bayer,* Berlex,* BG Medicine,* Biogen,* Biolex Therapeutics,* Biomarker Factory,* Biosite,* Boehringer Ingelheim Biogen,* Boston Scientific,* Bristol-Myers Squibb,* BMS Pfizer,* Carbomed,* CardioDx,* CardioKinetix,* Cardiovascular Systems,* Cardiovox,* Celsion Corp.,* Centocor,* Cerexa,* Chase Medical,* Conatus Pharmaceuticals,* Conor Medsystems,* Cortex,* Corgentech,* CSL Behring,* CV Therapeutics,* Daiichi Pharmaceuticals,* Daiichi-Sankyo,* Daiichi-Sankyo Lilly,* Datascope, Dendreon,* Dainippon,* Dr. Reddy's Laboratories, Eclipse Surgical Technologies,* Edwards Lifesciences,* Eisai,* Endicor,* EnteroMedics,* Enzon Pharmaceuticals,* Eli Lilly,* Ethicon,* Ev3,* Evalve,* F2G,* Flow Cardia,* Fox Hollow Pharmaceuticals,* Fujisawa,* Genetech,* GE Healthcare,* Genzyme Corp.,* Genome Canada,* Gilead Sciences,* GlaxoSmithKline,* Guidant Corp.,* HeartScape Technologies,* Hoffman-LaRoche,* Hospira,* Idera Pharmaceuticals,* Ikaria,* Incor Pharmaceuticals,* Immunex,* INFORMD,* Inimex,* Inspire Pharmaceuticals,* Ischemix,* Janssen,* Johnson & Johnson,* Jomed,* Juventus Therapeutics,* KAI Pharmaceuticals,* King Pharmaceuticals,* Kyowa Pharma,* Luitpold,* Mardil,* MedImmune,* Medscape,* Medtronic Diabetes,* Medtronic,* Medtronic Vascular,* Merck Group,* MicroMed Technology,* Millennium Pharmaceuticals,* Mitsubishi Tanabe,* Momenta,* Nabriva,* Neuron Pharmaceuticals,* NitroMed, NovaCardia Inc.,* Novartis AG Group,* Novartis Pharmaceuticals,* Oncura,* Orexigen,* Ortho-McNeil-Janssen,* OSI Eyetech,* OSI Pharmaceuticals,* Pfizer,* Pharmacyclics,* Pharmasset,* Pharms,* Phylxus Pharmaceuticals, Pharsight,* Pluristem Therapeutics,* Portola Pharmaceuticals,* Proventys,* Radiant,* Regado Biosciences,* Regeneron Pharmaceuticals,* Roche Molecular Systems,* Roche Group,* Roche Diagnostic,* Salix Pharmaceuticals,* Sanofi-Pasteur, Inc., Sanofi-Aventis,* Santaris Pharmaceuticals,* Schering-Plough,* Scios,* Siemens,* Southwest Oncology Group,* Spectranetics,* Summit,* Sunovion Pharmaceuticals,* TAP Pharmaceutical Products,* Tengion,* The Medicines Company,* Theravance,* TherOx,* Tethys Bioscience,* Theregen,* Three Rivers Pharmaceuticals,* The EMMES Corporation,* UCB,* Valentis,* Valleylab,* Vertex,* Viacor,* and Wyeth.*

ACC indicates American College of Cardiology; AHA, American Heart Association; DCRI, Duke Clinical Research Institute; UCLA, University of California, Los Angeles; VA, Veterans Affairs.

Appendix B. Peer Reviewer Relationships With Industry and Other Entities (Relevant)—ACC/AHA/STS Statement on the Future of Registries and the Performance Measurement Enterprise

Peer Reviewer	Representation	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
John Harold	Official ACC (BOT)	None	None	None	None	<ul style="list-style-type: none"> • ABIM Foundation* • American Heart Association* 	None
Dhanunjaya Lakkireddy	Official ACC (BOG)	None	<ul style="list-style-type: none"> • Boehringer Ingelheim* • St. Jude Medical 	None	None	None	None
Richard L. Prager	Official STS	None	None	None	None	None	None
Graham Nichol	Official AHA	None	None	None	<ul style="list-style-type: none"> • Dynamic AED Registry (FDA; Philips Healthcare Inc. Physio-Control Inc., ZOLL Inc.), 2012–2015; PI* • Hypothermia Duration After Resuscitation Trial (HART) Pilot Study (Submitted to NHLBI, CR Bard Medical Division Inc., Cincinnati Sub-Zero Inc., EMCools AG, Gaymar/Stryker Inc. ZOLL Circulation Inc.; 2013–2015* • Mild hypothermia for resuscitated out-of-hospital cardiac arrest patients (R01-HL089554-01), 2007–2013; Co-I • Randomized Trial of Hemofiltration After Resuscitation from Cardiac Arrest (NHLBI R21 HL093641-01A1), 2009–2011; PI • Resuscitation Outcomes Consortium (National Institutes of Health U01 HL077863-05), 2004–2010; Co-PI† • Sotera Wireless, San Diego, California • Velocity Pilot Study of Ultrafast Hypothermia in Patients with ST-elevation Myocardial Infarction (Velomedix Inc.), 2012–2014; PI (waived personal compensation) • Washington Study of Ultrasound in Resuscitation (Philips Healthcare Inc.), 2013–2014; PI* 	<ul style="list-style-type: none"> • Medic One Foundation* • Novel method of tracking location of monitor/defibrillators in time and space* 	None
Randal J. Thomas	Content AHA GWTG Steering Committee	None	None	None	None	None	None
Martha Radford	Content NCDR Management Board	None	None	None	None	None	None
Debra Ness	Content: National Partnership for Women and Families	None	None	None	None	None	None
Frederic Resnic	Content: NCDR Science and Quality Oversight Committee	<ul style="list-style-type: none"> • St. Jude Medical 	None	None	None	<ul style="list-style-type: none"> • FDA† • National Institutes of Health† 	None

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*No financial relationship.

†Significant ($> \$10\,000$) relationship.

ACC indicates American College of Cardiology; AED, automated external defibrillator; AHA, American Heart Association; BOG, Board of Governors; BOT, Board of Trustees; Co-I, co-investigator; FDA, Food and Drug Administration; GWTG, Get With The Guidelines; NCDR, National Cardiovascular Data Registry; NHLBI, National Heart, Lung, and Blood Institute; PI, principal investigator; STS, The Society of Thoracic Surgeons.

ACC/AHA/STS Statement on the Future of Registries and the Performance Measurement Enterprise: A Report of the American College of Cardiology/American Heart Association Task Force on Performance Measures and The Society of Thoracic Surgeons

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ACC/AHA/STS Statement on the Future of Registries and the Performance Measurement Enterprise

Name	Employment	Consultant	Speaker	Ownership/ Partnership/ Principal	Registries	Research	Salary	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Deepak L. Bhatt, <i>Chair</i>	Harvard Medical School, Brigham and Women's Hospital	<ul style="list-style-type: none"> • Elsevier Practice Update Cardiology • Population Health Research Institute • DCRI: Novartis † • DCRI: Bristol-Meyers Squibb/Pfizer • DCRI: Eli Lilly 	None	• None	Chair, AHA GWTG Steering Committee* REACH Registry co-Chair	<ul style="list-style-type: none"> • Roche† • FlowCo* • Amarin† • Medtronic† • Takeda* • PLx Pharma* • Astra Zeneca† • The Medicines Co. † • Sanofi Aventis† • Ethicon† • Eisai † • Bristol Myers Squibb† 	None	<ul style="list-style-type: none"> • Advisory Board: Elsevier Practice Update Cardiology • Associate Editor-Clinical Cardiology* • Belovoir Publications † • Regado Biosciences-Advisory Board * • Journal of Invasive Cardiology † • Medscape Cardiology-Advisory Board* • WebMD Steering Committee† • Slack Publications/Cardiology Research Foundation: Editor† • Harvard Clinical Research Institute: Boehringer Ingelheim • Harvard Clinical Research Institute: St. Jude • Mayo Clinic: DSMB • DCRI: DSMB ‡ • Society of Chest Pain Centers • Boston VA Research Institute: Novartis • 	None
Joseph P. Drozda, Jr., <i>Co-Chair</i>	Mercy Health— Director, Outcomes Research	None	None	None	<ul style="list-style-type: none"> • Member, NCDR Management Board 	None		<ul style="list-style-type: none"> • Boston Scientific Rhythm Management† • PCPI* 	None
David M. Shahian, <i>Co-Chair</i>	Massachusetts General Hospital— Director of Research, Center for Quality and Safety	None	None	None	<ul style="list-style-type: none"> • Chair, STS Database Committee • National Quality Registry Network 	<ul style="list-style-type: none"> • STS* 		<ul style="list-style-type: none"> • ACCF/AHA Task Force on Performance Measures* • STS* 	None

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*No financial relationship.

†Significant (greater than \$10,000) relationship.

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ACC indicates American College of Cardiology; AHA, American Heart Association; DCRI, Duke Clinical Research Institute; UCLA, University of California, Los Angeles; and VA, Veterans Administration.

