The explosion of cardiovascular registries during the past 2 decades has been remarkable but not surprising. Registries have become an important component of current quality initiatives that were started after the Institute of Medicine’s call in 1999 for the United States to better address the quality of care. Three important publications ensued, including the report “Crossing the Quality Chasm” in 2001. Several national efforts—including establishment of standards of care through guideline development, performance measures, public reporting, and appropriate use criteria—have been initiated as a result and now are part of our daily lives.

Prospective registries gained in popularity when they were components of randomized trials. Their intent was to determine the relevance of randomized trials in relation to real-world practice. In the case of the Coronary Artery Surgery Study (CASS), a randomized trial of bypass surgery versus medical therapy done in the 1980s, the registry component demonstrated that the findings of the randomized trial were generalizable and provided additional insights into subgroups not treated in the randomized trial. Local databases, such as the Duke database, were early pioneers in the field, which were followed by regional and national registries, such as the NHLBI PTCA Registry in 1980. It was the Cooperative Cardiovascular Project started by the Health Care Finance Administration (Centers for Medicare & Medicaid Services [CMS]) in the early 1990s that was the first to measure quality in large patient populations with acute myocardial infarction (AMI). In 1987, the American College of Cardiology (ACC) established the National Cardiovascular Data Registry (NCDR) to define the clinical characteristics and outcomes of patients undergoing cardiac catheterization and coronary interventions. The New York State Cardiac Registry started in 1988 to assess quality and outcomes in percutaneous coronary intervention (PCI) and coronary artery bypass graft. The largest and most successful national registry has been The Society of Thoracic Surgery (STS) registry, which was established in 1989 and now has >5.8 million surgical cases and 90% of all adult cardiac surgical centers participating. Participation in the NCDR also has grown rapidly; >1500 US hospitals and 12 million patients records are now part of the database. The ACC’s NCDR includes 11 voluntary registries (9 inpatient and 2 outpatient registries). Other cardiology organizations, such as the European Society of Cardiology (ESC), maintain their own voluntary registries that number 13 (Figure). Comparing the NCDR with the European registries, the ACC’s is more general and the ESC’s are more focused.

The importance of registries to the quality effort is clear. Registries provide data on what we are actually doing in everyday practice and form a cornerstone for all quality initiatives. A recent statement from the ACC/American Heart Association/STS on the future of registries is a thorough and thoughtful description of the current status and future opportunities for national registries. The benefits include measurement of performance criteria, determination of guideline adherence, estimation of compliance with appropriate use criteria, and measurement of safety and outcomes. The statement provides data for public reporting and physician-quality reporting. For new devices such as transcatheter aortic valve replacement, the registries provide postmarketing surveillance. It has been suggested that the registries may provide a new way to collect data for randomized clinical trials or could be a means to conduct sequential trials of new treatments such as are conducted at cancer centers.

There is no question that there are many positive attributes associated with prospective observational registries, but there are clearly shortcomings as well. One is the growing number of registries. New registries are being added every few months. At Brigham and Women’s Hospital, we currently participate in 6 registries, including the STS, STS/ACC TVT (Transcatheter Valve Therapy), the CathPCI, the Implantable Cardiac Defibrillator (ICD) Registries and 2 state registries. The state of Massachusetts requires registry reporting for cath/PCI and for cardiac surgery. We anticipate that we will be joining the Peripheral Vascular Intervention (PVI) and the Atrial Fibrillation Ablation (AFib Ablation) Registries and, perhaps, the Left Atrial Appendage Occlusion (LAAO) Registry. Although we have submitted some of the required data elements from our electronic medical records (EMRs) and hope to capture more in the future, much of the needed information is manually extracted and validated by nurse abstractors, data managers, and study coordinators. We have 6 full-time staff in performing these tasks and, currently, we do not receive direct compensation for this work from any of the registries. This means that the institution must bear the cost, and they do so reluctantly.

One of the key limitations is the redundancy of collecting similar data for many of the registries, compounded by differing definitions among registries. For example, cerebrovascular disease, diabetes mellitus, and dyslipidemia are different...
Figure. Cardiovascular registries sponsored by the American College of Cardiology (ACC) and European Society of Cardiology (ESC): ACS indicates acute coronary syndrome; AFib, atrial fibrillation; CV, cardiovascular; GWTG, Get With The Guidelines; ICD, implantable cardiac defibrillator; NCDR, National Cardiovascular Data Registry; PCI, percutaneous coronary intervention; and STS, The Society of Thoracic Surgery.

Among the PCI, ICD, and STS registries, we cannot rely on physician or house staff reporting in the electronic medical record (EMR) because they are unaware of the different definitions and cannot be expected to know the differences. The lack of standardized definitions across all registries is a major national problem and will limit the use of EMRs as a means to more easily complete registry requirements.

Another problem is that when patients are admitted from other hospitals, they are transferred with limited data and often have minimal or no information in our EMR. This requires nurse abstractors, data managers, and coordinators to request records, and talk to the patient, family, and referring physician to obtain the correct information to complete the registry forms. Oftentimes, this information is difficult or unable to be obtained.

Another limitation is that the forms collect a substantial amount of data (often >80 individual items), and it is unclear that all of the required data are useful. Performance measures and appropriate use criteria are limited to specific data elements that can be collected accurately and reliably and are meaningful as a measure of quality. Currently, there are only 12 cardiovascular performance measures required by the CMS (eg, 30-day mortality for myocardial infarction and heart failure, aspirin use for AMI, angiotensin-converting enzyme use for left ventricular systolic dysfunction, β-blocker use for AMI, lytics within 30 minutes for AMI, PCI for AMI within 120 minutes, smoking counseling, and assessment of LV function). Thus, most of the registry data relate to the patient’s baseline characteristics, previous treatments, and outcomes. These data elements provide useful clinical information and better characterize the patients who are included in the registry, but some are not of help in better defining quality. The reliability of these finer details could also be questioned.

Because more registries are added, the workload increases proportionally. Limiting the data to be reported to only the essential components is one solution to the growing demands placed on the hospitals and physicians. Similar problems exist in those registries that require long-term follow-up.

Although the quality of registry data has been studied, accurate data can only be obtained by careful and meticulous data cleaning and verification. Quality audits in the NCDR show a range of 85% to 95% accuracy of data abstraction. Underreporting of adverse events or missing data is a concern. The audits assume that the record is accurate. If the data in the medical record are incorrect or missing, then this assessment overestimates their accuracy. Although this degree of accuracy may be adequate for many aspects of quality programs, it would not be for many of the efforts, such as determining mortality or morbidity. The STS database has been a model for registry data. However, when STS registry hospitalizations were matched against CMS hospitalizations, there was only a 45% agreement in 2000. This agreement fortunately increased to 98% in 2012. Likewise, linking the Social Security database for 30-day mortality with the STS registry showed good concordance for in-hospital death, but 30-day death was only 60% sensitive. This has implications when 30-day death rate is a quality performance measure.

Registries are now required and will increase in the future. We need to make sure it is accurate, easier to collect, and ideally automated by integration into the EMR. We need to urge the ACC and STS, and other organizations, to develop standardized definitions that apply to all registries. A national advisory board should be established to oversee the registry development and to ensure that the critical information is collected in a uniform and accurate way. The registries should come together to limit the data to key elements that have been demonstrated to measure quality, as well as to include enough additional information to adequately describe the patients who are being treated. When data elements are not used, they should be removed from the forms. The problem of incomplete follow-up should be resolved with ongoing measurement of accuracy.

Although registries have focused on compliance with guideline-recommended treatments, we are missing an opportunity to understand the factors that lead to complex medical decisions so we can improve the guideline recommendations. It is much more interesting why a physician decided not to follow the usual recommendations in the care of a patient. Many times, the reason is sound and justifiable. Medicine is complicated and often the clinician balances multiple factors when determining a specific therapy. We can learn a lot when we understand why guidelines, performance measures, or appropriate use criteria do not apply to an individual patient rather than when they do.

The Standardized Clinical Assessment and Management Plans (SCAMPS) program is an example of how the exceptions are more important than the rules and how we can use the exceptions to shape guidelines. In this program, standardized clinical pathways are developed by consensus, and treatments are recorded. If a physician deviates from the pathway, the physician is asked to explain the reason for deviation. Periodically, a panel of physicians reviews these exceptions and, if the exception is reasonable and common, the pathway is revised to reflect actual practice. Thus, the guideline is continually improved. If this type of feedback was part of data
collection, then we could improve not only the guidelines but also performance measures and appropriate use criteria.

Although data are great, how we interpret and use the data is most important. Good clinical care assesses the data using judgment and wisdom. Sometimes, the data are rejected or questioned because they do not fit with the clinical situation or other pieces of information about the patient. Quality care is data and good clinical judgment combined. It is difficult to measure, but you know it when you see an experienced clinician reason through a tough and complicated case. We need to be careful not to rely on the data alone when we assess quality.

As Alvin Toffler said, “You can use all the quantitative data you can get, but you still have to distrust it and use your own intelligence and judgment.”

Disclosures

None.

References


Key Words: cardiology ⊗ electronic medical record ⊗ quality ⊗ registries
Cardiovascular Registries: Too Much of Good Thing?
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Circ Cardiovasc Inter. 2016;9:
doi: 10.1161/CIRCINTERVENTIONS.116.003866
Circulation: Cardiovascular Interventions is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 1941-7640. Online ISSN: 1941-7632

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