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The evolving landscape of quality measurement for heart failure

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Abstract

Heart failure (HF) is a major cause of mortality and morbidity, representing a leading cause of death and hospitalization among U.S. Medicare beneficiaries. Advances in science have generated effective interventions to reduce adverse outcomes in HF, particularly in patients with reduced left ventricular ejection fraction. Unfortunately, effective therapies for heart failure are often not utilized in an effective, safe, timely, equitable, patient-centered, and efficient manner. Further, the risk of adverse outcomes for HF remains high. The last decades have witnessed the growth of efforts to measure and improve the care and outcomes of patients with HF. This paper will review the evolution of quality measurement for HF, including a brief history of quality measurement in medicine; the measures that have been employed to characterize quality in heart failure; how the measures are obtained; how measures are employed; and present and future challenges surrounding quality measurement in heart failure.

Keywords

quality measurement; heart failure; outcomes

Introduction

The goal of health care is to help people live longer and better lives. Therefore, the extent to which health care delivery accomplishes this overall goal represents the quality of that care. The Institute of Medicine's (IOM) report, *Crossing the Quality Chasm: A New Health System for the 21st Century*, defines quality as "the degree to which health care systems, services, and supplies for individuals and populations increase the likelihood for desired health outcomes in a manner consistent with current professional knowledge."¹ The IOM further defined six domains of the highest quality health care: effectiveness—providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit; safety—avoiding harm to patients from the care that is intended to help them; patient-centeredness—providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions; timeliness—reducing waits and sometimes harmful delays for both those who receive and those who give care; efficiency—avoiding waste, including waste of equipment, supplies, ideas, and energy; and equity—providing care that

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Conflicts of interest

The authors declare no conflicts of interest.

does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.

Poor quality results from errors in any one of the characteristics of high-quality health care: unsafe practices; use of ineffective therapies; application of the wrong therapy to the wrong patient; delayed delivery of care; use of resource intensive care for marginal benefit; and differential health care delivery strictly based on age, gender, race or ethnicity. Deficits in the quality of health care are also framed as deriving from three types: underuse (i.e., the failure to provide a beneficial therapy); overuse (i.e., the provision of a therapy without significant benefit or for which the risks outweigh the possible advantages); or misuse (i.e., medical errors or other sources of potentially avoidable complications).²

Ultimately, the quality of care cannot be understood without accurate measurement. While the concept of quality is seemingly intuitive, developing a rigorous quantitative underpinning of quality assessment has proven more challenging. As with other areas of science in medicine, quality measurement has evolved as the result of a body of knowledge resulting from a rigorous study as described below.

Certain conditions are more amenable to quality measurement than others. Heart failure has been a particular focus of quality measurement efforts for several reasons. First, heart failure has a high prevalence—affecting an estimated 5.7–6.6 million adults in the United States. Second, it has an important effect on individual and population health. Heart failure is the most common cause of hospital admission in the older U.S. population.³ Elderly Medicare patients hospitalized for heart failure have a higher readmission rate within 30 days—more than 26%—than for any other medical condition.⁴ Patients with the syndrome are also at high risk for other adverse consequences, including death and poor quality of life.^{5,6} As a corollary, because of its prevalence and poor outcomes, the financial consequences of heart failure are substantial—projected to account for more than \$44 billion in direct costs in the United States in 2015, or almost one in \$12 that will be spent on cardiovascular diseases.⁷ Finally, the evidence base for treating heart failure is extensive, resulting in robust practice guidelines that provide the basis for the development of some of the measures that are used to characterize quality.⁸

A historical perspective of quality measurement

Quality measurement, seemingly a recent development in medicine, is not a new concept. In the early 20th century, the surgeon Ernest Amory Codman (Fig. 1) first proposed the measurement of surgical outcomes when he left his traditional surgical practice to found the “End Results Hospital” in Boston, which routinely described and reported the quality of the care it delivered.⁹ However, like many visionary ideas, Codman’s systematic approach to quality measurement would not be embraced for decades.

The prevailing model of quality assessment in health care over most of the 20th century diverged from Codman’s vision of universal quality measurement, consisting largely of committees focusing on medical care and utilization review. In 1983, the Medicare Utilization and Quality Control Peer Review Organization Program was founded with the responsibility of identifying “outliers:” hospitals or practitioners whose care fell well outside the spectrum of normal.¹⁰ These approaches reflected a philosophy that suboptimal quality was rare, sporadic, and the responsibility of only a few individual providers or institutions.

Ultimately, it was recognized that failures to achieve optimal quality in medical care were endemic and resulted primarily from systematic failures to deliver the best care.¹⁰ Efforts to measure medical quality reflected this philosophical shift. In 1992, the Health Care Financing Administration (HCFA, now the Centers for Medicare and Medicaid Services, or

CMS) implemented a national effort to measure the quality of care of Medicare patients with acute myocardial infarction (AMI): the Cooperative Cardiovascular Project (CCP).¹¹ The CCP focused on evidence-based processes of care for AMI (e.g., aspirin, beta blockers, and thrombolytic agents). In an observational follow-up study in four participating states, CCP investigators found that between 1992 and 1995 performance on key process quality indicators improved significantly with associated declines in mortality.¹² Contemporaneously, a substantial effort was dedicated to understanding the quality of care for cardiovascular surgery.^{13,14}

A systematic understanding of the quality of care for heart failure developed more slowly. Based upon the perceived success of the CCP and local measurement projects dedicated to heart failure,¹⁵ the CMS launched the National Heart Failure Project (NHF) in 1999 as part of a broader effort to understand and improve the quality of care for health conditions of greatest importance to Medicare beneficiaries. The NHF Project focused upon four inpatient processes of care: assessment of left ventricular ejection fraction; the use of angiotensin-converting enzyme inhibitors in patients with left ventricular systolic dysfunction; providing complete heart failure discharge instructions; and providing smoking cessation counseling in current or recent smokers. Baseline measurements of the four process measures were conducted in 1998–1999 before quality improvement efforts by state Quality Improvement Organizations and repeated subsequently in 2000–2001. The measurements for this project identified significant and widespread gaps in the quality of heart failure care at the beginning of the last decade.^{16,17} Subsequently, the CMS and The Joint Commission (TJC) harmonized their measures of inpatient care. Hospitals were first required to submit these performance metrics for the CMS reimbursement (“pay-for-reporting”) and for TJC accreditation.¹⁸

Since the inception of the NHF Project, the landscape of quality measurement for heart failure has evolved dramatically. The scope of measurement has expanded beyond processes of care, the uses of measurement have expanded beyond reporting and accreditation alone, and the opportunities for collecting data have grown. These changes and the associated challenges will be addressed below.

What is measured?

The conceptual framework proposed by Avedis Donabedian in 1966 underlies most contemporary efforts to assess quality of care for medical conditions, including heart failure.¹⁹ Donabedian described three distinct dimensions of quality: structures, processes, and outcomes of care. These dimensions are interrelated, in that high-quality structures should result in a higher likelihood of providing appropriate processes of care, which in turn should result in better patient outcomes.

Structural measures

Structures of care characterize the health care environment, such as personnel, facilities, training, certification, and the implementation of protocols. Perhaps the most commonly employed structural measures are case volume for procedures. Structural measures are convenient because they are often easy to measure; however, they are most often employed when other types of measures are not feasible because of typically weak relationships between structures of care and health outcomes. In the area of heart failure, structural measures have generally not been employed, in large part because more robust process and outcomes measures for heart failure are available. It is worth mentioning that a volume–outcome relationship in heart failure care exists; in a study of Medicare beneficiaries in 4,679 U.S. hospitals, larger volume hospitals had modestly but significantly lower 30-day risk-standardized mortality.²⁰ However, there is substantial overlap in the mortality

distribution among the strata of heart failure case volume, suggesting that this structural characteristic discriminates poorly despite the statistical significance of the relationship.

Process measures

Process measures characterize the care that is delivered to patients. Examples include the prescription of medications, the performance of procedures, and the provision of education. Processes of care measures are calculated by identifying patients with an indication for a particular therapy in the absence of any contraindication (denominator) and assess the proportion that receives the therapy (numerator). Strong evidence is a prerequisite for process measures, which generally focus on those aspects of care that are unequivocally recommended (i.e., class I or III recommendations in clinical practice guidelines). However, while necessary, evidence alone is not sufficient. Process measures must also be interpretable, actionable, valid, reliable, and feasible to calculate.^{21,22} Thus, only a subset of evidence-based processes of care qualify for consideration as quality measures. Furthermore, while a larger group of measures may be suitable for the purposes of feedback, benchmarking, and quality improvement, only a subset are considered adequately robust for the purposes of accountability (i.e., public reporting or pay-for-performance), as discussed below.²³

Several process measures exist to characterize heart failure care. As mentioned above, the CMS, in conjunction with TJC, have used the four “core” heart failure measures in their hospital quality program. More recently, the American College of Cardiology (ACC) and American Heart Association (AHA), in conjunction with the Physician Consortium for Performance Improvement (PCPI), developed a broader group of process measures to assess both inpatient and outpatient care (Table 1).²⁴

Process measures have important strengths. First, because they are invariably based upon the most robust evidence; they possess strong face validity.²¹ Further, when properly constructed, process measures do not require risk adjustment, further lending credibility and interpretability.²⁵ However, such measures are also limited for several reasons, including the following: they apply only to those patients who qualify for the measure denominator;²⁶ they assess only a small fraction of the processes of care that are routinely delivered; and performance on many process measures, particularly those that are components of accountability programs, has reached very high levels, such that process measures for which performance is “topped out” fail to discriminate among institutions.²⁷ Further complicating their practical use, accurate determination of denominator exclusions can pose additional challenges; in particular, retrospective determination of contraindications to therapy is often problematic for many heart failure therapies.²⁷ Also notably, the process measures that are currently widely used to characterize heart failure quality focus entirely on eliminating underuse; issues of overuse and misuse are not addressed.

Finally, the relationship between quality of care as determined by process performance measures and important patient outcomes has been controversial. In a study from the OPTIMIZE registry, an analysis comparing patients who received processes of care with those who did not found that only beta-blocker therapy—which is not currently used by the CMS/TJC as part of the hospital quality measurement program—and ACE inhibitor therapy were associated with better patient outcomes.²⁸ A subsequent analysis from the same registry focusing on hospital-level performance found that the relationship between these processes and outcomes were substantially attenuated and only beta-blocker prescription was modestly associated with lower mortality.²⁹ In a third study using the same registry, hospital-level performance, measured by established quality measures as well as others that have not been widely used, found modest associations with quality- and hospital-level outcomes.³⁰ The seemingly discrepant results of these studies may be in part explained by a

number of factors, including differences in the level of analysis (patient vs. institution level), differences in the time frame of follow-up for outcomes, and the fact that performance on established measures was generally higher with less variation than for other measures. However, other studies have found that the relationship between process measures used to characterize the quality of care for heart failure and patient outcomes is weak,³¹ raising questions about the extent to which existing process measures are adequate reflections of quality of care.

Outcome measures

Because of the limitations of the process of care measures in heart failure, there has been an increasing focus on directly measuring heart failure outcomes. With respect to patients with heart failure, widely used outcomes measures include mortality and readmission following hospitalization.^{32,33} These outcomes are appealing on a clinical and policy level because they occur relatively frequently in patients who have been hospitalized with heart failure. Readmission is also associated with significant costs.³⁴ At least among patients for whom administrative data are available (e.g., Medicare fee-for-service patients), these outcomes are relatively easy to collect longitudinally.

The ACC and AHA have developed standards for outcome measures, which include (1) a clearly defined patient sample; (2) clinically coherent variables for risk adjustment; (3) high-quality and timely data; (4) specification of a reference time before which risk adjustment variables are collected and after which outcomes are ascertained; (5) a standardized period of assessment for outcomes (e.g., one month or one year rather than in-hospital); (6) an analytic approach that accounts for clustering of patients within systems; and (7) transparency of the methods used.³⁵

The primary strength of outcome measures is that they are patient centered and meaningful not only to individual patients, but also to society as a whole.^{25,36} Further, unlike process measures, outcome measures do not require restriction to patients who qualify for a specific therapy. Finally, outcome measures reflect the overall performance of health systems. There are several important limitations that have to be considered with outcome measures, including (1) risk adjustment techniques must be fair in order to account for differences in case mix; (2) decisions about when to measure the outcome of interest are arbitrary; (3) some meaningful outcomes (e.g., health status) are difficult to measure in large populations and across health systems; (4) some meaningful outcomes are relatively rare, limiting power to differentiate important variations in institutional performance; and (5) attributing the outcome to the condition of interest can be complicated by coexisting conditions.³⁶

Furthermore, there is a need for caution in interpreting individual outcomes in the context of potentially competing outcomes. This phenomenon is particularly important in patients with heart failure. In a study in the United States of almost seven million Medicare beneficiaries hospitalized for heart failure between 1993 and 2006, there were dramatic declines in the mean length of hospital stay (8.81–6.33 days), in-hospital mortality (8.5–4.3%), and 30-day mortality (12.8–10.7%).³⁷ However, discharges to skilled nursing facilities simultaneously increased from 13.0% to 19.9%. Further, 30-day readmission rates increased from 17.2% to 20.1%. The assessment of multiple patient outcomes in this study demonstrates the importance of attempting to represent the overall patient experience through simultaneous capture of potential competing outcomes.

Composite measures

Composite measures have been constructed and deployed to address the proliferation of numerous measures of care quality and the need to ensure that these measures

comprehensively represent health care quality.³⁸ Indeed, a substantial challenge of interpretation of various measures within different domains of quality is the lack of association between different metrics within hospitals.³⁹ Composite measures allow for data reduction to simplify presentation and interpretation and promote better integration of multiple metrics into a more comprehensive assessment of provider performance. However, these advantages come at a cost: standard psychometric properties of composites can be more complex to determine, methods for scoring (e.g., all-or-none vs. any vs. weighting) can lead to different conclusions, and problems with missing data can be amplified.³⁸ Currently, there are no widely used composite measures to characterize heart failure care, which creates challenges in interpreting the collective importance of individual quality metrics.

How is it measured?

Ultimately, the value of any quality measure depends fundamentally upon the integrity of the data that serves as its foundation. Measuring quality requires commitment, planning, and resources. Contemporary quality measurement relies upon data obtained from administrative sources (i.e., data collected by payers for the purposes of billing), clinical chart abstraction, or clinical registries. Each of these approaches has strengths and limitations.

Administrative data (also known as claims data) from payers typically include large numbers of patients systematically and are relatively inexpensive to use. However, because administrative data are generated primarily to facilitate billing, they often do not provide adequate clinical detail or may be discordant with clinical reality. Further, they are often not generated in a timely manner and are limited only to those patients who are covered by the health plan or system from which they are derived.

In contrast, chart abstraction provides substantially greater clinical detail, thus lending greater face validity to the data. However, chart abstraction is labor intensive and relies entirely on available documentation, which is not standardized and may be incomplete. Clinical data from chart abstraction are used to calculate the process performance measures for heart failure that are reported on the CMS Hospital Compare website.

Clinical registries—observational databases of a clinical condition, procedure, therapy, or population—are perhaps the most effective approach to measuring quality.⁴⁰ In the area of heart failure, the AHA Get With The Guidelines Heart Failure (GWTG-HF) program is perhaps the best-known example with a national scope. Unlike administrative data, registries provide clinically granular data. In contrast to data from chart abstraction, registries apply data quality processes and implement standard definitions.⁴¹ Registries thus ensure that critical data elements are consistently collected, and that they are defined identically across care settings. Further, linkages with supplemental data sources such as claims data can provide the benefits of both clinical and administrative data. Such clinical–longitudinal databases create the opportunity to study process–outcome associations. However, because registries are often voluntary, they can be limited by selection bias. Other considerations with clinical registries are the barriers to creating such databases include the administrative burden of current privacy regulations, the difficulty of integrating data collection more seamlessly into clinical care, and the scarcity of funding to support and create current and future registries.

A number of clinical registries have been developed to characterize the quality of inpatient heart failure care.^{42–45} These registries have played an important role in shaping quality improvement efforts in heart failure and have the potential to inform future clinical trials, guidelines, and health policy for heart failure.⁴⁰

The proliferation of electronic health records (EHR) promises to enhance further the value of clinical registries and quality measurement. EHRs have the potential to combine and the automated systematic capture of administrative databases with the detailed clinical data of prospective registries chart reviews. However, this potential is not guaranteed; without data standards across EHR platforms, the promise of ubiquitous electronic data sources will not be recognized. Existing registries can help guide what data are critical to capture within EHR, provide feedback on care and patient outcomes based on data obtained from EHRs, and integrate data collection into clinical care.⁴⁰

How are measurements used?

Quality measurements for heart failure are employed on both on a local and national level. Locally, quality measurements serve to provide feedback to physicians and both inpatient and outpatient care facilities, with how they are performing based on national standards, and overall adherence to the national guidelines and performance measures. Registries such as the AHA GWTG-HF Registry provide users with periodic feedback on performance with respect to processes of care.⁴⁴

However, the use of measures of quality in heart failure has expanded well beyond the important areas of feedback, benchmarking, and quality improvement. As part of its hospital quality program, the CMS made hospital-level data available online for the public beginning in 2005. Performance data—both for processes of heart failure care, 30-day risk-adjusted mortality after heart failure hospitalization, and 30-day risk-adjusted readmission after heart failure readmission—are accessible at the CMS Hospital Compare website.⁴⁶ The CMS has also incorporated heart failure quality as part of its “value-based purchasing” program with the hopes of stimulating higher quality care through the use of financial incentives.⁴⁷ Although the CMS pay-for-quality programs focus on a wide range of medical conditions, heart failure remains a focus because of its impact on the health of Medicare beneficiaries.

Future challenges

There remains a critical need for further evolution in the quality measurement in heart failure. Generally, quality measurement for heart failure has focused principally on the inpatient setting. This has been the case largely for practical reasons; reliable access to outpatient data has been limited. However, much of the care for heart failure is delivered in the outpatient setting. The prospects for measuring the quality of outpatient care are improved with the development of outpatient cardiovascular registries and the increased penetrance of EHRs.^{44,48} However, these registry programs still face the challenge of standardizing data collection across a wide range of practices and clinical data collection platforms.

Furthermore, quality measurement for heart failure has generally focused on underuse and has largely ignored issues around the costs of care or safety. Given the unsustainable trajectory of health care expenditures in the United States, future quality efforts can no longer turn a blind eye to costs. Thus, rather than focusing simply upon the under-use of care, quality measurement must also consider overuse and the value of therapies (defined as the outcomes of healthcare as a function of the cost of delivering that care).^{49,50} The measurement of heart failure readmissions—which are undesirable for the patient and invariably incur costs for society—represents an indirect initial foray into characterizing the value of heart failure care. Processes of care that are particularly expensive, such as implantable cardioverter defibrillators, represent specific targets for measures of value, especially as there is evidence of both underuse and overuse of ICD therapy.^{51,52} The ACC/AHA have described explicit methodology for measuring value and efficiency; however, important challenges in operationalizing such measurements persist.⁵³

Overuse or misuse can create threats to patient safety. For example, in the case of heart failure, aldosterone antagonists reduce the risk of death and hospitalization in carefully selected patients,⁵⁴ but risk causing hyperkalemia, particularly in patients with poor renal function. Unfortunately, these agents are often prescribed to patients who are not good candidates for therapy because of renal insufficiency,⁵⁵ which has been linked to higher rates of hospitalization for hyperkalemia.⁵⁶ Measurement of misuse, while itself also challenging, could ensure that the full potential of therapies that are useful for some but impart higher risk for others, are deployed in a manner that maximizes the population benefit of these therapies.

Other arenas for improvement in quality measurement include (1) leveraging proliferating information technology to improve data sources and provide real-time feedback on quality; (2) constructing process measures with stronger relationships to important health outcomes; (3) the use of patient-centered outcomes such as physical function, symptoms, and quality of life as metrics of quality; (4) focusing on patient subgroups that are underrepresented in clinical trials, such as the elderly;⁵⁷ (5) reducing disparities in care and outcomes for racial and ethnic minorities;^{58,59} and (6) expanding measurement into the realms of palliative and end-of-life care, which are often relevant to many patients with heart failure.⁶⁰

Conclusions

The measurement of quality of care for heart failure has evolved and expanded substantially over the last decade. The focus of measurement, the methods whereby measurement is performed, and the uses of measurement will continue to change in the coming years. Although the future may be unclear, it is certain that quality measurement is intrinsic to delivering medical care for heart failure patients. To this extent, Ernest Codman's vision of understanding and reporting health care quality has been realized.

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Figure 1.
Ernest Amory Codman (source, <http://commons.wikimedia.org/>).

Table 1

ACC/AHA/PCPI performance measures

Measure	Care setting	Attribution
LVEF assessment	Inpatient	Facility
	Outpatient	Practitioner
ACE (or ARB) for LVSD	Inpatient	Facility
	Outpatient	Practitioner
Beta blocker for LVSD	Inpatient	Facility
	Outpatient	Practitioner
Postdischarge appointment	Inpatient	Facility
Symptom assessment	Outpatient	Practitioner
Symptom management *	Outpatient	Practitioner
Patient self-care education *	Outpatient	Practitioner
ICD counseling *	Outpatient	Practitioner

* Measures proposed for quality improvement purposes but not for accountability.

Adapted from Ref. 24