

Evaluating Quality of Care for Patients With Heart Failure

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The First American Heart Association/American College of Cardiology Scientific Forum on Quality of Care and Outcomes Research in Cardiovascular Disease and Stroke was held from May 24 to May 26, 1999, in San Diego, Calif. In this report, the Heart Failure Working Group examines efforts to assess care for patients with heart failure (HF) and makes recommendations about quality measures. The working group includes healthcare professionals (cardiologists, general internists, and nurses) from academia. Representatives of governmental agencies, industry, and healthcare systems also have input. The group has expertise in the treatment of HF and/or quality improvement. Several panel members have participated in writing guidelines for management of HF, and several were involved in the 1994 effort by the Agency for Health Care Policy and Research (AHCPR) to develop guidelines for management of patients with HF and left ventricular (LV) systolic dysfunction.

In its effort to develop recommendations for evaluating quality of care, the working group reviewed the literature and evaluated ongoing national efforts in this area. These efforts and specific issues related to measuring structure, process, and outcome of care are reviewed here. This report is intended to provide information for future efforts by national or local organizations to develop quality measures, define research priorities for funding agencies by indicating gaps in current knowledge, and summarize current issues in this field for persons interested in improving the care and outcomes of patients with HF.

Heart Failure

There is no universally accepted definition of heart failure. HF is a clinical syndrome manifested by characteristic symptoms and signs, none of which are specific, caused by an abnormality(ies) of ventricular function resulting in the inability of the heart to deliver adequate cardiac output at normal filling pressures at rest or during exercise. As the syndrome progresses, a variety of hemodynamic, renal, hormonal, neural, and cellular responses, initially compensatory, occur. These compensatory mechanisms allow many patients

to remain without symptoms despite major LV dysfunction and (sometimes) a poor prognosis.

The pathophysiology of the cardiac dysfunction must be an integral part of the definition of HF because therapy and prognosis are greatly influenced by the specific abnormalities present. Cardiac pathophysiology is a critical feature in developing quality indicators and risk-stratification models for this complex and diverse syndrome. Echocardiography is best suited for evaluating pathophysiology to determine if HF is principally related to contractile dysfunction or filling abnormalities. This technique can determine systolic left or right ventricular function, ventricular hypertrophy, diastolic filling abnormalities, regional myocardial wall motion abnormalities, valvular abnormalities, and pericardial thickening or effusions. Echocardiography can also estimate pulmonary artery systolic pressure. In patients with suspected ischemic heart disease, an echocardiographic study with dobutamine infusion might be useful for determining myocardial viability and the presence or absence of inducible myocardial ischemia. Other laboratory studies, particularly cardiac catheterization, if indicated, and nuclear imaging studies can provide similar information.

Age and etiology are of extraordinary importance when considering pathophysiology. The primary abnormality of cardiac function with aging is the development of diastolic dysfunction (abnormality of filling with preserved systolic function) and, to a lesser degree, LV hypertrophy associated with age-related changes in the aorta. Hypertension, a common cause of HF, also results in hypertrophy and abnormalities of filling with preserved systolic function early in the course of hypertensive HF.

Because the pathophysiology of HF is diverse, there are multiple etiologies. Myocardial damage caused by ischemia and long-term, inadequately treated hypertension are the most common etiologies in our society. "Primary" myocardial disease is less common but of great clinical interest and can be associated with idiopathic, dilated cardiomyopathy with abnormalities of contractility (systolic dysfunction) or hypertrophic cardiomyopathy (with abnormalities of filling, dia-

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stolic dysfunction, preserved systolic function). Infiltrative processes, toxic causes, infections of the myocardium, and systemic conditions, such as collagen vascular diseases with important myocardial involvement, are causes of HF. Cardiac valvular abnormalities and pericarditis can be present with normal myocardial function for long periods of time. Finally, noncardiac abnormalities, sometimes associated with high cardiac output and HF, including anemia, arterial venous shunting, and thyrotoxicosis, may be responsible for the syndrome.

It has been estimated that >4.6 million persons in the United States are being treated for HF and that there are >400 000 new cases per year.¹ The incidence of HF has been estimated to be ≈ 10 per 1000 population after age 65 years. HF is the most frequently occurring Medicare diagnosis-related group (DRG). Despite major advances in understanding congestive HF (CHF) and multiple new pharmaceutical approaches to therapy, costs associated with treating HF patients are likely to increase over the next decade due to the aging of the population. Whereas systolic LV dysfunction due to ischemic heart disease has been the most common cause of disease in the United States, it is expected that the incidence of HF with preserved LV function (diastolic HF) will increase as the result of the aging population. Although there is considerable information about the prognosis and effects of therapy in patients with systolic LV dysfunction, based on prospective randomized trials, there is relatively little information on patients with HF due to preserved systolic function.

In summary, it is clear that HF is a complex clinical syndrome with highly variable symptomatic manifestations, diverse causes, and a wide array of pathophysiology (particularly when compensatory mechanisms are considered). Although clinically obvious HF generally portends a poor prognosis, that too is highly variable. Most cases of HF occur in the elderly, and age greatly modifies every consideration, in part because of frequent comorbidity, but age-related myocardial and conduction system problems also alter prognostic and therapeutic implications. There is widespread inaccuracy in diagnosis when only clinical criteria are used, making laboratory evaluation of cardiac function and structure important for all patients with known or suspected HF. Echocardiography is the preferred approach because it provides the best information about pathophysiology and prognosis.

National Initiatives

Several ongoing national initiatives are assessing the quality of care for HF patients. The largest of these are sponsored by the Health Care Financing Administration (HCFA) and the US Department of Veterans Affairs (VA). Other major organizations such as the National Committee for Quality Assurance (NCQA), the American Medical Association (AMA), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and many state and local organizations are also engaged in efforts to assess care in this population. A description of all of these efforts is beyond the scope of this report. The efforts of HCFA and the VA are described below.

HCFA National Heart Failure Project

The National Heart Failure (NHF) project, an HCFA quality-improvement initiative, began in January 1999. The project will assess the care process for a nationwide sample of Medicare beneficiaries with HF and will measure adherence of care to a set of quality measures. Baseline measurements will be made before quality-improvement efforts by state peer review organizations (PROs) in upcoming work cycles and will be repeated in 3 years. The primary purpose of the measurements is to compare the effectiveness of PROs in quality improvement. This will require ensuring that the number of records and demographic distribution of cases are comparable between states.

Sampling Methodology

The goal of the project is to gather data from 40 000 records. Data will be abstracted from 800 Medicare fee-for-service hospital discharge records per state or all eligible discharges if a state has <800 discharges. For about one third of the states, discharges occurred between April and September 1998. The 6-month periods for the other two thirds are July to December 1998 and October 1998 to March 1999. The sampling will not be random but systematic. Discharge records will be sorted by age, sex, race, and hospital provider number. A sampling fraction will be calculated, and after a random start, each n th record (not necessarily an integer) will be chosen to exhaust the entire list while selecting the specified number of records.

Quality Measures

The first step in the project is development of a set of quality measures. The primary measure is the proportion of CHF discharges with appropriate use of angiotensin-converting enzyme (ACE) inhibitors as defined by the following:

Inclusion criterion: Alive at discharge

Exclusion criterion: Taking an angiotensin-receptor blocker (ARB) but not an ACE inhibitor at discharge

Denominator: HF as principal diagnosis

Numerator: Those in the denominator who meet ≥ 1 of the following conditions:

1. Taking an ACE inhibitor at discharge *or*
2. Documented LV ejection fraction (LVEF) ≥ 0.40 or equivalent narrative description *or*
3. Chart documentation of ≥ 1 of the following absolute contraindications to use of ACE inhibitors: (a). Moderate or severe aortic stenosis *or* (b). Bilateral renal artery stenosis *or* (c). A history of angioedema, hives, or severe rash with use of an ACE inhibitor *or* (d). Physician's note of a specific reason why an ACE inhibitor is not being used *or* (e). Charted documentation of participation in a clinical trial testing alternatives to ACE inhibitors *or* (f). Discharge plan for evaluation of LV function after discharge.

This measure is a composite index designed to measure compliance with guideline-based recommendations both for measuring LV systolic function in all patients with HF and prescribing ACE inhibitors for those with reduced systolic function. Patients treated with ARBs were excluded because of a lack of definitive mortality data for this HF class and preliminary data showing high rates of usage in some regions of the country.

There also are “test measures” for which experience with data abstraction is more limited and links between process and outcome are less well investigated. These are

1. Proportion of eligible hospital discharges to home with appropriate instructions for smoking cessation, taking medications, monitoring weight, adhering to diet, activity level, follow-up appointments, and what to do if symptoms worsen.
2. Proportion of hospital discharges with admission diagnosis of HF with weight recorded on $\geq 50\%$ of days in hospital.
3. Proportion of those admitted who were taking ACE inhibitors with a dose $\geq 50\%$ of that shown to be effective in clinical trials.
4. Proportion of those with a history of HF who were admitted and taking β -blockers.
5. Proportion of hospital discharges with a follow-up provider visit within 4 weeks of discharge.
6. Proportion of hospital discharges with coronary artery disease and taking aspirin.

Database Construction

The NHF project database contains 195 elements in 3 categories: identification elements such as “name” and “social security number,” elements for calculating quality measures such as “medications at discharge,” and clinical data elements for future use in research. Clinical data elements had to meet 2 criteria: they must be accurately extractable from the medical record and must have been associated in the literature with readmission or mortality. In particular, consensus about the use of β -blockers and spironolactone has developed after the baseline sampling period, and definitive evidence regarding ARBs is likely to develop in the near future. Data on the use of these agents are being collected but will not be used to judge quality of care for the baseline period.

Assessment of Validity of Data Collection Instrument and Reliability of Data Abstraction Process

Records are abstracted by 2 HCFA contractors, which employ trained chart abstractors and have considerable experience. The validity of the abstraction instrument is assessed by comparing results obtained by abstractors who used a computerized instrument with results obtained by a physician who used best clinical judgment. The reliability of the abstraction is routinely assessed; each month, 80 charts are abstracted by 2 individuals, 1 at each center. When agreement falls below a specified threshold, the abstraction of that variable is reviewed.

Chart abstraction began in May 1999 and was completed at the end of 1999.

Intervention

No quality-improvement interventions are specified nationally. Individual PROs work with hospitals in their state on the basis of their experience with interventions that have worked locally. It is recognized that universally effective quality-improvement interventions have not been identified.

Remeasurement

After a 3-year period of quality improvement by state PROs in association with individual hospitals, the same data ab-

straction will be performed on a sample equal in size and composition to the baseline sample. The primary purpose of remeasurement is to assess the effectiveness of PRO quality-improvement efforts but will also allow accurate assessment of temporal trends in treatment of HF in the elderly.

VA Chronic Heart Failure Quality Enhancement Research Initiative

The mission of the VA Chronic Heart Failure Quality Enhancement Research Initiative (CHF QUERI) is to create measurable, rapid, and sustainable improvements in quality of care and health outcomes of veterans with HF. The goals of CHF QUERI are (1) to identify gaps in science, practice, informatics, and health-services administration that, if closed, would yield the highest and most rapid returns in improving the process and outcome of care for patients with CHF, and (2) to translate research results rapidly and effectively into routine clinical treatment of CHF.

CHF QUERI has 7 specific objectives:

1. To recommend to the VA how best to use its existing research and administrative resources to close important gaps in research and practice.
2. To recommend and influence the research portfolio of the VA to cover the best science and the most pressing issues in clinical care and delivery of service to CHF patients.
3. To create and foster a network within the VA of clinicians, researchers, policy makers, managers, and information specialists who are deeply committed to improving care for HF patients.
4. To monitor clinical practice (process and outcomes) in HF patients both from the perspective of the healthcare system and that of the patient to determine the extent to which the QUERI process is having its intended effects.
5. To create an information-dissemination loop that ensures that VA researchers, clinicians, managers, policy makers, information specialists, and patients are kept up-to-date with the best practices for CHF and the most pressing need for new knowledge in CHF.
6. To conduct an inventory of ongoing data collection efforts related to quality assessment and improvement in CHF throughout the VA system (eg, performance agreements, the external peer review program) and to advocate for improvements in these efforts.
7. To eventually be able to compare and benchmark selected VA data on process and outcomes in CHF with the non-VA sector.

In the first year, CHF QUERI had the following major achievements:

- Creation of the CHF Coordinating Center (hired and trained staff, established office operations, met with the CHF QUERI Executive Committee).
- Creation of a research portfolio in CHF.
- Establishment of itself as a resource for HF research and practice in the VA by taking an inventory of CHF literature. (Results are posted on the CHF QUERI Web site [<http://www.va.gov/resdev/queri.htm>].) Shortening of the time required for dissemination of new research findings into practice.

During the next year the CHF Coordinating Center will continue to fulfill its research objectives and begin the following new initiatives:

- Development of the “best packages” in CHF study, the “heart” of the CHF QUERI strategic plan. This study will determine which structure of care (case manager or HF clinic) provides the maximum number of CHF patients with appropriate therapy, results in the greatest reduction in hospitalizations and/or improvements in survival, and is the most cost-effective.
- Active involvement of CHF patients in CHF QUERI through patient interviews and inventory and distribution of patient education materials.
- Posting on the Web site of initial findings on utilization, survival, and quality of care from the nationwide CHF Database Cohort.
- Conduction of systematic reviews of the literature on comprehensive CHF care. A series of 8 articles will be submitted for publication in the next year and is the foundation for the Best Packages study.
- Design of a “costs of care” study.
- Establishment of a group of 10 to 20 VA hospitals to provide detailed clinical data on CHF patients.
- Conduction of an inventory of quality-assessment and quality-improvement initiatives throughout the VA.
- Conduction of an inventory of CHF guidelines distribution and implementation in the VA.

Measuring Quality of Care

The following section reviews the major issues in evaluating quality of care for patients with HF. Separate sections address structure, process, and outcomes.

Structure

In Donabedian’s structure, process, and outcome framework for quality of care, “structure” means the geographic location and physical plants of healthcare facilities; laboratory and testing facilities; medical equipment and supplies; information systems technology; telecommunications systems; personnel qualifications, certification, and training; staffing mix, policies and procedures as stated in manuals, and hours of operation, etc. Clinical practice guidelines, preset treatment protocols, and clinical reminder systems also represent structural elements of care. Organizational culture, although intangible, is also an element (some would say an attribute) of healthcare structure. The structure of health care is not an end in itself but rather a means to an end: high-quality health care. High-quality structure can lead to high-quality processes of care, which in turn should lead to high-quality outcomes of care.

Clinicians can generally agree on what constitutes high-quality processes of care. For example, high-quality processes of care are embodied and codified in clinical practice guidelines for the care of people with CHF. Unfortunately, there is much less agreement—and a great deal less evidence—on what structures are necessary if medical-care processes are to be of high quality. Moreover, the benefit of specific structural characteristics that are self-evident to

specialty groups (eg, the need for specialty training) may be controversial to generalists and perceived as self-serving by others. Very little research has been done to examine the links between medical-care structure and medical-care process or outcome. Consequently, at this time, many recommendations on medical-care structure rest on expert opinion rather than empirical evidence. With these caveats, the working group believes that 4 important characteristics of structure can be supported as indicators of quality.

Clinical Practice Guidelines

Clinical practice guidelines cover discrete elements of the process of care that have been shown or in the absence of evidence are believed by clinical experts to lead to the best possible health outcomes for patients. A systematic review² (not specific for HF) has shown that guidelines do affect the process and sometimes the outcome of care. Of the 59 studies in the synthesis, 11 included outcome assessments. Nine of the 11 studies showed a small but statistically significant improvement in patient outcomes. Several professional groups have published guidelines for the care of persons with HF. Because practice in accordance with clinical guidelines is likely to improve the process and outcome of care, the working group recommends that each care facility adopt and disseminate the HF guidelines.

Monitoring Care and Outcomes of Patients

Another critical element of the structure of care for HF patients is an ongoing quality assessment and improvement program specific for HF. Each facility should have a method of reviewing the extent to which clinicians practice in accordance with clinical guidelines. Optimally, these assessment efforts are automated (ie, built into the facility’s clinical computing systems).³ However, this is not yet possible in most facilities, and the program must depend on manual chart review. The facility should also strive to implement a program for assessing the outcome of HF patients, though this is less important than process-of-care assessment. Getting clinicians to comply with practice guidelines can be difficult. The most powerful method appears to be feedback of data comparing clinicians with their peers, combined with education carried out at the local level by respected colleagues.^{4–9} Therefore, regular feedback of data to clinicians should be part of the facility’s quality-assessment efforts.

Disease Management

The scientific literature indicates that disease-management programs for HF patients can reduce hospital stays and improve functional status.^{10–16} These programs cover such matters as patient education about the disease and its treatment, dietary counseling about sodium restriction, efforts to improve patients’ compliance with medical regimens, and interventions to help patients achieve and maintain control of their volume status. Important questions about these programs remain unanswered.¹⁷ Their cost-effectiveness has not yet been formally evaluated, and the most efficacious way of designing the program and delivering its elements is not yet known. However, on the basis of the evidence, the working group recommends that facilities either establish disease-management programs for HF or create referral systems by

which patients with severe disease can be enrolled in such programs.

Structure for Referral of Patients to Advanced HF Care Facilities

There are currently no published criteria for referral of HF patients to specialized centers. The data reviewed here are derived from single-center experiences with patients who have been referred for HF management or transplantation. Patients with HF can present at different stages of the disease process and over a wide range of time from onset of symptoms and severity of presentation. It has been shown that patients with symptoms of >3 months' duration and a more severe initial presentation are less likely to improve with therapy and may need earlier referral to more specialized centers, including transplantation.¹⁷ In addition, if medical therapy fails to stabilize a patient, data suggest that referral to a specialized center may result in a 1-year survival rate of 98% without transplantation and an actuarial 1-year freedom from listing for transplantation rate of 95%.¹⁸ Others have shown that referral to an HF program can result in a decrease in frequency of hospitalization of ≈50% in patients not listed for transplantation.¹⁹ Of note, the majority of referrals are prompted by frequent hospitalizations. Identification of the patient who is refractory to medical therapy or who has a poor prognosis should be the basis of the criteria and threshold for transfer and should be part of an ongoing review of patients in a practice or hospital setting. The working group recommends that as part of a structure and as a minimum, a plan of referral to a specialized HF center should exist. This plan of action requires an established relationship with the center and a coordinated plan of patient transfer. The plan should be carefully created a priori and not as a reaction to a patient crisis.

Process Measures

Measuring Process of Care for HF Patients

Of the methods for measuring quality of care, the most widely used is measurement of the process of care. In this technique, patients' charts are reviewed or patients are interviewed to determine whether they received diagnostic tests and therapies that have been shown to increase survival or improve health-related quality of life (ie, reduce symptoms of breathlessness, fatigue, etc). A large number of clinical trials have identified beneficial treatments for patients with HF. In other words, a process-outcome link has been established: if a patient receives treatment, he or she will be more likely to be alive and in good health in the future. Compliance with these process-of-care measures can be used to assess the performance of physicians, hospitals, and healthcare organizations for quality reports and quality-improvement projects.

There are advantages and disadvantages to measuring process of care, relative to measuring outcome. Because improvement in clinical outcome is the goal of all clinical care, tracking quality of care by assessing outcome is attractive. Furthermore, because outcome is driven by multiple processes, optimal compliance with a particular care process may be offset by inadequate delivery of care in a way that is not being measured. On the other hand, tracking process

indicators has several advantages. First, adverse outcomes, particularly mortality, are often relatively rare, even among hospitalized patients, rendering such outcomes insensitive to differences in quality of care. The advantage of using process measures is even greater when outpatient care is evaluated, because death is even more rare in that setting. Second, patient outcomes cannot be compared (among providers or over time) without accounting for differences in case mix (ie, the likelihood that patients will die or their health will decline). Such risk-adjustment measures often have limited accuracy and may therefore not fully account for case-mix differences among providers. Therefore, differences in process-of-care measures may have greater credibility and be more easily interpreted.

Challenges in Measuring Process of Care for HF Patients

Although there is now an abundance of potential measures, process-of-care measurement for HF poses some special challenges. First, HF is not a single disease. Instead, it is a clinical syndrome with heterogeneous etiologies and pathophysiology, and treatment recommendations vary according to type of HF. Therefore, proper diagnosis of the type of HF is a quality issue in itself; it is also essential to know the type of HF before determining whether process-of-care measures are applicable for a given patient. For example, if it is not documented whether a patient's HF is associated with reduced or relatively preserved ("diastolic dysfunction") systolic function, it is impossible to determine whether the care received is in accordance with recommended standards.^{19,20}

Moreover, for the large proportion of patients with HF and preserved systolic function, no treatments have unequivocally been shown to improve outcome. For other types of HF (eg, due to valvular disease), the number of cases of any 1 type would probably be too small to obtain meaningful data, even if process-of-care measures were clearly established. Therefore, measurement of process of care for HF must focus primarily on patients with depressed LV systolic dysfunction (ie, LVEF ≤0.40). Unfortunately, ability to measure process of care for a large proportion of HF patients is limited.

Finally, patients' symptoms of HF vary greatly (eg, New York Heart Association [NYHA] classes I through IV), and future quality-of-care recommendations may vary according to severity of symptoms. For example, the benefits of β -blockers in HF have been adequately documented only in patients with NYHA class II and III HF. This class of agents (specifically carvedilol) has received US regulatory approval only for patients with mild to moderate symptoms, not those with more severe (class IV) symptoms. Therefore, it may be necessary to assess patients' symptoms to determine whether their quality of care complies with recommendations. This problem is likely to become more important in the future as the range of beneficial therapies for patients with HF increases. Studies of quality of care for patients with asthma have already struggled with this issue, and the NHLBI has now established criteria for classifying patients' symptom frequency and severity. A similar effort for HF may be needed in the future. The difficulty in assessing symptom-dependent process measures is compounded by the fact that physicians rarely document functional status in their patients'

charts. Patient interviews may sometimes be needed to assess symptoms and determine which quality-of-care measures apply.

Selecting Process-of-Care Measures

Despite difficulties in measuring process of care for HF, process measures for treating HF have been widely used by state PROs and individual healthcare organizations to assess quality of care. When selecting what measures to use for a project, the goals of the project must be clearly defined. Is the goal to (1) identify the best and worst providers (eg, generate rankings or report cards) or (2) identify areas for quality-improvement activities? Is the goal to define the minimum standard of care (the “floor”) or provide targets for optimal care? A large number of recommended practices have been identified by expert panels and clinical practice guidelines as representing the best care possible for HF patients.^{19,20} However, the process-outcome link may be tenuous for some measures that most experts would agree represent good care (eg, patient education about dietary restrictions and monitoring daily weight). In instances in which a process-of-care measure has not been clearly shown to improve outcomes, physicians may not be willing to criticize (or penalize) an individual provider or healthcare organization for not prescribing a treatment or providing other types of care. Nevertheless, group members may want to use a weak process measure to identify opportunities for quality improvement within their own organization that they think will improve patient outcomes.

For example, if a patient with an LVEF <0.40 does not receive an ACE inhibitor (and has no clear contraindications to this class of agents), most would say that care for this patient is below an acceptable level (ie, necessary care has not been provided). However, if this same patient was not prescribed digoxin or did not receive recommendations for smoking cessation as documented in the chart, this variance from “optimal” care might be viewed differently. Should the latter data be used to measure quality of care and as the basis for adjusting the physician’s salary? If it were known that a healthcare plan would base hospital contract decisions in part on CHF quality report cards, would these still be appropriate indicators? The answer is probably not. However, a healthcare organization may well decide to measure its compliance with these process measures and make strides to improve performance if its compliance is low.

Even if a diagnostic test or therapy has been clearly shown to improve outcomes (eg, multicenter, randomized, controlled trials show the therapy to be effective), it is also important to know whether the results apply to all HF patients. Are the benefits of treatment the same for all patients? As a corollary, should process-of-care measures be applied equally to everyone? HF presents a particular problem because it is predominantly a disease of the elderly. For example, the average age of patients in the Studies of Left Ventricular Dysfunction (SOLVD) treatment trial²¹ was 61 years, and those >80 years old were excluded. By comparison, in the largest study to date of the quality of care for Medicare patients hospitalized with HF, the average age was 78 years.²² So, although the AHCPR guideline²⁰ recommends trying an ACE inhibitor

regardless of age or serum creatinine, should this process-of-care measure be used for an 80-year-old with a serum creatinine level of 2 mg/dL? One alternative is to define “ideal candidates” for therapy. However, this may cause a large number of patients to be excluded from a quality-of-care study, reducing the power and utility of the project. The tradeoff between wanting to include as many patients as possible but wishing to ensure that a process measure is truly appropriate for all patient subgroups requires careful consideration.

Is the Measure Measurable?

Even if a process of care has clearly been shown to improve outcomes, it may not be possible to use it as a process measure. Are data required to determine compliance with the process measure routinely recorded (eg, how often do physicians record LVEF in the chart, even when this testing has been done)? Conversely, if a process of care was recorded in the chart, was it done appropriately? For example, it may be noted that the patient received counseling on smoking cessation and education about eating a low-salt diet, but were the instructions/information presented in a perfunctory fashion that would be unlikely to actually change behaviors?

Can the information be reliably abstracted from charts? What effort is required to abstract it? Is it worth the additional cost? For example, determining whether a patient with HF was ever evaluated for reversible ischemia may be an extremely time-consuming task with questionable reliability and validity. The answers to these questions partly depend on the data sources available. Hospital records underreport past diagnostic tests but are very accurate for medications. The converse may be true for outpatient charts. To a large degree, measuring process of care is currently the art of the possible based on chart review. This situation may improve in the future with advances in healthcare information systems and electronic medical records.

Ideal Process Measure

On the basis of the discussion above, it is possible to identify characteristics of process measures that are likely to receive consensus approval regarding appropriateness and applicability to clinical care. The ideal process measure

- Has a well-documented process-outcome link.
- Is broadly applicable to HF patients or a subpopulation that is readily defined through chart abstraction.
- Is readily measurable through chart abstraction, based on documentation standards that are either presently accepted or may be readily developed.

Only a minority of the recommendations that appear in HF practice guidelines meet the criteria for ideal process measures. Nevertheless, the opportunity for outcome improvement based on the influence of implementing and acting on such measures is substantial.

The standard for establishing a process indicator is quite different from that required for regulatory approval of a pharmaceutical agent or to recommend a therapy within a clinical practice guideline. The efficacy component of the safety and efficacy requirement for approval by the US Food

TABLE 1. Process-of-Care Measures in Use and Ratings of Evidence Supporting Measure, Ability to Abstract Information From Charts, and Opportunities for Quality Improvement

	Process-Outcome Link*			Abstraction*			Opportunity for Improvement		
	Mortality	Quality of Life	Decreased Admissions	Reliability	Validity	Burden	Estimated Compliance	Barriers to Change	Projects
LVEF recorded or qualitative description of LV function	C	C	C	A	B	B	60%	Moderate	HCFA State PROs
ACEI prescribed if LVEF ≤0.40 or documented reason for not receiving ACEI	A	A	A	A	A	A	50–80%	Moderate	HCFA State PROs
• ARB an acceptable alternative	?	?	?	A	A	A	10%	?	State PROs
• ISDN/HYD an acceptable alternative	B	B	?	A	A	A	10%	High	State PROs
ACEI prescribed at >50% of target dose (or had ACEI dose increased from baseline)	?	?	?	A	B	A	20–40%	Moderate	State PROs
Digoxin prescribed if LVEF ≤0.40	no	A	A	A	A	A	80%	Moderate	State PROs
Warfarin prescribed for patients with atrial fibrillation and no contraindications	A	A	?	A	C	A	30–40%	High	State PROs
Patient education, including medications, low-salt diet, signs and symptoms of worsening HF, monitoring daily weight, smoking cessation	?	?	A	?	C	B	Varies across measures	High	State PROs

*Level of evidence for a process-outcome link: A indicates multiple randomized controlled trials; B, single randomized trial or nonrandomized trials; and C, consensus of experts. Question mark indicates contradictory studies or insufficient published data to provide a rating. Ratings for abstraction reliability, validity, and burden are subjective: A indicates excellent; B, good; and C, fair or poor.

ACEI indicates angiotensin-converting enzyme inhibitor.

and Drug Administration (FDA) demands that scientific evidence leave little doubt that an agent improves a clinically relevant outcome. The standard that the FDA has set for this conclusion is a statistically significant effect replicated in 2 well-controlled clinical trials. (Although approval has often been granted to agents that do not literally meet this requirement, the argument for approval generally revolves around showing that the strength of evidence is equivalent to this standard.) In contrast, criteria for guideline recommendation can be more closely described as an indication that the weight of the evidence (or expert opinion) supports a clinically favorable effect without necessarily reaching the degree of scientific certainty required for regulatory approval. A single well-controlled clinical trial is generally considered as “level A” evidence in favor of a recommendation. Furthermore, recommendations may be based on trials that are either not prospective or not ideally controlled (ie, case-control or prospective cohort studies [level B]) or even on the basis of a consensus among experts (level C). Thus, a guideline may recommend off-label use of a drug. The recommendation of isosorbide dinitrate and hydralazine (ISDN-HYD) in patients with an intolerance to ACE inhibitors is an example of an off-label recommendation. Standards for establishing process indicators fall somewhere between the strict standards for regulatory approval and the more lenient standards required for guideline recommendations.

Defining the Target Population

As mentioned above, HF is an extremely heterogeneous disease. Therefore, every study must identify the subset of patients with HF whose charts are to be reviewed. Studies of patients hospitalized with HF should include only those with HF as the principal reason for admission. Cases of valvular

heart disease should not be included. The working group advocates the use of the following list of primary discharge ICD-9-CM (*International Classification of Diseases, Ninth Revision, Clinical Modification*) diagnosis codes for inclusion in studies of process of care: 402.01, 402.11, 402.91, 404.01, 404.11, 404.91, and 428.x. For outpatients, the situation is somewhat different. Most clinics and offices rely on checklists of diagnoses for billing purposes, and the corresponding administrative databases therefore contain a more limited range of ICD-9-CM codes. Most systems use the 428.x code as their sole outpatient diagnosis code. Outpatient quality-of-care projects should therefore probably identify all patients with an outpatient diagnosis code of 428.x for any visit during the previous year and select charts to review from this study population. This strategy is likely to miss patients with less severe HF or HF that is well controlled, because the outpatient physician may only record active problems.

Other strategies for identifying outpatients, such as using pharmacy records of patients receiving combinations of medications (eg, an ACE inhibitor and furosemide), have the disadvantage of frequent false-positive results and bias the population toward those receiving higher-quality care. Wider use of electronic medical records with problem lists that can be queried should greatly improve ability to conduct outpatient quality-of-care studies. Most of the process-of-care measures discussed below apply equally to inpatients and outpatients; others are more appropriate for outpatients (β -blockers, control of blood pressure, and exercise training).

Process-of-Care Measures Used in Current Projects

Table 1 shows process-of-care measures used in current projects. Table 1 also provides ratings for the level of evidence supporting the recommendation, the feasibility of

abstracting the information needed to assess compliance with the process measure, and opportunities for improvement in terms of the current level of compliance and difficulties that will likely be encountered in trying to increase the compliance rate. Each measure is discussed individually in more detail below, including an operational definition of the numerator and denominator.

Assessment of LV Function

Assessment of LV systolic function by echocardiography, radionuclide study, or contrast ventriculography is a high priority for inclusion on most lists of process indicators for managing patients with HF, despite the absence of a direct link between this action and a relevant clinical outcome. Rather, its inclusion is necessitated by the fact that reduced LV systolic function (usually <35% or 40%) is an inclusion criterion for most of the major clinical trials in HF that have documented a drug effect on outcome. Conversely, almost no randomized controlled trials have demonstrated benefits of treatment for patients with more preserved systolic performance. (The principal exception is the Digitalis Investigators Group Study,²³ in which patients with more normal systolic function were included and showed the same directional benefit of digoxin in reducing frequency of hospitalization as that in patients with depressed ejection fraction.) In fact, the panel that developed the AHCPR guideline on HF²⁰ chose to deal only with patients with systolic dysfunction in view of the absence of useful data on the remainder of HF patients.

Thus, most existing quality indicators concerning drug treatment for HF cannot be justified unless the patient is known to have reduced systolic function. This is unfortunate because patients with relatively preserved systolic function represent a substantial proportion (estimated as being as high as 40%) of the HF population. Furthermore, the demographics of these patients differ (ie, older age, higher proportion of women, higher prevalence of a hypertensive etiology) from those of the population that has been investigated in most clinical trials. Pathophysiological arguments may be made to support use of many of the same treatments—eg, diuretics or ACE inhibitors—that have shown documented efficacy in patients with reduced ejection fraction. Nevertheless, these circumstances strongly justify the inclusion of measurement of systolic function as a process indicator for HF management.

The process indicator relative to LV function assessment must take into account the timing of the measurement and criteria for adequate assessment. In both cases, indicators have tended to be fairly liberal. With respect to the timing of LV measurement, studies of hospitalized patients have generally accepted any measurement of LV function during admission or documentation of results of previous testing (before admission).

It cannot be concluded from any clinical trial of HF that the timing of LV function assessment is relevant to the indication for a medication. It is certainly reasonable to presume that LV function ought to be measured at a time of relative clinical stability, removed from the time of an acute ischemic insult. However, such a distinction would be difficult to incorporate into a process measure and cumbersome to discern during

chart abstraction. There are circumstances (eg, acute myocarditis) in which function may be expected to improve. Furthermore, ACE inhibitors, and particularly β -blockers, may have a favorable effect on LV function. In the Veterans Administration Heart Failure (V-HeFT) trials,²⁴ the change in LV ejection fraction during treatment was correlated with clinical outcome. Nevertheless, no clinical trial data support the view that changes in ejection fraction should be used to monitor or alter treatment. As a result, at least some guidelines (eg, AHCPR) have specifically discouraged routine remeasurement of LV function.

Either a quantitative or qualitative description of LV function is generally considered adequate to achieve compliance with this process-of-care measure. It is common practice in many echocardiography laboratories to describe LV function qualitatively (ie, normal or mildly, moderately, or severely depressed). Even laboratories that report ejection fraction may do so on the basis of a subjective assessment of images. Thus, despite the quantitative ejection fraction requirement of most clinical trials, most process measures have accepted the more subjective style of reporting. The same is true of physicians' descriptions of previous studies.

The above points impose challenges to data abstraction. If the medical record from a single hospitalization is all that is available, then proper performance assessment requires a standard for physician documentation of prior LV function measurement in the assessment notes. Such a standard has not been clearly articulated or accepted. Previous studies have used the following descriptors to classify a patient as having reduced LVEF (ie, "systolic dysfunction"): LVEF described as "moderately" or "severely" decreased or a physician's note reporting "systolic dysfunction," "dilated cardiomyopathy," or "diffuse" and/or "global hypokinesis." Patients have been classified as having preserved LV systolic function if the LVEF is described as "normal," "increased," or "mildly decreased," or if a physician's note reported "diastolic dysfunction," "LV hypertrophy" (by echocardiography), or "hypertrophic cardiomyopathy." Therefore, the numerator of the measure is the number of patients who have been documented as ever having had LVEF measured as evidenced by either an actual report of a study of LV systolic function or a physician's description of LV function that implies formal testing was done in the past. The denominator includes all patients.

There appears to be much room for improvement in measurement of LV function. National studies of Medicare patients aged ≥ 65 years who were hospitalized with HF in 1993 to 1994 found that 59% of patients had documented ejection fraction in their medical records, with a variation of 45% to 73% across 10 states.²² It is not known how much national patterns have changed in recent years, although studies from some individual state projects have reported higher rates.²⁵ There are no national studies of outpatients.

Prescription of ACE Inhibitors for Patients With Systolic Dysfunction

Several large, multicenter, randomized, controlled clinical trials have shown that ACE inhibitors improve survival and reduce symptoms for patients with HF and LVEF ≤ 0.40 .²⁵⁻²⁷

These benefits appear to apply to all classes (ie, NYHA classes II, III, and IV) of HF patients, as well as patients with asymptomatic LV dysfunction. Because of the large number of ACE inhibitors that have been shown to be beneficial in randomized controlled trials of cardiovascular disease, it is likely that all ACE inhibitors achieve similar benefits. Thus, use of any ACE inhibitor should indicate compliance with this process measure and comprise the numerator.

However, there are limited data on the benefits of ACE inhibitors for patients aged ≥ 75 years²⁸ and those with renal insufficiency. Such patients may be at higher risk and have more limited benefits than younger patients and those with normal renal function. Nevertheless, quality-of-care studies have evaluated use of ACE inhibitors for all patients with LV systolic dysfunction (LVEF ≤ 0.40 or a qualitative description of “moderate” or “severe” LV systolic dysfunction), regardless of age.²² Some studies have defined ideal candidates for ACE inhibitor therapy as having an LVEF ≤ 0.40 , serum creatinine level before hospital discharge ≤ 3.0 mg/dL, serum potassium level before hospital discharge ≤ 5.5 , systolic blood pressure before hospital discharge ≥ 90 mm Hg, and no documented history of allergy to or intolerance of ACE inhibitors.²² Persons who meet these criteria (including those with qualitative descriptions of LV function that imply that LVEF is ≤ 0.40 , such as moderate to severe systolic dysfunction or global or diffuse hypokinesia) form the denominator of the quality indicator.

ACE inhibitor use can be easily and accurately abstracted from inpatient charts.²² When assessing compliance in hospitalized patients, it is probably best to review both the medication list from the final day of hospitalization and discharge medications; some patients may receive an ACE inhibitor throughout hospitalization but not have it prescribed at the time of discharge if their supply at home is adequate. To evaluate outpatients, a comprehensive review of physicians’ notes over the past year, including medication lists, is needed. There are no published data on the accuracy of outpatient chart abstraction for ACE inhibitors.

National studies²² of Medicare patients hospitalized in 1993 to 1994 with a primary diagnosis of HF found that 54.7% of all patients and 73.0% of those who were considered ideal candidates (as defined above) were prescribed an ACE inhibitor at discharge. More recent unpublished studies from several states suggest that the rate of ACE inhibitor use is even higher now, leaving relatively little room for improvement. Although there is much less information about use of ACE inhibitors among outpatients, the available studies suggest that the rate of ACE inhibitor use is significantly below that of hospitalized patients. Only half of patients with HF and low LVEF in the Cardiovascular Health Study²⁹ in 1994 to 1995 were prescribed an ACE inhibitor, and data from the 1994 National Ambulatory Medical Care Survey³⁰ suggest that the rate may be even lower. Thus, there is still much room for improvement in quality.

Theoretically, it should be possible to achieve 100% compliance if the process indicator is either (1) receipt of an ACE inhibitor or (2) documentation of the reason for not prescribing an ACE inhibitor. However, it is unlikely that most physicians document their reasons for not using an ACE

inhibitor, and it is even less likely that this could be reliably abstracted from the chart. Therefore, it may not be possible to increase the rate of ACE inhibitor use to $>85\%$.

Alternative Therapies to ACE Inhibitors

In some projects, use of an ARB or ISDN/HYD has been considered an acceptable alternative to use of an ACE inhibitor. There is limited evidence to support a process-outcome link regarding ARBs. In the Evaluation of Losartan in the Elderly (ELITE) trial,³¹ patients treated with losartan had a lower mortality rate than those treated with captopril, although the actual number of deaths was small and mortality was a secondary end point. However, in the RESOLVD trial,³² there was no difference in 6-minute walking distance, NYHA class, or health-related quality of life for patients treated with candesartan, enalapril, and enalapril plus candesartan. There were also no differences in mortality or CHF hospitalizations between these groups, and there was a trend toward worse outcomes for the candesartan group. It is necessary to await the results of additional clinical trials before any definite recommendation may be made about ARBs. Thus, use of ARBs as an alternative regimen to ACE inhibitors (ie, “patient receiving an ACE inhibitor *or* ARB”) cannot be endorsed as a quality indicator at this time.

ISDN/HYD has been shown to decrease mortality for patients with HF,³³ and the AHCPR guideline²⁰ recommends the use of this combination for patients who cannot tolerate ACE inhibitors. Although this would justify use of these agents as a quality indicator (ie, “patient receiving an ACE inhibitor or ISDN/HYD”), the working group does not recommend it. This combination is rarely used in practice, and these drugs are probably rarely used at the doses and dosing schedule (4 times daily) that were shown to improve survival in the first V-HeFT trial.²⁴

Dosing of ACE Inhibitors

The AHCPR clinical practice guideline²⁰ recommends that ACE inhibitors be titrated to the doses shown to improve survival in clinical trials. Some studies have used “percent of ACE target dose” as a process-of-care measure (with target doses as defined in the guideline). However, few clinical trials have compared low- and high-dose ACE inhibitors. The Assessment of Treatment With Lisinopril and Survival (ATLAS) trial³⁴ found that high-dose lisinopril (32.5 to 35.0 mg/d) compared with lower doses (2.5 to 5.0 mg/d) reduced the combined end point of death or hospitalization (79.8% versus 83.9%, $P=0.002$). In contrast, NETWORK (the Network of General Practitioners and Hospital Physicians Involved in the Study of Low Versus High Doses of Enalapril in Patients With Heart Failure) investigators³⁵ compared enalapril given in doses of 2.5 mg, 5 mg, and 10 mg twice daily and found no difference in the rate of the combined end point of death, HF-related hospitalization, or worsening HF. However, two thirds of patients in this trial were considered NYHA class II. Another study³⁶ treated patients with imidapril given in doses of 2.5, 5, or 10 mg daily for 12 weeks. Plasma ACE inhibitor activity was similarly suppressed on all 3 doses, but exercise tolerance improved more on the 10-mg dose. Because of the limited data supporting the use of

higher-dose ACE inhibitors, it is not recommended that ACE inhibitor dose be used as a process measure at this time.

Several studies have shown that ACE inhibitors are often used at doses below the recommended targets. However, this does not account for the fact that many of the elderly with HF have significant renal impairment that may preclude or contraindicate the use of typical target doses. If ACE inhibitor dosing is to be used as a quality indicator, it is important to stratify by renal function or to identify ideal candidates with no significant renal impairment. For example, (1) the recommended target of an ACE inhibitor could be decreased by half for patients with low estimated creatinine clearance (based on age, sex, and serum creatinine level) or (2) the process measure of ACE inhibitor dose could be applied only to patients with estimated creatinine clearance above a certain threshold. Even if future studies show important benefits from high-dose ACE inhibitors, further work is needed before ACE inhibitor dosing can be broadly used as a quality indicator.

Prescription of Digoxin for Patients With Systolic Dysfunction

All major clinical practice guidelines and consensus recommendations for HF have recommended digoxin for patients with LV systolic dysfunction who continue to be symptomatic despite adequate treatment with an ACE inhibitor and a diuretic.^{19,20,37} The AHCPR²⁰ and ACC/AHA¹⁹ recommendations were based on several small trials that showed improved exercise tolerance in patients treated with digoxin or increases in symptoms and reduction in functional capacity among patients randomly assigned to withdrawal from digoxin.^{38,39} The Digitalis Investigation Group Study²³ went beyond the prior trials in its scope and documented reduction in hospitalization frequency in patients randomly assigned to take digoxin. This finding held up among patients who were "naïve" to digoxin use and, interestingly, among those with relatively preserved LV systolic function. However, the trial failed to demonstrate any benefit from digoxin on survival.

The opportunity for improvement and the potential impact of such improvement with use of digoxin are less than those for ACE inhibitors. Although strong evidence indicates that digoxin may decrease symptoms and frequency of hospitalization, the marginal benefits when added to other therapies appear small. In particular, it is not clear whether digoxin provides additional benefits for patients treated with an ACE inhibitor and a β -blocker. Nevertheless, a process indicator for digoxin use appears to be warranted for all patients hospitalized with HF and depressed LVEF. Digoxin is not routinely recommended for outpatients whose symptoms are well controlled with diuretics, ACE inhibitors, and β -blockers; therefore, this process indicator does not apply to this group. Additional studies are needed of patients with preserved LVEF (ie, >0.40) before digoxin use is routinely considered as a process indicator for this group.

Anticoagulation for Patients With Comorbid Atrial Fibrillation

In the SOLVD treatment trial,²¹ $\approx 10\%$ of patients had atrial fibrillation. The Stroke Prevention in Atrial Fibrillation (SPAF) Trial⁴⁰ identified HF as an important risk factor for

stroke among patients with atrial fibrillation. The estimated stroke risk for this group is 7% per year, and older patients are at even higher risk. Proper use of warfarin can reduce the risk of stroke by approximately two thirds.⁴¹⁻⁴⁵ Although the risk of serious bleeding is substantial (0.6 to 0.8 per year), the risk-benefit ratio still greatly favors use of warfarin. Risk factors for major bleeding include a history of gastrointestinal or other serious bleeding and previous hemorrhagic stroke. Major risk factors for falls are the use of sedatives, dementia, leg disability, unstable gait, or a history of falls. However, it is unclear whether these contraindications to use of warfarin are typically recorded in the chart or whether they could be reliably abstracted at a reasonable cost. The relatively low proportion of patients with atrial fibrillation and the difficulties in identifying ideal candidates for anticoagulation from chart review alone limits the ability to use anticoagulation for atrial fibrillation as a process-of-care measure.

In 1 study, only one third of Medicare patients hospitalized with HF and atrial fibrillation received anticoagulation, which suggests that there is considerable room for quality improvement. However, it may be difficult to change physician practice in this area. The majority of patients with HF are elderly, and physicians may be reluctant to prescribe warfarin because of concerns over the risk of bleeding complications for this population.

Patient Education

Scant data support the use of patient education as a quality indicator, even though it was recommended in the AHCPR clinical practice guideline.²⁰ One randomized controlled trial⁴⁶ showed that patients hospitalized with HF who were managed by a multidisciplinary team had fewer readmissions for HF, but it is not possible to say whether the educational component of the disease-management program caused this improvement. Several observational studies also suggest benefits from multidisciplinary disease-management programs, but it is again unclear whether isolated educational interventions are beneficial for either inpatients or outpatients.

It is also unclear whether educational components can be reliably extracted from charts unless it is documented that the patient participated in a formal educational program with defined components. For example, doctors and nurses may tell a patient about medications, low-salt diet, signs and symptoms of worsening HF, and daily weight monitoring but may not note it in the patient's chart. Conversely, patient education may be documented in the chart even if it was done hastily or perfunctorily at the time of discharge, with little expectation that the information would be retained. Significant effort may also be required to abstract this information from physicians' and nurses' notes. Therefore, at this time, the working group does not recommend the use of patient education as a quality measure. Nevertheless, at least some state PRO projects have established patient education as a process measure for patients hospitalized with HF. In addition, 1 test criterion in the next HCFA NHF project will be the proportion of patients discharged to home who had documentation of instructions for medication doses, daily weight monitoring, low-salt diet, activity level, follow-up appoint-

TABLE 2. Proposed Future Process-of-Care Measures, Ratings of Evidence Supporting Measure, and Ability to Abstract Information From Charts

	Process-Outcome Link*			Abstraction*			Limitations
	Mortality	Quality of Life	Admissions	Reliability	Validity	Burden	
β -Blockers prescribed if LVEF ≤ 0.35	A	A	A	A	A	A	Applicable to outpatients with NYHA class I–III. Functional status may not be recorded.
Spironolactone prescribed if LVEF ≤ 0.35	B	?	B	A	A	A	Generalizability and target population (ie, “ideal candidates”) not defined.
Patients with a history of past MI or current angina should be evaluated for ischemia	C	C	C	B	C	C	Does not apply to patients who are not candidates for revascularization or who refuse procedures. Difficult to assess by chart review.
Daily weight recorded on $\geq 50\%$ of days in hospital	?	?	?	A	A	B	No data linking this measure to outcomes. Not recommended by an expert panel.
Blood pressure control (systolic blood pressure ≤ 120 mm Hg and diastolic blood pressure ≤ 80 mm Hg for patients with LVEF ≤ 0.40 . Systolic blood pressure ≤ 140 mm Hg and diastolic blood pressure ≤ 90 mm Hg for patients with LVEF > 0.40 .)	?	?	?	A	A	A	No direct process-outcome link, although studies have shown that blood pressure control can prevent development of HF. Not recommended by an expert panel to date.
Exercise training	?	A	?	A	A	A	Unclear if formal training program superior to informal training program. No financing mechanism for most patients. Generalizability and target population (ie, ideal candidates) not defined. Many patients may refuse.

*Level of evidence for a process-outcome link: A indicates multiple randomized controlled trials; B, single randomized trial or nonrandomized trials; and C, consensus of experts. Question mark indicates contradictory studies or insufficient published data to provide a rating. Ratings for abstraction reliability, validity, and burden are subjective: A indicates excellent; B, good; and C, fair or poor.

ments, smoking cessation, and what to do if symptoms worsen.

The need for patient education appears to be great. Unpublished data from Medicare patients hospitalized in several states and from outpatients in a large managed-care organization suggest that many patients do not receive adequate information about medications, diet, and self-monitoring. However, the cost of providing patient education and the lack of adequate support for inpatient and outpatient educational programs is a significant obstacle to improvement.

Proposed Process-of-Care Measures

Table 2 lists 6 measures that have been discussed as possible future process-of-care measures and ratings for the level of evidence supporting the recommendation and feasibility of abstracting the information. Although clinical trials have clearly documented the benefits of some of these therapies, all have somewhat unique problems in translation into process-of-care measures. Each measure is discussed in detail below.

β -Blockers for Patients With Systolic Dysfunction

Since publication of the AHCPR²⁰ and ACC/AHA¹⁹ guidelines, several randomized, controlled, clinical trials have documented improvement in clinical outcomes with the use of β -blockers in patients with reduced LV systolic function and stable, mild to moderate HF. The US carvedilol trials,⁴⁷ the Cardiac Insufficiency Bisoprolol Study II (CIBIS-II),⁴⁸ and Metoprolol CR/XL Randomised Intervention Trial in Congestive Heart Failure (MERIT-HF) (long-acting metopro-

lol)⁴⁹ support the contention that the use of β -blockers reduces mortality and frequency of hospitalization for HF within this patient population.

On the basis of the findings of these 3 trials, and despite differences across the β -blockers, it seems highly likely that the major benefit of β -blockers is derived from a class effect. For example, findings are at least directionally the same for carvedilol, a nonselective β_1 , β_2 , and α -antagonist and bisoprolol, a relatively selective β_1 antagonist. An ongoing trial comparing carvedilol with metoprolol may shed further light on the issue of class versus specific drug efficacy. The findings of these trials have prompted the endorsement of β -blockers for patients with NYHA class II or III HF in recently published consensus recommendations³⁷ by an ad hoc group.

Recent attempts have been made to develop process measures of β -blocker use. This task has proved difficult for the setting in which data abstraction is easiest: the inpatient setting. By definition, patients admitted to the hospital for HF have recently been in unstable condition, generally NYHA class IV. These patients are at the greatest risk for immediate prescription of β -blockers and have not been included in adequate numbers in any of the trials that have documented clinical efficacy. FDA approval for use of carvedilol for managing HF is limited to patients with mild to moderate symptoms. It is likely that subsets of hospitalized, sicker patients may undergo initiation of treatment safely, that these patients present a significant opportunity for benefit, and that the inpatient setting represents a valuable opportunity for

initiating treatment. However, the absence of both documented criteria for initiation during acute hospitalization and definitive data on outcome impact for patients treated with β -blockers in this setting represents a difficult hurdle to overcome. It is hoped that ongoing and future trials and guideline recommendations will permit us to overcome it.

At the other end of the spectrum, it is ironic that no data from randomized, controlled trials exist to definitively support the use of β -blockers among patients without clinical HF, who have reduced ejection fraction and either dilated cardiomyopathy or a remote history of MI. Nevertheless, a wealth of pathophysiological data may be drawn on to recommend the use of β -blockers in these patients (level C recommendation).

At present, a process measure of β -blocker use in the outpatient setting appears warranted for patients with NYHA classes I through III HF and reduced ejection fraction who do not presently manifest an acute worsening of signs or symptoms and who do not have a contraindication (eg, history of bradyarrhythmia or bronchospasm). Community use of β -blockers in HF is in its infancy, and the opportunity for improvement and benefit is immense.

Spironolactone for Patients With Systolic Dysfunction

The recently published results of the Randomized Aldactone Evaluation Study (RALES)⁵⁰ showed that spironolactone reduced mortality compared with placebo among patients with severe HF and reduced LVEF who were already receiving an ACE inhibitor. Use of this aldosterone antagonist has therefore been incorporated into guideline recommendations from the Heart Failure Society of America.⁵¹ At this time it is probably premature to incorporate this treatment as a process-of-care measure, because more information is needed about the generalizability of the findings and the definition of ideal candidates.

Evaluation for Ischemia

Clinical practice guidelines and consensus recommendations have stressed the importance of considering active or inducible ischemia in patients who present with HF and/or LV systolic dysfunction. Although no prospective, randomized trial has been performed to show improvement in outcome with revascularization in patients presenting with HF, several cohort analyses have supported this conclusion.⁵² Thus, guidelines have typically recommended catheterization for patients presenting with HF and concomitant limiting angina.^{19,20} In addition, guidelines have set a low threshold for noninvasive testing for viability and inducible ischemia in the remaining patient population. Revascularization is recommended for patients with HF and/or LV systolic dysfunction who manifest inducible ischemia or significant viability in regions of contractile dysfunction and operable coronary disease.^{20,52}

Because of the importance of this issue and the potential for achieving significant prolongation of life in appropriate patients, interest has arisen in implementing performance measures to address the frequency with which the possibility of ischemia is addressed and acted on. Unfortunately, a number of practical issues make it difficult to implement such a quality measure. First, there is considerable population

variability regarding the relevance of this issue. In many community hospital settings, a large proportion of patients admitted with HF are elderly, often residents of extended-care facilities, in whom the issue of revascularization may not be deemed appropriate or desirable by the patient. Second, it may be difficult to ascertain from current hospitalization records whether the issue of active ischemic heart disease has been addressed during a prior hospitalization. Third, the indication for proceeding with noninvasive testing (in the absence of active ischemia) as described in the guidelines is somewhat vague. The guidelines defer to clinical judgment regarding whether the constellation of findings warrants serious consideration of ischemic heart disease. For example, a clinician might not be faulted for not performing such tests in a young woman who has developed HF postpartum, with no suggestion of infarction on the ECG, no regional wall motion abnormalities, and no risk factors for coronary artery disease. Thus, a defensible performance measure relative to the work-up of ischemia may be difficult to define precisely.

It might be reasonable to construct a performance measure related to patients with either (1) active angina or (2) clear evidence of MI on the ECG. In these patients, evidence should be sought in the record that (1) catheterization was scheduled or performed, (2) noninvasive testing for inducible ischemia or viability was scheduled or performed, or (3) an explanation was provided for why such a workup was not undertaken (eg, the patient's condition was debilitated or an evaluation had been performed recently). Given these caveats and the complexity of such a proposed measure, pilot testing is warranted before evaluation for ischemia can be recommended as a quality measure.

Daily Weight Measurement of Hospitalized Patients

In the next HCFA NHF project, 1 test criterion will be whether weights were recorded on $\geq 50\%$ of days in the hospital. No study has explicitly evaluated whether daily monitoring of weight is associated with lower mortality, improved quality of life, or fewer readmissions. However, weight monitoring was a nursing-quality indicator in the RAND study⁵³ of quality of care for patients hospitalized with HF, and better nursing care was associated with lower in-hospital mortality.⁵⁴ Nevertheless, it is more plausible to hypothesize a true causal relation between daily weight monitoring and length of stay (ie, more frequent monitoring of weight leads to shorter length of stay) rather than mortality.

Although it should be possible to reliably abstract these data in a reasonable period of time, it cannot be viewed as a valid measure of process of care until studies show a link between weight monitoring and clinical outcome. This may be possible through the pending HCFA project.

Blood Pressure Control

The ongoing Assessing the Care of Vulnerable Elders project has proposed that tight control of blood pressure be used as a process-of-care measure. Specifically, investigators advocate a systolic blood pressure ≤ 120 mm Hg and diastolic blood pressure ≤ 80 mm Hg for patients with LVEF ≤ 0.40 . For patients with an LVEF > 0.40 , systolic blood pressure ≤ 140 mm Hg and diastolic blood pressure ≤ 90 mm Hg are advocated. Although strong evidence shows that control of

high blood pressure can prevent the development of HF,⁵⁵ there are fewer data on the benefits of blood pressure control for patients with established HF. Although this indirect evidence provides some support for use of blood pressure control as a quality measure, the working group does not recommend it at this time.

Numerous studies have shown that blood pressure control in hypertensive persons is frequently inadequate. This suggests that there is probably substantial room for improvement in blood pressure control among HF patients. However, additional consensus panels should address this issue and identify blood pressure targets before blood pressure control can be advocated as a process-of-care measure. Presumably, this measure would be primarily applied to outpatients with HF. Multiple blood pressure readings would need to be abstracted to determine compliance with blood pressure control targets. It is unlikely that a patient hospitalized with HF would be kept in the hospital to achieve blood pressure control except in extreme circumstances. Despite these issues, blood pressure control would be a very desirable measure as one of the few measures that apply to patients with preserved systolic function as well as those with moderate to severe LV systolic dysfunction.

Exercise Training

Several randomized controlled trials have shown that exercise training can decrease symptoms for patients with HF.^{56–66} However, all of these studies have been fairly small, and generalizability of the results to the overall population of patients with HF is not known. Many patients with HF have arthritis or other conditions that limit their ability to participate in exercise training, so it may be difficult to define the “target population” to which a quality indicator for exercise training might apply. In addition, it is not known whether formal, structured training programs are more beneficial than advising patients to exercise on their own. There is little information on the effect of exercise training on mortality and hospital admission rates, although 1 study⁶⁷ reported lower mortality and hospital admission rates among patients randomly assigned to 8 weeks of exercise training.

This quality-of-care indicator would apply mostly to outpatients with HF. Little is known about the reliability and validity of chart abstraction for outpatients. Even if participation in an exercise program is well documented and can be reliably abstracted, identification of patients with contraindications to exercise training or who refuse to participate would probably be much more problematic. Despite the possible benefits of exercise training, all of the above reasons make it unlikely that exercise training could be used as a process-of-care measure now or in the future.

Other Indicators

In addition to the measures described above, several other process-of-care measures have been proposed for HF patients. These include

- Complete history and physical examination at the time of diagnosis.
- Performance of a chest x-ray, an ECG, and key blood tests at the time of diagnosis.

- Physical examination, including weight measurement, within 7 days of discharge.
- Avoidance of first- or second-generation calcium-channel blockers and type I antiarrhythmic agents.

Although all of these are consistent with recommendations made by expert panels, their use as process-of-care measures is questionable. There is little evidence suggesting inadequacies in the initial evaluation of patients with HF (history, physical examination, chest x-ray, and ECG), and the validity of chart review for the history and physical examination is questionable. Similarly, it is not known how many patients with depressed LV function are not seen within 7 days of hospital discharge or how many are receiving first- or second-generation calcium-channel blockers and type I antiarrhythmic agents. Additional studies are needed to determine patterns of care and whether there are deficiencies large enough to justify the time and effort to abstract this information.

Conclusions

Process-of-care measures are highly useful for assessing the quality of care for patients with HF, although there are important challenges to their development. Measurement of LV function and the use of ACE inhibitors for patients with LVEF ≤ 0.40 have served as the main measures in most large studies to date. Although there is still substantial room for improvement in these areas, additional quality-improvement targets (and measures) are needed. The working group endorses the use of β -blockers as a quality measure for outpatients with HF and NYHA classes I through III symptoms. Because β -blockers have not been shown conclusively to be safe and effective for patients with NYHA class IV symptoms, their use should not be recommended as a quality measure for hospitalized patients. Dosing of ACE inhibitors or digoxin and patient education probably represent the next-best opportunities for quality measurement and improvement. Additional work, including both research and expert panels, is needed before these can be supported.

Other important issues are on the horizon. Implantable defibrillators may prove to be highly effective in future clinical trials. However, their cost-effectiveness may remain uncertain. How should the cost-effectiveness and availability of innovative technologies be weighed in establishing process-of-care measures? In addition, even though the number of treatments for HF is likely to expand, clinicians and patients may be reluctant to increase the number of medications taken. If a patient is taking digoxin, a diuretic, an ACE inhibitor, and 5 other medications for comorbid conditions, should a physician be held responsible if the patient refuses or cannot afford to take another medication? Will there be a need to risk adjust process-of-care measures for age and income so that providers who care for vulnerable populations will not appear to deliver worse-quality care? Finally, process-of-care studies for HF must strive to understand *why* recommended treatments are not received. This information is critical in the effort to move from quality measurement to quality improvement.

Outcome Measures

The essence of quality is the coordination and application of care so that the best possible outcomes are achieved. Patient-based outcome measures must be distinguished from laboratory measures that are often assessed in clinical investigations, including ejection fraction, aerobic capacity, or neurohormonal status. Although the latter may provide insights into the effect of therapy on the pathophysiology of HF, they are not directly observed by patients and are best considered mediators or surrogates of more relevant outcomes.

In addition to being meaningful to patients and society, outcome measures used as quality indicators should be measurable, sensitive to modifications in the structure and process of care, and practical to use. Furthermore, to provide a "level playing field" for comparing providers, outcome measures should take into account patients' underlying risk for both good and bad outcomes.

Identifying measures that fulfill all of these criteria is difficult. Meaningful outcomes include mortality, symptoms, quality of life, functional status, use of healthcare resources, cost (value), and patient satisfaction. Although techniques exist for valid quantification of these outcomes, many factors other than the care provided have a profound effect on outcomes. Factors that enter risk-adjustment models of outcomes include age, severity of LV dysfunction, and degree of comorbidity.⁶⁸⁻⁷¹ These factors often are not subject to modification by the healthcare system. Because factors such as disease severity or socioeconomic status⁷² may vary substantially between providers, well-validated risk-adjustment models are essential before outcomes assessment can be used as a tool for comparing providers' quality of care.

Once outcome measures that meet the 5 criteria above are selected, the timing of assessment is another major issue in quantifying quality. HF is a chronic progressive condition. It is very difficult to determine a patient's state during the natural history of the disease. Ideally, a quality-assessment program would track a patient's disease course from the time of initial diagnosis. Because this is not feasible, several ongoing projects have used hospitalization as an index point for assessing outcomes. Although this cannot completely eliminate the confounding introduced by "lead time bias," reasonable models do exist for predicting mortality, readmission and cost during (and after) a particular HF admission. Nevertheless, these models are limited in that they generally do not explain much of the variation in measured outcomes. Furthermore, these models do not include many relevant outcomes such as health status, symptom control, and/or satisfaction with care. Much more work in this area is needed, including development of models for additional outcomes and identification of new index points such as outpatients.

Defining the subset of HF to be evaluated is a final challenge in measuring quality with outcomes assessment. This is different from the description in the preceding paragraph, in which the primary concern is when in the course of a patient's disease should assessment take place. Instead, the issue is the number of patients at any given point in the disease process who ought to be assessed. It is often necessary to survey a provider population for patients meet-

ing the inclusion criteria, and without sophisticated electronic medical records, this can be difficult. Although this situation is often addressed by including only patients with hospital admissions for CHF, administrative records often lack sufficient details to verify the accuracy of DRG codes for HF admissions. Once the subset is identified, obtaining data from all members of the group is impossible, and understanding the bias introduced by incomplete ascertainment of outcomes is difficult, especially if only limited baseline information is available for comparing responders and nonresponders.

Although outcome assessments may not be appropriate for interinstitutional comparisons, they may be valuable components of intrainstitutional quality-improvement initiatives. Outcome measures can be used for this purpose because the ability to differentiate institutions or providers is less important when tracking outcomes over time or identifying opportunities for quality improvement within a healthcare organization. Documenting patient outcomes and longitudinal tracking of mortality, readmissions, quality of life (physical function, emotional status, and symptoms), and patient satisfaction can facilitate these internal quality-improvement programs. Table 3 identifies several outcome measures and associated issues.

Given the current limitations of available outcome measures, particularly the lack of sound risk-adjustment methods, the working group does not currently recommend the use of outcome measures for comparing care provided to HF patients. The working group does recommend that HF care providers document patient outcomes over time and include these outcomes of HF care as a part of quality-improvement projects within institutions and systems. The working group acknowledges the difficulties inherent in obtaining and analyzing these data; however, efforts to overcome these barriers are warranted by institutions providing outstanding care for HF patients. The following measures are recommended:

1. Mortality rates after index hospitalization or initial diagnosis should be monitored over time within systems. When possible, these data should be used for quality-improvement initiatives and compared with data from comparable institutions with like patient characteristics.
2. Readmissions and emergency department visits, short-term (eg, 60 to 90 days) and long-term (eg, 1 year), after index hospitalization or diagnosis should be recorded.
3. Objective and patient ratings of health status, quality of life, including symptoms, and physical and emotional function are important, but methods and standards in this area are evolving. Ideally, these measures should be obtained and examined individually and in aggregate form to determine change over time, relationship with structure and process-of-care measures, and quality-improvement needs. The ability to interpret these measures and determine the best timing for measurement requires further work to become a standardized component of quality assessment.
4. Measures of individual patient self-management behaviors such as weighing and adherence to diet and medications can be extremely useful in designing quality-improvement processes and modifying approaches to

TABLE 3. Selected Outcome Measures and Related Issues

Outcome	Examples of Measures	Issues/Unanswered Questions
Mortality	Number/percent of HF patients who die within a given time frame	<ul style="list-style-type: none"> ● Differentiating deaths from all causes versus CHF. ● Confounding factors. ● Impact of issues related to end of life and advanced directives has not been well studied. ● Appropriate timing of mortality assessment has not been determined.
Health resource use	<ul style="list-style-type: none"> ● CHF-specific (or all-cause) readmission within a specific time frame ● Emergency department visits related to HF within a specific time frame ● Clinic visits, phone calls, and other contacts 	<ul style="list-style-type: none"> ● Methods to track readmission to multiple institutions, emergency departments, etc are needed. ● Methods to distinguish primary CHF admission from sequelae (angina, arrhythmia) are needed. ● Methods to identify preventable versus nonpreventable CHF admissions are needed. ● Translation of measured resource consumption into costs is difficult and may vary by level of provider (primary care, specialist, midlevel provider).
Health status and quality of life	SF-36 ⁷³ Minnesota LHFQ ⁷⁴ Guyatt Chronic HFQ ⁷⁵ Kansas City Cardiomyopathy Questionnaire ⁷⁶ Utilities: not well tested in HF patients Functional status: 6-minute walk	<ul style="list-style-type: none"> ● Standard definitions of health status and quality of life need to be established: usually include domains of physical and emotional function and emotional and symptom status. ● Methods to distinguish functional ability from functional performance/lack of performance for other reasons (comorbidity, motivation issues) need to be developed. ● Clinically significant improvements in overall quality of life and its components have not been defined. ● Traditional assessment of symptoms (dyspnea, activity intolerance, gastrointestinal symptoms, fatigue) need to be expanded to include other CHF-related symptoms such as decreased attention/memory and cachexia.
Patient and/or caregiver knowledge and performance of self-management behaviors: <ul style="list-style-type: none"> ● medication administration ● dietary sodium and fluid adherence ● daily weight measurements ● physical activity 	Serum drug levels Pill counts, pharmacy refill data 3-Day diet recall and Na calculation; urinary sodium ⁷⁷⁻⁸⁰ Weight logs Self-report instruments Reports from family/friends	<ul style="list-style-type: none"> ● Self-management behaviors are clearly related to other outcomes, yet the best methods to assess and achieve optimal behaviors have not been systematically defined. ● Approaches to measurement have not been standardized within or between healthcare systems. ● Costs involved in laboratory measures such as urinary sodium may be prohibitive.
Patient satisfaction	Picker Instrument ⁸¹ PSQ Forms I and II ⁸² Patient Satisfaction with Health Care Provider Scale (PSHCPS) ⁸³	<ul style="list-style-type: none"> ● Current methods do not differentiate general patient satisfaction from satisfaction with CHF care. ● Dimensions of satisfaction with HF care need consensus and definition (domains may include access to care, finances, technical competence, interpersonal aspects, and overall satisfaction).

care that promote optimal self-care behaviors in HF patients.

5. Generic patient-satisfaction measures can be targeted for analysis and comparison with like institutions, but controversy remains about whether this outcome is a legitimate measure of quality.

Need for Future Work

Outcome measurement of quality indicators for HF care requires much work for use in improving both internal quality improvement and public reporting. Issues of appropriate timing of outcome measurement as well as

cost-effective approaches with low respondent burden are important to address. The working group recommends that future research and clinical efforts in this area be directed toward

1. Development of patient identification methods that facilitate understanding of the proportion of potentially studied patients who were evaluated during outcomes assessment. This is critical for defining the generalizability of observed results.
2. Development of specific risk-adjustment models to account for patient variability for each HF care outcome.

3. Development and definition of valid, reliable, cost-effective, and responsive measures for tracking HF-specific components of quality of life, self-management behaviors, and patient satisfaction.
4. Establishment of a standardized index or battery of instruments for quality indicators that can summate the variety of outcome measures into an interpretable framework understood by both patients and providers.

Summary and Recommendations

HF is an increasingly common condition that results in substantial morbidity, mortality, and consumption of medical resources, particularly among older Americans. National efforts by HCFA and the VA are under way to assess and improve the quality of care and outcome of patients with HF. Furthermore, other organizations such as the AMA, JCAHO, and the NCQA have a strong interest in incorporating HF measures into their assessments of care.

Despite the importance of HF and the extensive medical literature on the subject, relatively few quality measures are endorsed as legitimate measures of quality of care. The working group's review reveals that operational issues (eg, feasibility and cost of collecting data) and the absence of evidence on the efficacy of many diagnostic and therapeutic modalities for specific subgroups of patients hamper efforts to define a set of quality measures for patients with HF. The purpose of this report is not to be prescriptive about current efforts but to emphasize issues that need to be addressed, ongoing initiatives, and areas of research that are essential to enhance understanding of the process and achieve better outcomes.

Structure

Although many structural measures can be proposed as quality-care indicators, few have been formally evaluated in terms of their relationship to outcomes. Measures that may be self-evident to specialty groups (eg, the need for specialty training) may be controversial to generalists and perceived as self-serving by others. Consequently, it is difficult to mandate specific training, personnel, or facilities as quality indicators.

Nevertheless, after a thorough review of the literature, the working group has endorsed 4 specific structural measures for consideration as quality measures.

1. Clinicians at the care facility should have clear, evidence-based guidelines for the care of patients with HF. These guidelines may take the form of either pathways or recommendations, but the facility should have a document that describes or endorses the best practice for their patients and that agrees with the medical literature.
2. Clinicians at the care facility should have a mechanism to monitor patient care and outcomes in a systematic way. The domains of care to be evaluated should align with the guideline recommendations they have endorsed. This information should be reviewed periodically (ie, at least annually) by the staff to evaluate trends over time as part of continued efforts to achieve optimal compliance with the recommendations.
3. Clinicians at the care facility should recognize that patients may require different levels of care, and there

must be an organizational structure to transfer patients to the appropriate level of care. For example, access to an advanced HF facility should be available to patients who need assistance in establishing a diagnosis, enhancing medical therapy, or making a decision about surgery, including cardiac transplantation.

4. Clinicians and care facilities could benefit patients by having specific programs to address the end-of-life needs of many patients with HF.

Process

The working group considered process measures to be an important area for quality assessment. Limitations of these measures were reviewed, and several were emphasized. First, HF is predominantly a condition in older patients, who commonly have many other coexisting diseases, and yet the randomized trials have generally evaluated the efficacy of therapies in younger patients with much less comorbidity. The value of guideline-based therapies for older patients is not definitively known. Second, HF tends to be a chronic condition for which care is delivered in many venues over time. Therapies may be initiated, modified, or terminated at any point. The assessment of quality of care in 1 setting (eg, the hospital) may be misleading if changes are made in the outpatient venue. For example, β -blockers are now considered a useful medication for patients with HF and systolic dysfunction. However, they should be initiated when the patient's condition is stable. Consequently, a hospital assessment may suggest underutilization when many physicians are legitimately waiting several weeks after discharge to start the medication.

Nevertheless, after a thorough review of the literature, the working group endorsed 3 items as quality measures. First, the medical records of patients with HF should have clear documentation of LV systolic function. This measure has implications for therapy and prognosis. Second, patients with HF and LV systolic dysfunction and no contraindications to ACE inhibitors should be prescribed ACE inhibitors. Given the current evidence, the working group did not believe that ARBs or a hydralazine-nitrate combination should be substituted for ACE inhibitors in patients who tolerate ACE inhibitors. The group also did not believe that the evidence about dosing was strong enough to warrant its inclusion as a quality indicator. Third, patients with NYHA classes II and III HF, LV systolic dysfunction, and no contraindication to β -blockers should be prescribed β -blockers. However, this assessment should apply strictly to outpatients, because this medication should be initiated when the patient is stable. Some physicians may reasonably choose not to initiate this therapy during hospitalization.

Several other indicators were thought by the working group to be important to these patients. In particular, the working group wanted to emphasize the importance of the appropriate diagnosis of HF by skilled clinicians, proper titration of diuretic therapy, effective patient education about HF and preventive strategies, and compassionate counseling of patients about their care and prognosis. The reluctance of the working group to recommend these domains as indicators derived from the difficulty of measuring them validly and reliably. Nevertheless, the working group urged efforts to

capture this information accurately and to transform it into useful quality indicators.

The working group also emphasized the importance of several general medical interventions as quality indicators for these patients. They recommended that these patients receive vaccinations against influenza and pneumonia. Anticoagulation for atrial fibrillation, evaluation of ischemia, and treatment of hyperlipidemia for coronary artery disease were also thought to be important indicators of quality of care.

Outcomes

The working group considered outcomes an important measure of the success of patient care. These measures could include mortality, readmission, resource consumption, health status, and satisfaction with care. The issue of overwhelming importance in assessing outcomes for these patients is the development of better risk-stratification models.

However, the working group had strong beliefs about appropriate use of these measures. The group did not believe that these measures should inform consumer choice because of the numerous limitations in risk-adjustment methods and lack of standards for minimum sample sizes and acceptable random variation. The group also acknowledged the logistic challenges of collecting this information. However, working group members strongly believed that outcome measures should be collected by clinicians and used for internal quality-improvement activities. The results over time should be used to identify potential opportunities for improving care.

The working group also acknowledges that mortality is not always a poor outcome in HF and may be the inevitable consequence of a long illness for which the patient may have received excellent care. Suffering associated with this condition may be substantial, and health-status measures are as important as survival rates.

Research Priorities

In the course of developing these recommendations, the working group identified some important areas of further research. The group believes that the science of assessing and improving the care of patients with HF will depend on the success of research efforts to add to knowledge in the following areas:

1. Development and testing of new quality-of-care indicators for HF patients, particularly in the outpatient venue or with the perspective of the continuum of care.
2. Development of risk-adjustment models and methods for various outcomes in HF patients.
3. Development of improved, easy-to-use, disease-specific instruments to evaluate functional status and quality-of-life domains for HF patients.
4. Determination of the association of specific structural characteristics with outcomes of HF patients and defining the essential features of disease-management programs.
5. Determination of the quality-improvement strategies that result in the most rapid adoption of new, proven diagnostic and therapeutic modalities.
6. Definition of the best clinical strategies for older patients, who are unlikely to be enrolled in clinical trials.

The use of carefully collected registries may be the best approach in the heterogeneous older group of patients.

7. Definition of the critical elements of high-quality, end-of-life care and development of quality indicators in this area.
8. Evaluation of the value of new technical and organizational interventions to improve the care of HF patients.
9. Development of methods to efficiently capture information, including information technology solutions, which can be used to assess quality of care for HF patients.

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