

## Consensus

## The Heart Failure Clinic: A Consensus Statement of the Heart Failure Society of America

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### ABSTRACT

**Background:** Outpatient care accounts for a significant proportion of total heart failure (HF) expenditures. This observation, plus an expanding list of treatment options, has led to the development of the disease-specific HF clinic.

**Methods and Results:** The goals of the HF clinic are to reduce mortality and rehospitalization rates and improve quality of life for patients with HF through individualized patient care. A variety of staffing configurations can serve to meet these goals. Successful HF clinics require an ongoing commitment of resources, the application of established clinical practice guidelines, an appropriate infrastructure, and a culture of quality assessment.

**Conclusions:** This consensus statement will identify the components of HF clinics, focusing on systems and procedures most likely to contribute to the consistent application of guidelines and, consequently, optimal patient care. The domains addressed are: disease management, functional assessment, quality of life assessment, medical therapy and drug evaluation, device evaluation, nutritional assessment, follow-up, advance planning, communication, provider education, and quality assessment. (*J Cardiac Fail* 2008;14:801–815)

**Key Words:** Heart failure, clinic, ambulatory care.

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Heart failure (HF) is a leading cause of hospitalization and death in the United States, and its prevalence continues to increase.<sup>1</sup> The clinical care of patients with HF encompasses

a continuum from the treatment of acute episodes requiring hospitalization to chronic management in the outpatient office setting. The latter provides an opportunity for providers to improve patient care and health outcomes through early identification of symptom progression, utilization of evidence-based medication, quality-of-life evaluation, and patient education to increase adherence.

Outpatient care accounts for a significant proportion of total HF expenditures, and HF is a leading cause for ambulatory visits in the Medicare population.<sup>2</sup> Providers face an expanding list of treatment options.<sup>3</sup> These factors, plus observations of an association between improved outcomes and care delivered by high volume, specially trained providers,<sup>3,4</sup> contributed to the development of a disease-specific clinic. The “HF clinic” has become a vital element in comprehensive care of the patient with HF.

A wide range of goals exists for the HF clinic: improvement in clinical outcomes; patient well being and quality of life through recognition of symptom and disease progression; identification of the contributors to HF progression, including poor adherence; management of the medical,

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socioeconomic, and psychologic factors that contribute to morbid events; and development of a mechanism to document and monitor quality. The provision of multidisciplinary individualized care has been cited as a way to minimize intermittent “crises.”<sup>5,6</sup> The documentation and reporting of performance measures, many reflecting processes of care, require the establishment of systems that can also identify and treat patients with HF in a way that will minimize hospitalizations and hence cost.

The establishment of the HF clinic requires the commitment of specific providers, as well as a physical home in which to deliver outpatient care. This commitment must be sustained<sup>7,8</sup> and should include financial resources adequate to support educational initiatives, provider training, and the infrastructure necessary for delivery of a high level of coordinated multidisciplinary care and quality assessment. This includes a provider-to-patient ratio that will support individualized patient care.

Criteria have been proposed for the types of patients who can most benefit from care in a HF clinic.<sup>9</sup> Patients with a recent HF hospitalization and other patients at high risk, such as those with renal insufficiency or multiple active comorbidities, are often considered suitable candidates. The HF clinic may be predominantly physician-directed or nurse-directed and generally includes or has access to a variety of other professionals with expertise in treating patients with HF, identified in other sections of this document.<sup>10</sup> Clinics that cannot provide all facets of advanced HF care should partner with a facility that can offer options such as mechanical support and heart transplantation in eligible populations.

Though there are many articles on disease management programs in heart failure and some on HF clinics,<sup>11</sup> there remains a lack of published standards on care processes and structural elements in a HF clinic. One source provides a “partial listing” of services available in self-identified HF clinics and a list of “potential outcome measures,” but does not establish standards or provide recommendations in either area.<sup>12</sup> Another calls for quality assurance and includes a list of proposed quality measures for a HF clinic, but again does not make recommendations.<sup>10</sup> The clinical practice guidelines of the Heart Failure Society of America (HFSA) and the American College of Cardiology/American Heart Association (ACC/AHA) advocate the use of disease management systems and recognize the potential usefulness of a HF clinic, but do not provide details about the nature of the clinics themselves.<sup>9,13</sup>

For these reasons, the Quality of Care Committee of the HFSA formed a working group to evaluate and reach consensus on the components of an effective HF Clinic. Implicit in this process is the recognition that most of the domains addressed in this article have not been subjected to standard trial methodology. Evidence supporting individual components, when available, is often in the form of pre-and-post evaluations of an intervention, rather than randomized, double-blinded, placebo-controlled trials. Few studies have adequate power, duration of follow-up, or statistical design to test the hypothesis that HF clinics are associated with a reduced

risk of death. At the same time, many studies have demonstrated that specialized care programs for HF improve patient quality of life, functional status, and satisfaction, while reducing the frequency of preventable hospitalizations.<sup>5</sup> Using the best available published data, this document provides a consensus justification for the important components of a HF clinic, recognizing that not every component can be readily translated to all practice settings or providers.

## Methods

Members of the Quality of Care Committee of the HFSA performed an extensive review of the literature and collaboratively developed a family of 11 domains of care that apply to the HF Clinic (Table 1). These domains are based on the presupposition that the patient has been correctly identified as having HF. The HF clinic was not viewed as a mechanism through which patient populations can be screened for the presence of left ventricular dysfunction or clinical HF.

To ensure both consensus and consistency, a series of meetings and teleconferences was used before and during the process of manuscript development. This article was subsequently reviewed and formally approved by the Executive Council of the HFSA.

This article does not address reimbursement or the financial models and tools required to assess the economic viability of the HF clinic, although these issues remain fundamental to any clinic’s long-term viability. In addition, a discussion about access to specialty outpatient HF care is beyond the scope of this document, though clearly disparities in access may adversely impact patients who meet criteria but are not referred. Further rigorous study of these topics is needed.

Each domain is organized into the following sections: description, rationale, and components. A brief summary of components can be found in Appendix 1. The bibliography provides key references in the field, but it is not designed to serve as a comprehensive literature review. The reader is referred to the HFSA 2006 Comprehensive Heart Failure Practice Guideline for detailed information about specific diagnostic and therapeutic recommendations that guide evaluation and management and the studies that form the basis for these recommendations. The recommendations in this document are applicable to the care of patients with HF with preserved or impaired left ventricular ejection fraction.

## Disease Management

### Description

Disease management has been defined as “a comprehensive, integrated system for managing patients across the

**Table 1.** Domains of a Heart Failure Clinic

Disease management
Functional assessment
Quality of life assessment
Medical therapy and drug evaluation
Device evaluation
Nutritional assessment
Follow-up
Advance planning
Communication
Provider education
Quality assessment

health care continuum by using best practices, clinical practice improvement, information technology, and other resources and tools to reduce overall costs and improve measurable outcomes in the quality of care.”<sup>14</sup> Disease management is most commonly applied in the outpatient setting to patients with chronic disease or risk states, often with particular concentration on those who are at highest risk for adverse clinical outcomes or excessive consumption of health care resources.<sup>5,6,15,16</sup>

HF disease management programs can be grouped into 3 overlapping categories: (1) HF clinics, (2) home care, and (3) telemonitoring.<sup>9</sup> HF clinics deliver care primarily in an outpatient office or in hospital- or office-based clinics<sup>17</sup> using a multidisciplinary team that may include physicians, nurses, pharmacists, nutritionists, social workers, exercise physiologists, and other health care professionals with specialized training and skills in HF management.<sup>18,19</sup> Operating on a foundation of consensus around treatment philosophies, practice guidelines, and goals of therapy, the team establishes a longitudinal relationship with each patient to provide optimization of medications, rigorous follow-up, patient/caregiver education, rapid response to clinical compromise, and coordination of care.

The HF clinic may provide oversight, personnel, and support for the other components of a formal disease management program. Home care may be performed in collaboration with home health care vendors employing visiting nurses or other home health care professionals<sup>20</sup>; home visitation by physicians has been reported as another strategy for HF disease management.<sup>21</sup> Care can also be provided from a distance to homebound patients using trans-telephonic methods by nurses with specialized training.<sup>22</sup>

The HF clinic may use technology to monitor patients in the home setting,<sup>23</sup> whether they are homebound or able to make intermittent clinic visits. For example, physiologic data such as body weight, blood pressure, and heart rate may be conveyed electronically to the HF team on a scheduled or ad hoc basis for review and action. Additional innovations in this area have been reported,<sup>24,25</sup> however, not all programs will be equally committed to or logistically capable of delivering expansive home care and telemanagement services, nor are those services a necessary component of a HF clinic.

## Rationale

Achieving the best possible clinical outcomes and cost-effective treatment through the ideal delivery of modern, evidence-based HF care is challenged by many factors, including the decentralized nature of health care delivery; the cost, complexity, and changing standards of care for HF; the need to identify and manage side effects, drug interactions, and other complications of treatment programs; and a patient population that is elderly, often with multiple concomitant medical disorders. A large and growing body of evidence suggests that the comprehensive disease management offered by the HF clinic addresses many of these barriers and thus will be successful in improving patient

**Table 2.** Candidates for Referral to a Heart Failure Clinic Providing Disease Management\*

Patients recently hospitalized for heart failure
Other high-risk patients, including those with:
Renal insufficiency
Diabetes
Chronic obstructive pulmonary disease
Persistent New York Heart Association Class III or IV symptoms
Frequent hospitalizations for any cause
Elderly patients and other patients with multiple active comorbidities
A history of depression, cognitive impairment, persistent nonadherence to therapeutic regimens, or inadequate social or economic support

\*Adapted from Adams KF, Lindenfeld J, Arnold JM, Baker D, Barnard DH, Baughman KL, et al. HFSA 2006 comprehensive heart failure practice guideline. *J Card Fail* 2006;12:e1–122.

quality of life and other clinical outcomes, such as mortality and hospitalizations.<sup>26</sup> Because studies vary in the disease management interventions used, the resources available, and the patient populations studied, it is difficult to isolate the factors key to the success of a disease management program in any given HF clinic.

Patients who should be considered for referral to a HF clinic providing individualized disease management are indicated in [Table 2](#).

## Components

The HFSA recommends that HF disease management programs include multiple components based on patient characteristics and needs.<sup>9</sup> Many of these recommendations are applicable to HF clinics. Disease management components in a HF clinic include but are not limited to the following:

1. Comprehensive education and counseling individualized to patient needs and cultural background and including family members and caregivers when possible and applicable.
2. A philosophy that promotes self-care, including self-adjustment of diuretic therapy in appropriate patients (with family member/caregiver assistance, as necessary).
3. Optimization of medical therapy, including an emphasis on behavioral strategies to increase adherence.
4. Mechanisms to ensure appropriate follow-up after hospital discharge or after periods of instability and early attention to signs and symptoms of fluid overload. Recommended time frames are provided in the section “Follow Up.”<sup>27</sup>
5. Ability to provide assistance with social and financial concerns either directly or through appropriate referrals.
6. A provider-to-patient ratio that will support, not compromise, individualized patient care, recognizing that the numerical value of such ratios has not been established by research and is likely dependent on patient population and provider type. Providers include physicians, nurse practitioners, and other qualified health professionals.
7. An infrastructure that allows for integration and coordination of care between the primary care physician and

HF care specialists and with other agencies, such as home health and cardiac rehabilitation.<sup>28</sup>

## Functional Status Assessment

### Description

The functional assessment of ambulatory HF patients in the outpatient setting is an important component of the initial and follow-up evaluations. Three methods to assess functional status have been subject to extensive research and clinical use: evaluation of New York Heart Association (NYHA) class; the 6-minute walk test (6MWT); and cardiopulmonary exercise stress (CPX) testing.<sup>29–33</sup> BNP testing may be useful in certain clinical settings, but its value for guiding therapy requires further study.

Although these are the standard functional assessments used in the outpatient clinic, other tools can be used to assess functional assessment, including pedometers<sup>34</sup> and physical activity scales (eg, Duke Activity Index scale, the International Physical Activity Questionnaire).<sup>35</sup>

**NYHA Class.** The NYHA classification is used widely in clinical practice and correlates with likelihood of death in stepwise fashion and mode of death in patients with HF and left ventricular (LV) systolic dysfunction. Using this simple tool, dynamic risk assessment is feasible for patients who progress or improve.<sup>36,37</sup> NYHA Class also allows for assessment of the risk of nonfatal events, such as hospitalization, the appropriateness of interventions, and the response to interventions.<sup>38</sup> However, assessment of functional class is often performed without rigor and consistency: interobserver variability is high, with nearly 50% discordance between cardiologists.<sup>39,40</sup>

**6MWT.** The 6MWT is a simple clinical tool that may reflect a patient's ability to carry out activities of daily living to a greater degree than peak oxygen uptake by cardiopulmonary exercise testing.<sup>41–44</sup> However, although the 6MWT correlates moderately with peak oxygen uptake (R values range from 0.68 to 0.76),<sup>45</sup> its utility with respect to risk stratification and assessment of response to therapies is less well defined.

The 6MWT should be conducted using a standardized protocol,<sup>46</sup> recognizing that 15% to 20% will be unable to perform the test because of marked obesity, arthritis, neurologic conditions, advanced age, or severe lung disease.<sup>47,48</sup> A 6MWT distance less than 300 m confers an increased risk of mortality. As noted previously, the relationship between change in symptoms and change in the 6MWT distance is not robust, but in most populations a difference of 50 m is considered clinically significant.<sup>49</sup>

**CPX Testing.** Cardiopulmonary exercise testing is a more sophisticated method to assess exercise performance and can provide baseline prognostic information as well as dynamic risk assessment.<sup>50–53</sup> CPX has been combined with NYHA classification<sup>54</sup> to determine suitability for high risk interventions such as cardiac transplantation. Peak oxygen values less than 14 mL/kg/min carry an increased risk of 2-year

mortality; patients with a peak oxygen less than 12 mL/kg/min in an appropriate age category may be considered for an accelerated evaluation for advanced therapy, such as LV assist devices or cardiac transplantation.<sup>55</sup>

The cardiopulmonary exercise test can be administered using a standard bicycle exercise ramp protocol or treadmill protocol.<sup>56</sup> CPX requires trained personnel to monitor the test and interpret the results; ideally, test-retest variability at peak oxygen consumption should be less than 10%.

### Rationale

Four categories of information can be obtained from conducting a proper functional assessment: baseline prognostic risk with respect to mortality and cardiovascular morbidity; determination of dynamic risk and the change in risk over time; determination of the appropriateness of therapies for the treatment of HF; and the assessment of response to administered therapies.

The NYHA Class functional assessment is simple and easily obtainable. It provides important risk assessment, a method for selecting appropriate therapies and a mechanism for assessing response to treatment. The 6MWT complements the NYHA Class by providing a more objective assessment of functional capacity. Its advantages are simplicity, negligible expense, and ready accessibility. The results provide valuable insight into prognosis both at baseline and through dynamic risk assessment. CPX may be best applied when patients with advanced HF are under consideration for advanced interventions or when the cause of dyspnea has not been fully elucidated.

### Components

The components of functional assessment in a HF clinic include but are not limited to the following:

1. Assessment of NYHA functional class at every clinic visit for patients with symptomatic HF documented in the medical record. A baseline 6MWT is desirable, with follow-up assessments as clinically necessary. Results should be easily accessible in the medical record and significant changes should be noted.
2. Baseline and serial CPX assessments in patients with NYHA Class III/IV symptoms who are candidates for advanced therapies such as LV assist device or cardiac transplantation or to measure response to therapy. Testing should be done by trained personnel with appropriate quality control; it is not necessary for the procedure to be performed in the HF clinic itself, especially if technical expertise is lacking.

## Quality of Life Assessment

### Description

Two important goals of HF treatment are to increase quality of life and improve health status, terms often used interchangeably. In this document, health status refers to

the sum of a patient's symptoms, functional status, and health-related quality of life. Quality of life is by definition patient-centered and may include not only the patient's view of his or her own level of functioning, but how that functioning differs from expectations.

Most instruments combine components of quality of life and other measures of health status. They are divided into generic measures that are used regardless of the condition and disease-specific measures. Both have been extensively reviewed.<sup>57–64</sup> The former include the 36-item Medical Outcomes Study short-form composed of 8 domains.<sup>57</sup> An abbreviated version of the instrument, the SF-12,<sup>58</sup> captures 90% of the variance and represents a validated alternative. Another option is the EuroQol-5D, a 5-item survey covering mobility, self-care, activities, pain, and anxiety/depression using a visual analog scale (0 to 100).<sup>59</sup> The disease-specific instruments include the Chronic Heart Failure Questionnaire,<sup>60</sup> which incorporates 20 items measuring dyspnea, fatigue, emotional status, and mastery domains. The Minnesota Living with Heart Failure Questionnaire is a 21-item survey scored 0 to 105, with 105 indicating the worst health status. Both a physical and an emotional dimension have been identified<sup>61</sup>; a change in score of 5 or more is considered to be clinically significant.<sup>62</sup> The Kansas City Cardiomyopathy Questionnaire is a 23-item survey scored 100 to 0, with 0 indicating the worst health status. Domains include physical limitations, symptoms, self-efficacy and knowledge, social interference, and quality of life.<sup>63</sup> A change of 5 or more is thought to be clinically important.<sup>64</sup> These measures can be self-administered whenever feasible or obtained during a structured interview. Their validity, reliability, and responsiveness to clinical change have been evaluated.<sup>60–64</sup>

Although the ACC/AHA guidelines recommend standardized assessment, the frequency of administration of quality-of-life instruments is not discussed.<sup>13</sup>

### Rationale

Scores on the Minnesota Living with Heart Failure Questionnaire and Kansas City Cardiomyopathy Questionnaire have been associated with survival and hospitalization for outpatients with HF.<sup>65,66</sup> Although correlated with other measurements of functioning (NYHA Class, 6MWT, LV ejection fraction), they have independent predictive value for death and hospitalization. Though infrequently performed in practice,<sup>67</sup> in the clinical trial setting several domains of the Minnesota Living with Heart Failure Questionnaire and Kansas City Cardiomyopathy Questionnaire have been associated with mortality and hospitalization, including activities of daily living, general health, and HF symptoms.<sup>65,68</sup> Objective measurement may also add valuable information about the patient's perception of disease, and serial measurements provide important insight into the patient's trajectory.<sup>69</sup>

The health status/quality of life measures allow standardized assessment that can be self-administered by patients

before clinic visits. They can be used between clinic visits to determine trajectory of health status. The surveys can also be used to identify higher risk patients for more intensive interventions, such as disease management and home monitoring.

### Components

The quality of life assessment components in a HF clinic include but are not limited to the following:

1. Familiarity with delivery and interpretation of at least 1 HF-specific health status/quality of life survey. Questionnaire administration at least once with every patient is desirable, repeated on an individualized basis, especially with changes in clinical status. The use of quality of life tools to screen patients for improvement or deterioration is also desirable.
2. Scoring and recording questionnaire results and an interpretation in the medical record.
3. An accessible medical record that can facilitate tracking of individual results and cumulative statistics for the clinic as a whole.

## Medical Therapy and Drug Evaluation

### Description

Evidence-based practice guidelines for the pharmacotherapy of HF have been established by HFSA and other professional organizations.<sup>9,13</sup> Compliance with these guidelines, however, varies considerably by region, hospital, and prescribing physician. HF clinics should include features that will promote optimal medication prescribing practices, including an effective drug therapy evaluation process.

### Rationale

Despite the fact that the beneficial effects of angiotensin-converting enzyme (ACE) inhibitors and  $\beta$ -blockers on mortality, hospitalizations, and quality of life in HF patients have been well-recognized for over 10 years, there is continued underutilization of both classes of drugs in routine clinical practice. For example, data from the Acute Decompensated Heart Failure National Registry indicate that at the median hospital, 83.6% of eligible patients were discharged on either an ACE inhibitor or angiotensin receptor blocker, with a range from 68.4% at the 10th percentile to 93.9% at the 90th percentile.<sup>70</sup> Similar data have been reported elsewhere.<sup>71</sup> Medication utilization in the outpatient setting has been less well studied, but is likely to be lower and more variable than in the inpatient setting, in part because medications are often discontinued because of side effects or cost.

In addition to underprescription of recommended drug therapies, many patients receive these agents at doses well below those proven to be effective in prospective clinical trials and recommended by practice guidelines.<sup>72,73</sup> Although the reasons for underdosing are not well characterized, it is

likely that physician perceptions about the potential for serious adverse side effects and uncertainty about the incremental benefit of higher dosages, particularly in clinically stable patients, are important factors limiting titration of medications to recommended dosage levels.

Because a primary objective of HF clinics is to provide high-quality care in accordance with evidence-based practice guidelines, it follows that high utilization rates of both renin-angiotensin system antagonists and  $\beta$ -blockers in eligible patients should be expected, and that dosages should be based on current recommendations.<sup>9,13</sup> Other agents should also be used as clinically indicated in accordance with guidelines. Mechanisms should be in place for systematic identification of patients who are not receiving optimal dosages of all medications, and for initiating and titrating drugs to recommended levels.

Drug evaluation involves a review process of the medical history and a comprehensive assessment of drug therapy. Particular emphasis is given to the appropriateness of the medical treatment regimen with respect to published standards of care, potential drug interactions, adverse effects, allergies and, importantly, patient understanding of the rationale for each drug, proper drug dosing, timing of administration, and adherence to prescribed therapy.

A comprehensive drug evaluation can effectively reduce hospital admission rates and other morbidity and potentially improve survival.<sup>18,74–79</sup> The goals of such an evaluation are to:

- devise a medical regimen consistent with evidence-based standards of care
- minimize interactions and other drug-related side effects
- improve patient adherence, quality of life, and satisfaction
- reduce the cost and complexity of the medical regimen
- improve clinical outcomes

Several studies involving intensive reviews of patients' medical records and treatment plans<sup>74–78</sup> have demonstrated improvement in various clinical outcomes compared with usual care.<sup>18,79</sup>

### Components

Components necessary to achieve optimal prescribing and dosing of proven medical therapies in a HF clinic include but are not limited to the following:

1. Medical therapy that is in accordance with established HF practice guidelines and recommended dosage levels. There is literature that can be used to establish expected eligibility rates for key medications, such as  $\beta$ -blockers and ACE inhibitors, in clinical practice and these data should be taken into account when benchmarks are established.
2. Clear and readily accessible documentation of reasons for not prescribing recommended medical therapies or for not titrating to recommended dosage levels.
3. When appropriate, self-management of diuretics, including adequate patient education and tracking functions to ensure safety.

4. Drug evaluation when the patient is enrolled in the HF clinic, to be repeated as indicated by clinical circumstances. The evaluation may be performed by the physician, a specially trained nurse, or a clinical pharmacist. To improve the effectiveness of the evaluation, the patient's family/caregiver should be engaged if possible, and patients should be advised to bring all medication bottles or a list of all current medications. Components to be considered for a drug therapy evaluation include the following.<sup>18,74–79</sup>

A. Clear, comprehensible, and standardized written instructions for the patient/caregiver regarding the indications for each drug, common side effects, and medications and dietary choices to avoid. Any changes to the drug regimen should be clearly explained to the patient/caregiver and documented in the medical record

B. A thorough review of all medications, including over-the-counter medications and supplements, in the context of medical comorbidities, dietary habits, and other patient-specific factors to avoid potential adverse drug-drug or drug-disease interactions.

C. Comprehensive review of the patient's allergy history. Reported intolerances to specific medications should be distinguished from true allergies, possibly through a re-challenge, when such medications are critical to patient care.

D. Assessment of adherence. At each clinic visit, patients should be asked specifically about adherence to the medication regimen, especially if there is evidence of clinical deterioration. When nonadherence is determined, causes should be identified and a strategy implemented to improve medication-taking behavior.

5. A system to identify patients not receiving optimal drug therapy. There are several forms this system could take, including an electronic medical record with "query" capability, pop-up reminders, or a spreadsheet or database providing similar functionality.

### Device Evaluation

#### Description

Implantable cardioverter defibrillators (ICDs) and biventricular pacing (CRT-P and CRT-D) are being used increasingly in patients with LV dysfunction and HF.<sup>80</sup> The role of the HF clinic in this aspect of care is evolving. At a minimum, HF clinic physicians should be able to identify patients who may be candidates for devices and should have some knowledge of device evaluation and management,<sup>81,82</sup> including a reporting process when programming issues or device recalls arise.

#### Rationale

The option of implantable cardiac devices and the advent of invasive monitoring capabilities mandate that the HF clinic institute a formal system to ensure that devices are monitored appropriately, including referral to providers

who manage devices, if rhythm monitoring is not performed directly in the HF clinic.<sup>83</sup> In addition, HF clinic personnel should have the requisite training and experience to manage questions about device functioning from remote sites<sup>84,85</sup> and to institute appropriate algorithms in response to reports of rhythm disturbances, device malfunction, and changes in monitored physiologic parameters (if the HF clinic is committed to the clinical interpretation of these parameters).

The HF clinic has the option of referring the patient to an electrophysiologist for device interrogations and for interventions based on the results of the interrogations. However, with the advent of dually trained physicians<sup>86</sup> or establishment of collaborative multidisciplinary care within the clinic framework, many of the programming tasks can be accomplished in the HF clinic itself. At a minimum, to provide continuity and seamless transitions in care, the HF clinic should establish a clear mechanism for communication with other physicians about device status and should have a recording system to document changes in device settings whether they are implemented within or outside the HF clinic.

Several considerations apply to appropriate patient identification and selection for device therapy.<sup>9,87,88</sup> First, as outlined in guidelines and emphasized here, reversible causes of cardiomyopathy should be sought and time allowed for improvement in clinical status and LV function following guideline-based treatment.<sup>87</sup> Second, because aggressive pharmacologic therapy, especially with  $\beta$ -blockers, can improve LV function in many patients, it is appropriate to wait until after medical therapy has been optimized before implementing device therapy.<sup>87</sup> Third, other considerations, such as life expectancy, should be reviewed in the context of practice guidelines.<sup>87</sup> Fourth, frank discussion with the patient should occur regarding appropriate expectations about the benefits and risks of an implantable cardio-defibrillators.<sup>9</sup>

## Components

The components related to device therapy in a HF clinic include but are not limited to the implementation of procedures that standardize documentation of device functioning and patient well being; facilitation of communication with the electrophysiologist (if participating in the care of the patient); and identification of patients who might benefit from the implantation of a device.

### Components Relevant to Patients Without an Implantable Cardiac Device

1. A system of screening that facilitates the identification of patients who might benefit from device therapy.
2. Documented discussion of therapeutic options, including potential benefits and risks, with each patient being considered for device therapy.

### Components Relevant to Patients With a Preexisting Implantable Cardiac Device

1. A site registry, updated and reviewed regularly, of all patients in whom cardiac devices have been implanted.
2. A clear and consistent system for device evaluation, including documentation in the medical record, and a mechanism to monitor patients with a frequency established by a protocol.
3. Coordination of care with electrophysiologists to avoid duplication of services and conflicting interventions.
4. A system to respond to alerts or recalls produced by regulatory agencies or device manufacturers. This includes a mechanism to rapidly identify affected patients and to permit early clinical follow-up.

## Nutritional Assessment

### Description

Nutritional screening, assessment, and guidance are essential components of patient management in the HF clinic. Special attention should be given to sodium and fluid restriction. In particular, tailored nutritional assessment and management is recommended for patients with comorbid conditions such as diabetes, hyperlipidemia, renal disease, alcoholism, cardiac cachexia, and obesity. The process should begin when a patient is first diagnosed or admitted with HF; outpatient follow-up is essential for prevention of readmission. A registered dietitian or cardiovascular practice nurse is generally in the best position to provide nutritional counseling, but it can be provided by other knowledgeable providers.

### Rationale

Nonadherence with diet accounts for at least 18% of preventable readmissions for HF.<sup>89</sup> Adherence with sodium restriction is particularly important, because it often complements pharmacologic therapy of HF. Appropriate adherence to sodium restriction can lead to a reduction of diuretic dosage; nonadherence can result in a diuretic-provoked electrolyte imbalance, such as hyponatremia or hypokalemia in the setting of thiazide and loop diuretics.<sup>90</sup>

Comorbid diseases common in patients with HF, such as coronary artery disease, hyperlipidemia, diabetes mellitus, and chronic kidney disease, often require special dietary management.<sup>90</sup> Depression, though it does not require dietary management itself, can contribute to poor nutrition and nonadherence to nutritional plans, and must be taken into account. The overall goal of such nutritional management is to retard disease progression and prevent episodes of decompensation.<sup>90</sup>

The risks represented by both obesity and cachexia should be recognized. The latter is an independent risk factor for poor outcome.<sup>91</sup> Right-sided HF can contribute to cachexia by affecting absorption of nutrients across the

gut wall or by impairing hepatic synthetic function. Obesity may be linked to insulin resistance, glucose intolerance, salt sensitivity, and plasma volume expansion, thereby contributing to volume overload and increased systemic vascular resistance.<sup>90</sup>

### Components

Nutritional assessment in a HF clinic should occur in the context of patient comorbidities. The components include but are not limited to the following:

1. A nutritional evaluation of the patient with HF, by a registered dietitian with knowledge and expertise in working with patients with HF, by an advance practice nurse with special training in nutrition, or by some other knowledgeable provider. An initial nutritional screening, assessment, and plan of care should be performed at the time of HF diagnosis and whenever possible during subsequent HF clinic appointments, taking into account ethnic, religious, and gender influences on nutritional habits and including, when possible, the person responsible for meal preparation. Recommendations regarding dietary sodium restriction and, in specific cases, fluid restriction are particularly important,<sup>4</sup> with appropriate documentation and reinforcement whenever clinically indicated.
2. A system to measure, record, and track body weight and body mass index on a regular basis. Calorie counts should be obtained if cachexia is clinically suspected and appropriate nutritional supplementation prescribed if unintended weight loss is documented.<sup>9</sup>

## Follow-up

### Description

HF is a chronic disease that cannot be adequately addressed by treating acute episodic exacerbations. Continuity of care is a hallmark of HF care, and the HF clinic is uniquely positioned to provide focused evaluation and management, thereby limiting potential complications, such as early rehospitalization.

A major contributor to early rehospitalization is inadequate discharge planning.<sup>89</sup> Patients should be told how to recognize and respond to a return of symptoms.<sup>92</sup> Providers should establish a mechanism for early outpatient follow-up after a HF hospitalization, emergency department visit, and both unscheduled and scheduled outpatient HF clinic visits.

In addition to a standard history and physical examination by the provider, follow-up may include repeat imaging, blood chemistries, functional studies, or a repeat visit with a dietitian or social worker. Strategies will vary with each patient presentation, but there is consensus about the need for regular evaluation of patients with HF at risk for adverse events and rehospitalization.<sup>9</sup> The frequency of follow-up will be guided by clinical judgment. At the same time,

the use of risk models<sup>93–95</sup> may help guide clinician decision-making.

### Rationale

Provision of follow-up care is essential for any chronic disease that limits patient well being, is punctuated by repeated hospitalizations, and has a high rate of morbidity and mortality. HF is the leading cause of 30-day rehospitalization in the Medicare cohort and has a high associated 1-year mortality rate. Lack of continuity may contribute to unnecessary utilization of resources, partly through inadequate provider-patient and provider-provider communication. To be consistent with the 2006 HFSA practice guideline, patients in a HF clinic should be followed until they or their family/caregiver demonstrate independence in following the prescribed treatment plan, adequate or improved adherence to treatment guidelines, improved functional capacity, and symptom stability.<sup>9</sup> Higher risk patients may require ongoing follow-up. Patients who experience increasing episodes of exacerbation or who demonstrate instability after discharge from a program should be referred again to the clinic.

### Components

The major focus of follow-up is the establishment of well-defined parameters for patient monitoring after a hospitalization or outpatient visit and the confirmation of patient/caregiver comprehension about these parameters. The follow-up components in a HF clinic include but are not limited to the following:

1. Systematic follow-up after HF hospitalization or emergency department visit. At the time of discharge, an outpatient visit should be scheduled in the HF clinic within 7 to 10 days, as clinically indicated. Higher risk patients should receive follow-up no longer than 72 hours after discharge via such means as telephone contact, home health visit, telemonitoring, or clinic visit. The patient should be instructed on symptoms that might occur and mechanisms to contact a provider at the HF clinic if symptoms recur. A clearly defined plan of action should be provided to the patient or caregiver in case of a sudden or unexplained change in clinical status.
2. Systematic follow-up after an outpatient HF clinic visit. A return visit should be scheduled within no more than 12 months for a stable patient and sooner for patients with advanced symptoms.
3. Serial evaluations of electrolytes, renal function, and other objective monitoring, such as assessment of LV function, with a frequency determined by the provider as part of individualized treatment plans. These frequencies may also be set by reasonable clinical standards of care; for example, at a minimum, patients on diuretics should have electrolytes and renal function monitored at least semiannually.



4. Telephone contact or the use of telemonitoring devices, if available, on an individualized basis.

## Advance Planning

### Description

Seriously ill patients or those with a chronic illness with a risk of mortality should be approached by the provider in an empathic and thoughtful manner to discuss care preferences before the disease has progressed to its near-terminal stage.<sup>96</sup> The process of mapping out the types of medical and nonmedical care a patient would like to receive, before the clinical condition makes it difficult for the patient to express these wishes, is known as advance care planning. This type of planning is an ongoing discussion between the patient, care providers, spouse, family members, and significant others. It is a dynamic process that may require modification or revision as the patient's illness and thought processes evolve.

Advance care plans address the challenges of living with chronic illness, the complications likely to arise, and the treatment options available. Conversations about advance directives often include decisions about code status and the patient's desire for cardiopulmonary resuscitation.<sup>97–99</sup> Explicit consideration of device deactivation is appropriate for patients with end-stage HF.<sup>100,101</sup> Discussions may also cover invasive procedures, surgery, and hospitalizations. The priority is to engage the patient in such a way that values and goals can be elicited.<sup>102</sup> There are no set formats for initiating these discussions, but open-ended questions represent one effective method.

A cardinal feature of advance care planning is the advance directive, which can take various forms, including a living will, health care proxy, or durable power of attorney for health care. Advance directives can be oral or written and, beyond documenting the patient's preferences, may also name a surrogate to make medical decisions if required. The identification of a surrogate also offers an opportunity for the physician to ask about what the patient has told, or would want to tell, the surrogate about his or her preferences.

### Rationale

With advance care planning, physicians can improve patient satisfaction and provide compassionate care at the end of life that is in accordance with the patient's wishes. However, because the patient remains autonomous, the type and intensity of care designated in advance care planning comes into effect only if the patient can no longer express his or her intentions.

### Components

It is the obligation of the provider to introduce the topic, provide resources, and offer access to a structured process that will lead to clarity about patient preferences. The

components related to advance care planning in a HF clinic in regard to advance planning include but are not limited to the following:

1. Incorporating advance care planning into the practice. The care team should be knowledgeable about and have the ability to implement advance care planning concepts.
2. Incorporating advance care planning discussions into the longitudinal care of HF patients.
3. Referring patients to other professionals and resources for assistance, if and when they express an interest in devising a formal advance directive.
4. Recording the status of advance care planning in the patient chart, including a copy of the advance directive, if one exists.

## Communication

### Description

Effective communication is associated with improved patient satisfaction and is ethically required so that patients and families can participate as much as desired in care decisions. Shared decision-making goes beyond informed consent by making the ends of care, as well as the means of care, a matter of negotiation. Shared decision-making is the best way to assure that patients and families receive care that is consistent with their own goals.<sup>103</sup>

The barriers to effective communication are significant.<sup>104</sup> In studies involving interviews of older patients with advanced HF, both a failure to share understandable information with the patient and a lack of discussion about prognosis have been reported.<sup>67,105–107</sup> Data from the Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments and other studies indicate that physician and patient perceptions about interactions, including the content of discussions, are often conflicting.<sup>108,109</sup> All verbal and written communication should be at an appropriate level for the patient and family members. The style of communication has been identified as one factor critical to its success.<sup>107</sup>

Further, given the high prevalence of comorbidities, patients often have multiple providers, requiring additional interactions within the health care system. Lack of communication between providers can lead to medication errors, conflicting treatment plans, and mixed messages for the patient about disease severity, prognosis, and best approaches to care.

### Rationale

Multiple layers of communication exist between provider and patient and among providers (including family members, physicians, nurses, and ancillary health care personnel). The patient, as an autonomous being, requires effective communication in order to receive information about prognosis, treatment options, adherence, advance care planning, and other facets of care. Incomplete or

poor information flow between provider and patient or between providers can lead to significant patient dissatisfaction, compromised medical outcomes, and increased hospitalizations. In addition, discordance has been reported about predictions of life expectancy between patients and validated risk stratification models, suggesting a potential deficit in patient understanding and patient-physician communication.<sup>110</sup>

There are no formal standards that can be used to measure the effectiveness of communication between provider and patient. Mechanisms that can be implemented to ensure or measure effective communication across providers remain undefined. Nevertheless, given the importance of improving the quality and efficiency of communication, providers should be focused on the role communication plays in HF care and should provide access to education as necessary.

### Components

The components in a HF clinic in regard to communication include but are not limited to the following.

1. A trusting patient-provider relationship that facilitates open communication.
2. Timely dialogue between providers across the care continuum. The patient should be informed that there is an adequate flow of information between providers. Documentation of such communication is essential.

## Provider Education

### Description

The Institute of Medicine recognizes that professional education is an integral component in the quality of HF care,<sup>111</sup> a fact confirmed in many studies.<sup>112–114</sup> It is also recognized by clinicians, as reflected in a national survey of clerkship directors in internal medicine in which HF was ranked 4th of a possible 60 disease targets.<sup>115</sup> Provider education in the HF clinic encompasses a full range of initiatives designed to ensure provider competence. Competence includes the knowledge of standards of care and their pathophysiologic foundations, effective communication skills, and development of a culture in the practice that is focused on performance assessment and continuous quality improvement. Educational options include such formats as lectures, skills workshops, online activities, and practice-based assessment and learning.

### Rationale

Decision-making in HF care is a dynamic process, given frequent advances in clinical trials and translational research that provide the framework for evidence-based practice. The literature on practice assessment and ongoing performance measurement<sup>116,117</sup> emphasizes the central importance of provider education, especially when focused

on the application of practice guidelines. Provider education can be defined by the implementation of standardized learning about treatment and evaluation modalities, practice assessment, performance measures, metrics, and mechanisms that help to ensure that improvements in HF care are readily translated into daily practice. An approach that incorporates practice-based learning has the potential to improve compliance with HF guidelines in the ambulatory setting in large group practices<sup>118,119</sup> and in hospital care.<sup>120,121</sup>

Barriers to provider education exist, due in part to time constraints in practice, short supply of resources, and difficulty in coordinating interdisciplinary teams.<sup>122</sup> Nevertheless, the mandate to update clinical competencies is unambiguous and explicit.

### Components

The educational program of a HF clinic should be designed to update clinical competencies.<sup>123</sup> The components in a HF clinic include but are not limited to the following:

1. Participation in formal continuing education preferably reflecting the key components of the 2006 HFSA Comprehensive Heart Failure Practice Guideline or the ACC/AHA 2005 Practice Guideline.<sup>9,13</sup>
  - A. Training for physicians that is consistent with Level 3 Core Cardiology Training Symposium requirements or, if the clinic provides services for patients with advanced HF and recipients of heart transplants, is consistent with the requirements of the ABIM secondary subspecialty in advanced HF cardiology and transplantation.
  - B. Training for nurses that includes pathophysiology, pharmacology, patient self-care management approaches, psychosocial influences on patient behaviors, and quality-of-life and palliative care issues.
2. The availability of multiple educational modes in the critical areas of HF care to maximize the translation of education into practice.<sup>124–126</sup>
3. Periodic practice assessment as a component of practice-based learning.

## Quality Assessment

### Description

Quality of HF care can be divided into outcome, process, and structural components.<sup>127</sup> The degree to which the HF clinic can evaluate quality using measures that reflect these components varies, depending on many factors, such as payer mix and clinic commitment.

### Outcome Measures

Outcome measures, such as survival and quality of life, are the most important quality measures from both the patient's and society's perspective. They are influenced by patient factors<sup>128</sup> and thus require substantial clinical data to adjust for patient characteristics. However, there are

scant data available that can be applied to the analysis of risk-adjusted survival for outpatients with chronic HF. This situation is in contrast to the inpatient and, more recently, the early outpatient setting. The Center for Medicare and Medicaid Services has reported 30-day mortality after a HF admission at the hospital level using administrative data to adjust for risk.<sup>129,130</sup>

There are at present no convenient tools for tracking readmission rates. The threshold for admission may vary widely depending on patient preference and across practices depending on the ability to deliver aggressive outpatient care. For those health care systems that are able to track these data, a conservative labeling of outliers is appropriate given the limitations of risk adjustment. Patient satisfaction is an additional important outcome related to quality, although there is no established HF-specific instrument.

### Process Measures

Process of care measures are the most accepted indicators of quality for hospitals and individual providers. Adoption of many of these process measures have been shown to improve outcomes in randomized trials. Furthermore, these measures can be obtained using many existing medical record systems. The HFSA has endorsed the performance measures published by the ACC/AHA,<sup>131</sup> reflecting consensus that nonadherence with the measures indicates poor quality.<sup>9,13</sup>

The performance measures pertaining to outpatient HF care include but are not necessarily limited to: measurement and documentation of LV ejection fraction (initial encounter); weight measurement; blood pressure measurement; assessment of symptoms of fluid overload; assessment of signs of fluid overload; assessment of activity level; patient education;  $\beta$ -blocker therapy if LV ejection fraction is  $<40\%$ , ACE inhibitors or angiotensin receptor blockers if LV ejection fraction is  $<40\%$ ; and warfarin for patients with paroxysmal or chronic atrial fibrillation.<sup>9</sup>

When using individual process of care and outcome measures at the provider level, sample sizes are often too small to clearly identify high- and low-quality providers. Additional research is needed on how to best combine quality measures over multiple patients to obtain adequate power for assessing the quality of an individual provider.

### Structural Measures

Few studies have examined specific structural elements of HF care and their impact on outcome. Such measures in the future may include the routine reporting of quality measures to a central regulatory body, such as the Center for Medicare and Medicaid Services, or a registry.

### Rationale

Quality assessment is a crucial component in the evaluation of the HF clinic, given the potential for identification of structural and process flaws that, when corrected, can favorably impact patient care and outcomes. In addition, quality assessment allows for benchmarking, a process by which

the HF clinic can gauge its performance relative to other practices and practice settings and monitor performance over time.

### Components

The quality assessment components in a HF clinic include but are not limited to the following.

1. Adoption of a philosophy that openly encourages process improvement. The HF clinic should set goals for quality improvement and institute structures and processes, such as morbidity and mortality reviews, designed to improve performance.
2. Development or participation in an existing review procedure (eg, a registry) to evaluate care using the ACC/AHA performance measures. Treatment measures known to improve survival, such as the use of ACE inhibitors and  $\beta$ -blockers, should be given priority.
3. Use of data to assess the performance of the specific HF clinic relative to other providers and to identify areas that require improvement, including patient satisfaction.
4. Flexibility in the use of assessment and reporting tools that will accommodate changes in performance measures and mechanisms to capture and report data.
5. Use of processes that allow for regular review of performance reports.
6. A process for tracking admission rates and, where feasible, HF mortality rates.

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## Appendix 1

### The HF Clinic: Component Summary\*

Domain	Components
Disease management	(1) Comprehensive education and counseling individualized to patient needs and promoting self-care with an infrastructure that facilitates integration and coordination of care.
Functional assessment	(1) Assessment of NYHA functional class at every patient visit. A baseline 6MWT is desirable, with follow-up assessments as clinically necessary.
Quality of life assessment	(1) Familiarity with delivery and interpretation of at least one HF-specific health status/quality-of-life survey. Administration and evaluation of a quality-of-life questionnaire at least once with every patient is desirable, repeated on an individualized basis.
Medical therapy and drug evaluation	(1) Medical therapy that is in accordance with established HF practice guidelines. (2) When appropriate, self-management of diuretics, with appropriate education and tracking. (3) Drug evaluation upon patient enrollment, repeated as indicated by clinical circumstances. (4) Assessment of adherence at each clinic visit and the development of strategies to improve adherence when necessary.
Device therapy	(1) A system of screening that facilitates the identification of patients who might benefit from device therapy and a discussion with those patients of therapeutic options, including risks and benefits. (2) A clear and consistent system for device evaluation and patient monitoring, including coordination of care with other professionals, as necessary. (3) A system to respond to alerts or recalls issued by regulatory agencies or device manufacturers.
Nutritional assessment	(1) A nutritional assessment in the context of patient comorbidities at the time of HF diagnosis and whenever possible during subsequent clinic visits. (2) When clinically indicated, recommendations for sodium and fluid restriction. (3) A system to track body weight, BMI, and, when cachexia is suspected, calorie counts.
Follow-up	(1) Systematic follow-up after a HF hospitalization or ED visit (according to published guidelines a clinic visit in 7 to 10 days or within 72 hours for high-risk patients). (2) Systematic follow-up after an outpatient visit, including a clinic visit no more than 12 months out for a stable patient and earlier for patients with more advanced symptoms. (3) Serial evaluation of electrolytes, renal function, and other objective monitoring, such as measurement of LV function, with a frequency determined as part of an individualized treatment plan.
Advance planning	(1) A care team knowledgeable about and able to implement advance care planning concepts. (2) The incorporation of advance care planning discussions into the longitudinal care of HF patients.
Communication	(1) Establishment of a trusting patient-provider relationship that facilitates open communication using patient-appropriate language. (2) Timely dialogue between providers across the care continuum, including professionals within and outside the HF clinic.
Provider education	(1) Provider participation in continuing education in the key components of HF care, HF training for cardiovascular fellows consistent at a minimum with COCATS requirements, and, in the case of clinics providing care for patients with advanced HF and cardiac transplantation, a provider who meets the requirements for the secondary subspecialty in advanced HF and transplantation cardiology. (2) Periodic practice assessment as a component of practice-based learning.
Quality assessment	(1) The formulation of goals for quality improvement and the presence of structures and processes designed to improve performance. (2) Participation in a review procedure to evaluate care against ACC/AHA performance measures. (3) Clinic performance assessment relative to other providers, including identification of areas needing improvement and the development of strategies to change.
Record keeping and data review <sup>†</sup>	(1) Documentation in the medical record of such information as NYHA functional class, 6MWT results, QOL test results, reasons for not prescribing guideline-recommended medications or for not titrating up to recommended dosage levels, discussion of device risk and benefits, body weight, BMI, status of advance care planning, and the existence of advance directives. (2) Systems for the identification, on a clinic-wide basis, of patients not receiving optimal therapy; a site registry of all patients with devices; record keeping that facilitates the tracking of device function for all patients; regular review of performance reports; flexible assessment and reporting tools that will reflect changes in performance measures; and mechanisms to capture and report data.

NYHA, New York Heart Association; 6MWT, 6-minute walk test; HF, heart failure; BMI, body mass index; ED, emergency department; LV, left ventricular; COCATS, Core Cardiology Training Symposium; ACC, American College of Cardiology; AHA, American Heart Association; QOL, quality of life.

\*See text for full set of components.

<sup>†</sup>Not a domain in text. Items collated from existing domains.