

**ACC/AHA HEART FAILURE CLINICAL DATA STANDARDS****ACC/AHA Key Data Elements and Definitions  
for Measuring the Clinical Management and  
Outcomes of Patients With Chronic Heart Failure**

A Report of the American College of Cardiology/American Heart  
Association Task Force on Clinical Data Standards (Writing Committee  
to Develop Heart Failure Clinical Data Standards)

*Endorsed by the Heart Failure Society of America*

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**TABLE OF CONTENTS**

Preamble.....	1180
I. Introduction.....	1181
II. Methodology.....	1181
A. Writing Committee Composition.....	1181
B. Relationships With Industry.....	1182
C. Review of the Literature and Existing Data Definitions.....	1182
D. Prioritizing Data Elements.....	1182
E. Defining Data Elements.....	1182
F. Consensus Development.....	1183
G. Peer Review, Public Comment, and Board Approval.....	1183
H. Considerations for Use of Data Elements and Definitions.....	1183
I. Special Considerations and Challenges for HF Data Standards.....	1183
1. Uses for HF Data Standards.....	1183
2. Balance Between Focus and Comprehensiveness.....	1184
3. Balance Between “Primary” and “Summary” Data Elements.....	1184
4. Variety of Disease States Leading to HF.....	1184

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5. Acute and Chronic Care, Inpatient and Outpatient Care Venues .....	1184
6. Therapy for HF .....	1184
7. Outcomes Assessment for HF.....	1184
III. HF Clinical Data Standards Elements and Definitions .....	1184
A. Patient Demographics.....	1184
B. Medical History .....	1186
C. Patient Assessment: Current Symptoms and Signs .....	1191
D. Patient Assessment: Summary Assessment .....	1192
E. Laboratory Tests .....	1194
F. Diagnostic Procedures.....	1194
G. Invasive Therapeutic Procedures.....	1197
H. Pharmacological Therapy.....	1199
I. End-of-Life Management .....	1201
J. Patient Education: Assessment of Status .....	1201
K. Patient Education: Intervention and Referral .....	1202
Appendix A: Health Status .....	1203
Appendix B: Writing Committee Relationships With Industry .....	1203
Appendix C: Peer Reviewer Relationships With Industry.....	1206
References.....	1206

**PREAMBLE**

The American College of Cardiology (ACC) and the American Heart Association (AHA) recognize the importance of refining the lexicon used to describe the process and outcomes of clinical care, whether in randomized trials, observational studies, registries, or quality improvement initiatives. Broad professional agreement on a common vocabulary with common definitions will facilitate cross-study comparisons or, when advantageous, combining of data across studies and improving the assessment of any project’s generalizability to clinical practice. To further efforts aimed at standardizing such a lexicon, the ACC and AHA have undertaken to develop and publish clinical data standards—sets of standardized data elements and corresponding definitions that can be used in a variety of data collection efforts for a range of cardiovascular conditions.

It is hoped that these clinical data standards will:

1. Improve cross-comparison of results and clinical outcomes between different trials and registries.
2. Facilitate the development and conduct of future registries, at both hospital and national levels, by providing a list of major variables, outcomes, and definitions.
3. Facilitate measurement for quality improvement programs.
4. Become the basis for a standardized medical documentation process with the anticipation that the medical record will progress to an electronic format.

The ACC/AHA Task Force on Clinical Data Standards makes every effort to avoid any actual or potential conflicts of interest that might arise as a result of an

outside relationship or a personal interest of a member of the writing panel. Specifically, all members of the writing panel are asked to provide disclosure statements of all such relationships that might be perceived as real or potential conflicts of interest. These statements are reviewed by the parent task force, reported orally to all members of the writing panel at the first meeting, and updated as changes occur.

The ACC/AHA Task Force on Clinical Data Standards selects cardiovascular conditions and procedures that would benefit from the creation of a standard dataset. Experts in the subject are selected to examine/consider existing data standards and develop a comprehensive, yet not exhaustive, standard dataset. Users should understand that, when undertaking a data collection effort, only a subset may be needed or, conversely, they may want to consider whether it may be necessary to collect some elements not listed. For example, in the setting of a randomized clinical trial of a new drug, additional information would likely be required regarding study procedures and drug therapies.

The ACC and AHA aim to standardize the language used to describe cardiovascular diseases and procedures, enhance consistency in cardiology, and increase opportunities for sharing data across various data sources. The ultimate goal of ACC/AHA clinical data standards is to contribute to the infrastructure necessary for accomplishing the ACC/AHA’s mission of fostering optimal cardiovascular care and disease prevention.

The ACC and AHA support the goals of their members to improve cardiovascular care and disease prevention through professional education, promotion of research, development of guidelines and standards for cardiovascular care, and fostering a policy that supports optimal patient outcomes. Both the ACC and the AHA recognize the importance of the use of clinical data for patient management, in the assessment of patient outcomes, and in research efforts focused on improving the clinical treatment of patients.

As a component of this objective, the ACC/AHA clinical data standards concentrate on the identification, definition, and standardization of data corresponding with various clinical topics in cardiology. The primary goal of clinical data standards is to assist in the collection of data by providing an initial platform of data elements and corresponding definitions applicable to various disease conditions in cardiology. These key elements and definitions are a compilation of variables applicable in the measurement of patient clinical management and outcomes, and for research and epidemiological assessments.

The Health Insurance Portability and Accountability Act (HIPAA) privacy regulations, which went into effect in April 2003, have heightened all practitioners’ awareness of our professional commitment to safeguard our patients’ privacy. Our goal is to treat every patient’s health information with the same respect and courtesy as

their person. The HIPAA privacy regulations (<http://www.hhs.gov/ocr/combinedregtext.pdf>, page 31) specify which elements are considered “protected health information.” These elements may not be disclosed to third parties (including registries and research studies) without the patient’s written permission. Protected health information may be included in databases used for health care operations under a data use agreement. Research studies using protected health information must be reviewed by an Institutional Review Board or a Privacy Board.

We have included identifying information in all clinical data standards, to facilitate uniform collection of these elements when appropriate. For example, a longitudinal clinic database may contain these elements, because access is restricted to the patient’s caregivers. Conversely, registries may not contain protected health information, unless specific permission is granted by each patient. These fields are indicated as protected health information (PHI) in the data standards.

Our understanding of the importance of data element standardization, the backbone of clinical care, clinical research, and quality performance measurement, derives from experience with clinical care, clinical research, and quality performance measurement. In clinical care, caregivers communicate with each other through a common vocabulary. The integrity of clinical research depends in large part on firm adherence to prespecified procedures for patient enrollment and follow-up; these procedures are guaranteed through careful attention to definitions enumerated in the study design and case report forms. When data elements and definitions are standardized across studies, comparisons, pooled analyses, and meta-analyses are enabled, thus deepening our understanding of individual clinical trials.

The recent development of quality performance measurement initiatives, particularly those for which comparison of providers is an implicit or explicit aim, has further raised awareness among the professional community about the importance of data standards. For the first time, a wide audience, including non-medical professionals such as payers, regulators, and consumers, may draw conclusions about care and outcomes. For understanding and comparison of care patterns and outcomes to be fair, the data elements that comprise the descriptions of these patterns and outcomes of care must be clearly defined, consistently used, and properly interpreted by a broader audience than ever before.

*Paul A. Heidenreich, MD, MS, FACC  
Chair, ACC/AHA Task Force on Clinical Data Standards*

## I. INTRODUCTION

The syndrome of heart failure (HF) is a common manifestation of the later stages of various cardiovascular diseases, including coronary artery disease, hypertension, valvular disease, and primary myocardial disease. It is the most

common reason for hospitalization among older individuals (1), and its appearance usually foreshadows the need for ongoing care for the duration of the patient’s life. Therapy for HF has benefited from scientific investigations into basic molecular mechanisms of disease (2,3) from advances in engineering, instrumentation, and surgery (4) and from large multicenter trials (5–7) and registries (8,9). Increasingly, care of patients with HF, particularly advanced HF, may take place in specialized clinics using a team approach (10–12). In addition, growing national interest in quality of treatment has focused scrutiny on patterns and outcomes of HF care (13,14).

Heart failure was identified for development of data standards by the ACC and the AHA. As with the first condition, acute coronary syndromes (ACS) (15), and the second condition, atrial fibrillation (AF) (16), the goal of the data standards is to provide a standardized information platform that will be useful in a variety of situations, particularly clinical trials, clinical registries, and quality performance measurement. Similar to the writing committees for ACS and AF clinical data standards, the ACC/AHA Writing Committee to Develop Clinical Data Standards for Heart Failure proceeded to develop data element definitions with the understanding that they might be useful in a variety of circumstances:

- Clinical programs, such as HF clinics, where many providers work together to achieve specific and specified goals for the care of patients with HF.
- Clinical registries, for ongoing care, prospective epidemiologic research, or prospective quality performance measurement.
- Clinical research, particularly prospective randomized clinical trials where eventual pooled analysis or meta-analysis is anticipated.
- Quality performance measurement initiatives, provider-based or external, retrospective or prospective.
- Organization and design of electronic medical information initiatives, such as electronic medical records, pharmacy databases, or computerized decision support.

## II. METHODOLOGY

### A. Writing Committee Composition

The ACC/AHA Task Force on Clinical Data Standards selected members for the ACC/AHA Writing Committee to Develop Clinical Data Standards for Heart Failure (Writing Committee). The Writing Committee consisted of 10 members who are active in clinical research in HF, clinical programs (HF clinics, transplant programs, centers of excellence), HF registries, and quality performance measurement initiatives. The Writing Committee included membership from the U.S., Great Britain, and Canada so as to ensure balance in the selection of data elements and consideration of variations in practice worldwide. A representative from cardiovascular nursing

provided expertise in the area of patient education. To ensure consistency between the clinical data standards and other ACC/AHA HF documents, the Task Force also appointed representatives from the ACC/AHA Heart Failure Guideline Update Writing Committee and the ACC/AHA Heart Failure Performance Measures Writing Committee.

### ***B. Relationships With Industry***

The American College of Cardiology makes every effort to avoid any actual or potential conflicts of interest that may arise as a result of an outside relationship or a personal, professional, or business interest of a member of the writing panel. Specifically, all members of the writing group are required to complete and submit a disclosure form showing all such relationships that might be perceived as real or potential conflicts of interest. These statements are reviewed by the ACC/AHA Task Force on Clinical Data Standards, reported orally to all members of the writing panel at the first meeting, and updated as changes occur. Please see Appendix B for Writing Committee relationships with industry and Appendix C for relationships with industry information for peer reviewers of this document.

### ***C. Review of the Literature and Existing Data Definitions***

The ACC/AHA Task Force on Clinical Data Standards supported gathering as many candidate data elements and definitions as possible, principally from large clinical trials, national quality performance measurement initiatives, and guidelines. The Writing Committee compiled and reviewed case report forms, data elements, and definitions from national, international, and local cardiovascular data collection efforts. Examples of these data sources include the ACC-NCDR (<http://www.accncdr.com/WebNCDR/Elements.aspx>), the ACC Key Data Elements and Definitions for Measuring the Clinical Management and Outcomes of Patients With Acute Coronary Syndromes (15), the Quality Indicators for Heart Failure Patients (<http://cms.hhs.gov/healthplans/chf/qapi-0601.pdf>), the Cardiac Transplant Research Database, Centers for Disease Control and Prevention Common Data Elements (<http://www.cdc.gov/data/impv24.pdf>), the Iowa Foundation for Medical Care's Heart Failure tools ([http://www.internetifmc.com/prof\\_inpatient\\_hf\\_tools.php](http://www.internetifmc.com/prof_inpatient_hf_tools.php)), and the Organized Program to Initiate Life-Saving Treatment in Hospitalized Patients with Heart Failure (OPTIMIZE-HF) Internet-based registry (17).

The HF data standards are meant to provide data elements that parallel and complement other ACC and AHA standards, specifically the guidelines and the performance measures. The ACC/AHA 2005 Guideline Update for the Diagnosis and Management of Chronic Heart Failure in the Adult (18) served as the primary evidence-based document that writers of this data ele-

ment set referenced in their development of data element definitions. The ACC/AHA Clinical Performance Measures for Adults With Chronic Heart Failure (19) were developed simultaneously with the HF data standards, with frequent exchange of information between these two committees. Other research articles, clinical trials, and reference sources were consulted as needed and are cited throughout this document.

### ***D. Prioritizing Data Elements***

After the Writing Committee reviewed the HF guidelines, other pertinent literature, and the data definitions from related sources, a comprehensive list of possible data elements to include in this set was created. This initial list aimed at capturing the universe of potential elements with the understanding that, by necessity, this set of data elements must be limited to those elements most likely to be needed in data collection efforts for research, clinical care, and quality improvement. From this initial list, the Writing Committee graded the importance of including each data element as "high," "medium," or "low." All of the data elements with an average "high" score and the majority of those with an average "medium" score were maintained in the set. The rest of the elements were not defined at this time, but they are maintained as possible elements to be defined and added at a later time.

The process of writing and revising data element definitions caused many data elements to move in or out of the set for a variety of reasons. In some instances, an element that on its own may have been ranked "low" was necessary to complete a subset of elements pertaining to a related concept. Conversely, an element that was ranked as "high" may later have been determined to be impossible to define in a manner that facilitates consistent data collection, or its content may have been determined to be contained within another data element. In this fashion, the process of prioritizing, adding, and removing data elements continued throughout the Writing Committee's process.

### ***E. Defining Data Elements***

Members of the Writing Committee drafted definitions for those data elements deemed to have priority for the first publication of the HF data standards. Each writer received a template to assist in drafting the definitions and to provide for a structured format across authors. Members were encouraged to write definitions broad enough to be applicable in a variety of data collection settings, but specific enough that the data elements can be uniformly interpreted. Data elements have also been defined to be usable in both inpatient and outpatient settings.

Writing team members received sample definitions from a variety of existing sources (see Section "C. Review of the Literature and Existing Data Definitions"). Data



definitions were linked whenever possible to the evidence-based national guidelines, specifically the ACC/AHA 2005 HF Guideline Update (18). To ensure consistency across ACC/AHA clinical data standards, writers were instructed to use an existing ACC/AHA definition verbatim unless there was a reason related to HF to change that definition.

Similar to guidelines and performance measures, data standards require regular review and updating. At the anniversary of the data standards publication, the Writing Committee chair, in conjunction with Writing Committee members, will review the data standards to ascertain whether or not modifications should be considered. Published ACC/AHA practice guidelines are reviewed one year after publication to determine whether significant advances have occurred in clinical practice to warrant changes in recommendations. To keep current, whenever the relevant guideline is updated the associated data standards will be reviewed and revised to reflect those changes.

#### **F. Consensus Development**

The ACC/AHA data standards are consensus, team-written documents that are based on judgments of experts in the field of cardiology. This Writing Committee met several times, both in person and through conference calls, over the course of several months to define and refine the data elements. Throughout the creation of the data element set, consensus was developed through discussions (either during face-to-face meetings or conference calls), e-mails, and sometimes written votes. The process of consensus development allowed for the incorporation of minority opinions in the few instances when a group consensus could not be achieved.

#### **G. Peer Review, Public Comment, and Board Approval**

The set of HF data elements was independently reviewed by three official reviewers nominated by the ACC and two official reviewers nominated by the AHA, the ACC/AHA Heart Failure Guideline Update Writing Committee chair, the ACC/AHA Task Force on Clinical Data Standards, and four independent content reviewers. To further increase its applicability, the document was posted on the ACC Web site ([www.acc.org](http://www.acc.org)) for a 30-day public comment period. The document was approved for publication by the governing bodies of the American College of Cardiology and the American Heart Association. The document has been formally endorsed by the Heart Failure Society of America (HFSA). To determine whether a revision is necessary, these clinical data standards will be reviewed a year after publication and yearly thereafter by the ACC/AHA Task Force on Clinical Data Standards.

#### **H. Considerations for Use of Data Elements and Definitions**

Although the ACC/AHA is not launching this set of data element definitions as the precursor to a national registry, it recognizes that definitions cannot be written effectively without the context of their intended use. The Writing Committee determined three major environments of data collection efforts:

1. Clinical research
2. Clinical care
3. Quality performance measurement

The needs of clinical researchers are frequently unique to the specific research objective. This necessitates specific data element design and definitions, and the definitions proposed in this document may be considered as a starting point. In contrast, quality performance measurement, particularly when quality comparison is the goal, requires standard definitions for all data elements. When caregivers anticipate outcomes research based on their patients' care and experiences, uniform definitions are also strongly advised. Discussion of the considerations for use in clinical care and quality performance measurement was as much a component of the consensus development process as were the data definitions themselves.

It should be noted that clinical data standards present a model of elements that might be employed in data collection efforts, such as operating a registry, and are *not functional databases* in themselves.

#### **I. Special Considerations and Challenges for HF Data Standards**

Several special considerations were raised by the Writing Committee in its deliberations about which data elements to include and how to define them.

**1. Uses for HF data standards.** In considering heart failure data elements, their importance and their use for specific goals need to be borne in mind. For clinical care, elements pertaining to patient assessment and medical decision-making are paramount. For clinical research, elements pertaining to patient classification and outcomes are most important. For quality performance measurement, elements pertaining to care patterns and patient characteristics modulating care patterns take precedence. For example, for a clinician following a patient with HF, specific physical examination findings that dictate alterations in management are more important to determine than even the eventual outcome, whereas for clinical research the importance of these data elements is reversed. For quality performance measurement, elements describing the health care provider's decision-making (what the provider did and why) are important to elucidate.

**2. Balance between focus and comprehensiveness.** Although it may be tempting to develop a very comprehensive data element catalogue encompassing every imaginable data need or use, the Writing Committee focused on commonly collected data elements to best focus and enable the use of these data elements in many situations by many users. In particular, the Writing Committee focused on the care of adults with HF. We acknowledge that congenital heart disease may be accompanied by HF, but have proceeded with the understanding that data elements specific to these conditions can be added at a later time or can be incorporated into a similar data standards effort directed toward congenital heart disease.

**3. Balance between “primary” and “summary” data elements.** In the process of diagnosis and treatment, clinicians gather detailed clinical information, synthesizing the details into a formulation and plan for each patient. It follows, then, that data elements making up a clinical dataset may consist of many individual data elements (e.g., the details of coronary anatomy assessed by angiography) or of summary concepts (e.g., the number of diseased coronary vessels or the physician’s assessment that coronary artery disease is or is not a contributing factor to the patient’s HF syndrome). More often than not, the committee emphasized primary data elements for those features characterizing the HF syndrome and summary data elements for etiologic and therapeutic characteristics. It was recognized, however, that specific projects involving, for example, a diagnostic test or a therapeutic technique, would amplify these core, summary measures with a richer vocabulary of primary data elements.

**4. Variety of disease states leading to HF.** Heart failure is a syndrome, not a disease. It is a physiologic state resulting from a variety of disease conditions and clinical situations including coronary artery disease, hypertension, valvular disease, hypertension, infection, cancer chemotherapy, and more. Given the Writing Committee’s focus on data elements pertaining to the HF syndrome and its care, the data elements contained herein will be most useful for data collection efforts directed toward patients in Stage C or Stage D heart failure as defined by the ACC/AHA 2005 HF Guideline Update staging classification scheme (18).

**5. Acute and chronic care, inpatient and outpatient care venues.** In contrast to acute coronary syndromes, HF is a chronic condition, usually with acute manifestations and exacerbations. Clinical care and clinical research are, in general, oriented toward gathering information prospectively about chronic outpatient-based care, whereas most quality performance measurement efforts are directed toward acute care received during hospitalization, usually gathered retrospectively. The Writing Committee con-

sidered data elements pertinent to the full range of acute and chronic care provided to these patients. The data elements are intended to be useful for both inpatient and outpatient care venues.

**6. Therapy for HF.** Defining data elements to describe therapy for HF is a particular challenge. The Writing Committee recognizes that for clinical care, detailed information about therapy is essential. Other uses for these data elements require a summary approach. Given the variety of potential uses of these data standards, the Writing Committee recommends collecting information about medications as total daily dose prescribed at outpatient encounters or upon discharge from acute care hospitalization, and as summary information for therapeutic procedures such as coronary revascularization device implantation. Specific registries and clinical trials of treatment would be expected to specify additional data elements to supplement the summary elements outlined in this document.

**7. Outcomes assessment for HF.** Mortality and hospitalization outcomes are more comparable and understandable when adjusted for risk; current understanding of important risk-adjustment domains for these outcomes has informed the inclusion of specific data elements. In addition, because HF is a chronic condition, HF care also encompasses outcomes such as symptom burden, functional status, psychological state, compliance with a therapeutic regimen, self-management, and quality of life (11,20–23). (Please see Appendix A for a more detailed discussion of assessment and interpretation.)

### III. HF CLINICAL DATA STANDARD ELEMENTS AND DEFINITIONS

#### A. Patient Demographics (Table 1)

Patient demographic information is used for patient identification for longitudinal care, for demographic grouping to assess issues of access and care quality for traditionally disadvantaged groups, and for risk adjustment. Association of any health information with unique patient identifiers and/or demographic information that can be linked to the individual patient (indicated by an asterisk in Table 1) identifies the dataset as “protected health information.” Unique patient identification information (Social Security number or medical record number) is necessary and appropriate for longitudinal clinical care, but given current legislation protecting patients’ privacy (24), such information is not included in multi-institution registries unless appropriate informed consent is obtained from all patients. For other uses, patient privacy concerns may need to be considered by hospital privacy officers and/or institutional review boards (IRBs).

**Table 1.** Patient Demographics

Data Element	Definition
*Gender	Indicate the patient's gender at birth. Choose one of the following: <ul style="list-style-type: none"> <li>• Male</li> <li>• Female</li> </ul>
*Date of birth	Patient date of birth (day, month, and year of patient's birth).
*Hispanic ethnicity	Is this patient Spanish, Hispanic, or Latino? Choose one of the following: <ul style="list-style-type: none"> <li>• Yes</li> <li>• No</li> </ul>
*Race	Patient's race as determined by the patient/family: <ul style="list-style-type: none"> <li>• American Indian or Alaska Native</li> <li>• Asian</li> <li>• Black or African American</li> <li>• Native Hawaiian or other Pacific Islander</li> <li>• White</li> <li>• Other (specify)</li> </ul>
*Patient zip code	Zip code where the patient typically resides.
*Care period	For inpatient, note the date the patient was admitted to the hospital and the date the patient was discharged from the hospital. For outpatient, note the date (day, month, year) of the encounter (physician visit, nurse visit, consultation, procedures, and so on).
Insurance payor	Indicate the patient's primary insurance payor for this admission. Choose one of the following: <ul style="list-style-type: none"> <li>• Government: Refers to patients who are covered by government-reimbursed care. In the U.S., this includes: <ul style="list-style-type: none"> <li>- Medicare</li> <li>- Medicaid (including all state or federal Medicaid-type programs)</li> <li>- Champus</li> <li>- Veterans Health Administration</li> <li>- Department of Defense</li> <li>- Other federal group (specify)</li> </ul> </li> <li>• Commercial: refers to all indemnity (fee-for-service) carriers and preferred provider organizations (PPOs).</li> <li>• HMO: refers to a health maintenance organization characterized by coverage that provides health care services for members on a pre-paid basis.</li> <li>• None: refers to individuals with no or limited health insurance; thus, the individual is the payor regardless of ability to pay. Only mark "None" when "self" or "none" is denoted as the first insurance in the medical record.</li> </ul>
Government payor type	If the patient's primary insurance payor for this encounter is "Government," choose the type of government insurance: <ul style="list-style-type: none"> <li>• Medicare</li> <li>• Medicaid</li> <li>• Other</li> </ul>
Presentation to health care facility	Type of presentation to health care facility: <ul style="list-style-type: none"> <li>• Emergency admission for HF</li> <li>• Emergency admission for other cardiovascular problem</li> <li>• Emergency admission for non-cardiovascular problem (e.g., pneumonia)</li> <li>• Planned admission for cardiovascular disease</li> <li>• Planned admission for non-cardiovascular disease</li> <li>• Regularly scheduled outpatient visit</li> <li>• Other outpatient visits, including urgent outpatient visits</li> <li>• Remote monitoring</li> <li>• Telephone contact</li> <li>• Electronic communication</li> <li>• Other (specify)</li> </ul>
Location of health care encounter	Note if patient is a new patient or a prior patient with a new entry. Type of location of health care encounter: <ul style="list-style-type: none"> <li>• Acute-care hospital</li> <li>• Long-term care facility</li> <li>• Emergency department</li> <li>• Caregiver office <ul style="list-style-type: none"> <li>- Heart failure clinic</li> <li>- Cardiology practice</li> <li>- Primary care physician office</li> <li>- Other caregiver office</li> </ul> </li> <li>• Other (specify)</li> </ul>

**Table 1 Continued**

Data Element	Definition
Disposition after health care encounter	Indicate disposition after health care encounter: <ul style="list-style-type: none"> <li>• Discharged to home or self care (routine discharge)</li> <li>• Discharged/transferred to another short-term general hospital for inpatient care</li> <li>• Discharged/transferred to skilled nursing facility (SNF)</li> <li>• Discharged/transferred to an intermediate care facility (ICF)</li> <li>• Discharged/transferred to another type of institution</li> <li>• Discharged/transferred to home under care of organized home health service organization</li> <li>• Left against medical advice or discontinued care</li> <li>• Discharged/transferred to home under care of a home IV drug therapy provider</li> <li>• Admitted as an inpatient to this hospital</li> <li>• Expired (or did not recover)</li> <li>• Hospice-home</li> <li>• Hospice-medical facility</li> <li>• Discharged/transferred to an inpatient rehabilitation facility including rehabilitation distinct part units of a hospital</li> </ul> Specify date.
Death	Specify date of death. Indicate cause of death, if available: <ul style="list-style-type: none"> <li>• Cardiovascular:                             <ul style="list-style-type: none"> <li>- Myocardial infarction</li> <li>- Cardiogenic shock</li> <li>- Heart failure</li> <li>- Sudden cardiac death</li> <li>- Cardiac arrest</li> <li>- Arrhythmia (specify)</li> <li>- Stroke</li> <li>- Other (specify)</li> </ul> </li> <li>• Non-cardiovascular:                             <ul style="list-style-type: none"> <li>- Pulmonary embolism</li> <li>- Cancer</li> <li>- Trauma</li> <li>- Sepsis</li> <li>- Chronic obstructive lung disease</li> <li>- Renal failure</li> <li>- Other (specify)</li> </ul> </li> </ul> Indicate location of death, if known: <ul style="list-style-type: none"> <li>• At home</li> <li>• In hospice care</li> <li>• In hospital</li> <li>• Other (specify)</li> </ul>

**B. Medical History (Table 2)**

Information about patients' medical history is important in quality performance measurement, clinical research, and clinical care. Presence of cardiac risk factors have both prognostic and management implications, as do elements describing current cardiovascular conditions. History of non-cardiac conditions may denote absolute or relative contraindications to various therapies, or may significantly impact outcomes. Inclusion of data elements pertinent to medical history is, therefore,

important to clinical decision-making, to design of quality performance measures, and to risk-adjusted outcomes assessment. For most purposes, these data elements can be recorded as either present or absent. Year of onset may be helpful, especially when data collection is used for longitudinal clinical follow-up. More detailed information about the severity of each condition (e.g., record of prior hospitalizations or specifics of therapy for the condition) might be considered for certain users.

**Table 2. Medical History**

Data Element	Definition
<b>Medical History: Heart Failure Risk Factors</b>	
History of smoking	History confirming cigarette smoking in the past. Choose from the following categories: <ul style="list-style-type: none"> <li>• Current: smoking cigarettes within one month of this encounter</li> <li>• Recent: stopped smoking cigarettes between 1 month and 1 year before this encounter</li> <li>• Former: stopped smoking cigarettes more than one year prior to this encounter</li> <li>• Never: never smoked cigarettes</li> </ul> For current or former smokers, total pack years may be useful.



**Table 2 Continued**

Data Element	Definition
<b>Medical History: Heart Failure Risk Factors, continued</b>	
History of alcohol consumption/dependency	<p>Alcohol consumption history. Choose from the following categories:</p> <ul style="list-style-type: none"> <li>• None</li> <li>• One or fewer alcoholic drinks per week</li> <li>• 2 to 7 alcoholic drinks per week</li> <li>• 8 or more alcoholic drinks per week</li> </ul> <p>Alcohol dependency history:</p> <ul style="list-style-type: none"> <li>• Documented alcohol dependency</li> <li>• Medical sequelae of alcohol consumption (alcoholic hepatitis, cirrhosis, alcohol neuropathy, Wernicke-Korsakoff syndrome)</li> <li>• Treatment for alcohol dependency</li> </ul> <p>For dependent consumers of alcohol, note treatment for dependency, cessation of use, or continued use.</p>
History of diabetes	<p>History of diabetes, regardless of duration of disease, need for antidiabetic agents, or a fasting blood sugar greater than 7 mmol/l or 126 mg/dl.</p> <p>The year of onset (first diagnosis) and whether juvenile or adult onset may be helpful.</p>
Diabetes treatment	<p>Method of diabetic treatment at time of encounter. Choose from the following categories:</p> <ul style="list-style-type: none"> <li>• None: no treatment for diabetes</li> <li>• Diet: diet treatment</li> <li>• Oral: oral agent treatment. Oral agent(s) should be specified:                             <ul style="list-style-type: none"> <li>- Metformin</li> <li>- Sulfonylureas</li> <li>- Thiazolidinediones (TZDs)</li> </ul> </li> <li>• Insulin: insulin treatment</li> <li>• Insulin and oral: insulin and oral agent treatment</li> </ul>
Hypertension	<p>Indicate if the patient has hypertension as documented by:</p> <ul style="list-style-type: none"> <li>• History of hypertension diagnosed and treated with medication, diet, and/or exercise</li> <li>• Blood pressure greater than 140 mm Hg systolic or 90 mm Hg diastolic on at least 2 occasions</li> <li>• Blood pressure greater than 130 mm Hg systolic or 80 mm Hg diastolic on at least 2 occasions for patients with diabetes or chronic kidney disease (25)</li> </ul> <p>More than one of the above may apply. The year of onset (first diagnosis) may be helpful.</p>
Dyslipidemia	<p>Indicate if the patient has dyslipidemia diagnosed and/or treated by a physician or other provider. Criteria may include documentation of:</p> <ul style="list-style-type: none"> <li>• Total cholesterol greater than 200 mg/dl, or</li> <li>• Low-density lipoprotein (LDL) greater than or equal to 130 mg/dl, or</li> <li>• High-density lipoprotein (HDL) less than 35 mg/dl, or</li> <li>• Use of lipid-lowering therapy</li> </ul> <p>Year of onset (first diagnosis) may be helpful.</p>
History of thyroid disorder	<p>Treatment at any time for hyperthyroidism or currently receiving thyroid supplementation for hypothyroidism.</p> <p>Year of onset (first diagnosis) may be helpful.</p>
History of exposure to cardiotoxic chemotherapy	<p>History of exposure to cardiotoxic chemotherapy:</p> <ul style="list-style-type: none"> <li>• Anthracyclines: adriamycin, daunorubicin, doxorubicin, epirubicin, idarubicin, etc.</li> <li>• Mitoxantrone</li> <li>• Cyclophosphamide</li> <li>• Mitomycin C</li> <li>• Trastuzumab (Herceptin)</li> </ul> <p>Total cumulative dose should be recorded for chemotherapeutic agents.</p>
History of thoracic radiation	<p>History of thoracic radiation therapy.</p> <p>Specify if radiation therapy was received before/after 20 years of age. Specify location (mediastinal, chest, breast, or other). Total radiation exposure should be recorded.</p>
History of exposure to cardiotoxic substances	<p>History of exposure to cardiotoxic substances through substance abuse:</p> <ul style="list-style-type: none"> <li>• Cocaine</li> <li>• Amphetamine</li> <li>• Ephedrine</li> <li>• Other (specify)</li> </ul>
Family history of sudden cardiac death	<p>Family history (parent or sibling) of sudden cardiac death, defined as natural death due to cardiac causes, heralded by abrupt loss of consciousness. The time and mode of death are unexpected even though pre-existing heart disease may have been known to be present (26). Sudden death without obvious cause is considered sudden cardiac death. Traumatic death subsequently proven to be due to sudden loss of control due to a cardiac problem is included.</p> <p>Age at time of sudden cardiac death may be specified.</p>

**Table 2 Continued**

Data Element	Definition
<b>Medical History: Heart Failure Risk Factors, continued</b>	
Family history of premature coronary artery disease	Any direct blood relatives (parents, siblings, children) who have had any of the following at age less than 55 years for male relatives or less than 65 years for female relatives (27): <ul style="list-style-type: none"> <li>• Angina</li> <li>• Acute myocardial infarction</li> <li>• Sudden cardiac death without obvious cause</li> <li>• Coronary artery bypass graft surgery</li> <li>• Percutaneous coronary intervention</li> </ul>
Family history of muscular dystrophy	Family history of muscular dystrophy.
Family history of conduction system disease	Family history of early onset of atrial or ventricular arrhythmias or conduction system disease.
Family history of cardiomyopathy	Family history of cardiomyopathy (dilated, poorly contracting left ventricle in the absence of coronary artery disease, arrhythmogenic right ventricular dysplasia (ARVD), hypertrophic heart disease, or other specific cardiac muscle disease) in one or more first-degree relative
Family history of hypertrophic cardiomyopathy	Family history of cardiomyopathy, with or without obstruction. May specify etiology if known.
HIV status	<ul style="list-style-type: none"> <li>• HIV seropositive</li> <li>• AIDS</li> </ul>
<b>Medical History: Cardiovascular</b>	
History of heart failure	Physician documentation or report of any of the following symptoms of heart failure prior to this care encounter described as unusual dyspnea on light exertion, recurrent dyspnea occurring in the supine position, fluid retention, low cardiac output secondary to cardiac dysfunction; or the description of rales, jugular venous distension, or pulmonary edema. A previous hospital admission with principal diagnosis of heart failure is considered evidence of heart failure history. Date of first onset may be helpful.
History of angina	History of angina may include: <ul style="list-style-type: none"> <li>• Stable angina</li> <li>• Unstable angina</li> </ul> Dates should be sought for the onset of either stable or unstable angina.
History of myocardial infarction	History of myocardial infarction as determined by any of the following: <ul style="list-style-type: none"> <li>• Hospital admission for acute myocardial infarction</li> <li>• EKG report indicating previous (old) or acute myocardial infarction</li> <li>• Increase in biochemical marker (creatinine kinase or troponin) consistent with myocardial infarction. Note that low elevation in troponin level may be seen in patients with heart failure and should not by themselves be considered diagnostic of infarction (15)</li> <li>• Patient reports history of acute myocardial infarction or heart attack.</li> </ul> Total number of myocardial infarctions and year of the first and the most recent episode may be helpful.
Previous coronary artery bypass graft (CABG)	Coronary artery bypass graft surgery prior to the current encounter. Total number of CABG procedures and year of most recent may be helpful.
Previous percutaneous coronary intervention (PCI)	PCI of any type (balloon angioplasty, atherectomy, stent, or other) prior to the current encounter. Total number of PCI procedures and year of most recent may be helpful.
Previous pacemaker or ICD implantation	Pacemaker or ICD implantation prior to the current encounter. Device type (pacemaker, ICD, combination), cardiac chamber(s) involved, and year of implantation may be helpful.
History of peripheral embolic event	History of peripheral embolic event as determined by: <ul style="list-style-type: none"> <li>• Hospital admission for peripheral embolic event</li> <li>• Patient reports history of peripheral embolic event</li> <li>• Report of diagnostic or therapeutic procedure indicating presence of peripheral embolic event (for example, embolectomy, angiography; nuclear study; ultrasound study)</li> </ul> Year of the first episode and number of events may be helpful.

**Table 2 Continued**

Data Element	Definition
<b>Medical History: Cardiovascular, continued</b>	
History of atrial arrhythmias	History of any of the following atrial arrhythmias: <ul style="list-style-type: none"> <li>• Atrial fibrillation or atrial flutter. Specify whether paroxysmal or chronic.</li> <li>• Atrial tachycardia</li> <li>• Sick sinus syndrome</li> <li>• Paroxysmal supraventricular tachycardia</li> </ul> Year of the first and the most recent episode may be helpful.
History of ventricular arrhythmias	History of either of the following ventricular arrhythmias: <ul style="list-style-type: none"> <li>• Ventricular tachycardia (sustained/nonsustained)</li> <li>• Ventricular fibrillation</li> </ul> Specify documentation source (e.g., Holter, event recorder, ICD, pacemaker, etc.). Year of the first and the most recent episode may be helpful.
History of arrhythmogenic disease, syndrome, or substrate	History of any of the following arrhythmogenic conditions: <ul style="list-style-type: none"> <li>• Right ventricular (RV) dysplasia</li> <li>• Brugada syndrome</li> <li>• Wolf-Parkinson-White syndrome</li> <li>• Sudden unexpected death syndrome (young Asian males)</li> <li>• Atrial ventricular nodal re-entrant tachycardia (AVNRT)</li> <li>• RV outflow tract ventricular tachycardia</li> <li>• Bundle-branch mediated ventricular tachycardia</li> </ul> Year of the first and the most recent episode may be helpful.
History of cerebrovascular disease	History of cerebrovascular disease, documented by any one of the following: <ul style="list-style-type: none"> <li>• Cerebrovascular ischemic or hemorrhagic stroke: patient has a history of stroke (i.e., any focal neurological deficit of abrupt onset caused by a disturbance in blood supply that did not resolve within 24 hours) confirmed by a standard neurological examination with or without a positive imaging study, or an event of presumed ischemic origin that did not resolve within 24 hours, but the imaging showed a new lesion.</li> <li>• Transient ischemic attack (TIA): patient has a history of any sudden new focal neurological deficit of presumed ischemic origin as determined by a standard neurological exam that resolved completely within 24 hours, with a brain image study not revealing a new lesion.</li> <li>• Noninvasive/invasive carotid test with greater than or equal to 75% occlusion</li> <li>• Previous carotid artery surgery</li> <li>• Previous carotid angioplasty</li> </ul> Year of the first and most recent episode may be helpful.
Level of disability following stroke	Level of disability following stroke: <ul style="list-style-type: none"> <li>• Recovered</li> <li>• Minor persisting disability</li> <li>• Major persisting disability</li> </ul>
History of peripheral arterial disease	History of peripheral arterial disease may include: <ul style="list-style-type: none"> <li>• Claudication either with exertion or at rest</li> <li>• Amputation for arterial vascular insufficiency</li> <li>• Vascular reconstruction, bypass surgery, or percutaneous intervention to the extremities</li> <li>• Documented aortic aneurysm</li> </ul> Year of the first episode and number of events may be helpful.
History of rheumatic valvular disease	History of primary valvular disease may include: <ul style="list-style-type: none"> <li>• History of acute rheumatic fever/carditis (usually determined through correspondence with major and minor criteria [28])</li> <li>• History of valve disease with echocardiographic findings suggestive of or diagnostic of rheumatic valvular disease</li> </ul> Year of the first episode may be helpful.
History of other valvular disease etiology	History of valvular disease of other etiology (specify): <ul style="list-style-type: none"> <li>• Congenital (present at birth or occurring association with congenital heart disease syndrome)</li> <li>• Degenerative (acquired during adulthood, usually after age 50)</li> <li>• Infectious (acquired as a result of infectious endocarditis)</li> <li>• Toxic (for example, as a result of exposure to fenfluramine phentermine dexfenfluramine)</li> <li>• Other (specify)</li> </ul> Year of the first episode may be helpful.

**Table 2 Continued**

Data Element	Definition
<b>Medical History: Cardiovascular, continued</b>	
History of congenital cardiac lesions	History of congenital cardiac lesions including: <ul style="list-style-type: none"> <li>• Patent ductus arteriosus</li> <li>• Atrial septic defect (ASD)</li> <li>• Ventricular septal defect (VSD)</li> <li>• Tetralogy of Fallot</li> <li>• Transposition of great vessels</li> <li>• Congenitally corrected transposition</li> <li>• Single ventricle</li> <li>• Other</li> </ul> Specify type of lesion. Note if lesion has had corrective therapy and specify date of correction.
History of Chagas disease	Documented history of Chagas disease.
<b>Medical History: Non-Cardiovascular</b>	
History of asthma	History of asthma. For patients with onset of asthma in adulthood, asthma diagnosis should precede heart failure diagnosis by at least 5 years or have documented pulmonary function test (PFT) evidence of reversible bronchospasm. Note: because patients with heart failure may present with wheezing and other clinical features mimicking asthma, care in distinguishing these conditions from one another is crucial.
History of chronic renal insufficiency	History of reduced glomerular filtration rate for at least 3 months. Degree of renal insufficiency may be further defined according to degree of depression in glomerular filtration rate (GFR): <ul style="list-style-type: none"> <li>• Mild renal insufficiency: GFR 60–89 ml/min/1.73 m<sup>2</sup></li> <li>• Moderate renal insufficiency: GFR 30–59 ml/min/1.73 m<sup>2</sup></li> <li>• Severe renal insufficiency: GFR 15–29 ml/min/1.73 m<sup>2</sup></li> <li>• Renal failure: GFR less than 15 ml/min/1.73 m<sup>2</sup>, or patient requires chronic dialysis treatment</li> </ul> Note: GFR may be estimated using the serum creatinine— $GFR = 186 \times (P_{Cr})^{-1.154} \times (age)^{-0.203} \times (0.742 \text{ if female}) \times (1.210 \text{ if black})$ Year of onset (first diagnosis) may be helpful.
History of acute renal insufficiency	History of reduced renal function (see “History of chronic renal insufficiency” element) for less than 3 months. Year of occurrence of and precipitant for acute renal insufficiency may be specified.
History of dialysis	History of renal dialysis, either by: <ul style="list-style-type: none"> <li>• Hemodialysis</li> <li>• Peritoneal dialysis</li> </ul> Year of onset may be helpful.
History of chronic lung disease	History of chronic lung disease (e.g., chronic obstructive pulmonary disease, chronic bronchitis, emphysema) or currently being chronically treated with inhaled or oral pharmacological therapy (e.g., beta-adrenergic agonist, anti-inflammatory agent, leukotriene receptor antagonist, or steroid). Year of onset (first diagnosis) may be helpful.
History of dementia	History of dementia, Alzheimer’s disease, chronic confusion (at least one month in duration), or senility. Year of onset (first diagnosis) may be helpful.
History of depression	History of treated depression, or currently taking antidepressant medication. Note if past or present episode has or is currently requiring drug treatment or electroconvulsive therapy (ECT). Year of onset (first diagnosis) may be helpful.
History of liver disease	History of chronic hepatitis or cirrhosis.
History of lupus or collagen vascular disease	History of collagen vascular disease such as lupus erythematosus, scleroderma, rheumatoid arthritis.
History of musculo-skeletal disease	History of primary musculo-skeletal disease, including muscular dystrophy, myasthenia gravis, dermatomyositis.
History of malignancy	History of cancer, excluding non-melanoma skin cancers. Cancer site and date of first diagnosis may be helpful.
History of influenza immunization	History of influenza immunization. Month and year of most recent immunization should be noted.
History of pneumococcal immunization	History of pneumococcal immunization. Month and year of most recent immunization should be noted.
History of urinary continence	History of urinary continence. Choose from the following categories: <ul style="list-style-type: none"> <li>• Continent</li> <li>• Occasionally incontinent</li> <li>• Totally incontinent</li> <li>• Dialysis</li> </ul>

**C. Patient Assessment: Current Symptoms and Signs (Table 3)**

For patients with HF, assessment of signs and symptoms is directed toward evaluation of volume status and cardiac output. For all symptoms reported by the patient, consider collecting time-frame (onset, current, course, and so on) and change in symptoms since last visit (better, worse,

unchanged). For inpatient care encounters, the first patient assessment (history and physical examination) should be reported.

Often these data can be captured with health status instruments. Please see Appendix A for discussion of systematic collection of patient’s functional status using structured survey/questionnaire instruments.

**Table 3.** Patient Assessment: Current Symptoms and Signs

Data Element	Definition
<b>Clinical Symptoms</b>	
Dyspnea at rest	Patient describes frequent uncomfortable awareness of breathing while resting in a sitting position. Date of onset and duration may be helpful.
Dyspnea on exertion	Patient describes uncomfortable awareness of breathing while exerting him/herself. Indicate degree of activity required to elicit dyspnea symptom: <ul style="list-style-type: none"> <li>• Running or other sport (specify sport)</li> <li>• Walking up an incline (specify distance)</li> <li>• Walking on a flat surface (specify distance)</li> <li>• Stopping to rest while dressing</li> <li>• Standing (specify length of time)</li> <li>• Other activity (i.e., shopping or housework; specify)</li> </ul> Date of onset and duration may be helpful.
Orthopnea	Patient describes at least one of the following: <ul style="list-style-type: none"> <li>• Uncomfortable awareness of breathing while in a supine position</li> <li>• Positioning with 3 or more pillows or in a chair or recliner to maintain comfortable breathing during sleep</li> <li>• Recurrent supine cough without other known cause may be an orthopnea equivalent</li> </ul> Date of onset and duration may be helpful.
Paroxysmal nocturnal dyspnea	Patient describes awakening suddenly from sleep with uncomfortable awareness of breathing, or with general distress relieved by the upright position. Any report of this symptom lasting greater than 5 minutes is considered positive. Date of onset and duration may be helpful.
Weight gain or loss	Amount of weight gain or loss, in pounds or kilograms, as reported by the patient. Time frame over which weight change occurred should be noted.
Swelling	Patient reports swelling or puffiness in extremities, abdomen, and/or other areas. Date of onset and duration may be helpful.
Fatigue	Patient describes unusual tiredness and inability to perform usual activities. Date of onset and duration may be helpful.
Angina	Angina refers to previous or current symptoms described as chest pain or pressure, jaw pain, arm pain, or other equivalent discomfort suggestive of cardiac ischemia. The Canadian Cardiovascular Society angina classification (29) is useful in determining the level of angina: <ul style="list-style-type: none"> <li>• Grade I: ordinary physical activity does not cause angina—for example walking or climbing stairs, angina occurs with strenuous or rapid or prolonged exertion at work or recreation.</li> <li>• Grade II: slight limitation of ordinary activity—for example, angina occurs walking or stair climbing after meals, in cold, in wind, under emotional stress or only during the few hours after awakening, walking more than two blocks on the level or climbing more than one flight of ordinary stairs at a normal pace and in normal conditions.</li> <li>• Grade III: marked limitation of ordinary activity—for example, angina occurs walking one or two blocks on the level or climbing one flight of stairs in normal conditions and at a normal pace.</li> <li>• Grade IV: inability to carry on any physical activity without discomfort—angina syndrome may be present at rest.</li> </ul> Year of onset (first diagnosis) may be helpful.
Syncope	Sudden loss of consciousness not related to anesthesia, with spontaneous recovery as reported by patient or observer. Patients losing consciousness prior to an implantable cardiac defibrillator (ICD) discharge will be considered to have syncope. Date of most recent episode may be helpful.



**Table 3 Continued**

Data Element	Definition
<b>Physical Examination</b>	
Heart rate	Heart rate (beats per minute) recorded closest to the time of presentation to the health care facility and/or on discharge (for inpatient). Specify whether heart rate is regular or irregular. Heart rate may be ascertained from electrocardiographic tracing or from record of physical examination.
Systolic and diastolic blood pressure	Systolic and diastolic blood pressure (mm Hg) recorded closest to the time of presentation to the health care facility. Patient position (supine, sitting, other) may be noted.
Jugular venous pressure	The estimated height of the mean jugular venous waveform above the right atrium in cm. When expressed as cm without further description, the number should be recorded as written. When it is expressed as cm above the sternal angle, 5 cm should be added to the number recorded. In the absence of a numerical estimate of jugular venous pressure, “jugular venous distension (JVD),” “distended neck veins,” and “halfway to the jaw” or “to the angle of the jaw” would be recorded as positive for elevated jugular venous pressure.
Respiratory rate	Respiratory rate in respiratory cycles per minute.
Height	Patient’s height in centimeters or inches. May be measured or reported by patient.
Weight at encounter	Patient’s weight in kilograms or pounds. Must be measured during encounter. It is advisable to standardize clothing worn (i.e., whether shoes are worn).
Body mass index (BMI)	Calculated according to formula: patient’s weight in kilograms, divided by height in meters squared. Obesity is defined as BMI greater than or equal to 30 kilograms per meter squared.
Third heart sound (S <sub>3</sub> )	Presence or absence of a third (mid-diastolic) heart sound.
Fourth heart sound (S <sub>4</sub> )	Presence or absence of a fourth (late-diastolic) heart sound.
Heart murmur	Presence or absence of heart murmur(s). Timing (systolic, diastolic), quality (harsh, blowing, ejection, etc.), and intensity of each murmur should be noted. Intensity is usually graded on 1–6 scale for systolic murmurs and 1–4 scale for diastolic murmurs.
Lung (pulmonary) examination	Lung (pulmonary) findings by auscultation: <ul style="list-style-type: none"> <li>• Clear or normal</li> <li>• Rales (height of rales when patient sitting upright should be noted)</li> <li>• Decreased breath sounds or dullness</li> <li>• Rhonchi</li> <li>• Wheezing</li> </ul> Other findings (for example, pleural rub) may also be noted.
Peripheral edema	Increased tissue fluid indicated by perceptible indentation on lower leg or foot after palpation.
Ascites	Intra-abdominal fluid accumulation as determined by physical examination.
Hepatomegaly	Documentation of liver edge detectable below the right costal margin during physical examination. Marked hepatomegaly is present if liver edge is detected 8 cm or more below the right costal margin.
Hepatojugular reflux (HJR)	Presence or absence of hepatojugular reflux (HJR). Degree of HJR should be noted.
Mobility	Assessment of patient’s mobility: <ul style="list-style-type: none"> <li>• Able to walk independently</li> <li>• Able to walk with assistance (cane, walker, etc.)</li> <li>• Unable to walk; mobility requires assistance (wheelchair, etc.)</li> <li>• Bedridden</li> </ul>

**D. Patient Assessment: Summary Assessment (Table 4)**

Specific HF etiologies are provided for those data collection efforts that require a more specific delineation than “ischemic or non-ischemic.” The possible etiologies allow for a pick-and-choose approach. A primary etiology and/or multiple etiologies may be chosen. The definitions of HF etiologies have been constructed to imply causality and not merely association. The list of potential etiologies represents a compromise between brevity and comprehensiveness.

Although the New York Heart Association (NYHA) functional class (30) has proven useful as a measure summarizing the patient’s overall HF symptom burden, it may be imprecise, subject to substantial interobserver variability, and may change over time. Heart failure stage (18) and patient-reported health status (21,31,32) are emerging as important constructs for delivering and evaluating HF care.

**Table 4.** Patient Assessment: Summary Assessment

Data Element	Definition
<b>Heart Failure Etiology</b>	
Evidence for ischemic heart disease	<p>Any of the following conditions indicates ischemic heart disease:</p> <ul style="list-style-type: none"> <li>• At least one major epicardial coronary artery with more than 70% obstruction by coronary angiography</li> <li>• History of acute myocardial infarction associated with wall motion abnormality by echocardiography or gated blood pool imaging</li> <li>• Stress testing (with or without imaging) diagnostic of coronary artery disease</li> </ul>
Evidence for valvular heart disease	<p>Primary valvular disease:</p> <ul style="list-style-type: none"> <li>• Moderately severe or severe, or 3+ or 4+ aortic insufficiency</li> <li>• Moderately severe or severe, or 3+ or 4+ mitral insufficiency with echocardiographic evidence that mitral insufficiency is a primary abnormality, and not secondary to ventricular dilation</li> <li>• Moderately severe or severe aortic stenosis defined by estimated aortic valve area by catheterization or Doppler echocardiography of less than or equal to 1.0 cm<sup>2</sup></li> <li>• Moderately severe or severe mitral stenosis defined by estimated mitral valve area by catheterization or echocardiography of less than 1.0 cm<sup>2</sup></li> </ul> <p>Contributory valvular disease:</p> <ul style="list-style-type: none"> <li>• Valve disease that is felt to be significant but does not fulfill the above definitions</li> </ul>
Evidence for myocardial infiltrative or storage disease	<ul style="list-style-type: none"> <li>• Systemic amyloidosis by biopsy</li> <li>• Hemochromatosis by biopsy or by serum markers in the presence of clinical evidence of multi-organ involvement</li> <li>• Heart failure in a patient with a storage disease known to involve the myocardium, including Fabry disease, Gaucher disease, or the glycogen storage diseases</li> </ul>
Evidence for inflammatory myocarditis	<ul style="list-style-type: none"> <li>• Biopsy-proven myocarditis</li> <li>• Sarcoidosis with biopsy evidence or diagnostic pulmonary radiographic appearance with reduced left ventricular systolic function</li> <li>• Documented Chagas disease</li> </ul>
Evidence for primary myocardial hypertrophic muscle disease	<p>Any of the following conditions indicates evidence for primary myocardial hypertrophic muscle disease:</p> <ul style="list-style-type: none"> <li>• Evidence for symmetric or asymmetric hypertrophy with or without outflow tract obstruction</li> <li>• Congenital muscular dystrophy</li> </ul>
Evidence for hypertensive cardiomyopathy	<p>One of the following conditions must be met:</p> <ul style="list-style-type: none"> <li>• Untreated systolic blood pressure greater than 160 mm Hg or diastolic greater than 105 mm Hg for at least 3 months</li> <li>• Hypertension requiring at least 2 drugs for control for at least 5 years</li> <li>• Presence of diabetes and hypertension, treated or untreated</li> <li>• Documented left ventricular hypertrophy (preferably by echocardiography or MRI)</li> <li>• Absence of other etiologies for heart failure</li> </ul>
Evidence for toxic cardiomyopathy	<ul style="list-style-type: none"> <li>• Alcohol abuse present for at least 5 years as defined by either heavy alcohol consumption (i.e., 75 g/day at least 5 days/wk) or alcohol dependence</li> <li>• Cocaine use</li> <li>• Ephedrine use</li> <li>• Temporally-related exposure to a drug or substance known to cause cardiomyopathy, including chemotherapeutic agents(s) and radiation to the chest</li> </ul>
Evidence for pregnancy-related cardiomyopathy	<p>Onset of cardiomyopathy associated with pregnancy (peri-, post-partum).          Indicate whether cardiomyopathy appears to be:</p> <ul style="list-style-type: none"> <li>• Reversed/resolved, or</li> <li>• Irreversible, causing permanent damage to the myocardium</li> </ul>
Evidence for thyroid disorder-related cardiomyopathy	<p>Presence of otherwise unexplained cardiomyopathy associated with thyroid disorder.</p>
Evidence for arrhythmogenic right ventricular dysplasia (ARVD) cardiomyopathy	<p>Arrhythmogenic right ventricular dysplasia (ARVD) is characterized by progressive fibrofatty replacement of right ventricular myocardium and right ventricular dysfunction, regional or global, usually demonstrated by echocardiography or cardiac magnetic resonance imaging. It is associated with arrhythmias and sudden death (33).</p>
Evidence for idiopathic cardiomyopathy	<p>Heart failure and reduced systolic function without evidence for any of the above etiologies or other disease known to cause cardiomyopathy.</p>
Familial cardiomyopathy	<ul style="list-style-type: none"> <li>• Possible familial cardiomyopathy: presence of otherwise unexplained cardiomegaly, diagnosis of heart failure, atrial fibrillation or life-threatening ventricular arrhythmias, conduction system disease, or sudden death in first degree relative under 60 years of age</li> <li>• Probable familial cardiomyopathy: presence of above in two relatives under 60 years of age who are related to each other and the patient</li> </ul>

**Table 4 Continued**

Data Element	Definition
<b>Heart Failure Etiology, continued</b>	
Evidence for ventricular dysfunction due to tachyarrhythmias	Heart failure attributed to sustained (usually greater than 1 week) tachycardia (usually greater than 120 beats per min) that is not attributable to any other cause and shows evidence for improvement after correction.
Evidence for ventricular dyssynchrony	Ventricular dyssynchrony evidenced by QRS greater than or equal to 120 ms, intraventricular conduction delay (IVCD), bundle branch block (BBB).
Heart failure stage (17)	<ul style="list-style-type: none"> <li>• A = patient at high risk for developing heart failure but who has no structural disorder of the heart</li> <li>• B = patient with a structural disorder of the heart but who has never developed symptoms of heart failure</li> <li>• C = patient with past or current symptoms of heart failure associated with structural heart disease</li> <li>• D = patient with end-stage disease who requires specialized treatment strategies such as mechanical circulatory support, continuous inotropic infusions, cardiac transplantation or hospice care</li> </ul>
New York Heart Association (NYHA) class (30)	NYHA class as reported by a physician: <ul style="list-style-type: none"> <li>• Class I: patients with cardiac disease but without resulting limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, or dyspnea.</li> <li>• Class II: patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, or dyspnea.</li> <li>• Class III: patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.</li> <li>• Class IV: patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms are present even at rest or minimal exertion.</li> </ul>
Health status (see Appendix A)	Health status of patient at the time of visit as documented by one of the following: <ul style="list-style-type: none"> <li>• 5-Point Likert Scale</li> <li>• Visual Analog Scale Score</li> <li>• Minnesota Living with Heart Failure Questionnaire</li> <li>• Kansas City Cardiomyopathy Questionnaire</li> <li>• SF-36 or SF-12</li> <li>• Other</li> </ul> See Appendix A for a more detailed discussion of potential measures.

**E. Laboratory Tests**

When collecting information about laboratory tests, the minimum suggested data to capture are: 1) value, 2) unit of measurement, 3) date, and 4) normal range (upper limit of normal when appropriate). More detailed information can be collected as needed. For outpatient care, serial values should be recorded, with dates to reflect first, highest, and lowest values. For inpatient care assessment, at least the first value obtained closest to admission should be recorded.

- Sodium
- Potassium (first, highest, and lowest values)
- Calcium
- Magnesium
- TSH (thyroid-stimulating hormone)
- CBC (complete blood count)

- Blood urea nitrogen (first and highest values)
- Serum creatinine (first and highest values)
- Hemoglobin A<sub>1C</sub>
- Hemoglobin or hematocrit (specify which)
- Serum albumin
- Glucose (fasting)
- Total cholesterol
- HDL (high-density lipoprotein) cholesterol
- LDL (low-density lipoprotein) cholesterol
- Triglycerides
- INR (international normalized ratio)
- BNP (brain natriuretic peptide) or N-terminal BNP

**F. Diagnostic Procedures (Table 5)**

Diagnostic procedures may be noted as either having been performed or the findings described. Date of procedure should be recorded.

**Table 5.** Diagnostic Procedures

Data Element	Definition
Ejection fraction (EF)	<p>Quantitative measurement of ejection fraction is preferred over qualitative measurement.</p> <ul style="list-style-type: none"> <li>• Quantitative:                             <ul style="list-style-type: none"> <li>- Ejection fraction, measured in percent</li> <li>- When a quantitative range is given, the midpoint of the range</li> </ul> </li> <li>• Qualitative:                             <ul style="list-style-type: none"> <li>- Normal (corresponds to LVEF greater than 50%)</li> <li>- Mildly diminished (corresponds to LVEF 41% to 49%)</li> <li>- Moderately diminished (corresponds to LVEF 26% to 40%)</li> <li>- Severely diminished (corresponds to LVEF 25% or less)</li> </ul> </li> </ul> <p>When multiple determinations are present, the hierarchy should be:</p> <ul style="list-style-type: none"> <li>• Radionuclide ventriculography</li> <li>• Magnetic resonance imaging (MRI)</li> <li>• Echocardiography                             <ul style="list-style-type: none"> <li>- 2-dimensional</li> <li>- 3-dimensional</li> </ul> </li> <li>• Contrast ventriculography</li> <li>• Technetium myocardial perfusion imaging</li> <li>• Other</li> </ul>
Ejection fraction modality	<p>Modality used to determine the ejection fraction:</p> <ul style="list-style-type: none"> <li>• Radionuclide ventriculography</li> <li>• Magnetic resonance imaging (MRI)</li> <li>• Echocardiography                             <ul style="list-style-type: none"> <li>- 2-dimensional</li> <li>- 3-dimensional</li> </ul> </li> <li>• Contrast left ventriculography</li> <li>• Technetium myocardial perfusion imaging</li> <li>• Other</li> </ul> <p>When multiple measures are available, the most recent is preferred.</p>
Radionuclide ventriculography	<p>Cardiac blood pool imaging (first pass or gated equilibrium) with or without stress.</p> <p>Documented findings may include:</p> <ul style="list-style-type: none"> <li>• LVEF: percentage (range 5% to 90%) for left ventricle</li> <li>• RVEF: percentage (range 5% to 90%) for right ventricle</li> </ul>
Echocardiography	<p>Resting two-dimensional or three-dimensional echocardiography with or without Doppler imaging. Ejection fraction or description of left ventricular systolic function should be enumerated as above. Other findings may include:</p> <ul style="list-style-type: none"> <li>• Description of right ventricular size and function</li> <li>• Description of focal left ventricular wall motion abnormalities</li> <li>• Valvular regurgitation (mitral, aortic, tricuspid, pulmonic), by Doppler color flow mapping:                             <ul style="list-style-type: none"> <li>- Qualitative descriptors: none or trace, mild, moderate, moderate-severe, severe, not evaluated</li> <li>- Quantitative descriptors: none or trace, mild, moderate, moderate-severe, severe, not evaluated</li> </ul> </li> <li>• Valvular stenosis (aortic, mitral), by continuous wave and/or pulsed wave Doppler interrogation. Maximum velocities, peak gradient, mean gradient, and/or valve area may be determined and reported using standard techniques.</li> <li>• Presence or absence of pericardial echo-free space, with description of whether there is imaging and/or Doppler evidence for hemodynamic significance</li> <li>• Maximum tricuspid regurgitant velocity, when present, to estimate pulmonary artery systolic pressure</li> <li>• Presence or absence of evidence for left ventricular diastolic dysfunction (ratio of early to atrial transmitral filling velocity by Doppler; description of pulmonary venous Doppler inflow pattern; deceleration time, and so on)</li> <li>• Presence or absence of patent foramen ovale (PFO)</li> <li>• Left ventricular end-diastolic dimension (mm). M-mode, parasternal view.</li> <li>• Left ventricular end-systolic dimension (mm). M-mode, parasternal view.</li> <li>• Left ventricular wall thickness (mm). M-mode, parasternal view, both septum and posterior wall.</li> <li>• Left atrial dimension (mm). M-mode, parasternal view, inferior vena cava (IVC) diameter.</li> </ul>

**Table 5 Continued**

Data Element	Definition
Electrocardiography	<p>12-lead electrocardiography. Documented findings may include:</p> <ul style="list-style-type: none"> <li>• Rhythm:                             <ul style="list-style-type: none"> <li>- Sinus rhythm</li> <li>- Atrial fibrillation or flutter</li> <li>- Paced or other rhythm</li> </ul> </li> <li>• Heart rate (beats per minute)</li> <li>• Left bundle branch block (LBBB), Minnesota criteria (34)</li> <li>• Right bundle branch block (RBBB), Minnesota criteria (34)</li> <li>• Location of abnormal Q waves (<math>\geq 0.03</math> second in width and <math>\geq 1</math> mm [0.1 mV] in depth in at least 2 contiguous leads)</li> <li>• QRS duration (in milliseconds): may be reported as the measured duration, or categorically as shorter than 120 milliseconds; 121 to 150 milliseconds; or longer than 150 milliseconds</li> <li>• Heart block:                             <ul style="list-style-type: none"> <li>- None</li> <li>- 1st degree</li> <li>- 2nd type 1 (Wenckebach)</li> <li>- 2nd type 2</li> <li>- 3rd degree</li> </ul> </li> </ul>
Chest radiography	<p>Radiological examination of the chest. Documented findings from the chest X-ray pertinent to heart failure patients may include:</p> <ul style="list-style-type: none"> <li>• Pulmonary vascular redistribution, pulmonary congestion, or pulmonary edema</li> <li>• Cardiomegaly</li> <li>• Pleural effusion(s)</li> </ul>
Myocardial perfusion imaging	<p>Radionuclide myocardial perfusion imaging (planar or SPECT) with or without stress (PET listed separately). Documented findings may include:</p> <ul style="list-style-type: none"> <li>• Stress-induced perfusion abnormalities</li> <li>• Fixed perfusion abnormalities</li> <li>• Perfusion imaging LVEF: percentage 5% to 90% for LV from perfusion (technetium) imaging</li> <li>• Regional wall motion assessment</li> </ul>
Coronary angiography	<p>Coronary angiography with or without left heart catheterization. Documented findings may include stenosis of any epicardial coronary artery (right, left anterior descending, circumflex) or major branch (diagonal, marginal). Degree (percentage) of stenosis should be specified. Coronary arteries may have insignificant or no stenosis. Bypass graft angiography may also be performed and reported.</p>
Left heart catheterization	<p>Left heart catheterization with or without coronary angiography or ventriculography. Documented findings may include:</p> <ul style="list-style-type: none"> <li>• Left ventricular end diastolic pressure (mm Hg). Pressure from left ventricular catheter at end-diastole.</li> <li>• Left ventriculography ejection fraction. Percentage 5% to 90% from left ventricular injection.</li> </ul>
Right heart catheterization	<p>Right heart catheterization with or without pulmonary angiography. Documented findings may include:</p> <ul style="list-style-type: none"> <li>• RA pressure (mm Hg): mean right atrial pressure from pulmonary artery catheter</li> <li>• PA systolic pressure (mm Hg): systolic pulmonary pressure from pulmonary artery catheter</li> <li>• PA diastolic pressure (mm Hg): diastolic pulmonary pressure from pulmonary artery catheter</li> <li>• Mean pulmonary artery occlusion pressure from pulmonary artery catheter (wedge pressure, mm Hg). May be recorded with or without V-wave.</li> <li>• Cardiac output/index (liters or milliliters per minute, specify which)</li> <li>• Pulmonary vascular resistance (Wood's units, or dynes/second/cm)</li> <li>• Systemic vascular resistance (dynes/second/cm<sup>2</sup>)</li> </ul>
Magnetic resonance imaging (MRI)	<p>Magnetic resonance imaging (may include angiography) of the chest. Document ejection fraction percentage if measured as part of the MRI.</p> <ul style="list-style-type: none"> <li>• Ejection fraction: document ejection fraction percentage if measured as part of the MRI</li> <li>• Ventricular volume assessment</li> <li>• Regional wall motion assessment</li> </ul>
Computerized axial tomography (CT scan)	<p>Computerized axial tomography of the chest.</p> <ul style="list-style-type: none"> <li>• Ejection fraction: document ejection fraction percentage if measured as part of the CT scan</li> <li>• Ventricular volume assessment</li> <li>• Regional wall motion assessment</li> </ul>
Heart biopsy	<p>Biopsy of the endomyocardium.</p>
Positron emission tomography (PET)	<p>Positron emission tomography of the myocardium including perfusion imaging and stress studies. Documented findings may include:</p> <ul style="list-style-type: none"> <li>• PET metabolic deficits</li> <li>• PET baseline perfusion deficits</li> <li>• PET metabolic/perfusion mismatch</li> </ul>



**Table 5 Continued**

Data Element	Definition
Stress testing	Cardiovascular stress test including exercise (treadmill, bicycle) and pharmacological stress. Documented findings may include: <ul style="list-style-type: none"> <li>• Maximal (symptom limited) or submaximal test</li> <li>• Workload achieved. May be expressed as Watts, exercise stage achieved (include exercise protocol) or metabolic equivalents (METs).</li> <li>• Reason for terminating exercise test:                             <ul style="list-style-type: none"> <li>- Chest pain</li> <li>- Dyspnea</li> <li>- Dizziness</li> <li>- Leg fatigue</li> <li>- Other discomfort (specify)</li> <li>- Tachyarrhythmias</li> <li>- Asymptomatic tachyarrhythmias</li> </ul> </li> <li>• Evidence for ischemia on stress test (positive or negative):                             <ul style="list-style-type: none"> <li>- Positive: on an exercise tolerance test, the patient developed either:                                     <ul style="list-style-type: none"> <li>. Greater than or equal to 1 mm of horizontal or downsloping ST-segment depression or elevation for at least 60 to 80 milliseconds (ms) after the end of the QRS complex, in asymptomatic patients, or</li> <li>. New ST-segment depression greater than or equal to 2 mm (0.2 mV) (horizontal or downsloping) believed to represent ischemia even in the absence of ischemic discomfort. If the patient had an equivalent type of exercise test (e.g., exercise thallium or MIBI test, stress echocardiography, or dipyridamole, thallium, or adenosine radioisotope scan) that showed definite evidence of ischemia (e.g., an area of clear reversible ischemia), this should be considered a positive test.</li> </ul> </li> <li>- Negative: no evidence of ischemia (i.e., no typical angina pain and no ST depressions, no imaging evidence for ischemia)</li> </ul> </li> </ul>
6-minute walk test	Distanced walked during 6-minute walk (on a flat surface), in feet or meters.
Continuous ambulatory ECG monitoring for heart failure	Specify type of ambulatory ECG monitor used (e.g., looping event monitor, implantable looping event monitor, Holter monitor). Significant findings may include: <ul style="list-style-type: none"> <li>• Duration of monitoring</li> <li>• Mean heart rate, as well as minimum and maximum for patients in atrial fibrillation</li> <li>• Number and/or density of ventricular extrasystoles</li> <li>• Number of episodes of non-sustained ventricular tachycardia (3–15 consecutive beats at greater than 100 beats per min)</li> <li>• Number of episodes of sustained ventricular tachycardia (greater than or equal to 30 seconds at greater than 100 beats per min)</li> <li>• Number of pauses greater than 2.4 seconds</li> <li>• Heart rate variability (normal/abnormal/not assessed)</li> <li>• Presence of persistent or episodic atrial fibrillation, including duration and number of episodes</li> </ul>

**G. Invasive Therapeutic Procedures (Table 6)**

Many cardiovascular diseases that either play a role in causing HF or influence its course are treated with invasive therapeutic procedures. A uniform description of the type of procedure and its indication for use would enhance coher-

ence between clinical and research databases used to follow patients with HF. The procedures listed in this section are among those frequently applied to patients who may have either impaired cardiac function or clinical HF. Date and indication should be specified for all procedures.

**Table 6.** Invasive Therapeutic Procedures

Data Element	Definition
<b>Surgical Procedures</b>	
Coronary artery bypass graft (CABG) surgery	The number and types of grafts and surgical approach may be further specified: <ul style="list-style-type: none"> <li>• Number and placement of vein bypass grafts</li> <li>• Number and placement of arterial bypass grafts</li> <li>• Standard bypass surgery approach</li> </ul> Approach may be further specified: <ul style="list-style-type: none"> <li>• Median sternotomy approach</li> <li>• Small thoracotomy</li> <li>• With or without cardiopulmonary bypass</li> </ul>
Transmyocardial laser revascularization (TMLR)	Transmyocardial laser revascularization (TMLR) performed either alone or in combination with CABG.
Valve repair	Mitral, aortic, and/or tricuspid valve surgical repair. Use of valve ring may be specified. Valve(s) and procedure(s) may be specified.

**Table 6 Continued**

Data Element	Definition
<b>Surgical Procedures, continued</b>	
Valve replacement	Mitral, aortic, tricuspid, and/or pulmonic valve surgical replacement with prosthetic valve. Valve prosthesis should be specified. Valve(s) and procedure(s) may be specified.
Valvuloplasty	Valvuloplasty for stenotic valve lesions (aortic, mitral, pulmonic). Valve(s) and procedure(s) may be specified.
Ventricular remodeling surgery	Ventricular remodeling surgery may include: <ul style="list-style-type: none"> <li>• Aneurysectomy</li> <li>• Anterior ventricular resection (surgical anterior ventricular restoration [SAVR], Dor procedure)</li> </ul>
Surgical intervention for hypertrophic cardiomyopathy	Hypertrophic cardiomyopathy may be treated by: <ul style="list-style-type: none"> <li>• Septal myectomy</li> <li>• Septal myectomy with mitral valve replacement or repair</li> </ul>
Pericardiectomy	Surgical removal of the pericardium, usually because of constrictive pericardial disease or infection.
Pericardiocentesis, surgical	Surgical drainage of fluid in the pericardium.
Closure of patent foramen ovale (PFO) or atrial septal defect	Open surgical PFO closure or correction of atrial septal defect may be performed for: <ul style="list-style-type: none"> <li>• Stroke</li> <li>• Left to right shunt</li> <li>• Right to left shunt</li> </ul>
Surgery for congenital heart disease	<ul style="list-style-type: none"> <li>• Fontan procedure</li> <li>• Mustard procedure</li> <li>• Senning procedure</li> <li>• Other procedure</li> </ul>
Atrial fibrillation surgery	Maze or modified Maze procedure.
Implantable circulatory support	May be pulsatile or non-pulsatile flow devices. Implantable circulatory support includes: <ul style="list-style-type: none"> <li>• Left ventricular assist device (LVAD)</li> <li>• Right ventricular assist device (RVAD)</li> <li>• Biventricular assist device (BiVAD)</li> <li>• Artificial heart</li> </ul>
Organ transplantation	Organ transplantation may encompass: <ul style="list-style-type: none"> <li>• Heart</li> <li>• Heart/lung</li> <li>• Lung, single/double</li> <li>• Kidney</li> <li>• Liver</li> <li>• Other (may include combination of organs)</li> </ul>
<b>Electrophysiological Procedures</b>	
Permanent pacemaker implantation	Permanent pacemaker implanted, usually transvenous. Specify pacemaker placement: <ul style="list-style-type: none"> <li>• Dual chamber (DDD)</li> <li>• Right ventricular (VVI)</li> <li>• Right atrial (AAI)</li> <li>• Anti-tachycardia</li> <li>• Biventricular pacing for heart failure</li> <li>• Left ventricular pacing for heart failure</li> </ul> The brand, model number, and serial number may be recorded.
Implantable cardioverter-defibrillator (ICD)	Implantable cardioverter-defibrillator may be placed for: <ul style="list-style-type: none"> <li>• Ventricular fibrillation (VF)</li> <li>• Symptomatic ventricular tachycardia (VT)</li> <li>• Asymptomatic ventricular tachycardia (VT)</li> <li>• Other (specify)</li> <li>• Inducible VT/VF at EP study</li> <li>• Syncope</li> <li>• Primary prevention for patients in high risk heart failure group</li> </ul> The brand, model number, and serial number may be recorded.

**Table 6 Continued**

Data Element	Definition
<b>Percutaneous Interventional Procedures</b>	
Percutaneous coronary intervention (PCI)	Percutaneous coronary intervention (PCI) may include: <ul style="list-style-type: none"> <li>• Percutaneous transluminal coronary angioplasty (PTCA)</li> <li>• Stent placement (may be drug-eluting stent)</li> <li>• Directional atherectomy</li> <li>• Rotational atherectomy</li> <li>• Intracoronary brachytherapy</li> </ul>
Electrophysiologic (EP) catheter ablation	EP ablation may be performed for: <ul style="list-style-type: none"> <li>• Supraventricular tachycardia (SVT)</li> <li>• Atrial fibrillation (AF)</li> <li>• Atrial flutter</li> <li>• Ventricular tachycardia (VT)</li> <li>• Wolf-Parkinson-White (WPW) syndrome</li> <li>• Atrioventricular nodal reentrant tachycardia (AVNRT)</li> </ul>
Peripheral vascular intervention	Peripheral vascular intervention may include: <ul style="list-style-type: none"> <li>• Percutaneous transluminal angioplasty</li> <li>• Stent placement</li> <li>• Aortic stent graft</li> <li>• Surgical bypass</li> <li>• Aneurysectomy</li> <li>• Carotid stenting</li> <li>• Carotid endarterectomy</li> <li>• Other</li> </ul> Specify vessel.
Percutaneous myocardial laser revascularization (PMLR)	Percutaneous myocardial laser revascularization performed either alone or in conjunction with transmyocardial laser revascularization.
Percutaneous intervention for hypertrophic cardiomyopathy	Hypertrophic cardiomyopathy may be percutaneously treated by: <ul style="list-style-type: none"> <li>• Ethanol septal ablation</li> </ul>
Percutaneous pericardiocentesis	Percutaneous drainage of fluid in the pericardium.
Other percutaneous procedures	Other percutaneous procedures include: <ul style="list-style-type: none"> <li>• Valve replacement</li> <li>• Valve repair</li> <li>• Valvuloplasty</li> <li>• Closure of patent foramen ovale</li> <li>• Closure of secundum atrial septal defect (ASD)</li> <li>• Closure of patent ductus arteriosus (PDA)</li> </ul> Specify type of date of procedure, type of device, and congenital defect.
<b>Circulatory/Ventilatory Support</b>	
Extra-corporeal circulatory support	Extra-corporeal circulatory support includes: <ul style="list-style-type: none"> <li>• Intra-aortic balloon counterpulsation (IABP)</li> <li>• Extracorporeal membrane oxygenation (ECMO)</li> </ul>
Mechanical ventilatory support	Mechanical ventilatory support includes: <ul style="list-style-type: none"> <li>• Mechanical ventilation/intubation</li> <li>• CPAP</li> <li>• BiPAP</li> </ul> Specify dates of initiation and termination of therapy.

**H. Pharmacological Therapy (Table 7)**

For each pharmacological therapy element, administration or prescription of a medication in the specified class should be noted. In addition, particularly for clinical care, consider recording specific medication, total daily dose, start date, and stop date (when applicable). For combination therapies (e.g., combination diuretic and ACE inhibitor), both classes of medications should be indicated. Accurate and complete information about pharmacological therapy can be facili-

tated by appending a list of drugs in each class that are commonly available for the setting and population under evaluation.

For all medications recommended with Class I evidence supporting the ACC/AHA Clinical Performance Measures for Heart Failure (19), it is prudent to collect all potential contraindications. As of now, those medications include ACE inhibitors, beta-blockers, and warfarin anticoagulation (for patients with atrial fibrillation).

**Table 7.** Pharmacological Therapy

Data Element	Definition
<b>Therapies for HF</b>	
Aldosterone inhibitor	Patient has been prescribed an aldosterone inhibitor.
Angiotensin-converting enzyme (ACE) inhibitor medication	Patient has been prescribed an angiotensin-converting enzyme (ACE) inhibitor.
Angiotensin II receptor blocker (ARB) medication	Patient has been prescribed an angiotensin receptor antagonist blocker (ARB) medication.
Beta-adrenergic antagonist (beta-blocker) medication	Patient has been prescribed a beta-adrenergic antagonist (beta-blocker) medication.
Digitalis	Patient has been prescribed digitalis.
Diuretic medication	Patient has been prescribed a diuretic. Aldosterone inhibitor is listed separately above.
Electrolytes	Patient has been prescribed electrolytes: <ul style="list-style-type: none"> <li>• Potassium</li> <li>• Magnesium</li> </ul>
Experimental drugs/clinical trial drugs	Patient participating in investigational new drug trial. List drug class being tested. Record date patient enrolled in trial.
Intravenous (IV) inotropic agent	Intravenous positive inotrope administered.
Intravenous (IV) natriuretic peptide	Intravenous natriuretic peptide administered.
Intravenous (IV) vasodilator agents	Intravenous vasodilator administered.
Morphine sulfate	Morphine sulfate may be administered orally or intravenously. May be administered for pain or pulmonary edema.
Nitrate therapy	Nitroglycerin may be topical, oral, or sublingual. Nitroglycerin used on an as-needed basis only should be noted in this category.
Oral vasodilators	Patient has been prescribed an oral vasodilator, other than specified in any above classes. Oral vasodilators most commonly prescribed for heart failure are nitrates (see “Nitrate therapy”) and hydralazine. Other oral vasodilators may be prescribed to treat hypertension.
Oxygen therapy	Patient has been prescribed oxygen for chronic use.
Antiarrhythmic agent	Antiarrhythmic drug administered. As antiarrhythmics other than amiodarone are generally contraindicated in patients with heart failure, specific indications for their use should be noted.
Calcium channel blockers	Calcium channel blockers administered. As calcium channel blockers are generally contraindicated in patients with heart failure, specific indications for their use should be noted.
Lipid-lowering agent	Lipid-lowering agent administered. Note the type of agent: statin (HMG Co-A reductase inhibitors), fibrates, nicotinic acid, resin drugs, other.
Aspirin	Patient has been prescribed aspirin.
Non-aspirin anti-platelet agent	Patient has been prescribed a non-aspirin anti-platelet agent.
Warfarin	Patient has been prescribed warfarin. Target INR may also be helpful to collect.
Heparin	Patient has been prescribed heparin. Type of heparin may be specified.
Antidepressants	Patient has been prescribed an antidepressant.
Female hormone replacement therapy	Patient has been prescribed female hormone replacement therapy.
Influenza immunization	Patient has been immunized for influenza.
Inhaled bronchodilator	Patient has been prescribed an inhaled bronchodilator.
Insulin	Patient has been prescribed insulin.
Non-steroidal anti-inflammatory drug (NSAID)	Patient has been prescribed a non-steroidal anti-inflammatory drug. As NSAIDs are generally contraindicated in patients with heart failure, specific indications for their use should be noted.
Oral hypoglycemic agent	Patient has been prescribed an oral hypoglycemic agent for treatment of diabetes. Specify agent.
Pneumococcal immunization	Patient has been immunized for pneumococcal pneumonia.
Vitamins, food supplements, and other non-prescription treatments	Therapy should be specified and may include vitamins, food supplements, homeopathic treatments.

**Table 7 Continued**

Data Element	Definition
<b>Medication Allergy/Side Effects</b>	
Medication allergy	Patient has allergy to medication. The following should be specified: <ul style="list-style-type: none"> <li>• Medication causing allergy</li> <li>• Allergic reaction</li> </ul> Date of allergic reaction may be specified.
Medication side effect	Patient experienced side effect from medication. The following should be specified: <ul style="list-style-type: none"> <li>• Medication associated with side effect</li> <li>• Side effect which occurred</li> <li>• Whether or not medication was discontinued</li> </ul> Date of side effect and/or medication discontinuation may be specified.

**I. End-of-Life Management (Table 8)**

Patients' preferences for treatment, particularly life-sustaining treatments, change over time. Providers need to assess patients' preferences regularly to help patients and family members make the appropriate choices and decisions.

Patients with HF who are near the end of life experience dyspnea and pain, and providers need to work to assure that symptoms are adequately managed and that patients remain as comfortable as possible (35). Patients and family members also require assistance from nurses and physicians in dealing with anxiety and loss.

**Table 8. End of Life Management**

Data Element	Definition
Limitation of resuscitation	Any documented order or decision regarding patient request to limit a component of emergency therapy to restore circulation or ventilation (e.g., no intubation, no chest compressions).
Do not resuscitate (DNR)	Explicit documentation by physician and/or patient indicating that no resuscitative efforts are to be performed in the event of circulatory or respiratory arrest.
Inactivation of ICD defibrillation mode	Documentation of inactivation of ICD defibrillation mode without plans to re-activate (excludes inactivation for specific surgical procedures).
Advance care planning	Documentation of discussion carried out with the patient and/or family (by physician or nurse) about advance directive.

**J. Patient Education: Assessment of Status (Table 9)**

Factors that negatively influence learning and self management, including cognitive impairment, low literacy or language skills, visual disturbances, depression, and lack

of family or caregiver support, are common among HF patients (36–38), and should be assessed prior to educating patients. Additionally, patients' understanding of and adherence to care recommendations should be assessed regularly.

**Table 9. Patient Education: Assessment of Status**

Data Element	Definition
<b>Assessment of Learning Readiness</b>	
Presence of cognitive impairment	Documentation in the medical record that patient is cognitively impaired. Documentation may take the form of a qualitative statement (for example, dementia) or a score on a formal mental status assessment.
Low literacy skills	Documentation in the medical record that the patient does not read or write well or is unable to read or write.
Language skills	Documentation in the medical record of the patient's preferred language for communication.
Visual disturbances	Documentation in the medical record that the patient has impaired sight (e.g., blindness, partial blindness, macular degeneration).
Hearing impairment (uncorrected)	Documentation in the medical record that the patient has an uncorrected hearing impairment.
Depression	Documentation in the medical record that the patient carries the diagnosis of depression, or that the patient demonstrates depressed mood or affect. (See section on "Medical History: Non-Cardiovascular").
Level of caregiver/family support	Documentation in the medical record of the living situation of the patient and level of support available to the patient in current living situation. Usually this is described as good, adequate, or inadequate, or a specific problem with family support is identified.



**Table 9.** Patient Education: Assessment of Status

Data Element	Definition
<b>Assessment of Learning Readiness, continued</b>	
Medication adherence history	History confirming adherence to medication regimen in the past.
Nutrition history	History confirming adherence to instructions regarding adequate nutrition.
Low-sodium diet history	History confirming adherence to dietary sodium restriction in the past.
Smoking cessation history	If a current smoker, has the patient undergone smoking cessation counseling in the past?
Alcohol abstinence history	History confirming adherence to alcohol abstinence, if patient has history of alcohol abuse.
Activity level history	History confirming adherence to activity level and exercise program.
Daily weight history	History confirming adherence to self-monitoring of daily weight.
Daily blood pressure/heart rate history	History confirming adherence to self-monitoring of daily blood pressure and heart rate.

**K. Patient Education:  
 Intervention and Referral (Table 10)**

Essential components of an educational program for patients with HF have been identified by several authors (22,39,40). Patient education may be provided by a physician or nurse. Other providers may supply specialized education (e.g., pharmacists, dietitians, exercise physiologists). Patient education is most effective when individual-

ized, based on patient assessment, and occurs over time with reinforcement from providers. Inclusion of family members in care may facilitate learning and behavior change. Multidisciplinary and transitional care models that frequently provide strong patient educational components have been effective in reducing hospitalizations and improving quality of life among patients with HF (10–12,20,23,41,42). Date of intervention may be useful.

**Table 10.** Patient Education: Intervention and Referral

Data Element	Definition
<b>Education/Counseling Intervention</b>	
Medication instruction	Verbal and written medication instructions provided to patient and/or family.
Recognition of worsening symptoms	Verbal and written instructions provided to patient and/or family (by physician or nurse) regarding worsening of symptoms and when to call the physician.
Weight counseling	May include any or all of the following elements: <ul style="list-style-type: none"> <li>• Verbal/written instructions regarding how to monitor/record daily weight</li> <li>• Target weight</li> <li>• Instructions on using a scale</li> <li>• Instructions on what to do when weight increases, including parameters for seeking immediate help</li> <li>• Written weight record</li> <li>• Daily self-assessment for edema</li> <li>• Counseling regarding fluid restriction</li> </ul>
Diet counseling pertinent to lowering cardiovascular risk	Advice given or discussion carried out with the patient and/or family regarding diet counseling. May include: <ul style="list-style-type: none"> <li>• Sodium restriction</li> <li>• Fluid restriction</li> <li>• Other (specify)</li> </ul>
Counseling about alcohol abstinence/restriction	Advice given or discussion carried out with the patient and/or family regarding the importance of abstaining from or reducing intake of alcohol (43,44).
Activity counseling	Advice given or discussion carried out with the patient and/or family regarding activity level and restrictions in activity, and/or exercise recommendations.
Smoking cessation counseling	Advice given or discussion carried out with the patient (by physician, nurse, or other personnel) regarding the importance of stopping smoking. May include: <ul style="list-style-type: none"> <li>• Counseling (may be basic or advanced)</li> <li>• Written materials</li> <li>• Referral to smoking cessation program</li> <li>• Nicotine replacement therapy</li> </ul>
Immunization counseling	Advice given or discussion carried out with the patient and/or family regarding the importance of obtaining influenza and pneumococcal immunizations.

**Table 10 Continued**

Data Element	Definition
<b>Referral</b>	
Referral to dietician for diet counseling	Referral to dietitian for weight management and/or advanced nutritional instruction.
Referral to cardiac rehabilitation program	Referral to cardiac rehabilitation or other structured exercise program.
Plan for follow-up care	Documentation of plan for follow-up care with physician and/or nurse. Should include date of follow up.
Follow-up visit	Documentation of follow-up evaluation for patients with established heart failure should include: <ul style="list-style-type: none"> <li>• Patient history</li> <li>• Functional status</li> <li>• Physical examination</li> <li>• Laboratory or other tests</li> </ul> Note date of follow-up visit.
Patient referral	Patient referred to other care: <ul style="list-style-type: none"> <li>• Heart failure specialty clinic</li> <li>• Heart failure transitional care by advanced practice nurses</li> <li>• Heart failure disease management program</li> <li>• Evaluation for heart transplant</li> </ul> Transitional care (specify duration): <ul style="list-style-type: none"> <li>• Home health care</li> <li>• Heart failure nurse case manager</li> <li>• Hospice or palliative care</li> <li>• Home telemonitoring</li> <li>• Ambulatory cardiac telemetric monitoring (e.g., mobile cardiac outpatient telemetry)</li> </ul> Period of time enrolled in program and/or qualitative characterization of level of patient's success/participation in the program(s) may be specified.

**APPENDIX A: Health Status**

Improving health status, decreasing patients' symptoms, and improving function and quality of life are primary goals for HF treatment and represent important outcomes for HF care. The Institute of Medicine, in *Crossing the Quality Chasm* (45), calls for a fundamental restructuring of the entire American health care system to establish a greater focus on optimizing patient-centered outcomes such as health status. It follows that systematic assessment using validated instruments should be incorporated into prospective clinical trials, into quality assessment registries, and ultimately insinuated throughout the process of HF care. Although such systematic assessment is not currently part of routine clinical practice, an overview of health status assessment is included in this clinical data standards document so that future applications may be more easily served.

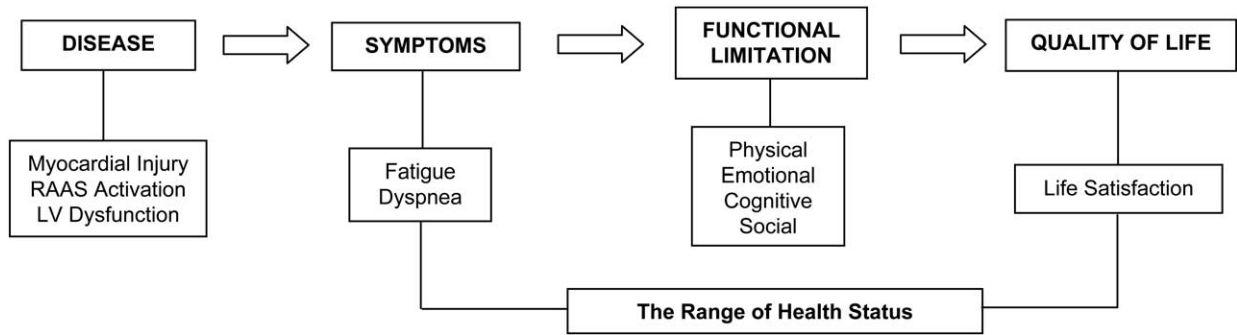
For clinicians and others who are interested in systematically assessing the health status of their HF patients, several choices for measures exist (32,46). They fall into three general types: single-item summary measures; generic health status measures; and disease-specific instruments. Single-item summary measures are simple and quick to use, but they provide few details about the components of patients' health status, may not be reproducible, and could have limited sensitivity to important clinical change.

Generic measures allow comparison across disease states, and capture the health status limitations of co-morbid conditions. Because these measures may be influenced by factors other than patients' HF status, they may lack the reproducibility and sensitivity to changes in HF status desired for many of the applications anticipated in this document. Information gleaned using disease-specific measures is directly relevant to HF care, and is generally more clinically interpretable, more reliable, and more sensitive to clinical change than other assessment techniques. An overview of various instruments for each of these assessment techniques is provided in [Table A1](#).

There is some lack of clarity with regard to the domains of health status that are being quantified with specific instruments. In fact, authors frequently use the words "symptoms," "function," "functional status," "quality of life," and "health status" interchangeably. [Figure A1](#) is designed to provide a framework of the different components of health status (used to represent the total of patients' experiences of symptoms, function, and quality of life). Modified from the concept of Wilson and Cleary (47) for patients with HF (48), it describes the underlying disease process of left ventricular dysfunction and neurohormonal imbalance that is manifested in patients as symptoms of fatigue, edema, and dyspnea. These symptoms can, in turn, affect patients' physical, emotional, cognitive, and social function.

**Table A1.** Measures of Health Status

Assessment Instrument	Self-Administered	Number of Items	Domains	Comments
<b>1. Disease Specific Measures for Heart Failure</b>				
Chronic Heart Failure Questionnaire (49)	No	Variable	<ul style="list-style-type: none"> <li>• Dyspnea during daily activities</li> <li>• Fatigue</li> <li>• Emotional function</li> </ul>	Interviewer-administered
Kansas City Cardiomyopathy Questionnaire (32)	Yes	23	<ul style="list-style-type: none"> <li>• Physical limitation</li> <li>• Symptoms (frequency, severity and recent change)</li> <li>• Quality of life</li> <li>• Social function</li> <li>• Self-efficacy</li> <li>• Summary scores</li> </ul>	More recent instrument with less published experience than other measures
Minnesota Living with Heart Failure Questionnaire (50)	Yes	21	<ul style="list-style-type: none"> <li>• Physical</li> <li>• Emotional</li> <li>• Total-quality of life</li> </ul>	Used in many previous clinical trials
New York Heart Association Classification (30)	No	Variable	<ul style="list-style-type: none"> <li>• Physical limitation and symptoms are assessed by a clinician and assigned a score of I-IV</li> </ul>	Most commonly used measure of functional status; however, a coarse measure from the physician's rather than the patient's point of view
<b>2. Generic Health Status Measures</b>				
EuroQol (51)	Yes	6	<ul style="list-style-type: none"> <li>• Mobility</li> <li>• Self-care</li> <li>• Usual activities</li> <li>• Pain/discomfort</li> <li>• Anxiety/depression</li> </ul>	Can be converted into a health utility measure
Nottingham Health Profile (52)	Yes	38	<ul style="list-style-type: none"> <li>• Sleep</li> <li>• Pain</li> <li>• Emotional reactions</li> <li>• Social isolation</li> <li>• Physical mobility</li> <li>• Energy level</li> </ul>	
Quality of Well-Being Scale (53)	No	38	<ul style="list-style-type: none"> <li>• Mobility</li> <li>• Physical activity</li> <li>• Symptoms/problems</li> </ul>	Can be converted into a health utility measure
SF-12 (21)	Yes	12	<ul style="list-style-type: none"> <li>• Physical Component Score</li> <li>• Mental Component Score</li> </ul>	Less response burden than SF-36; however, provides only summary measures of physical and mental function
SF-36 (54)	Yes	36	<ul style="list-style-type: none"> <li>• Physical functioning</li> <li>• Role-emotional</li> <li>• Mental health</li> <li>• Role-physical</li> <li>• Bodily pain</li> <li>• General health</li> <li>• Vitality</li> <li>• Social functioning</li> </ul>	Most frequently used health status measure
Sickness Impact Profile (55)	Yes	136	<ul style="list-style-type: none"> <li>• Activities of daily living including physical and psychosocial interactions</li> </ul>	Documented validity, reliability, and sensitivity; frequently used; however, significant response burden
<b>3. Single-Item Rating Scales</b>				
Global Assessment (56)	Yes	1	Generally a 5-point Likert scale rating current health or change in health	Simple; however, validity, reliability and responsiveness may be poor. The greater the duration of time that a global health assessment of change is supposed to quantify, the poorer the validity.
Single-item Visual Analogue Scale (57,58)	Yes	1	Generally rates current health along a continuum of death to perfect health	Simple; however, can be difficult to score, may not be reliable or sufficiently valid



**Figure A1.** Health status components. Quality of life is a distinct concept that refers to patients’ integration of their current symptoms and functioning with their desired symptoms and functioning. In other words, are patients living as they would like to? The greater the discrepancy between patients’ desired and actual health, the worse is their quality of life. Different instruments capture different domains to a varying extent, and those designing clinical studies, quality improvement registries, and quality assessment programs need to be explicit with regard to which domains of patients’ experiences they wish to quantify.

**APPENDIX B: ACC/AHA Heart Failure Clinical Data Standards Writing Committee—Relationships With Industry**

Committee Member	Research Grant	Speakers Bureau/ Honoraria/Expert Witness	Stock Ownership	Consultant/Advisory Board
Dr. J. Malcolm O. Arnold	None	<ul style="list-style-type: none"> <li>• Aventis</li> <li>• Merck-Frosst</li> <li>• Novartis</li> <li>• Pfizer</li> </ul>	None	<ul style="list-style-type: none"> <li>• Aventis</li> <li>• Merck-Frosst</li> <li>• Novartis</li> <li>• Pfizer</li> </ul>
Dr. Susan J. Bennett	None	None	None	None
Dr. Michael P. Cinquegrani	None	None	<ul style="list-style-type: none"> <li>• Medtronic</li> <li>• Pfizer</li> </ul>	None
Dr. John G. F. Cleland	<ul style="list-style-type: none"> <li>• Roche</li> <li>• Agilent</li> <li>• Medtronic</li> <li>• Servier</li> </ul>	None	None	None
Dr. Edward P. Havranek	None	None	None	None
Dr. Paul A. Heidenreich	None	None	None	None
Dr. Martha J. Radford	None	None	None	None
Dr. John D. Rutherford	None	None	None	None
Dr. John A. Spertus	<ul style="list-style-type: none"> <li>• CVT</li> </ul>	None	None	<ul style="list-style-type: none"> <li>• Amgen</li> <li>• CVT</li> <li>• Orqis</li> <li>• Otsuka</li> <li>• World Heart</li> </ul>
Dr. Lynne Warner Stevenson	<ul style="list-style-type: none"> <li>• Medtronic</li> </ul>	None	None	<ul style="list-style-type: none"> <li>• Medtronic</li> <li>• Novacardia</li> <li>• Scios</li> </ul>

**APPENDIX C:** Peer Reviewers of the ACC/AHA Heart Failure Clinical Data Standards Writing Committee—Relationships With Industry

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Ms. Lynn Doering, RN	• American Heart Association	None	None	None	None
Dr. Robert Hong	• ACCF Board of Governors	None	None	None	None
Dr. Sharon Ann Hunt	• ACC/AHA HF Guideline (Chair)	None	None	None	None
Dr. Jagat Narula	• American Heart Association	None	None	None	None
Dr. Rita Redberg	• ACC/AHA Task Force on Data Standards Lead Reviewer	None	None	None	None
<b>Content Reviewers</b>					
Dr. Nancy Albert	• AHA Heart Failure and Transplant Committee	None	• Medtronic • Glaxo Smith Kline • Scios Pharmaceuticals	None	None
Dr. Charles Canter	• AHA Heart Failure and Transplant Committee	None	None	None	None
Dr. Stanley Cortell	• AHA Heart Failure and Transplant Committee	None	None	None	None
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