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ACC/AHA CLINICAL DATA STANDARDS

2021 ACC/AHA Key Data Elements and Definitions for Heart Failure

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

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TOP 10 TAKE-HOME MESSAGES

1. This document (an update of the 2005 "ACC/AHA Key Data Elements and Definitions for Measuring the Clinical Management and Outcomes of Patients With Chronic Heart Failure") presents a clinical lexicon comprising data elements related to heart failure (HF), without differentiation for chronic HF versus acute decompensated HF; inpatient versus outpatient; or medical management with or without palliative care, or hospice. Because HF is a chronic condition, and a patient can experience periodic acute decompensation, the writing committee considered data elements that are pertinent to the full range of care provided to these patients and intended to be useful for all care venues.
2. Data elements for HF risk factors, cardiovascular history, and noncardiovascular health determinants, including COVID-19 infection, are included.
3. Patient assessment with more detailed elements for symptoms, signs and physical exam findings, stages, and functional assessment were updated.
4. Structural and ejection fraction sub-phenotypes were added, including data elements for heart failure with reduced ejection fraction (HFrEF), heart failure with mid-range ejection fraction (HFmEF), and heart failure with preserved ejection fraction (HFpEF).
5. Data elements related to cause of HF and cardiomyopathy were added, emphasizing the importance of specific diagnoses such as cardiac amyloidosis and peripartum cardiomyopathy.
6. Data elements for noninvasive and invasive diagnostic modalities (echocardiogram, cardiac magnetic resonance imaging, cardiopulmonary exercise testing, left and right heart catheterization) were expanded and updated.
7. Data elements for invasive therapeutic procedures, device therapies, and percutaneous mechanical circulatory support devices were added.
8. Pharmacological treatment options with new classes of medications were updated, and new data elements for new classes of medications were added.
9. Data elements for patient education and counseling on self-care and patient-reported outcome measures were added.
10. These clinical data standards should be broadly applicable in various settings, including clinical programs such as HF clinics, transitions of care, clinical registries, clinical research, quality performance improvement initiatives, electronic health records and digital health information technology interoperability, public reporting programs, and education/self-care.

PREAMBLE

The American College of Cardiology (ACC) and the American Heart Association (AHA) support their members' goal to improve the prevention and care of cardiovascular diseases through professional education, research, and development of guidelines and standards and by fostering policy that supports optimal patient outcomes. The ACC and AHA recognize the importance of the use of clinical data standards for patient management, assessment of outcomes, and conduct of research, and the importance of defining the processes and outcomes of clinical care, whether in randomized trials, observational studies, registries, or quality improvement initiatives.

Hence, clinical data standards strive to define and standardize data relevant to clinical topics in cardiovascular medicine, with the primary goal of assisting data collection by providing a platform of data elements and definitions applicable to various conditions. Broad agreement on a common vocabulary with reliable definitions used by all is vital to pool and/or compare data across studies to promote interoperability of electronic health records (EHRs) and to assess the applicability of research to clinical practice. The increasing national focus on adoption of certified EHRs along with financial incentives for providers to demonstrate "meaningful use" of those EHRs to improve healthcare quality render even more imperative and urgent the need for such

definitions and standards. Therefore, the ACC and AHA have undertaken to define and disseminate clinical data standards—sets of standardized data elements and corresponding definitions—to collect data relevant to cardiovascular conditions. The ultimate purpose of clinical data standards is to contribute to the infrastructure necessary to accomplish the ACC's mission of fostering optimal cardiovascular care and disease prevention and the AHA's mission of being a relentless force for a world of longer, healthier lives.

The specific goals of clinical data standards are:

1. To establish a consistent, interoperable, and universal clinical vocabulary as a foundation for clinical care and clinical research
2. To facilitate the exchange of data across systems through harmonized, standardized definitions of key data elements
3. To facilitate the further development of clinical registries, quality and performance improvement programs, outcomes evaluations, public reporting, and clinical research, including the comparison of results within and across these initiatives

The key data elements and definitions are a compilation of variables intended to facilitate the consistent, accurate, and reproducible capture of clinical concepts; standardize the terminology used to describe cardiovascular diseases and procedures; create a data environment conducive to the assessment of patient management and outcomes for quality and performance improvement and clinical and translational research; and increase opportunities for sharing data across disparate data sources. The ACC/AHA Task Force on Clinical Data Standards (Task Force) selects cardiovascular conditions and procedures that will benefit from creation of a clinical data standard set. Experts in the subject area are selected to examine and consider existing standards and develop a comprehensive, yet not exhaustive, data standard set. When undertaking a data collection effort, only a subset of the elements contained in a clinical data standard listing may be needed or, conversely, users 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. Another example is as follows: If the data set is to be used for quality improvement, safety initiatives, or administrative functions, other elements such as Current Procedural Terminology (CPT) codes and *International Statistical Classification of Diseases and Related Health Problems*, 10th revision (*ICD-10-CM*) codes, or outcomes may be added. The intent of the Task Force is to standardize the clinical concepts, keeping the focus on the patient and the clinical care, not necessarily on administrative billing or coding concepts, and the clinical concepts selected for development are generally cardiovascular specific, where a standardized terminology already exists. The clinical data standards can therefore serve as a guide for development of administrative data sets, and complementary administrative or quality assurance elements can evolve from these core clinical concepts and elements. Thus, rather than forcing the clinical data standards to harmonize with existing administrative codes, such as *ICD-10-CM* or CPT codes, we would envision the administrative codes to follow the lead of the clinical data standards. This approach would allow the clinical care to lead standardization of the terminologies in health care.

The ACC and AHA recognize that there are other national efforts to establish clinical data standards, and every attempt is made to harmonize newly published standards with existing standards. Writing committees are instructed to consider adopting or adapting existing nationally recognized data standards if the definitions and characteristics are validated, useful, and applicable to the set under development. In addition, the ACC and AHA are committed to continually expanding their portfolio of clinical data standards and will create new standards and update existing ones as needed to maintain their currency and promote harmonization with other standards as health information technology and clinical practice evolve.

The Privacy Rule of the Health Insurance Portability and Accountability Act, which went into effect in April 2003, heightened all practitioners' awareness of our professional commitment to safeguard our patients' privacy. The Health Insurance Portability and Accountability Act privacy regulations specify which information 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 healthcare 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 healthcare providers.

In clinical care, healthcare providers communicate with each other through a common vocabulary. In an analogous manner, the integrity of clinical research depends 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, comparison, pooled analysis, and

meta-analysis are enabled, thus deepening our understanding of individual studies.

The recent development of quality performance measurement initiatives, particularly those for which the comparison of providers and institutions is an implicit or explicit aim, has further raised awareness about the importance of clinical data standards. Indeed, a wide audience, including nonmedical professionals such as payers, regulators, and consumers, may draw conclusions about care and outcomes. To understand and compare care patterns and outcomes, the data elements that characterize them must be clearly defined, consistently used, and properly interpreted.

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1. INTRODUCTION

The Task Force has been spearheading the initiative to standardize the lexicon of cardiovascular medicine to enhance the use of clinical data, improve clinical communication, optimize quality assurance and improvement, assess outcomes, enhance process improvement efforts, and facilitate clinical research, development, and analysis of registries. Because the ACC and AHA are committed to updating existing standards as needed to maintain their currency and promote harmonization with other standards as health information technology and clinical practice evolve, this document is provided as an update of the 2005 ACC/AHA key data elements and definitions for chronic heart failure.[1] The goal of this publication is to provide new data elements consistent with practice guidelines and updated terminology and attributes in compliance with current methodology of the Task Force[2] and current policies of the ACC and AHA regarding harmonization of data across organizations and disciplines.

Heart failure (HF) data standards are of critical importance to clinical providers, investigators, administrators, healthcare services and institutions, regulators, legislators, and payers more than ever as a result of: 1) increasing prevalence and burden of HF[3,4]; 2) increased focus on performance metrics for HF[5]; 3) increasing need for large data sets to examine comparative effectiveness and safety of treatment strategies in real world patients[6]; 4) increased recognition of healthcare disparities that require understanding of patient, healthcare delivery, and system variables[7]; 5) growing need for new effective preventive and treatment strategies in HF targeted for different stages or types of HF[8]; subgroups of interest and comorbidities requiring better classification and documentation of patient and treatment variables; 6) need for improved communication and for shared decision-making and transitions of care between different levels of care and providers[9,10]; 7) development of models for prediction of therapeutic benefit and outcomes[11]; 8) universally understandable data for individualization of therapies and management strategies for patients with complex HF by different providers; and 9) development and conduct of future registries, at both hospital and national levels, by providing a list of major variables, outcomes, and definitions.

Approximately 6.2 million persons ≥20 years of age in the United States have HF, with approximately 1 million new HF cases diagnosed annually, and the prevalence continues to rise.[3,12] Despite improvements in age-adjusted HF-related survival rates between 2000 and 2012, there has been a recent increase in mortality rates for all age and sex subgroups.[12–14] HF remains as the primary diagnosis in >1 million hospitalizations annually, and the total cost of HF care in the United States exceeds $30 billion annually, with over half of these costs spent on hospitalizations.[15] The mortality rates after hospitalization for HF remains high, at approximately 20% to 25% at 1 year, with similar mortality rates for heart failure with preserved ejection fraction or heart failure with reduced ejection fraction.[16]

The clinical syndrome of HF may result from different causes. Thus, despite a common syndrome of HF, different etiologies may imply different prognosis and varying treatment strategies, underlining the importance of specific data elements for emphasizing these differences in HF.[8] Similarly, the syndrome of HF commonly overlaps with other cardiovascular diseases, such as coronary artery disease, hypertension, valvular disease, and primary myocardial disease, which are common causes of HF. Specifying these data elements for patients with HF is important for clinical care, performance improvement, research, and endpoints. Standardized data elements and definitions across studies can help accelerate and facilitate research in HF through dissemination and sharing of relevant information, comparisons, pooled analyses, and meta-analyses.[17]

In clinical care, a broad spectrum of clinicians provides a continuum of care for patients with HF, ranging from primary care/family medicine providers, HF specialists and/or cardiologists, cardiac and transplant surgeons, interventional cardiologists, electrophysiologists, advanced practice providers such as nurse practitioners and physician assistants, pharmacists, hospitalists, home healthcare providers, palliative care specialists and nurses, hospice specialists and nurses, social workers, and cardiac rehabilitation specialists to investigators, who must communicate with each other through a common vocabulary. Care of patients with HF may take place in specialized clinics delivered by a variety of providers previously mentioned, necessitating care coordination comprising common terminology with a patient-centered approach.[18] Furthermore, HF is a chronic problem, and patients are likely to transition through different stages of HF, which requires recognition and definition of these states with common

terminology standardized across different providers and encounters of care.

Similarly, given the recent emphasis on quality performance measurement initiatives, particularly those for which institutions and providers are compared against each other or against benchmarks, and reimbursement strategies and penalties that are attached to such metrics, the necessity for reliable, risk adjustable, and analyzable data is gaining more importance for the professional community, as well as for payers, regulators, legislators, and consumers.[5,19,20]

The writing committee envisions that the data elements might be useful in these broad categories:

- Clinical programs, such as HF clinics, where many clinicians work together to achieve specific goals for the care and care coordination of patients with HF.
- Transitions of care, in which patients with HF move through different locations and levels of care (ie, inpatient, outpatient [eg, home, rehabilitation center, nursing home], palliative care, and hospice) or progress through different stages of HF (Stages A to D), with providers ranging from HF specialists, cardiac transplant physicians, home healthcare or palliative care providers, and primary care providers.
- Clinical registries, for ongoing care, prospective epidemiologic and comparative effectiveness research, pre- or postmarket analysis for efficacy and safety in populations of interest.
- Clinical research, particularly prospective randomized clinical trials where eventual pooled analysis or meta-analysis is anticipated.
- Quality performance measurement initiatives, provider or institutional based or external, retrospective, or prospective.
- Organization and design of electronic medical information initiatives, such as EHRs, pharmacy databases, computerized decision support, and cloud technologies incorporating health information.
- Public health policy, healthcare coverage, insurance coverage, and legislation development to provide appropriate and timely care for patients with HF and to prevent disparities in HF care.

The data element tables are also included as an Excel file in the Online Data Supplement.

1.1. Special Considerations

Several points are important to recognize regarding the scope of this document. First, given the magnitude of additional data elements that cardiac transplantation and mechanical circulatory support device therapies would entail, the writing group decided to focus on HF and not include cardiac transplantation and mechanical circulatory support data elements in detail in this document.

Second, the data elements were not differentiated for chronic HF versus acute decompensated HF; or for inpatient, outpatient, palliative care, or hospice status, because HF is a chronic condition that is not an episodic event, and a patient can transition from one status to the other through his/her life time. The writing committee considered data elements pertinent to the full range of care provided to these patients and are intended to be useful for all care venues.

Third, the data elements were not differentiated for new onset incident versus prevalent cases or number of encounters, and databases can be built and customized according to users' needs to capture such information.

Fourth, the writing committee would like to alert the readers to the existence of other documents and guidelines with which we tried to harmonize and are likely to complement the content of our document, including the "2020 AHA/ACC Key Data Elements and Definitions for Coronary Revascularization,"[21] "2019 ACC/AHA/ASE Key Data Elements and Definitions for Transthoracic Echocardiography,"[22] "2014 ACC/AHA Key Data Elements and Definitions for Cardiovascular Endpoint Events in Clinical Trials,"[23] "2013 ACCF/AHA Guideline for the Management of Heart Failure,"[24] "2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure,"[9] Centers for Medicare & Medicaid Services (https://www.medicare.gov/hospitalcompare/search.html), and The Joint Commission core HF performance measures; meaningful use criteria; The Agency for Healthcare Research and Quality's quality indicators for HF; Get With The Guidelines and National Cardiovascular Data Registry CathPCI Registry data elements. We made every attempt to use guideline- and evidence-based definitions.

Finally, we did not include data element fields for entry of calculated risk scores, as databases can be programmed and customized to calculate risks scores according to the user's objective as different risk models can be used for different purposes.

The intent of this writing committee was not to be overly prescriptive.

2. METHODOLOGY

2.1. Writing Committee Composition

The Task Force selected the members of the writing committee. The writing committee consisted of 8 individuals with domain expertise in HF, cardiomyopathy, cardiovascular disease, outcomes assessment, medical informatics, health information management, and healthcare services research and delivery.

2.2. Relationships With Industry and Other Entities

The Task Force made every effort to avoid actual or potential conflicts of interest that might arise as a result of an outside relationship or a personal, professional, or business interest of any member of the writing committee. Specifically, all members of the writing committee were required to complete and submit a disclosure form showing all such relationships that could be perceived as real or potential conflicts of interest. These statements were reviewed by the Task Force and updated when changes occurred. Authors' and peer reviewers' relationships with industry and other entities pertinent to this data standards document are disclosed in Appendixes 1 and 2, respectively. In addition, for complete transparency, the disclosure information of each writing committee member—including relationships not pertinent to this document—is available as a Supplemental Table. The work of the writing committee was supported exclusively by the AHA and ACC without commercial support. Writing committee members volunteered their time for this effort. Meetings of the writing committee were confidential and attended only by committee members and staff.

2.3. Review of Literature and Existing Data Definitions

A substantial body of literature was reviewed to create this article.[1,9,21–24] This information was augmented by multiple peer-reviewed references listed in the tables under the column "Mapping/Source of Definition."

2.4. Development of Terminology Concepts

The writing committee aggregated, reviewed, harmonized, and extended these terms to develop a controlled, semantically interoperable, machine-computable terminology set that would be usable, as appropriate, in as broad a number of contexts as possible. As necessary, the writing committee identified the contexts where individual terms required differentiation according to their proposed use (ie, research/regulatory versus clinical care contexts).

This publication was developed with the intent that it will serve as a common lexicon and base infrastructure that can be used by end users to augment work related to standardization and healthcare interoperability including, but not limited to, structural, administrative, and technical metadata development. The resulting appendixes (Appendixes 4–10) list the data element in the first column, followed by a clinical definition of the data element. The allowed responses ("permissible values") for each data element in the next column are the acceptable "answers" for capturing the information. For data elements with multiple permissible values, a bulleted list of the permissible values is provided in the row listing the data element, followed by multiple rows listing each permissible value and corresponding permissible value definition, as needed. Where possible, clinical definitions (and clinical definitions of the corresponding permissible values) are repeated verbatim as authored by the Standardized Data Collection for Cardiovascular Trials Initiative[23] or as previously published in reference documents.

2.5. Consensus Development

The Task Force established the writing committee per the processes described in the Task Force's methodology paper.[2] The primary responsibility of the writing committee was to review and refine the "ACC/AHA Key Data Elements and Definitions for Measuring the Clinical Management and Outcomes of Patients With Chronic Heart Failure"[1] and develop a harmonized data set for coronary revascularization that will provide the attributes and other informatics formalisms required to attain interoperability of the terms. The work of the writing committee was accomplished via a series of teleconference and web conference meetings, along with extensive email correspondence. The review work was distributed among subgroups of the writing committee based on interest and expertise in the components of the terminology set. The proceedings of the workgroups were then assembled, resulting in the vocabulary and associated descriptive text in Appendixes 4–10. All members reviewed and approved the final vocabulary.

2.6. Relation to Other Standards

The writing committee reviewed the available published data standards, including registry data dictionaries from registries, which were specifically developed for HF. Relative to published data standards, the writing committee anticipates that this terminology set will facilitate the uniform adoption of these terms, where appropriate, by the clinical, clinical and translational research, regulatory, quality and outcomes, and EHR communities.

2.7. Peer Review, Public Review, and Board Approval

This document was reviewed by official reviewers nominated by ACC and AHA. To increase its applicability further, the document was posted on the ACC and AHA websites for a 30-day public comment period. This document was approved for publication by the ACC Clinical Policy Approval Committee in October 2020, by the AHA Science Advisory and Coordinating Committee in

September 2020, and by the AHA Executive Committee in December 2020. The writing committee anticipates that these data standards will require review and updating in the same manner as other published guidelines, performance measures, and appropriate use criteria. The writing committee will, therefore, review the set of data elements on a periodic basis, starting with the anniversary of publication of the standards, to ascertain whether modifications should be considered.

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ARTICLE INFORMATION

This document was approved by the American College of Cardiology Clinical Policy Approval Committee in October 2020, by the American Heart Association Science Advisory and Coordinating Committee in September 2020, and by the American Heart Association Executive Committee in December 2020.

Appendix 4 includes data elements used to describe congenital heart disease obtained from the International Paediatric and Congenital Cardiac Code (IPCCC) as published by the International Society for Nomenclature of Paediatric and Congenital Heart Disease (ISNPCHD) (https://ipccc.net/).

Supplemental materials (Data Supplement [Appendix 4 in an Excel file] and a Comprehensive RWI table) are available with this article at https://www.ahajournals.org/doi/suppl/10.1161/HCQ.0000000000000102

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Appendix 1. Author Relationships With Industry and Other Entities (Relevant)—2021 ACC/AHA Key Data Elements and Definitions for Heart Failure

Committee Member	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Biykem Bozkurt, Co-Chair	Baylor College of Medicine—Mary and Gordon Cain Chair Professor of Medicine and Director, Winters Center for Heart Failure Research; Michael E. DeBakey VA Medical Center—Chief, Cardiology Section	None	None	None	None	None	None
Ray E. Hershberger, Co-Chair	Ohio State University, Wexner Medical Center—Professor of Medicine, Cardiovascular Medicine and Human Genetics, and Director, Division of Human Genetics	None	None	None	None	None	None
Javed Butler	University of Mississippi, Medical Center—Professor	None	None	None	None	None	None
Kathleen L. Grady	Northwestern University—Professor of Surgery and Medicine, Feinberg School of Medicine and Northwestern Memorial Hospital; Bluhm Cardiovascular Institute—Administrative Director, Center for Heart Failure	None	None	None	None	None	None
Ed Havranek*	Denver Health Medical Center—Director of Medicine	None	None	None	None	None	None
Paul A. Heidenreich	Stanford University School of Medicine—Professor of Medicine and Professor of Health Research and Policy	None	None	None	None	None	None
Maria Lizza Isler	AHA—Interoperability Project Manager	None	None	None	None	None	None
James K. Kirklin	University of Alabama at Birmingham—Professor of Surgery, Division of Cardiothoracic Surgery and Director, Kirklin Institute for Research in Surgical Outcomes (KIRSO)	None	None	None	None	None	None
William S. Weintraub	MedStar Heart & Vascular Institute—Director, Outcomes Research; Georgetown University—Professor of Medicine	None	None	None	None	None	None

This table represents the relationships of committee members with industry and other entities that were determined to be relevant to this document. These relationships were reviewed and updated in conjunction with all meetings and/or conference calls of the writing committee during the document development process. The table does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of ≥5% of the voting stock or share of the business entity, or ownership of ≥$5000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted. According to the ACC/AHA, a person has a *relevant* relationship IF: a) the *relationship or interest* relates to the same or similar subject matter, intellectual property or asset, topic, or issue addressed in the *document*; or b) the *company/entity* (with whom the relationship exists) makes a drug, drug class, or device addressed in the *document*, or makes a competing drug or device addressed in the *document*; or c) the *person* or a *member of the person's household*, has a reasonable potential for financial, professional or other personal gain or loss as a result of the issues/content addressed in the *document*.

*Dr. Havranek resigned from the writing committee in February 2019. The writing committee thanks him for his contributions, which were extremely beneficial to the development of the draft.

ACC indicates American College of Cardiology; AHA, American Heart Association; and VA, Veterans Affairs.

Appendix 2. Reviewer Relationships With Industry and Other Entities (Comprehensive)—2021 ACC/AHA Key Data Elements and Definitions for Heart Failure

Reviewer	Representation	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Adam DeVore	Official Reviewer—AHA	Duke University School of Medicine—Assistant Professor of Medicine, Division of Cardiology; Duke Clinical Research Institute—Member	• Amgen • AstraZeneca Pharmaceuticals • Bayer Healthcare Pharmaceuticals* • InnaMed • LivaNova • Mardil Medical • Novartis* • Procyrion • scPharmaceuticals • Zoll	None	None	• AHA* • Amgen* • AstraZeneca* • Bayer Healthcare Pharmaceuticals • Intra-Cellular Therapies • Luitpold Pharmaceuticals • Merck & Co. • NHLBI* • Novartis* • PCORI	• NHLBI‡ • PCORI‡ • Intra-Cellular Therapies‡	None
Gregg C. Fonarow	Official Reviewer—ACC Clinical Policy Approval Committee; Content Reviewer	UCLA—Professor of Medicine	• Abbott Laboratories* • Amgen* • CHF Solutions • Edwards Lifesciences • Janssen • Medtronic • Merck • Novartis* • Regeneron	• Novartis*	None	• Medtronic • NHLBI* • Novartis*	• ACC/AHA Task Force on Performance Measures† • ACTION Registry GWTG Steering Committee Chair† • AHA Consumer Health Quality Coordinating Committee† • *JAMA Cardiology*† • Steering Committee GWTG†	None
Corrine Y. Jurgens	Official Reviewer—ACC/AHA Task Force on Data Standards	Boston College—Associate Professor; Stony Brook University School of Nursing—Associate Professor, Emeritus	None	None	None	None	• HFSA†	None
Daniel J. Levine	Official Reviewer—ACC Board of Governors	Lifespan Physician Group—Director, Advanced Heart Failure Program; The Warren Alpert Medical School of Brown University—Clinical Associate Professor of Medicine	None	None	None	None	• NIH‡ • Novartis‡ • Sanofi‡ • St. Jude Medical‡	None
Kavita Sharma	Official Reviewer—AHA	JHU School of Medicine—Assistant Professor of Medicine; JHU Heart Failure with Preserved Ejection Fraction Program—Director	• Novartis	• Novartis	None	• AHA*	• Pfizer (King Pharmaceuticals)‡ • Novartis‡ • St. Luke's Hospital‡	None
H. Vernon Anderson	Content Reviewer	University of Texas Health Science Center at Houston McGovern Medical School—Professor of Medicine, Cardiology	• Accreditation for Cardiovascular Excellence • American Medical Foundation for Education*	None	None	None	• None	None
Maria Rosa Costanzo	Content Reviewer	Advocate Heart Institute—Medical Director, Heart Failure Research; Edward Hospital Center for Advanced Heart Failure—Medical Director	• Abbott Laboratories • CHF Solutions • Respicardia	None	None	• Novartis†	• CHF Solutions* • Abbott Laboratories*	None

(*Continued*)

Appendix 2. Continued

Reviewer	Representation	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Akshay Desai	Content Reviewer	Harvard Medical School—Associate Professor of Medicine; Brigham and Women's Hospital—Associate Physician	• Abbot Laboratories* • Alnylam* • Amgen* • AstraZeneca Pharmaceuticals* • Biofourmis* • Boehringer Ingelheim Pharmaceuticals • Boston Scientific* • Corvidia Therapeutics* • DalCor Pharmaceuticals* • Merck & Co. • Novartis* • Regeneron* • Relypsa*	None	None	• Alnylam* • AstraZeneca Pharmaceuticals* • Bayer Healthcare Pharmaceuticals† • MyoKardia† • Novartis*	• Baim Institute for Clinical Research* • TIMI Study Group*	• Defendant, cardiomyopathy, 2019 • Plaintiff, out-of-hospital cardiac arrest, 2018
Lee Goldberg	Content Reviewer	University of Pennsylvania—Professor of Medicine; Vice Chair for Informatics, Department of Medicine; Section Chief, Advanced Heart Failure and Cardiac Transplant	• Abbott Laboratories • Respicardia	None	None	• Respicardia† • NIH	None	None
Nkechinyere N. Ijioma	Content Reviewer	Mayo Clinic—Cardiologist, Department of Cardiovascular Medicine	None	None	None	None	None	None
Anuradha Lala-Trindade	Content Reviewer	Mount Sinai Health System—Assistant Professor, Medicine, and Population Health Science And Policy; NHLBI Cardiothoracic Surgery Network—Director, Heart Failure Research	None	None	None	None	• Zoll • American Regent‡ • NHLBI‡	None
Gurusher Panjrath	Content Reviewer	George Washington School of Medicine & Health Sciences—Associate Professor of Medicine, and Director, Advanced Heart Failure and Mechanical Circulatory Support Program	None	• Pfizer*	None	None	• Abbott Laboratories‡ • HFSA†	None
Pamela N. Peterson	Content Reviewer	University of Colorado Anschutz Medical Campus—Professor of Medicine, Cardiology	• AHA*	None	None	• NHLBI†	None	None

This table represents all relationships of reviewers with industry and other entities that were reported at the time of peer review, including those not deemed to be relevant to this document, at the time this document was under review. The table does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of ≥5% of the voting stock or share of the business entity, or ownership of ≥$5000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted. Names are listed in alphabetical order within each category of review. Please refer to https://www.acc.org/guidelines/about-guidelines-and-clinical-documents/relationships-with-industry-policy for definitions of disclosure categories or additional information about the ACC/AHA Disclosure Policy for Writing Committees.

*Significant relationship.

†No financial benefit.

‡This disclosure was entered under the Clinical Trial Enroller category in the ACC's disclosure system. To appear in this category, the author acknowledges that there is no direct or institutional relationship with the trial sponsor as defined in the ACC/AHA Disclosure Policy for Writing Committees.

ACC indicates American College of Cardiology; AHA, American Heart Association; GWTG, Get With The Guidelines; HFSA, Heart Failure Society of America; *JAMA*, *Journal of the American Medical Association*; JHU, Johns Hopkins University; NHLBI, National Heart, Lung, and Blood Institute; NIH, National Institutes of Health; PCORI, Patient-Centered Outcomes Research Institute; TIMI, Thrombolysis in Myocardial Infarction; and UCLA, University of California–Los Angeles.

Appendix 3. Abbreviations

ACC	American College of Cardiology
AHA	American Heart Association
CMS	Centers for Medicare & Medicaid Services
CPT	Current Procedural Terminology
EHR	electronic health record
HF	heart failure
HFpEF	heart failure with preserved ejection fraction
HFrEF	heart failure with reduced ejection fraction
ICD-10	*International Statistical Classification of Diseases and Related Health Problems, 10th revision*
NCDR	National Cardiovascular Data Registry
TJC	The Joint Commission

Appendix 4. Medical History

A. Heart Failure Risk Factors

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Date of event	The date an event occurred	• Date, in mm/dd/yyyy			The format mm/dd/yyyy is commonly used in the United States. Other formats used to capture date include dd/mm/yyyy and yyyy-mm-dd.
Diabetes	A metabolic disorder characterized by abnormally high blood sugar levels due to diminished production of insulin or insulin resistance/desensitization. American Diabetes Association criteria for diabetes mellitus includes the documentation of the following: • HbA1c ≥6.5%; or • Fasting plasma glucose ≥126 mg/dL (7.0 mmol/L); or • 2-h plasma glucose ≥200 mg/dL (11.1 mmol/L) during an oral glucose tolerance test; or • In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose ≥200 mg/dL (11.1 mmol/L)	• Type 1 diabetes • Type 2 diabetes • No • Unknown		NCI Thesaurus Code: C2985[25] American Diabetes Association. 2. Classification and diagnosis of diabetes: standards of medical care in diabetes–2018. Diabetes Care. 2018;41:S13-27.[26]	This does not include gestational diabetes.
		Type 1 diabetes	Type 1 diabetes is an autoimmune disease in which the body does not produce insulin.		
		Type 2 diabetes	Type 2 diabetes is a form of diabetes that is characterized by high blood sugar, insulin resistance, and relative lack of insulin.		
		No	No history of diabetes		
		Unknown			

(*Continued*)

Appendix 4. Continued

A. Heart Failure Risk Factors (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Acutely decompensated diabetes	An emergency condition in which blood glucose level is extremely high	• Diabetic ketoacidosis • Hyperosmolar hyperglycemic nonketotic syndrome		Kitabchi AE, Umpierrez GE, Miles JM, et al. Hyperglycemic crises in adult patients with diabetes. Diabetes Care. 2009;32:1335-43.[27]	
		Diabetic ketoacidosis	Diabetic ketoacidosis is characterized by uncontrolled hyperglycemia, metabolic acidosis, and increased total body ketone concentration.		
		Hyperosmolar hyperglycemic nonketotic syndrome	Hyperosmolar hyperglycemic syndrome is characterized by severe hyperglycemia, hyperosmolality, and dehydration in the absence of significant ketoacidosis.		
Diabetes duration	Duration since first diagnosis of diabetes	• Newly diagnosed • <5 y • 5–10 y • 10 to <20 y • ≥20 y		American Heart Association. Get With The Guidelines–Heart Failure. Available at: https://www.heart.org/en/professional/quality-improvement/get-with-the-guidelines/get-with-the-guidelines-heart-failure. Accessed October 26, 2020.[28]	
Diabetes treatment	A therapeutic modality used to aid in the management of an individual's diabetes	• None • Diet • Oral • Insulin • Noninsulin subcutaneous medication • Unknown		NCI Thesaurus Code: C99532[25]	
		None	No treatment for diabetes		
		Diet	Diet treatment		
		Oral	Treatment with oral agent (includes oral agent with or without diet treatment)		
		Insulin	A synthetic or animal-derived form of insulin used in the treatment of diabetes mellitus. Therapeutic insulin is formulated to be short-, intermediate-, and long-acting in order to individualize an insulin regimen according to individual differences in glucose and insulin metabolism. Therapeutic insulin may be derived from porcine, bovine, or recombinant sources. Endogenous human insulin, a pancreatic hormone composed of 2 polypeptide chains, is important for the normal metabolism of carbohydrates, proteins, and fats and has anabolic effects on many types of tissues.		
		Noninsulin subcutaneous medication	Includes GLP-1 agonists, which stimulate insulin release and inhibit glucagon release, and amylin analogs, which slow gastric emptying, regulate postprandial glucagon, and decrease of food intake		
		Unknown	Diabetes treatment unknown		

(*Continued*)

Appendix 4. Continued

A. Heart Failure Risk Factors (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Oral diabetes medications	Types of oral therapeutic medications for diabetes	(Multi-select) • Metformin • Sulfonylurea • Thiazolidinediones • GLP-1 agonists • DPP-4 inhibitors • SGLT-2 inhibitors • Other • None • Unknown			Because different oral agents have differential effects on development of HF and outcomes in established HF patients, we recommend data capture separately for each agent.
		Metformin	An agent belonging to the biguanide class of antidiabetics with antihyperglycemic activity	NCI Thesaurus Code: C61612[25]	
		Sulfonylurea	Sulfonamide urea derivatives with antihyperglycemic activity that induce secretion of insulin to increase glucose uptake from the blood	NCI Thesaurus Code: C97936[25]	
		Thiazolidinediones	Insulin-sensitizing agents that overcome insulin resistance by activation of the PPAR-gamma	UMLS CUI C1257987	
		GLP-1 agonists	Chemical agents that stimulate insulin release and inhibit glucagon release		
		DPP-4 inhibitors	Chemical agents that prevent inactivation of GLP-1 levels and stimulate insulin release		
		SGLT-2 inhibitors	Chemical agents that reduce renal glucose reabsorption, thereby increasing urinary glucose		
		Other			
		None	No oral agent for diabetes treatment		
		Unknown	Unknown oral agent for diabetes treatment		
Prediabetes	Patient has glucose levels that do not meet the criteria for diabetes but are too high to be considered normal. Patients with prediabetes are defined by the presence of impaired fasting glucose and/or impaired glucose tolerance and/or HbA1c 5.7%–6.4% (39–47 mmol/mol).	• Yes • No • Unknown		American Diabetes Association. Standards of medical care in diabetes–2020. Diabetes Care. 2019;43:S1-212.[29]	

(*Continued*)

Appendix 4. Continued

A. Heart Failure Risk Factors (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Hypertension	Pathological increase in blood pressure	• Yes • No • Unknown		Whelton PK, Carey RM, Aronow WS, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation. 2018;138:e484–594.[30]	
		Yes	Blood pressure is categorized as: • Elevated (120–129/<80 mm Hg) • Hypertension stage 1 (130–139 or 80–89 mm Hg), or • Hypertension stage 2 (≥140 or ≥90 mm Hg)		
		No	Blood pressure is categorized as: Normal (<120/<80 mm Hg)		
		Unknown			
Hypertension controlled by medication	Use of antihypertensive medications for the indication of treating high blood pressure	• Yes • No • Unknown			
Antihypertensive medications	Oral medications taken for hypertension	• Thiazide or thiazide-type diuretic agents • ACE inhibitor • ARB • CCB, dihydropyridine • CCB, nondihydropyridine • Secondary agent(s) • No • Unknown		Whelton PK, Carey RM, Aronow WS, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation. 2018;138:e484–594.[30]	
		Thiazide or thiazide-type diuretic agents	Thiazide and thiazide-type diuretic agents include chlorthalidone, hydrochlorothiazide, indapamide, and metolazone.		
		ACE inhibitor	ACE inhibitors include benazepril, captopril, enalapril, fosinopril, lisinopril, moexipril, perindopril, quinapril, ramipril, and trandolapril.		
		ARB	ARBs include azilsartan, candesartan, eprosartan, irbesartan, losartan, olmesartan, telmisartan, and valsartan.		

(*Continued*)

Appendix 4. Continued

A. Heart Failure Risk Factors (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		CCB, dihydropyridine	Dihydropyridine CCBs include amlodipine, felodipine, isradipine, nicardipine, nifedipine, and nisoldipine.		
		CCB, nondihydropyridine	Nondihydropyridine CCBs include diltiazem and verapamil.		
		Secondary agent(s)	Secondary agents include loop and potassium-sparing diuretics, aldosterone antagonists, beta blockers, direct renin inhibitors, alpha-1 blockers, central alpha-2 antagonist and other centrally acting drugs, and direct vasodilators.		
		No			
		Unknown	A proper value is applicable but not known.		
White coat hypertension	Patient has white coat hypertension, which is characterized by elevated office blood pressure but normal readings when measured outside the office with either ambulatory blood pressure monitoring or home blood pressure monitoring.	• Yes • No • Unknown		Whelton PK, Carey RM, Aronow WS, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation. 2018;138:e484–594.[30]	The white coat effect is usually considered clinically significant when office systolic and diastolic blood pressures are >20/10 mm Hg higher than home blood pressure monitoring or ambulatory blood pressure monitoring systolic and diastolic blood pressures.
Dyslipidemia	History of dyslipidemia, most commonly hyperlipidemia, that was diagnosed and/or treated by a healthcare provider. Criteria include documentation of the following: • Total cholesterol >200 mg/dL (5.18 mmol/L); or • LDL ≥130 mg/dL (3.37 mmol/L); or • HDL <40 mg/dL (1.04 mmol/L) in men and <50 mg/dL (1.30 mmol/L) in women; or • Lipoprotein a >50 mg/dL (125 nmol/L), or persistent elevations of triglycerides ≥175 mg/dL (≥1.97 mmol/L)	• Yes • No • Unknown		NCI Thesaurus Code: C80385[25] Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA guideline on the management of blood cholesterol: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation. 2019;139:e1082-143.[31]	
Dyslipidemia currently receiving treatment	Currently receiving antilipidemic treatment for treatment of hyperlipidemia or dyslipidemia	• Yes • No • Unknown			

(*Continued*)

Appendix 4. Continued

A. Heart Failure Risk Factors (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Metabolic syndrome	Presence of at least 3 of the following: • Increased waist circumference (by ethnically appropriate cutpoints) • Elevated triglycerides (>150 mg/dL, nonfasting) or drug treatment for elevated triglycerides • Elevated blood pressure, or antihypertensive drug treatment in a patient with a history of hypertension • Elevated glucose (fasting glucose ≥100 mg/dL), or drug treatment for elevated glucose • Low HDL cholesterol (<40 mg/dL in men; <50 mg/dL in women), or drug treatment for low HDL cholesterol	• Yes • No • Unknown		Arnett DK, Blumenthal RS, Albert MA, et al. 2019 ACC/AHA guideline on the primary prevention of cardiovascular disease: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation. 2019;140:e596-646.[32] Alberti KG, Eckel RH, Grundy SM, et al. Harmonizing the metabolic syndrome: a joint interim statement of the International Diabetes Federation Task Force on Epidemiology and Prevention; National Heart, Lung, and Blood Institute; American Heart Association; World Heart Federation; International Atherosclerosis Society; and International Association for the Study of Obesity. Circulation. 2009;120:1640-5.[33]	
Tobacco use	Current or previous use of any combustible tobacco product (eg, cigarettes, cigars, and pipes) or heated tobacco product captured as smoking status	• Current everyday user • Current some day user • Current user, frequency unknown • Former user • Never user • User, current status unknown • Unknown		Barua RS, Rigotti NA, Benowitz NL, et al. 2018 ACC expert consensus decision pathway on tobacco cessation treatment: a report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents. J Am Coll Cardiol. 2018;72:3332-65.[34] NCDR CathPCI Registry Coder's Data Dictionary v5.0 (element #4625)[35]	
		Current everyday user	As defined in the NHIS, a person who reports currently smoking tobacco every day and has smoked at least 100 cigarettes (5 packs) in his or her lifetime.[36]		The only permissible value definition, as shown, currently available is for cigarette smoking. There are no current definitions for cigar, pipe, or heated tobacco product use.
		Current some day user	As defined in the NHIS, a person who reports currently smoking tobacco on some days (nondaily smoker) and has smoked at least 100 cigarettes (5 packs) in his or her lifetime.[36]		
		Current user, frequency unknown	The patient smokes tobacco, but the frequency is unknown.		

(*Continued*)

Appendix 4. Continued

A. Heart Failure Risk Factors (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Former user	As defined in the NHIS, a person who does not currently smoke tobacco but has smoked at least 100 cigarettes in his or her lifetime. Because relapse to smoking occurs frequently after quitting, long-term abstinence is often operationally defined as 6 mo of abstinence. Abstinence from smoking for at least 7 d in a row is the criterion often required in clinical studies for an individual to be considered a former smoker in the short term.		
		Never user	A person who has not smoked tobacco regularly and does not now smoke every day or some days. NHIS defines never smoker as an individual who has not smoked 100 cigarettes (5 packs) in his or her lifetime.[35]		
		User, current status unknown	The patient smokes tobacco, but the frequency is unknown.		
		Unknown	A proper value is applicable but not known.		
Tobacco type	The type of tobacco product the patient uses	• Cigarettes • Cigars • Pipe • Heated tobacco products • Other smokeless tobacco products		NCDR CathPCI Registry Coder's Data Dictionary v5.0 (element #4626)[35] Barua RS, Rigotti NA, Benowitz NL, et al. 2018 ACC expert consensus decision pathway on tobacco cessation treatment: a report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents. J Am Coll Cardiol. 2018;72:3332-65.[34]	
		Cigarettes			
		Cigars			
		Pipe			
		Heated tobacco products	A category of tobacco products that heats tobacco to a lower temperature than required for combustion. The result is an aerosol (but not smoke) that the user inhales.		
		Other smokeless tobacco products	Includes chewing tobacco and oral snuff		
Quantity of cigarettes smoked	Quantification of lifetime tobacco exposure defined as number of cigarettes smoked/day (pack-years)	• Numerical, pack-years		NCI Thesaurus Code: C73993[25]	One pack-year is defined as smoking 20 cigarettes/d for 1 y.
Former smoker abstinence period	Period of abstinence of former smoker	• Between 7 d and 6 mo • ≥6 mo			

(*Continued*)

Appendix 4. Continued

A. Heart Failure Risk Factors (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Exposure to second-hand smoke	The IOM defines second-hand smoke as a complex mixture that is made up of gases and particles and includes smoke from burning cigarettes, cigars, and pipe tobacco (sidestream smoke) and exhaled mainstream smoke. This includes aged smoke that lingers after smoking ceases.	• Current ongoing exposure • Recent past exposure (<1 y) • Remote past exposure (>1 y)		Institute of Medicine Committee on Second-hand Smoke Exposure and Acute Coronary Events. Secondhand Smoke Exposure and Cardiovascular Effects: Making Sense of the Evidence. Washington, DC: National Academies Press (US); 2010.[37]	
Use of electronic nicotine delivery system	Use of electronic cigarettes (e-cigarettes), which are battery-operated devices that heat a liquid containing nicotine, propylene glycol, and/or vegetable glycerin and flavorants to generate an aerosol that the user inhales (ie, vaping), or heat-not-burn tobacco products, which are tobacco products that heat tobacco to a lower temperature than required for combustion	• Yes • No • Unknown		Barua RS, Rigotti NA, Benowitz NL, et al. 2018 ACC expert consensus decision pathway on tobacco cessation treatment: a report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents. J Am Coll Cardiol. 2018;72:3332-65.[34]	Electronic nicotine delivery systems generate an aerosol (but not smoke) that the user inhales. Users' exposure to nicotine and other chemicals in the aerosol depends on factors such as the type of device, the components of the e-liquid, and on how the devices are used.
Alcohol consumption	Consumption of liquids containing ethanol	• None • ≤1 alcoholic drinks/wk • 2–7 alcoholic drinks/wk • ≥8 alcoholic drinks/wk • Unknown		NCI Thesaurus Code: C16273[25] Centers for Disease Control and Prevention Fact Sheets - Alcohol use and your health. Available at: https://www.cdc.gov/alcohol/fact-sheets/alcohol-use.htm. Accessed October 26, 2020.[38]	A standard drink is equal to 14.0 g (0.6 oz) of pure alcohol. Generally, this amount of pure alcohol is found in • 12 oz of beer (5% alcohol content) • 8 oz of malt liquor (7% alcohol content) • 5 oz of wine (12% alcohol content) • 1.5 oz or a "shot" of 80-proof (40% alcohol content) distilled spirits or liquor (eg, gin, rum, vodka, whiskey)[38]
Alcohol dependency	Chronic disease in which a person craves drinks that contain alcohol and is unable to control his or her drinking	• Yes • No • Unknown		NCI Thesaurus Code: C93040[25]	
Treatment for alcohol dependency	Documented treatment for alcohol dependency	• Yes • No • Unknown			

(*Continued*)

Appendix 4. Continued

A. Heart Failure Risk Factors (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Medical sequelae of alcohol consumption	Pathological condition resulting from alcohol consumption	• Alcoholic cardiomyopathy • Alcoholic hepatitis • Alcoholic cirrhosis • Alcohol neuropathy • Wernicke–Korsakoff syndrome • No • Unknown			
		Alcoholic cardiomyopathy	A dilated cardiomyopathy that is associated with consumption of large amounts of alcohol over a period of years	NCI Thesaurus Code: C53653[25]	
		Alcoholic hepatitis	Acute or chronic degenerative and inflammatory lesion of the liver due to alcohol abuse. Depending on its severity, the inflammatory lesion may be reversible or potentially progress to liver cirrhosis.	NCI Thesaurus Code: C34684[25]	
		Alcoholic cirrhosis	A disorder of the liver characterized by the presence of fibrotic scar tissue instead of healthy liver tissue. This condition is attributed to excessive consumption of alcoholic beverages.	NCI Thesaurus Code: C34782[25]	
		Alcohol neuropathy	Damage to the nerves that results from excessive drinking of alcohol		
		Wernicke–Korsakoff syndrome	A syndrome caused by thiamine deficiency. It usually occurs in alcoholics and is characterized by confusion, ataxia, and ophthalmoplegia.	NCI Thesaurus Code: C35764[25]	
Illicit drug use	Documented history of current, recent, or remote use of any illicit drug (eg, cocaine, methamphetamine, heroin) or controlled substance, or misuse of prescription drugs	• Current user • Recent user (within 1 y but not current) • Former user (>1 y) • No • Unknown			Because laws regarding marijuana vary by state, marijuana use is excluded from consideration for this data element and listed separately.
Cannabis use	History of cannabis use	• Prescribed use • Nonprescribed use • No • Unknown			
Cannabis product used	The type of cannabis product the patient has used	• Ingested • Inhaled (smoked or vaporized) • Other			

(*Continued*)

Appendix 4. Continued

A. Heart Failure Risk Factors (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Frequency of cannabis use	Frequency of the patient's cannabis use in the past 3 mo	• Daily/almost daily • Weekly • Monthly • Once or twice • Never		World Health Organization. The Alcohol, Smoking and Substance Involvement Screening Test (ASSIST): Manual for Use in Primary Care. Available at: https://www.who.int/management-of-substance-use/assist/. Accessed October 26, 2020.[39]	
		Daily/almost daily	5–7 d/wk		
		Weekly	1–4 times/wk		
		Monthly	Average of 1–3 times/mo over the past 3 mo		
		Once or twice	1–2 times in the past 3 mo		
		Never	Not used in the past 3 mo		
Abuse of over-the-counter or medicinal substances with cardiotoxicity	History of exposure to substances that may be cardiotoxic in excessive amounts, or prolonged use, or with chemical modifications	• Yes • No • Unknown			
Over-the-counter and medicinal substances with potential cardiotoxicity at excessive doses or prolonged use	Over-the-counter and medicinal substances that have been reported to result in cardiotoxicity with excessive and prolonged use or abuse	• Amphetamine/dextroamphetamine • Anabolic steroids • Decongestants • Ephedrine • Ephedra • NSAID • Other (specify)			
		Amphetamine/ dextroamphetamine	Central nervous system stimulants used to treat attention deficit hyperactivity disorder and narcolepsy		
		Anabolic steroids	A synthetic steroid hormone that resembles testosterone in promoting the growth of muscle. Such hormones are used medicinally to treat some forms of weight loss and (illegally) by some athletes and others to enhance physical performance.		
		Decongestants	An agent that relieves congestion of mucous membranes, such as pseudoephedrine, phenylephrine		
		Ephedrine	Ephedrine is a crystalline alkaloid drug obtained from ephedra causing constriction of the blood vessels and widening of the bronchial passages.		
		Ephedra	Ephedra is an herb also known as ma huang, which contains the stimulant ephedrine. It is closely related to compounds found in the drugs pseudoephedrine and phenylpropanolamine. It was promoted for weight loss. The FDA banned supplements with ephedra after the herb was linked to serious cardiovascular side effects.		

(*Continued*)

Appendix 4. Continued

A. Heart Failure Risk Factors (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		NSAID	A pharmacological agent that is not a steroid and has potential anti-inflammatory, analgesic, antipyretic, and antiplatelet activities. Most NSAIDs act by inhibiting the conversion of arachidonic acid to the precursors of prostaglandin and thromboxane by cyclooxygenase enzymes.	NCI Thesaurus Code: C257[25]	
		Other (specify)			
Exposure to cardiotoxic chemotherapy	The use of synthetic or naturally occurring chemicals for the treatment of diseases. Although this term is used to describe any therapy involving the use of chemical-based agents, it is particularly used to refer to the use of chemical-based agents to treat cancer. Chemotherapy may also include agents that enhance immune function or alter hormonal activity.	• Yes • No • Unknown			
Cardiotoxic chemotherapy agents	Synthetic or naturally occurring chemicals for the treatment of diseases	• Anthracycline antibiotics • Trastuzumab (Herceptin) • Natural products • Immune checkpoint inhibitors • Alkylating agents • Tyrosine kinase inhibitors • Other potentially cardiotoxic chemotherapy agents		NCI Thesaurus Code: C15632[25]	
		Anthracycline antibiotics	Includes anthracycline, daunorubicin, doxorubicin, epirubicin, idarubicin	NCI Thesaurus Codes: C1594, C1583, C456, C62028, C562[25]	
		Trastuzumab (Herceptin)	Trastuzumab (Herceptin)	NCI Thesaurus Code: C1647[25]	
		Natural products	Mitoxantrone, Mitomycin C	NCI Thesaurus Codes: C62050, C1820[25]	
		Immune checkpoint inhibitors	Includes ipilimumab, pembrolizumab, and nivolumab		
		Alkylating agents	For example, cyclophosphamide	NCI Thesaurus Code: C405[25]	
		Tyrosine kinase inhibitors	Includes imatinib mesylate, dasatinib, nilotinib, bosutinib		
		Other potentially cardiotoxic chemotherapy agents	Other chemotherapy agents with potential cardiotoxicity, specify name		
Cumulative dose of cardiotoxic chemotherapy agent	Total chemotherapy dose	• Numeric			

(*Continued*)

Appendix 4. Continued

A. Heart Failure Risk Factors (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Chemotherapy dose units		• mg/m^2 • mg/kg • mg/d			
History of thoracic radiation before 20 y of age	Radiation therapy received before 20 y of age	• Yes • No • Unknown			
History of thoracic radiation after 20 y of age	Radiation therapy received ≥20 y of age	• Yes • No • Unknown			
Thoracic radiation location	The location of radiation therapy	• Mediastinal • Chest • Left breast • Right breast • Other potentially cardiotoxic chemotherapy agents			
		Mediastinal	The central region of the thoracic cavity		
		Chest	The anterior side of the thorax from the neck to the abdomen	NCI Thesaurus Code: C25389[25]	
		Left breast	The hemispheric projection, including the mammary gland, located on the anterior portion of the chest, lateral to the midline, on the side of the body to the west when facing north	NCI Thesaurus Code: C47855[25]	
		Right breast	The hemispheric projection, including the mammary gland, located on the anterior portion of the chest, lateral to the midline, on the side of the body to the east when facing north	NCI Thesaurus Code: C47856[25]	
		Other potentially cardiotoxic chemotherapy agents			
Total radiation exposure	Total therapeutic radiation dose	• Numeric			
Radiation units of measure		• Gray (Gy) • Centigray (cGy) • Milligray (mGy) • Millisievert (mSV) • Rad • Millirem (mRem)			
Family history of sudden cardiac death	Family history of sudden cardiac death, defined as natural death due to cardiac causes, heralded by abrupt loss of consciousness in first-degree relatives (parents, siblings, children). The time and mode of death are unexpected even though preexisting heart disease may have been known to be present. Sudden death without obvious cause is considered sudden cardiac death. Age at time of sudden cardiac death and cause, if known, may be specified.	• Yes • No • Unknown		NCI Thesaurus Code: C50911[25]	

(*Continued*)

Appendix 4. Continued

A. Heart Failure Risk Factors (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Family history of premature CAD	History of having any first-degree relatives (parents, siblings, children) who have had any of the following conditions at age <55 y for male relatives or <65 y for female relatives: • AMI • Sudden cardiac death without obvious cause • CABG surgery • PCI	• Yes • No • Unknown		Cannon CP, Brindis RG, Chaitman BR, et al. 2013 ACCF/AHA key data elements and definitions for measuring the clinical management and outcomes of patients with acute coronary syndromes and coronary artery disease: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Acute Coronary Syndromes and Coronary Artery Disease Clinical Data Standards). Circulation. 2013;127:1052-89.[40]	
Family history of muscular dystrophy	Family history of muscular dystrophy. Muscular dystrophy is a group of inherited progressive muscle disorders characterized by muscle weakness and eventual death of the muscle tissues.	• Yes • No • Unknown		NCI Thesaurus Code: C84910[25]	
Family history of conduction system disease	Family history of atrial or ventricular arrhythmias or conduction system disease	• Atrial arrhythmia • Ventricular arrhythmia • Conduction disorder • None • Unknown			
		Atrial arrhythmia	Irregular heartbeat resulting from a pathological process in the cardiac atria		
		Ventricular arrhythmia	Irregular heartbeat resulting from a pathological process in the cardiac ventricles	NCI Thesaurus Code: C26924[25]	
		Conduction disorder	A disorder affecting the conduction system that sends electrical signals in the myocardium	NCI Thesaurus Code: C78245[25]	
		None			
		Unknown			
Family history of cardiomyopathy	Family history of cardiomyopathy in ≥1 first-degree relative	• Dilated cardiomyopathy • HCM • ARVC or ARVD • Restrictive cardiomyopathy • Duchenne or other muscular dystrophy associated with cardiomyopathy • Fabry disease • Other • No • Unknown			

(*Continued*)

Appendix 4. Continued

A. Heart Failure Risk Factors (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Dilated cardiomyopathy	Dilated, poorly contracting left ventricle in absence of coronary artery disease	Bozkurt B, Colvin M, Cook J, et al. Current diagnostic and treatment strategies for specific dilated cardiomyopathies: a scientific statement from the American Heart Association. Circulation. 2016;134:e579-646.[8]	
		HCM	Disorder of the heart characterized by increased and abnormal hypertrophy of the left ventricle that cannot be explained by loading changes of the heart. It can be with or without left ventricular outflow obstruction. HCM is usually a monogenic disorder with primarily autosomal dominant inheritance and is caused by 1 of hundreds of mutations in up to 18 genes that primarily encode components of the sarcomere.		Mutations in *MYH7* and cardiac myosin-binding protein C (*MYBPC3*) are the most common. A mutation is identifiable in 50% to 75% of cases of familial HCM.
		ARVC or ARVD	ARVC or ARVD or arrhythmogenic cardiomyopathy usually caused by genetic defects of desmosomes resulting in nonischemic cardiomyopathy that primarily involves the right ventricle		
		Restrictive cardiomyopathy	Restrictive cardiomyopathy is a rare genetic cardiomyopathy exhibiting restrictive physiology, usually with no or minimal left ventricular dilatation and no or minimal decrement in systolic function.		
		Duchenne or other muscular dystrophy associated with cardiomyopathy	Genetic disorders characterized by progressive muscle degeneration and weakness, usually caused by a gene defect that affects the ability of the body to produce a protein called dystrophin		
		Fabry disease	An X-linked lysosomal storage disorder characterized by deficiency of the enzyme alpha-galactosidase A, which results in the accumulation of glycolipids in the blood vessels and tissues. Signs and symptoms include hypertension, cardiomyopathy, angiokeratomas, neuropathy, hypohidrosis, keratopathy, proteinuria, and renal failure.	NCI Thesaurus Code: C84701[25]	
		Other	Other types of cardiomyopathy		
		No			
		Unknown			

(*Continued*)

Appendix 4. Continued

A. Heart Failure Risk Factors (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Genetic variant for cardiomyopathy	Known disease-causing mutation for cardiomyopathy identified	• Yes • No • Unknown			
Family history of amyloidosis	Family history of known hereditary amyloidosis, often affecting the liver, nerves, heart, and kidneys. Many genetic defects are implicated. For example, hereditary form of transthyretin can be the cause.	• Yes (if yes, specify organ involvement and, if known, mutation type) • No • Unknown			

ACE indicates angiotensin-converting enzyme; AMI, acute myocardial infarction; ARB, angiotensin II receptor blocker; ARVC, arrhythmogenic right ventricular cardiomyopathy; ARVD, arrhythmogenic right ventricular dysplasia; CABG, coronary artery bypass grafting; CCB, calcium channel blocker; CUI, concept unique identifier; DPP-4, dipeptidyl peptidase-4; FDA, US Food and Drug Administration; GLP-1, glucagon-like peptide-1; HbA1c, hemoglobin A1c; HCM, hypertrophic cardiomyopathy; HDL, high-density lipoprotein; HF, heart failure; IOM, Institute of Medicine; LDL, low-density lipoprotein; mm/dd/yyyy, month/day/year; NCI, National Cancer Institute; NHIS, National Health Interview Survey; NSAID, nonsteroidal anti-inflammatory drug; PCI, percutaneous coronary intervention; PPAR-gamma, peroxisome proliferator-activated receptor-gamma; SGLT-2, sodium-glucose cotransporter-2; and UMLS, Unified Medical Language System.

B. Cardiovascular History

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
HF	HF is a complex clinical syndrome that results from any structural or functional impairment of ventricular filling or ejection of blood. The cardinal manifestations of HF are dyspnea and fatigue, which may limit exercise tolerance and cause or lead to fluid retention, which may lead to pulmonary and/or splanchnic congestion and/or peripheral edema. Some patients have exercise intolerance but little evidence of fluid retention, whereas others complain primarily of edema, dyspnea, or fatigue. Because some patients present without signs or symptoms of volume overload, the term HF is preferred over congestive HF. Provider documentation or report of a former diagnosis of HF before a care encounter, or a previous hospital admission with a diagnosis of HF, is considered evidence of HF history.	• Yes • No • Unknown		Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2013;128:e240-327.[24]	There is no single diagnostic test for HF because it is largely a clinical diagnosis based on a careful history and physical examination. A low EF alone, without clinical evidence of HF does not qualify as HF. HF subtypes are specified in Appendix 6.

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Appendix 4. Continued

B. Cardiovascular History (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Typical angina	1) Substernal chest discomfort with a characteristic quality and duration that is 2) provoked by exertion or emotional stress and 3) relieved by rest or nitroglycerin.	• Yes • No • Unknown		Fihn SD, Gardin JM, Abrams J, et al. 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS guideline for the diagnosis and management of patients with stable ischemic heart disease: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, and the American College of Physicians, American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. Circulation. 2012;126:e354-471.[41]	
Atypical angina	Meets 2 of these characteristics: 1) Substernal chest discomfort with a characteristic quality and duration that is 2) provoked by exertion or emotional stress and 3) relieved by rest or nitroglycerin.	• Yes • No • Unknown		Fihn SD, Gardin JM, Abrams J, et al. 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS guideline for the diagnosis and management of patients with stable ischemic heart disease: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, and the American College of Physicians, American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. Circulation. 2012;126:e354-471.[41]	
Anginal equivalent	Symptom such as dyspnea, diaphoresis, nausea, extreme fatigue, ventricular arrhythmias, or pain at a site other than the chest, occurring in a patient at high cardiac risk. Anginal equivalents have the same importance as angina pectoris.	• Yes • No • Unknown		Anderson JL, Adams CD, Antman EM, et al. 2012 ACCF/AHA focused update incorporated into the ACCF/AHA 2007 guidelines for the management of patients with unstable angina/non–ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2013;127:e663-828.[42]	Anginal equivalents are considered symptoms of myocardial ischemia. For high cardiac risk determination, please refer to 2013 ACC/AHA Guideline on the Assessment of Cardiovascular Risk. ACC/AHA ASCVD Risk Calculator http://www.cvriskcalculator.com/
Angina grade	Grade symptoms or signs in patients with suspected or presumed stable angina (or angina equivalent) according to the Canadian Cardiovascular Society grading scale	• Class 0 • Class I • Class II • Class III • Class IV • Unknown		Campeau L. The Canadian Cardiovascular Society grading of angina pectoris revisited 30 years later. Can J Cardiol. 2002;18:371-9.[43]	Both preprocedure and postprocedure timing Canadian Cardiovascular Society class can be collected.

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Appendix 4. Continued

B. Cardiovascular History (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Class 0	Asymptomatic		
		Class I	Ordinary physical activity, such as walking or climbing stairs, does not cause angina. Angina occurs with strenuous, rapid, or prolonged exertion at work or recreation.		
		Class II	Slight limitation of ordinary activity. Angina occurs on walking or climbing stairs rapidly, walking uphill, walking or climbing stairs after meals, or in cold, in wind, or under emotional stress, or only during the few hours after awakening. Angina occurs on walking >2 blocks on the level and climbing >1 flight of ordinary stairs at a normal pace and in normal conditions.		
		Class III	Marked limitation of ordinary physical activity. Angina occurs on walking 1 to 2 blocks on the level and climbing 1 flight of stairs in normal conditions and at a normal pace.		
		Class IV	Inability to perform any physical activity without discomfort; angina symptoms may be present at rest.		
		Unknown	A proper value is applicable but not known.		
Previous myocardial infarction	Any MI occurrence between birth and arrival at this facility, excludes AMI	• Yes • No • Uncertain			Presence of any 1 of the following criteria that meets the diagnosis of previous MI: • Pathological Q waves with or without symptoms in the absence of nonischemic causes. • Imaging evidence of a region of loss of myocardium that is thinned and/or fails to contract, in the absence of nonischemic cause.
Atherosclerotic cardiovascular disease risk	10-y risk of ASCVD for primary prevention patients (those without ASCVD)	• Numeric, %		American College of Cardiology. ASCVD Risk Estimator Plus. Available at: http://tools.acc.org/ASCVD-Risk-Estimator-Plus/#!/calculate/estimate/. Accessed October 26, 2020.[44]	

(*Continued*)

Appendix 4. Continued

B. Cardiovascular History (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
AMI	The term AMI should be used when there is acute myocardial injury with clinical evidence of acute myocardial ischemia and with detection of a rise and/or fall of cTn values with at least 1 value above the 99th percentile URL and at least 1 of the following: • Symptoms of myocardial ischemia; • New ischemic changes on the ECG; • Development of pathological Q waves; • Imaging evidence of new loss of myocardium or new regional wall motion abnormality in a pattern consistent with an ischemic cause; • Identification of a coronary thrombus by angiography or autopsy (not for type 2 or 3 MIs).	• Type 1: Spontaneous • Type 2: Ischemic imbalance • Type 3: Death, no biomarkers • Type 4a: PCI-related • Type 4b: Stent thrombosis • Type 4c: PCI restenosis • Type 5: CABG-related • Unknown		Thygesen K, Alpert JS, Jaffe AS, et al. Fourth universal definition of myocardial infarction (2018). Circulation. 2018;138:e618-51.[45]	
		Type 1: Spontaneous	Spontaneous clinical syndrome related to atherosclerotic plaque rupture, ulceration, fissuring, erosion, or dissection, with resulting intraluminal thrombus and leading to decreased myocardial blood flow or distal platelet emboli with ensuing myocyte necrosis. This classification requires a detection of a rise and/or fall of cardiac biomarker values (preferably cTn) with at least 1 value >99th percentile of the URL and at least 1 of the following: • Symptoms of myocardial ischemia • New or presumed new significant ST-segment T wave changes or new LBBB on the ECG • Development of pathological Q waves on the ECG • Imaging evidence of new loss of myocardium or new regional wall motion abnormality • Identification of an intracoronary thrombus by angiography or autopsy.		cTn—I or T—is the preferred biomarker. If a cTn assay is unavailable, the best alternative is CK-MB. ≥1 Coronary artery may be involved. Note: This definition does not require a severe underlying coronary stenosis. Typically, some degree of CAD is found by angiography, but less frequently there may be nonobstructive or no coronary artery disease. The term myocardial infarction with nonobstructed coronary arteries (MINOCA) is often used to describe this clinical finding. In some patients, acute myocarditis may also present with acute myocardial injury and/or ST-segment changes.[45]

(*Continued*)

Appendix 4. Continued

B. Cardiovascular History (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Type 2: Ischemic imbalance	Spontaneous clinical syndrome where a condition other than coronary artery disease contributes to an imbalance between myocardial oxygen supply and/or demand (eg, coronary endothelial dysfunction, coronary artery spasm, coronary embolism, tachy-/bradyarrhythmias, anemia, respiratory failure, hypotension, and hypertension with or without LVH). This classification requires a) detection of a rise and/or fall of cardiac biomarker values (preferably cTn) with at least 1 value >99th percentile of the URL, and b) at least 1 of the following: • Symptoms of myocardial ischemia • New or presumed new significant ST-segment T wave changes or new LBBB on the ECG • Development of pathological Q waves on the ECG • Imaging evidence of new loss of myocardium or new regional wall motion abnormality.		cTn—I or T—is the preferred biomarker. If a cTn assay is unavailable, the best alternative is CK-MB.
		Type 3: Death, no biomarkers	Death where symptoms suggestive of myocardial ischemia are present, and with (presumed) new ischemic changes or new LBBB on the ECG, but where death occurs before cardiac biomarkers can be obtained, or before cardiac biomarker values could rise		
		Type 4a: PCI-related	MI associated with and occurring within 48 h of PCI, with elevation of cardiac biomarker values to >5× 99th percentile of the URL in patients with normal baseline values (≤99th percentile URL), or a rise of cardiac biomarker values ≥20% if the baseline values are elevated and are stable or falling. This classification also requires at least 1 of the following: • Symptoms of myocardial ischemia • New ischemic changes on the ECG or new LBBB • Angiographic loss of patency of a major coronary artery or a side branch or persistent slow- or no-flow or embolization • Imaging evidence of new loss of myocardium or new regional wall motion abnormality.		
		Type 4b: Stent thrombosis	MI associated with stent thrombosis as detected by coronary angiography or at autopsy, where symptoms suggestive of myocardial ischemia are present, and with a rise and/or fall of cardiac biomarkers values, with at least 1 value >99th percentile of the URL		cTn—I or T—is the preferred biomarker. If a cTn assay is unavailable, the best alternative is CK-MB.

(*Continued*)

Appendix 4. Continued

B. Cardiovascular History (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Type 4c: PCI restenosis	Spontaneous clinical syndrome occurring >48 h after PCI, with elevation of cardiac biomarker values to >99th percentile of the URL in patients with normal baseline values (≤99th percentile URL), or a rise of cardiac biomarker values ≥20% if the baseline values are elevated and are stable or falling. This classification also requires the following: • Does not meet criteria for any other classification of MI • Presence of a ≥50% stenosis at the site of previous successful stent or balloon PCI (<50% result).		cTn—I or T—is the preferred biomarker. If a cTn assay is unavailable, the best alternative is CK-MB.
		Type 5: CABG-related	MI associated with and occurring within 48 h of CABG surgery, with elevation of cardiac biomarker values to >10 × 99th percentile of the URL in patients with normal baseline cardiac biomarker values (≤99th percentile URL). This classification also requires at least 1 of the following: • New pathologic Q waves or new LBBB on the ECG • Angiographic new graft or new native coronary artery occlusion • Imaging evidence of new loss of myocardium or new regional wall motion abnormality.		cTn—I or T—is the preferred biomarker. If a cTn assay is unavailable, the best alternative is CK-MB.
		Unknown	A proper value is applicable but not known.		
Diagnostic coronary angiography (history of previous)	The passage of a catheter into the aortic root or other great vessels for angiography of the native coronary arteries or bypass grafts supplying native coronary arteries. This element would NOT include noninvasive CT angiography.	• Yes • No • Unknown			
Previous PCI	Previous PCI (even if unsuccessful) of any type (balloon angioplasty, stent, or other) performed before the current admission	*(Multi-select)* • None • Balloon angioplasty • Atherectomy or other plaque-modifying device • Bare-metal stent • Drug-eluting stent • Drug-eluting stent with bioabsorbable polymer • Bioresorbable stent • Covered stent • Other • Unknown			Timeframe does NOT include current admission.
		None	.		

(*Continued*)

Appendix 4. Continued

B. Cardiovascular History (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Balloon angioplasty	PCI performed only by the use of a balloon		
		Atherectomy or other plaque-modifying device	PCI performed with the adjunctive or stand-alone use of any atherectomy device (rotational, orbital, directional, laser, or cutting balloon)		
		Bare-metal stent	Coronary stent without eluting drugs		
		Drug-eluting stent	Coronary stent placed into narrowed, diseased coronary arteries that slowly releases a drug to prevent cell proliferation, thereby preventing fibrosis, that together with clots, could block the stented artery (restenosis)		
		Drug-eluting stent with bioabsorbable polymer	Metallic coronary stent with a bioabsorbable polymer with an antiproliferative drug coating		
		Bioresorbable stent	A coronary stent placed into narrowed or diseased coronary arteries that is manufactured from a material that may dissolve or be absorbed by the body		
		Covered stent	Metallic coronary stent scaffold incorporating fabric or graft material, such as polytetrafluoroethylene or polyurethane as a membrane component		
		Other			
		Unknown	A proper value is applicable but not known.		
Previous CABG surgery	CABG surgery before the current admission	• Yes • No • Unknown			Timeframe does NOT include current admission.
Number and location of previous CABG surgeries	Number and location of previous CABG surgeries, if applicable	• Number • Location (specify) • Not applicable • Unknown			
		Number	Number of distal sites receiving a bypass graft		
		Location (specify)	The specific vessels receiving bypass grafts		
		Not applicable			
		Unknown	A proper value is applicable but not known.		
Date of previous CABG	The date of the most recent CABG done on patient	• Date, in mm/dd/yyyy • Unknown			

(*Continued*)

Appendix 4. Continued

B. Cardiovascular History (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
CAD	CAD is present as documented by invasive coronary angiography at any time before the current admission. Additional acceptable evidence documenting the presence of CAD includes: 1) presence of a previous MI with Q-waves and/or fixed perfusion defect, 2) history of previous revascularization procedure (either PCI or CABG), and 3) coronary CT angiography showing obstructive coronary stenoses and other noninvasive imaging studies showing findings diagnostic of CAD.	• Yes • No • Unknown		Hillis LD, Smith PK, Anderson JL, et al. 2011 ACCF/AHA guideline for coronary artery bypass graft surgery: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2011;124:e652-735.[46] Levine GN, Bates ER, Blankenship JC, et al. 2011 ACCF/AHA/SCAI guideline for percutaneous coronary intervention: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. Circulation. 2011;124:e574-651.[47]	
		Yes	Significant stenosis defined as: • ≥50% for left main • ≥70% stenosis for other vessels • Physiological criteria of significant stenosis defined by a fractional flow reserve of <0.80		
		No			
		Unknown	A proper value is applicable but not known.		
Cerebral artery disease	A disorder resulting from inadequate blood flow in the arteries that supply to the brain	Diagnostic criteria may include: • Ischemic stroke • TIA • Noninvasive or invasive arterial imaging test • Previous cervical or cerebral artery revascularization surgery or percutaneous intervention • None • Unknown		Cannon CP, Brindis RG, Chaitman BR, et al. 2013 ACCF/AHA key data elements and definitions for measuring the clinical management and outcomes of patients with acute coronary syndromes and coronary artery disease: a report of the American College of Cardiology Foundation / American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Acute Coronary Syndromes and Coronary Artery Disease Clinical Data Standards). Circulation. 2013;127:1052-89.[40]	This does not include chronic (nonvascular) neurological diseases or other acute neurological insults such as metabolic and anoxic ischemic encephalopathy.
		Ischemic stroke	An episode of neurological dysfunction caused by focal cerebral, spinal, or retinal infarction. (Note: Evidence of CNS infarction is defined above.) Definition of silent CNS infarction: imaging or neuropathological evidence of CNS infarction, without a history of acute neurological dysfunction attributable to the lesion.	Sacco RL, Kasner SE, Broderick JP, et al. An updated definition of stroke for the 21st century: a statement for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. 2013;44:2064-89.[48] Hicks KA, Mahaffey KW, Mehran R, et al. 2017 Cardiovascular and stroke endpoint definitions for clinical trials. Circulation. 2018;137:961-72.[49]	Hemorrhage may be a consequence of ischemic stroke. In this situation, the stroke is an ischemic stroke with hemorrhagic transformation. The newer definitions as described by Hicks KA et al. have been included wherever possible.

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Appendix 4. Continued

B. Cardiovascular History (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		TIA	Transient episode of neurological dysfunction caused by focal or global brain, spinal cord, or retinal ischemia without acute infarction	Hicks KA, Mahaffey KW, Mehran R, et al. 2017 Cardiovascular and stroke endpoint definitions for clinical trials. Circulation. 2018;137:961-72.[49] Sacco RL, Kasner SE, Broderick JP, et al. An updated definition of stroke for the 21st century: a statement for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. 2013;44:2064-89.[48]	The distinction between a TIA and ischemic stroke is the presence of infarction. The unifying concept driving the definition is that stroke is a marker of potentially disabling vascular brain injury. The duration of ≥24 h has been used as an operational definition of persisting symptoms of stroke rather than TIA, based mostly on consensual practice rather than objective evidence.
		Noninvasive or invasive arterial imaging test	Noninvasive or invasive arterial imaging test demonstrating ≥50% stenosis of any of the major extracranial or intracranial vessels to the brain. Examples include carotid Doppler ultrasound and contrast angiography.	Cannon CP, Brindis RG, Chaitman BR, et al. 2013 ACCF/AHA key data elements and definitions for measuring the clinical management and outcomes of patients with acute coronary syndromes and coronary artery disease: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Acute Coronary Syndromes and Coronary Artery Disease Clinical Data Standards). Circulation. 2013;127:1052-89.[40]	
		Previous cervical or cerebral artery revascularization surgery or percutaneous intervention	History of cervical or cerebral artery revascularization surgery or percutaneous intervention	Cannon CP, Brindis RG, Chaitman BR, et al. 2013 ACCF/AHA key data elements and definitions for measuring the clinical management and outcomes of patients with acute coronary syndromes and coronary artery disease: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Acute Coronary Syndromes and Coronary Artery Disease Clinical Data Standards). Circulation. 2013;127:1052-89.[40]	
		None			
		Unknown	A proper value is applicable but not known.		

(*Continued*)

Appendix 4. Continued

B. Cardiovascular History (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Stroke	An episode of neurological dysfunction caused by focal cerebral, spinal, or retinal infarction. In the absence of pathological, imaging, or other objective evidence of ischemic injury in a defined vascular distribution, clinical evidence of symptoms persisting ≥24 h or until death, with other etiologies excluded.	• Yes • No • Unknown		Hicks KA, Mahaffey KW, Mehran R, et al. 2017 Cardiovascular and stroke endpoint definitions for clinical trials. Circulation. 2018;137:961-72.[49] Sacco RL, Kasner SE, Broderick JP, et al. An updated definition of stroke for the 21st century: a statement for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. 2013;44:2064-89.[48]	
Type of stroke	Categories of stroke	• Ischemic • Hemorrhagic • Undetermined • Unknown		NCDR CathPCI Registry Coder's Data Dictionary Supplement v5.0 (data element #9001)[50] Sacco RL, Kasner SE, Broderick JP, et al. An updated definition of stroke for the 21st century: a statement for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. 2013;44:2064-89.[48]	
		Ischemic	An episode of neurological dysfunction caused by focal cerebral, spinal, or retinal infarction. (Note: Evidence of CNS infarction is defined above.) Definition of silent CNS infarction: imaging or neuropathological evidence of CNS infarction without a history of acute neurological dysfunction attributable to the lesion.	Sacco RL, Kasner SE, Broderick JP, et al. An updated definition of stroke for the 21st century: a statement for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. 2013;44:2064-89.[48]	Hemorrhage may be a consequence of ischemic stroke. In this situation, the stroke is an ischemic stroke with hemorrhagic transformation and not a hemorrhagic stroke. If ischemic stroke, list most likely etiologies: • Large artery atherosclerosis of the extracranial vessels (eg, carotid) • Large artery atherosclerosis of the intracranial vessels (eg, middle cerebral artery stenosis) • Cardioembolism • Small vessel occlusion (lacunar) • Ischemic stroke of other determined cause (eg, arterial dissection) Large artery atherosclerosis of the extracranial vessels (eg, carotid)

(*Continued*)

Appendix 4. Continued

B. Cardiovascular History (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Hemorrhagic	Rapidly developing clinical signs of neurological dysfunction attributable to a focal collection of blood within the brain parenchyma, ventricular system, or bleeding into the subarachnoid space, that is not caused by trauma	Sacco RL, Kasner SE, Broderick JP, et al. An updated definition of stroke for the 21st century: a statement for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. 2013;44:2064-89.[48]	Subdural hematomas are intracranial hemorrhagic events and not strokes.
		Undetermined	An episode of acute neurological dysfunction presumed to be caused by ischemia or hemorrhage, persisting ≥24 h or until death but without sufficient evidence to be classified as one of the above	Sacco RL, Kasner SE, Broderick JP, et al. An updated definition of stroke for the 21st century: a statement for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. 2013;44:2064-89.[48]	
		Unknown	A proper value is applicable but not known.		
Cerebrovascular event timing	Time period between last documented cerebrovascular event (TIA or stroke) and presentation	• Recent • Remote • Unknown		STS Risk Calculator[51]	
		Recent	≤2 wk		
		Remote	>2 wk		
		Unknown	A proper value is applicable but not known.		
PAD	Diagnosis of PAD, which includes lower extremity from iliac to tibialis and upper extremity with subclavian and brachial vessels but excludes renal (kidney), coronary, cerebral, and mesenteric vessels and aneurysms. The criteria for the diagnosis of PAD include: • Claudication on exertion that is relieved by rest • Positive noninvasive test (eg, ankle-brachial index ≤0.9, ultrasonography, MRI, or CT scanning of >50% diameter stenosis in any peripheral artery [ie, subclavian, femoral, iliac]) or angiographic imaging • Vascular reconstruction, bypass surgery, or percutaneous revascularization in the arteries of the lower and upper extremities • Amputation for severe arterial vascular insufficiency.	• Yes • No • Unknown		Cannon CP, Brindis RG, Chaitman BR, et al. 2013 ACCF/AHA key data elements and definitions for measuring the clinical management and outcomes of patients with acute coronary syndromes and coronary artery disease: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Acute Coronary Syndromes and Coronary Artery Disease Clinical Data Standards). Circulation. 2013;127:1052-89.[40] Creager MA, Belkin M, Bluth EI, et al. 2012 ACCF/AHA/ACR/SCAI/SIR/STS/SVM/SVN/SVS key data elements and definitions for peripheral atherosclerotic vascular disease: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Clinical Data Standards for Peripheral Atherosclerotic Vascular Disease). Circulation. 2012;125:395-467.[52]	

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Appendix 4. Continued

B. Cardiovascular History (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Previous pacemaker implantation (non-ICD)	Non-ICD pacemaker implantation, before the current encounter, usually indicated for abnormality of electrical impulse generation or conduction. An electronic device that is implanted in the body to monitor heart rate and rhythm. It gives the heart electrical stimulation when it does not beat normally.	• Yes • No • Unknown		NCI Thesaurus Code: C94198[25]	Device type (pacemaker, cardiac chamber(s) involved, and year of implantation may be helpful
Previous implantation of an ICD	ICD: a battery-powered electrical impulse generator implanted in patients at risk of sudden cardiac death to detect cardiac arrhythmia and correct it, usually with antitachycardia pacing and then by delivering a jolt of electricity, implanted before the current encounter	• ICD • No • Unknown		Cannon CP, Brindis RG, Chaitman BR, et al. 2013 ACCF/AHA key data elements and definitions for measuring the clinical management and outcomes of patients with acute coronary syndromes and coronary artery disease: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Acute Coronary Syndromes and Coronary Artery Disease Clinical Data Standards). Circulation. 2013;127:1052-89.[40]	Information about the type of device (pacemaker, biventricular/resynchronization/CRT, implantable cardioverter-defibrillator, combination), cardiac chamber(s) involved, and year of implantation may be helpful.
		ICD	Implantable cardioverter-defibrillator: a battery-powered electrical impulse generator implanted in patients at risk of sudden cardiac death to detect cardiac arrhythmia and correct it		
		No	No ICD history		
		Unknown			
ICD shock	The patient received an ICD shock.	• Yes, shock appropriate • Yes, shock inappropriate • Yes, shock appropriateness unknown • No • Unknown			
Previous cardiac resynchronization therapy	Patient has history of implantation of CRT device before the current encounter. A CRT device is a biventricular pacemaker that sends electrical signals to both ventricles that resynchronizes the heart chambers and helps it pump more effectively. It may or may not have an atrial pacing wire.	• CRT or CRT-P • CRT-D • No • Unknown			
		CRT or CRT-P	Cardiac resynchronization therapy (CRT or CRT-P). A CRT device is a biventricular pacemaker that sends electrical signals to both ventricles that resynchronizes the heart chambers and helps it pump more effectively. It may or may not have an atrial pacing wire. CRT-P has the pacing function in addition to resynchronization but does not entail defibrillator function.		

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Appendix 4. Continued

B. Cardiovascular History (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		CRT-D, CRT with ICD	CRT-Ds also incorporate the additional function of an ICD.		
		No			
		Unknown			
Atrial fibrillation	History of atrial fibrillation, which is an abnormal heart rhythm characterized by rapid and irregular beating of the atrial chambers of the heart	• Paroxysmal • Persistent • Permanent • No • Unknown		NCI Thesaurus Code: C80391[25] January CT, Wann LS, Alpert JS, et al. 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. Circulation. 2014;130:e199–267.[53]	
		Paroxysmal	Atrial fibrillation that terminates spontaneously or with intervention within 7 d of onset. Episodes may recur with variable frequency.		
		Persistent	Continuous atrial fibrillation that is sustained >7 d		
		Permanent	The term "permanent atrial fibrillation" is used when the patient and clinician make a joint decision to stop further attempts to restore and/or maintain sinus rhythm.		
		No			
		Unknown			
Atrial flutter	History of atrial flutter, which is a well-organized but overly rapid contraction of the atrium of the heart (usually at a rate of 250–350 contractions/min)	• Paroxysmal • Persistent • Permanent • No • Unknown		NCI Thesaurus Code: C51224[25]	
History of atrial arrhythmias other than atrial fibrillation or flutter	History of any of the following atrial arrhythmias:	• Atrial tachycardia • Sick sinus syndrome • Paroxysmal supraventricular tachycardia			
		Atrial tachycardia	An electrocardiographic finding of a cardiac rhythm >100 bpm that originates from the atria or sinoatrial node	NCI Thesaurus Code: C35481[25]	
		Sick sinus syndrome	A constellation of signs and symptoms which may include syncope, fatigue, dizziness, and alternating periods of bradycardia and atrial tachycardia, which is caused by sinoatrial node and/or AV nodal dysfunction	NCI Thesaurus Code: C62244[25]	
		Paroxysmal supraventricular tachycardia	An electrocardiographic finding of episodic supraventricular tachycardia with abrupt onset and termination	NCI Thesaurus Code: C34901[25]	

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Appendix 4. Continued

B. Cardiovascular History (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
History of ventricular arrhythmias	History of rhythm abnormalities arising from the ventricles	• Frequent PVCs • Nonsustained ventricular tachycardia • Sustained ventricular tachycardia • Ventricular fibrillation			Specify documentation source (eg, Holter, event recorder, ICD, pacemaker).
		Frequent PVCs	Frequent PVCs, defined as >20% of all QRS complexes being PVCs on standard 24-h Holter monitoring		
		Nonsustained ventricular tachycardia	Nonsustained ventricular tachycardia is a type of ventricular tachycardia that stops on its own within 30 s.	NCI Thesaurus Code: C71053[25]	
		Sustained ventricular tachycardia	Sustained ventricular tachycardia is a ventricular rhythm faster than 100 bpm lasting at least 30 s or requiring termination earlier due to hemodynamic instability. Ventricular tachycardia is defined as a wide complex tachycardia (QRS ≥120 ms) that originates from 1 of the ventricles and is not caused by aberrant conduction of supraventricular arrhythmias.	NCI Thesaurus Code: C71052[25]	
		Ventricular fibrillation	An electrocardiographic finding of a rapid grossly irregular ventricular rhythm with marked variability in the QRS cycle length, morphology, and amplitude. The rate is typically >300 bpm.	NCI Thesaurus Code: C50799[25]	
History of arrhythmogenic disease, syndrome, or substrate	History of conditions known to be associated with tachycardia	• ARVC • Brugada syndrome ventricular arrhythmia • Wolff-Parkinson-White syndrome • Sudden unsuspected death syndrome (young Asian males) • AV nodal reentry tachycardia • RV outflow tract ventricular tachycardia • Bundle branch-mediated ventricular tachycardia			

(*Continued*)

Appendix 4. Continued

B. Cardiovascular History (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		ARVC	An inherited cardiomyopathy that predominantly affects the right ventricle but can affect the left ventricle, causing areas of myocardial replacement with fibrosis and adipose tissue that frequently causes ventricular arrhythmia and sudden cardiac death	Al-Khatib SM, Stevenson WG, Ackerman MJ, et al. 2017 AHA/ACC/HRS guideline for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. Circulation. 2018;138:e272-e391.[54]	
		Brugada syndrome ventricular arrhythmia	An electrocardiographic finding of a pattern of right bundle branch block and ST-segment elevation within electrocardiogram leads V1–V3. This pattern emerges as a result of a defect in ion channel genes, resulting in atypical electrophysiological activity in the right ventricle and a propensity for malignant tachyarrhythmias.	NCI Thesaurus Code: C71059[25]	
		Wolff-Parkinson-White syndrome	A congenital electrical function abnormality in the heart. It is characterized by the presence of an accessory conductive pathway between the atria and the ventricles that causes the activation of the ventricles earlier than anticipated. Characteristic electrocardiographic findings are a short PR interval and a wide QRS complex with a delta wave.	NCI Thesaurus Code: C35132[25]	
		Sudden unsuspected death syndrome (young Asian males)	Sudden unexplained death syndrome describes the death of apparently healthy individuals—usually young Southeast Asian men—in whom postmortem examination does not reveal the cause of death. The victims are in apparently good health and usually die at night while sleeping. They die within minutes after the onset of agonal respiration. Patients who have been resuscitated were found to have ventricular fibrillation and inducible polymorphic ventricular tachycardia in the electrophysiological laboratory.	Veerakul G, Nademanee K. What is the sudden death syndrome in Southeast Asian males? Cardiol Rev. 2000;8:90-5.[55]	
		AV nodal reentry tachycardia	An electrocardiographic finding of a supraventricular tachycardia due to reentry along a circuit contained within the AV node	NCI Thesaurus Code: C35058[25]	

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Appendix 4. Continued

B. Cardiovascular History (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		RV outflow tract ventricular tachycardia	An electrocardiographic finding of ventricular tachycardia originating in the right ventricular outflow tract	NCI Thesaurus Code: C71064[25]	
		Bundle branch-mediated ventricular tachycardia	Bundle branch re-entrant ventricular tachycardia: an electrocardiographic finding of ventricular tachycardia incorporating both bundle branches into the reentry circuit	NCI Thesaurus Code: C71062[25]	
Persistent tachycardia	Persistent or chronic tachycardia with heart rate >100 bpm, defined as the one occurring in >10% of cardiac rhythm during 24 h. It may begin at any age, persisting months or years. If the mechanism of arrhythmia is not sinus, tachycardia-induced cardiomyopathy may result.	• Yes • No • Unknown		NCI Thesaurus Code: C38029[25]	
History of rheumatic valvular disease	History of rheumatic fever, an inflammatory disease that can involve the heart, joints, skin, and brain that develops after a streptococcal throat infection, resulting in carditis and valvular disease. It can manifest with pericarditis, heart murmur, congestive HF, polyarthritis, subcutaneous nodules, and erythema marginatum.	• Yes • No • Unknown		NCI Thesaurus Code: C34984[25]	
History of other valvular disease cause	History of valvular disease of other cause (specify):	• Congenital • Degenerative • Functional • Infectious • Toxic • Other (specify)			
		Congenital	Present at birth or occurring association with congenital heart disease syndrome		
		Degenerative	Acquired during adulthood, usually after age 50 y		
		Functional	Valvular regurgitation (usually mitral regurgitation or tricuspid regurgitation) seen with left ventricular dilation, annular dilation (or papillary muscle displacement in the setting of mitral regurgitation) rather than a primary valvular abnormality		
		Infectious	Acquired as a result of infectious endocarditis		
		Toxic	For example: as a result of exposure to fenfluramine phentermine dexfenfluramine		
		Other (specify)			

(*Continued*)

Appendix 4. Continued

B. Cardiovascular History (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
History of congenital cardiac lesions	A malformation of the heart, aorta, or other large blood vessels noted as a birth defect in newborns	• Patent arterial duct (patent ductus arteriosus) • Interatrial communication (atrial septal defect) • Ventricular septal defect • Tetralogy of Fallot • Transposition of the great arteries • Congenitally corrected transposition of great arteries • Functionally univentricular heart (single ventricle defect) • Other			
		Patent arterial duct (patent ductus arteriosus)	A congenital cardiovascular finding in which the arterial duct (ductus arteriosus) is open beyond the normal age of spontaneous closure	IPCCC 09.27.21	
		Interatrial communication (atrial septal defect)	A congenital cardiac malformation in which there is a hole or pathway between the atrial chambers	IPCCC 05.04.01	
		Ventricular septal defect	A congenital cardiac malformation in which there is a hole or pathway between the ventricular chambers	IPCCC 07.10.00	
		Tetralogy of Fallot	A group of congenital cardiac malformations with biventricular AV alignments or connections characterized by anterosuperior deviation of the conal or outlet septum or its fibrous remnant, narrowing or atresia of the pulmonary outflow, a ventricular septal defect of the malalignment type, and biventricular origin of the aorta. Tetralogy of Fallot will always have a ventricular septal defect, narrowing or atresia of the pulmonary outflow, aortic override, and most often RV hypertrophy.	IPCCC 01.01.01	
		Transposition of the great arteries	A congenital cardiovascular malformation in which the morphologically right ventricle connects to the aorta and the morphologically left ventricle connects to the pulmonary trunk	IPCCC 01.05.01	

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Appendix 4. Continued

B. Cardiovascular History (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Congenitally corrected transposition of great arteries	A congenital cardiovascular malformation in which the morphologically right atrium connects to the morphologically left ventricle, the morphologically left atrium connects to the morphologically right ventricle, the morphologically right ventricle connects to the aorta, and the morphologically left ventricle connects to the pulmonary trunk	IPCCC 01.01.03	
		Functionally univentricular heart (single ventricle defect)	The term "functionally univentricular heart" describes a spectrum of congenital cardiac malformations in which the ventricular mass may not readily lend itself to partitioning that commits one ventricular pump to the systemic circulation, and another to the pulmonary circulation.	IPCCC 01.01.22	
		Other			
Repair of congenital cardiac lesion	Procedure was performed to treat a congenital cardiac lesion	• Yes (if yes, specify type of repair) • No • Unknown			
Date of congenital cardiac lesion repair	The date of the congenital cardiac lesion repair	• Date, in mm/dd/yyyy • Unknown			

AMI indicates acute myocardial infarction; ASCVD, atherosclerotic cardiovascular disease; AV, atrioventricular; bpm, beats per minute; CABG, coronary artery bypass grafting; CAD, coronary artery disease; CK-MB, creatine kinase MB; CNS, central nervous system; CRT, cardiac resynchronization therapy; CRT-D, cardiac resynchronization therapy defibrillator; CRT-P, cardiac resynchronization therapy pacemaker; CT, computed tomography; cTn, cardiac troponin; ECG, echocardiography; EF, ejection fraction; HF, heart failure; ICD, implantable cardioverter-defibrillator; IPCCC, International Paediatric and Congenital Cardiac Code; LBBB, left bundle branch block; left ventricular hypertrophy; MI, myocardial infarction; mm/dd/yyyy, month/day/year; MRI, magnetic resonance imaging; NCI, National Cancer Institute; PAD, peripheral artery disease; PCI, percutaneous coronary intervention; PVC, premature ventricular contraction; RV, right ventricular; STS, Society of Thoracic Surgeons; TIA, transient ischemic attack; and URL, upper reference limit.

C. Noncardiovascular History

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
History of asthma	A respiratory condition marked by spasms in the bronchi of the lungs, causing difficulty in breathing. It usually results from an allergic reaction or other forms of hypersensitivity.	• Yes • No • Unknown			Patients with onset of asthma in adulthood, asthma diagnosis should precede HF diagnosis by ≥5 y or have documented pulmonary function test evidence of reversible bronchospasm.

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Appendix 4. Continued

C. Noncardiovascular History (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
History of chronic lung disease	Chronic obstructive pulmonary disease: a chronic and progressive lung disorder characterized by the loss of elasticity of the bronchial tree and the air sacs, destruction of the air sacs wall, thickening of the bronchial wall, and mucus accumulation in the bronchial tree, resulting in the disruption of the air flow in the bronchial airways. Signs and symptoms include shortness of breath, wheezing, productive cough, and chest tightness. Includes chronic obstructive bronchitis and is usually treated with inhaled or oral pharmacological therapy (eg, beta-adrenergic agonist, anti-inflammatory agent, leukotriene receptor antagonist, or steroid).	• Yes • No • Unknown		NCI Thesaurus Codes: C3199, C26722, C3348[25]	
History of chronic kidney disease	Reduced GFR for ≥3 mo. Degree of kidney disease may be further defined according to degree of depression in GFR. Note: GFR may be estimated using the serum creatinine-GFR = 186 × $(PCr)^{-1.154}$ × $(age)^{-0.203}$ × (0.742 if female) × (1.210 if Black).	• CKD stage 1 • CKD stage 2 • CKD stage 3 • CKD stage 4 • CKD stage 5			
		CKD stage 1	GFR ≥90 mL/min/1.73 m^2 and evidence of proteinuria		
		CKD stage 2	GFR 60–89 mL/min/1.73 m^2		
		CKD stage 3	GFR 30–59 mL/min/1.73 m^2		
		CKD stage 4	GFR 15–29 mL/min/1.73 m^2		
		CKD stage 5	GFR <15 mL/min/1.73 m^2 or patient requires chronic dialysis treatment		
History of acute kidney injury (or acute worsening renal function)	Reduced renal function for <3 mo duration, that can be seen in acute HF. Worsening renal function defined as 1 of the following: • Increase in serum creatinine by ≥0.3 mg/dL. • Decline in estimated GFR by >20%	• Yes • No • Unknown			Year of occurrence of and precipitant for acute kidney injury may be specified.
History of dialysis	Dialysis is the process of removing excess water, solutes, and toxins from the blood in people whose kidneys can no longer perform these functions naturally. This is referred to as renal replacement therapy.	• Hemodialysis • Peritoneal dialysis • No • Unknown			

(*Continued*)

Appendix 4. Continued

C. Noncardiovascular History (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Hemodialysis	A process of renal replacement therapy that clears the blood by diffusion and removes fluid by convection		
		Peritoneal dialysis	Dialysis fluid being introduced into and removed from the peritoneal cavity as either a continuous or an intermittent procedure	NCI Thesaurus Code: C15297[25]	
		No			
		Unknown			
History of dementia	History of dementia, loss of intellectual abilities interfering with an individual's social and occupational functions. Causes include Alzheimer's disease, brain injuries, brain tumors, and cerebrovascular disorders.	• Yes • No • Unknown		NCI Thesaurus Codes: C4786, C4786[25]	
History of depression	History of treated depression, or currently taking antidepressant medication. Note if past or present episode has required or is currently requiring drug treatment or electroconvulsive therapy.	• Yes • No • Unknown		NCI Thesaurus Code: C2982[25]	
History of obstructive sleep apnea	A blockage of the airway, usually when the soft tissue in the back of the throat collapses during sleep	• Yes • No • Unknown		American Heart Association. Get With The Guidelines–Heart Failure. Available at: https://www.heart.org/en/professional/quality-improvement/get-with-the-guidelines/get-with-the-guidelines-heart-failure. Accessed October 26, 2020.[28]	
History of chronic liver disease	Disease of the liver that lasts >6 mo. It consists of a wide range of liver pathologies that include chronic hepatitis and liver cirrhosis.	• Yes • No • Unknown			
		Yes	Presence of chronic liver disease such as chronic hepatitis, an active inflammatory process affecting the liver for >6 mo or cirrhosis, which is a disorder characterized by replacement of the liver parenchyma with fibrous tissue and regenerative nodules, usually caused by alcoholism, hepatitis B, hepatitis C, or nonalcoholic fatty liver disease. Complications include development of ascites, esophageal varices, coagulopathy, and encephalopathy.	NCI Thesaurus Codes: C82978, C2951[25]	
		No			
		Unknown			

(*Continued*)

Appendix 4. Continued

C. Noncardiovascular History (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
History of systemic lupus erythematosus	SLE is an autoimmune disease with autoantibodies targeted against skin, heart, lungs, kidneys, joints, and nervous system resulting in organ damage, arthritis, and skin disorders. SLE is marked by many different symptoms; however, not every patient with SLE has all of the symptoms.	• Yes • No • Unknown		NCI Thesaurus Code: C3201[25]	
History of rheumatoid arthritis	Rheumatoid arthritis is a chronic systemic disease, primarily of the joints, marked by inflammatory changes in the synovial membranes and articular structures, widespread fibrinoid degeneration of the collagen fibers in mesenchymal tissues, and by atrophy and rarefaction of bony structures. Cause is unknown, but autoimmune mechanisms have been implicated.	• Yes • No • Unknown		NCI Thesaurus Code: C2884[25]	
History of scleroderma	Scleroderma is a localized or systemic chronic and progressive autoimmune disorder characterized by thickening of the skin and the connective tissue. Localized scleroderma affects only the skin. Systemic scleroderma also affects internal organs, including the heart, lungs, gastrointestinal tract, and kidneys.	• Yes • No • Unknown		NCI Thesaurus Code: C26746[25]	
History of dermatomyositis	Dermatomyositis is a subacute or chronic inflammatory disease of muscle and skin, marked by proximal muscle weakness and a characteristic skin rash.	• Yes • No • Unknown		NCI Thesaurus Code: C26744[25]	
History of muscular dystrophy	Muscular dystrophy is a group of inherited progressive muscle disorders characterized by muscle weakness and eventual death of the muscle tissues. Some may be associated with cardiomyopathy.	• Yes • No • Unknown		NCI Thesaurus Code: C84910[25]	This condition may lead to advanced HF and heart transplant in appropriately selected patients.
History of sarcoidosis	Sarcoidosis is a disease characterized by development of granulomas most commonly affecting the lungs, lymph nodes, and skin. It can affect the heart, usually manifested by infiltrative cardiomyopathy and arrhythmia.	• Yes • No • Unknown			
History of hemochromatosis	Inherited disorder characterized by abnormally high absorption of iron by the intestinal tract, resulting in excessive storage of iron, particularly in the liver, skin, pancreas, heart, joints, and testes	• Yes • No • Unknown			
History of thyroid disorder	Disorder that affects the thyroid gland	• Hyperthyroidism • Hypothyroidism • None • Unknown			

(*Continued*)

Appendix 4. Continued

C. Noncardiovascular History (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Hyperthyroidism	Overactivity of the thyroid gland resulting in overproduction of thyroid hormone and increased metabolic rate. Causes include diffuse hyperplasia of the thyroid gland (Graves' disease), single nodule in the thyroid gland, and thyroiditis. The symptoms are related to the increased metabolic rate and include weight loss, fatigue, heat intolerance, excessive sweating, diarrhea, tachycardia, insomnia, muscle weakness, and tremor.	NCI Thesaurus Code: C3123[25]	
		Hypothyroidism	A condition in which the production of thyroid hormone by the thyroid gland is diminished. Signs and symptoms of hypothyroidism include low metabolic rate, tendency to weight gain, somnolence, and sometimes myxedema.	NCI Thesaurus Code: C26800[25]	
		None			
		Unknown			
History of amyloidosis	A disorder in which abnormal proteins, known as amyloid fibrils, build up in tissues and organs	• AL amyloidosis • ATTR • Other types of amyloidosis • No • Unknown			
		AL amyloidosis	AL amyloidosis (immunoglobulin light chain amyloidosis), previously known as primary amyloidosis, occurs with increased production of light chain portions of antibodies by plasma cells in the bone marrow, which come together to form amyloid deposits. Can be seen with multiple myeloma or Waldenström's macroglobulinemia.		
		ATTR	ATTR amyloidosis is a form of systemic amyloidosis caused by amyloid deposits made up of a protein called TTR. ATTR amyloidosis can be either hereditary or acquired (nonhereditary).		
		Other types of amyloidosis	Amyloidosis other than AL or ATTR amyloidosis, such as AA amyloidosis (previously known as secondary amyloidosis), is a condition that is the result of another chronic infectious or inflammatory disease such as rheumatoid arthritis, Crohn's disease, or ulcerative colitis, which results from deposition of amyloid type A protein in organs, or hemodialysis-associated amyloidosis, or organ-specific amyloidosis such as familial visceral amyloidosis, familial corneal amyloidosis.		
		No			
		Unknown			

(*Continued*)

Appendix 4. Continued

C. Noncardiovascular History (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
History of ATTR amyloidosis	ATTR amyloidosis is a form of systemic amyloidosis caused by amyloid deposits made up of a protein called TTR. ATTR amyloidosis can be either hereditary or acquired (nonhereditary).	• Hereditary ATTR amyloidosis • Acquired (nonhereditary) or wild-type ATTR amyloidosis • No • Unknown			
		Hereditary ATTR amyloidosis	Hereditary ATTR amyloidosis is caused by a mutation in *TTR*, which is heritable, resulting in abnormal, amyloidogenic, "variant" TTR. It can manifest as familial amyloid polyneuropathy when disease mainly affects the nerves or familial amyloid cardiomyopathy when disease mainly affects the heart.		
		Acquired (nonhereditary) or wild-type ATTR amyloidosis	In acquired (nonhereditary), wild-type ATTR amyloidosis, normal, "wild-type" TTR protein misfolds to form the amyloid deposits, usually due to aging. Formerly known as senile amyloidosis.		
		No			
		Unknown			
History of HIV	Infection and seropositivity status with HIV, a retrovirus that causes AIDS	• HIV seropositive • AIDS • HIV negative • Unknown			HIV can be associated with cardiomyopathy and pulmonary arterial hypertension.
		HIV seropositive	Development of neutralizing antibodies in individuals who have been exposed to HIV	NCI Thesaurus Code: C15175[25]	
		AIDS	A syndrome resulting from the acquired deficiency of cellular immunity caused by HIV. It is characterized by the reduction of the helper T-lymphocytes in the peripheral blood and the lymph nodes. Symptoms include generalized lymphadenopathy, fever, weight loss, and chronic diarrhea. Patients with AIDS are especially susceptible to opportunistic infections and the development of malignant neoplasms.	NCI Thesaurus Code: C2851[25]	
		HIV negative			
		Unknown			
Acute COVID-19 infection	COVID-19 is an infectious disease caused by SARS-CoV-2	• Confirmed COVID-19 infection • Suspected COVID-19 infection • Asymptomatic COVID-19 infection • No • Unknown			

(*Continued*)

Appendix 4. Continued

C. Noncardiovascular History (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Confirmed COVID-19 infection	Confirmed diagnosis of COVID-19 as documented by the provider, with a clinical presentation supportive of the COVID-19 infection or documentation of a positive COVID-19 test result, or a presumptive positive COVID-19 test result	World Health Organization. COVID-19 coding in ICD-10. Available at: https://www.who.int/classifications/icd/COVID-19-coding-icd10.pdf?ua=1. Accessed October 26, 2020.[56]	COVID-19 testing is usually done by RT-PCR testing. The role of convalescent antibodies is evolving and needs further validation for specificity and sensitivity for COVID-19 infection.
		Suspected COVID-19 infection	If the provider documents "suspected," "possible," "probable," or "inconclusive" COVID-19 infection but not confirmed by a COVID-19 test	World Health Organization. COVID-19 coding in ICD-10. Available at: https://www.who.int/classifications/icd/COVID-19-coding-icd10.pdf?ua=1. Accessed October 26, 2020.[56]	
		Asymptomatic COVID-19 infection	Incidental diagnosis of COVID-19 in an asymptomatic patient with the finding of a positive COVID-19 test during screening	World Health Organization. COVID-19 coding in ICD-10. Available at: https://www.who.int/classifications/icd/COVID-19-coding-icd10.pdf?ua=1. Accessed October 26, 2020.[56]	COVID-19 testing is usually done by RT-PCR testing. The role of convalescent antibodies is evolving and needs further validation for specificity and sensitivity for COVID-19 infection.
		No			
		Unknown			
Exposure to COVID-19	Exposure to someone who is confirmed or suspected to have COVID-19, and the exposed individual either tests negative or the test results are unknown	• Yes • No • Unknown		World Health Organization. COVID-19 coding in ICD-10. Available at: https://www.who.int/classifications/icd/COVID-19-coding-icd10.pdf?ua=1. Accessed October 26, 2020.[56]	
Previous COVID-19 infection	Patient had COVID-19 infection >14 d ago and has recovered.	• Yes • No • Unknown			Patients usually would have tested positive by RT-PCR during the acute infection, and if repeat testing obtained, recovery is usually defined after 2 negative RT-PCR tests. The role of convalescent antibodies (IgM and IgG) is evolving and needs further validation for specificity and sensitivity for previous COVID-19 infection.
Date of COVID-19 diagnosis	The date the COVID-19 diagnosis occurred	• Date, in mm/dd/yyyy			
Hospitalization due to COVID-19 infection	Hospitalization due to COVID-19 infection	• Yes • No • Unknown			
Date of COVID-19 hospitalization	The date the COVID-19 hospitalization occurred	• Date, in mm/dd/yyyy			

(*Continued*)

Appendix 4. Continued

C. Noncardiovascular History (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
COVID-19 cardiovascular complications	Common cardiovascular complications related to COVID-19 infection	• Acute myocardial injury due to COVID-19 without cardiomyopathy, without coronary obstruction or acute coronary syndrome • Acute myocardial injury due to COVID-19 with left ventricular cardiomyopathy without acute coronary syndrome or coronary obstruction • Acute myocardial injury due to COVID-19 with RV cardiomyopathy without acute coronary syndrome • Acute myocardial injury with COVID-19 with acute coronary syndrome • Persistent sinus tachycardia with acute COVID-19 infection • Ventricular arrhythmia with acute COVID-19 infection • Atrial tachyarrhythmia with acute COVID-19 infection • Asystole with COVID-19 infection • Pericarditis/pericardial effusion with COVID-19 • DVT with acute COVID-19 infection • Pulmonary embolus with COVID-19 infection • Acute ischemic limb with COVID-19 infection • Sudden cardiac death with COVID-19 infection • Cardiogenic shock with COVID-19 • Stroke with COVID-19 • None • Unknown			

(*Continued*)

Appendix 4. Continued

C. Noncardiovascular History (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Acute myocardial injury due to COVID-19 without cardiomyopathy, without coronary obstruction or acute coronary syndrome	Acute myocardial injury diagnosed with elevation in cardiac troponin and/or with cardiac imaging such as cardiac MRI, without any evidence of decline in LVEF, with no evidence of obstructive coronary artery disease or without clinical or electrocardiographic evidence of acute coronary syndrome presentation during acute COVID-19 infection	Hendren NS, Drazner MH, Bozkurt B, et al. Description and proposed management of the acute COVID-19 cardiovascular syndrome. Circulation. 2020;141:1903-14.[57]	
		Acute myocardial injury due to COVID-19 with left ventricular cardiomyopathy without acute coronary syndrome or coronary obstruction	Acute myocardial injury diagnosed with elevation in cardiac troponin and/or with cardiac imaging such as cardiac MRI, with evidence of a decline in LVEF, with no evidence of obstructive coronary artery disease or without clinical or electrocardiographic evidence of acute coronary syndrome presentation during acute COVID-19 infection	Hendren NS, Drazner MH, Bozkurt B, et al. Description and proposed management of the acute COVID-19 cardiovascular syndrome. Circulation. 2020;141:1903-14.[57]	
		Acute myocardial injury due to COVID-19 with RV cardiomyopathy without acute coronary syndrome	Acute myocardial injury diagnosed with elevation in cardiac troponin and/or with cardiac imaging such as cardiac MRI, with evidence of a decline in RV function, with no evidence of obstructive coronary artery disease or without clinical or electrocardiographic evidence of acute coronary syndrome presentation during acute COVID-19 infection	Hendren NS, Drazner MH, Bozkurt B, et al. Description and proposed management of the acute COVID-19 cardiovascular syndrome. Circulation. 2020;141:1903-14.[57]	
		Acute myocardial injury with COVID-19 with acute coronary syndrome	Acute myocardial injury diagnosed with elevation in cardiac troponin, along with clinical presentation suggestive of acute coronary syndrome with chest pain and electrocardiographic changes during acute COVID-19 infection	Hendren NS, Drazner MH, Bozkurt B, et al. Description and proposed management of the acute COVID-19 cardiovascular syndrome. Circulation. 2020;141:1903-14.[57]	
		Persistent sinus tachycardia with acute COVID-19 infection	Persistent sinus tachycardia with COVID-19 infection that cannot be explained by the degree of hypoxia, hypotension, fever, or anemia during acute COVID-19 infection	Hendren NS, Drazner MH, Bozkurt B, et al. Description and proposed management of the acute COVID-19 cardiovascular syndrome. Circulation. 2020;141:1903-14.[57]	
		Ventricular arrhythmia with acute COVID-19 infection	PVCs, ventricular tachycardia, or ventricular fibrillation during acute COVID-19 infection	Hendren NS, Drazner MH, Bozkurt B, et al. Description and proposed management of the acute COVID-19 cardiovascular syndrome. Circulation. 2020;141:1903-14.[57]	
		Atrial tachyarrhythmia with acute COVID-19 infection	Atrial flutter or atrial fibrillation during acute COVID-19 infection	Hendren NS, Drazner MH, Bozkurt B, et al. Description and proposed management of the acute COVID-19 cardiovascular syndrome. Circulation. 2020;141:1903-14.[57]	

(*Continued*)

Appendix 4. Continued

C. Noncardiovascular History (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Asystole with COVID-19 infection	Asystole during acute COVID-19 infection	Hendren NS, Drazner MH, Bozkurt B, et al. Description and proposed management of the acute COVID-19 cardiovascular syndrome. Circulation. 2020;141:1903-14.[57]	
		Pericarditis/ pericardial effusion with COVID-19	Pericardial fluid accumulation and/or pericarditis during acute COVID-19 infection	Hendren NS, Drazner MH, Bozkurt B, et al. Description and proposed management of the acute COVID-19 cardiovascular syndrome. Circulation. 2020;141:1903-14.[57]	
		DVT with acute COVID-19 infection	Thrombosis formation within deep veins during acute COVID-19 infection	Bikdeli B, Madhavan MV, Jimenez D, et al. COVID-19 and thrombotic or thromboembolic disease: implications for prevention, antithrombotic therapy, and follow-up. J Am Coll Cardiol. 2020;75:2950-73.[58]	
		Pulmonary embolus with COVID-19 infection	Thrombus formation or lodging in an artery in the lung during acute COVID-19 infection	Poissy J, Goutay J, Caplan M, et al. Pulmonary embolism in patients with COVID-19: awareness of an increased prevalence. Circulation. 2020;142:184-6.[59]	
		Acute ischemic limb with COVID-19 infection	Quickly developing or sudden decrease in limb perfusion, usually producing new or worsening symptoms or signs, and often threatening limb viability during acute COVID-19 infection		
		Sudden cardiac death with COVID-19 infection	Unexpected death caused by sudden cardiac arrest with asystole, ventricular tachycardia, or ventricular fibrillation during acute COVID-19 infection	Hendren NS, Drazner MH, Bozkurt B, et al. Description and proposed management of the acute COVID-19 cardiovascular syndrome. Circulation. 2020;141:1903-14.[57]	
		Cardiogenic shock with COVID-19 infection	Low cardiac index (<2.2 L/min/m^2) accompanied with hypotension and/or impaired tissue perfusion during acute COVID-19 infection	Hendren NS, Drazner MH, Bozkurt B, et al. Description and proposed management of the acute COVID-19 cardiovascular syndrome. Circulation. 2020;141:1903-14.[57]	COVID-19 infection may result in septic or vasodilatory shock. If there is cardiac involvement with inability of the heart to pump sufficient blood for the needs of the body, concomitant cardiac failure may result in mixed (cardiogenic and vasodilatory) shock or cardiogenic shock.
		Stroke with COVID-19 infection	Acute interruption or reduction of blood supply to brain, preventing brain tissue from getting oxygen and nutrients during acute COVID-19 infection	Oxley TJ, Mocco J, Majidi S, et al. Large-vessel stroke as a presenting feature of Covid-19 in the young. N Engl J Med. 2020;382:e60.[60]	
		None			
		Unknown			

(*Continued*)

Appendix 4. Continued

C. Noncardiovascular History (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
COVID-19 noncardiovascular complications		• ARDS with COVID-19 infection • Pneumonia with COVID-19 infection • Cytokine surge syndrome with COVID-19 infection • Acute kidney injury with COVID-19 infection • Acute liver failure with COVID-19 infection • Disseminated intravascular coagulation with COVID-19 infection • Rhabdomyolysis with COVID-19 infection • Seizures and/or encephalopathy with COVID-19 infection • Loss of smell and/or taste with COVID-19 infection • Other • None • Unknown			
		ARDS with COVID-19 infection	Respiratory failure of sudden (acute) onset due to the rapid accumulation of fluid in the lungs (pulmonary edema) after an abrupt increase in the permeability of the normal barrier between the capillaries and alveoli in COVID-19 infection	Guan WJ, Ni ZY, Hu Y, et al. Clinical characteristics of coronavirus disease 2019 in China. N Engl J Med. 2020;382:1708-20.[61]	
		Pneumonia with COVID-19 infection	Acute COVID-19 infection accompanied with symptoms, signs of pneumonia, and pulmonary consolidation by imaging	Guan WJ, Ni ZY, Hu Y, et al. Clinical characteristics of coronavirus disease 2019 in China. N Engl J Med. 2020;382:1708-20.[61]	
		Cytokine surge syndrome with COVID-19 infection	Systemic inflammatory response syndrome triggered in the setting of acute COVID-19 infection usually manifested by marked elevations in ferritin, C-reactive protein, proinflammatory cytokines such as IL-6, IL-1, or TNF, accompanied with end-organ damage in liver, kidney, and other organs during COVID-19 infection	Haberman R, Axelrad J, Chen A, et al. Covid-19 in immune-mediated inflammatory diseases–case series from New York. N Engl J Med. 2020;283:85-8.[62]	May also be called cytokine storm syndrome

(*Continued*)

Appendix 4. Continued

C. Noncardiovascular History (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Acute kidney injury with COVID-19 infection	Abrupt reduction in kidney function based on an elevation in serum creatinine level, a reduction in urine output, the need for renal replacement therapy (dialysis), or a combination of these during acute COVID-19 infection	Guan WJ, Ni ZY, Hu Y, et al. Clinical characteristics of coronavirus disease 2019 in China. N Engl J Med. 2020;382:1708-20.[61]	
		Acute liver failure with COVID-19 infection	Loss of liver function rapidly during acute COVID-19 infection, usually manifested by rise in liver enzymes	Guan WJ, Ni ZY, Hu Y, et al. Clinical characteristics of coronavirus disease 2019 in China. N Engl J Med. 2020;382:1708-20.[61]	
		Disseminated intravascular coagulation with COVID-19 infection	Abnormalities in blood clotting and a condition in which blood clots form throughout the body, blocking small blood vessels during acute COVID-19 infection	Guzik TJ, Mohiddin SA, Dimarco A, et al. COVID-19 and the cardiovascular system: implications for risk assessment, diagnosis, and treatment options. Cardiovasc Res. 2020;116:1666-87.[63] Connors JM, Levy JH. COVID-19 and its implications for thrombosis and anticoagulation. Blood. 2020;135:2033-40.[64]	
		Rhabdomyolysis with COVID-19 infection	Destruction or degeneration of muscle tissue accompanied by the release of breakdown products into the bloodstream during acute COVID-19 infection	Jin M, Tong Q. Rhabdomyolysis as potential late complication associated with COVID-19. Emerg Infect Dis. 2020;26:1618-20.[65]	
		Seizures and/or encephalopathy with COVID-19 infection	Convulsions, sensory, cognitive disturbances, or loss of consciousness resulting from abnormal electrical discharges in the brain during acute COVID-19 infection	Mao L, Jin H, Wang M, et al. Neurologic manifestations of hospitalized patients with coronavirus disease 2019 in Wuhan, China. JAMA Neurol. 2020;77:683-90.[66]	
		Loss of smell and/or taste (anosmia and/or ageusia) with COVID-19 infection	Loss of or impairment of olfactory and gustatory function during COVID-19 infection	Centers for Disease Control and Prevention. Coronavirus Disease 2019 (COVID-19) Symptoms. Available at: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html. Accessed October 26, 2020.[67]	
		Other			
		None			
		Unknown			
Highest level of care needed due to COVID-19		• ECMO • ICU • Wards • Observation • ED/acute care • Home • Unknown			

(*Continued*)

Appendix 4. Continued

C. Noncardiovascular History (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
History of hepatitis B infection	A viral infection caused by the hepatitis B virus	• Positive, fully treated • Positive, partially treated • Positive, untreated • Negative • Unknown			
History of hepatitis C infection	A viral infection caused by the hepatitis C virus	• Positive, fully treated • Positive, partially treated • Positive, untreated • Negative • Unknown			
History of Chagas disease	Documented history of Chagas disease, which is a parasitic infection caused by *Trypanosoma cruzi*. It is transmitted by insect bites. It is characterized by an acute and chronic phase; in the acute phase patients may have fever, malaise, and swelling at the site of the insect bite; in the chronic phase patients develop hepatosplenomegaly, lymphadenopathy, cardiomyopathy, and arrhythmias.	• Yes • No • Unknown			
Influenza immunization	Influenza vaccines are vaccines that protect against infection from influenza viruses.	• Up to date with annual influenza vaccination • Not up to date • Unknown			
Pneumococcal immunization	Pneumococcal vaccines are vaccines against the bacterium *Streptococcus pneumoniae*.	• Up to date with pneumococcal conjugate vaccination (PCV13) • Up to date with pneumococcal polysaccharide vaccine (PPSV23) • Not up to date with PCV13 • Not up to date with PPSV23 • Unknown		Centers for Disease Control and Prevention. Pneumococcal Disease. Pneumococcal Vaccination. Available at: https://www.cdc.gov/pneumococcal/vaccination.html. Accessed October 26, 2020.[68]	
SARS-CoV-2 immunization	Patient has received a vaccine for SARS-CoV-2.	• Yes • No • Unknown			We are working with the presumption a safe and effective vaccine will be developed for COVID-19

AIDS indicates acquired immunodeficiency syndrome; AL, amyloid light-chain; ARDS, acute respiratory distress syndrome; ATTR, transthyretin amyloidosis; CKD, chronic kidney disease; COVID-19, coronavirus disease 2019; DVT, deep vein thrombosis; ECG, echocardiography; ECMO, extracorporeal membrane oxygenation; ED, emergency department; GFR, glomerular filtration rate; HF, heart failure; HIV, human immunodeficiency virus; ICD-10, *International Statistical Classification of Diseases and Related Health Problems, 10th revision*; ICU, intensive care unit; IgG, immunoglobulin G; IgM, immunoglobulin M; IL-1, interleukin-1; IL-6, interleukin-6; LVEF, left ventricular ejection fraction; mm/dd/yyyy, month/day/year; MRI, magnetic resonance imaging; NCI, National Cancer Institute; PVC, premature ventricular contractions; RT-PCR, reverse transcription-polymerase chain reaction; RV, right ventricular; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; SLE, systemic lupus erythematosus; TNF, tumor necrosis factor; and TTR, transthyretin.

Appendix 5. Patient Assessment

A. Current Symptoms and Signs: Clinical Symptoms

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Dyspnea at rest	Patient describes frequent uncomfortable awareness of breathing while resting in a sitting position.	• Yes • No • Unknown			
Dyspnea on exertion	Patient describes uncomfortable awareness of breathing while exerting him/herself.	• Yes • No • Unknown			
Activities that elicit dyspnea on exertion	Indicate degree of activity required to elicit dyspnea symptom.	• Difficulty breathing while recumbent • Running or other sport (specify sport) • Walking up an incline (specify distance) • Walking on a flat surface (specify distance) • Stopping to rest while dressing • Standing (specify length of time) • Other activity (eg, shopping or housework; specify)			
Orthopnea	Difficulty breathing while recumbent. Patient describes uncomfortable awareness of breathing while in a supine position, usually accompanied with positioning with ≥2–3 pillows or in a chair or recliner to maintain comfortable breathing during sleep.	• Yes • No • Unknown			Recurrent supine cough with other known cause may be an orthopnea equivalent.
Bendopnea	Patient describes shortness of breath while bending over.	• Yes • No • Unknown			
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 >5 min is considered positive.	• Yes • No • Unknown			
Weight change	Weight change either as weight gain (+ value) or loss (– value), as reported by the patient	• Numeric, kg			
Time frame of weight gain or weight loss	Time frame over which weight change occurred	• Numeric, d, wk, or mo			
Fatigue	Unusual tiredness and inability to perform usual activities	• Yes • No • Unknown			

(*Continued*)

Appendix 5. Continued

A. Current Symptoms and Signs: Clinical Symptoms (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Gastrointestinal symptoms	Patient experiences gastrointestinal symptoms.	• Anorexia • Early satiety • Abdominal pain • Ascites • Other • No • Unknown		Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2013;128:e240-327.[24] Sundaram V, Fang JC. Gastrointestinal and liver issues in heart failure. Circulation. 2016;133:1696-703.[69]	
Cognitive decline	Decline in cognitive function such as memory, attention, executive function, or psychomotor speed	• Yes • No • Unknown		Hajduk AM, Kiefe CI, Person SD, et al. Cognitive change in heart failure: a systematic review. Circ Cardiovasc Qual Outcomes. 2013;6:451-60.[70]	
Syncope	Sudden loss of consciousness not related to anesthesia, with spontaneous recovery noted by patient or observer. Patients losing consciousness before an ICD discharge will be considered to have syncope.	• Yes • No • Unknown			
Acute pulmonary edema	Rapid progression or acute onset of pulmonary edema causing significant hypoxemia and/or need for mechanical ventilation	• Yes • No • Unknown		American Heart Association. Get With The Guidelines–Heart Failure. Available at: https://www.heart.org/en/professional/quality-improvement/get-with-the-guidelines/get-with-the-guidelines-heart-failure. Accessed October 26, 2020.[28]	
Pulmonary congestion	Progressive symptoms of dyspnea on exertion, orthopnea, paroxysmal nocturnal dyspnea, peripheral edema, or other HF symptoms, usually but not always accompanied by weight gain. Rales may be heard on examination, and usually there is evidence of elevated ventricular filling pressures (may be evidenced by natriuretic peptide levels, invasive or noninvasive hemodynamic assessment, or by Doppler imaging by echocardiography), and mild to moderate pulmonary congestion/edema on chest x-ray. This category should not include patients with fulminant acute pulmonary edema/significant hypoxemia potentially requiring intubation.	• Yes • No • Unknown		American Heart Association. Get With The Guidelines–Heart Failure. Available at: https://www.heart.org/en/professional/quality-improvement/get-with-the-guidelines/get-with-the-guidelines-heart-failure. Accessed October 26, 2020.[28]	

HF indicates heart failure; and ICD, implantable cardioverter-defibrillator.

Appendix 5. Continued

B. Current Symptoms and Signs: Physical Examination

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Heart rate	Heart rate recorded closest to the time of presentation to the healthcare facility and/or on discharge (for inpatient)	• Numeric, bpm • Unknown			
Heart rate regularity	Regularity of heart rate	• Regular heart rhythm • Irregular heart rhythm			
		Regular heart rhythm	Normal heart rate range for adults is 60–100 bpm; however, this may vary from person to person.		
		Irregular heart rhythm	Heart beats more slowly, irregularly, or more quickly than normal		
Systolic blood pressure	The blood pressure during the contraction of the left ventricle of the heart. Value recorded closest to the time of presentation to the healthcare facility.	• Numeric, mm Hg • Unknown		NCI Thesaurus Code: C25298[25]	
Diastolic blood pressure	The blood pressure after the contraction of the heart while the chambers of the heart refill with blood. Value recorded closest to the time of presentation to the healthcare facility.	• Numeric, mm Hg • Unknown		NCI Thesaurus Code: C25299[25]	
Jugular venous pressure	The estimated height of the mean jugular venous waveform above the right atrium, measured at a 45-degree angle. When expressed in 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.	• Numeric, cm • Unknown		Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2013;128:e240-327.[24]	
Jugular venous distension	Increased pressure of the superior vena cava causing the jugular vein to bulge, making it visualized at a level of the neck that is higher than normal	• Yes • No • Unknown		Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2013;128:e240-327.[24]	
Hepatojugular reflux	Distension of the neck veins precipitated by the maneuver of firm pressure over the liver. Also referred to as abdominojugular reflux	• Yes • No • Unknown			
Respiratory rate	Respiratory rate in respiratory cycles/min	• Numeric, cycles/min			
Height	Patient's height	• Numeric, cm			

(*Continued*)

Appendix 5. Continued

B. Current Symptoms and Signs: Physical Examination (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Weight at encounter	Patient's weight	• Numeric, kg			
Body mass index	Calculated according to formula: patient's weight in kg, divided by height (m)^2	• Numeric, kg/m^2 • Unknown			
Third heart sound (S3)	Presence of a third (mid-diastolic) heart sound	• Yes • No • Unknown		Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on practice guidelines. Circulation. 2013;128:e240-327.[24]	
Fourth heart sound (S4)	Presence of a fourth (late-diastolic) heart sound	• Yes • No • Unknown		Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on practice guidelines. Circulation. 2013;128:e240-327.[24]	
Heart murmur	Presence of heart murmur(s)	• Yes • No • Unknown			
Heart murmur-timing	The point in the cardiac cycle when heart murmur is heard	• Systolic • Diastolic • Continuous • Other			
Lung (pulmonary) examination findings	Findings on auscultation of the lungs	• Clear or normal • Rales • Decreased breath sounds or dullness • Rhonchi • Wheezing • Crepitations • Pleural friction rub • Absent breath sounds • Other findings			
		Clear or normal	Lungs are normal on auscultation.		
		Rales	Abnormal breath sounds (crackles) heard on auscultation indicating inflammation, fluid, or infection of the lung	NCI Thesaurus Code: C119216[25]	
		Decreased breath sounds or dullness	Diminished breath sounds		
		Rhonchi	Abnormal breath sounds similar to snoring heard on auscultation of the bronchial airways, suggesting a partial obstruction due to thick secretions, a muscular spasm, or a neoplasm	NCI Thesaurus Code: C87116[25]	

(*Continued*)

Appendix 5. Continued

B. Current Symptoms and Signs: Physical Examination (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Wheezing	Abnormal breath sounds characterized by a high-pitched, whistling sounds during breathing	NCI Thesaurus Code: C78718[25]	End-expiratory wheezes may indicate bronchospasm.
		Crepitations	Crackling sounds heard usually in lung infection or with pulmonary fibrosis	NCI Thesaurus Code: C26860[25]	
		Pleural friction rub	An abnormal lung sound that is caused by inflammation of the pleural layer of the lungs rubbing together. Pleural friction rub is heard on inspiration and expiration and sounds like a low-pitch harsh/grating noise.	NCI Thesaurus Code: C26860[25]	
		Absent breath sounds	Absence of breath sounds during auscultation		
		Other findings			
Peripheral edema	Increased tissue fluid indicated by perceptible indentation on lower leg or foot after palpation	• Yes • No • Unknown			
Ascites	Intra-abdominal fluid accumulation as determined by physical examination	• Yes • No • Unknown			Abdominal ultrasound may also reflect presence of ascites.
Hepatomegaly	Documentation of liver edge detectable below the right costal margin during examination	• Yes • No • Unknown			
Mobility	Ability to walk	• Able to walk unassisted • Able to walk with assistance (walker/cane) • Requires wheelchair/nonambulatory • Unknown			

bpm indicates beats per minute; and NCI, National Cancer Institute.

C. Summary Assessment: Heart Failure Stages, Functional Assessment

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Stage of HF	Presence or absence of a HF stage by ACCF/AHA criteria	• None • Stage A • Stage B • Stage C • Stage D		Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2013;128:e240-327.[24]	

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Appendix 5. Continued

C. Summary Assessment: Heart Failure Stages, Functional Assessment (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		None			
		Stage A	Patient at high risk for developing HF but who has no structural disorder of the heart		
		Stage B	Patient with a structural disorder of the heart but who has never developed symptoms of HF		
		Stage C	Patient with past or current symptoms of HF associated with structural heart disease		
		Stage D	Patient with end-stage disease who requires specialized treatment strategies such as mechanical circulatory support, continuous inotropic infusions, cardiac transplantation, or hospice care		
New York Heart Association class	NYHA class as reported by a healthcare provider	• None • Class I • Class II • Class III • Class IV		Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2013;128:e240-327.[24]	
		None			
		Class I	Patients with cardiac disease but without resulting limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, or dyspnea.		
		Class II	Patients with cardiac disease resulting in slight limitation of physical activity. Patients are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, or dyspnea.		
		Class III	Patients with cardiac disease resulting in marked limitation of physical activity. Patients are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.		
		Class IV	Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms are present even at minimal exertion.		

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Appendix 5. Continued

C. Summary Assessment: Heart Failure Stages, Functional Assessment (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
HF with reduced EF	HFrEF is also referred to as systolic HF or cardiomyopathy. HF in a patient with documented LVEF of ≤40%.	• Yes • No • Unknown		Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2013;128:e240-327.[24]	
HF with preserved EF	HFpEF is HF in a patient with documented LVEF of ≥50%	• Yes • No • Unknown		Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2013;128:e240-327.[24]	
HF with mid-range EF	HFmEF is HF in a patient with documented LVEF >40% and <50%	• Yes • No • Unknown			
HF with recovered EF	HFrecovEF is HF in a patient with reduced EF in the past but with improved ejection fraction to ≥50%	• Yes • No • Unknown			
HF duration	Length of time patient has experienced HF symptoms	• Numeric, mo			
Cardiomyopathy	Disease of the heart muscle that causes HF. Cause and types of cardiomyopathies vary.	• Dilated cardiomyopathy • HCM • Restrictive cardiomyopathy • Other • No • Unknown			
		Dilated cardiomyopathy	Dilated, poorly contracting left ventricle. Usually implies depressed LVEF (LVEF <40%).	Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2013;128:e240-327.[24]	

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Appendix 5. Continued

C. Summary Assessment: Heart Failure Stages, Functional Assessment (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		HCM	Disorder of the heart characterized by increased and abnormal hypertrophy of the left ventricle that cannot be explained by loading changes of the heart. It can be with or without LV outflow obstruction.	Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2013;128:e240-327.[24]	
		Restrictive cardiomyopathy	A rare form of heart muscle disease that is characterized by restrictive filling of the ventricles. In this disease the contractile function (squeeze) of the heart and wall thicknesses are usually normal, but the relaxation or filling phase of the heart is very abnormal.	Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2013;128:e240-327.[24]	
		Other	Other types of cardiomyopathy		
		No			
		Unknown			
Cause of dilated cardiomyopathy	Causes of dilated cardiomyopathy, resulting in the abnormality of the heart muscle	*(Multi-select)* • Ischemic cardiomyopathy • Nonischemic cardiomyopathy • Unknown		Bozkurt B, Colvin M, Cook J, et al. Current diagnostic and treatment strategies for specific dilated cardiomyopathies: a scientific statement from the American Heart Association. Circulation. 2016;134:e579-646.[8]	
		Ischemic cardiomyopathy	Ischemic cardiomyopathy is a type of cardiomyopathy caused by significant coronary artery disease. Typically, patients with ischemic cardiomyopathy have extensive coronary artery disease with significant ischemic burden, or history of myocardial infarction.	Bozkurt B, Colvin M, Cook J, et al. Current diagnostic and treatment strategies for specific dilated cardiomyopathies: a scientific statement from the American Heart Association. Circulation. 2016;134:e579-646.[8] Felker GM, Shaw LK, O'Connor CM. A standardized definition of ischemic cardiomyopathy for use in clinical research. J Am Coll Cardiol. 2002;39:210-8.[71]	Ischemic cause of HF usually develops in the setting of significant ≥1 coronary artery disease with ≥75% stenosis and/or in patients with history of myocardial infarction, history of coronary revascularization. It can be a result of irreversible loss of myocardium due to previous myocardial infarction, or ischemic but still viable myocardium.

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Appendix 5. Continued

C. Summary Assessment: Heart Failure Stages, Functional Assessment (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Nonischemic cardiomyopathy	Nonischemic cardiomyopathy refers to diseases of the heart that are not the result of reduced blood flow or ischemia in the context of coronary artery disease but rather caused by other factors.	Bozkurt B, Colvin M, Cook J, et al. Current diagnostic and treatment strategies for specific dilated cardiomyopathies: a scientific statement from the American Heart Association. Circulation. 2016;134:e579-646.[8]	
		Unknown			
Cause of nonischemic cardiomyopathy	Causes of nonischemic dilated cardiomyopathy, resulting in the abnormality of the heart muscle	• Idiopathic dilated cardiomyopathy • Familial dilated cardiomyopathy • Chemotherapy-induced dilated cardiomyopathy • Tachycardia-induced dilated cardiomyopathy • Diabetic dilated cardiomyopathy • Infection-related dilated cardiomyopathy • Thyroid disease–mediated dilated cardiomyopathy • Toxin-mediated dilated cardiomyopathy • Infiltrative heart disease–related dilated cardiomyopathy • Nutritional deficiency-related cardiomyopathy • Stress-induced cardiomyopathy • Systemic autoimmune disease-related cardiomyopathy • Peripartum cardiomyopathy • Dilated cardiomyopathy due to hypertensive heart disease • Other • Unknown		Bozkurt B, Colvin M, Cook J, et al. Current diagnostic and treatment strategies for specific dilated cardiomyopathies: a scientific statement from the American Heart Association. Circulation. 2016;134:e579-646.[8]	
		Idiopathic dilated cardiomyopathy	Primary myocardial disease of unknown cause characterized by LV or biventricular dilatation and impaired myocardial contractility	Bozkurt B, Colvin M, Cook J, et al. Current diagnostic and treatment strategies for specific dilated cardiomyopathies: a scientific statement from the American Heart Association. Circulation. 2016;134:e579-646.[8]	

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Appendix 5. Continued

C. Summary Assessment: Heart Failure Stages, Functional Assessment (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Familial dilated cardiomyopathy	Familial dilated cardiomyopathy is a hereditary disease, presenting as dilated cardiomyopathy.	Bozkurt B, Colvin M, Cook J, et al. Current diagnostic and treatment strategies for specific dilated cardiomyopathies: a scientific statement from the American Heart Association. Circulation. 2016;134:e579-646.[8]	
		Chemotherapy-induced dilated cardiomyopathy	Dilated cardiomyopathy that develops after exposure to cardiotoxic chemotherapy agents	Bozkurt B, Colvin M, Cook J, et al. Current diagnostic and treatment strategies for specific dilated cardiomyopathies: a scientific statement from the American Heart Association. Circulation. 2016;134:e579-646.[8]	For further information regarding cardiotoxic chemotherapy agent and dose, please refer to Appendix 4.
		Tachycardia-induced dilated cardiomyopathy	Dilated cardiomyopathy that is caused by sustained increased heart rate. It is usually reversible.	Bozkurt B, Colvin M, Cook J, et al. Current diagnostic and treatment strategies for specific dilated cardiomyopathies: a scientific statement from the American Heart Association. Circulation. 2016;134:e579-646.[8]	For specific tachyarrhythmias, please refer to Appendix 4B.
		Diabetic dilated cardiomyopathy	Dilated cardiomyopathy attributed to diabetes, in the absence of significant obstructive CAD or other causes of cardiomyopathy	Bozkurt B, Colvin M, Cook J, et al. Current diagnostic and treatment strategies for specific dilated cardiomyopathies: a scientific statement from the American Heart Association. Circulation. 2016;134:e579-646.[8]	Usually seen in patients with long-standing or uncontrolled diabetes
		Infection-related dilated cardiomyopathy	Dilated cardiomyopathy related to infections known to or suspected to cause myocardial injury and/or myocarditis	Bozkurt B, Colvin M, Cook J, et al. Current diagnostic and treatment strategies for specific dilated cardiomyopathies: a scientific statement from the American Heart Association. Circulation. 2016;134:e579-646.[8]	Common infectious causes include viral myocarditis due to CMV, Coxsackie, other enteroviruses, parvovirus B19, herpes virus 6, HIV, SARS-CoV-2, rubella, and others. Bacterial causes may include poststreptococcal disease. Protozoal causes can include Chagas disease caused by the parasite *Trypanosoma cruzi*.

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Appendix 5. Continued

C. Summary Assessment: Heart Failure Stages, Functional Assessment (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Thyroid disease–mediated dilated cardiomyopathy	Dilated cardiomyopathy attributed to uncontrolled hyperthyroidism or severe hypothyroidism	Bozkurt B, Colvin M, Cook J, et al. Current diagnostic and treatment strategies for specific dilated cardiomyopathies: a scientific statement from the American Heart Association. Circulation. 2016;134:e579-646.[8]	
		Toxin-mediated dilated cardiomyopathy	Dilated cardiomyopathy attributed to excessive alcohol intake, or illicit drug or substance abuse, or cardiotoxic drug or chemical exposure	Bozkurt B, Colvin M, Cook J, et al. Current diagnostic and treatment strategies for specific dilated cardiomyopathies: a scientific statement from the American Heart Association. Circulation. 2016;134:e579-646.[8]	Alcoholism is associated with development of dilated cardiomyopathy. Illicit drugs that are cardiotoxic and that have been implicated in the development of dilated cardiomyopathy include cocaine, amphetamine, methamphetamine, methylphenidate, dextroamphetamine, ecstasy, bath salts, and synthetic cathinones. Other myocardial toxins include cobalt, phenothiazines, clozapine, ephedrine, carbon monoxide, lead, lithium, methysergide, pseudoephedrine, ephedrine, cobalt, anabolic steroids, hydroxychloroquine, catecholamines, and high doses of pseudoephedrine or ephedrine. New synthetic drugs or substances may have components that are cardiotoxic.
		Infiltrative heart disease–related dilated cardiomyopathy	Dilated cardiomyopathy that develops in advanced stages of infiltrative cardiomyopathies such as cardiac amyloidosis, hemochromatosis, sarcoidosis	Bozkurt B, Colvin M, Cook J, et al. Current diagnostic and treatment strategies for specific dilated cardiomyopathies: a scientific statement from the American Heart Association. Circulation. 2016;134:e579-646.[8]	Patients with infiltrative cardiomyopathies, if diagnosed early, have restrictive cardiomyopathy phenotype. In advanced stages, infiltrative cardiomyopathies may progress to a dilated cardiomyopathy form.

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Appendix 5. Continued

C. Summary Assessment: Heart Failure Stages, Functional Assessment (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Nutritional deficiency-related cardiomyopathy	Dilated cardiomyopathy attributed to nutritional deficiencies such as thiamine, carnitine, selenium deficiency	Bozkurt B, Colvin M, Cook J, et al. Current diagnostic and treatment strategies for specific dilated cardiomyopathies: a scientific statement from the American Heart Association. Circulation. 2016;134:e579-646.[8]	Usually seen in extreme deficiencies, and some can be related to genetic causes.
		Stress-induced cardiomyopathy	Stress-induced cardiomyopathy is characterized by acute, usually reversible LV dysfunction in the absence of significant CAD, usually triggered by acute emotional or physical stress.	Bozkurt B, Colvin M, Cook J, et al. Current diagnostic and treatment strategies for specific dilated cardiomyopathies: a scientific statement from the American Heart Association. Circulation. 2016;134:e579-e646.[8]	Other commonly used terminology is Tako-tsubo cardiomyopathy. Most patients have a clinical presentation similar to that of acute coronary syndrome and may have transiently elevated cardiac enzymes such as cardiac troponin. Although apical ballooning is seen in most (termed as Tako-tsubo cardiomyopathy), other diverse ventricular contraction patterns have been defined by cardiovascular imaging.
		Systemic autoimmune disease–related cardiomyopathy	Dilated cardiomyopathy attributed to existing systemic autoimmune diseases	Bozkurt B, Colvin M, Cook J, et al. Current diagnostic and treatment strategies for specific dilated cardiomyopathies: a scientific statement from the American Heart Association. Circulation. 2016;134:e579-646.[8]	Systemic autoimmune diseases commonly associated with dilated cardiomyopathy include systemic lupus erythematosus, dermatomyositis, rheumatoid arthritis, scleroderma, and polyarteritis nodosa.
		Peripartum cardiomyopathy	HF caused by systolic dysfunction presenting usually during the last month of pregnancy or in the first 5 mo postpartum	Bozkurt B, Colvin M, Cook J, et al. Current diagnostic and treatment strategies for specific dilated cardiomyopathies: a scientific statement from the American Heart Association. Circulation. 2016;134:e579-646.[8]	It can present during other times during pregnancy and early postpartum. Multiparity, advanced maternal age, obesity, and hypertension are some of the risk factors for peripartum cardiomyopathy.
		Dilated cardiomyopathy due to hypertensive heart disease	HF with reduced EF and dilated chambers, seen in patients with long-standing uncontrolled hypertension, usually accompanied with LV hypertrophy		Other commonly used terminology includes hypertensive dilated cardiomyopathy. The classic paradigm of hypertensive heart disease involves concentric LV hypertrophy. As the disease progresses, the left ventricle dilates, and LVEF declines in what is described as a "burned out" left ventricle.
		Other			

(*Continued*)

Appendix 5. Continued

C. Summary Assessment: Heart Failure Stages, Functional Assessment (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Health status	Health status of patient at the time of visit as documented by 1 of the following:	• 5-Point Likert Scale • Visual Analog Scale • Minnesota Living with Heart Failure Questionnaire • Kansas City Cardiomyopathy Questionnaire • SF-36 or SF-12 • PHQ-2 • PHQ-9 • Other			
		5-Point Likert Scale	A psychometric scale commonly used in questionnaires where a respondent is asked to evaluate an opinion according to subjective or objective criteria, by rating their level of agreement or disagreement with a statement	NCI Thesaurus Code: C85429[25]	
		Visual Analog Scale	A pain scale marked off like a ruler from 0 to 10 on which the patient marks the current level of pain experienced	NCI Thesaurus Code: C21120[25]	
		Minnesota Living with Heart Failure Questionnaire	Patient-reported outcome questionnaire specifically designed for HF status. Lower scores indicate better health-related quality of life.		
		Kansas City Cardiomyopathy Questionnaire	Patient-reported outcome questionnaire specifically designed for HF status. Higher scores indicate better health-related quality of life.		
		SF-36 or SF-12	SF-36: A question survey for measuring health status and outcomes from the patient's point of view. Designed for use in surveys of general and specific populations, health policy evaluations, and clinical practice and research. Measures limitations in physical activities due to health problems, bodily pain, general health perceptions, vitality, mental health, etc. SF-12: A 12-question subset of the SF-36. Designed to be administered in a shorter time.	NCI Thesaurus Codes: C20078, C20079[25]	

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Appendix 5. Continued

C. Summary Assessment: Heart Failure Stages, Functional Assessment (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		PHQ-2	PHQ-2 consists of the first 2 questions from the PHQ-9. Patients who screen positive should be further evaluated with the PHQ-9.		
		PHQ-9	PHQ-9 is a component of the longer Patient Health Questionnaire. This 9-item depression scale based on the diagnostic criteria for major depressive disorder in the DSM-IV and has been validated for use in primary care.		
		Other			

ACCF indicates American College of Cardiology Foundation; AHA, American Heart Association; CAD, coronary artery disease; CMV, cytomegalovirus; DSM-IV, *Diagnostic and Statistical Manual of Mental Disorders*, fourth edition; EF, ejection fraction; HCM, hypertrophic cardiomyopathy; HF, heart failure; HFmEF, heart failure with mid-range ejection fraction; HFpEF, heart failure with preserved ejection fraction; HFrEF, heart failure with reduced ejection fraction; HFrecovEF, heart failure with recovered ejection fraction; HIV, human immunodeficiency virus; LV, left ventricular; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; PHQ-2, Patient Health Questionnaire-2; PHQ-9, Patient Health Questionnaire-9; S3, third heart sound; S4, fourth heart sound; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; SF-12, 12-item Short Form Health Survey; and SF-36, 36-item Short Form Health Survey.

Appendix 6. Diagnostic Procedures

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
EF	A measurement of how much blood is being pumped out of the left ventricle of the heart with each contraction, expressed as a percentage	• Quantitative • Qualitative			
		Quantitative	• EF, % • When a quantitative range is given, the midpoint of the range		When multiple determinations are present, the most recent is preferred. Please note modality (eg, radionuclide ventriculography, MRI, echocardiography, contrast, ventriculography, nuclear imaging).
		Qualitative	• Normal (≥50%) • Mildly reduced (≥40% and <50%) • Moderately reduced (≥30% and <40%) • Severely reduced (approximately <30%)		If a quantitative EF is provided, it is preferred to enter the quantitative value rather than the qualitative ranges.
EF modality	Modality used to determine the EF	• Radionuclide ventriculography • MRI • Echocardiography • Invasive contrast left ventriculography • Myocardial perfusion imaging • Other			

(*Continued*)

Appendix 6. Continued

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Radionuclide ventriculography	A multigated acquisition scan and a form of radionuclide imaging that provides a comprehensive look at blood flow and the function of the lower chambers of the heart ventricles.	NCI Thesaurus Code: C38073[25]	
		MRI	Imaging that uses radiofrequency waves and a strong field rather than x-rays to provide amazingly clear and detailed pictures of internal organs and tissues. The technique is valuable for the diagnosis of many pathologic conditions, including cancer, heart and vascular disease, stroke, and joint and musculoskeletal disorders.	NCI Thesaurus Code: C16809[25]	
		Echocardiography	A test that uses high-frequency sound waves (ultrasound) to create an image of the heart.	NCI Thesaurus Code: C16525[25]	
		Contrast left ventriculography	Radiography of the ventricles of the heart after injection of a contrast medium		
		Myocardial perfusion imaging	Myocardial perfusion imaging or scanning is a nuclear medicine procedure that illustrates the function of the heart muscle.		
		Other			
Radionuclide ventriculography	Cardiac blood pool imaging (first pass or gated equilibrium) with or without stress	• LVEF: percentage (range: 5%–90%) for left ventricle • RVEF: percentage (range: 5%–90%) for right ventricle			
Echocardiography data elements	Refer to the 2019 ACC/AHA/ASE Key Data Elements and Definitions for Transthoracic Echocardiography			Douglas PS, Carabello BA, Lang RM, et al. 2019 ACC/AHA/ASE key data elements and definitions for transthoracic echocardiography: a Report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Clinical Data Standards for Transthoracic Echocardiography) and the American Society of Echocardiography. Circ Cardiovasc Imaging. 2019;12:e000027.[22]	

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Appendix 6. Continued

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Electrocardiographic elements relevant for HF	12-lead electrocardiographic data elements relevant to HF care	• Rhythm • Heart rate, bpm • LBBB • RBBB • Presence of abnormal Q waves • QRS duration, ms • QTc interval • Heart block			
		Rhythm	Presence of: • Sinus rhythm: an electrocardiographic finding of a cardiac rhythm that originates in the sinoatrial node • Atrial fibrillation: an arrhythmia characterized by uncoordinated atrial myocardium due to multiple reentry circuits with consequent deterioration of atrial mechanical function. Instead of intermittently contracting, the atria quiver continuously in a chaotic pattern, causing a totally irregular often tachycardic ventricular rate. • Paced rhythm: an electrocardiographic finding that the cardiac rhythm is initiated by an electrical impulse from a mechanical cardiac pacemaker • Other	NCI Thesaurus Codes: C100076, C50466, C111094, C88140[25]	

(*Continued*)

Appendix 6. Continued

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Heart rate, bpm	A measurement that describes the frequency of rate of contractions of the heart measured within a unit time		
		LBBB	LBBB is a cardiac conduction abnormality seen on the ECG. In this condition, activation of the left ventricle of the heart is delayed, which causes the left ventricle to contract later than the right ventricle.		
		RBBB	RBBB is a heart block in the right bundle branch of the electrical conduction system.		
		Presence of abnormal Q waves	≥0.03 s in width and ≥1 mm (0.1 mV) in depth in at least 2 contiguous leads		
		QRS duration, in ms			
		QTc interval	The time interval between the start of the Q wave and the end of the T wave in the cardiac cycle as corrected with a nonspecified correction formula	NCI Thesaurus Code: C100391[25]	
		Heart block	An electrocardiographic finding of blocked cardiac electrical impulses along the fibers normally responsible for impulse conduction	NCI Thesaurus Code: C34665[25]	
Chest radiography	Documented findings from the radiological examination of the chest	• Pulmonary vascular redistribution, pulmonary congestion, or pulmonary edema • Cardiomegaly, chamber enlargement • Pleural effusion(s) • No abnormalities related to HF			
		Pulmonary vascular redistribution, pulmonary congestion, or pulmonary edema	Pulmonary edema: Accumulation of fluid in the lung tissues causing disturbance of the gas exchange that may lead to respiratory failure. It is caused by direct injury to the lung parenchyma or congestive HF.	NCI Thesaurus Code: C26868[25]	
		Cardiomegaly, chamber enlargement	Abnormal enlargement of the heart	NCI Thesaurus Code: C61453[25]	
		Pleural effusion(s)	Increased amounts of fluid within the pleural cavity. Symptoms include shortness of breath, cough, and chest pain. It is usually caused by lung infections, congestive HF, pleural and lung tumors, connective tissue disorders, and trauma.	NCI Thesaurus Code: C3331[25]	
		No abnormalities related to HF			

(*Continued*)

Appendix 6. Continued

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Myocardial perfusion imaging	Refer to the 2020 AHA/ACC Key Data Elements and Definitions for Coronary Revascularization			Dehmer GJ, Badhwar V, Bermudez EA, et al. 2020 AHA/ACC key data elements and definitions for coronary revascularization: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Clinical Data Standards for Coronary Revascularization). Circ Cardiovasc Qual Outcomes. 2020;13:e000059.[21]	
Coronary angiography	Refer to the 2020 AHA/ACC Key Data Elements and Definitions for Coronary Revascularization			Dehmer GJ, Badhwar V, Bermudez EA, et al. 2020 AHA/ACC key data elements and definitions for coronary revascularization: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Clinical Data Standards for Coronary Revascularization). Circ Cardiovasc Qual Outcomes. 2020;13:e000059.[21]	
Left heart catheterization	Refer to the 2020 AHA/ACC Key Data Elements and Definitions for Coronary Revascularization			Dehmer GJ, Badhwar V, Bermudez EA, et al. 2020 AHA/ACC key data elements and definitions for coronary revascularization: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Clinical Data Standards for Coronary Revascularization). Circ Cardiovasc Qual Outcomes. 2020;13:e000059.[21]	Important variables for HF include LV end-diastolic pressure (mm Hg) and left ventriculography EF.

(*Continued*)

Appendix 6. Continued

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Right heart catheterization	Findings of right heart catheterization with or without pulmonary angiography	• RA mean pressure, mm Hg • PA mean pressure, mm Hg • PA systolic pressure, mm Hg • PA diastolic pressure, mm Hg • PAPI • Mean pulmonary capillary wedge pressure, mm Hg • Cardiac output, L/min • CPO, watts • Cardiac index, L/min/m^2 • Transpulmonary gradient, mm Hg • Pulmonary vascular resistance, Wood units, or dynes/s/cm • Systemic vascular resistance, dynes/s/cm^2 • Mixed venous O_2 saturation, %			
		RA mean pressure, mm Hg	Mean RA pressure from pulmonary artery catheter		
		PA mean pressure, mm Hg	Mean PA pressure		
		PA systolic pressure, mm Hg	Systolic pulmonary pressure from PA catheter		
		PA diastolic pressure, mm Hg	Diastolic pulmonary pressure from PA catheter		
		PAPI	Pulse pressure across pulmonary artery divided by RA (calculated systolic pulmonary arterial pressure – diastolic pulmonary pressure)/right atrial pressure		
		Mean pulmonary capillary wedge pressure, mm Hg	Pulmonary capillary wedge pressure, or pulmonary artery occlusion pressure, is the pressure measured by wedging a pulmonary catheter with an inflated balloon into a small pulmonary arterial branch.		May be recorded with or without V-wave
		Cardiac output, L/min	Volume of blood being pumped by the heart, per unit time. Cardiac output can be assessed by thermodilution or Fick formula.		
		CPO, watts	Cardiac power is the product of simultaneously measured cardiac output (or index) and mean arterial blood pressure. By coupling both pressure and flow domains of the cardiovascular system, it is a measure of cardiac pumping.		Resting CPO is measured in watts using the following formula: cardiac output (L/min) × mean arterial pressure divided by 451.

(*Continued*)

Appendix 6. Continued

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Cardiac index, L/min/m^2	Hemodynamic parameter that relates the cardiac output to body surface area		
		Transpulmonary gradient, mm Hg	Difference between mean pulmonary artery pressure and pulmonary capillary wedge pressure		
		Pulmonary vascular resistance, Wood units, or dynes/s/cm	Resistance offered by the pulmonary circulation to the flow of blood from the right ventricle		Pulmonary vascular resistance is calculated as (mean PA pressure minus mean pulmonary capillary wedge pressure) divided by cardiac output.
		Systemic vascular resistance, dynes/s/cm^2	The resistance offered by the systemic circulation		Systemic vascular resistance is calculated as the systemic mean arterial blood pressure minus right arterial pressure divided by cardiac output.
		Mixed venous O_2 saturation, %	Saturation measured via a sample of blood from a pulmonary artery catheter measures the end result of O_2 consumption, and delivery is used in the ICU as a measure of O_2 extraction by the body.		
Cardiopulmonary exercise testing	Findings of cardiopulmonary exercise testing, which provides assessment of the integrative exercise responses involving the pulmonary, cardiovascular, hematopoietic, neuropsychological, and skeletal muscle systems	• Maximal or submaximal (symptom limited) test • Workload achieved			Peak VO_2 max refers to the highest value of VO_2 attained on a particular exercise test. Max VO_2 refers to the highest value of VO_2 that is deemed attainable by an individual. Despite this difference, peak VO_2 and max VO_2 are often mistakenly used interchangeably. Submaximal exercise tests can be used to measure VO_2 peak and/or estimate VO_2 max.
		Maximal or submaximal (symptom limited) test			
		Workload achieved	May be expressed as watts, exercise stage achieved (include exercise protocol), or metabolic equivalents		
VO_2 max	Measurement of the maximum amount of oxygen a person can utilize during intense exercise by cardiopulmonary exercise testing. Other names used: peak VO_2, maximum aerobic capacity. VO_2 max is the point at which oxygen uptake no longer increases with an increase in workload.	• Numeric, mL/kg/min			

(*Continued*)

Appendix 6. Continued

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Percent predicted VO_2 max	Peak oxygen consumption calculated according to the Wasserman/Hansen equation	• Numeric		Hansen JE, Sue DY, Wasserman K. Predicted values for clinical exercise testing. Am Rev Respir Dis. 1984;129:S49-55.[72] Wasserman K, Hansen JE, Sue DY, et al. Principles of Exercise Testing and Interpretation: Including Pathophysiology and Clinical Applications. 3rd ed. Philadelphia, PA: Lippincott, Williams & Wilkins; 1999.[73]	
VCO_2	Amount of carbon dioxide exhaled from the body per unit time	• Numeric, mL/min			
V_E/VCO_2 slope	Ventilatory efficiency, defined as the slope of the linear relationship between ventilation and CO_2 output.	• Numeric			(V_E/VCO_2 slope) can be calculated as $863/(1–V_D/V_T)\times(PaCO_2)$, where V_D is dead space, V_T is tidal volume, and $PaCO_2$ is arterial CO_2 tension.
Ventilatory anaerobic threshold	Index used to estimate exercise capacity. The VO_2 at the onset of blood lactate accumulation is called the lactate threshold or the VAT. The VAT is also defined as the point at which minute ventilation increases disproportionately relative to VO_2, a response that is generally seen at 60%–70% of VO_2 max.	• % of VO_2 max			
Respiratory exchange ratio	The ratio of carbon dioxide output/oxygen uptake (VCO_2/VO_2) (gas exchange ratio)	• Numeric			
6-min walk test	Distance walked during 6-min walk (on a flat surface)	• Distance, m			
Continuous ambulatory electrocardiographic monitoring	Type of ambulatory electrocardiographic monitor used	• External cardiac event (loop) monitor • Implanted cardiac event (loop) monitor • Holter monitor • Personal (consumer) wearable • Other • None			

(*Continued*)

Appendix 6. Continued

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Documented findings of continuous ambulatory electrocardiographic monitoring	Findings documented during continuous ambulatory electrocardiographic monitoring	• Duration of continuous ambulatory electrocardiographic monitoring, h • AV block • Mean heart rate, bpm • Minimum heart rate, bpm • Maximum heart rate, bpm • Number of ventricular extrasystoles • Nonsustained ventricular tachycardia • Sustained ventricular tachycardia • Sinus pause • Heart rate variability • Atrial fibrillation			
		Duration of continuous ambulatory electrocardiographic monitoring, h	Time during which the monitor is recording the heart's electrical signals		
		AV block	Electrical signal from the atria to the ventricles delayed or blocked at the AV node		
		Mean heart rate, bpm	Mean heart rate for patient in atrial fibrillation during continuous ambulatory electrocardiographic monitoring		
		Minimum heart rate, bpm	Minimum heart rate for patient in atrial fibrillation during continuous ambulatory electrocardiographic monitoring		
		Maximum heart rate, bpm	Maximum heart rate for patient in atrial fibrillation during continuous ambulatory electrocardiographic monitoring		
		Number of ventricular extrasystoles	Premature ventricular characterized by abnormal shape and duration of the QRS complex (generally >129 ms) during continuous ambulatory electrocardiographic monitoring		
		Nonsustained ventricular tachycardia	Number of nonsustained ventricular tachycardia episodes (3–15 consecutive beats at >100 bpm) during continuous ambulatory electrocardiographic monitoring		
		Sustained ventricular tachycardia	Number of sustained ventricular tachycardia episodes (≥30 s at >100 bpm) during continuous ambulatory electrocardiographic monitoring		
		Sinus pause	Number of pauses >2.4 s during continuous ambulatory electrocardiographic monitoring		

(*Continued*)

Appendix 6. Continued

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Heart rate variability	Changes in the time intervals between consecutive heartbeats, indicated as normal, abnormal, or not assessed		
		Atrial fibrillation	Number of atrial fibrillation episodes during continuous ambulatory electrocardiographic monitoring		
Implanted remote pulmonary artery pressure monitoring system	An implantable miniaturized sensor system positioned in the pulmonary artery signals the pulmonary artery pressures; data are monitored remotely, and treatment decisions are made according to measurements.	• Present • Absent			
Reported measurements from implantable remote pulmonary artery pressure monitoring system	Measurements from implanted pulmonary artery remote monitoring system	• PA systolic pressure, mm Hg • PA diastolic pressure, mm Hg • Mean PA pressure, mm Hg • Heart rate, bpm			May need to specify baseline data, specific dates of measurements
		PA systolic pressure, mm Hg	Systolic pulmonary pressure from PA sensor		
		PA diastolic pressure, mm Hg	Diastolic pulmonary pressure from PA sensor		
		Mean PA pressure, mm Hg	Mean pulmonary pressure from PA sensor		
		Heart rate, bpm	Recorded by PA sensor		
Implanted left atrial pressure monitoring system	An implantable miniaturized sensor system positioned in left atrium signaling left atrial pressures; data are monitored remotely, and treatment decisions are made according to measurements.	• Left atrial pressure, mm Hg			
		Left atrial pressure, mm Hg	Left atrial pressure from left atrial sensor		
Monitoring of volume accumulation and/or increased filling pressures by indirect measurements from ICD or CRT-D	Detection of volume accumulation or increased filling pressures by measurement of intrathoracic impedance or by multisensory algorithm	• Present • Absent • Unknown			Examples include OptiVol system, MultiSENSE system
Noninvasive remote monitoring of physiological parameters	Devices, applications, or wearables that provide noninvasive remote measurement and monitoring of physiological parameters	• Home durable devices for remote monitoring of physiological parameters • Wearable devices or apps on smartphones for remote monitoring of physiological parameters • None			

(*Continued*)

Appendix 6. Continued

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Home durable devices for remote monitoring of physiological parameters	Durable devices and platforms that measure blood pressure, heart rate, weight, or oxygen saturation and that also can transmit data for remote monitoring of patient		
		Wearable devices or apps on smartphones for remote monitoring of physiological parameters	Watches, electrodes, patches, smartphones that can measure or indirectly calculate blood pressure, heart rate, weight, or oxygen saturation and that analyze and report data or can transmit data for remote monitoring of patient		
		None			
Noninvasive remote monitoring of physiological parameter(s)	Wearable noninvasive remote monitoring devices that measure physiological parameters	• Weight, kg • Systolic blood pressure, mm Hg • Heart rate, bpm • Pulse oximetry, % • Respiratory rate, numeric value/min • None			

AV indicates atrioventricular; bpm, beats per minute; CPO, cardiac power output; CRT-D, cardiac resynchronization therapy defibrillator; EF, ejection fraction; HF, heart failure; ICD, implantable cardioverter-defibrillator; ICU, intensive care unit; LBBB, left bundle branch block; LV, left ventricular; LVEF, left ventricular ejection fraction; MRI, magnetic resonance imaging; NCI, National Cancer Institute; PA, pulmonary artery; PAPI, pulmonary artery pressure index; PCWP, pulmonary capillary wedge pressure; RA, right atrial; RBBB, right bundle branch block; RVEF, right ventricular ejection fraction; VAT, ventilatory anaerobic threshold; VCO_2, carbon dioxide output; VO_2, oxygen consumption; and VO_2 max, maximal oxygen uptake.

Appendix 7. Invasive Therapeutic Procedures for Heart Failure

A. Surgical Procedures

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Coronary revascularization surgery	Refer to the 2020 AHA/ACC Key Data Elements and Definitions for Coronary Revascularization.			Dehmer GJ, Badhwar V, Bermudez EA, et al. 2020 AHA/ACC key data elements and definitions for coronary revascularization: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Clinical Data Standards for Coronary Revascularization). Circ Cardiovasc Qual Outcomes. 2020;13:e000059.[21]	
Valve surgery performed	Refer to the 2020 AHA/ACC Key Data Elements and Definitions for Coronary Revascularization.	• Yes • No • Unknown		Dehmer GJ, Badhwar V, Bermudez EA, et al. 2020 AHA/ACC key data elements and definitions for coronary revascularization: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Clinical Data Standards for Coronary Revascularization). Circ Cardiovasc Qual Outcomes. 2020;13:e000059.[21]	

(*Continued*)

Appendix 7. Continued

A. Surgical Procedures (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Implantation of a durable mechanical circulatory support device performed	Implantation of mechanical pump that helps pump blood from the ventricle(s) to the body	• Left ventricular assist device • Right ventricular assist device • Biventricular assist device • Total artificial heart • None			
		Left ventricular assist device	A left ventricular assist device pumps blood from left ventricle to the rest of the body.		May be pulsatile or nonpulsatile flow devices. Examples include Heartware LVAS and HeartMate III.
		Right ventricular assist device	A right ventricular assist device pumps blood from right ventricle or right atrium into pulmonary artery and to the lungs.		
		Biventricular assist device	A biventricular assist device is a mechanical device that supports both right and left ventricles.		
		Total artificial heart	A total artificial heart is a pump that is surgically installed to provide circulation and replace both heart ventricles, as well as heart valves, that are diseased or damaged.		
		None			
Cardiac transplantation performed	A heart transplant is an operation in which a failing, diseased heart is replaced with a healthier donor heart.	• Yes • No			

B. Electrophysiological Procedures

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Catheter ablation/radiofrequency ablation/cryoablation	Patient underwent catheter ablation, which is an invasive procedure used to remove or terminate a faulty electrical pathway from sections of the hearts of those who are prone to developing cardiac arrhythmias such as atrial fibrillation, atrial flutter, supraventricular tachycardia, and Wolff-Parkinson-White syndrome.	• Atrial fibrillation • Atrial flutter • Supraventricular tachycardia • Ventricular tachycardia • Other • No • Unknown			

(*Continued*)

Appendix 7. Continued

B. Electrophysiological Procedures (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Implantation of an ICD performed	A battery-powered electrical impulse generator implanted in patients at risk of sudden cardiac death to detect cardiac arrhythmia and correct it with antitachycardia pacing and then by delivering a jolt of electricity, implanted during current encounter	• ICD • No • Unknown		Cannon CP, Brindis RG, Chaitman BR, et al. 2013 ACCF/AHA key data elements and definitions for measuring the clinical management and outcomes of patients with acute coronary syndromes and coronary artery disease: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Acute Coronary Syndromes and Coronary Artery Disease Clinical Data Standards). Circulation. 2013;127:1052-89.[40]	Information about the type of device (pacemaker, biventricular/resynchronization/CRT, ICD, combination), cardiac chamber(s) involved, and year of implantation may be helpful.
		ICD	A battery-powered electrical impulse generator implanted in patients at risk of sudden cardiac death to detect cardiac arrhythmia to quickly terminate an abnormally fast, life-threatening heart rhythm		
		No	No ICD history		
		Unknown			
Implantation of cardiac resynchronization therapy device	Implantation of a CRT device during current encounter. A CRT device is a biventricular pacemaker that sends electrical signals to both ventricles that resynchronize the heart chambers and help it pump more effectively. It may or may not have an atrial pacing wire.	• CRT or CRT-P • CRT-D, CRT with ICD • His bundle pacing • Multisite pacing • No • Unknown			

(*Continued*)

Appendix 7. Continued

B. Electrophysiological Procedures (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		CRT or CRT-P	CRT device is a biventricular pacemaker that sends electrical signals to both ventricles that resynchronizes the heart chambers and helps it pump more effectively. It may or may not have an atrial pacing wire. CRT-P has the pacing function in addition to resynchronization but does not entail defibrillator function.		
		CRT-D, CRT with ICD	CRT-D also incorporates the additional function of an ICD, to quickly terminate an abnormally fast, life-threatening heart rhythm.		
		His bundle pacing	A transvenous pacemaker system that can produce normal physiological ventricular activation with a lead positioned on the His bundle		
		Multisite pacing			
		No			
		Unknown			

CRT indicates cardiac resynchronization therapy; CRT-D, cardiac resynchronization therapy defibrillator; CRT-P, cardiac resynchronization therapy pacemaker; and ICD, implantable cardioverter-defibrillator.

C. Percutaneous Interventional Procedures

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
PCI	Refer to the 2020 AHA/ACC Key Data Elements and Definitions for Coronary Revascularization	• Yes • No • Unknown		Dehmer GJ, Badhwar V, Bermudez EA, et al. 2020 AHA/ACC key data elements and definitions for coronary revascularization: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Clinical Data Standards for Coronary Revascularization). Circ Cardiovasc Qual Outcomes. 2020;13:e000059.[21]	
TAVR performed	Percutaneous TAVR performed for aortic stenosis	• Yes • No • Unknown			
TMV repair performed	Percutaneous TMV repair for patients with HF symptoms and moderate-to-severe or severe MR due to a secondary or functional MR	• Yes • No • Unknown			
Type of device used for TMV repair	Type of device designed to reduce MR	• MitraClip • Other			

(*Continued*)

Appendix 7. Continued

C. Percutaneous Interventional Procedures (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		MitraClip	Device that reduces mitral regurgitation by attaching a clip to connect the middle edges of the anterior and posterior mitral leaflets		
		Other			
Transcatheter tricuspid valve repair procedure performed	Percutaneous transcatheter tricuspid valve repair for tricuspid regurgitation	• Yes • No • Unknown			

HF indicates heart failure; MR, mitral regurgitation; PCI, percutaneous coronary intervention; TAVR, transcatheter aortic valve replacement; and TMV, transcatheter mitral valve.

D. Circulatory/Ventilatory Support

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Percutaneous MCS	Use of percutaneously inserted devices and/or catheters intended to provide varying degrees of hemodynamic support to the left, right, or both ventricles temporarily as a bridge to recovery, decision, VAD implantation, or transplantation	• IABP • VA-ECMO • TandemHeart • Microaxial flow pump (eg, Impella) • None • Unknown			
		IABP	Intra-aortic balloon pump: A medical device that increases myocardial oxygen perfusion while at the same time increasing cardiac output	NCI Thesaurus Code: C100087[25]	
		VA-ECMO	Extracorporeal membrane oxygenation. In VA-ECMO, a venous cannula is usually placed in the right or left common femoral vein for extraction, and an arterial cannula is usually placed into the right or left femoral artery for infusion, with an oxygenator between the extraction and infusion cannulae.		
		TandemHeart	TandemHeart provides ventricular support via a left atrial-to-femoral artery bypass system comprising a transseptal cannula, arterial cannulae, and a centrifugal blood pump. The inflow cannula aspirates oxygenated blood from the left atrium. Blood is then pumped into the femoral artery.		
		Microaxial flow pump (eg, Impella)	A microaxial flow pump provides temporary ventricular support by pulling blood from the left ventricle through an inlet area near the tip and expels blood into the ascending aorta.		
		None			
		Unknown			

(*Continued*)

Appendix 7. Continued

D. Circulatory/Ventilatory Support (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Mechanical ventilatory support	Mechanical ventilation, or assisted ventilation, is the medical term for artificial ventilation where mechanical means are used to assist or replace spontaneous breathing.	• Mechanical ventilation • CPAP • BiPAP • Adaptive servo-ventilation • None			
		Mechanical ventilation	Mechanical ventilation technique is a life-sustaining technique through which gas is moved toward and from the lungs through an external device connected directly to the patient.		
		CPAP	Continuous positive airway pressure/power is a form of positive airway pressure ventilator, which applies mild air pressure on a continuous basis to keep the airways continuously open in patients who are able to breathe spontaneously on their own but need help keeping their airway unobstructed.		
		BiPAP	Bilevel positive airway pressure is a noninvasive form of therapy in which positive air pressure is higher during inspiration and lower during expiration.		
		Adaptive servo-ventilation	Positive airway pressure therapy in which air pressure target is adjusted according to the patient's breathing patterns		In patients with NYHA class II–IV HFrEF and central sleep apnea, adaptive servo-ventilation causes harm.[9]
		None			

BiPAP indicates bilevel positive airway pressure; CPAP, continuous positive airway pressure; CRT, cardiac resynchronization therapy; HF, heart failure; HFrEF, heart failure with reduced ejection fraction; IABP, intra-aortic balloon counterpulsation; MCS, mechanical circulatory support; NCI, National Cancer Institute; NYHA, New York Heart Association; VAD, ventricular assist device; and VA-ECMO, veno-arterial extracorporeal membrane oxygenation.

Appendix 8. Pharmacological Therapy

A. Therapies for Heart Failure

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Loop diuretic	Patient has been prescribed a loop diuretic such as furosemide, torsemide, or bumetanide.	• Yes • No • Unknown			
Total daily dose of loop diuretic	Total daily dose of loop diuretic	• Numeric, furosemide equivalents			
Metolazone	Patient has been prescribed metolazone.	• Yes • No • Unknown			
Total daily dose of metolazone	Total daily dose of metolazone	• Numeric, mg/d			
Other thiazide-like diuretic	Patient has been prescribed a thiazide-like diuretic other than metolazone, such as hydrochlorothiazide, indapamide, or chlorthalidone.	• Yes • No • Unknown			
Total daily dose of other thiazide-like diuretic	Total daily dose of other thiazide-like diuretic	• Numeric, mg/d			
Aldosterone inhibitor (mineralocorticoid receptor antagonist)	Patient has been prescribed a mineralocorticoid receptor antagonist or aldosterone inhibitor such as spironolactone or eplerenone.	• Yes • No • Unknown			
Total daily dose of aldosterone inhibitor	Total daily dose of mineralocorticoid receptor antagonist or aldosterone inhibitor such as spironolactone or eplerenone	• Numeric, mg/d			
ACE inhibitor medication	Patient has been prescribed an ACE inhibitor, which is a substance that inhibits ACE, an enzyme that catalyzes the conversion of angiotensin I to angiotensin II. Inhibition of ACE results in a reduction in angiotensin II and angiotensin II-induced aldosterone secretion, causing vasodilation and natriuresis.	• Yes • No • Unknown		NCI Thesaurus Code: C247[25]	
Total daily dose of ACE inhibitor	Total daily dose of ACE inhibitor	• Numeric, mg/d			
ARB medication	Patient has been prescribed an ARB medication, which is a class of agents that act by selectively inhibiting angiotensin II receptor activation in the renin-angiotensin-aldosterone system. ARBs bind to and block the activation of AT1 receptors, thereby reducing production and secretion of aldosterone, among other actions. The combined effects result in reduction of blood pressure. They are primarily used for the treatment of hypertension or HF in cases where the patient is intolerant of ACE inhibitor therapy.	• Yes • No • Unknown		NCI Thesaurus Code: C66930[25]	
Total daily dose of ARB	Total daily dose of ARB	• Numeric, mg/d			
ARNi	Patient has been prescribed an ARNi (sacubitril/valsartan)	• Yes • No • Unknown			

(*Continued*)

Appendix 8. Continued

A. Therapies for Heart Failure (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Total daily dose of ARNi	Total daily dose of ARNi	• Numeric, mg/d			
Beta-adrenergic antagonist (beta blocker) medication	Patient has been prescribed a guideline-directed beta-adrenergic antagonist (beta blocker) medication for the indication of HF with reduced EF.	• Bisoprolol • Carvedilol • Metoprolol succinate • Other • No • Unknown		Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2013;128:e240-327.[24]	
Total daily dose of beta blocker	Total daily dose of beta-blocker medication	• Numeric, mg/d			
Ivabradine	Patient has been prescribed ivabradine, a drug with negative chronotropic effect on the sinoatrial node, slowing the heart rate.	• Yes • No • Unknown			
Total daily dose of ivabradine	Total daily dose of ivabradine	• Numeric, mg/d			
Digoxin	Patient has been prescribed digoxin, a medication isolated from digitalis, a substance that enhances cardiac contractility.	• Yes • No • Unknown		NCI Thesaurus Code: C28990[25]	
Total daily dose of digoxin	Total daily dose of digoxin	• Numeric, mg/d			
Oral nitrate therapy	Patient has been prescribed oral nitrates such as isosorbide dinitrate or mononitrate.	• Yes • No • Unknown			
Total daily dose of oral nitrate therapy	Total daily dose of nitrate	• Numeric, mg/d			
Hydralazine	Patient has been prescribed hydralazine.	• Yes • No • Unknown			
Total daily dose of hydralazine	Total daily dose of hydralazine	• Numeric, mg/d			
Fixed-dose combination of isosorbide dinitrate and hydralazine	Patient has been prescribed a prepared fixed-dose combination of isosorbide dinitrate and hydralazine.	• Yes • No • Unknown			
Total daily dose of hydralazine/isosorbide dinitrate combination	Total daily dose of hydralazine/isosorbide dinitrate	• Numeric, mg/d			
Intravenous inotropic agent	Intravenous positive inotropic agents are a group of medicines that stimulate and increase the force of contraction of the heart muscle.	• Milrinone • Dobutamine • Norepinephrine • Epinephrine • Dopamine • Other • None			

(*Continued*)

Appendix 8. Continued

A. Therapies for Heart Failure (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Milrinone	Milrinone is a phosphodiesterase 3 inhibitor that works to increase the heart's contractility and decrease pulmonary vascular resistance.		
		Dobutamine	Dobutamine is a direct-acting inotropic agent whose primary activity results from stimulation of the beta receptors of the heart while producing comparatively mild chronotropic, hypertensive, arrhythmogenic, and vasodilative effects.		
		Norepinephrine	Norepinephrine is a sympathomimetic amine that increases blood pressure and enhances ventricular contractility.		
		Epinephrine	Epinephrine, when injected into an intravenous fluid solution, increases blood pressure, coronary artery pressure, thereby promoting increased coronary blood flow and ventricular contractility.		
		Dopamine	Dopamine at low doses acts through the sympathetic nervous system to increase heart muscle contraction force and heart rate, thereby increasing cardiac output and blood pressure; at higher doses, causes vasoconstriction that further increases blood pressure.		
		Other			
		None			
Intravenous vasodilator agents	Intravenous vasodilators, medicines that dilate blood vessels, are administered.	• Nitroglycerin (intravenous) • Nitroprusside (intravenous) • Nesiritide (intravenous) • None • Unknown			
		Nitroglycerin (intravenous)	Nitroglycerin belongs to the group of medicines called nitrates. It works by relaxing the blood vessels and increasing the supply of blood and oxygen to the heart while reducing its workload.		
		Nitroprusside (intravenous)	Nitroprusside is a strong vasodilator that works by relaxing the muscles in blood vessels, and results in reduction in systemic vascular resistance.		

(*Continued*)

Appendix 8. Continued

A. Therapies for Heart Failure (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Nesiritide (intravenous)	Nesiritide is the recombinant form of the 32-amino acid human B-type natriuretic peptide, which is normally produced by the ventricular myocardium. Nesiritide works to facilitate cardiovascular fluid homeostasis through counter-regulation of the renin–angiotensin–aldosterone system, stimulating cyclic guanosine monophosphate, leading to smooth muscle cell relaxation.		
		None			
		Unknown			
Intravenous iron infusion	A procedure in which iron is delivered to the body intravenously	• Yes • No • Unknown			
Oxygen therapy	Patient has been prescribed oxygen by nasal cannulae or chronic use.	• Yes (if yes, specify L/min) • No • Unknown			
Antiarrhythmic agent	Antiarrhythmic drug administered. As antiarrhythmics other than amiodarone are generally contraindicated in patients with HF, specific indications for their use should be noted.	• Amiodarone • Other antiarrhythmic agent • No • Unknown			
		Amiodarone	Amiodarone is a class III antiarrhythmic agent that prolongs phase 3 of the cardiac action potential, the repolarization phase where there is normally decreased calcium permeability and increased potassium permeability.		
		Other antiarrhythmic agent			
		No			
		Unknown			
Calcium channel blockers	Calcium channel blockers administered. As calcium channel blockers are generally contraindicated in patients with HF, specific indications for their use should be noted.	• Verapamil • Diltiazem • Amlodipine • Other • None • Unknown			
SGLT-2 inhibitor	SGLT-2 inhibitor administered	• Canagliflozin • Dapagliflozin • Empagliflozin • Ertugliflozin • None • Unknown			
Total daily dose of SGLT-2 inhibitor	Total daily dose of SGLT-2 inhibitor	• Numeric, mg/d			
Soluble guanylate cyclase stimulator	Soluble guanylate cyclase stimulator administered	• Riociguat • Vericiguat • None • Unknown			

(*Continued*)

Appendix 8. Continued

A. Therapies for Heart Failure (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Myosin activator	Myosin activator administered	• Omecamtiv mecarbil • Other • Unknown			
Lipid-lowering agent	Lipid-lowering agent administered	• Statin • Fibrate • Ezetimibe • Bile acid sequestrant • PCSK-9 inhibitor • Bempedoic acid • Icosapent ethyl • Other • None • Unknown			
		Statin	The statins (or HMG-CoA reductase inhibitors) are a class of drugs that lower cholesterol levels in people by inhibiting the enzyme HMG-CoA reductase, which is the rate-limiting enzyme of the mevalonate pathway of cholesterol synthesis.		
		Fibrate	Fibrates, used in accessory therapy in hypertriglyceride-mia, stimulate peroxisome PPAR-alpha, which controls the expression of gene products that mediate the metabolism of triglycerides and HDL.		
		Ezetimibe	Ezetimibe inhibits the absorption of cholesterol from the small intestine and decreases the amount of cholesterol normally available to liver cells, leading them to absorb more from circula-tion, thus lowering levels of circulating cholesterol.		
		Bile acid sequestrant	The bile acid sequestrants are a group of resins used to bind certain components of bile in the gastrointestinal tract. They disrupt the en-terohepatic circulation of bile acids by combining with bile constituents and prevent-ing their reabsorption from the gut.		
		PCSK-9 inhibitor	Enzyme that binds to LDL receptors, which stops LDL being removed from the blood, leading to an increase in blood levels of LDL		
		Bempedoic acid	Bempedoic acid decreases LDL cholesterol by inhibiting ATP-citrate lyase.		
		Icosapent ethyl	A type of omega-3 fatty acid used as an adjunctive therapy to decrease serum triglyceride levels.		

(*Continued*)

Appendix 8. Continued

A. Therapies for Heart Failure (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Other			
		None			
		Unknown			
Aspirin	Patient has been prescribed aspirin.	• Yes • No • Unknown			
Total daily dose of aspirin	Total daily dose of aspirin	• Numeric, mg/d			
P2Y12 inhibitor	Patient has been prescribed a nonaspirin P2Y12 inhibitor such as clopidogrel, ticagrelor, or prasugrel as an antiplatelet agent.	• Yes • No • Unknown			
Total daily dose of P2Y12 inhibitor	Total daily dose of P2Y12 inhibitor	• Numeric, mg/d			
Warfarin	Patient has been prescribed warfarin (anticoagulant). Target INR may also be helpful to collect.	• Yes • No • Unknown			
DOAC	Patient has been prescribed a DOAC such as rivaroxaban, apixaban, dabigatran, or edoxaban.	• Yes • No • Unknown			
Total daily dose of DOAC	Total daily dose of DOAC	• Numeric, mg/d			
Heparin	Patient has been prescribed heparin. Type of heparin may be specified.	• Unfractionated heparin • Low-molecular-weight heparin • No • Unknown			
Antidepressants	Patient has been prescribed an antidepressant.	• Yes • No • Unknown			
Female hormone replacement therapy	Patient has been prescribed female hormone replacement therapy.	• Yes • No • Unknown			
Inhaled bronchodilator	Patient has been prescribed an inhaled bronchodilator.	• Yes • No • Unknown			
NSAID	Patient has been prescribed a NSAID	• Yes • No • Unknown			
Nonprescription treatments	Nonprescription treatment used by the patient	• Vitamins • Food supplements • Homeopathic treatment • Other			

ACE indicates angiotensin-converting enzyme; ARB, angiotensin receptor blocker; ARNi, angiotensin receptor blocker with neprilysin inhibitor, AT1, angiotensin II type 1; DOAC, direct oral anticoagulant; EF, ejection fraction; HDL, high-density lipoprotein; HF, heart failure; INR, international normalized ratio; IV, intravenous; LDL, low-density lipoprotein; NCI, National Cancer Institute; NSAID, nonsteroidal anti-inflammatory drug; PCSK-9, proprotein convertase subtilisin/kexin type 9; PPAR-alpha, peroxisome proliferator-activated receptor-alpha; and SGLT-2, sodium-glucose cotransporter-2.

Appendix 8. Continued

B. Medication Allergy/Side Effects

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Medication causing allergy	Medication that causes an allergic reaction in the patient	• Name of medication			Specify allergic reaction and date.
Medication causing side effect	Medication that causes a side effect in the patient. Date of side effect and/or medication discontinuation may be specified.	• Name of medication			Specify side effect and date.

Appendix 9. End of Life Management

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Limitation of resuscitation	Any documented order or decision regarding patient request to limit a component of emergency therapy to restore circulation or ventilation (eg, no intubation, no chest compressions)	• Yes • No • Unknown			
DNR	Explicit documentation by healthcare provider and/or patient indicating that no resuscitative efforts are to be performed in the event of circulatory or respiratory arrest	• Yes • No • Unknown			
Inactivation of ICD defibrillation mode	Documentation of inactivation of ICD defibrillation mode without plans to reactivate (excludes inactivation for specific surgical procedures)	• Yes • No • Unknown			
Advance care planning	Documentation of discussion carried out with the patient and/or family (by healthcare provider or social worker) about advance directive	• Yes • No • Unknown			Advance directive is defined as documentation in the medical record that the patient has an advance directive. An advance directive is instructions given by individuals specifying what actions should be taken for their health in the event that they are no longer able to make decisions due to illness or incapacity, and therefore appoints a person to make such decisions on their behalf.
Medical order for life-sustaining treatment	A written medical order by a physician, advanced practice registered nurse, or physician's assistant that records a patient's treatment preferences	• Yes • No • Unknown			

DNR indicates do not resuscitate; and ICD, implantable cardioverter-defibrillator.

Appendix 10. Patient Education

A. Assessment of Status: Assessment of Learning Readiness

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/ Source of Definition	Additional Notes
Presence of cognitive impairment	Documentation in the medical record that patient is cognitively impaired. Documentation may take the form of a qualitative statement (eg, dementia) or a score on a formal mental status assessment.	• Yes • No • Unknown			
Low literacy skills	Documentation in the medical record that the patient does not read or write well or is unable to read or write	• Yes • No • Unknown			
Language skills	Documentation in the medical record of the patient's preferred language for communication	• Yes • No • Unknown			
Visual disturbances	Documentation in the medical record that the patient has impaired sight (eg, blindness, partial blindness, macular degeneration)	• Yes • No • Unknown			
Hearing impairment (uncorrected)	Documentation in the medical record that the patient has an uncorrected hearing impairment	• Yes • No • Unknown			
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 "Medical History: Noncardiovascular.")	• Yes • No • Unknown			
Anxiety	Documentation in the medical record that the patient carries the diagnosis of anxiety, or that the patient demonstrates high levels of anxiety	• Yes • No • Unknown			
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.	• Good • Adequate • Inadequate • Unknown			
Medication adherence history	History confirming adherence to medication regimen in the past	• Yes • No • Unknown			
Nutrition history	History confirming adherence to instructions regarding adequate nutrition	• Yes • No • Unknown			
Low-sodium diet history	History confirming adherence to dietary sodium restriction	• Yes • No • Unknown			
Low-fat diet history	If patient has hyperlipidemia, history confirming adherence to low-fat diet	• Yes • No • Unknown • Not applicable			
Diabetic diet history	If patient has diabetes mellitus, history confirming adherence to diabetic diet	• Yes • No • Unknown • Not applicable			
Weight-loss diet history	If patient is obese, history confirming adherence to weight loss diet and/ or other interventions (eg, counseling)	• Yes • No • Unknown • Not applicable			
Smoking cessation history	If a current smoker, has the patient undergone smoking cessation counseling in the past?	• Yes • No • Unknown			
Alcohol abstinence history	History confirming adherence to alcohol abstinence, if patient has history of alcohol abuse	• Yes • No • Unknown			

(*Continued*)

Appendix 10. Continued

A. Assessment of Status: Assessment of Learning Readiness (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/ Source of Definition	Additional Notes
Illicit drug history	History confirming adherence to abstinence from illicit drug abuse, if patient has a history of illicit drug abuse	• Yes • No • Unknown			
Activity level history	History confirming adherence to activity level and exercise program	• Yes • No • Unknown			
Daily weight history	History confirming adherence to self-monitoring of daily weight	• Yes • No • Unknown			
Daily blood pressure/heart rate history	History confirming adherence to self-monitoring of daily blood pressure and heart rate	• Yes • No • Unknown			

B. Intervention and Referral: Education/Counseling Intervention to Promote Self-Care

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/ Source of Definition	Additional Notes
Medication instruction	Verbal and written medication instructions provided to patient and/or family	• Yes • No • Unknown			
Recognition of worsening symptoms	Verbal and written instructions provided to patient and/or family (by healthcare provider) regarding worsening of symptoms and when to call the healthcare provider. Patients should be instructed to assess symptoms with activity versus at rest.	• Yes • No • Unknown			
Weight counseling	May include any or all of the following elements:	• Verbal/written instructions regarding how to monitor/ record daily weight • Target weight • Instructions on using a scale • Instructions on what to do when weight increases, including parameters for seeking immediate help • Written weight record • Daily self-assessment for edema • Counseling regarding fluid restriction			
Diet counseling pertinent to lowering cardiovascular risk	Advice given or discussion carried out with the patient and/or family regarding diet counseling. May include:	• Sodium restriction • Fluid restriction • Other (specify)			
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	• Yes • No • Unknown			
Counseling about illicit drug abuse	Advice given or discussion carried out with the patient and/or family regarding the importance of abstaining from illicit drug use	• Yes • No • Unknown			
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	• Yes • No • Unknown			
Smoking cessation counseling	Advice given or discussion carried out with the patient (by healthcare provider or other personnel) regarding the importance of stopping smoking. May include:	• Counseling (may be basic or advanced) • Written materials • Referral to smoking cessation program • Nicotine replacement therapy			

(*Continued*)

Appendix 10. Continued

B. Intervention and Referral: Education/Counseling Intervention to Promote Self-Care (Continued)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/ Source of Definition	Additional Notes
Immunization counseling	Advice given or discussion carried out with the patient and/or family regarding the importance of obtaining influenza and pneumococcal immunizations	• Yes • No • Unknown			
Diabetes management/ follow-up	Patient provided appropriate follow-up for management and treatment of diabetes.	• Yes • No • Unknown			
Anticoagulation therapy education	Patient provided education on therapies for anticoagulation.	• Yes • No • Unknown			
Outpatient HF management program	Patient referred to outpatient HF management program.	• Yes • No • Unknown			

HF indicates heart failure.

C. Intervention and Referral

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/ Source of Definition	Additional Notes
Referral to dietician for diet counseling	Referral to dietitian for weight management and/or specialized nutritional instruction	• Yes • No • Unknown			
Referral to cardiac rehabilitation program	Referral to cardiac rehabilitation or other structured exercise program (including a home exercise program)	• Yes • No • Unknown			
Plan for follow-up care	Documentation of plan for follow-up care with healthcare provider. Should include the date of follow-up.	• Yes • No • Unknown			
Plan for follow-up visit	Documentation of follow-up evaluation for patients with established HF should include date of next follow-up visit.	• Patient history • Functional status • Current symptoms • Physical examination • Laboratory or other tests			
Patient referral	Patient referred to other care:	• HF specialty clinic • HF transitional care by advanced practice nurses • HF disease management program • Endocrinology for diabetes care • Mental health provider for follow-up of psychosocial/behavioral/cognitive issues • Palliative care • Hospice • Skilled nursing facility • Long-term acute care hospital • Long-term care facility (nursing home) • Evaluation for heart transplant and/or MCS			
Transitional care	Coordination and continuity of health care during a movement from 1 healthcare setting to either another or to home, between healthcare practitioners and settings as their condition and care needs change during the course of a chronic or acute illness	• Home health care • HF nurse case manager • Hospice or palliative care • Home telemonitoring • Ambulatory cardiac telemetric monitoring (eg, mobile cardiac outpatient telemetry) • None • Unknown			

HF indicates heart failure; and MCS, mechanical circulatory support.