## AHA/ACC CLINICAL DATA STANDARDS

2022 AHA/ACC Key Data Elements and Definitions for Cardiovascular and Noncardiovascular Complications of COVID-19: A Report of the American College of Cardiology/ American Heart Association Task Force on Clinical Data Standards

Endorsed by the Heart Failure Society of America and Society for Cardiac Angiography and Interventions

## Writing Committee Members

Biykem Bozkurt, MD, PhD, FACC, FAHA, Chair; Sandeep R. Das, MD, MPH, FACC, FAHA, Vice Chair; Daniel Addison, MD; Aakriti Gupta, MD, MS; Hani Jneid, MD, FACC, FAHA\*; Sadiya S. Khan, MD, MSc, FACC, FAHA; George Augustine Koromia, MD, MMCi; Prathit A. Kulkarni, MD; Kathleen LaPoint, MS†; Eldrin F. Lewis, MD, MPH, FACC, FAHA; Erin D. Michos, MD, MHS, FACC, FAHA; Pamela N. Peterson, MD, MSPH, FACC, FAHA; Mohit K. Turagam, MD, MS, FACC; Tracy Y. Wang, MD, MHS, MSc, FACC, FAHA; Clyde W. Yancy, MD, MSc, MACC, FAHA

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#### \*Task Force liaison. †ACC/AHA staff.

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## **TOP 10 TAKE-HOME MESSAGES**

- This document presents a clinical lexicon comprising data elements related to cardiovascular and noncardiovascular complications of COVID-19 (coronavirus disease-2019). 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, including presentations related to acute COVID-19 in the ambulatory as well as the hospital setting.
- Data elements for COVID-19 diagnoses include confirmed, probable, and suspected acute COVID-19 case definitions. Postacute sequelae of SARS-CoV-2 (severe acute respiratory syndromecoronavirus-2) infection were also included.
- 3. Acute cardiovascular complications related to COVID-19, including acute myocardial injury, heart failure, shock, arrhythmia, thromboembolic complications, and stroke, were defined.
- 4. Data elements related to COVID-19 vaccination status, comorbidities, and preexisting cardiovascular conditions were provided.
- 5. Postacute cardiovascular sequelae of SARS-CoV-2 infection and long-term cardiovascular complications of COVID-19 were defined.
- 6. Data elements for cardiovascular mortality during acute COVID-19 were provided.
- 7. Data elements for noncardiovascular complications were provided to help document severity of

illness and other competing diagnoses and complications that may affect cardiovascular outcomes.

- 8. Symptoms and signs related to COVID-19 and cardiovascular complications were listed.
- 9. Data elements for diagnostic and therapeutic strategies for COVID-19 and cardiovascular conditions were provided.
- 10. Advanced therapies, including mechanical ventilation, extracorporeal membrane oxygenation, and end-of-life management strategies, were provided.

## PREAMBLE

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

Clinical data standards aim to identify, define, and standardize data elements relevant to clinical topics in cardiovascular medicine, with the primary goal of assisting data collection and use by providing a corpus of data elements and definitions applicable to various conditions. Broad agreement on common vocabulary and definitions is needed to pool or compare data from the electronic health records (EHRs), clinical registries, administrative datasets, and other databases and to assess whether these data are applicable to clinical practice and research endeavors. Emerging federal standards, such as the US Department of Health & Human Services. Office of the National Coordinator for Health Information Technology, and the US Core Data for Interoperability support efforts to "promote interoperability" and the more effective use of EHR data to improve health care quality. The purpose of clinical data standards is to contribute to the infrastructure necessary to accomplish the ACC's mission to transform cardiovascular care and improve heart health and the AHA's mission of being a relentless force for a world of longer and healthier lives for all individuals.

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 research
- 2. To facilitate the exchange of data across systems through harmonized, standardized definitions of key data elements

- 3. To facilitate further development of clinical registries, implementable clinical guidelines, quality and performance improvement programs, outcomes evaluations, public reporting, and clinical research, including the comparison of results within and across these initiatives
- 4. To ensure equity across all endeavors related to clinical data standards

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 CVDs and procedures; create a data environment conducive to the implementation of clinical guidelines, 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, procedures, and other topics related to cardiovascular health and medicine that will benefit from the 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 and incorporate additional elements. For example, in the setting of a randomized, clinical trial of a new drug, additional information would likely be required regarding study procedures and medical therapies. Alternatively, if a data set is to be used for quality improvement, safety initiatives, or administrative functions, elements such as Current Procedural Terminology (CPT) codes, International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) codes, or outcomes may be added. The intent of the Task Force is to standardize clinical concepts, focusing on the patient and clinical care and not on administrative billing or coding concepts. The clinical concepts selected for development are commonly cardiovascular specific, where a standardized terminology does not already exist. The clinical data standards can, therefore, serve as a guide to develop 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 envision the administrative codes to follow the lead of the clinical data standards. This approach would allow clinical care to lead standardization of cardiovascular health care terminology.

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 ones. 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 (HIPAA) privacy regulations, which went into effect in April 2003, heightened all health care professionals awareness of our professional commitment to safeguard patients' privacy. HIPAA 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 permission and meeting all relevant privacy sharing requirements. Protected health information may be included in databases used for health care operations under a data use agreement. Research studies using protected health information must be reviewed by an institutional review board. 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 health care team.

In clinical care, health care 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. Harmonizing data elements and definitions across studies facilitates comparisons and enables the conduct of pooled analyses and meta-analyses, thus deepening our understanding of individual study results.

The recent development of quality performance measurement initiatives, particularly those for which the comparison of health care professionals 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 from these comparisons. To understand and compare care patterns and outcomes, the data elements that characterize them must be clearly defined, consistently used, and properly interpreted.

Hani Jneid, MD, FACC, FAHA Chair, ACC/AHA Task Force on Clinical Data Standards

## 1. INTRODUCTION

The Task Force has undertaken the task to standardize the lexicon of cardiovascular medicine. This document provides data standards for cardiovascular and other complications related to COVID-19 infection caused by SARS-CoV-2. Our intent is to provide data elements consistent with current practice guidance and to include updated terminology and attributes in compliance with the methodology of the Task Force<sup>1</sup> and with current policies of the ACC and AHA regarding harmonization of data across organizations and disciplines. There is increased importance of understanding acute and longitudinal impact of COVID-19 on cardiovascular health. Unfortunately, there has not been clarity or consensus on definitions of cardiovascular conditions related to COVID-19. Different diagnostic terminologies are being used for overlapping conditions such as "myocardial injury," "myocarditis," "type II myocardial infarction," "stress cardiomyopathy," or "inflammatory cardiomyopathy."

These data standards will help standardize definitions and set the framework to capture and better understand how COVID-19 impacts cardiovascular health. This document is intended for use by researchers, registry developers, and clinicians and is proposed as a framework for *ICD-10* code development of COVID-19–related cardiovascular conditions.

Specifically, COVID-19 cardiovascular data standards are of great importance to patients, providers, investigators, scientists, administrators, public health officials, policy makers, and payers. The ACC/AHA Writing Committee on Clinical Data Standards for COVID-19 (writing committee) envisions these data elements would be useful in the following broad additional categories:

- Communication with patients
- Inpatient and outpatient clinical programs
- Clinical registries
- Basic and translational research programs
- Clinical research, particularly where eventual pooled analysis or meta-analysis is anticipated
- Public health organizations
- Organization and design of electronic medical information initiatives, such as EHRs, pharmacy databases, computerized decision support, and cloud technologies
- Public health policy, health insurance coverage, and legislation development
- Health system administrators for estimation of necessary resources such as protective personal equipment (PPE), testing, space and

staffing needs, isolation, sanitation, or quarantine requirements

 Alternative models of health care such as telemedicine, virtual visits, and point-of-care diagnostic platforms.

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

## **1.1. Special Considerations**

In this document, data elements were not differentiated for specific encounters, such as for inpatients versus outpatients, dates of encounter, number of encounters, baseline or repeated data elements. Databases can be built and customized according to users' needs to capture such information. The intent of this writing committee was not to provide recommendations regarding COVID-19 treatment, and the writing committee recommends that readers follow prevailing COVID-19 management guidelines.

#### 1.2. Abbreviations

Abbreviation	Meaning/Phrase
ACE	angiotensin-converting enzyme
ACS	acute coronary syndrome
ARB	angiotensin receptor blocker
CDC	Centers for Disease Control and Prevention
COVID-19	coronavirus disease-2019
CPT	Current Procedural Terminology
CT	computed tomography
CVD	cardiovascular disease
ECMO	extracorporeal membrane oxygenation
EHR	electronic health record
HIPAA	Health Insurance Portability and Accountability Act
ICD-10-CM	International Classification of Diseases, 10th Revision, Clinical Modification
MIS	multisystem inflammatory syndrome
MRI	magnetic resonance imaging
NCDR	National Cardiovascular Data Registry
PASC	postacute sequelae of SARS-CoV-2 infection
PPE	protective personal equipment
SARS-CoV-2	severe acute respiratory syndrome-coronavirus-2

## 2. METHODOLOGY

## 2.1. Writing Committee Composition

The Task Force selected the members of this writing committee. The writing committee consisted of 15 individuals with domain expertise in cardiomyopathy, infectious disease, CVD, myocarditis, cardiovascular registries, outcomes assessment, medical informatics, health information management, and health care 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 because of personal, professional, or business interests or relationships of any member of the writing committee. Specifically, all members of the writing committee were required to disclose all such relationships that could be perceived as real or potential conflicts of interest in writing. The included documentation was updated when any 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 in a Supplemental Appendix. 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 for this manuscript. The primary sources of information were the "Infectious Diseases Society of America Guidelines on the Treatment and Management of Patients with COVID-19,"<sup>2</sup> NIH COVID-19 Treatment Guidelines,<sup>3</sup> data definitions from the US Centers of Disease Control and Prevention (CDC), and previous Task Force publications. 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 in as many contexts as possible. As necessary, the writing committee identified contexts where individual terms required differentiation according to their proposed use (ie, research/regulatory vs. clinical care contexts).

This publication was developed to serve as a common lexicon and base infrastructure by end users to augment work related to standardization and health care interoperability including, but not limited to, structural, administrative, and technical metadata development. The resulting appendixes (Appendixes 3 to 10) list the data element in the first column, followed by the clinical definition of the data element. The allowed responses ("permissible values") for each data element in the next column are the acceptable means of recording this 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 previously published in reference documents.

## 2.5. Consensus Development

The Task Force established the writing committee as described in the Task Force's methodology paper.<sup>1</sup> The primary responsibility of the writing committee was to aggregate existing information relevant to the care of patients with CVD from external sources, such as society guidelines and existing COVID-19 data elements from the National Cardiovascular Data Registry (NCDR)<sup>4</sup> and AHA COVID-19 Registry.<sup>5</sup> The work of the writing committee was accomplished via a series of virtual 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 3 to 10. All members reviewed and approved the final lexicon.

## 2.6. Relation to Other Standards

The writing committee reviewed the available published data standards, including relevant data dictionaries from registries. 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

The "2022 AHA/ACC Key Data Elements and Definitions for Cardiovascular and Noncardiovascular Complications of COVID-19" was reviewed by official reviewers nominated by the ACC and AHA. To increase its applicability, the document was posted on the ACC and AHA websites for a 30-day public comment period. This document was approved by the ACC Clinical Policy Approval Committee and the AHA Science Advisory and Coordinating Committee in February 2022, and the AHA Executive Committee in March 2022. 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.

## **3. DATA ELEMENTS AND DEFINITIONS**

The writing committee explicitly elected not to include patient identification, demographic, and administrative information, such as patient sex or site of service, diagnosis, and other fundamental concept terms, including data by specific medication, as defined data elements. Comprehensive EHR solutions are anticipated to collect this information as discrete data. Furthermore, a robust solution for patient identification (eg, the unique patient identifier) is a universal requirement, whether within the context of the EHR of an individual practice or the registry aggregation of information across multiple disparate inpatient and ambulatory encounters.

## 3.1. Patient Demographics Including Age, Sex, Race, Ethnicity, and Social Determinants of Health

Patient age, sex, race, ethnicity, and social determinants of health are key elements in risk of infection and outcomes for COVID-19. Age, sex, race, and ethnicity are expected to be available in all EHR solutions and therefore have not been listed. We recognize the critical importance of social determinants of health, including race/ethnicity and sex, to COVID-19 and its outcomes and would like to emphasize that these variables should be captured. The Task Force has commissioned a separate data standards document to address social determinants of health for overall CVD, which we expect to be pertinent and complementary to this document, in addition to other documents published and being developed.<sup>6</sup>

## 3.2. COVID-19 Diagnosis

Appendix 3 provides definitions for the diagnosis of COVID-19. A case of COVID-19 can be confirmed, probable, or suspected based on definitions from the CDC.<sup>7</sup> A person with COVID-19 might be symptomatic or asymptomatic. Other categories of COVID-19 diagnosis provided include postacute sequelae of SARS-CoV-2 infection (PASC) (also termed "postacute COVID-19 syndrome" or "long COVID" in the literature); persons with COVID-19 who continue to have persistently positive molecular or antigen tests after the end of their isolation period; multisystem inflammatory syndrome (MIS), a rare postinfectious inflammatory condition; prior COVID-19;

and COVID-19 reinfection. The category of COVID-19 reinfection is divided into reinfection with best evidence, moderate evidence, and poor evidence, as outlined by the CDC.<sup>8</sup> Other data elements included in this section are date of diagnosis of acute COVID-19, whether a patient was hospitalized for COVID-19 specifically or was found to have incidental SARS-CoV-2 infection at the time of hospitalization for another cause, and dates of initial hospitalization. A category also exists for exposure to someone with COVID-19 during their infectious period, with criteria based on CDC recommendations.

## 3.3. COVID-19 Cardiovascular Complications

Patients with underlying cardiovascular risk factors or established CVD are at greater risk for severe presentations of COVID-19. COVID-19 can also confer significant cardiovascular morbidity and mortality in patients with or without prior CVD. Approximately 10% to 20% of hospitalized patients can have evidence of myocardial injury in the setting of COVID-19.9 Proposed mechanisms include activation of inflammatory and thrombotic cascades, direct viral injury to myocytes or vascular endothelium, and worsening of underlying baseline atherosclerotic and structural abnormalities. Acute cardiovascular presentations are varied and include myocardial injury, myocarditis, acute coronary syndrome (ACS), heart failure, cardiogenic shock, arrhythmia, thromboembolic and cerebrovascular complications, and cardiac involvement and coronary artery ectasia in the setting of MIS in children (MIS-C). COVID-19 can trigger acute heart failure or cardiogenic shock. New-onset left ventricular systolic dysfunction is hypothesized to be related to myocarditis, endothelial and microvascular injury, myocardial stress in the setting of increased myocardial demand and reduced myocardial oxygenation in the setting of hypoxia, myocardial inflammation, and proinflammatory cytokine surge.<sup>10</sup> New-onset right ventricular dysfunction can result from acute pulmonary embolism or strain from acute respiratory distress syndrome and elevated pulmonary artery pressures. Both atrial and ventricular arrhythmias have been noted.<sup>10</sup> COVID-19 is associated with an increased risk of stroke, transient ischemic attack, and venous and arterial thromboembolic events.<sup>10</sup> Appendix 4A summarizes the more common acute cardiovascular presentations and lists of standard data elements that describe these presentations.

A significant proportion of patients may experience long-term complications of SARS-CoV-2 infection ≥4 weeks from the index infection, sometimes called postacute COVID-19 syndrome.<sup>11-13</sup> Long-term cardiovascular sequelae of COVID-19 may include chest pain, palpitations, inappropriate sinus tachycardia, postural orthostatic tachycardia syndrome, atrial arrhythmia, cardiomyopathy, and thromboembolism.<sup>14-16</sup> Possible

mechanisms for long-term cardiovascular complications of COVID-19 include direct and indirect viral-mediated cellular damage, procoagulant state, the immunologic response affecting the structural integrity of the myocardium, pericardium, and conduction system, and downregulation of angiotensin-converting enzyme-2 (ACE2).<sup>17-19</sup> Myocardial abnormalities and injury have been reported on magnetic resonance imaging (MRI), and cardiac troponin elevations have occurred in some patients >2 months after diagnosis of COVID-19.20 Myocardial fibrosis or scar associated with cardiomyopathy from viral infection can lead to arrhythmias.<sup>21</sup> The risk for occurrence of thromboembolic complications in the postacute COVID-19 phase is possibly associated with the duration and severity of hyperinflammatory state.<sup>13</sup> Standard data elements that describe the long-term cardiovascular complications of COVID-19 are summarized in Appendix 4B, and data elements pertaining to cardiovascular mortality from COVID-19 are summarized in Appendix 4C.

## 3.4. COVID-19 Noncardiovascular Complications

Appendix 5 defines the broad range of noncardiovascular complications that can occur in a probable or confirmed case of COVID-19. SARS-CoV-2 is primarily a respiratory virus that infects the upper airway and, in severe cases, can progress into a lower airway infection (pneumonia), progressive respiratory failure (acute respiratory distress syndrome), and many other systemic complications. It is uncertain whether extrapulmonary cardiovascular, as well as noncardiovascular, complications are related to indirect injury caused by systemic inflammation or to direct viral tissue damage, or both. Shock and multiorgan failure observed in severe cases of COVID-19 may be related to septic shock, cytokine storm, cardiogenic shock, obstructive shock, or mixed distributive combined with cardiogenic shock. In addition to lung and heart complications, COVID-19 can contribute to renal, hepatic, hematologic, and neurological complications. Pregnant women with COVID-19 have been identified by the CDC to be at increased risk for severe illness, and COVID-19 may be associated with pregnancy loss and other adverse pregnancy outcomes. Many other noncardiovascular symptoms during COVID-19 have been noted and include microvascular thrombosis, thrombophilia, cerebral venous thrombosis, anosmia, ageusia, rhabdomyolysis, peripheral neuropathy, gastrointestinal symptoms, de novo or acute worsening of chronic hyperglycemia, ocular symptoms, encephalopathy, skin changes, and livedo reticularis.

## 3.5. Symptoms and Signs

Appendix 6 outlines and defines common cardiovascular and noncardiovascular symptoms in patients with COVID-19, as well as an abbreviated list of physical examination findings. Symptom data elements may be derived from structured variables within the EHR (eg, chief complaint or problem list), as components of patient-reported outcomes in applied survey instruments, or as free text within clinical source documents. Because COVID-19 physical examination findings are less uniformly captured, this list focuses on signs related to potential acute cardiovascular complications from COVID-19. Future research on the postacute COVID-19 syndrome will elucidate important persistent or postacute symptoms and signs of relevance.

Although the signs and symptoms of SARS-CoV-2 infection in children may be similar to those in adults, many children are asymptomatic or may have only a few symptoms. The most common signs and symptoms of COVID-19 in hospitalized children are fever, nausea/vomiting, cough, shortness of breath, and upper respiratory symptoms.<sup>3</sup> Although the true incidence of asymptomatic SARS-CoV-2 infection is unknown, asymptomatic infection was reported in up to 45% of children who underwent surveillance testing at the time of hospitalization for a non-COVID-19 indication.<sup>3</sup> SARS-CoV-2 has been associated with a potentially severe inflammatory syndrome in children (MIS-C) and young adults (MIS-A) (Appendix 3).

## 3.6. Diagnostic Procedures

As discussed previously, COVID-19 may result in a number of cardiovascular complications. The approach to these complications can involve a number of standard diagnostic procedures. Laboratory testing, including cardiac troponin, natriuretic peptide levels, complete metabolic profile, blood cell counts, coagulation parameters, and inflammatory biomarkers, can be helpful. Electrocardiography is used to identify rhythm and conduction abnormalities. Echocardiography is the most common means of assessing left ventricular ejection fraction, right ventricular function, wall motion abnormalities, and pulmonary artery systolic pressure. Other imaging procedures such as MRI may be used to assess myocardial involvement (ie, myocarditis, myocardial wall edema, myocardial fibrosis and scar), as well as other structural abnormalities and ventricular function. Several imaging techniques, including computed tomography (CT), nuclear, and coronary angiography, may be used to evaluate for obstructive coronary disease. Coronary angiography can be used to evaluate for ACS. Chest x-ray is first line for evaluating acute lung processes, and chest CT angiography may be used to further define or to evaluate for pulmonary embolus. Right heart catheterization may be used to diagnose cardiogenic shock, evaluate filling pressures, or evaluate pulmonary pressures. Venous and arterial thromboses are known to occur and can often be identified by ultrasonography, vascular, or nuclear

imaging. In the case of arterial thrombosis and stroke, CT and MRI are used to define the extent and nature (ischemic vs. hemorrhagic). Appendix 7 summarizes the more common diagnostic procedures and lists standard data elements that describe the diagnostic procedures and potential findings.

## 3.7. Pharmacological Therapy

A growing body of available evidence primarily supports the continuation of traditional cardiovascular therapies, including ACE inhibitors and angiotensin receptor blockers (ARBs).<sup>22-25</sup> These agents, as well as most other cardiovascular therapeutics, do not appear to confer an increased risk of acquiring SARS-CoV-2 infection.<sup>26,27</sup> Large multicenter studies have demonstrated no difference in infection or mortality associated with ACE inhibitors, ARB, or any other cardiovascular therapies (antihypertensives in most cases) when continued after development of COVID-19.<sup>22-24</sup> Appendix 8A summarizes the more common cardiovascular therapies and provides definitions for their associated data elements.

The clinical manifestations of COVID-19 can range from asymptomatic or mild respiratory disease to severe, life-threatening respiratory and hemodynamic failure. Supportive therapies are a common part of the management strategy for treatment of COVID-19. In addition to therapies used for direct antiviral activity (eq, remdesivir), other interventions (eg, proning) or medications without direct antiviral activity (eg, steroids) can be used in selected patients to decrease the morbidity and mortality associated with COVID-19. In cases of cardiogenic shock and low cardiac output associated with COVID-19, intravenous inotropic and vasopressor agents can be administered as supportive therapies. COVID-19 is also associated with a prothrombotic state and an increased incidence of thromboembolic disease.<sup>28</sup> Prophylactic anticoagulation against venous thromboembolism is recommended.<sup>29</sup> Therapeutic anticoagulation needs to be individualized. In critically ill patients with COVID-19, an initial strategy of therapeutic-dose anticoagulation with heparin did not result in a greater probability of survival to hospital discharge or a greater number of days free of cardiovascular or respiratory organ support than did usual-care pharmacological thromboprophylaxis.<sup>30</sup> However, in noncritically ill patients with COVID-19, an initial strategy of therapeutic-dose anticoagulation with heparin increased the probability of survival to hospital discharge with reduced use of cardiovascular or respiratory organ support compared with usual-care thromboprophylaxis.<sup>31,32</sup> The management of COVID-19 from the standpoint of antiviral and anti-inflammatory agents continues to evolve as new insights are discovered. In addition, although certain supportive strategies have now been shown to be effective in addressing the exaggerated inflammatory response and uncontrolled cytokine release, this remains an ongoing area of active study. Appendix 8C briefly summarizes these supportive therapies and provides definitions for their associated data elements.

Guidance for the treatment of COVID-19 in children is mostly extrapolated from recommendations for adults with COVID-19.<sup>33,34</sup> High-quality studies, including randomized trials, are urgently needed in children and in other special populations.<sup>3</sup> With emerging new variants of SARS-CoV-2, further studies will be needed to better understand the epidemiology, prevention, and treatment of COVID-19.

## 3.8. Preventive, Therapeutic, and Supportive Procedures for COVID-19

COVID-19 vaccinations have been demonstrated to be highly effective and safe in tested populations and confer protection against COVID-19.<sup>35,36</sup> As of February 2022, the CDC recommends vaccination for everyone  $\geq$ 5 years of age. Vaccination prevents not only COVID-19 but also potential cardiovascular complications related to COVID-19.<sup>3738</sup> In addition to vaccinations, wearing face masks, physical distancing, hand hygiene, and compliance with public health guidelines are effective in reducing spread of COVID-19.<sup>39-42</sup>

Comprehensive and reliable capture of data elements pertinent to therapeutic procedures in patients with COVID-19 is important to monitor and assess quality of care of these patients with the goal to improve their outcomes. These include but are not limited to data elements pertinent to ventilation and circulatory support, percutaneous interventional therapies, and electrophysiological procedures (Appendix 9).

Some patients with COVID-19 may experience severe cardiopulmonary complications, which can include acute respiratory distress syndrome, ACS, cardiomyopathy, acute congestive heart failure, cardiogenic shock, isolated respiratory failure, malignant ventricular arrhythmias, and cardiopulmonary arrest.<sup>43</sup> Ventilatory support may range from noninvasive support to mechanical support, depending on severity of hypoxia. COVID-19 can result in renal injury attributable to systemic inflammation, multiorgan failure, and massive release of inflammatory cytokines, resulting in tubular and glomerular cell damage.44 Renal replacement therapy can be considered supportive in those patients without antecedent end-stage kidney disease, for whom these therapies are considered temporary. Some patients may have concomitant cardiogenic shock necessitating mechanical circulatory support, such as intra-aortic balloon pumps to more advanced percutaneous ventricular assist devices, such as Impella or TandemHeart, which unload the left ventricle directly or upstream from the left atrium.<sup>45</sup> Patients with cardiogenic shock unresponsive to vasoactive therapies may require a circulatory support device, such as venoarterial extracorporeal membrane oxygenation (ECMO). In specialized centers, ECMO devices may be used to provide adequate

oxygenation (venovenous ECMO) or cardiac circulatory support (venoarterial ECMO) in patients with advanced cardiac and cardiopulmonary failure.<sup>45</sup>

## 3.9. End-of-Life Management

Patients who experience COVID-19 can have life-threatening conditions attributable to respiratory, cardiovascular, and multisystem organ failure. Decisions are often made regarding escalation (and de-escalation) of therapies based on clinical course, probability of survival, and the possibility and severity of residual deficits after recovery from the acute illness. Patients who were healthy prior to COVID-19 may have different perceptions and needs about goals of care than patients with preexisting CVD. Advance care planning with the patient or family is recommended to clarify patient preferences and goals of care. Advance care planning should include advance directives and explicit documentation by health care providers regarding preferences for resuscitation and treatment preferences. For patients with severe illness, limited probability of recovery to an acceptable functional status, or poor prognosis, multidisciplinary care coordination with involvement of palliative care providers and social workers in tandem with the primary team is important. Appendix 10 provides data elements for end-of-life management.

# ACC/AHA TASK FORCE ON CLINICAL DATA STANDARDS

Hani Jneid, MD, FACC, FAHA, Chair; Bruce E. Bray, MD, FACC, Chair-Elect; Faraz S. Ahmad, MD, MS, FACC; Deepak L. Bhatt, MD, MPH, FACC, FAHA\*; Jeffrey R. Boris, MD, FACC; Mauricio G. Cohen, MD, FACC; Monica Colvin, MD, MS, FAHA; Thomas C. Hanff, MD, MSCE; Nasrien E. Ibrahim, MD, FACC, FAHA; Corrine Y. Jurgens, PhD, RN, ANP, FAHA; Dhaval Kolte, MD, PhD, FACC; Arnav Kumar, MBBS\*; Nidhi Madan, MD, MPH\*; Amgad N. Makaryus, MD, FACC\*; Paul Muntner, PhD, FAHA; Kevin S. Shah, MD, FACC\*; April W. Simon, RN, MSN; Nadia R. Sutton, MD, MPH, FACC; Anne Marie Valente, MD, FACC, FAHA

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Grace D. Ronan, Team Leader, Clinical Policy Publications Leah Patterson, Project Manager, Clinical Content Development

## American College of Cardiology/American Heart Association

Abdul R. Abdullah, MD, Director, Guideline Science and Methodology

## **American Heart Association**

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- Radhika Rajgopal Singh, PhD, Senior Vice President, Office of Science and Medicine
- Cammie Marti, MPH, PhD, Science and Medicine Advisor, Office of Science, Medicine and Health
- Jody Hundley, Production and Operations Manager, Scientific Publications, Office of Science Operations

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\*Former Task Force member; current member during the writing effort.

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## Appendix 1. Author Relationships With Industry and Other Entities (Relevant)–2022 AHA/ACC Key Data Elements and Definitions for Cardiovascular and Noncardiovascular Complications of COVID-19

Committee Member	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Biykem Bozkurt, 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
Sandeep R. Das, Vice Chair	UT Southwestern Medical Center–Pro- fessor of Internal Medicine, Division of Cardiology	None	None	None	None	None	None
Daniel Addison	The Ohio State University–Assistant Profes- sor and Co-Director, Cardio-Oncology Pro- gram, Division of Cardiovascular Medicine	None	None	None	None	None	None
Aakriti Gupta	Cedars-Sinai Medical Center–Structural Interventional Fellow	None	None	None	None	None	None
Hani Jneid	Baylor College of Medicine–Associate Professor of Medicine and Director of Interventional Cardiology Fellowship and Research; Michael E. DeBakey VA Medical Center–Director, Interventional Cardiology	None	None	None	None	None	None
Sadiya S. Khan	Northwestern University Feinberg School of Medicine–Assistant Professor of Medi- cine (Cardiology) and Preventive Medicine (Epidemiology)	None	None	None	None	None	None
George Augustine Koromia	Marshall University Cardiology–Fellow, Joan C. Edwards School of Medicine	None	None	None	None	None	None
Prathit A. Kulkarni	Baylor College of Medicine–Assistant Professor, Infectious Diseases; Michael E. DeBakey VA Medical Center–Assistant Chief of Medicine	None	None	None	Vessel Health, Inc.*	None	None

Committee Member	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Kathleen LaPoint†	American College of Cardiology/American Heart Association–Clinical Healthcare Data Manager	None	None	None	None	None	None
Eldrin F. Lewis	Stanford University School of Medicine– Simon H. Stertzer, MD, Professor of Medi- cine and Chief, Cardiovascular Medicine	None	None	None	None	None	None
Erin D. Michos	Johns Hopkins University School of Medi- cine–Associate Professor of Medicine and Epidemiology; Director, Women's Cardio- vascular Health; and Associate Director, Preventive Cardiology	None	None	None	None	None	None
Pamela N. Peterson	University of Colorado School of Medicine– Professor of Medicine, Cardiology; Denver Health Medical Center–Cardiologist	None	None	None	None	None	None
Mohit K. Turagam	Icahn School of Medicine at Mount Si- nai–Assistant Professor of Medicine, Cardiology	None	None	None	None	None	None
Tracy Y. Wang	Duke University Medical Center-Professor of Medicine and Director, Health Services & Outcomes Research	None	None	None	None	None	None
Clyde W. Yancy	Northwestern University Feinberg School of Medicine–Vice Dean, Diversity & Inclusion; Magerstadt Professor of Medicine; Chief, Division of Cardiology	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.

\*Significant relationship.

tKathleen LaPoint is an ACC/AHA joint staff member and acts as the Clinical Healthcare Data Manager for the "2022 AHA/ACC Key Data Elements and Definitions for Cardiovascular and Noncardiovascular Complications of COVID-19." No relevant relationships to report. Not included/counted in the RWI balance for this committee.

ACC indicates American College of Cardiology; AHA, American Heart Association; COVID-19, coronavirus disease-2019; UT, University of Texas; and VA, Veterans Affairs.

#### Appendix 2. Reviewer Relationships With Industry and Other Entities (Comprehensive)-2022 AHA/ACC Key Data Elements and Definitions for Cardiovascular and Noncardiovascular Complications of COVID-19 (August 2021)

Reviewer	Representation	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Finan- cial Benefit	Expert Witness
Monica Colvin	Official Reviewer– ACC/AHA Task Force on Data Standards	University of Michigan Health System–Pro- fessor of Medicine, Advanced Heart Fail- ure and Transplant, Cardiovascular Divi- sion; Associate Direc- tor, Heart Transplant Program	None	None	None	<ul> <li>CareDx</li> <li>SRTR/ HRSA*</li> <li>University of Michigan†</li> </ul>	• Abbott‡	None
Elissa Driggin	Content Reviewer-ACC	New York-Pres- byterian Hospital/ Columbia University Irving Medical Cen- ter–Fellow, Division of Cardiology	None	None	None	None	None	None

Reviewer	Representation	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Finan- cial Benefit	Expert Witness
Nisha Gilotra	Official Reviewer–AHA	Johns Hopkins Univer- sity–Director, Cardiac Sarcoidosis Program and Assistant Profes- sor of Medicine	• scPharma- ceuticals	None	None	None	None	None
Lee Goldberg	Content Reviewer–ACC/ AHA	University of Pennsyl- vania–Professor of Medicine, Vice Chair of Medicine for Informat- ics, and Section Chief, Advanced Heart Failure and Cardiac Transplant	• Respicardia*	None	None	• NIH† • Respicardia†	None	None
Saurabh Gupta	Content Reviewer-ACC	St. Charles Health System-Chief of Car- diology, and Director, Structural Cardiology	<ul> <li>Edwards*</li> <li>Medtronic*</li> </ul>	None	None	None	None	None
Mary Heitschmidt	Content Reviewer-AHA	Rush University Medi- cal Center–Director of Clinical Research, Rush College of Nursing	None	None	None	None	Rush University, COVID-19 Scientific/ Ops. Review Committee†	None
David Herrington	Content Reviewer-AHA	Wake Forest University School of Medicine–Professor of Internal Medicine/ Section on Cardiovas- cular Medicine	None	None	None	None	<ul> <li>Amgen‡</li> <li>Cardiovascular Science Center Director*</li> <li>CDC*</li> <li>DalCor Pharmaceuticals‡</li> <li>Esperion‡</li> <li>Mount Sinai Medical Center (Miami)‡</li> <li>NC State Legislature (HHS/ CARES Act)*</li> <li>NHLBI*</li> </ul>	None
Norma Keller	Official Reviewer-ACC	NYU Grossman School of Medicine– Assistant Professor	None	None	None	None	None	None
R. Kannan Mutharasan	Content Reviewer-ACC/ AHA	Northwestern University Feinberg School of Medicine– Associate Professor of Medicine, Cardi- ology	• Abbott*	• Astra- Zeneca*	None	None	Cardiosense	None
Gurusher Panjrath	Content Reviewer–ACC/ AHA	George Washington School of Medicine & Health Sciences–As- sociate Professor, and Director, Heart Failure and Mechanical Circulatory Support Program	• CVRx	• Pfizer*	None	None	• Abbott‡	None
Andrea Price	Official Reviewer-ACC	Indiana University Health–Director, Quality Reporting & Analytics	None	None	None	<ul> <li>ACC, Accreditation Foundation Board*</li> </ul>	None	None

Reviewer	Representation	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Finan- cial Benefit	Expert Witness
Michael Salerno	Content Reviewer-ACC	University of Virginia– Associate Professor of Medicine, Radiol- ogy and Biomedical Engineering	• Valo Health*	None	None	• NIH*	<ul><li>Heart Flow‡</li><li>Siemens†</li></ul>	Defendant, SPECT table mal- function, 2020*
Sanjum S. Sethi	Official Reviewer–AHA	Columbia University Medical Center–As- sistant Professor of Medicine	• Inari	<ul> <li>Chiesi</li> <li>Janssen Pharma- ceuticals</li> </ul>	None	None	• Terumo‡	None
Robin Trupp	Content Reviewer–ACC/ AHA		None	None	None	None	None	None
Eugene Yang	Content Reviewer-ACC	University of Washing- ton-Clinical Professor of Medicine, Carl and Renée Behnke En- dowed Professorship for Asian Health	Genentech*	None	Clocktree	• Amgen*	None	None

This table represents all relationships of committee members 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  $\geq$ 5% of the voting stock or share of the business entity, or ownership of  $\geq$ 5% 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 note. 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.

tNo financial benefit.

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

ACC indicates American College of Cardiology; AHA, American Heart Association; CDC, US Centers for Disease Control and Prevention; COVID-19, coronavirus disease-2019; HHS, US Department of Health and Human Services; HRSA, Health Resources and Services Administration; NC, North Carolina; NHLBI, National Heart, Lung, and Blood Institute; NIH, National Institutes of Health; Ops., Operations; NYU, New York University; SPECT, single photon emission computed tomography; SRTR, Scientific Registry of Transplant Recipients; and TFDS, Task Force on Data Standards.

#### Appendix 3. COVID-19 Diagnosis

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Acute COVID-19 case	Patient with an episode of acute ill- ness caused by SARS-CoV-2	<ul> <li>Confirmed acute COVID-19 case</li> <li>Probable acute COVID-19 case</li> <li>Suspected acute COVID-19 case</li> <li>Unknown</li> <li>No</li> </ul>		Centers for Disease Control and Prevention. Coronavirus disease 2019 (COVID-19). 2020 interim case definition, approved August 5, 2020. Accessed March 4, 2022. https://ndc. services.cdc.gov/case-def- initions/coronavirus-dis- ease-2019-2020-08-05/7	Can specify date of diagnosis of confirmed COVID-19 status.
		Confirmed acute COVID-19 case	Requires detection of SARS-CoV-2 RNA in a clinical or autopsy speci- men <b>using a molecular</b> <b>amplification test</b> (eg, RT-PCR)		

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Probable acute COVID-19 case	Detection of SARS- CoV-2 by antigen test in a respiratory specimen OR Meets <b>clinical criteria</b> and <b>epidemiologi-</b> <b>cal linkage criteria</b> for COVID-19 with no confirmatory laboratory testing performed OR A death certificate that lists COVID-19 disease or SARS-CoV-2 as an underlying cause of death or a significant condition contributing to death with no confirma- tory laboratory evidence of SARS-CoV-2		Clinical criteria (In the absence of a more likely diagnosis) At least 2 of the follow- ing: fever (measured or subjective), chills, rigors, myalgia, headache, sore throat, nausea or vomit- ing, diarrhea, fatigue, con- gestion, or runny nose OR Any 1 of the following: cough, shortness of breath, difficulty breath- ing, new olfactory disor- der, new taste disorder OR Severe respiratory ill- ness with clinical or radiographic evidence of pneumonia or ARDS In hospital setting, prob- able cases have been sometimes identified as PUI. <b>Epidemiological link- age criteria</b> = close contact, as defined by the CDC while the person was deemed to be infec- tious (see <b>infectious pe-</b> <b>riod</b> below), or a member of a risk cohort as defined by public health authori- ties during an outbreak
		Suspected acute COVID-19 case	Requires detection of specific antibody in serum, plasma, or whole blood, or detection of specific antigen by im- munocytochemistry in an autopsy specimen.		Requires there is no his- tory of previously being a confirmed or probable case.
		Unknown	COVID-19 testing not performed and COVID-19 symptoms not addressed		
		No	COVID-19 test negative and no symptoms to suggest COVID-19		
COVID-19 symptom status	Presence or absence of symptoms attributable to acute COVID-19	<ul><li>Symptomatic</li><li>Asymptomatic</li><li>Unknown</li></ul>			See list of possible symptoms in Appen- dix 6.
Exposure to infectious COVID-19 case	Being in close contact, as defined by the CDC, with a person with a probable or confirmed acute COVID-19 case while the person was in the presumptive <b>infectious</b> <b>period</b>	• Yes • No • Unknown		Centers for Disease Control and Prevention. Coronavirus disease 2019 (COVID-19). Appendix A - glossary of key terms. Accessed March 4, 2022. https://www.cdc.gov/ coronavirus/2019-ncov/ php/contact-tracing/con- tact-tracing-plan/appendix. html#Key-Terms <sup>46</sup>	Infectious period Refer to guidance from the CDC, which moni- tors the emerging sci- ence on when and for how long a person is infectious. <sup>47</sup>

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Persistently positive SARS-CoV-2 antigen or molecular test	Persistently positive virological test (molecular amplification or antigen test) in a patient who is out of the presumptive infectious period of acute COVID-19	• Yes • No • Unknown		Centers for Disease Con- trol and Prevention. Coro- navirus disease 2019 (COVID-19). Ending isola- tion and precautions for adults with COVID-19: interim guidance. Ac- cessed March 4, 2022. https://www.cdc.gov/ coronavirus/2019-ncov/ hcp/duration-isolation. html <sup>49</sup>	Any decision on poten- tial retesting for symp- toms within 3 mo of an acute COVID infection should be individualized.
Postacute sequelae of SARS-CoV-2 infection (PASC)	Symptoms that significantly impair quality of life, which started during or after probable or confirmed acute COVID-19 and have persisted 4 wk to 3 mo after the initial diagnosis of COVID-19	• Yes • No • Unknown		World Health Organiza- tion. A clinical case defini- tion of post COVID-19 condition by a Delphi consensus, 6 October 2021. Accessed March 4, 2022. https://www. who.int/publications/i/ item/WHO-2019-nCoV- Post_COVID-19_condi- tion-Clinical_case_defini- tion-2021.1 <sup>49</sup> Nalbandian A, Sehgal K, Gupta A, et al. Post-acute COVID-19 syndrome. <i>Nat Med</i> . 2021;27:601-615. <sup>13</sup> Amenta EM, Spallone A, Rodriguez-Barradas MC, et al. Postacute COVID-19: an overview and approach to classifi- cation. Open <i>Forum Infect Dis</i> . 2020;7:ofaa509. <sup>50</sup> Datta SD, Talwar A, Lee JT. A proposed frame- work and timeline of the spectrum of disease due to SARS-CoV-2 infection: illness beyond acute infection and public health implications. <i>JAMA</i> . 2020;324:2251-2252. <sup>51</sup> National Institutes of Health. NIH launches new initiative to study "Long COVID. <sup>19</sup> Accessed March 4, 2022. https://www. nih.gov/about-nih/who- we-are/nih-director/state- ments/nih-launches-new- initiative-study-long-covid <sup>52</sup> National Institute for Health and Care Excel- lence. COVID-19 rapid guideline: managing the long-term effects of COVID-19. Accessed March 4, 2022. https:// www.nice.org.uk/guid- ance/ng188/resources/ covid19-rapid-guideline- managing-the-longterm- effects-of-covid19- pdf-66142028400325 <sup>53</sup>	Also referred to as "postacute COVID-19 syndrome" or "long CO- VID." Not well character- ized currently.

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Multisystem inflammatory syndrome in children (MIS-C)	The occurrence of fever, labora- tory evidence of inflammation, and evidence of clinically severe illness requiring hospitalization with multi- system (≥2) organ involvement AND No plausible alternative diag- noses AND Positive for current or recent SARS-CoV-2 infection by RT-PCR, se- rology, or antigen test OR exposure to a suspected or confirmed COVID-19 case within 4 wk prior to symptom on- set in an individual aged <21 y	• Yes • No • Unknown		Centers for Disease Con- trol and Infection. Informa- tion for healthcare provid- ers about multisystem inflammatory syndrome in children (MIS-C). Ac- cessed March 4, 2022. https://www.cdc.gov/mis- c/hcp/ <sup>54</sup>	
Multisystem inflammatory syndrome in adults (MIS-A)	<ul> <li>A patient aged ≥21 y hospitalized for ≥24 h, or with an illness resulting in death, who meets the following clinical and laboratory criteria. The patient should not have a more likely alternative diagnosis for the illness (eg, bacterial sepsis, exacerbation of a chronic medical condition).</li> <li>I. Clinical criteria</li> <li>Subjective fever or documented fe- ver (≥38.0°C) for ≥24 h prior to hos- pitalization or within the first 3 d of hospitalization and at least 3 of the following clinical criteria occurring prior to hospitalization or within the first 3 d of hospitalization.* At least 1 must be a primary clinical criterion:</li> <li>A. Primary clinical criteria</li> <li>Severe cardiac illness includes myocarditis, peri- carditis, coronary artery dilatation/aneurysm, or new- onset right or left ventricular dysfunction (LVEF &lt;50%), 2nd/3rd degree AV block, or ventricular tachycardia. (Note: cardiac arrest alone does not meet this criterion)</li> <li>Rash and nonpurulent con- junctivitis</li> <li>B. Secondary clinical criteria</li> <li>New-onset neurological signs and symptoms: includes encephalopathy in a patient without prior cognitive impair- ment, seizures, meningeal signs, or peripheral neuropa- thy (including Guillain-Barré syndrome)</li> <li>Shock or hypotension not attributable to medical therapy (eg, sedation, renal replacement therapy)</li> <li>Abdominal pain, vomiting, or diarrhea</li> </ul>	• Yes • No • Unknown		Centers for Disease Con- trol and Prevention. Multi- system inflammatory syn- drome in adults (MIS-A). Case definition information for healthcare providers. Accessed March 4, 2022. https://www.cdc.gov/mis/ mis-a/hcp.html <sup>55</sup>	
	count <150 000/microliter)				

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
	<ul> <li>II. Laboratory evidence The presence of laboratory evidence of inflammation and SARS-CoV-2 infection.</li> <li>A. Elevated levels of at least 2 of the following: C-reactive protein, ferritin, IL-6, erythrocyte sedimen- tation rate, procalcitonin</li> <li>B. A positive SARS-CoV-2 test for current or recent infection by RT-PCR, serology, or antigen detection</li> <li>NOTE: *These criteria must be met by the end of hospital day 3, where the date of hospital admission is hospital day 0.</li> </ul>				
Prior COVID-19	Prior evidence of COVID-19 in an individual who is no longer in the infectious period	<ul> <li>Prior COVID-19 without residual sequelae of post- acute COVID-19</li> <li>Prior COVID-19 with residual sequelae of post- acute COVID-19</li> </ul>			Out of infectious period of acute COVID-19 as specified by CDC. <sup>47</sup>
COVID-19 reinfection	New discrete episode of acute COVID-19 in person with a prior history of probable/confirmed COVID-19. Other information can provide supporting but not defini- tive evidence for reinfection, such as culture or subgenomic mRNA analysis (to detect the presence of replication-competent virus) or serology, which could be useful to document a serological response to SARS-CoV-2.	• Yes • No • Unknown	Criteria to distinguish a new case from an exist- ing case The following should be enumerated as a new case: • SARS-CoV-2 sequenc- ing results from the new positive specimen and a positive speci- men from the most recent previous case demonstrate a different lineage. OR • Person was most recently enumerated as a confirmed or prob- able case with onset date (if available) or first positive specimen collection date for that classification >90 d prior. OR • Person was previ- ously reported but not enumerated as a confirmed or probable case (ie, suspect), but now meets the criteria for a confirmed or probable case. Repeat suspect cases should not be enumerated.	Centers for Disease Control and Prevention. Coronavirus disease 2019 (COVID-19) 2021 case definition. Accessed March 4, 2022. https:// ndc.services.cdc.gov/ case-definitions/coronavi- rus-disease-2019-2021/ <sup>56</sup>	Some individuals (eg, severely immunocom- promised persons) can shed SARS-CoV-2 detected by molecular amplification tests >90 d after infection. For severely immunocom- promised individuals, clinical judgment should be used to determine if a repeat positive test is likely to result from long-term shedding and, therefore, not be enu- merated as a new case. CDC defines severe immunocompromise as certain conditions, such as being on che- motherapy for cancer, untreated HIV infection with CD4 T lymphocyte count <200, combined primary immunodeficien- cy disorder, and receipt of prednisone >20 mg/d for >14 d.
Date of acute COVID-19 diagnosis	Date that viral testing confirming a diagnosis of acute COVID-19 was obtained	• Date, mm/dd/yyyy			
Hospitaliza- tion attribut- able to COVID-19	Hospitalization attributable to COVID-19	• Yes • No • Unknown			

Data Element	Data Element Definition	Permissible	Permissible Value	Mapping/Source of Definition	Additional Notes
Hospitalization	Hospitalization for any non-	• Yes	Deminions	Deminion	Additional Notes
for any reason with incidental diagnosis of SARS-CoV-2 infection	COVID-19-related indication with incidental diagnosis of SARS-CoV-2 infection	No     Unknown			
Date of first COVID-19- related hospitalization	Date that the first COVID-19– related hospitalization occurred	• Date, mm/dd/yyyy			
Date of first hospitalization with incidental diagnosis of SARS-CoV-2 infection	Date that hospitalization for any non-COVID-19-related indication occurred with incidental first diagno- sis of SARS-CoV-2 infection	Date, mm/dd/yyyy			
Coinfection of COVID-19 with other respiratory infections	Other respiratory infection in patient an episode of acute illness caused by SARS-CoV-2	<ul> <li>Influenza</li> <li>Other viral infection</li> <li>Bacterial infection</li> <li>Fungal infection</li> </ul>		Bai L, Zhao Y, Dong J, et al. Coinfection with influenza A virus enhances SARS- CoV-2 infectivity. <i>Cell Res.</i> 2021;31:395-403. <sup>57</sup> Belongia EA, Osterholm MT. COVID-19 and flu, a perfect storm. <i>Science.</i> 2020;368:1163. <sup>58</sup> Lansbury L, Lim B, Bas- karan V, et al. Co-infections in people with COVID-19: a systematic review and meta-analysis. <i>J Infect.</i> 2020;81:266-275. <sup>59</sup> Rubin R. What happens when COVID-19 collides with flu season? <i>JAMA.</i> 2020;324:923-925. <sup>60</sup> Su S, Liu Z, Jiang S. Double insult: flu bug enhances SARS-CoV-2 infectivity. <i>Cell</i> <i>Res.</i> 2021;31:491-492. <sup>61</sup>	
SARS-CoV-2 variant	Variant lineage of SARS-CoV-2	<ul> <li>Alpha (B.1.1.7 and Q lineages)</li> <li>Beta (B.1.351 and descendent lineages)</li> <li>Delta (B.1.617.2 and AY lineages)</li> <li>Gamma (P.1 and descendent lin- eages)</li> <li>Epsilon (B.1.427 and B.1.429)</li> <li>Eta (B.1.525)</li> <li>lota (B.1.526)</li> <li>Kappa (B.1.617.1)</li> <li>B.1.617.3</li> <li>Mu (B.1.621, B.1.621.1)</li> <li>Zeta (P.2)</li> <li>Omicron (B.1.1.529 and BA lineages)</li> <li>Other, specify</li> <li>Unknown</li> </ul>		Centers for Disease Control and Prevention. SARS-CoV-2 variant clas- sifications and definitions. Accessed March 4, 2022. https://www.cdc.gov/ coronavirus/2019-ncov/ variants/variant-info.html <sup>62</sup> NCI Thesaurus Codes: C179573, C179575, C179576, C179577, C179579, C179580, C179585, C179586, C179596, C179598, C179599, C180913, C181075, C184327 <sup>63</sup>	

ARDS indicates acute respiratory distress syndrome; CDC, Centers for Disease Control and Prevention; COVID-19, coronavirus disease-2019; HIV, human immunodeficiency virus; MIS-A, multisystem inflammatory syndrome in adults; MIS-C, multisystem inflammatory syndrome in children; PASC, postacute sequelae of SARS-CoV-2 infection; PUI, person under investigation; RNA, ribonucleic acid; RT-PCR, reverse transcription-polymerase chain reaction; and SARS-CoV-2, severe acute respiratory syndrome-coronavirus-2.

#### Appendix 4. COVID-19 Cardiovascular Complications

#### A. Acute Cardiovascular Complications Related to COVID-19 Infection

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Acute myocardial injury related to acute COVID-19	Acute myocardial injury diagnosed by rise and fall in car- diac troponin above the 99th percentile of a reference population in a pa- tient with probable or confirmed acute COVID-19 and no alternative explana- tion for acute myo- cardial injury	<ul> <li>Select all that apply</li> <li>Acute myocardial injury without ischemia, HF, ventricular dysfunction, or myocarditis</li> <li>Acute myocardial injury with type I myocardial infarction</li> <li>Acute myocardial injury with myocardial injury with myocarditis</li> <li>Acute myocardial injury with LV dysfunction</li> <li>Acute myocardial injury with RV dysfunction</li> <li>Acute myocardial injury with HF</li> <li>Acute myocardial injury with cardiogenic shock</li> <li>No</li> <li>Unknown</li> </ul>		Hendren NS, Drazner MH, Bozkurt B, et al. Description and proposed management of the acute COVID-19 cardiovascular syndrome. <i>Circulation</i> . 2020;141:1903-1914. <sup>10</sup> Thygesen K, Alpert JS, Jaffe AS, et al. Fourth universal definition of myo- cardial infarction (2018). <i>Circulation</i> . 2018;138:e618–e651. <sup>64</sup>	See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.
		Acute myocardial injury without ischemia, HF, ven- tricular dysfunction, or myocarditis	Acute myocardial injury, without evidence of a newly reduced LVEF or RVEF, HF, cardiogenic shock, myocarditis, or acute ischemia in a patient with probable or confirmed acute COVID-19		See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.
		Acute myocardial injury with type I myocardial in- farction	<ul> <li>Acute myocardial injury with clinical presentation suggestive of type I myocardial infarction with detection of a rise or fall of cardiac troponin values with at least 1 value above the 99th percentile upper reference limit and with at least 1 of the following:</li> <li>Symptoms of acute myocardial ischemia;</li> <li>New ischemic ECG changes;</li> <li>Development of pathological Q waves;</li> <li>Imaging evidence of new loss of vable myocardium or new regional wall motion abnormality in a pattern consistent with an ischemic etiology;</li> <li>Identification of a coronary thrombus by angiography including intracoronary imaging or by autopsy, occurring in a patient with probable or confirmed acute COVID-19</li> </ul>	Hendren NS, Drazner MH, Bozkurt B, et al. Description and proposed management of the acute COVID-19 cardiovascular syndrome. <i>Circulation</i> . 2020;141:1903-1914. <sup>10</sup> Thygesen K, Alpert JS, Jaffe AS, et al. Fourth universal definition of myo- cardial infarction (2018). <i>Circulation</i> . 2018;138:e618–e651. <sup>54</sup>	See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.
		Acute myocardial injury with myocarditis	Acute myocardial injury with clinical, imaging, and pathology evidence supporting inflamma- tion and myocarditis in a patient with probable or confirmed acute COVID-19	Kindermann I, Barth C, Mahfoud F, et al. Update on myocarditis. <i>J Am Coll</i> <i>Cardiol.</i> 2012;59:779-792. <sup>65</sup> Ferreira VM, Schulz-Menger J, Holmvang G, et al. Cardiovascular magnetic resonance in nonischemic myocardial inflammation: expert recommendations. <i>J Am Coll Cardiol.</i> 2018;72:3158-3176. <sup>66</sup>	If tissue is available, inflamma- tory disease of the myocardium and myocarditis can be diag- nosed by histological, immuno- logic, and immunohistochemi- cal criteria of myocarditis. Cardiac MRI evidence of myocardial edema, non- ischemic myocardial injury, hyperemia, LV dysfunction, or fibrosis can support diagno- sis of myocarditis. See Appendix 3 for the defini- tion of a probable or confirmed acute COVID-19 case.

#### A. Acute Cardiovascular Complications Related to COVID-19 Infection

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Acute myocardial injury with LV dysfunction	Acute myocardial injury with evidence of new systolic dys- function with reduced LVEF (LVEF <50%) in a patient with probable or confirmed acute COVID-19	Bozkurt B, Hershberger RE, Butler J, et al. 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). <i>Circ Cardiovasc Qual Outcomes</i> . 2021;14:e000102. <sup>67</sup> Hendren NS, Drazner MH, Bozkurt B, et al. Description and proposed management of the acute COVID-19 cardiovascular syndrome. <i>Circulation</i> . 2020;141:1903-1914. <sup>10</sup> Bozkurt B, Coats AJ, Tsutsui H, et al. Universal definition and classifica- tion of heart failure: a report of the Heart Failure Society of America, Heart Failure Society of Cardiology, Japanese Heart Failure Society and Writing Committee of the Universal Definition of Heart Failure. J <i>Card Fail</i> .	LV dysfunction can be further subclassified as HFrEF if LVEF is <40%; HFmrEF if LVEF is 41%-49%; and HFpEF if LVEF >50%, if accompanied with HF symp- toms. See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.
		Acute myocardial injury with RV dysfunction	Acute myocardial injury with evidence of newly reduced RV function in a patient with probable or confirmed acute COVID-19	2021;27:387-413. <sup>68</sup> Hendren NS, Drazner MH, Bozkurt B, et al. Description and proposed management of the acute COVID-19 cardiovascular syndrome. <i>Circulation</i> . 2020;141:1903-1914. <sup>10</sup>	Right heart strain may be due to pulmonary embolism, elevated pulmonary pres- sures arising from severe COVID-associated lung dis- ease, left heart dysfunction, or RV infarct. See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.
		Acute myocardial injury with HF	Acute myocardial injury with evidence of new or worsening signs and symptoms of HF in a patient with probable or con- firmed acute COVID-19	Bozkurt B, Hershberger RE, Butler J, et al. 2021 ACC/AHA key data ele- ments and definitions for heart failure: a report of the American College of Cardiology/American Heart As- sociation Task Force on Clinical Data Standards (Writing Committee to Develop Clinical Data Standards for Heart Failure). <i>Circ Cardiovasc Qual Outcomes</i> . 2021;14:e000102. <sup>67</sup> 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. <i>Circulation</i> . 2013;128:e240–e327. <sup>69</sup> Bozkurt B, Coats AJ, Tsutsui H, et al. Universal definition and classifica- tion of heart failure: a report of the Heart Failure Society of America, Heart Failure Society of America, Heart Failure Society of Cardiology, Japanese Heart Failure Society and Writing Committee of the Universal Definition of Heart Failure. J <i>Card Fail</i> . 2021;27:387-413. <sup>68</sup>	HF can be further subclas- sified as HFrEF if LVEF is <40%; HFmrEF if LVEF is 41%-49%; and HFpEF if LVEF >50% and accompa- nied by HF symptoms. See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.

#### A. Acute Cardiovascular Complications Related to COVID-19 Infection

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Acute myocardial injury with cardiogenic shock	Acute myocardial injury with evidence of cardiogenic shock defined as clinical evidence of low cardiac index (eg, <2.2 L/min/m <sup>2</sup> ) accompanied by impaired tissue perfusion in a patient with probable or con- firmed acute COVID-19		Cardiogenic shock with or without comorbid distributive shock data element below should be used for patients without evidence of myocar- dial injury or cardiac troponin elevation. See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.
		No			
		Unknown	A proper value is applicable but not known.		
Acute heart failure	HF with new or worsening signs and symptoms in a patient with prob- able or confirmed acute COVID-19. Acute HF can be in the setting of either a preserved or reduced LVEF. This can be the first presentation of HF, or it can reflect an acute decompensa- tion in a patient with history of chronic HF.	• Yes • No • Unknown		Bozkurt B, Hershberger RE, Butler J, et al. 2021 ACC/AHA key data ele- ments and definitions for heart failure: a report of the American College of Cardiology/American Heart As- sociation Task Force on Clinical Data Standards (Writing Committee to Develop Clinical Data Standards for Heart Failure). <i>Circ Cardiovasc Qual</i> <i>Outcomes</i> . 2021;14:e000102. <sup>67</sup> 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. <i>Circulation</i> . 2013;128:e240–e327. <sup>69</sup> Bozkurt B, Coats AJ, Tsutsui H, et al. Universal definition and classifica- tion of heart failure: a report of the Heart Failure Society of America, Heart Failure Society of America, Heart Failure Association of the European Society of Cardiology, Japanese Heart Failure Society and Writing Committee of the Universal Definition of Heart Failure. J <i>Card Fail</i> . 2021;27:387-413. <sup>68</sup>	Clinical syndrome resulting from either impairment of LV filling or reduction in LV ejection fraction, accompa- nied by signs or symptoms of either volume overload (congestion) or low cardiac output (hypoperfusion). Important to distinguish be- tween respiratory failure from acute COVID-19 and con- comitant acute HF to identify treatment options. The differ- ence from acute myocardial injury with HF data definition above is acute HF data ele- ment does not require a rise in cardiac troponin and pa- tients may not exhibit acute cardiac injury. See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.
Acute peri- carditis or pericardial effusion	Inflammatory process involving the pericardium, can occur with or without the new development of a pericardial effu- sion, in a patient with probable or confirmed acute COVID-19	• Yes • No • Unknown		O'Gallagher K, Kanyal R, Sado DM, et al. COVID-19 myopericarditis. Accessed March 4, 2022. https:// www.acc.org/latest-in-cardiology/ articles/2020/09/25/17/22/covid- 19-myopericarditis <sup>70</sup> Chiabrando JG, Bonaventura A, Vec- chié A, et al. Management of acute and recurrent pericarditis: JACC state-of-the-art review. <i>J Am Coll Car- diol.</i> 2020;75:76-92. <sup>71</sup>	Inflammation of the pericar- dial layers characterized by chest pain, ECG changes, and often pericardial effusion detected by ECG or cardiac MRI. Pericardial effusion as- sociated with COVID-19 is usually exudative reflective of an inflammatory process. Can occur with concomitant myocarditis. However, the size (volume) of the peri- cardial effusion does not necessarily correlate with the severity of myocardial involvement. See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.

#### A. Acute Cardiovascular Complications Related to COVID-19 Infection

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Sustained ventricular arrhythmia	Sustained ven- tricular tachycardia (≥30 s or requiring DCCV) or ventricu- lar fibrillation in a patient with prob- able or confirmed acute COVID-19	• Yes • No • Unknown		Hendren NS, Drazner MH, Bozkurt B, et al. Description and proposed management of the acute COVID-19 cardiovascular syndrome. <i>Circulation</i> . 2020;141:1903-1914. <sup>10</sup> Turagam MK, Musikantow D, Gold- man ME, et al. Malignant arrhyth- mias in patients with COVID-19: incidence, mechanisms, and out- comes. <i>Circ Arrhythm Electrophysiol</i> . 2020;13:e008920. <sup>72</sup>	A sustained ventricular tachycardia event is one that lasts >30 s in duration or one that lasts <30 s but requires electrical termination due to hemodynamic compromise. For sudden cardiac death, see separate data element below. See Appendix 3 for the defini- tion of a probable or con- firmed acute COVID-19 case.
New-onset AF or atrial flutter	Newly occurring AF or atrial flutter in a patient with prob- able or confirmed acute COVID-19, further categorized as: 1) first detected AF, 2) paroxysmal AF: AF that is self- terminating within 7 d of recognized onset, 3) persistent AF: AF that is not self-terminating within 7 d	• Yes • No • Unknown		Musikantow DR, Turagam MK, Sartori S, et al. Atrial fibrillation in patients hospitalized with COVID-19: incidence, predictors, outcomes and comparison to influenza. <i>J Am Coll Cardiol EP</i> . 2021;7:1120-1130. <sup>73</sup> Hendren NS, Drazner MH, Bozkurt B, et al. Description and proposed management of the acute COVID-19 cardiovascular syndrome. <i>Circulation</i> . 2020;141:1903-1914. <sup>10</sup> McNamara RL, Brass LM, Drozda JP Jr, et al. ACC/AHA key data elements and definitions for measuring the clinical management and outcomes of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Data Standards on Atrial Fibrillation). <i>Circulation</i> . 2004;109:3223–3243. <sup>74</sup>	See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.
Sustained atrial tachyarrhyth- mia other than AF or atrial flutter	Other types of supraventricular tachycardia, includ- ing AV nodal re- entry, orthodromic re-entrant tachycar- dia, multifocal atrial tachycardia, other atrial tachycardia, in a patient with prob- able or confirmed acute COVID-19	• Yes • No • Unknown		Musikantow DR, Turagam MK, Sartori S, et al. Atrial fibrillation in patients hospitalized with COVID-19: inci- dence, predictors, outcomes and comparison to influenza. <i>J Am Coll</i> <i>Cardiol EP</i> . 2021;7:1120-1130. <sup>73</sup> Hendren NS, Drazner MH, Bozkurt B, et al. Description and proposed management of the acute COVID-19 cardiovascular syndrome. <i>Circulation</i> . 2020;141:1903-1914. <sup>10</sup> McNamara RL, Brass LM, Drozda JP Jr, et al. ACC/AHA key data elements and definitions for measuring the clin- ical management and outcomes of patients with atrial fibrillation: a report of the American College of Cardiol- ogy/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Data Standards on Atrial Fibrillation). <i>Cir- culation</i> . 2004;109:3223–3243. <sup>74</sup>	Supraventricular tachycar- dias other than AF or atrial flutter See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.
Bradyar- rhythmia requiring temporary or permanent pacing	Bradycardia (ventricular rate <60 bpm) that is symptomatic reflecting signs of hypoperfusion and that requires temporary or per- manent pacemaker intervention in a pa- tient with probable or confirmed acute COVID-19	• Yes • No • Unknown		Chinitz JS, Goyal R, Harding M, et al. Bradyarrhythmias in patients with COVID-19: marker of poor prognosis? <i>Pacing Clin Electrophysiol.</i> 2020;43:1199-1204. <sup>75</sup> Turagam MK, Musikantow D, Gold- man ME, et al. Malignant arrhyth- mias in patients with COVID-19: incidence, mechanisms, and out- comes. <i>Circ Arrhythm Electrophysiol.</i> 2020;13:e008920. <sup>72</sup>	Can include sinus brady- cardia or 2nd or 3rd degree AV block. See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.

#### A. Acute Cardiovascular Complications Related to COVID-19 Infection

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Deep venous thrombosis	Thrombus formation within deep veins in a patient with prob- able or confirmed acute COVID-19	• Yes • No • Unknown		Bikdeli B, Madhavan MV, Jimenez D, et al. COVID-19 and thrombotic or thromboembolic disease: implica- tions for prevention, antithrombotic therapy, and follow-up: JACC state- of-the-art review. J Am Coll Cardiol. 2020;75:2950-2973. <sup>76</sup>	See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.
Pulmonary embolus	Thrombus formation or lodging in an artery in the lung in a patient with prob- able or confirmed acute COVID-19	• Yes • No • Unknown		Poissy J, Goutay J, Caplan M, et al. Pulmonary embolism in patients with COVID-19: awareness of an increased prevalence. <i>Circulation</i> . 2020;142:184-186. <sup>77</sup> Shah S, Shah K, Patel SB, et al. Elevated D-dimer levels are associ- ated with increased risk of mortality in coronavirus disease 2019: a system- atic review and meta-analysis. <i>Cardiol</i> <i>Rev.</i> 2020;28:295-302. <sup>78</sup>	See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.
Intracardiac thrombus	Thrombus formation in the left or right ventricle or atria of the heart in a pa- tient with probable or confirmed acute COVID-19	• Yes • No • Unknown		Sethi SS, Zilinyi R, Green P, et al. Right ventricular clot in transit in COVID-19: implications for the pulmonary embolism response team. <i>J Am Coll Cardiol Case Rep.</i> 2020;2:1391-1396. <sup>79</sup>	See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.
Acute isch- emic limb	Acute decrease in limb perfusion, usually producing new or worsening symptoms or signs, and often threaten- ing limb viability or resulting in limb amputation in a pa- tient with probable or confirmed acute COVID-19	• Yes • No • Unknown		Bellosta R, Luzzani L, Natalini G, et al. Acute limb ischemia in patients with COVID-19 pneumonia. <i>J Vasc</i> <i>Surg.</i> 2020;72:1864-1872. <sup>28</sup>	See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.
Sudden car- diac death with ROSC	Unexpected death caused by sudden cardiac arrest with asystole, pulseless electrical activity, sustained ventricular tachycardia, or ven- tricular fibrillation with successful ROSC in a patient with prob- able or confirmed acute COVID-19	• Yes • No • Unknown		Turagam MK, Musikantow D, Gold- man ME, et al. Malignant arrhyth- mias in patients with COVID-19: incidence, mechanisms, and out- comes. <i>Circ Arrhythm Electrophysiol.</i> 2020;13:e008920. <sup>72</sup>	See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.
Cardiogenic shock with or without comorbid distributive shock	Clinical evidence of low cardiac index (eg, <2.2 L/min/ m <sup>2</sup> ) accompanied by impaired tissue perfusion in a pa- tient with probable or confirmed acute COVID-19	<ul> <li>Stage A</li> <li>Stage B</li> <li>Stage C</li> <li>Stage D</li> <li>Stage E</li> <li>No</li> <li>Unknown</li> </ul>		Bozkurt B, Hershberger RE, Butler J, et al. 2021 ACC/AHA key data ele- ments and definitions for heart failure: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Stan- dards (Writing Committee to Develop Clinical Data Standards for Heart Failure). <i>Circ Cardiovasc Qual Outcomes</i> . 2021;14:e000102. <sup>67</sup> Hendren NS, Drazner MH, Bozkurt B, et al. Description and proposed management of the acute COVID-19 cardiovascular syndrome. <i>Circulation</i> . 2020;141:1903-1914. <sup>10</sup> Baran DA, Grines CL, Bailey S, et al. SCAI clinical expert consensus statement on the classification of car- diogenic shock. <i>Catheter Cardiovasc Interv</i> . 2019;94:29-37. <sup>80</sup>	COVID-19 may result in sep- tic or vasodilatory shock. If there is cardiac involvement with inability of the heart to pump sufficient blood for the needs of the body, con- comitant cardiac failure may result in mixed (cardiogenic and vasodilatory) shock or cardiogenic shock. Note that invasive measurement of car- diac output is not required. See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.

#### A. Acute Cardiovascular Complications Related to COVID-19 Infection

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Stage A	At risk: A patient who is not currently experiencing signs or symptoms of cardiogenic shock but is at risk for its de- velopment. These patients may include those with large acute myocardial infarction or prior infarction, acute or acute on chronic HF symptoms.		
		Stage B	Beginning cardiogenic shock: A patient who has clinical evi- dence of relative hypotension or tachycardia without hypo- perfusion		
		Stage C	Classic cardiogenic shock: A patient that manifests with hypoperfusion that requires in- tervention (inotrope, pressor or mechanical support, including ECMO) beyond volume resus- citation to restore perfusion. These patients typically present with relative hypotension.		
		Stage D	Deteriorating/doom: A patient that is similar to category C but is getting worse. They have failure to respond to initial in- terventions.		
		Stage E	Extremis: A patient that is experiencing cardiac arrest with ongoing CPR or ECMO, being supported by multiple interventions		
		No			
Acute stroke	An acute neurologi- cal deficit attributed to an acute focal injury of the central nervous system by a vascular cause in a patient with prob- able or confirmed acute COVID-19, accompanied with neuropathological, neuroimaging, or clinical evidence of permanent injury	Unknown  Ischemic stroke  Intracerebral hemor- rhage  Subarachnoid hemor- rhage  Epidural hemorrhage  Cerebral venous sinus thrombosis  Stroke not otherwise specified  No  Unknown  Ischemic stroke	An acute episode of focal or	Oxley TJ, Mocco J, Majidi S, et al. Large-vessel stroke as a presenting feature of Covid-19 in the young. <i>N</i> <i>Engl J Med.</i> 2020;382:e60. <sup>81</sup> 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. <i>Stroke.</i> 2013;44:2064-2089. <sup>82</sup> Shakil SS, Emmons-Bell S, Rutan C, et al. Stroke among patients hospitalized with COVID-19: results from the American Heart Association COVID-19 Cardiovascular Disease Registry. <i>Stroke.</i> 2022;53:800–807. <sup>83</sup> NCDR CathPCI Registry Coder's	Hemorrhages in the CNS should be classified as stroke if they are nontrau- matic, caused by a vascular event, and result in injury to the CNS. See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.
			global neurological dysfunction caused by brain, spinal cord, or retinal vascular injury as a result of infarction of central nervous system tissue.	Data Dictionary v5.0 (data element #9001) <sup>84</sup>	
		Intracerebral hemorrhage	Rapidly developing clinical signs of neurological dysfunc- tion attributable to a focal collection of blood within the brain parenchyma or ventricular system 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. <i>Stroke</i> . 2013;44:2064-2089. <sup>82</sup>	Intracerebral hemorrhage in- cludes parenchymal hemor- rhages after CNS infarction, types I and II

#### A. Acute Cardiovascular Complications Related to COVID-19 Infection

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Subarachnoid hemorrhage	Rapidly developing signs of neurological dysfunction or headache because of bleed- ing into the subarachnoid space (the space between the arachnoid membrane and the pia mater of the brain or spinal cord), which 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. <i>Stroke</i> . 2013;44:2064-2089. <sup>82</sup>	
		Epidural hemorrhage	Intracranial hemorrhage into the epidural space	NCI Thesaurus Code: C5055563	
		Subdural hemorrhage	Bleeding between the dura mater and the brain, usu- ally secondary to a tear of the bridging vein	NCI Thesaurus Code: C50759 <sup>63</sup>	
		Cerebral venous sinus thrombosis	Stroke because of thrombosis of a cerebral venous structure	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. <i>Stroke</i> . 2013;44:2064-2089. <sup>82</sup>	Symptoms or signs caused by reversible edema without infarction or hemorrhage do not qualify as stroke. Common locations for sinus thrombosis include the dural sinuses, the cavernous sinus, and deep sinuses of the cortex
		Stroke not otherwise specified	An episode of acute neurologi- cal dysfunction presumed to be caused by ischemia or hemor- rhage, persisting ≥24 h or until death but without sufficient evidence to be classified as one of the above		
		No			
		Unknown			
Transient ischemic attack	A brief episode of neurological dys- function, caused by focal brain or retinal ischemia without imaging evidence of acute infarction	• Yes • No • Unknown		Easton JD, Saver JL, Albers GW, et al. Definition and evaluation of transient ischemic attack: a scientific statement for healthcare profes- sionals from the American Heart Association/American Stroke As- sociation Stroke Council; Council on Cardiovascular Surgery and Anesthesia; Council on Cardiovas- cular Radiology and Intervention; Council on Cardiovascular Nursing; and the Interdisciplinary Council on Peripheral Vascular Disease. <i>Stroke</i> . 2009;40:2276-2293. <sup>55</sup>	
Left ventricular thrombus	New diagnosis of left ventricular thrombus in a pa- tient with probable or confirmed acute COVID-19	• Yes • No • Unknown			See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.

#### A. Acute Cardiovascular Complications Related to COVID-19 Infection

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Coronary ectasia	Diffuse dilation of coronary artery segment (≥1.5× the adjacent normal segment) in a pa- tient with probable or confirmed acute COVID-19	• Yes • No • Unknown		Boris JR, Béland MJ, Bergensen LJ, et al. 2017 AHA/ACC key data ele- ments and definitions for ambulatory electronic health records in pediatric and congenital cardiology: a report of the American College of Cardiology/ American Heart Association Task Force on Clinical Data Standards. <i>Circ Cardiovasc Qual Outcomes</i> . 2017;10:e000027. <sup>86</sup>	Coronary ectasia not previously known See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.
Coronary artery aneurysm	Focal dilation of a coronary artery (≥1.5× the adjacent normal segment) in a patient with prob- able or confirmed acute COVID-19	• Yes • No • Unknown		Boris JR, Béland MJ, Bergensen LJ, et al. 2017 AHA/ACC key data ele- ments and definitions for ambulatory electronic health records in pediatric and congenital cardiology: a report of the American College of Cardiology/ American Heart Association Task Force on Clinical Data Standards. <i>Circ Cardiovasc Qual Outcomes</i> . 2017;10:e000027. <sup>86</sup>	Coronary artery aneurysm not previously known See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.
Microvascular thrombosis	Blood clotting that is occurring in small blood vessels in the body in a patient with probable or confirmed acute COVID-19	• Yes • No • Unknown		Bray MA, Sartain SE, Gollamudi J, et al. Microvascular thrombosis: experimental and clinical implications. <i>Transl Res.</i> 2020;225:105-130. <sup>87</sup>	See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.
Thrombo- philia	A condition char- acterized by an ab- normally high level of thrombi. Causes include thrombotic thrombocytopenic purpura, dissemi- nated intravascular coagulation, bone marrow disorders, and antiphospho- lipid antibody syn- drome in a patient with probable or confirmed acute COVID-19.	• Yes • No • Unknown		NCI Thesaurus Code: C84479 <sup>63</sup>	Thrombophilia not previously known See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.
Cardiovascu- lar adverse events related to medications aimed at COVID-19	Cardiovascular adverse events attributable to or associated with medications used for COVID-19	<ul> <li>Arrythmia</li> <li>Coronary artery disorder</li> <li>HF</li> <li>Blood pressure disorder, shock</li> <li>Embolism</li> <li>Thrombosis</li> <li>Vascular hypertensive disorder</li> <li>Other</li> <li>No</li> <li>Unknown</li> </ul>		Gérard AO, Laurain A, Fresse A, et al. Remdesivir and acute renal failure: a potential safety signal from dis- proportionality analysis of the WHO safety database. <i>Clin Pharmacol Ther</i> . 2021;109:1021-1024. <sup>88</sup> Rafaniello C, Ferrajolo C, Sullo MG, et al. Cardiac events potentially asso- ciated to remdesivir: an analysis from the European spontaneous adverse event reporting system. <i>Pharmaceuti- cals (Basel)</i> . 2021;14:611. <sup>89</sup> Naksuk N, Lazar S, Peeraphatdit TB. Cardiac safety of off-label COVID-19 drug therapy: a review and proposed monitoring protocol. <i>Eur Heart J Acute Cardiovasc Care</i> . 2020;9:215-221. <sup>90</sup> US Food and Drug Administration. Guideline for industry. Clinical safety data management: defini- tions and standards for expedited reporting. Accessed March 4, 2022. https://www.fda.gov/media/71188/ download <sup>91</sup>	

#### A. Acute Cardiovascular Complications Related to COVID-19 Infection

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Cardiovascu- lar adverse effects from vaccines to prevent COVID-19	Cardiovascular adverse events associated with COVID-19 vaccina- tions	<ul> <li>Myocarditis</li> <li>Thrombocytopenia and thrombosis</li> <li>Other</li> <li>No</li> <li>Unknown</li> </ul>		Bozkurt B, Kamat I, Hotez PJ. Myocar- ditis with COVID-19 mRNA vaccines. <i>Circulation</i> . 2021;144:471-484. <sup>37</sup>	

AF indicates atrial fibrillation; AV, atrioventricular; bpm, beats per minute; CNS, central nervous system; COVID-19, coronavirus disease-2019; CPR, cardiopulmonary resuscitation; CVD, cardiovascular disease; DCCV, DC cardioversion; ECG, electrocardiogram; ECMO, extracorporeal membrane oxygenation; EF, ejection fraction; HF, heart failure; HFmrEF, heart failure with mildly reduced ejection fraction; HFrEF, heart failure with reduced ejection fraction; LV, left ventricular; LVEF, left ventricular ejection fraction; MRI, magnetic resonance imaging; ROSC, return of spontaneous circulation; RV, right ventricular; and RVEF, right ventricular ejection fraction.

### Appendix 4. Continued

#### **B. Physical Examination**

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
PASC HF	New-onset HF with clinical syndrome of dyspnea, fatigue, fluid retention/peripheral edema that started during probable or confirmed acute COVID-19 and persisted beyond 4 wk after the initial diagnosis of COVID-19. Preexisting cardiovascular condi- tions, or those that did not develop until after COVID-19 had resolved, should not be listed here.	• Yes • No • Unknown		Bozkurt B, Hershberger RE, Butler J, et al. 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). <i>Circ Cardiovasc Qual Outcomes</i> . 2021;14:e000102. <sup>67</sup> Bozkurt B, Coats AJ, Tsutsui H, et al. Uni- versal definition and classification of heart failure: a report of the Heart Failure Soci- ety of America, Heart Failure Association of the European Society of Cardiology, Japanese Heart Failure Society and Writ- ing Committee of the Universal Definition of Heart Failure. <i>J Card Fail</i> . 2021;27:387- 413. <sup>69</sup> Nalbandian A, Sehgal K, Gupta A, et al. Post-acute COVID-19 syndrome. <i>Nat Med</i> . 2021;27:601-615. <sup>13</sup> Hendren NS, Drazner MH, Bozkurt B, et al. Description and proposed management of the acute COVID-19 cardiovascular syn- drome. <i>Circulation</i> . 2020;141:1903-1914. <sup>10</sup>	HF can be subclassi- fied according to LVEF as HF with preserved EF (LVEF ≥50), HF with reduced EF (LVEF <40%), HF with mildly reduced EF (LVEF 41%-49%), or HF with improved EF (HF with a baseline LVEF ≤40%, a ≥10-point increase from baseline LVEF, and a second measurement of LVEF >40%). See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.
PASC ischemic cardiomyopa- thy	Reduced LV function with LVEF <50% in a patient with history of suspected or confirmed myocardi- al ischemia or ACS with confirmed acute COVID-19 and persisted beyond 4 wk after the initial diag- nosis of COVID-19. Preexisting cardiovascular conditions, or those that did not develop until after COVID-19 had resolved, should not be listed here.	• Yes • No • Unknown		Nalbandian A, Sehgal K, Gupta A, et al. Post-acute COVID-19 syndrome. <i>Nat Med.</i> 2021;27:601-615. <sup>13</sup> Hendren NS, Drazner MH, Bozkurt B, et al. Description and proposed management of the acute COVID-19 cardiovascular syndrome. <i>Circulation.</i> 2020;141:1903- 1914. <sup>10</sup> Gupta A, Madhavan MV, Sehgal K, et al. Extrapulmonary manifestations of COVID-19. <i>Nat Med.</i> 2020;26:1017- 1032. <sup>92</sup>	See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.
PASC nonischemic cardiomyopa- thy	Reduced LV function with LVEF <50% without evidence of myo- cardial ischemia that started during probable or confirmed acute COVID-19 and persisted beyond 4 wk after the initial diagnosis of COVID-19. Preexisting cardiovas- cular conditions, or those that did not develop until after COVID-19 had resolved, should not be listed here.	• Yes • No • Unknown		Hendren NS, Drazner MH, Bozkurt B, et al. Description and proposed management of the acute COVID-19 cardiovascular syndrome. <i>Circulation</i> . 2020;141:1903- 1914. <sup>10</sup> Gupta A, Madhavan MV, Sehgal K, et al. Extrapulmonary manifestations of COVID-19. <i>Nat Med</i> . 2020;26:1017- 1032. <sup>92</sup>	See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.

## **B.** Physical Examination

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
PASC inappropriate sinus tachycardia	Inappropriate sinus tachycardia at rest with heart rate >100 bpm that cannot be explained by any identifiable cause, including ane- mia, hypoxia, hypotension, or fever that started during probable or confirmed acute COVID-19 and persisted beyond 4 wk after the initial diagnosis of COVID-19. Preexisting cardiovascular condi- tions, or those that did not develop until after COVID-19 had resolved, should not be listed here.	• Yes • No • Unknown		Nalbandian A, Sehgal K, Gupta A, et al. Post-acute COVID-19 syndrome. <i>Nat Med.</i> 2021;27:601-615. <sup>13</sup> Mitrani RD, Dabas N, Goldberger JJ. COVID-19 cardiac injury: implications for long-term surveillance and outcomes in sur- vivors. <i>Heart Rhythm.</i> 2020;17:1984-1990. <sup>93</sup> Sheldon RS, Grubb BP 2nd, Olshansky B, et al. 2015 Heart Rhythm Society expert consensus statement on the diagnosis and treatment of postural tachycardia syndrome, inappropriate sinus tachycardia, and vasovagal syncope. <i>Heart Rhythm.</i> 2015;12:e41-e63. <sup>94</sup> Ståhlberg M, Reistam U, Fedorowski A, et al. Post-COVID-19 tachycardia syndrome: a distinct phenotype of post- acute COVID-19 syndrome. <i>Am J Med.</i> 2021;134:1451-1456. <sup>95</sup>	See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.
PASC POTS	PASC POTS is a clinical syndrome that started during probable or confirmed acute COVID-19 and lasts ≥3 mo. POTS is defined as 1) sustained heart rate increment ≥30 bpm within 10 min of stand- ing or head-up tilt (for individuals who are age 12–19 y, the required heart rate increment is ≥40 bpm); 2) absence of orthostatic hypo- tension (ie, no sustained systolic blood pressure drop of ≥20 mm Hg); 3) frequent symptoms of or- thostatic intolerance during stand- ing, with rapid improvement on return to a supine position. Symp- toms may include lightheaded- ness, palpitations, tremulousness, generalized weakness, blurred vision, and fatigue; 4) duration of symptoms for at least 3 mo; and 5) absence of other conditions ex- plaining sinus tachycardia such as anorexia nervosa, primary anxiety disorders, hyperventilation, anemia, fever, pain, infection, dehydration, hyperthyroidism, pheochromocy- toma, use of cardioactive drugs (eg, sympathomimetics, anticholin- ergics) or severe deconditioning caused by prolonged bed rest.	• Yes • No • Unknown		Vernino S, Bourne KM, Stiles LE, et al. Postural orthostatic tachycardia syndrome (POTS): state of the science and clinical care from a 2019 National Institutes of Health Expert Consensus Meeting - part 1. <i>Auton Neurosci.</i> 2021;235:102828. <sup>96</sup> Boris JR, Béland MJ, Bergensen LJ, et al. 2017 AHA/ACC key data elements and definitions for ambulatory electronic health records in pediatric and congeni- tal cardiology: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards. <i>Circ Cardiovasc Qual Outcomes.</i> 2017;10:e000027. <sup>86</sup> Bryarly M, Phillips LT, Fu Q, et al. Postural orthostatic tachycardia syndrome: JACC focus seminar. <i>Circ Cardiovasc Qual Out- comes.</i> 2017;10:e000027. <sup>97</sup>	See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.
PASC AF or atrial flutter	AF or atrial flutter in a patient with- out prior history of atrial tachyar- rhythmias that started during prob- able or confirmed acute COVID-19 and persisted beyond 4 wk after the initial diagnosis of COVID-19. Preexisting cardiovascular condi- tions, or those that did not develop until after COVID-19 had resolved, should not be listed here.	• Yes • No • Unknown		Nalbandian A, Sehgal K, Gupta A, et al. Post-acute COVID-19 syndrome. <i>Nat Med.</i> 2021;27:601-615. <sup>13</sup> Mitrani RD, Dabas N, Goldberger JJ. COVID-19 cardiac injury: implications for long-term surveillance and outcomes in survivors. <i>Heart Rhythm.</i> 2020;17:1984- 1990. <sup>93</sup>	See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.

## **B.** Physical Examination

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Data Element	Data Element Definition	Values	Value Definitions	Mapping/Source of Definition	Additional Notes
PASC supra- ventricular tachyarrhyth- mia other than AF or atrial flutter	Supraventricular tachycardia other than AF or atrial flutter in a patient without prior history of atrial tachyar- rhythmias that started during prob- able or confirmed acute COVID-19 and persisted beyond 4 wk after the initial diagnosis of COVID-19. Preexisting cardiovascular condi- tions, or those that did not develop until after COVID-19 had resolved, should not be listed here.	• Yes • No • Unknown		Mitrani RD, Dabas N, Goldberger JJ. COVID-19 cardiac injury: implications for long-term surveillance and outcomes in survivors. <i>Heart Rhythm</i> . 2020;17:1984- 1990. <sup>93</sup>	See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.
PASC pericarditis/ pericardial effusion	Pericarditis characterized by chest pain, electrocardiographic changes or pericardial effusion, that started during probable or confirmed acute COVID-19 and persisted beyond 4 wk after the initial diagnosis of COVID-19. Preexisting cardiovascular condi- tions, or those that did not develop until after COVID-19 had resolved, should not be listed here.	• Yes • No • Unknown		NCDR Auxiliary Data Collection CathPCI Registry Data Dictionary v1.0 (data ele- ment #14617) <sup>98</sup> Carfi A, Bernabei R, Landi F. Persistent symptoms in patients after acute COVID-19. <i>JAMA</i> . 2020;324:603-605. <sup>14</sup>	See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.
PASC cardiac structural abnormalities	Cardiac structural changes or abnormalities characterized by myocardial systolic dysfunction or myocardial edema or fibrosis on noninvasive cardiac imaging that started during probable or confirmed acute COVID-19 and persisted beyond 4 wk after the initial diagnosis of COVID-19. Preexisting cardiovascular condi- tions, or those that did not develop until after COVID-19 had resolved, should not be listed here.	• Yes • No • Unknown		Huang L, Zhao P, Tang D, et al. Cardiac involvement in patients recovered from COVID-2019 identified using magnetic resonance imaging. <i>J Am Coll Cardiol Img.</i> 2020;13:2330-2339. <sup>99</sup> Bajaj R, Sinclair HC, Patel K, et al. Delayed-onset myocarditis following COVID-19. <i>Lancet Respir Med.</i> 2021;9:e32-e34. <sup>100</sup>	See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.
PASC deep venous thrombosis	Formation of ≥1 blood clots or thrombi in large veins of the body, diagnosed with Doppler ultra- sound, occurring most frequently in lower extremities or upper ex- tremities that started during proba- ble or confirmed acute COVID-19 and persisted beyond 4 wk after the initial diagnosis of COVID-19. Preexisting cardiovascular condi- tions, or those that did not develop until after COVID-19 had resolved, should not be listed here.	• Yes • No • Unknown		Gupta A, Madhavan MV, Sehgal K, et al. Extrapulmonary manifestations of COVID-19. <i>Nat Med.</i> 2020;26:1017- 1032. <sup>92</sup> Bikdeli B, Madhavan MV, Jimenez D, et al. COVID-19 and thrombotic or thromboem- bolic disease: implications for prevention, antithrombotic therapy, and follow-up: JACC state-of-the-art review. <i>J Am Coll</i> <i>Cardiol.</i> 2020;75:2950-2973. <sup>76</sup>	See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.
PASC pulmonary thromboem- bolic disease	Intravascular migration of a venous thrombus or embolus to the pulmo- nary arterial circulation, microvascu- lar thrombosis in the pulmonary cap- illaries, or pulmonary artery thrombus in situ diagnosed by a positive pulmonary angiogram, an unequivo- cally positive helical CT scan, a high-probability ventilation-perfusion scan, or autopsy that started during probable or confirmed acute COVID-19 and persisted beyond 4 wk after the initial diagnosis of COVID-19. Preexisting cardiovascu- lar conditions, or those that did not develop until after COVID-19 had resolved, should not be listed here.	• Yes • No • Unknown		Gupta A, Madhavan MV, Sehgal K, et al. Extrapulmonary manifestations of COVID-19. <i>Nat Med.</i> 2020;26:1017- 1032. <sup>92</sup> Bikdeli B, Madhavan MV, Jimenez D, et al. COVID-19 and thrombotic or thromboem- bolic disease: implications for prevention, antithrombotic therapy, and follow-up: JACC state-of-the-art review. <i>J Am Coll</i> <i>Cardiol.</i> 2020;75:2950-2973. <sup>76</sup> Ackermann M, Verleden SE, Kuehnel M, et al. Pulmonary vascular endothelialitis, thrombosis, and angiogenesis in Covid-19. <i>N Engl J Med.</i> 2020;383:120-128. <sup>101</sup>	See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.

#### **B. Physical Examination**

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
PASC         Disorder of the nervous system           neurovascular         related to a vascular etiology           disorder         that started during probable or	Ischemic ( stroke s     Hemor-	Carfi A, Bernabei R, Landi F. Persistent symptoms in patients after acute COVID-19. <i>JAMA</i> . 2020;324:603-605. <sup>14</sup>			
	confirmed acute COVID-19 and persisted beyond 4 wk after the initial diagnosis of COVID-19. Preexisting cardiovascular condi- tions, or those that did not develop until after COVID-19 had resolved, should not be listed here.	<ul> <li>rhagic stroke</li> <li>Cerebral venous thrombosis</li> <li>Myalgic encepha- lomyelitis/ chronic fatigue syn- drome</li> <li>Other</li> </ul>		Moghimi N, Di Napoli M, Biller J, et al. The neurological manifestations of post-acute sequelae of SARS-CoV-2 infection. <i>Curr</i> <i>Neurol Neurosci Rep.</i> 2021;21:44. <sup>102</sup> Clark DE, Dendy JM, Li DL, et al. Cardio- vascular magnetic resonance evaluation of soldiers after recovery from symptomatic SARS-CoV-2 infection: a case-control study of cardiovascular post-acute sequel- ae of SARS-CoV-2 infection (CV PASC). J <i>Cardiovasc Magn Reson.</i> 2021;23:106. <sup>103</sup> Oh ES, Vannorsdall TD, Parker AM. Post- acute sequelae of SARS-CoV-2 infection and subjective memory problems. <i>JAMA</i> <i>Netw Open.</i> 2021;4:e2119335. <sup>104</sup>	

ACS indicates acute coronary syndrome; AF, atrial fibrillation; bpm, beats per minute; COVID-19, coronavirus disease-2019; CT, computed tomography; EF, ejection fraction; HF, heart failure; LV, left ventricular; LVEF, left ventricular ejection fraction; PASC, postacute sequelae of SARS-CoV-2 infection; POTS, postural orthostatic tachycardia syndrome; and SARS-CoV-2, severe acute respiratory syndrome-coronavirus-2.

#### Appendix 4. Continued

#### C. Cardiovascular Mortality During Acute COVID-19 Infection

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Death attributable to acute MI	Death by any cardiovascular mechanism (eg, arrhythmia, sudden death, HF, stroke, pulmonary embolus, peripheral arterial disease) ≤30 d after a MI, related to the immediate consequences of the MI, such as progressive HF or recalci- trant arrhythmia in a patient with prob- able or confirmed acute COVID-19 There may be assessable mechanisms of cardiovascular death during this time period, but for simplicity, if the cardio- vascular death occurs ≤30 d of the MI, it will be considered a death attributable to MI.	• Yes • No • Unknown		Hicks KA, Mahaffey KW, Mehran R, et al. 2017 Cardiovascular and stroke endpoint definitions for clinical trials. <i>J Am Coll Cardiol.</i> 2018;71:1021-1034. <sup>105</sup>	Acute MI should be verified to the extent possible by the diagnostic criteria outlined for acute MI or by autopsy findings showing recent MI or recent coronary thrombosis. Death resulting from a procedure to treat an MI (PCI, CABG), or to treat a complication resulting from MI, should also be considered death attributable to acute MI. Death resulting from an elective coronary procedure to treat myocardial ischemia (ie, chronic stable angina), or death attributable to an MI that occurs as a direct consequence of a cardiovascular investigation/ procedure/operation, should be considered as a death attributable to a cardiovascular procedure.
Sudden cardiac death	<ul> <li>Death that occurs unexpectedly and suddenly without ROSC in a patient with probable or confirmed acute COVID-19 and not within 30 d of an acute MI. Sud- den cardiac death includes the following scenarios:</li> <li>a. Death witnessed and occurring with- out new or worsening symptoms</li> <li>b. Death witnessed within 60 min of the onset of new or worsening cardiac symptoms, unless the symptoms sug- gest acute MI</li> </ul>	• Yes • No • Unknown		Hicks KA, Mahaffey KW, Mehran R, et al. 2017 Cardiovascular and stroke endpoint definitions for clinical trials. <i>J Am Coll Cardiol.</i> 2018;71:1021-1034. <sup>105</sup> Turagam MK, Musi- kantow D, Goldman ME, et al. Malignant arrhythmias in patients with COVID-19: inci- dence, mechanisms, and outcomes. <i>Circ</i> <i>Arrhythm Electrophysiol.</i> 2020;13:e008920. <sup>72</sup>	Unless additional information sug- gests an alternate specific cause of death (eg, death attributable to other cardiovascular causes), if a patient is seen alive ≤24 h of being found dead, sudden cardiac death should be recorded. For patients who were not observed alive within 24 h of death, undetermined cause of death should be recorded (eg, a subject found dead in bed, but who had not been seen by family for >24 h). Patients with respiratory failure, progressive hypoxia, multiorgan failure, septic shock attributable to COVID-19 should not be catego- rized as sudden cardiac death.

#### C. Cardiovascular Mortality During Acute COVID-19 Infection

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
	<ul> <li>c. Death witnessed and attributed to an identified arrhythmia (eg, captured on an ECG recording, witnessed on a monitor, with asystole, pulseless electrical activity, ventricular tachycardia, or ventricular fibrillation, or unwitnessed but found on implantable cardioverter-defibrillator review)</li> <li>d. Unwitnessed death in a subject seen alive and clinically stable ≤24 h prior to being found dead without any evidence supporting a specific noncardiovascular cause of death (information regarding the patient's clinical status preceding death should be provided, if available)</li> </ul>				
Death attributable to HF	Death in association with clinically worsening symptoms or signs of HF re- gardless of HF etiology in a patient with probable or confirmed acute COVID-19. Deaths attributable to HF with COVID-19 can have various etiolo- gies, including myocarditis, myocardial injury, cardiogenic shock, cardiomyopa- thy, MI, ischemic or nonischemic cardio- myopathy.	• Yes • No • Unknown		Hicks KA, Mahaffey KW, Mehran R, et al. 2017 Cardiovascular and stroke endpoint definitions for clinical trials. <i>J Am Coll Cardiol.</i> 2018;71:1021-1034. <sup>105</sup>	
Death attributable to stroke	Death after a stroke that is either a direct consequence of the stroke or a com- plication of the stroke in a patient with probable or confirmed acute COVID-19. Acute stroke should be verified to the extent possible by the diagnostic criteria outlined for stroke.	• Yes • No • Unknown		Hicks KA, Mahaffey KW, Mehran R, et al. 2017 Cardiovascular and stroke endpoint definitions for clinical trials. <i>J Am Coll Cardiol.</i> 2018;71:1021-1034. <sup>105</sup>	
Death attributable to cardio- vascular procedure	Death caused by the immediate compli- cations of a cardiovascular procedure in a patient with probable or confirmed acute COVID-19	• Yes • No • Unknown		Hicks KA, Mahaffey KW, Mehran R, et al. 2017 Cardiovascular and stroke endpoint definitions for clinical trials. <i>J Am Coll Cardiol.</i> 2018;71:1021-1034. <sup>105</sup>	
Death attributable to cardio- vascular hemorrhage	Death related to hemorrhage such as a nonstroke intracranial hemorrhage (eg, subdural hematoma), nonprocedural or nontraumatic vascular rupture (eg, aortic aneurysm), or hemorrhage causing cardi- ac tamponade in a patient with probable or confirmed acute COVID-19	• Yes • No • Unknown		Hicks KA, Mahaffey KW, Mehran R, et al. 2017 Cardiovascular and stroke endpoint definitions for clinical trials. <i>J Am Coll Cardiol.</i> 2018;71:1021-1034. <sup>105</sup>	
Death attribut- able to pulmonary embolus	Death caused by pulmonary embolus in a patient with probable or confirmed acute COVID-19	• Yes • No • Unknown		Hicks KA, Mahaffey KW, Mehran R, et al. 2017 Cardiovascular and stroke endpoint definitions for clinical trials. <i>J Am Coll Cardiol.</i> 2018;71:1021-1034. <sup>105</sup>	
Death attributable to other cardio- vascular causes	Cardiovascular death not included in the above categories but with a specific, known cause (eg, peripheral arterial disease)	• Yes • No • Unknown		Hicks KA, Mahaffey KW, Mehran R, et al. 2017 Cardiovascular and stroke endpoint definitions for clinical trials. <i>J Am Coll Cardiol.</i> 2018;71:1021-1034. <sup>105</sup>	

CABG indicates coronary artery bypass graft surgery; COVID-19, coronavirus disease-2019; ECG, electrocardiogram; HF, heart failure; MI, myocardial infarction; PCI, percutaneous coronary intervention; and ROSC, return of spontaneous circulation.

Appendix 5. COVID-19 Noncardiovas	scular Complications
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Data Flement	Data Element Definition	Permissible	Permissible	Mapping/Source of Definition	Additional Notes
ARDS	ARDS meeting standard clinical criteria in a patient with probable or confirmed COVID-19 and felt to be secondary to COVID-19	Yes     No     Unknown		Guan WJ, Ni ZY, Hu Y, et al. Clinical characteristics of coronavirus dis- ease 2019 in China. <i>N Engl J Med.</i> 2020;382:1708-1720. <sup>106</sup> Ranieri VM, Rubenfeld GD, Thompson BT, et al. Acute respira- tory distress syndrome: the Berlin definition. <i>JAMA</i> . 2012;307:2526- 2533. <sup>107</sup>	ARDS could be defined according to the Berlin criteria.
Pneumonia	Clinical pneumonia or asymp- tomatic pulmonary infiltrates in a patient with probable or confirmed COVID-19 and felt to be second- ary to COVID-19	• Yes • No • Unknown		Guan WJ, Ni ZY, Hu Y, et al. Clinical characteristics of coronavirus dis- ease 2019 in China. <i>N Engl J Med.</i> 2020;382:1708-1720. <sup>106</sup>	
Distributive shock	Distributive shock (eg, attributable to sepsis or SIRS), defined as an inadequate supply of oxygen at the tissue level to meet metabolic needs in a vasodilated state in a patient with probable or confirmed COVID-19	• Yes • No • Unknown		Haberman R, Axelrad J, Chen A, et al. Covid-19 in immune-mediated inflammatory diseases-case series from New York. <i>N Engl J Med.</i> 2020;383:85-88. <sup>108</sup> Channappanavar R, Perlman S. Pathogenic human coronavirus in- fections: causes and consequences of cytokine storm and immuno- pathology. <i>Semin Immunopathol.</i> 2017;39:529-539. <sup>109</sup>	Cytokine release syndrome was also ob- served in patients with SARS-CoV and MERS- CoV and may also be referred to as cytokine storm syndrome. For patients with both distributive and car- diogenic shock, both should be coded.
Acute kidney injury with renal replacement therapy	Abrupt reduction in kidney func- tion in a patient with probable or confirmed COVID-19, measured by urine output and renal biomark- ers requiring any renal replacement therapy	• Yes • No • Unknown		Guan WJ, Ni ZY, Hu Y, et al. Clinical characteristics of coronavirus dis- ease 2019 in China. <i>N Engl J Med.</i> 2020;382:1708-1720. <sup>106</sup> Gupta A, Madhavan MV, Sehgal K, et al. Extrapulmonary manifes- tations of COVID-19. <i>Nat Med.</i> 2020;26:1017-1032. <sup>92</sup>	Only for patients who were not previously on chronic renal replace- ment therapy for end- stage kidney disease
Acute kidney injury without renal replace- ment therapy	Abrupt reduction in kidney function in a patient with probable or con- firmed COVID-19, measured by urine output and renal biomarkers not requiring temporary or perma- nent renal replacement therapy	• Yes • No • Unknown		Guan WJ, Ni ZY, Hu Y, et al. Clinical characteristics of coronavirus dis- ease 2019 in China. <i>N Engl J Med.</i> 2020;382:1708-1720. <sup>106</sup> Gupta A, Madhavan MV, Sehgal K, et al. Extrapulmonary manifes- tations of COVID-19. <i>Nat Med.</i> 2020;26:1017-1032. <sup>92</sup>	Only for patients who were not previously on chronic renal replace- ment therapy for end- stage kidney disease
Acute liver injury with fulminant failure	Acute liver injury manifested by abnormalities in liver enzymes in a patient with probable or confirmed COVID-19. A minority of patients experience severe liver injury that can result in hepatic failure, de- fined as rapid loss of liver function during acute COVID-19, which is associated with coagulopathy or encephalopathy, and often multior- gan failure.	• Yes • No • Unknown		Guan WJ, Ni ZY, Hu Y, et al. Clinical characteristics of coronavirus dis- ease 2019 in China. <i>N Engl J Med.</i> 2020;382:1708-1720. <sup>106</sup> Phipps MM, Barraza LH, LaSota ED, et al. Acute liver injury in COVID-19: prevalence and as- sociation with clinical outcomes in a large US cohort. <i>Hepatology.</i> 2020;72:807-817. <sup>110</sup>	
Acute liver in- jury without ful- minant failure	Acute liver injury in a patient with probable or confirmed COVID-19, defined as abnormal liver chem- istries >2× ULN in the absence of signs of hepatic failure (eg, no coagulopathy or encephalopathy), is usually mild, transient, and does not require intervention.	• Yes • No • Unknown		Fix OK, Hameed B, Fontana RJ, et al. Clinical best practice advice for hepatology and liver transplant providers during the COVID-19 pandemic: AASLD expert panel consensus statement. <i>Hepatology</i> . 2020;72:287-304. <sup>111</sup>	

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Disseminated intravascular coagulation	Abnormalities in coagulation and fibrinolysis, resulting in a condition in which blood clots form through- out the body, thereby causing clotting in small blood vessels and increasing risk for hemorrhage, in a patient with probable or confirmed COVID-19	• Yes • No • Unknown		Guzik TJ, Mohiddin SA, Dimarco A, et al. COVID-19 and the cardio- vascular system: implications for risk assessment, diagnosis, and treatment options. <i>Cardiovasc Res.</i> 2020;116:1666-1687. <sup>112</sup> Connors JM, Levy JH. COVID-19 and its implications for thrombo- sis and anticoagulation. <i>Blood.</i> 2020;135:2033-2040. <sup>113</sup>	Coagulopathy may oc- cur in acute COVID-19 in the absence of dis- seminated intravascular coagulation.
Rhabdomyolysis	Destruction or degeneration of muscle tissue accompanied by the release of breakdown products from muscle cells into the blood- stream (eg, creatine kinase, aldol- ase) that may lead to acute kidney injury in a patient with probable or confirmed COVID-19	• Yes • No • Unknown		Jin M, Tong O. Rhabdomyolysis as potential late complication associ- ated with COVID-19. <i>Emerg Infect</i> <i>Dis.</i> 2020;26:1618-1620. <sup>114</sup>	
Seizures	Convulsions, sensory, cognitive disturbances, or loss of conscious- ness resulting from abnormal elec- trical discharges in the brain in a patient with probable or confirmed COVID-19	<ul><li>Yes</li><li>No</li><li>Unknown</li></ul>		Mao L, Jin H, Wang M, et al. Neuro- logic Manifestations of hospitalized patients with coronavirus disease 2019 in Wuhan, China. <i>JAMA Neu-</i> <i>rol.</i> 2020;77:683-690. <sup>115</sup>	
Encephalopathy	A functional or structural disorder of the brain	• Yes • No • Unknown		Liotta EM, Batra A, Clark JR, et al. Frequent neurologic manifestations and encephalopathy-associated mor- bidity in Covid-19 patients. <i>Ann Clin</i> <i>Transl Neurol.</i> 2020;7:2221-2230. <sup>116</sup>	
Loss of smell (anosmia)	Loss or impairment of olfactory function during COVID-19	• Yes • No • Unknown		Centers for Disease Control and Prevention. Coronavirus disease 2019 (COVID-19). Symptoms of coronavirus. Accessed March 4, 2022. https://www.cdc.gov/ coronavirus/2019-ncov/symptoms- testing/symptoms.html <sup>117</sup>	
Loss of taste (ageusia)	Loss or impairment of gustatory function during COVID-19	• Yes • No • Unknown		Centers for Disease Control and Prevention. Coronavirus disease 2019 (COVID-19). Symptoms of coronavirus. Accessed March 4, 2022. https://www.cdc.gov/ coronavirus/2019-ncov/symptoms- testing/symptoms.html <sup>117</sup>	
Pregnancy loss or other adverse pregnancy out- come	Pregnancy loss or other adverse pregnancy outcome (hypertensive disorders of pregnancy, preterm delivery, small for gestational age birth, gestational diabetes) in a patient with probable or confirmed COVID-19	• Yes • No • Unknown		Zambrano LD, Ellington S, Strid P, et al. Update: characteristics of symp- tomatic women of reproductive age with laboratory-confirmed SARS- CoV-2 infection by pregnancy status - United States, January 22-October 3, 2020. <i>MMWR Morb Mortal Wkly</i> <i>Rep.</i> 2020;69:1641-1647. <sup>118</sup>	
Syncope	Abrupt, transient, complete loss of consciousness, associated with the inability to maintain postural tone and rapid, spontaneous re- covery in a patient with probable or confirmed COVID-19	• Yes • No • Unknown		Shen WK, Sheldon RS, Benditt DG, et al. 2017 ACC/AHA/HRS guideline for the evaluation and management of patients with syncope: a report of the American College of Cardiology/ American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. <i>Circu- lation</i> . 2017;136:e60–e122. <sup>119</sup> Oates CP, Turagam MK, Musikan- tow D, et al. Syncope and presyn- cope in patients with COVID-19. <i>Pacing Clin Electrophysiol</i> . 2020;43:1139-1148. <sup>120</sup>	The presumed mecha- nism is cerebral hypo- perfusion. There should not be clinical features of other nonsyncopal causes of loss of con- sciousness, such as septic shock, seizure, antecedent head trauma, or apparent loss of con- sciousness (ie, pseudo- syncope).

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Presyncope	The symptoms before syncope. These symptoms could include ex- treme lightheadedness; visual sen- sations, such as "tunnel vision" or "graying out"; and variable degrees of altered consciousness without complete loss of consciousness. Presyncope could progress to syncope, or it could abort without syncope.	• Yes • No • Unknown		Shen WK, Sheldon RS, Benditt DG, et al. 2017 ACC/AHA/HRS guideline for the evaluation and management of patients with syncope: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. <i>Circula-</i> <i>tion</i> . 2017;136:e60–e122. <sup>119</sup>	
Cerebral vein thrombosis	The formation of a blood clot in a cerebral vein	• Yes • No • Unknown		NCI Thesaurus Code: C132727 <sup>63</sup>	
Other noncar- diovascular complication	Other noncardiovascular symptom(s) in a patient with prob- able or confirmed COVID-19 such as peripheral neuropathy, gastro- intestinal distress or diarrhea, de novo or acute worsening of chronic hyperglycemia, ocular symptoms, and livedo reticularis, which may be related to direct viral tissue dam- age or systemic inflammation and immunopathological damage	• Yes • No • Unknown		Gupta A, Madhavan MV, Sehgal K, et al. Extrapulmonary manifes- tations of COVID-19. <i>Nat Med.</i> 2020;26:1017-1032. <sup>92</sup>	

ARDS indicates acute respiratory distress syndrome; COVID-19, coronavirus disease-2019; MERS-CoV, Middle East respiratory syndrome coronavirus; SARS-CoV-2, severe acute respiratory syndrome-coronavirus-2; SIRS, systemic inflammatory response syndrome; and ULN, upper limit of normal.

#### Appendix 6. Symptoms and Signs A. Current Symptoms and Signs: Clinical Symptoms

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Cough	A sudden, often repetitive, spasmodic contraction of the thoracic cavity, resulting in violent release of air from the lungs, and usually accompa- nied by a distinctive sound	• Yes • No • Unknown		Boris JR, Béland MJ, Bergensen LJ, et al. 2017 AHA/ACC key data elements and defi- nitions for ambulatory electronic health re- cords in pediatric and congenital cardiology: a report of the American College of Cardiol- ogy/American Heart Association Task Force on Clinical Data Standards. <i>Circ Cardiovasc</i> <i>Qual Outcomes.</i> 2017;10:e000027. <sup>86</sup>	
Presence and severity of dyspnea	Indicate degree of activity required to elicit dyspnea symptom.	<ul> <li>No limitation of physical activity by dyspnea</li> <li>Dyspnea with moderate physi- cal activity</li> <li>Dyspnea with mild physical activity</li> <li>Dyspnea at rest</li> </ul>		Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the man- agement of heart failure: a report of the American College of Cardiology Founda- tion/American Heart Association Task Force on Practice Guidelines. <i>Circulation</i> . 2013;128:e240–e327. <sup>69</sup> Bozkurt B, Coats AJ, Tsutsui H, et al. Universal definition and classification of heart failure: a report of the Heart Failure Society of America, Heart Failure Associa- tion of the European Society of Cardiology, Japanese Heart Failure Society and Writing Committee of the Universal Definition of Heart Failure. <i>J Card Fail</i> . 2021;27:387- 413. <sup>69</sup>	Consider reporting extent of activity required to elicit dyspnea.

#### A. Current Symptoms and Signs: Clinical Symptoms

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Orthopnea	Uncomfortable awareness of breathing while in a supine position, improved by sitting upright or standing	• 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 As- sociation Task Force on Practice Guidelines. <i>Circulation</i> . 2013;128:e240–e327. <sup>69</sup> Bozkurt B, Coats AJ, Tsutsui H, et al. Universal definition and classification of heart failure: a report of the Heart Failure Society of America, Heart Failure Association of the European Society of Cardiology, Japanese Heart Failure Society and Writing Committee of the Uni- versal Definition of Heart Failure. <i>J Card Fail</i> . 2021;27:387-413. <sup>68</sup>	Recurrent supine cough without other known cause may be an orthopnea equivalent.
Paroxysmal nocturnal dyspnea	Sudden awakening from sleep with uncomfortable awareness of breathing, relieved by sitting upright or standing. A reported dura- tion >5 min is considered positive.	• 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 As- sociation Task Force on Practice Guidelines. <i>Circulation</i> . 2013;128:e240–e327. <sup>69</sup> Bozkurt B, Coats AJ, Tsutsui H, et al. Universal definition and classification of heart failure: a report of the Heart Failure Society of America, Heart Failure Association of the European Society of Cardiology, Japanese Heart Failure Society and Writing Committee of the Uni- versal Definition of Heart Failure. <i>J Card Fail</i> . 2021;27:387-413. <sup>68</sup>	
Fatigue	Unusual tiredness and inabil- ity to perform usual activities	• 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 As- sociation Task Force on Practice Guidelines. <i>Circulation</i> . 2013;128:e240–e327. <sup>69</sup> Bozkurt B, Coats AJ, Tsutsui H, et al. Universal definition and classification of heart failure: a report of the Heart Failure Society of America, Heart Failure Association of the European Society of Cardiology, Japanese Heart Failure Society and Writing Committee of the Uni- versal Definition of Heart Failure. <i>J Card Fail</i> . 2021;27:387-413. <sup>68</sup>	
Syncope	Abrupt, transient, complete loss of consciousness, asso- ciated with inability to main- tain postural tone, with rapid and spontaneous recovery	• Yes • No • Unknown		Shen WK, Sheldon RS, Benditt DG, et al. 2017 ACC/AHA/HRS guideline for the evaluation and management of patients with syncope: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. <i>Circulation</i> . 2017;136:e60–e122. <sup>119</sup> Oates CP, Turagam MK, Musikantow D, et al. Syncope and presyncope in patients with COVID-19. <i>Pacing Clin Electrophysiol</i> . 2020;43:1139-1148. <sup>120</sup>	The presumed mech- anism is cerebral hypoperfusion. There should not be clini- cal features of other nonsyncopal causes of loss of conscious- ness, such as septic shock, seizure, ante- cedent head trauma, or apparent loss of consciousness (ie, pseudosyncope).
Presyncope	The symptoms before syn- cope. These symptoms could include extreme lightheaded- ness, visual sensations, such as "tunnel vision" or "graying out," and variable degrees of altered consciousness without complete loss of conscious- ness. Presyncope could prog- ress to syncope, or it could abort without syncope.	• Yes • No • Unknown		Shen WK, Sheldon RS, Benditt DG, et al. 2017 ACC/AHA/HRS guideline for the evaluation and management of patients with syncope: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. <i>Circulation</i> . 2017;136:e60–e122. <sup>119</sup>	

#### A. Current Symptoms and Signs: Clinical Symptoms

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Acute pulmonary edema	Acute onset or rapid pro- gression of pulmonary edema causing significant hypoxemia or need for supplemental oxygen	• Yes • No • Unknown		American Heart Association. Get With The Guidelines - Heart Failure. Accessed March 4, 2022. https://www.heart.org/en/profes- sional/quality-improvement/getwith-the-guide- lines/get-with-the-guidelines-heartfailure <sup>121</sup>	
Fever	Temperature ≥100.4°F (38.0°C)	• Yes • No • Unknown		O'Grady NP, Barie PS, Bartlett JG, et al. Guidelines for evaluation of new fever in criti- cally ill adult patients: 2008 update from the American College of Critical Care Medicine and the Infectious Diseases Society of Ameri- ca. <i>Crit Care Med.</i> 2008;36:1330-1349. <sup>122</sup>	
Loss of smell (anosmia)	Loss or impairment of olfac- tory function during COVID-19	• Yes • No • Unknown		Centers for Disease Control and Prevention. Coronavirus disease 2019 (COVID-19). Symptoms of coronavirus. Accessed March 4, 2022. https://www.cdc.gov/ coronavirus/2019-ncov/symptoms-testing/ symptoms.html <sup>117</sup>	
Loss of taste (ageusia)	Loss or impairment of gustatory function during COVID-19	• Yes • No • Unknown		Centers for Disease Control and Prevention. Coronavirus disease 2019 (COVID-19). Symp- toms of coronavirus. Accessed March 4, 2022. https://www.cdc.gov/coronavirus/2019-ncov/ symptoms-testing/symptoms.html <sup>117</sup>	
Diarrhea	Passage of ≥3 loose or liq- uid stools per day (or more frequent passage than is normal for the individual)	• Yes • No • Unknown		World Health Organization. Diarrhoeal dis- ease. Accessed March 4, 2022. https://www. who.int/en/news-room/fact-sheets/detail/ diarrhoeal-disease <sup>123</sup>	
Nausea or vomiting	Vomiting or the inclination to vomit	• Yes • No • Unknown		NCI Thesaurus Codes: C3258, C344263	
Seizures	Transient neurological symp- toms attributable to abnormal excessive or synchronous neuronal activity in the brain	• Yes • No • Unknown		Hauser WA, Beghi E. First seizure definitions and worldwide incidence and mortality. <i>Epi-</i> <i>lepsia</i> . 2008;49(Suppl 1):8-12. <sup>124</sup>	
Skin rash	Any change in the skin that affects its appearance or texture. A rash may be local- ized to one part of the body or affect all the skin. Rashes may cause the skin to change col- or, itch, become warm, bumpy, dry, cracked, or blistered, swell, and may be painful.	• Yes • No • Unknown		Boris JR, Béland MJ, Bergensen LJ, et al. 2017 AHA/ACC key data elements and definitions for ambulatory electronic health re- cords in pediatric and congenital cardiology: a report of the American College of Cardiol- ogy/American Heart Association Task Force on Clinical Data Standards. <i>Circ Cardiovasc</i> <i>Qual Outcomes</i> . 2017;10:e000027. <sup>86</sup>	
Limb edema	Swelling of upper or lower extremities	• Yes • No • Unknown		American Heart Association. Get With The Guidelines - Heart Failure. Accessed March 4, 2022. https://www.heart.org/en/profes- sional/quality-improvement/getwith-the-guide- lines/get-with-the-guidelines-heartfailure <sup>121</sup>	
Myalgias	Painful sensation originating from a muscle or group of muscles	• Yes • No • Unknown		NCI Thesaurus Code: C2700963	
Headache	Pain in any region of the head	• Yes • No • Unknown		American Academy of Neurology. Understand- ing of headaches improves with revised criteria. Accessed March 4, 2022. https://www.aan. com/PressRoom/home/PressRelease/223 <sup>125</sup>	
Altered mental state	A change to an individual's judgment, orientation (to place, time, and self), intel- lectual functioning, or mood from their baseline	• Yes • No • Unknown		Díaz-Pérez C, Ramos C, López-Cruz A, et al. Acutely altered mental status as the main clinical presentation of multiple strokes in critically ill patients with COVID-19. <i>Neurol</i> <i>Sci.</i> 2020;41:2681-2684. <sup>126</sup> NCI Thesaurus Code: C121628 <sup>83</sup>	

COVID-19 indicates coronavirus disease 2019.

## **B.** Physical Examination

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Heart rate	Number of heartbeats per unit of time (typically 1 min) recorded closest to the time of presentation to the health care facility or on discharge (for inpatient)	<ul><li>Numeric, bpm</li><li>Unknown</li></ul>		NCI Thesaurus Code: C49677 <sup>83</sup>	
Systolic blood pressure	Systolic blood pressure value recorded closest to the time of presentation to the health care facility	Numeric, mm Hg     Unknown		NCI Thesaurus Code: C25298 <sup>63</sup>	
Diastolic blood pressure	Diastolic blood pressure value recorded closest to the time of presentation to the health care facility	<ul><li>Numeric, mm Hg</li><li>Unknown</li></ul>		NCI Thesaurus Code: C25299 <sup>63</sup>	
Pulse pressure	The force of a heart contraction measured by the difference be- tween the diastolic and systolic blood pressure measurements	<ul><li>Numeric, mm Hg</li><li>Unknown</li></ul>		NCI Thesaurus Code: C100945 <sup>63</sup>	
Respiratory rate	A measurement that describes the rate of breathing (inhalation and exhalation) measured with- in a unit time (typically 1 min)	<ul><li>Numeric, cycles/min</li><li>Unknown</li></ul>		Boris JR, Béland MJ, Bergensen LJ, et al. 2017 AHA/ACC key data elements and definitions for ambulatory electronic health records in pediatric and con- genital cardiology: a report of the American College of Cardi- ology/American Heart Associa- tion Task Force on Clinical Data Standards. <i>Circ Cardiovasc Qual</i> <i>Outcomes.</i> 2017;10:e000027. <sup>86</sup>	
Height	A measurement that describes the vertical measurement or distance from the base, or bot- tom, of the patient, to the top of the patient; this can be taken as the dimension of extension of a patient who cannot stand.	<ul><li>Numeric, cm</li><li>Unknown</li></ul>		Boris JR, Béland MJ, Bergensen LJ, et al. 2017 AHA/ACC key data elements and definitions for ambulatory electronic health records in pediatric and con- genital cardiology: a report of the American College of Cardi- ology/American Heart Associa- tion Task Force on Clinical Data Standards. <i>Circ Cardiovasc Qual</i> <i>Outcomes.</i> 2017;10:e000027. <sup>86</sup>	
Weight at encounter	A measurement that describes the vertical force exerted by a mass of the patient as a result of gravity	<ul><li>Numeric, kg</li><li>Unknown</li></ul>		Boris JR, Béland MJ, Bergensen LJ, et al. 2017 AHA/ACC key data elements and definitions for ambulatory electronic health records in pediatric and con- genital cardiology: a report of the American College of Cardi- ology/American Heart Associa- tion Task Force on Clinical Data Standards. <i>Circ Cardiovasc Qual</i> <i>Outcomes.</i> 2017;10:e000027. <sup>86</sup>	
Body mass index	A measurement that is used to indicate the body fat an individual is carrying based on the ratio of weight to height as measured in kilograms per square meters	<ul> <li>Numeric, kg/m<sup>2</sup></li> <li>Unknown</li> </ul>		Boris JR, Béland MJ, Bergensen LJ, et al. 2017 AHA/ACC key data elements and definitions for ambulatory electronic health records in pediatric and con- genital cardiology: a report of the American College of Cardi- ology/American Heart Associa- tion Task Force on Clinical Data Standards. <i>Circ Cardiovasc Qual</i> <i>Outcomes.</i> 2017;10:e000027. <sup>86</sup>	

## **B.** Physical Examination

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Jugular venous pressure	The estimated height of the mean jugular venous waveform above the right atrium, mea- sured at a 45° 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.	<ul><li>Numeric, cm</li><li>Unknown</li></ul>		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 Cardiol- ogy Foundation/American Heart Association Task Force on Practice Guidelines. <i>Circulation</i> . 2013;128:e240–e327. <sup>69</sup>	
Jugular venous distention	Increased pressure of the su- perior 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 Cardiol- ogy Foundation/American Heart Association Task Force on Practice Guidelines. <i>Circulation</i> . 2013;128:e240–e327. <sup>69</sup>	
Hepatojugu- Iar reflux	Distention of the neck veins precipitated by the maneuver of firm sustained pressure over the liver. Also referred to as abdomino-jugular reflux.	• Yes • No • Unknown		Wiese J. The abdomino- jugular reflux sign. <i>Am J Med.</i> 2000;109:59-61. <sup>127</sup>	
Third heart sound (S <sub>3</sub> )	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 Cardiol- ogy Foundation/American Heart Association Task Force on Practice Guidelines. <i>Circulation</i> . 2013;128:e240–e327 <sup>69</sup>	
Fourth heart sound (S <sub>4</sub> )	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 Cardiol- ogy Foundation/American Heart Association Task Force on Practice Guidelines. <i>Circulation</i> . 2013;128:e240–e327. <sup>69</sup>	
Rub	An auscultated finding describ- ing high or medium pitched and scratchy sound, generated by inflammation of the pericardial sac	• Yes • No • Unknown		Boris JR, Béland MJ, Bergensen LJ, et al. 2017 AHA/ACC key data elements and definitions for ambulatory electronic health records in pediatric and con- genital cardiology: a report of the American College of Cardi- ology/American Heart Associa- tion Task Force on Clinical Data Standards. <i>Circ Cardiovasc Qual</i> <i>Outcomes.</i> 2017;10:e000027. <sup>86</sup>	
Heart murmur	An auscultated finding de- scribing a series of audible vibrations of varying intensity (loudness), frequency (pitch), quality, configuration, and dura- tion created by turbulent blood flow in the heart or surrounding vessels	• Yes • No • Unknown		Boris JR, Béland MJ, Bergensen LJ, et al. 2017 AHA/ACC key data elements and definitions for ambulatory electronic health records in pediatric and con- genital cardiology: a report of the American College of Cardi- ology/American Heart Associa- tion Task Force on Clinical Data Standards. <i>Circ Cardiovasc Qual</i> <i>Outcomes.</i> 2017;10:e000027. <sup>86</sup>	

### **B.** Physical Examination

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Heart murmur – timing	The classification of a heart murmur based on the phase of the cardiac cycle or timing of its occurrence	<ul><li>Systolic</li><li>Diastolic</li></ul>		NCI Thesaurus Code: C167438 <sup>63</sup>	
Heart sounds - location (including murmurs)	The classification of a heart murmur based on location	<ul> <li>Apex</li> <li>Left lower sternal border</li> <li>Left middle sternal border</li> <li>Left upper sternal border</li> <li>Right upper sternal border</li> </ul>		Boris JR, Béland MJ, Bergensen LJ, et al. 2017 AHA/ACC key data elements and definitions for ambulatory electronic health records in pediatric and con- genital cardiology: a report of the American College of Cardi- ology/American Heart Associa- tion Task Force on Clinical Data Standards. <i>Circ Cardiovasc Qual</i> <i>Outcomes.</i> 2017;10:e000027. <sup>86</sup>	
		Арех	The location on the precordium that cor- responds to the location of the blunt extremity of the heart formed by the left ventricle.	Stedman's Medical Diction- ary. 28th ed. Wolters Kluwer; 2006 <sup>128</sup>	
		Left lower sternal border	The location on the precordium that corre- sponds to the tricuspid region, between the fifth and sixth intercostal spaces at the left sternal border	Tavel ME. Cardiac ausculta- tion. A glorious past-but does it have a future? <i>Circulation</i> . 1996;93:1250-1253. <sup>129</sup>	
		Left middle sternal border	The location on the precordium that corre- sponds to the region be- tween the third and fifth intercostal spaces at the left sternal border		
		Left upper sternal border	The location on the precordium that corre- sponds to the pulmonic region, between the second and third inter- costal spaces at the left sternal border	Tavel ME. Cardiac ausculta- tion. A glorious past-but does it have a future? <i>Circulation</i> . 1996;93:1250-1253. <sup>129</sup>	
		Right upper sternal border	The location on the precordium that cor- responds to the aortic region, between the second and third inter- costal spaces at the right sternal border	Tavel ME. Cardiac ausculta- tion. A glorious past-but does it have a future? <i>Circulation</i> . 1996;93:1250-1253. <sup>129</sup>	
Lung (pulmonary) examination findings	Findings on auscultation of the lungs	<ul> <li>Clear or normal</li> <li>Rales</li> <li>Decreased breath sounds or dullness</li> <li>Rhonchi</li> <li>Wheezing</li> <li>Crepitations</li> <li>Pleural friction rub</li> <li>Absent breath sounds</li> <li>Other findings</li> </ul>			
		Clear or normal	Lungs are normal on auscultation.		

#### **B.** Physical Examination

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Rales	Abnormal breath sounds (crackles) heard on auscultation indicating inflammation, fluid, or infection of the lung	NCI Thesaurus Code: C119216 <sup>63</sup>	
		Decreased breath sounds or dullness	Diminished breath sounds		
		Rhonchi	Abnormal breath sounds similar to snoring heard on auscultation of the bron- chial airways, suggesting a partial obstruction attribut- able to thick secretions, a muscular spasm, or a neoplasm	NCI Thesaurus Code: C87116 <sup>83</sup>	
		Wheezing	Abnormal breath sounds characterized by a high-pitched, whistling sounds during breathing	NCI Thesaurus Code: C78718 <sup>83</sup>	End-expiratory wheezes may indicate broncho- spasm.
		Crepitations	Crackling sounds typically heard in lung infection or with pulmonary fibrosis	NCI Thesaurus Code: C26860 <sup>63</sup>	
		Pleural friction rub	An abnormal lung sound that is caused by inflam- mation of the pleural lay- er of the lungs rubbing together. Pleural friction rub is heard on inspira- tion and expiration and sounds like a low-pitch harsh/grating noise.		
		Absent breath sounds	Absence of breath sounds during auscultation		
Peripheral edema	Increased tissue fluid indicated by perceptible indentation on lower leg or foot after palpation	Other findings • 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 Cardiol- ogy Foundation/American Heart Association Task Force on Practice Guidelines. <i>Circulation</i> . 2013;128:e240–e327. <sup>69</sup>	
Ascites	Intra-abdominal fluid accumula- tion as determined by physical examination	• 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 Cardiol- ogy Foundation/American Heart Association Task Force on Practice Guidelines. <i>Circulation</i> . 2013;128:e240–e327. <sup>69</sup>	Abdominal ultra- sound may also demonstrate pres- ence of ascites.
Hepato- megaly	Liver edge detectable below the right costal margin during examination	• 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 Cardiol- ogy Foundation/American Heart Association Task Force on Practice Guidelines. <i>Circulation</i> . 2013;128:e240–e327. <sup>69</sup>	

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Neurological examination findings		<ul> <li>Dizziness</li> <li>Headache</li> <li>Impaired consciousness</li> <li>Seizure</li> <li>Agitation</li> <li>Confusion</li> <li>Visual agnosia</li> <li>Encephalopathy</li> <li>Acute cerebrovascular accident</li> <li>Corticospinal tract signs (eg, enhanced tendon reflexes, clonus, hyperreflexia)</li> <li>Stroke</li> <li>Guillain-Barré syndrome</li> <li>Critical illness polyneuropathy/myopathy</li> <li>Miller-Fisher syndrome</li> <li>Other, specify</li> </ul>		Whittaker A, Anson M, Harky A. Neurological manifestations of COVID-19: a systematic review and current update. <i>Acta Neurol</i> <i>Scand</i> . 2020;142:14-22. <sup>130</sup> Heneka MT, Golenbock D, Latz E, et al. Immediate and long-term consequences of COVID-19 infections for the development of neurological disease. <i>Alzheimers Res Ther</i> . 2020;12:69. <sup>131</sup>	
Frailty	Canadian Study of Health and Aging Clinical Frailty Scale score	<ul> <li>1 (very fit)</li> <li>2 (well)</li> <li>3 (managing well)</li> <li>4 (vulnerable)</li> <li>5 (mildly frail)</li> <li>6 (moderately frail)</li> <li>7 (severely frail)</li> <li>8 (very severely frail)</li> <li>9 (terminally ill)</li> </ul>		NCDR CathPCI Registry Cod- er's Data Dictionary v5.0 (data element #4561) <sup>84</sup> Rockwood K, Song X, MacKnight C, et al. A global clinical measure of fitness and frailty in elderly people. <i>CMAJ</i> . 2005;173:489-495. <sup>132</sup>	Scoring frailty in people with dementia: The degree of frailty corresponds to the degree of de- mentia. Common symptoms in mild dementia include forgetting the details of a recent event, although still remembering the event itself, repeating the same question/ story, and social withdrawal. In moderate demen- tia, recent memory is very impaired, even though they seemingly can remember their past life events well. They can do personal care with out help.
		1 (very fit)	People who are robust, active, energetic, and motivated. These people commonly exercise reg- ularly. They are among the fittest for their age.		

#### **B.** Physical Examination

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		2 (well)	People who have no ac- tive disease symptoms but are less fit than category 1. Often, they exercise or are very ac- tive occasionally (eg, seasonally)		
		3 (managing well)	People whose medi- cal problems are well controlled but are not regularly active beyond routine walking		
		4 (vulnerable)	Although not dependent on others for daily help, symptoms often limit ac- tivities. A common com- plaint is being "slowed up" or being tired during the day.		
		5 (mildly frail)	These people often have more evident slow- ing and need help in high-order instrumental activities of daily living (finances, transporta- tion, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation, and housework.		
		6 (moderately frail)	People need help with all outside activities and with keeping house. Inside, they often have problems with stairs and need help with bathing and might need minimal assistance (cueing, standby) with dressing.		
		7 (severely frail)	Completely dependent for personal care, from whatever cause (physi- cal or cognitive). Even so, they seem stable and not at high risk of dying (within ~6 mo).		
		8 (very severely frail)	Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.		
		9 (terminally ill)	Approaching the end of life. This category applies to people with a life expectancy <6 mo, who are not otherwise evidently frail.		

bpm indicates beats per minute.

#### Appendix 7. Diagnostic Procedures

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
EF, quantitative	Proportion of blood pumped out of the left ventricle of the heart with each contraction, expressed as a per- centage	<ul> <li>EF, %</li> <li>When a quantitative range is given, the midpoint of the range</li> </ul>	The fraction of blood expelled from the left ventricle with each cardiac systole (stroke volume/end diastolic volume)	NCI Thesaurus Code: C80418 <sup>83</sup>	When multiple determina- tions are present, the most recent is preferred. Please note modality (eg, radionuclide ventriculog- raphy, MRI, ECG, con- trast, ventriculography, nuclear imaging).
EF, qualitative	Proportion of blood pumped out of the left ventricle of the heart with each contraction, expressed as qualitative description	Normal (ie, ≥50%)     Mildly reduced (ie, ≥40% and <50%)     Moderately reduced (ie, ≥30% and <40%)     Severely reduced (ie, <30%)	The qualitative estimate of the amount of blood expelled from the left ventricle with each cardiac systole	NCI Thesaurus Code: C80418 <sup>63</sup>	If a quantitative EF is provided, it is preferred to enter the quantitative value rather than the qualitative ranges.
EF modality	Modality used to deter- mine the EF	<ul> <li>Radionuclide ventriculography</li> <li>Cardiac MRI</li> <li>Echocardiography</li> <li>Invasive contrast left ventriculography</li> <li>Myocardial perfusion imaging</li> <li>Other</li> </ul>			
		Radionuclide ventricu- lography	A multigated acquisition scan and a form of radionuclide imaging that pro- vides a comprehensive look at blood flow and the function of the lower chambers of the heart ventricles	NCI Thesaurus Code: C38073 <sup>83</sup>	
		Cardiac MRI	Imaging that uses radiofrequency waves and a strong field rather than x-rays to provide amazingly clear and detailed pictures of cardiac structures. The technique is valuable for the diagnosis of many cardiovascular pathological condi- tions, including myocarditis, wall motion abnormalities, structural cardiac abnor- malities, infiltrative diseases, intracardiac thrombus, and pericardial disease.	NCI Thesaurus Code: C16809 <sup>43</sup>	
		Echocardiography	A test that uses high-frequency sound waves (ultrasound) to create an image of the heart	NCI Thesaurus Code: C16525 <sup>63</sup>	
		Invasive contrast left ventriculography	A medical imaging test that involves injecting contrast media into the heart's ventricle(s) to determine a patient's cardiac function	NCI Thesaurus Code: C124142 <sup>63</sup>	
		Myocardial perfusion imaging	A procedure that captures pictures of blood flow throughout the heart muscle	NCI Thesaurus Code: C102676 <sup>63</sup>	
		Other			
Echocardiography data elements	Refer to the 2019 ACC/ AHA/ASE Key Data Ele- ments and Definitions for Transthoracic Echo- cardiography.			Douglas PS, Carabello BA, Lang RM, et al. 2019 ACC/AHA/ASE key data elements and definitions for transthoracic echocardiog- raphy: a report of the Ameri- can College of Cardiology/ American Heart Association Task Force on Clinical Data Standards (Writing Com- mittee to Develop Clinical Data Standards for Trans- thoracic Echocardiography) and the American Society) and the American Society. <i>Circ Cardiovasc Imaging</i> . 2019;12:e000027. <sup>133</sup>	

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Data Element electrocardio- graphic elements	Definition 12-lead electrocardiographic data elements	<ul> <li>Permissible Values</li> <li>Rhythm</li> <li>Heart rate, bpm</li> <li>QRS axis</li> <li>LBBB</li> <li>RBBB</li> <li>Nonspecific intraventricular conduction delay</li> <li>Presence of abnormal Q waves</li> <li>Mean QRS duration, ms</li> <li>PR interval</li> <li>QTc interval</li> <li>AV block</li> <li>ST-segment changes</li> <li>Rhythm</li> </ul>	Permissible Value Definitions Presence of: • Sinus rhythm: an electrocardio- graphic finding of a cardiac rhythm	NCI Thesaurus Codes: C100076, C50466, C51224, C26924,	Additional Notes
			<ul> <li>Supplies in the sineatrial node</li> <li>AF: an arrhythmia characterized by uncoordinated atrial myocardium attributable to multiple reentry circuits with consequent deteriora- tion of atrial mechanical function. Instead of intermittently contract- ing, the atria quiver continuously in a chaotic pattern, causing a totally irregular often tachycardic ventricular rate</li> <li>Atrial flutter: a disorder character- ized by an electrocardiographic finding of an organized, regular atrial rhythm with atrial rate of 240–340 bpm. Multiple P waves typically appear in the inferior leads in a saw- tooth-like pattern between the QRS complexes.</li> <li>Ventricular arrhythmia: a disorder characterized by an electrocar- diographic finding of an atypical cardiac rhythm resulting from a pathological process in the cardiac ventricles</li> <li>Supraventricular tachycardia: a disorder characterized by an elec- trocardiographic finding of a tachy- cardia that does not originate in the ventricles or His Purkinje system</li> </ul>	C35061, C111094, C88140 <sup>83</sup>	
			<ul> <li>Paced rhythm: an electrocardio- graphic finding that the cardiac rhythm is initiated by an electrical impulse from a mechanical cardiac pacemaker</li> <li>Other</li> </ul>		
		Heart rate, bpm	The number of heartbeats per unit of time, usually expressed as beats per min	NCI Thesaurus Code: C49677 <sup>63</sup>	
		QRS axis	A numerical representation of the electrocardiographic vector assessed at maximum deviation of the QRS complex from the isoelectric baseline, usually reported for the frontal plane	NCI Thesaurus Code: C11816583	

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		LBBB	An electrocardiographic finding of delayed conduction to the left ven- tricle, manifested as a widened QRS complex and absence of Q waves in leads V5, V6, I, and aVL with QRS duration ≥120 ms	NCI Thesaurus Code: C62269 <sup>83</sup>	
		RBBB	An electrocardiographic finding of de- layed conduction to the right ventricle, manifested by a widened QRS in V <sub>1</sub> and V <sub>2</sub> , a widened S-wave in V <sub>5</sub> , V <sub>6</sub> , I and aVL, and with QRS duration $\geq$ 120 ms. An RsR' complex is typically pres- ent in leads V <sub>1</sub> and V <sub>2</sub>	NCI Thesaurus Code: C62270 <sup>63</sup>	
		Nonspecific intraventric- ular conduction delay	An electrocardiographic finding of a widened QRS duration typically >110 ms that does not meet the morpho- logical criteria for any of the standard bundle branch or fascicular block patterns	NCI Thesaurus Code: C62271 <sup>63</sup>	
		Presence of abnormal Q waves	≥0.03 s in width and ≥1 mm (0.1 mV) in depth in at least 2 contiguous leads		
		Mean QRS duration, ms	The mean duration of the QRS inter- val, obtained from a set of measure- ments of the QRS interval. The QRS interval is defined as the time from the beginning of the QRS complex to the end of the QRS complex, representing the time it takes for the ventricles to depolarize.	NCI Thesaurus Code: C62087 <sup>83</sup>	
		PR interval	The time interval between the start of the P-wave and the beginning of the QRS complex in the cardiac cycle	NCI Thesaurus Code: C83502 <sup>63</sup>	
		QTc interval	The time interval between the start of the O-wave and the end of the T-wave in the cardiac cycle as corrected with a nonspecified correction formula	NCI Thesaurus Code: C100391 <sup>63</sup>	
		AV block	An electrocardiographic finding of blocked cardiac electrical impulses along the fibers normally responsible for impulse conduction	NCI Thesaurus Code: C26703 <sup>63</sup>	
		ST-segment changes	An electrocardiographic finding of ST- segment elevation or depression	NCI Thesaurus Code: C26703 <sup>63</sup>	
Chest Documented find radiography from the radiolog examination of th (chest x-ray)	Documented findings from the radiological examination of the chest (chest x-ray)	<ul> <li>Pulmonary infiltrates</li> <li>Pulmonary vascular redistribution</li> <li>Pulmonary congestion</li> <li>Pulmonary edema</li> </ul>			
		<ul> <li>Cardiomegaly, chamber enlargement</li> <li>Pleural effusion(s)</li> <li>No abnormalities related to cardiovascular diseases</li> </ul>			
		Pulmonary infiltrates	Increased soft tissue density indicat- ing the filling of airspaces with fluid, inflammatory exudate, or cells		

#### Data Element Mapping/Source of Data Element Permissible Values Definition Additional Notes Definition Permissible Value Definitions Pulmonary vascular Distension of the pulmonary veins, parredistribution ticularly in the upper lung fields during acute COVID-19 Pulmonary congestion Imaging findings consistent with NCI Thesaurus Code: increased intravascular blood volume C11921763 in the lunas Accumulation of fluid in the lung NCI Thesaurus Code: Pulmonary edema tissues, typically characterized by C2686863 imaging findings such as pulmonary infiltrates, Kerley B lines, or peribronchial cuffing NCI Thesaurus Code: Cardiomegaly, chamber Abnormal enlargement of the heart enlargement C6145363 NCI Thesaurus Code: Pleural effusion(s) Increased amounts of fluid within the pleural cavity. Symptoms include C333163 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. No abnormalities related to cardiovascular diseases Chest CT Documented findings Pulmonary embolism from the CT examination · Pulmonary infiltrates of the chest, with or · Pulmonary vascular without angiography redistribution · Pulmonary congestion • Pulmonary edema · Cardiomegaly, chamber enlargement · Pleural effusion(s) • Thrombus · Coronary artery aneurysm · No abnormalities related to cardiovascular diseases Pulmonary embolism The obstruction of the pulmonary artery NCI Thesaurus Code: or one of its branches by an embolus, C5071363 sometimes associated with infarction of the lung, during acute COVID-19 Pulmonary infiltrates Imaging-defined opacification and consolidation of lungs suggesting injury and substance denser than air, such as pus, blood, or protein, within the parenchyma of the lungs during acute COVID-19 Pulmonary vascular re-Distension of the pulmonary veins, pardistribution ticularly in the upper lung fields during acute COVID-19 Pulmonary congestion Imaging findings consistent with in-NCI Thesaurus Code: creased intravascular blood volume in C11921763 the lungs during acute COVID-19 Pulmonary edema Accumulation of fluid in the lung tis-NCI Thesaurus Code:

sues

#### Appendix 7. Continued

(Continued)

C2686863

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Cardiomegaly, chamber enlargement	Abnormal enlargement of the heart or heart chambers during acute COVID-19	NCI Thesaurus Code: C61453 <sup>63</sup>	
		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 infec- tions, congestive HF, pleural and lung tumors, connective tissue disorders, and trauma	NCI Thesaurus Code: C3331 <sup>83</sup>	
		Thrombus	The formation of a blood clot in the lumen of a vessel or heart chamber		
		Coronary artery aneu- rysm	Focal dilation of a coronary artery (≥1.5× the adjacent normal segment)	Boris JR, Béland MJ, Bergensen LJ, et al. 2017 AHA/ACC key data ele- ments and definitions for ambulatory electronic health records in pediatric and congenital cardiology: a report of the American College of Cardiology/ American Heart Associa- tion Task Force on Clinical Data Standards. <i>Circ Cardiovasc Qual Outcomes</i> . 2017;10:e000027. <sup>86</sup>	
		No abnormalities re- lated to cardiovascular diseases			
CCTA	CAD-RADS (Report- ing and Data System) score specifically for CCTA, based on degree of maximal coronary stenosis	<ul> <li>0</li> <li>1</li> <li>2</li> <li>3</li> <li>4</li> <li>5</li> <li>Unknown</li> </ul>		Cury RC, Abbara S, Achenbach S, et al. CAD- RADS <sup>™</sup> Coronary Artery Disease - Reporting and Data System. An expert consensus document of the Society of Car- diovascular Computed Tomography (SCCT), the American College of Radiology (ACR) and the North American So- ciety for Cardiovascular Imaging (NASCI). J Car- diovasc Comput Tomogr. 2016;10:269-281. <sup>134</sup>	
		0	0%		
		1	1%-24%		
		2	25%-49%		
		3	50%-69%		
		4	A. 70%–99% or B. Left main >50% or 3-vessel obstructive disease		
		5	100%		
		Unknown			
Lower extremity ultrasound	Documented findings from the ultrasound examination	DVT     Arterial thrombosis			
		DVT	Thrombosis formation within deep veins during acute COVID-19	NCI Thesaurus Code: C49343 <sup>63</sup>	
		Arterial thrombosis	Formation of a blood clot in the lumen of an artery during acute COVID-19	NCI Thesaurus Code: C98826 <sup>63</sup>	

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Myocardial perfusion imaging	An imaging procedure that quantifies blood flow throughout the heart muscle Refer to the 2020 AHA/ ACC Key Data Elements and Definitions for Coro- nary Revascularization.			Dehmer GJ, Badhwar V, Bermudez EA, et al. 2020 AHA/ACC key data ele- ments and definitions for coronary revascularization: a report of the American College of Cardiology/ American Heart Asso- ciation Task Force on Clinical Data Standards (Writing Committee to Develop Clinical Data Standards for Coronary Revascularization). <i>Circ Cardiovasc Qual Outcomes</i> . 2020;13:e000059. <sup>135</sup> NCI Thesaurus Code: C102676 <sup>83</sup>	
Coronary angiography	Documented findings from coronary angiog- raphy Refer to the 2020 AHA/ ACC Key Data Elements and Definitions for Coro- nary Revascularization.			Dehmer GJ, Badhwar V, Bermudez EA, et al. 2020 AHA/ACC key data ele- ments and definitions for coronary revascularization: a report of the American College of Cardiology/ American Heart Asso- ciation Task Force on Clinical Data Standards (Writing Committee to Develop Clinical Data Standards for Coronary Revascularization). <i>Circ Cardiovasc Qual Outcomes</i> . 2020;13:e000059. <sup>135</sup>	
Left heart catheterization	Documented findings from left heart catheter- ization Refer to the 2020 AHA/ ACC Key Data Elements and Definitions for Coro- nary Revascularization.			Dehmer GJ, Badhwar V, Bermudez EA, et al. 2020 AHA/ACC key data ele- ments and definitions for coronary revascularization: a report of the American College of Cardiology/ American Heart Asso- ciation Task Force on Clinical Data Standards (Writing Committee to Develop Clinical Data Standards for Coronary Revascularization). <i>Circ</i> <i>Cardiovasc Qual Outcomes</i> . 2020;13:e000059. <sup>135</sup>	Important variables for HF include left ventricular end-diastolic pressure (mm Hg) and left ven- triculography EF.
RA mean pressure	Mean right atrial pres- sure measured from pul- monary artery catheter	• Numeric, mm Hg			
PA mean pressure	Mean blood pressure in the pulmonary artery	• Numeric, mm Hg		NCI Thesaurus Code: C129958 <sup>63</sup>	
PA systolic pressure	The blood pressure in the pulmonary artery during the contraction of the left ventricle of the heart	• Numeric, mm Hg		NCI Thesaurus Code: C120943 <sup>63</sup>	
PA diastolic pressure	The blood pressure in the pulmonary artery during ventricular relax- ation (diastole)	• Numeric, mm Hg		NCI Thesaurus Code: C120941 <sup>63</sup>	
ΡΔΡί	Pulse pressure across pulmonary artery divided by RA (calculated sys- tolic pulmonary arterial pressure – diastolic pul- monary pressure)/right atrial pressure)	• Numeric			

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Mean pulmonary capillary wedge pressure	The pressure measured by wedging a pulmonary catheter with an inflated balloon into a small pul- monary arterial branch	• Numeric, mm Hg		NCI Thesaurus Code: C129955 <sup>63</sup>	May be recorded with or without V-wave.
Cardiac output	The total volume of blood pumped by the heart over a set period of time, conventionally 1 min; it is calculated as heart rate times stroke volume and is addi- tionally dependent on preload and afterload for functional output.	• Numeric, L/min		NCI Thesaurus Code: C119246 <sup>63</sup>	
Cardiac index	The measure of an individual's cardiac out- put as divided by their body surface area). This calculation is a useful function to determine an individual's cardiac performance in rela- tion to their body size, providing an overview of global cardiovascular function.	• Numeric, L/min/m <sup>2</sup>		NCI Thesaurus Code: C119245 <sup>63</sup>	
Transpulmonary gradient	Difference between mean pulmonary artery pressure and mean pul- monary capillary wedge pressure	• Numeric, mm Hg			
Pulmonary vascular resistance	Pulmonary vascular resistance is calculated as (mean PA pressure minus mean pulmonary capillary wedge pres- sure) divided by cardiac output.	• Numeric, Wood units or dynes/s/cm		NCI Thesaurus Code: C119247 <sup>63</sup>	The resistance to blood flow generated by the pulmonary vasculature, which is normally one- sixth of systemic vascular resistance. The major determinant of pulmo- nary vascular resistance is pulmonary vessel constriction, most often caused by hypoxia. Pro- longed elevated pulmo- nary vascular resistance can cause right HF.
Systemic vascular resistance	Systemic vascular resistance is calculated as the systemic mean arterial blood pressure minus right arterial pres- sure divided by cardiac output.	Numeric, dynes/s/cm <sup>2</sup>		NCI Thesaurus Code: C119248 <sup>83</sup>	The resistance to blood flow generated by all systemic vasculature, excluding pulmonary vasculature. The major determinant of systemic vascular resistance is arteriolar tone, but blood viscosity and vascular capacitance are also contributing factors.
Mixed venous O <sub>2</sub> saturation	Saturation measured via a sample of blood from a pulmonary artery cath- eter measures the end result of $O_2$ consump- tion and delivery, used in the ICU as a measure of $O_2$ extraction by the body.	• Numeric, %			

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Cardiac MRI	Medical imaging with MRI technology for noninvasive assess- ment of the function and structure of the cardiovascular system using ECG gating and high temporal resolution protocols with an intent to assess myocarditis, cardiac function, and structures during or after COVID-19	<ul> <li>Myocardial edema by T2 mapping or T2- weighted imaging</li> <li>Myocardial injury by T1 mapping</li> <li>Myocardial injury by late gadolinium en- hancement</li> <li>Myocarditis</li> <li>Pericardial changes</li> <li>Ventricular function abnormalities</li> <li>Other cardiac struc- tural abnormalities</li> </ul>		NCI Thesaurus Code: C16809 <sup>83</sup> Ferreira VM, Schulz- Menger J, Holmvang G, et al. Cardiovascular magnetic resonance in nonischemic myocardial inflammation: expert recommenda- tions. <i>J Am Coll Cardiol</i> . 2018;72:3158-3176. <sup>65</sup> Friedrich MG, Sechtem U, Schulz-Menger J, et al. Cardiovascular magnetic resonance in myocarditis: a JACC white paper. <i>J Am Coll Cardiol</i> . 2009;53:1475-1487. <sup>138</sup> National Institute of Neu- rological Disorders and Stroke. Common data elements. Cardiac mag- netic resonance imaging (MRI). Accessed March 4, 2022. https://www. commondataelements. ninds.nih.gov/cde_de- tailed_report/23564/ Imaging%20Diagnostics/ Assessments%20and%20 Examinations/Stroke/Car- diac%20Magnetic%20 Resonance%20Imag- ing%20%28MRI%29 <sup>137</sup>	Cardiac MRI criteria (Up- date to the Lake Louise Consensus Criteria for myocarditis) <sup>ee</sup> In the setting of clinically suspected myocarditis, cardiac MRI findings are consistent with myocar- dial inflammation, if both of the following criteria are present: 1. T2-based imaging: regional high T2 signal intensity; or global T2 signal intensity ratio ≥2.0 in T2-weighted CMR images; or regional or global increase of myocardial T2 relaxation time 2. T1-based imaging: re- gional or global increase of native myocardial T1 relaxation time or extracellular volume; or areas with high signal intensity in a nonisch- emic distribution pattern in late-gadolinium en- hancement images The presence of LV dysfunction or pericardial effusion provides ad- ditional, supportive evi- dence for myocarditis.
		Myocardial edema by T2 mapping or T2-weighted imaging	Regional or global myocardial SI increase in T2-weighted images sug- gestive of edema		
		Myocardial injury by T1 mapping	Regional or global myocardial injury by T1 mapping		
		Myocardial injury by late gadolinium enhancement	Increased global myocardial late gado- linium enhancement in gadolinium- enhanced T1-weighted images		
		Myocarditis	Acute viral myocarditis, usually lasting 1–3 d, is characterized by cardiomyo- cyte necrosis directly triggered by the viral infection. Humoral and cellular immunologic responses in the myo- cardium may persist for months and may result in a chronic postinfectious autoimmune myocarditis		
		Pericardial changes	Pericardial effusion, thickening, in- creased signal intensity on late gado- linium enhancement		
		Ventricular functional abnormalities	LV systolic or diastolic dysfunction, RV systolic or diastolic dysfunction, func- tional valvular regurgitation		
		Other cardiac structural abnormalities	LV, RV, LA, RA chamber enlargement, wall motion abnormalities, valvular structural abnormalities, cardiac masses		
FDG-PET	Documented findings from FDG-PET	<ul><li>Myocarditis</li><li>Pericarditis</li><li>Other</li></ul>		NCI Thesaurus Code: C103400 <sup>63</sup>	Focal/diffuse FDG up- take in the myocardium with/without perfusion mismatch can be help- ful in the diagnosis of myocarditis, especially in patients who cannot undergo cardiac MRI.

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Brain CT without contrast	Documented findings from brain CT without contrast	<ul> <li>Hemorrhagic stroke</li> <li>Acute ischemic stroke</li> <li>Hypoxic ischemic encephalopathy</li> </ul>			
		Hemorrhagic stroke	Brain tissue necrosis due to an intra- cerebral bleed	NCI Thesaurus Code: C95803 <sup>63</sup>	
		Acute ischemic stroke	Acute onset of neurological deficits resulting from a loss of blood supply to brain tissue in an area of arterial distribution.	NCI Thesaurus Code: C95802 <sup>63</sup>	
		Hypoxic ischemic en- cephalopathy	Injury to the central nervous system that occurs when there is insufficient delivery of oxygen to all or part of the brain	NCI Thesaurus Code: C35549 <sup>63</sup>	
Brain MRI	Documented findings from brain MRI	<ul> <li>Hemorrhagic stroke</li> <li>Acute ischemic stroke</li> <li>Hypoxic ischemic encephalopathy</li> </ul>		Powers WJ, Rabinstein AA, Ackerson T, et al. Guidelines for the early management of patients with acute ischemic stroke: 2019 update to the 2018 guidelines for the early management of acute ischemic stroke: a guideline for healthcare professionals from the American Heart Asso- ciation/American Stroke Association. <i>Stroke</i> . 2019;50:e344-e418. <sup>138</sup> NCI Thesaurus Code: C137913 <sup>63</sup>	
		Hemorrhagic stroke	Brain tissue necrosis due to an intra- cerebral bleed	NCI Thesaurus Code: C95803 <sup>63</sup>	
		Acute ischemic stroke	Acute onset of neurological deficits resulting from a loss of blood supply to brain tissue in an area of arterial distribution.	NCI Thesaurus Code: C95802 <sup>63</sup>	
		Hypoxic ischemic en- cephalopathy	Injury to the central nervous system that occurs when there is insufficient delivery of oxygen to all or part of the brain	NCI Thesaurus Code: C35549 <sup>63</sup>	

AV indicates atrioventricular; BSA, body surface area; bpm, beats per minute; CAD-RADS, Coronary Artery Disease - Reporting and Data System; CCTA, coronary computed tomography angiography; CI, cardiac index; CO, cardiac output; COVID-19, coronavirus disease-2019; CT, computed tomography; DVT, deep vein thrombosis; ECG, electrocardiogram; EF, ejection fraction; FDG, fluorodeoxyglucose; HF, heart failure; HR, heart rate; ICU, intensive care unit; LA, left atrial; LBBB, left bundle branch block; LV, left ventricular; MRI, magnetic resonance imaging; PA, pulmonary artery; PAPi, pulmonary artery pulsatility index; PET, positron emission tomography; PVR, pulmonary vascular resistance; RA, right atrial; RBBB, right bundle branch block; RV, right ventricular; SV, stroke volume; and SVR, systemic vascular resistance.

#### Appendix 8. Pharmacological Therapy

#### A. Therapies for Preexisting Cardiovascular Disease (Patient Taking Prior to Admission)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Aldosterone in- hibitor (mineralo- corticoid receptor antagonist)	Spironolactone or eplerenone, which antagonize the action of aldosterone at mineralocorticoid receptors	• 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. <i>Circulation</i> . 2013;128:e240– e327. <sup>69</sup> NCI Thesaurus Code: C101255 <sup>63</sup>	
ACE inhibitor medication	A medication that inhibits ACE, an enzyme that catalyzes the conver- sion 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		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. <i>Hypertension</i> . 2018;71:e13–e115. <sup>139</sup> NCI Thesaurus Code: C247 <sup>83</sup>	
ARB medication	An ARB medication, a class of agents that act by selectively inhibit- ing angiotensin II receptor activation in the renin-angiotensin-aldosterone system. Angiotensin II receptor an- tagonists bind to and block the acti- vation of angiotensin II type 1 (AT1) receptors, thereby reducing produc- tion and secretion of aldosterone, among other actions. The combined effects result in reduction of blood pressure. It is primarily used for the treatment of hypertension or HF.	• 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. <i>Hypertension</i> . 2018;71:e13–e115. <sup>139</sup> NCI Thesaurus Code: C66930 <sup>83</sup>	
ARNI	Combination of an angiotensin receptor blocker (above) and a neprilysin inhibitor (eg, sacubitril). Additionally, inhibits neprilysin, a neutral endopeptidase that degrades vasoactive peptides, such as bradykinin, and natriuretic peptides.	• Yes • No • Unknown		Yancy CW, Jessup M, Bozkurt B, et al. 2016 ACC/AHA/HFSA focused update on new pharmacological therapy for heart failure: an update of the 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology/ American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. <i>Circulation.</i> 2016;134:e282–e293. <sup>140</sup>	
Beta-adrenergic antagonist (beta blocker) medica- tion	A beta-adrenergic receptor an- tagonist (beta blocker) medication. Includes bisoprolol, carvedilol, metoprolol succinate, metoprolol tartrate, atenolol.	• 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. <i>Circulation</i> . 2013;128:e240– e327. <sup>69</sup> NCI Thesaurus Code: C29576 <sup>63</sup>	
Metformin	A specific agent belonging to the biguanide class of antihyperglyce- mic agents	• Yes • No • Unknown		American Diabetes Association. 10. Car- diovascular disease and risk management: standards of medical care in diabetes-2020. <i>Diabetes Care</i> . 2020;43:S111-S134. <sup>141</sup> NCI Thesaurus Code: C61612 <sup>63</sup>	
SGLT2 inhibitor	SGLT2 inhibitors inhibit the sodi- um glucose cotransporter-2 in the kidney, and selected agents in this class have demonstrated benefit in HF, CKD, ASCVD, and diabetes.	<ul><li>Yes</li><li>No</li><li>Unknown</li></ul>		American Diabetes Association. 10. Car- diovascular disease and risk management: standards of medical care in diabetes-2020. <i>Diabetes Care</i> . 2020;43:S111-S134. <sup>141</sup> NCI Thesaurus Code: C98083 <sup>83</sup>	
GLP-1 receptor agonist	Select medications in this class have been shown to improve ASCVD outcomes, drive weight loss, and lower glucose.	• Yes • No • Unknown		American Diabetes Association. 10. Car- diovascular disease and risk management: standards of medical care in diabetes-2020. <i>Diabetes Care</i> . 2020;43:S111-S134. <sup>141</sup>	

#### A. Therapies for Preexisting Cardiovascular Disease (Patient Taking Prior to Admission)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Statin	An HMG-CoA reductase inhibitor ("statin"). Lipid-lowering medica- tions with proven ASCVD benefits.	• Yes • No • Unknown		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 cho- lesterol: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. <i>Circu-</i> <i>lation</i> . 2019;139:e1082–e1143. <sup>142</sup>	
Ezetimibe	A cholesterol absorption inhibitor with lipid-lowering activity	• Yes • No • Unknown		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 cho- lesterol: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. <i>Circu-</i> <i>lation.</i> 2019;139:e1082–e1143. <sup>142</sup> NCI Thesaurus Code: C47529 <sup>63</sup>	
PCSK9 inhibitor	Inhibits an enzyme (PCSK9), re- sulting in a reduction in circulating LDL cholesterol	• Yes • No • Unknown		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 cho- lesterol: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. <i>Circu-</i> <i>lation</i> . 2019;139:e1082–e1143. <sup>142</sup>	
Bempedoic acid	Bempedoic acid decreases LDL cholesterol by inhibiting ATP- citrate lyase.	• Yes • No • Unknown		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 cho- lesterol: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. <i>Circu-</i> <i>lation</i> . 2019;139:e1082–e1143. <sup>142</sup>	
Aspirin	Acetylsalicylic acid decreases synthesis of prostaglandin, platelet aggregation, and inflammation. This agent exhibits analgesic, antipyretic, and anticoagulant properties.	• Yes • No • Unknown		Levine GN, Bates ER, Bittl JA, et al. 2016 ACC/AHA guideline focused update on duration of dual antiplatelet therapy in pa- tients with coronary artery disease: a report of the American College of Cardiology/ American Heart Association Task Force on Clinical Practice Guidelines. <i>Circulation</i> . 2016;134:e123-e155. <sup>143</sup> NCI Thesaurus Code: C287 <sup>63</sup>	
P2Y12 inhibitor	A nonaspirin P2Y12 inhibitor such as clopidogrel, ticagrelor, prasug- rel as an antiplatelet agent	• Yes • No • Unknown		Levine GN, Bates ER, Bittl JA, et al. 2016 ACC/AHA guideline focused update on duration of dual antiplatelet therapy in pa- tients with coronary artery disease: a report of the American College of Cardiology/ American Heart Association Task Force on Clinical Practice Guidelines. <i>Circulation</i> . 2016;134:e123–e155. <sup>143</sup>	
Warfarin	A vitamin K antagonist antico- agulant	• Yes • No • Unknown		January CT, Wann LS, Calkins H, et al. 2019 AHA/ACC/HRS focused update of the 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrilla- tion: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. <i>Circulation</i> . 2019;140:e125–e151. <sup>144</sup> NCI Thesaurus Code: C945 <sup>63</sup>	

#### A. Therapies for Preexisting Cardiovascular Disease (Patient Taking Prior to Admission)

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
DOAC	Oral anticoagulant that directly inhibits specific proteins within the coagulation cascade (rivaroxaban, apixaban, dabigatran, or edoxaban)	• Yes • No • Unknown		January CT, Wann LS, Calkins H, et al. 2019 AHA/ACC/HRS focused update of the 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrilla- tion: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. <i>Circulation</i> . 2019;140:e125–e151. <sup>144</sup> Julia S, James U. Direct oral antico- agulants: a quick guide. <i>Eur Cardiol</i> .	

ACE indicates angiotensin-converting enzyme; ARB, angiotensin receptor antagonist blocker; ARNi, angiotensin receptor-neprilysin inhibitor; ASCVD, atherosclerotic cardiovascular disease; AT1, angiotensin II type 1; ATP, adenosine triphosphate; CKD, chronic kidney disease; DOAC, direct oral anticoagulant; GLP-1, glucagon-like peptide; HF, heart failure; HMG-CoA,  $\beta$ -Hydroxy  $\beta$ -methylglutaryl-CoA; LDL, low-density lipoprotein; PCSK9, proprotein convertase subtilisin kexin 9; and SGLT2, sodium-glucose cotransporter-2.

#### Appendix 8. Continued

#### B. Therapies for COVID-19

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
SARS-CoV-2 antiviral agents (rem- desivir, mol- nupiravir)	A prodrug of an ATP analog, with potential antiviral activity against a variety of RNA viruses. Competes with ATP for incorporation into RNA and inhibits the action of viral RNA-dependent	• Yes • No • Unknown		Bhimraj A, Morgan RL, Shumaker AH, et al. Infectious Diseases Society of America guidelines on the treatment and manage- ment of patients with COVID-19. Accessed March 4, 2022. https://www.idsociety. org/practice-guideline/covid-19-guideline- treatment-and-management <sup>2</sup>	
	RNA polymerase.			COVID-19 Treatment Guidelines Panel. Coronavirus disease 2019 (COVID-19) treatment guidelines. National Institutes of Health. Accessed March 4, 2022. https:// www.covid19treatmentguidelines.nih.gov/ <sup>3</sup>	
				Chiotos K, Hayes M, Kimberlin DW, et al. Multicenter initial guidance on use of anti- virals for children with coronavirus disease 2019/severe acute respiratory syndrome coronavirus 2. <i>J Pediatric Infect Dis Soc</i> . 2020;9:701-715. <sup>33</sup>	
SARS-CoV-2 protease inhibitors (nirmatrelvir/ ritonavir)	Nirmatrelvir inhibits the SARS-CoV-2 main protease (M <sup>pro</sup> ), which re- sults in inhibition of viral replication. Ritonavir has no direct activity against SARS- CoV-2 but is a pharma- cokinetic boosting agent that results in higher plasma concentrations of nirmatrelvir.	• Yes • No • Unknown		NCI Thesaurus Code: C152185 <sup>63</sup> Bhimraj A, Morgan RL, Shumaker AH, et al. Infectious Diseases Society of America guidelines on the treatment and management of patients with COVID-19. Accessed March 4, 2022. https://www. idsociety.org/practice-guideline/covid-19- guideline-treatment-and-management <sup>2</sup> COVID-19 Treatment Guidelines Panel. Coronavirus disease 2019 (COVID-19) treatment guidelines. National Institutes of Health. Accessed March 4, 2022. https:// www.covid19treatmentguidelines.nih.gov/ <sup>3</sup>	

## B. Therapies for COVID-19

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Corticoste- roids	Hormones synthesized in the cortex of the adrenal gland and consisting of 2 subclasses, glucocor- ticoids (carbohydrate regulation) and miner- alocorticoids (electrolyte regulation)	• Yes • No • Unknown		Bhimraj A, Morgan RL, Shumaker AH, et al. Infectious Diseases Society of America guidelines on the treatment and manage- ment of patients with COVID-19. Accessed March 4, 2022. https://www.idsociety. org/practice-guideline/covid-19-guideline- treatment-and-management <sup>2</sup> COVID-19 Treatment Guidelines Panel. Coronavirus disease 2019 (COVID-19) treatment guidelines. National Institutes of Health. Accessed March 4, 2022. https:// www.covid19treatmentguidelines.nih.gov/ <sup>3</sup> Chiotos K, Hayes M, Kimberlin DW, et al. Multicenter initial guidance on use of anti- virals for children with coronavirus disease 2019/severe acute respiratory syndrome coronavirus 2. <i>J Pediatric Infect Dis Soc.</i> 2020;9:701-715. <sup>33</sup> NCI Thesaurus Code: C2322 <sup>63</sup>	
IL-6 receptor monoclonal antibodies (tocilizumab, sarilumab)	An antibody that recog- nizes and binds the IL-6 receptor	• Yes • No • Unknown		Bhimraj A, Morgan RL, Shumaker AH, et al. Infectious Diseases Society of America guidelines on the treatment and manage- ment of patients with COVID-19. Accessed March 4, 2022. https://www.idsociety. org/practice-guideline/covid-19-guideline- treatment-and-management <sup>2</sup> COVID-19 Treatment Guidelines Panel. Coronavirus disease 2019 (COVID-19) treatment guidelines. National Institutes of Health. Accessed March 4, 2022. https:// www.covid19treatmentguidelines.nih.gov/ <sup>3</sup> Dulek DE, Fuhlbrigge RC, Tribble AC, et al. Multidisciplinary guidance regarding the use of immunomodulatory therapies for acute coronavirus disease 2019 in pediatric patients. <i>J Pediatric Infect Dis Soc.</i> 2020;9:716-737. <sup>34</sup> NCI Thesaurus Code: C124046 <sup>63</sup>	Recommended by IDSA and NIH COVID-19 Treat- ment Guidelines Panel for patients with progressive severe or critical COVID-19 who have evidence of systemic inflammation
COVID-19 convalescent plasma	Plasma that has been collected from patients who have recovered from the novel coronavi- rus disease, COVID-19. This plasma contains antibodies developed against the SARS- CoV-2 virus and is being investigated for the treat- ment of COVID-19.	• Yes • No • Unknown		Bhimraj A, Morgan RL, Shumaker AH, et al. Infectious Diseases Society of America guidelines on the treatment and manage- ment of patients with COVID-19. Accessed March 4, 2022. https://www.idsociety. org/practice-guideline/covid-19-guideline- treatment-and-management <sup>2</sup> COVID-19 Treatment Guidelines Panel. Coronavirus disease 2019 (COVID-19) treatment guidelines. National Institutes of Health. Accessed March 4, 2022. https:// www.covid19treatmentguidelines.nih.gov/ <sup>3</sup> Dulek DE, Fuhlbrigge RC, Tribble AC, et al. Multidisciplinary guidance regarding the use of immunomodulatory therapies for acute coronavirus disease 2019 in pediatric patients. <i>J Pediatric Infect Dis Soc</i> . 2020;9:716-737. <sup>34</sup> NCI Thesaurus Code: C171633 <sup>83</sup>	As of February 2022, both IDSA and the NIH COVID-19 Treatment Guidelines Panel recommend against its use in hospitalized patients. Among ambulatory patients with mild to moderate COVID-19 at high risk for pro- gression to severe disease who have no other treatment op- tions, the IDSA sug- gests FDA-qualified high-titer COVID-19 convalescent plasma within 8 d of symp- tom onset.

## B. Therapies for COVID-19

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
JAK inhibitors (baricitinib, tofacitinib)	A substance that inhibits the biological action of tyrosine-protein kinase JAK1, an enzyme that plays a key role in certain types of cancer and cy- tokine signaling	• Yes • No • Unknown		Bhimraj A, Morgan RL, Shumaker AH, et al. Infectious Diseases Society of America guidelines on the treatment and manage- ment of patients with COVID-19. Accessed March 4, 2022. https://www.idsociety. org/practice-guideline/covid-19-guideline- treatment-and-management <sup>2</sup> COVID-19 Treatment Guidelines Panel. Coronavirus disease 2019 (COVID-19) treatment guidelines. National Institutes of Health. Accessed March 4, 2022. https://www.covid19treatmentguidelines. nih.gov/ <sup>3</sup> NCI Thesaurus Code: C129650 <sup>63</sup>	Recommended by IDSA and NIH COVID-19 Treat- ment Guidelines panel in patients with severe COVID-19 and evidence of sys- temic inflammation
Monoclonal antibod- ies against SARS-CoV-2 (eg, bam- lanivimab/ etesevimab, casirivimab/ imdevimab, sotrovimab, tixagevimab/ cilgavimab, bebtelovimab)	Any monoclonal antibody that is directed against the spike (S) protein of SARS-CoV-2	• Yes • No • Unknown		Bhimraj A, Morgan RL, Shumaker AH, et al. Infectious Diseases Society of America guidelines on the treatment and manage- ment of patients with COVID-19. Accessed March 4, 2022. https://www.idsociety. org/practice-guideline/covid-19-guideline- treatment-and-management <sup>2</sup> COVID-19 Treatment Guidelines Panel. Coronavirus disease 2019 (COVID-19) treatment guidelines. National Institutes of Health. Accessed March 4, 2022. https:// www.covid19treatmentguidelines.nih.gov/ <sup>3</sup> NCI Thesaurus Code: C173741 <sup>83</sup>	
SARS-CoV-2 vaccine	Any vaccine that de- creases the risk of ac- quiring SARS-CoV-2 in- fection and development of acute COVID-19	<ul> <li>Fully vaccinated</li> <li>Partially vaccinated</li> <li>Unvaccinated</li> <li>Unknown</li> </ul>		NCI Thesaurus Code: C17302383	Booster dose is cov- ered separately.
		Fully vaccinated	>2 wk after comple- tion of the relevant vaccination series (currently 2 doses for the mRNA vac- cines)		
		Partially vaccinated	>2 wk from the initial dose of a 2-dose series (currently applies only to the mRNA vaccines)		
		Unvaccinated	No vaccine, or <2 wk from first vaccine dose		
		Unknown			
SARS-CoV-2 vaccine type	Type of SARS-CoV-2 vaccine received	<ul> <li>BNT162b2 (Pfizer- BioNTech)</li> <li>mRNA-1273 (Moderna)</li> <li>Ad26.COV2.S (Johnson &amp; Johnson/Janssen)</li> <li>Other, specify</li> <li>Unknown</li> </ul>		COVID-19 Treatment Guidelines Panel. Coronavirus disease 2019 (COVID-19) treatment guidelines. National Institutes of Health. Accessed March 4, 2022. https:// www.covid19treatmentguidelines.nih.gov/ <sup>3</sup> Centers for Disease Control and Preven- tion. Different COVID-19 vaccines. Ac- cessed March 4, 2022. https://www.cdc. gov/coronavirus/2019-ncov/vaccines/ different-vaccines.html <sup>146</sup>	

## B. Therapies for COVID-19

	Data Element	Dormiosible	Dormicsible		
Data Element	Definition	Values	Value Definitions	Mapping/Source of Definition	Additional Notes
Date of SARS-CoV-2 immunization	Date that SARS-CoV-2 immunization was com- pleted. This would be the date of the second dose for a 2-dose series vaccine (currently the mRNA vaccines). Do not use date of booster dose.	• Date, mm/dd/yyyy			
Manufacturer of SARS- CoV-2 vaccine received	The manufacturer of the vaccine received	<ul> <li>Pfizer/BioNTech</li> <li>Moderna</li> <li>Johnson &amp; Johnson</li> <li>AstraZeneca</li> <li>Mixed (received doses from &gt;1 manufacturer)</li> <li>Other</li> <li>Unknown</li> </ul>			
Booster dose of SARS- CoV-2 vaccine received	Receipt of additional SARS-CoV-2 vaccine dose after completion of a full vaccination series	<ul><li>Yes</li><li>No</li><li>Unknown</li></ul>			
Date of SARS-CoV-2 booster dose	Date that SARS-CoV-2 booster was given	• Date, mm/dd/yyyy			
IVIG	Blood product derived from pooled Ig antibod- ies extracted from donor plasma delivered intra- venously	• Yes • No • Unknown		COVID-19 Treatment Guidelines Panel. Coronavirus disease 2019 (COVID-19) treatment guidelines. National Institutes of Health. Accessed March 4, 2022. https:// www.covid19treatmentguidelines.nih.gov/ <sup>3</sup> NCI Thesaurus Code: C121331 <sup>63</sup>	The NIH COVID-19 Treatment Guidelines Panel recommends against the use of non–SARS-CoV- 2-specific IVIG for the treatment of COVID-19. IVIG is often used as first- line treatment for MIS-C, although the optimal choice for immunomodulatory therapy in MIS-C has not been entirely established.

ATP indicates adenosine triphosphate; COVID-19, coronavirus disease-2019; IDSA, Infectious Diseases Society of America; IgG, immunoglobulin G; IL-6, interleukin-6; IVIG, intravenous immunoglobulin; JAK, Janus kinase; MIS-C, multisystem inflammatory syndrome in children; mRNA, messenger ribonucleic acid; NIH, National Institutes of Health; RNA, ribonucleic acid; and SARS-CoV-2, severe acute respiratory syndrome-coronavirus-2.

#### C. Therapies for Supportive Care During COVID-19 Infection

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
IV vasopressors	IV vasopressor agents are a group of medicines that augment blood pressure predominantly through an increase in vascular tone.	Norepinephrine     Epinephrine     Dopamine     Vasopressin     Phenylephrine     Other     None	Noreninenhrine is a sympathomi-	Bozkurt B, Hershberger RE, Butler J, et al. 2021 ACC/ AHA key data elements and definitions for heart failure: a report of the American Col- lege of Cardiology/American Heart Association Task Force on Clinical Data Stan- dards (Writing Committee to Develop Clinical Data Stan- dards for Heart Failure). <i>Circ Cardiovasc Qual Outcomes</i> . 2021;14:e000102. <sup>67</sup> NCDR Auxiliary Data Col- lection CathPCI Registry Data Dictionary v1.0 (data element #14617) <sup>98</sup>	
			metic drug that increases blood pressure and enhances ventricu- lar contractility.		
		Epinephrine	Epinephrine is a sympathomi- metic drug that increases blood pressure and enhances ventricu- lar contractility.		
		Dopamine	Dopamine is a sympathomimetic drug that increases blood pres- sure and enhances ventricular contractility.		
		Vasopressin	Vasopressin is a vasoactive hormone used synergistically with another sympathomimetic drug (typically norepinephrine) to increase and maintain peripheral vascular tone in patients with distributive shock.		
		Phenylephrine	Phenylephrine is a sympathomi- metic drug whose primary activity results from stimulation of the alpha receptors of the vascula- ture, resulting in vasoconstriction while producing comparatively mild direct cardiac effects.		
		Other			
		None			
IV inotropic agent	IV positive inotropic agents are a group of medicines that stimulate and increase the force of contraction of the heart muscle.	<ul> <li>Milrinone</li> <li>Dobutamine</li> <li>Other</li> <li>None</li> </ul>		Bozkurt B, Hershberger RE, Butler J, et al. 2021 ACC/ AHA key data elements and definitions for heart failure: a report of the American Col- lege of Cardiology/American Heart Association Task Force on Clinical Data Stan- dards (Writing Committee to Develop Clinical Data Stan- dards for Heart Failure). <i>Circ Cardiovasc Qual Outcomes</i> . 2021;14:e000102. <sup>67</sup> NCDR Auxiliary Data Col- lection CathPCI Registry Data Dictionary v1.0 (data element # 14617) <sup>98</sup>	

#### C. Therapies for Supportive Care During COVID-19 Infection

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, decrease pulmonary vascular resistance, and as a systemic vasodilator.		
		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.		
		Other			
		None			
COVID-19-spe- cific intermedi- ate- or full-dose anticoagulation (heparin, low- molecular-weight heparin, DOAC, warfarin)	Intermediate- or full-dose anticoagulation used to prevent VTE complications attributable to SARS- CoV-2 specifically and not because of documented VTE or another noninfec- tious indication. Note that this excludes the low-dose prophylactic anticoagula- tion often given to inpa- tients for VTE prophylaxis (see below).	• Yes • No • Unknown		Piazza G, Morrow DA. Diagnosis, management, and pathophysiology of arterial and venous throm- bosis in COVID-19. <i>JAMA</i> . 2020;324:2548-2549. <sup>147</sup> COVID-19 Treatment Guide- lines Panel. Coronavirus disease 2019 (COVID-19) treatment guidelines. Ac- cessed March 4, 2022. https://www.covid19treat- mentguidelines.nih.gov/ <sup>3</sup>	Therapeutic an- ticoagulation in the absence of documented VTE or another non- COVID-19 indica- tion is not routine- ly recommended for hospitalized patients with COVID-19 out- side of the context of a clinical trial.
COVID-19-specific anticoagulation dosing strategy	For patients receiving in- termediate- or full-dose an- ticoagulation because of SARS-CoV-2 specifically and not because of docu- mented VTE or another noninfectious indication.	<ul> <li>Full dose</li> <li>Intermediate dose</li> <li>Unknown</li> </ul>			Note that "low- dose" antico- agulation is spe- cifically excluded from this element (see below).
		Full dose	Standard treatment dose		
		Intermediate dose	Intermediate dose is defined here as a dosing strategy target- ing levels of anticoagulation less than standard treatment doses but greater than standard VTE prophylaxis doses.		
		Unknown	A proper value is applicable but not known.		
Anticoagulation for VTE prophy- laxis	Administration of a prophylactic dose (not therapeutic dose) of anti- coagulant to prevent VTE during hospitalization for COVID-19	• Yes • No • Unknown		NCI Thesaurus Code: C116684 <sup>63</sup>	
Anticoagulant medication administered for VTE prophylaxis	Name of the anticoagulant medication administered to prevent VTE during hos- pitalization for COVID-19	<ul> <li>Unfractionated heparin</li> <li>Low-molecular- weight heparin</li> <li>Fondaparinux</li> <li>Bivalirudin</li> <li>Other</li> <li>Unknown</li> </ul>		COVID-19 Treatment Guide- lines Panel. Coronavirus disease 2019 (COVID-19) treatment guidelines. Na- tional Institutes of Health. Accessed March 4, 2022. https://www.covid19treat- mentguidelines.nih.gov/ <sup>3</sup>	
		Unfractionated heparin	Heparin is an indirect thrombin inhibitor composed of a mixture of heterogeneous mucopolysac- charides with a molecular weight of 5–30 kDa.		

#### C. Therapies for Supportive Care During COVID-19 Infection

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Low-molecular- weight heparin	Low-molecular-weight heparin compounds are fractions of hep- arin that primarily act by inhibiting the activated clotting factor X. Examples include enoxaparin and dalteparin.		
		Fondaparinux	Fondaparinux is a synthetic an- ticoagulant based on the penta- saccharide sequence that makes up the minimal antithrombin- binding region of heparin.		
		Bivalirudin	Bivalirudin is a semisynthetic de- rivative of hirudin and is a highly specific inhibitor of thrombin.		
		Other			
		Unknown	A proper value is applicable but not known.		
Renal replace- ment therapy	Use of renal replacement therapy during hospitaliza- tion for COVID-19 in a patient without end-stage renal disease prior to such hospitalization. These ther- apies may include CRRT, prolonged intermittent renal replacement therapy, IHD, or other forms of re- nal replacement therapy.	• Yes • No • Unknown		COVID-19 Treatment Guide- lines Panel. Coronavirus disease 2019 (COVID-19) treatment guidelines. Na- tional Institutes of Health. Accessed March 4, 2022. https://www.covid19treat- mentguidelines.nih.gov/ <sup>3</sup>	

COVID-19 indicates coronavirus disease-2019; CRRT, continuous renal replacement therapy; DOAC, direct oral anticoagulant; IHD, intermittent hemodialysis; IV, intravenous; SARS-CoV-2, severe acute respiratory syndrome-coronavirus-2; and VTE, venous thromboembolism.

### Appendix 9. Therapeutic and Supportive Procedures for COVID-19

#### A. Mechanical Support

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
MCS	MCS required. MCS is circulatory support using implanted devices most commonly used to supple- ment vasopressors and inotropes in the management of patients with low cardiac output and car- diogenic shock.	• Yes • No • Unknown		NCDR CathPCI Registry Coder's Data Diction- ary v5.0 (data element #7422) <sup>84</sup>	
Implantation of temporary MCS device	MCS device used. MCS devices are the implanted devices used to supplement vasopressors and inotropes in the management of patients with low cardiac output and cardiogenic shock.	<ul> <li>IABP</li> <li>Impella</li> <li>TandemHeart</li> <li>VA ECMO</li> <li>VV ECMO</li> <li>Other</li> <li>Unknown</li> </ul>		NCDR CathPCI Registry Coder's Data Diction- ary v5.0 (data element #7423) <sup>84</sup>	
Implantation of a long- term durable MCS device performed	Mechanical pump to help pump blood from the ventricle(s) to the body, used in the management of patients with low cardiac output and cardiogenic shock	<ul> <li>LVAD</li> <li>RVAD</li> <li>BiVAD</li> <li>Total artificial heart</li> <li>None</li> </ul>			
Date of MCS	Date that MCS was used	• Date, mm/dd/yyyy			
MCS time	Time that MCS was used	• Time, hh:mm (using 24-h clock)			

#### A. Mechanical Support

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Noninvasive mechanical venti- latory support	A type of mechanical ventilation procedure that uses a noninvasive means, such as a face mask or nasal mask, to deliver oxygenated air into the lungs	CPAP     BiPAP     None     Unknown		NCI Thesaurus Code: C171457 <sup>63</sup>	
		СРАР	A form of noninvasive mechani- cal pressure support ventila- tion that uses a CPAP level to support spontaneous breath- ing activity	NCI Thesaurus Code: C124040 <sup>63</sup>	
		BiPAP	A type of noninvasive mechan- ical ventilation procedure that that uses BiPAP to support spontaneous breathing activity	NCI Thesaurus Code: C171500 <sup>63</sup>	
		None			
		Unknown	A proper value is applicable but not known.		
Invasive mechani- cal ventilatory support	Artificial ventilation to assist or replace spontaneous breathing through tracheostomy or endotra- cheal tubes	<ul> <li>Mechanical ventilation</li> <li>Adaptive servoventilation</li> <li>None</li> </ul>			
		Mechanical ventilation	Mechanical ventilation technique is a life-sustaining technique through which gas is moved toward and from the lungs through an external device con- nected directly to the patient.		
		Adaptive servo- ventilation	Positive airway pressure thera- py 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, adap- tive servo-ven- tilation causes harm. <sup>148</sup>
		None			
Oxygen therapy	The administration of oxygen to an individual, usually to aid in respiration	<ul> <li>Yes (if yes, specify L/min)</li> <li>No</li> <li>Unknown</li> </ul>		NCI Thesaurus Code: C94624 <sup>63</sup>	
Maximum fraction of inspired oxygen (Fio <sub>2</sub> )	Maximum molar fraction of oxygen in an inhaled gas	Numeric		NCI Thesaurus Code: C38082 <sup>83</sup>	
PEEP	The maximum end-expiratory alve- olar pressure above atmospheric pressure supplied to patients on invasive or noninvasive ventilation	• Numeric, cm H <sub>2</sub> O		COVID-19 Treatment Guidelines Panel. Corona- virus disease 2019 (COVID-19) treatment guidelines. National Insti- tutes of Health. Accessed March 4, 2022. https:// www.covid19treatment- guidelines.nih.gov/ <sup>3</sup>	
Fio <sub>2</sub> /PEEP ratio	Ratio of Fio <sub>2</sub> to PEEP used to achieve desired arterial oxygenation	Numeric			

#### A. Mechanical Support

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
VA ECMO	ECMO, in which a venous cannu- la is usually placed in the right or left common femoral vein for ex- traction, and an arterial cannula is usually placed into the right or left femoral artery for infusion, with an oxygenator between the extrac- tion and infusion cannulae. Used to provide circulatory support and to facilitate gas exchange.	• Yes • No • Unknown		NCI Thesaurus Code: C171507 <sup>63</sup>	
VV ECMO	ECMO to provide adequate gas exchange, usually in respira- tory failure/ARDS. The access cannula is usually placed in the inferior vena cava via the femoral vein. The tip of the return cannula should sit close to the right atri- um, and it may be placed via the femoral or internal jugular vein.	• Yes • No • Unknown		NCI Thesaurus Code: C17150783	
Prone position- ing in ventilated patient	Positioning of a mechanically ventilated patient so that their an- terior chest is dependent, which allows for improved oxygenation by ameliorating the ventral-dorsal transpulmonary pressure dif- ference, reducing dorsal lung compression, and improving lung perfusion.	• Yes • No • Unknown		COVID-19 Treatment Guidelines Panel. Coro- navirus disease 2019 (COVID-19) treatment guidelines. National Insti- tutes of Health. Accessed March 4, 2022. https:// www.covid19treatment- guidelines.nih.gov/ <sup>3</sup> NCI Thesaurus Code: C173751 <sup>63</sup>	
Cardiac arrest re- quiring CPR	Cardiac arrest that is treated by CPR or defibrillation, regardless of outcome	• Yes • No • Unknown		NCI Thesaurus Code: C141268 <sup>63</sup>	
Date of CPR for cardiac arrest	Date that CPR for cardiac arrest was performed	Date, mm/dd/yyyy			
Time of CPR for cardiac arrest	Time that CPR for cardiac arrest was performed	• Time, hh:mm (using 24-h clock)			

ARDS indicates acute respiratory distress syndrome; BiPAP, bilevel positive airway pressure; BiVAD, biventricular assist device; CPAP, continuous positive airway pressure; CPR, cardiopulmonary resuscitation; FiO<sub>2</sub>, fraction of inspired oxygen; HFrEF, HF with reduced ejection fraction; IABP, intra-aortic balloon pump; LVAD, left ventricular assist device; MCS, mechanical circulatory support; PEEP, positive end expiratory pressure; RVAD, right ventricular assist device; VA ECMO, venoarterial extracorporeal membrane oxygenation; and VV-ECMO, venovenous extracorporeal membrane oxygenation.

#### Appendix 9. Continued

#### **B. Electrophysiological Procedures**

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Insertion of a tem- porary transvenous pacing wire	Temporary transvenous pacing wire was in- serted. Indications for temporary transvenous pacing are similar to indications for perma- nent pacing. Typically, temporary transvenous pacing is performed via a pacing wire placed in the RV from a central venous access site.	• Yes • No • Unknown		Kusumoto FM, Schoenfeld MH, Barrett C, et al. 2018 ACC/ AHA/HRS guideline on the evaluation and management of patients with bradycardia and cardiac conduction delay: a re- port of the American College of Cardiology/American Heart As- sociation Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. <i>Circula-</i> <i>tion</i> . 2019;140:e382–e482. <sup>149</sup>	
Date of temporary transvenous pacing wire insertion	Date temporary transve- nous pacing wire was inserted	• Date, mm/dd/yyyy			

## **B. Electrophysiological Procedures**

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Implantation of a cardioverter-defi- brillator performed	A battery-powered elec- trical impulse generator implanted in patients at risk of sudden cardiac death to detect cardiac arrhythmia and correct it by delivering a jolt of electricity, implanted dur- ing current encounter	• Yes • No • Unknown		Cannon CP, Brindis RG, Chait- man 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 Car- diology Foundation/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Acute Coronary Syndromes and Coronary Artery Disease Clini- cal Data Standards). <i>Circulation</i> . 2013;127:1052–1089. <sup>150</sup>	Information about the type of device (pacemaker, BiV/ resynchroniza- tion/CRT, ICD, combination), cardiac chamber(s) involved, and year of implantation may be helpful.
		Yes	ICD: a battery-powered electrical impulse gen- erator implanted in pa- tients at risk of sudden cardiac death to detect cardiac arrhythmia and correct it by delivering a jolt of electricity. This would include BiV-ICDs.		
		No	No ICD history		
		Unknown	A proper value is appli- cable but not known.		
Type of permanent cardioverter-defi- brillator implanted	A battery-powered elec- trical impulse generator implanted in patients at risk of sudden cardiac death to detect cardiac arrhythmia and correct it by delivering a jolt of electricity, implanted dur- ing current encounter	<ul><li>Transvenous</li><li>Subcutaneous</li><li>Unknown</li></ul>			
Date of ICD implantation	Date that ICD was im- planted	<ul> <li>Date, mm/dd/yyyy</li> </ul>			
Insertion of a permanent pacemaker	A cardiac pacemaker where the generator is im- planted inside the body	• Yes • No • Unknown	This would include a BiV pacemaker without an ICD function	NCI Thesaurus Code: C99552 <sup>63</sup>	
Electric cardioversion	The administration of electric current to correct abnormal heart rhythm	• Yes • No • Unknown		NCI Thesaurus Code: C99948 <sup>63</sup>	
Date of electric cardioversion	Date that DC cardiover- sion was performed	<ul> <li>Date, mm/dd/yyyy</li> </ul>			
Cardiac arrest requiring defibrillation	The sudden cessation of cardiac activity in an individual who becomes unresponsive, without normal breathing and no signs of circulation. Cer- tain forms of cardiac ar- rest (eg, ventricular fibril- lation) may be reversed by defibrillation.	• Yes • No • Unknown		NCI Thesaurus Code: C50479 <sup>63</sup>	
Date of defibrillation	Date that defibrillation was performed	Date, mm/dd/yyyy			

BiV indicates biventricular; CRT, cardiac resynchronization therapy; DC, direct current; ICD, implantable cardioverter-defibrillator; and RV, right ventricle.

#### C. Invasive Coronary/Vascular/Neurovascular Revascularization Treatment

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 Coro- nary 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 (Writ- ing Committee to Develop Clinical Data Standards for Coronary Revascularization). <i>Circ Cardiovasc Qual Outcomes</i> . 2020;13:e000059. <sup>135</sup>	Any attempt (suc- cessful or unsuc- cessful) to treat a stenosis by any technique, or even failed attempts to cross the stenosis with a wire or device, should be counted as PCI at any time point.
Date of PCI	Date that PCI was per- formed	Date, mm/dd/yyyy		NCDR CathPCI Registry Coder's Data Dictionary v5.0 (data element #7000) <sup>84</sup>	
Time of PCI	Time that PCI was per- formed	• Time, hh:mm (using 24-h clock)		NCDR CathPCI Registry Coder's Data Dictionary v5.0 (data element #7000) <sup>84</sup>	
PCI status	Classification of the urgen- cy of PCI procedure at the time the operator decides to perform the PCI	<ul> <li>Elective</li> <li>Urgent</li> <li>Emergency</li> <li>Salvage</li> </ul>		Hicks KA, Tcheng JE, Bozkurt B, et al. 2014 ACC/AHA key data elements and definitions for cardiovascular endpoint events in clinical trials: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writ- ing Committee to Develop Cardiovascular Endpoints Data Standards). <i>Circulation.</i> 2015;132:302–361. <sup>151</sup> NCDR CathPCI Registry Coder's Data Dictionary v5.0 (data element #7800) <sup>84</sup>	
		Elective	The procedure can be performed on an outpatient basis or during a subsequent hospitalization with- out significant risk of infarction or death. For stable inpatients, the procedure is being performed during this hospitalization for con- venience and ease of scheduling and NOT because the patient's clinical situation demands the procedure before discharge. If the diagnostic catheterization was elective and there were no complications, the PCI would also be elective.		
		Urgent	The procedure is performed on an inpatient basis and before discharge because of significant concerns that there is risk of ischemia, infarction, or death. Patients who are outpatients or in the emergency department at the time that the cardiac cath- eterization is requested would warrant an admission based on their clinical presentation.		

#### C. Invasive Coronary/Vascular/Neurovascular Revascularization Treatment

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Emergency	The procedure is performed as soon as possible because of substantial concerns that ongoing ischemia or infarction could lead to death. "As soon as possible" refers to a case of sufficient acuity that a sched- uled case would be cancelled to perform this procedure im- mediately in the next available room during business hours, or the on-call team would be activated if this were to occur during off-hours.		
		Salvage	The procedure is a last resort in a patient with cardiogenic shock when the PCI begins (ie, at the time of introduction into a coronary artery or bypass graft of the first guidewire or intra- coronary device for the purpose of mechanical revascularization). Within the last 10 min before the start of the case or during the diagnostic portion of the case, the patient may have re- ceived chest compressions for a total of at least 60 s or have been on unanticipated extra- corporeal circulatory support (eg, extracorporeal mechanical oxygenation, or cardiopulmonary support).		
Stent used	A small stainless steel expandable mesh tube, inserted within the lumen of tubular body structures, to help keep it open	• Yes • No		NCI Thesaurus Code: C17168 <sup>63</sup>	
Stent type	Type of stent used to treat lesion	<ul> <li>Bare-metal</li> <li>Drug-eluting</li> <li>Drug-eluting with bioabsorbable polymer</li> <li>Bioresorbable</li> <li>Covered</li> <li>Multiple types</li> <li>Other</li> </ul>		Dehmer GJ, Badhwar V, Ber- mudez EA, et al. 2020 AHA/ ACC key data elements and definitions for coronary revas- cularization: a report of the American College of Cardiol- ogy/American Heart Associa- tion Task Force on Clinical Data Standards (Writing Committee to Develop Clini- cal Data Standards for Coro- nary Revascularization). <i>Circ Cardiovasc Qual Outcomes</i> . 2020;13:e000059. <sup>135</sup>	
		Bare-metal	Metallic coronary stent without a polymer or antiproliferative drug coating		
		Drug-eluting	Metallic coronary stent with or without a polymer but with an antiproliferative drug coating		
		Drug-eluting with bio- absorbable polymer	Metallic coronary stent with a bioabsorbable polymer with an antiproliferative drug coating		
		Bioabsorbable	Stent struts composed of bioab- sorbable materials also contain- ing an antiproliferative drug		

#### C. Invasive Coronary/Vascular/Neurovascular Revascularization Treatment

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
		Covered	Metallic coronary stent scaffold in- corporating fabric or graft material, such as PTFE or polyurethane as a membrane component		
		Multiple types	Treatment of several arteries using different stent types		
		Other	A proper value is applicable but not known.		
TIMI flow prior to PCI	Indicate if the previously treated and stented lesion is being treated for in-stent restenosis.	<ul> <li>TIMI 0</li> <li>TIMI 1</li> <li>TIMI 2</li> <li>TIMI 3</li> <li>Unknown</li> </ul>		NCDR CathPCI Registry Coder's Data Dictionary v5.0 (data element #8007) <sup>84</sup>	
		TIMI 0	No flow/no perfusion		
		TIMI 1	Slow penetration without perfusion		
		TIMI 2	Partial flow/partial perfusion (>TIMI 1 but <timi 3)<="" th=""><th></th><th></th></timi>		
		ТІМІ З	Complete and brisk flow/com- plete perfusion		
		Unknown	A proper value is applicable but not known.		
TIMI flow after PCI	Indicate the postinterven- tion TIMI flow.	TIMI 0     TIMI 1     TIMI 2     TIMI 3     Unknown		NCDR CathPCI Registry Coder's Data Dictionary v5.0 (data element #8026) <sup>84</sup>	
		ТІМІ О	No flow/no perfusion		
		TIMI 1	Slow penetration without perfusion		
		TIMI 2	Partial flow/partial perfusion (>TIMI 1 but <timi 3)<="" th=""><th></th><th></th></timi>		
		ТІМІ З	Complete and brisk flow/com- plete perfusion		
		Unknown	A proper value is applicable but not known.		
% stenosis prior to PCI	Percent diameter stenosis immediately before the treatment of this lesion	• Numeric, %	Percentage diameter reduction, ranging from 0 to 100, associ- ated with the identified vessels. Percent stenosis at its maximal point is estimated to be the amount of reduction in the diam- eter of the "normal" reference vessel proximal to the lesion. In instances where multiple lesions are present, enter the single highest percent stenosis noted.	NCDR CathPCI Registry Coder's Data Dictionary v5.0 (data element #8004) <sup>84</sup>	
% stenosis after PCI	Percent diameter stenosis after treatment of this lesion	• Numeric, %	Percentage diameter reduction, ranging from 0 to 100, associ- ated with the identified vessels. Percent stenosis at its maximal point is estimated to be the amount of reduction in the diam- eter of the "normal" reference vessel proximal to the lesion. In instances where multiple lesions are present, enter the single highest percent stenosis noted.	NCDR CathPCI Registry Coder's Data Dictionary v5.0 (data element #8025) <sup>84</sup>	

#### C. Invasive Coronary/Vascular/Neurovascular Revascularization Treatment

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Percutaneous arterial access	Arterial access site(s)	(Multi-select) • Femoral artery • Brachial artery • Radial artery • Other • Unknown		NCDR CathPCI Registry Coder's Data Dictionary v5.0 (data element #7320) <sup>84</sup>	
Thrombec- tomy for pulmonary embolism	Interventional procedure to remove a blood clot from a pulmonary artery in a pa- tient with acute pulmonary embolism	• Yes • No • Unknown			
Thrombecto- my for stroke	Interventional procedure to remove a blood clot from an artery in a patient with acute ischemic stroke	• Yes • No • Unknown			
Thrombecto- my for periph- eral arterial thrombus	Interventional procedure to remove a blood clot from a peripheral artery, excluding acute ischemic stroke	<ul><li>Yes</li><li>No</li><li>Unknown</li></ul>			
Thrombolysis for pulmonary embolism	Treatment to remove a blood clot from a pulmo- nary artery in a patient with acute ischemic stroke	<ul><li>Yes</li><li>No</li><li>Unknown</li></ul>			
Thrombolysis for stroke	Treatment to remove a blood clot from an artery in a patient with acute isch- emic stroke	• Yes • No • Unknown			

PCI indicates percutaneous coronary intervention; PTFE, polytetrafluoroethylene; and TIMI, Thrombolysis in Myocardial Infarction.

#### Appendix 10. 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 emer- gency therapy to restore circulation or ventilation (eg, no intubation, no shocking, no chest com- pressions)	• Yes • No • Unknown		Bozkurt B, Hershberger RE, Butler J, et al. 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 Com- mittee to Develop Clinical Data Stan- dards for Heart Failure). <i>Circ Cardiovasc</i> <i>Qual Outcomes.</i> 2021;14:e000102. <sup>57</sup>	
DNR	Explicit documentation by health care provider or patient indicating that no resuscitative efforts are to be performed in the event of circulatory or respiratory arrest	• Yes • No • Unknown		Bozkurt B, Hershberger RE, Butler J, et al. 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). <i>Circ Cardiovasc Qual Outcomes</i> . 2021;14:e000102. <sup>67</sup>	
Inactivation of ICD defibrilla- tion mode	Inactivation of ICD defibrillation mode with- out plans to reactivate (excludes inactivation for specific surgical proce- dures)	• Yes • No • Unknown		Bozkurt B, Hershberger RE, Butler J, et al. 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). <i>Circ Cardiovasc Qual Outcomes</i> . 2021;14:e000102. <sup>57</sup>	

Data Element	Data Element Definition	Permissible Values	Permissible Value Definitions	Mapping/Source of Definition	Additional Notes
Advance care planning	The process of clarifying goals of care, communi- cating wishes and goals for medical care in the event of an emergency, and documenting those wishes or plan in an ad- vance directive	• Yes • No • Unknown		Bozkurt B, Hershberger RE, Butler J, et al. 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). <i>Circ Cardiovasc Qual Outcomes</i> . 2021;14:e000102. <sup>67</sup> Fried TR, Redding CA, Robbins ML, et al. Stages of change for the component behaviors of advance care planning. <i>J Am Geriatr Soc.</i> 2010;58:2329-2336. <sup>152</sup> Sudore RL, Lum HD, You JJ, et al. Defining advance care planning for adults: a con- sensus definition from a multidisciplinary Delphi panel. <i>J Pain Symptom Manage</i> . 2017;53:821-832.e1. <sup>153</sup>	Advance directive is defined as documenta- tion in the medical record that the patient has an advance directive. An ad- vance directive is instruc- tions 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 de- cisions on their behalf.
Medical order for life-sustain- ing treatment	A written medical order by a physician, advanced practice registered nurse, or physician assistant that records a patient's treatment preferences as to life- sustaining treatment	• Yes • No • Unknown		Bozkurt B, Hershberger RE, Butler J, et al. 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). <i>Circ Cardiovasc Qual Outcomes</i> . 2021;14:e000102. <sup>67</sup>	
Discharge to hospice	Discharge to either home hospice or to a facility with hospice care	<ul><li>Yes</li><li>No</li><li>Unknown</li></ul>			
Palliative care consultation	Consultation with a pal- liative care provider	• Yes • No • Unknown			Note that "palliative care provider" does not re- quire that person has for- mal training in palliative care, but rather, anyone acting in that role.

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