

DATA STANDARDS

2013 ACCF/AHA Key Data Elements and Definitions for Measuring the Clinical Management and Outcomes of Patients With Acute Coronary Syndromes and Coronary Artery Disease

A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Acute Coronary Syndromes and Coronary Artery Disease Clinical Data Standards)

Developed in Collaboration with American College of Emergency Physicians, Emergency Nurses Association, National Association of Emergency Medical Technicians, National Association of EMS Physicians, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Patient Care, and Society of Thoracic Surgeons

Writing Committee Members

Christopher P. Cannon, MD, FACC, *Chair*

Ralph G. Brindis, MD, MPH, FACC

Bernard R. Chaitman, MD, FACC

David J. Cohen, MD, MSc

J. Thomas Cross, JR, MD, MPH*

Joseph P. Drozda, JR, MD, FACC†

Francis M. Fesmire, MD, FACEP‡

Dan J. Fintel, MD, FACC§

Gregg C. Fonarow, MD, FACC, FAHA

Keith A. Fox, MB, ChB

Darryl T. Gray, MD, ScD, FAHA||

Robert A. Harrington, MD, FACC, FAHA

Karen A. Hicks, MD, FACC¶

Judd E. Hollander, MD, FACEP#

Harlan Krumholz, MD, SM, FACC

Darwin R. Labarthe, MD, MPH, PhD**

Janet B. Long, MSN, ACNP, FAHA††

Alice M. Mascette, MD, FACC, FAHA, FACP‡‡

Connie Meyer, MICT, AAS§§

Eric D. Peterson, MD, FACC, FAHA

Martha J. Radford, MD, FACC, FAHA

Matthew T. Roe, MD, MHS, FACC

James B. Richmann, RN, BS, MHA, CEN|||

Harry P. Selker, MD, MSPH, FAHA¶¶

David M. Shahian, MD, FACC, FAHA##

Richard E. Shaw, MA, PhD, FACC, FAHA
Sharon Sprenger, RHIA, CPHQ, MPA***

Robert Swor, DO, FACEP†††

James A. Underberg, MD‡‡‡

Frans Van de Werf, MD, FACC

Bonnie H. Weiner, MD, MSEC, MBA§§§

William S. Weintraub, MD, FACC, FAHA

*American College of Physicians Representative. †American Medical Association Representative. ‡American College of Emergency Physicians Representative. §American College of Chest Physicians Representative. ||Agency for Healthcare Research and Quality Representative. The findings and conclusions in this report are those of the author and do not necessarily represent the official positions of the Agency for Healthcare Research and Quality. ¶Food and Drug Administration Representative. The findings and conclusions in this report are those of the author and do not necessarily represent the official positions of the Food and Drug Administration. #Society for Academic Emergency Medicine Representative. **Centers for Disease Control and Prevention Representative. The findings and conclusions in this report are those of the author and do not necessarily represent the official positions of the Centers for Disease Control and Prevention. ††Preventive Cardiovascular Nurses Association Representative. ‡‡National Heart, Lung, and Blood Institute Representative. The findings and conclusions in this report are those of the author and do not necessarily represent the official positions of the National Heart, Lung, and Blood Institute. §§National Association of Emergency Medical Technicians Representative. |||Emergency Nurses Association Representative. ¶¶Society of General Internal Medicine Representative. ##Society of Thoracic Surgeons Representative. ***The Joint Commission Representative. The findings and conclusions in this report are those of the author and do not necessarily represent the official positions of The Joint Commission. †††National Association of EMS Physicians Representative. ‡‡‡American College of Preventive Medicine Representative. §§§Society for Cardiovascular Angiography and Interventions Representative.

**ACCF/AHA
 Task Force
 Members**

Robert C. Hendel, MD, FACC, FAHA,
Chair

Véronique L. Roger, MD, MPH, FAHA,
 FACC

Biykem Bozkurt, MD, FACC, FAHA

Gregg C. Fonarow, MD, FACC, FAHA

Jeffrey P. Jacobs, MD, FACC

Judith H. Lichtman, MPH, PHD

Pamela N. Peterson, MD, FACC, FAHA

Eric E. Smith, MD, FAHA

James E. Tcheng, MD, FACC

Tracy Wang, MD, FACC, FAHA

William S. Weintraub, MD, FACC, FAHA

Former Task Force Chair during this writing effort. Former Task Force Member during this writing effort.

TABLE OF CONTENTS

Preamble993

1. Introduction995

2. Methodology995

2.1. Writing Committee Composition995

2.2. Relationships With Industry and Other Entities995

2.3. Review of Literature and Existing Data Definitions995

2.4. Defining Data Elements996

2.5. Relation to Other Standards996

2.6. Consensus Development996

2.7. Peer Review, Public Review, and Board Approval996

2.8. Considerations for ACS and CAD Data Standards998

3. ACS and CAD Clinical Data Standard Elements and Definitions1002

3.1. Demographic and Admission Data Elements1002

3.2. History and Risk Factors Data Elements1003

3.3. Clinical Presentation Data Elements1003

3.4. Diagnostic Procedure Data Elements1003

3.5. Invasive Therapeutic Intervention Data Elements1003

3.6. Medications Table of Data Elements1004

3.7. Outcomes Data Elements1014

References1021

Appendix 1. Author Relationships With Industry and Other Entities1022

Appendix 2. Peer Review Relationships With Industry and Other Entities1024

Preamble

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

Hence, clinical data standards strive to define and standardize data relevant to clinical topics in cardiology, with the primary goal of assisting data collection by providing a

This document was approved by the American College of Cardiology Foundation Board of Trustees October 19, 2012, and by the American Heart Association Science Advisory and Coordinating Committee November 30, 2012, as well as endorsed by the following societies in November 2012: American College of Emergency Physicians, Emergency Nurses Association, National Association of Emergency Medical Technicians, National Association of EMS Physicians, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Patient Care, and Society of Thoracic Surgeons.

The American College of Cardiology Foundation requests that this document be cited as follows: Cannon CP, Brindis RG, Chaitman BR, Cohen DJ, Cross JT Jr, Drozda JP Jr, Fesmire FM, Fintel DJ, Fonarow GC, Fox KA, Gray DT, Harrington RA, Hicks KA, Hollander JE, Krumholz H, Labarthe DR, Long JB, Mascette AM, Meyer C, Peterson ED, Radford MJ, Roe MT, Richmann JB, Selker HP, Shahian DM, Shaw RE, Sprenger S, Swor R, Underberg JA, Van de Werf F, Weiner BH, Weintraub WS. 2013 ACCF/AHA key data elements and definitions for measuring the clinical management and

outcomes of patients with acute coronary syndromes and coronary artery disease: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Acute Coronary Syndromes and Coronary Artery Disease Clinical Data Standards). *J Am Coll Cardiol* 2013;61:xxx-xxx, doi:10.1016/j.jacc.2012.10.005.

This article is copublished in *Circulation* and *Critical Pathways in Cardiology*.

Copies: This document is available on the World Wide Web sites of the American College of Cardiology (<http://www.cardiosource.org>) and the American Heart Association (my.americanheart.org). For copies of this document, please contact Elsevier Inc. Reprint Department, fax 212-633-3820, e-mail reprints@elsevier.com.

Permissions: Multiple copies, modification, alteration, enhancement, and/or distribution of this document are not permitted without the express permission of the American College of Cardiology Foundation. Please contact healthpermissions@elsevier.com.

platform of data elements and definitions applicable to various conditions. Broad agreement on a common vocabulary with reliable definitions used by all is vital to pool and/or compare data across studies to promote interoperability of electronic health records (EHRs) and to assess the applicability of research to clinical practice. The increasing national focus on adoption of certified EHRs along with financial incentives for providers to demonstrate “meaningful use” of those EHRs to improve healthcare quality render even more imperative and urgent the need for such definitions and standards. Therefore, the ACCF and AHA have undertaken to define and disseminate clinical data standards—sets of standardized data elements and corresponding definitions—to collect data relevant to cardiovascular conditions. The ultimate purpose of clinical data standards is to contribute to the infrastructure necessary to accomplish the ACCF/AHA mission of fostering optimal cardiovascular care and disease prevention and building healthier lives, free of cardiovascular diseases and stroke.

The specific goals of clinical data standards are

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

The key elements and definitions are a compilation of variables intended to facilitate the consistent, accurate, and reproducible capture of clinical concepts; standardize the terminology used to describe cardiovascular diseases and procedures; create a data environment conducive to the assessment of patient management and outcomes for quality and performance improvement and clinical and translational research; and increase opportunities for sharing data across disparate data sources. The ACCF/AHA Task Force on Clinical Data Standards selects cardiovascular conditions and procedures that will benefit from creation of a data standard set. Experts in the subject are selected to examine/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 standards listing may be needed, or conversely, users may want to consider whether it may be necessary to collect some elements not listed. For example, in the setting of a randomized clinical trial of a new drug, additional information would likely be required regarding study procedures and drug therapies.

The ACCF and AHA recognize that there are other national efforts to establish clinical data standards, and every attempt is made to harmonize newly published standards

with existing standards. Writing committees are instructed to consider adopting or adapting existing nationally recognized data standards if the definitions and characteristics are useful and applicable to the set under development. In addition, the ACCF and AHA are committed to continually expanding their portfolio of data standards and will create new standards and update existing standards as needed to maintain their currency and promote harmonization with other standards as health information technology and clinical practice evolve.

The Health Insurance Portability and Accountability Act privacy regulations, which went into effect in April 2003, have heightened all practitioners’ awareness of our professional commitment to safeguard our patients’ privacy. The Health Insurance Portability and Accountability Act privacy regulations (1) specify which information elements are considered “protected health information.” These elements may not be disclosed to third parties (including registries and research studies) without the patient’s written permission. Protected health information may be included in databases used for healthcare operations under a data use agreement. Research studies using protected health information must be reviewed by an institutional review board or a privacy board.

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

The ACCF/AHA Task Force on Clinical Data Standards makes every effort to avoid any actual or potential conflicts of interest that may arise as a result of an outside relationship or a personal, professional, or business interest of a member of the writing panel. Specifically, all members of the writing committee were required to submit a disclosure form showing all such relationships that might be perceived as real or potential conflicts of interest. These statements were reviewed by the ACCF/AHA Task Force on Clinical Data Standards, reported orally to all members of the writing panel at the first meeting, and updated as changes occur.

In clinical care, caregivers communicate with each other through a common vocabulary. In an analogous fashion, the integrity of clinical research depends on firm adherence to prespecified procedures for patient enrollment and follow-up; these procedures are guaranteed through careful attention to definitions enumerated in the study design and case report forms. When data elements and definitions are standardized across studies, comparison, pooled analysis, and meta-analysis are enabled, thus deepening our understanding of individual studies.

The recent development of quality-performance measurement initiatives, particularly those for which the comparison of providers is an implicit or explicit aim, has further

raised awareness about the importance of data standards. Indeed, a wide audience, including nonmedical professionals such as payers, regulators, and consumers, may draw conclusions about care and outcomes. To understand and compare care patterns and outcomes, the data elements that characterize them must be clearly defined, consistently used, and properly interpreted, now more than ever before.

*Robert C. Hendel, MD, FACC, FAHA
Chair, ACCF/AHA Task Force on Clinical Data Standards*

1. Introduction

In the field of cardiology, large-scale clinical trials and registries have provided a wealth of data on the treatment and outcomes for hundreds of thousands of patients. Many of these efforts have focused on patients with acute coronary syndromes (ACS), which range from ST-segment elevation myocardial infarction (STEMI) to non-ST-segment elevation myocardial infarction (NSTEMI) to unstable angina (UA). These data have been used to evaluate the effectiveness of the pharmacological and interventional management of these patients, define new therapies, and guide clinical care through evaluation of both the process and the quality of care and outcomes for patients with ACS.

The ACCF and AHA, in conjunction with other professional medical organizations and government agencies, recognize the importance of using clinical data and, to that end, have aimed to establish a series of datasets in the major areas of cardiology (2–7). In 2001, a dataset was established for the field of ACS; a working group developed a list of key data elements to characterize patients with ACS. This document served as the basis for data definitions for many data elements in the ACTION Registry–Get With The Guidelines (AR-G), Get With The Guidelines–CAD (GWTG-CAD), and other trials and registries. To date, this document has been cited in 255 publications.

Given the overlap of ACS and coronary artery disease (CAD), it was decided to update this list of data elements and expand it to include CAD. The current group of organizations also has been expanded to include as many organizations with an interest in clinical data standards for ACS/CAD as could be identified. In addition, the cardiac catheterization/percutaneous coronary intervention (Cath/PCI) registry of the National Cardiovascular Data Registry also includes patients with ACS and CAD, and as such the elements overlap as well. Thus, the goal was to create definitions that could serve registries in all these areas and in particular those that matched between AR-G and Cath/PCI.

The writing committee hopes that this set of data elements and definitions for patients with ACS and CAD will help facilitate research and assessment of quality of care, thereby advancing the practice of medicine.

2. Methodology

2.1. Writing Committee Composition

The process undertaken in developing these clinical data standards began with the ACCF/AHA Task Force on Clinical Data Standards, which identified ACS as an important area in which to standardize definitions and registries. A writing committee was formed that included a select group of physicians who have been involved in large-scale ACS clinical trials or registries and who are recognized experts in the field. The committee also included members who are considered to be experts in the diagnosis and treatment of stable CAD. Additionally, the writing committee includes several international members to ensure balance in the data elements and the type of practice worldwide that would be reflected by the data collected in this dataset. The writing committee also included representatives from the American College of Chest Physicians, American College of Emergency Physicians, American College of Physicians, American College of Preventive Medicine, American Medical Association, Emergency Nurses Association, National Association of Emergency Medical Technicians, National Association of EMS Physicians, Preventive Cardiovascular Nurses Association, Society for Academic Emergency Medicine, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Patient Care, Society of General Internal Medicine, and Society of Thoracic Surgeons.

2.2. Relationships With Industry and Other Entities

Disclosure of all relationships with industry and other entities (RWI) is required of every member of ACCF/AHA data standards writing committees and peer reviewers. This writing effort was initiated before the implementation of the updated ACCF and AHA policy on relationships with industry and other entities, which requires that a majority of the writing committee plus the writing committee chair have no relationships with industry and other entities relevant to the document. Relevant relationships disclosed by writing committee members and peer reviewers are listed in Appendixes 1 and 2, respectively. The work of the writing committee was supported exclusively by the ACCF and AHA (and the other partnering organizations) 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

Writing committee members compiled and reviewed case report forms, data elements, and data definitions from national and international ACS registries and previous or ongoing clinical trials to develop an initial set of data

elements. Examples of these data sources included in the first round are the NRM (National Registry of Myocardial Infarction) (8), GRACE (Global Registry of Acute Coronary Events) (9), TIMI (Thrombolysis in Myocardial Infarction) (10–12), and the GUSTO (Global Use of Streptokinase and Tissue Plasminogen Activator to Open Occluded Arteries) (13–15) trials, and in this update, the definitions for the Cath/PCI and AR-G, CRUSADE (Can Rapid risk stratification of Unstable angina patients Suppress Adverse outcomes with Early implementation of the ACC/AHA Guidelines) (16), and ACTION Registry-GWTG (17) were reviewed in detail.

This document also considered data elements and how they pertain to the emergency department (16), the prehospital setting, and Mission: Lifeline (18).

2.4. Defining Data Elements

The data elements reflect an ongoing review of the medical literature to focus on new developments. Current scientific evidence provided the basis for the selection and definition of appropriate data elements required to evaluate and manage patients with ACS and stable CAD. Therefore, data elements and definitions were linked whenever possible to evidence-based national guidelines. For the purposes of these clinical data standards, the writing committee chose to review and cite several ACCF/AHA guidelines, including but not limited to the “ACCF/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction” (19,20) and the “ACCF/AHA Guidelines for the Management of Patients With Unstable Angina/Non-ST-Elevation Myocardial Infarction” (21). Data element definitions particularly in the Outcomes section were also matched to the upcoming Food and Drug Administration (FDA) definitions for major cardiovascular endpoints. In addition, the writing committee adopted the definition of myocardial infarction (MI) as published in a European Society of Cardiology/ACCF/AHA/World Heart Federation consensus document on the universal definition of MI (22). On a few occasions, data elements and definitions were linked to other national guidelines, such as the National Cholesterol Education Program (NCEP III) guidelines (23).

The writing committee members reviewed the list of data elements, bearing in mind the intent of their use. For example, some data elements are suitable for use in developing and implementing risk adjustment models, whereas others can be used to construct performance measures. Several data elements can be used for multiple purposes. Additional uses of the data include identification of patient demographics for combining data across registries and disease states, institutional and regional variances that may be addressed in health services research, patient follow-up for evaluation of long-term effects of therapy, and outcomes analysis.

2.5. Relation to Other Standards

The writing committee reviewed other standards, including those developed for heart failure, atrial fibrillation, electrophysiology, and cardiac imaging. It was thought that this writing committee possessed key levels of expertise needed to address issues related to ACS and CAD in a consistent fashion.

2.6. Consensus Development

The writing committee met several times in person and by conference call to refine the data standards to their present form. The overriding goals were to focus on important variables needed to assess patients' characteristics, their treatment with both medication and interventional therapies, and their outcomes. In developing the list of data elements, the writing committee worked to balance the completeness of the dataset in describing ACS with the length of the data element set. The goal was to be as concise as possible to facilitate the use of these variables in real-world registry or trial settings. Standardized definitions for each variable are provided. In assembling these, the writing committee again balanced the increased complexity of obtaining more specific and detailed data required to satisfy more comprehensive definitions against information that can be readily and reliably obtained from medical records to make these definitions more functional and applicable in the various real-world settings in which they may be used.

2.7. Peer Review, Public Review, and Board Approval

The “2013 ACCF/AHA Key Elements and Data Definitions for Measuring the Clinical Management and Outcomes of Patients With Acute Coronary Syndromes and Coronary Artery Disease” was reviewed by official reviewers nominated by the ACCF and AHA, as well as official reviewers designated by collaborating societies. To increase its applicability further, the document was posted on the ACC World Wide Web site for a 30-day public comment period. This document was approved for publication by the ACCF Board of Trustees on October 19, 2012, and AHA Science Advisory and Coordinating Committee on November 30, 2012, and was formally endorsed by the American College of Emergency Physicians, Emergency Nurses Association, National Association of Emergency Medical Technicians, National Association of EMS Physicians, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Patient Care, and Society of Thoracic Surgeons. The writing committee anticipates that these data standards will require review and updating, just as with other published guidelines, performance measures, and appropriateness criteria. The writing committee will 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.

Table 1. Demographic and Admission Data Elements and Definitions

Element Name	Element Definition
Demographics	
Unique patient ID	Patient ID is a unique number that permanently identifies each patient. Once assigned to a patient, this number can never be changed or reassigned to a different patient. Each time a patient returns to the site, the patient MUST receive the same unique patient identifier.
Sex	Indicate the patient's sex at birth as either male or female. Choose 1 of the following: <ul style="list-style-type: none"> • Male • Female
Date of birth	Indicate the patient's date of birth.
Race	Indicate the patient's race as determined by the patient or family. Choose 1 of the following: <ul style="list-style-type: none"> • White • Black or African American • Asian Indian • Chinese • Filipino • Japanese • Korean • Vietnamese • Other Asian • American Indian or Alaska Native • Native Hawaiian • Guamanian or Chamorro • Samoan • Other Pacific Islander
Ethnicity	Indicate if the patient is of Hispanic or Latino ethnicity as determined by the patient or family. Hispanic ethnicity includes patient reports of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. Choose 1 of the following: <ul style="list-style-type: none"> • No • Yes
Postal code	Indicate the postal code for the patient's residence. For US ZIP codes, the hyphen is implied. If the patient is determined to not have a permanent residence, then the patient is considered homeless.
Admission/encounter date	Indicate the date the patient was admitted as an inpatient to the facility for the current episode of care. For outpatients, note the date (month/day/year) of the encounter (e.g., physician visit, nurse visit, consultation, procedures).
Admission source	Indicate the source of the patient's admission as an inpatient to your facility. Choose 1 of the following: <ul style="list-style-type: none"> • Physician referral: The patient was admitted to this facility on the recommendation of his or her personal physician. • Clinic referral: The patient was admitted to this facility on the recommendation of this facility's clinic physician. • HMO referral: The patient was admitted to this facility on the recommendation of an HMO physician. • Transfer from a hospital (different facility): The patient was admitted to this facility as a hospital transfer from a different acute care facility where he or she was an inpatient. • Transfer from SNF: The patient was admitted to this facility as a transfer from an SNF where he or she was an inpatient. • Transfer from another healthcare facility: The patient was admitted to this facility as a transfer from a healthcare facility other than an acute care facility or an SNF. This includes transfers from nursing homes and long-term care facilities and SNF patients who are at a nonskilled level of care. • ED: The patient was admitted to this facility on the recommendation of this facility's emergency physician. • Court/law enforcement: The patient was admitted to this facility on the direction of a court of law or the request of a law enforcement agency representative. • Information not available: The means by which the patient was admitted to this hospital is not known. <ul style="list-style-type: none"> - Transfer from a critical access hospital: The patient was admitted to this facility as a transfer from a critical access hospital where he or she was an inpatient. - Transfer from hospital inpatient in the same facility resulting in a separate claim to the payer: The patient was admitted to this facility as a transfer from hospital inpatient within this facility resulting in a separate claim to the payer.
Insurance payer	Indicate the patient's primary insurance payer for this admission. Choose 1 of the following: <ul style="list-style-type: none"> • Government: Refers to patients who are covered by government-reimbursed care. In the United States this includes <ul style="list-style-type: none"> - Medicare - Medicaid (including all state or federal Medicaid-type programs) - Veterans Health Administration - Department of Defense - Other federal group (specify) • Commercial: Refers to all indemnity (fee-for-service) carriers and PPOs • HMO: Refers to a HMO characterized by coverage that provides healthcare services for members on a prepaid basis • None: Refers to patients with limited or no health insurance; thus, the patient is the payer regardless of ability to pay. Only mark "None" when "self" or "none" is denoted as the first insurance in the medical record.
Presentation (to healthcare facility) date/time	Date and time the patient first presented to the hospital

Table 1. Continued

Element Name	Element Definition
Location of first evaluation in ED	Indicate if the patient was first evaluated in your facility's ED. This includes traditional ED locations, as well as ED-based chest pain units, clinics, and short-stay CCUs housed in the ED.
Transfer out of ED date/time	If the patient was first evaluated in your facility's ED, enter the date and time the patient was moved out of the ED, either to another location within your facility or to another acute care center.
Type of admission	The categories of type of admission are <ul style="list-style-type: none"> • Elective (i.e., scheduled >24 h before hospital arrival) • Urgent (i.e., through the ED or directly from a health care provider's office or transferred from another facility)
Admission location	The categories of location of a patient at the time of admission to the hospital or observation unit are <ul style="list-style-type: none"> • CCU/ICU • Step-down unit/monitored bed/cardiac ward • Unmonitored hospital floor • Observation unit/ED chest pain unit
Means of transport of nontransfer patient	Indicate the means by which a nontransfer patient was transported to your facility. Choose 1 of the following: <ul style="list-style-type: none"> • Self/family • Ground-transport ambulance (includes 911 provider, private provider, or hospital based) • Air ambulance (helicopter or fixed wing) • Mobile ICU • Unknown
Prearrival first medical contact date/time	Indicate the date and time of prearrival first medical contact, when the patient was first evaluated by either EMS or another healthcare professional before arrival at your facility. This is not the date and time of arrival at your facility. Note: Enter the date and time of first medical contact only for patients who were transported by ambulance (ground or air) or mobile ICU.
Transfer patient	Indicate if the patient was transferred directly to your facility from another ED or hospital unit and indicate which.
Means of transport of transfer patient	Indicate the means by which the transfer patient was transported to your facility. Choose 1 of the following: <ul style="list-style-type: none"> • Mobile ICU • Air ambulance (helicopter or fixed wing) transfer from another facility • Ground-transport ambulance transfer from another acute care facility <ul style="list-style-type: none"> - 911 Provider - Hospital based - Private provider - Unknown
Arrival at outside hospital date/time	Indicate the date and time the patient arrived at the outside hospital. If unknown, leave blank.
Transfer from outside hospital date/time	Indicate the date and time the patient left the outside facility.
Time points for STEMI patients	Indicate the following time points for STEMI patients: <ul style="list-style-type: none"> • Symptom-onset date/time • EMS dispatch date/time <ul style="list-style-type: none"> - If ground or air ambulance, indicate EMS first medical contact date/time • Non-EMS first medical contact date/time • EMS leaving scene date/time • Hospital arrival date/time • First ECG date/time • Catheterization lab activation date/time

CCU indicates coronary care unit; ECG, electrocardiogram; ED, emergency department; EMS, emergency medical services; HMO, health maintenance organization; ICU, intensive care unit; ID, identification; PPO, preferred provider organization; SNF, skilled nursing facility; and STEMI, ST-segment elevation myocardial infarction.

2.8. Considerations for ACS and CAD Data Standards

There are many goals that this project hopes to fulfill by providing a list of key data elements and standardized definitions in ACS and CAD (Table 1). First, it is hoped that standardized definitions will facilitate better cross-comparison of results and clinical outcomes between different clinical trials and registries. This is particularly true for meta-analyses of clinical trials, where differences in data collection methods and variations in definitions have hampered the validity of these analyses. Furthermore, the standardized definitions would also facilitate the application of research findings that come from the

clinical trials and registries, because the key elements needed for assessment of efficacy, safety, and appropriate risk adjustment would be included in the clinical data standards.

Second, the provision of a list of the major variables, outcomes, and definitions should facilitate the development and implementation of future registries at both individual hospital and national levels. The standardized definitions should also standardize and enhance the reporting of research findings coming from the clinical trials and registries, because the key elements needed for assessment of efficacy and safety and for appropriate risk adjustment would be included in the dataset. In fact, the ACS CAD clinical data

Table 2. History and Risk Factor Data Elements and Definitions

Element Name	Element Definition
Prior angina	History of angina before the current admission. "Angina" refers to evidence or knowledge of symptoms before this acute event described as chest pain or pressure, jaw pain, arm pain, or other equivalent discomfort suggestive of cardiac ischemia. Indicate if angina existed >2 wk before admission and/or within 2 wk before admission.
Average number of episodes of angina in the prior week	Average number of distinct episodes of anginal pain that occurred in the last week before hospital admission or this visit
Number of angina episodes in the prior 6 wk	Total number of distinct episodes of anginal pain that occurred in the last 6 wks before hospital admission or visit should be recorded. Duration of each episode and requirement for sublingual nitroglycerin are also documented.
Intermittent claudication	History of claudication that typically presents as exertional fatigue, cramping, or aching in the muscles of the legs that is reproducible and resolves promptly with rest. Choose 1 of the following: <ul style="list-style-type: none"> • Yes • No
Prior MI	<p>Indicate if the patient has had at least one documented previous myocardial infarction. Any occurrence between birth and arrival at first facility. The term <i>acute MI</i> should be used when there is evidence of myocardial necrosis in a clinical setting consistent with myocardial ischemia. Under these conditions, any 1 of the following criteria meets the diagnosis for MI:</p> <ul style="list-style-type: none"> • Detection of the rise and/or fall of cardiac biomarkers (preferably cTn) with at least 1 value above the 99th percentile and with at least 1 of the following: <ul style="list-style-type: none"> - Symptoms of ischemia - New or presumed new significant ST-T changes or new LBBB - Development of pathological Q waves on the ECG - Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality. - Identification of an intracoronary thrombus by angiography or autopsy • Cardiac death with symptoms suggestive of myocardial ischemia and presumed new ischemic electrocardiographic changes or new LBBB, but death occurred before cardiac biomarkers were obtained or before cardiac biomarker values would be increased. • PCI-related MI is arbitrarily defined by elevation of cTn values (>5 times the 99th percentile URL) in patients with normal baseline values (\leq99th percentile URL) or a rise in cTn values \geq20% if baseline values are elevated and stable or falling; in addition, either symptoms suggestive of myocardial ischemia OR NEW ISCHEMIC electrocardiographic changes or angiographic findings consistent with a procedural complication or imaging demonstration of new loss of viable myocardium or new regional wall motion abnormality. • Stent thrombosis associated with MI when detected by coronary angiography or autopsy in the setting of myocardial ischemia and with a rise and/or fall of cardiac biomarker values with at least 1 value >99th percentile URL. • CABG-related MI is arbitrarily defined by elevation of cardiac biomarker values (>10 times the 99th percentile URL) in patients with normal baseline cTn values (\leq99th percentile URL) plus either new pathological Q waves or new LBBB, or angiographically documented new graft or new native coronary artery occlusion, or imaging evidence of new loss of viable myocardium. • The 99th percentile is observed after the procedure in conjunction with symptoms suggestive of myocardial ischemia or new ischemic electrocardiographic changes or angiographic findings consistent with a procedural complication or imaging demonstration of new loss of viable myocardium or in patients with a preprocedure elevated biomarker that is stable or falling, a rise of biomarker values \geq20% in conjunction with the PCI-related criteria stated above. <p>A prior MI can also be documented if the patient has any 1 of the following criteria that meets the diagnosis for prior MI:</p> <ul style="list-style-type: none"> • Pathological Q waves with or without symptoms in the absence of nonischemic causes • Imaging evidence of a region of loss of viable myocardium that is thinned and fails to contract, in the absence of a nonischemic cause • Pathological findings of a prior MI
Previous history of heart failure	<p>Indicate if there is a previous history of heart failure before this care encounter. A previous hospital admission with the principal diagnosis of heart failure is considered evidence of a history of heart failure.</p> <p>Heart failure is defined as physician documentation or report of any of the following clinical symptoms of heart failure described as unusual dyspnea on light exertion, recurrent dyspnea occurring in the supine position, fluid retention, or the description of rales, jugular venous distention, pulmonary edema on physical examination, or pulmonary edema on chest x-ray. A low ejection fraction without clinical evidence of heart failure does not qualify as heart failure.</p>
NYHA functional class	<p>If heart failure is present, indicate the NYHA functional class.</p> <p>Choose 1 of the following:</p> <ul style="list-style-type: none"> • Class I: patients with cardiac disease but without resulting limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, or dyspnea. • Class II: patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, or dyspnea. • Class III: patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea. • Class IV: patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms are present even at rest or minimal exertion. If any physical activity is undertaken, discomfort is increased.
Prior PCI	<p>Indicate if the patient had a previous PCI (even if unsuccessful) of any type (balloon angioplasty, stent, or other), performed before the current admission.</p> <p>Check all that apply:</p> <ul style="list-style-type: none"> • None • Balloon angioplasty • Bare metal stent • Drug-eluting stent • Other <p>Note: Timeframe does NOT include the current admission.</p>
Date of prior PCI	If the patient had a previous PCI of any type (balloon angioplasty, stent, or other) performed before the current admission, indicate the date of the most recent PCI. If month or day is unknown, year is sufficient.

Table 2. Continued

Element Name	Element Definition
Prior CABG	Indicate whether the patient had a previous CABG surgery before the current admission. <i>Note:</i> Timeframe does NOT include the current admission.
Date of prior CABG	If the patient had a previous CABG before the current admission, indicate the date of the most recent CABG. If month or day is unknown, year is sufficient.
Prior catheterization with stenosis $\geq 50\%$	The patient has documented CAD at coronary angiography at any time before the current admission, with at least a 50% stenosis in the diameter of a major coronary artery. If the patient had a cardiac catheterization before the index event that demonstrated a stenosis of 90% that was successfully stented to a 0% residual, this should be coded as “yes,” because a stenosis $\geq 50\%$ diameter was documented.
Cerebral artery disease	Current or previous history of any of the following: <ul style="list-style-type: none"> • Ischemic stroke: an acute episode of focal, cerebral, spinal, or retinal dysfunction caused by infarction of the central nervous system tissue • TIA: transient episode of neurological dysfunction caused by focal or global brain, spinal cord, or retinal ischemia without acute infarction • Noninvasive or invasive arterial imaging test demonstrating $\geq 50\%$ stenosis of any of the major extracranial or intracranial vessels to the brain • Previous cervical or cerebral artery revascularization surgery or percutaneous intervention This does not include chronic (nonvascular) neurological diseases or other acute neurological insults such as metabolic and anoxic ischemic encephalopathy.
Prior stroke	Indicate whether the patient has a history of stroke, which is defined as an acute episode of neurological dysfunction caused by focal or global brain, spinal cord, or retinal vascular injury as a result of hemorrhage or infarction. If present, record type of stroke: <ul style="list-style-type: none"> • Ischemic stroke • Intracerebral hemorrhage • Subarachnoid hemorrhage • Unknown type If ischemic, list the most likely etiologies: <ul style="list-style-type: none"> • Large artery atherosclerosis of the extracranial vessels (e.g., carotid) • Large artery atherosclerosis of the intracranial vessels (e.g., middle cerebral artery stenosis) • Cardioembolism • Small vessel occlusion (lacunar) • Ischemic stroke of other determined etiology (e.g., arterial dissection) • Ischemic stroke of undetermined etiology
PAD	Current or previous history of PAD (includes lower extremity from iliac to tibials and upper extremity with subclavian and brachials. Excludes renal, coronary, cerebral, and mesenteric vessels and aneurysms.) This can include <ul style="list-style-type: none"> • Claudication on exertion that is relieved by rest • Amputation for severe arterial vascular insufficiency • Vascular reconstruction, bypass surgery, or percutaneous revascularization in the arteries of the lower and upper extremities • Positive noninvasive test (e.g., ankle brachial index ≤ 0.9, ultrasound, MR imaging or CT scanning of $>50\%$ diameter stenosis in any peripheral artery [i.e., subclavian, femoral, iliac]) or angiographic imaging
Aorta disease	Current or previous history of disease of the thoracic, thoracoabdominal, or abdominal aorta (typically aneurysm)
Renal artery disease	Current or previous history of disease of the main renal arteries or extrarenal branches
History of alcohol consumption/dependency	Specify alcohol consumption history. Choose from the following categories: <ul style="list-style-type: none"> • None • ≤ 1 alcoholic drink per week • 2–7 alcoholic drinks per week • ≥ 8 alcoholic drinks per week Specify alcohol dependency history. Choose all that apply: <ul style="list-style-type: none"> • Documented alcohol dependency • Medical sequelae of alcohol consumption (alcoholic hepatitis, cirrhosis, alcohol neuropathy, Wernicke-Korsakoff syndrome) • Treatment for alcohol dependency For patients with alcohol dependency, note treatment for dependency, cessation of use, or continued use.
Erectile dysfunction	Indicate if the patient has a history of erectile dysfunction. Choose 1 of the following: <ul style="list-style-type: none"> • Yes • No • Unknown • N/A
Depression	Current or previous diagnosis of depression or documentation of a depressed mood or affect
Diabetes	History of diabetes diagnosed and/or treated by a healthcare provider. The American Diabetes Association criteria (33) include documentation of the following: <ol style="list-style-type: none"> 1. Hemoglobin A1c $\geq 6.5\%$; or 2. Fasting plasma glucose ≥ 126 mg/dL (7.0 mmol/L); or 3. 2-h Plasma glucose ≥ 200 mg/dL (11.1 mmol/L) during an oral glucose tolerance test; or 4. In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose ≥ 200 mg/dL (11.1 mmol/L) This does not include gestational diabetes.

Table 2. Continued

Element Name	Element Definition
Diabetes control	<p>Indicate the patient's diabetes control method as presented on admission. Patients placed on a preprocedure diabetic pathway of insulin drip at admission but whose diabetes was controlled by diet or oral methods are not coded as being treated with insulin.</p> <p>Choose the most aggressive therapy from the order below</p> <ul style="list-style-type: none"> • Insulin: insulin treatment (includes any combination with insulin) • Other subcutaneous medications (e.g., GLP-1 agonist) • Oral: treatment with oral agent (includes oral agent with or without diet treatment) • Diet only: Treatment with diet only • None: no treatment for diabetes • Other: other adjunctive treatment, non-oral/insulin/diet
Hypertension	<p>Indicate if the patient has a current diagnosis of hypertension defined by any 1 of the following:</p> <ul style="list-style-type: none"> • History of hypertension diagnosed and treated with medication, diet, and/or exercise • Prior documentation of blood pressure ≥ 140 mm Hg systolic and/or 90 mm Hg diastolic for patients without diabetes or chronic kidney disease, or prior documentation of blood pressure ≥ 130 mm Hg systolic or 80 mm Hg diastolic on at least 2 occasions for patients with diabetes or chronic kidney disease • Currently undergoing pharmacological therapy for treatment of hypertension
Tobacco use (34)	<p>Current or previous use of any tobacco product, including cigarettes, cigars, pipes, and chewing tobacco, captured as smoking status:</p> <ul style="list-style-type: none"> • Current everyday smoker • Current some day smoker • Former smoker • Never smoker • Smoker, current status unknown
Illicit drug use	<p>Documented history of current, recent, or remote abuse of any illicit drug (e.g., cocaine, methamphetamine, marijuana) or controlled substance.</p>
Dyslipidemia	<p>Indicate if the patient has a history of dyslipidemia that was diagnosed and/or treated by a physician. NCEP criteria include documentation of the following:</p> <ul style="list-style-type: none"> • Total cholesterol >200 mg/dL (5.18 mmol/L); or • LDL ≥ 130 mg/dL (3.37 mmol/L); • HDL <40 mg/dL (1.04 mmol/L) in men and <50 mg/dL (1.30 mmol/L) in women; • Currently receiving antilipidemic treatment
Family history of premature CAD	<p>Indicate if the patient has any direct blood relatives (parents, siblings, children) who have had any of the following at age <55 y for male relatives or <65 y for female relatives:</p> <ul style="list-style-type: none"> • Angina • Acute MI • Sudden cardiac death without obvious cause • CABG surgery • PCI
Previous implantation of a pacemaker or ICD	<p>Indicate if the patient had a pacemaker or ICD implanted before the current encounter.</p> <p>Information about the type of device (pacemaker, biventricular/resynchronization/CRT, ICD, combination), cardiac chamber(s) involved, and year of implantation may be helpful.</p>
Prior atrial fibrillation or flutter	<p>Indicate whether atrial fibrillation or flutter is present within 2 wk before admission.</p> <p>Whether or not the patient is currently experiencing atrial fibrillation or flutter should also be noted.</p>
History of influenza immunization	<p>Indicate if the patient has a history of influenza immunization. The month and year of the most recent immunization should be noted.</p>
History of pneumococcal immunization	<p>Indicate if the patient has a history of pneumococcal immunization. The month and year of the most recent immunization should be noted.</p>
Current dialysis	<p>Indicate if the patient currently requires dialysis treatment, including hemodialysis or peritoneal dialysis.</p>
Angina grade	<p>Indicate grade symptoms or signs in patients with suspected or presumed stable angina (or anginal equivalent) according to the CCS grading scale (35):</p> <ul style="list-style-type: none"> • Class I: ordinary physical activity, such as walking or climbing stairs, does not cause angina. Angina occurs with strenuous, rapid, or prolonged exertion at work or recreation. • Class II: slight limitation of ordinary activity. Angina occurs on walking or climbing stairs rapidly, walking uphill, walking or climbing stairs after meals, or in cold, in wind, or under emotional stress, or only during the few hours after awakening. Angina occurs on walking >2 blocks on the level and climbing >1 flight of ordinary stairs at a normal pace and in normal conditions. • Class III: marked limitation of ordinary physical activity. Angina occurs on walking 1 to 2 blocks on the level and climbing 1 flight of stairs in normal conditions and at a normal pace. • Class IV: inability to perform any physical activity without discomfort—angina symptoms may be present at rest.
Amount of sublingual nitroglycerin consumed	<p>Record the number of sublingual nitroglycerin tablets or spray used each week for symptomatic episodes. Record prophylactic usage also. Average the total number of sublingual uses over the 6-wk interval and record the weekly range.</p>

CABG indicates coronary artery bypass graft; CAD, coronary artery disease; CCC, Canadian Cardiovascular Society; cTn, cardiac troponins; CRT, cardiac resynchronization therapy; CT, computed tomography; ECG, electrocardiogram; GLP-1, glucagon peptide-like-1; HDL, high-density lipoprotein; ICD, implantable cardioverter-defibrillator; LBBB, left bundle-branch block; LDL, low-density lipoprotein; MI, myocardial infarction; MR, magnetic resonance; N/A, not available; NCEP, National Cholesterol Education Program; NYHA, New York Heart Association; PAD, peripheral artery disease; PCI, percutaneous coronary intervention; TIA, transient ischemic attack; and URL, upper reference limit.

standards could be used in their entirety to develop a registry. For example, the AR-G includes 81 of the data elements discussed in this document.

Third, the use of standardized definitions and registry data should facilitate quality improvement by collecting data on these data elements as part of a quality-improvement program at a hospital, state, or national level and thereby improve both the process of care and clinical outcomes.

Fourth, these data elements and definitions can be used in the development of performance measures by identifying underutilization of therapies (24–27). They could be used to compare various subgroups of patients in the various performance measures and to identify certain groups for whom medications are underused (e.g., the GWTG age and gender paper). These elements would also fit very well with longitudinal follow-up studies, where the same definitions could be used by hospitals and outpatient providers to monitor a patient's adherence to medication and clinical course.

Fifth, the list of data elements and definitions could become the basis for developing a standardized charting process with the anticipation that medical charting used in the process of delivering care could progressively move toward an electronic format. The specifics of coding elements in EHRs are a large and evolving area. Many other groups are working on this; details are beyond the scope of this document but would need to be provided before implementation.

Sixth, appropriate collection of confounding characteristics will allow adjustment for comorbidities and other variables that may affect outcomes and quality metrics between different providers, hospitals, and geographical networks and ensure scientific comparisons.

Finally, considering the application of these data elements to use in the real-world setting, the writing committee paid close attention to the level of detail required to fully describe certain variables, such as timing of prior cardiovascular events, timing of procedures, specific drug names versus classes of drugs, and types of insurance. The committee agreed that for these or any of the data elements listed, the user can decide to collect more or less information, depending on the circumstance. For example, if a hospital association were compiling a registry to assess the relationship of patient insurance status with use of cardiac procedures and their outcomes, the group might elect to use more subcategorizations than listed in this document. On the other hand, if a pharmaceutical company were doing a study to evaluate the use of a new drug for UA, type of insurance might not matter and could be omitted. A third example would be if a community hospital wished to track its use of new therapies, such as new antiplatelet agents, for which as few as 10 of the listed elements might be collected on patients. Thus, this listing of data elements and definitions could be expanded or condensed to meet the needs of the study or project in which they are being

used. However, the users would not want to adapt the individual definitions since that would no longer allow direct comparison of these elements to other studies using these standard definitions.

These data elements could also be expanded to include additional information, such as all the detailed relative contraindications to aspirin or beta blockers or for careful measurement of performance measures, as was done in the Cooperative Cardiovascular Project (28). Expansion of the variables collected would also be expected in the setting of a randomized clinical trial of a new drug, for which more information would be required on additional study procedures and drug therapies. Thus, depending on the intended use of the variables, the number of data elements used could be restricted or expanded. In either case, the definitions provided in this document should assist in standardizing the process. It should also be noted that other data elements and measures may be important in the assessment of patients with ACS. For example, quality-of-life measures such as the Seattle Angina Questionnaire (29) and the Medical Outcomes Study 36-Item Short Form Health Survey (SF-36) (30) have been used extensively in the evaluation of outcome in cardiac patients. Those developing registries and performing clinical trials are encouraged to adopt a similar approach in evaluating and choosing measures so that these efforts will be more easily integrated into future data standards for patients with ACS.

3. ACS and CAD Clinical Data Standard Elements and Definitions

3.1. Demographic and Admission Data Elements

There are 5 demographic data elements that include the patient's sex, date of birth, race, and ethnicity, and the postal code for the patient's residence. It is intended that these elements be collected once for each patient. The race and ethnicity data elements are defined in a way that is consistent with the standard formats suggested by the U.S. Department of Health and Human Services, which includes identification of Hispanic or Latino ethnicity. The postal code for the patient's residence is included to permit geographical analysis of results and comparison with other cardiovascular registry data analyses.

Sixteen data elements and definitions describe the status of care for the current data collection (inpatient or outpatient); for inpatients, details include date of admission, source of admission, information about payment type, information about first medical contact, date and time of arrival and transfer to an outside facility, mode of transport to the local facility, and location and time of first evaluation in the local facility. These data elements define the critical aspects of timing and level of acuity for the presentation of this patient to the healthcare system. They provide the initial elements of information that articulate risk for the patient and the impact of these factors on the entire episode

of care and its outcomes. Data elements for admission source and type have been standardized in recent recommendations by the Centers for Medicare & Medicaid Services and The Joint Commission.

3.2. History and Risk Factors Data Elements

Assessment of the patient's cardiovascular and general medical history is necessary for assessing risk and for a fuller understanding of variations in outcome. The information is also critical in applying these results to targeted quality-improvement efforts and for comparison of these data with clinical trial results. Many of the data elements in this section (Table 2) are common to risk models that have been developed to predict outcome in patients undergoing PCI and cardiac surgery (31). The element capturing the history of MI (and all data elements in this dataset referring to MI) incorporates the recent elements for the universal definition of MI (22). Definitions and categorization of stages of heart failure follow recent recommendations proposed by the ACCF/AHA data standards document on heart failure (4). The definitions for peripheral arterial disease were taken from recent work by the Peripheral Atherosclerotic Vascular Disease Data Standards document (32). The writing committee attempted to include only data elements that were pertinent to characterizing the risk of the patient. In addition, specific coding descriptors and detailed definitions have been provided so that medical abstractors should be able to code most of these data elements with information that is available as part of the standard process of documenting the delivery of care. Software and applications are now being developed to automatically pull information on some data elements from EHRs. It would be optimal if the algorithms these programs use could follow the standard definitions.

3.3. Clinical Presentation Data Elements

Clinical presentation data elements (Table 3) include the date and time of symptom onset, the presence of positive biomarkers (troponin I or T, CK-MB, or bedside troponin) within the first 24 hours of initial presentation that exceed the locally defined upper limits of normal, heart failure on first medical contact, height, weight, waist circumference, Killip class, heart rate, systolic blood pressure on first medical contact, angina type with number of episodes and possible secondary causes, and syncope. Presenting symptoms are well described in the data definition and along with the presence of biomarkers are key indicators for defining the patient with ACS. Height and weight are important parameters in calculating body surface area and determining whether pharmacological dosing was therapeutic or above acceptable thresholds. Killip class has been a useful classification system and is included with specific criteria for determination of the appropriate level.

3.4. Diagnostic Procedure Data Elements

Findings on the ECG provide the most important information in stratifying patients as those with STEMI and those with NSTEMI. Because it is becoming more common for emergency medical services personnel to perform a prehospital 12-lead ECG on initial contact with a patient with suspected MI or ACS in the field, data elements are included to track the date, time, and location of the first ECG. The data definition provides detailed criteria for categorizing electrocardiographic findings as ST-segment elevation, new left bundle-branch block, or isolated inferobasal MI. Location of electrocardiographic changes and other pertinent findings (new ST-segment depression, new T-wave inversion, etc.) are collected. Data elements are also included for laboratory tests that are routinely performed on patients with CAD, including total cholesterol, low-density lipoprotein, high-density lipoprotein, and triglycerides. Other laboratory values supporting the evaluation of cardiac function, metabolic syndrome, and liver and renal function (brain natriuretic peptide, glucose, hemoglobin A1c, hematocrit, and creatinine) are collected and provide easily obtained information that characterizes the patient's general status and gives data that can be used to further risk-stratify patient outcomes. Table 4 includes troponin, creatinine kinase (CK) and creatinine kinase-MB isoenzyme (CK-MB) with first and peak levels for these markers. However, if more precision on timing of CK-MB is desired, the full set of these markers could be collected with dates and times so as to ensure being able to distinguish initial biomarker elevation versus post-PCI elevations.

3.5. Invasive Therapeutic Intervention Data Elements

Many clinical trials have been conducted to establish effective therapeutic approaches for the treatment of ACS as well as studies that have identified optimal timing for invasive strategies based on risk stratification of the patient (36-38). The invasive therapeutic interventions section (Table 5) includes data elements covering noninvasive stress testing, results of evaluation of maximum stenosis percent narrowing in the major epicardial systems, assessment of left ventricular ejection fraction and the modality used for this measurement, and results of diagnostic coronary angiography if performed (definition of the culprit artery, TIMI flow in the culprit artery, and stenoses in the major coronary artery systems). Because primary PCI has been established as the preferred revascularization approach for patients with STEMI and an early invasive strategy as the most effective strategy for patients with NSTEMI, data elements are included that capture the time of arrival at the catheterization laboratory, first device activation date, and time for calculating door-to-balloon time for patients with STEMI, which has been related to improved immediate and long-term outcomes in these patients (21,39,40). An important data

Table 3. Clinical Presentation Data Elements and Definitions

Element Name	Element Definition
Symptom onset date/time	Indicate the date and time the patient first noted ischemic symptoms lasting ≥ 10 min. If the patient had intermittent ischemic symptoms, record the date and time of the most recent ischemic symptoms before hospital presentation. Symptoms may include jaw pain, arm pain, shortness of breath, nausea, vomiting, fatigue/malaise, or other equivalent discomfort suggestive of an MI. In the event of stuttering symptoms, ACS symptom onset is the time at which symptoms became constant in quality or intensity.
Heart failure on first medical contact	Indicate if there is physician documentation or a report of heart failure on the first medical contact. Heart failure is defined as physician documentation or report of any of the following clinical symptoms of heart failure described as unusual dyspnea on light exertion, recurrent dyspnea occurring in the supine position, fluid retention; or the description of rales, jugular venous distention, pulmonary edema on physical exam, or pulmonary edema on chest x-ray. A low ejection fraction without clinical evidence of heart failure does not qualify as heart failure. Note: Killip class 2 is defined as rales over $\leq 50\%$ of the lung fields or the presence of an S_3 . Killip class 3 is defined as rales over $>50\%$ of the lung fields. Either class would qualify as a “yes.”
Killip class	Indicate the patient’s Killip class at the time of hospital admission: • Class 1: absence of rales over the lung fields and absence of S_3 • Class 2: rales over $\leq 50\%$ of the lung fields or the presence of an S_3 • Class 3: rales over $>50\%$ of the lung fields • Class 4: shock
Heart rate	Indicate the first measurement or earliest record of heart rate (in beats per minute) for this episode of care. Measurement from the transferring facility is acceptable.
Systolic blood pressure on first medical contact	Indicate the first measurement or earliest record of systolic blood pressure (in millimeters of mercury) for this episode of care. Measurement from the transferring facility is acceptable.
Angina type	Indicate the category of the patient’s type of angina if present. Choose 1 of the following: • I. Atypical chest pain: pain, pressure, or discomfort in the chest, neck, or arms not clearly exertional or not otherwise consistent with pain or discomfort of myocardial ischemic origin. • II. Stable angina: angina without a change in frequency or pattern for the 6 wk before this procedure. Angina is controlled by rest and/or sublingual/oral/transcutaneous medications. • III. ACS (choose 1 of the following): - A. UA: The patient was hospitalized for UA documented in the medical record with serial ECGs and biochemical profiles. One of the following criteria is necessary: 1. Angina that occurred at rest and was prolonged, usually lasting ≥ 10 min 2. New-onset angina of at least CCS classification III severity 3. Recent acceleration of angina reflected by an increase in severity of at least 1 CCS class to at least CCS class III. The patient must also not have any biochemical evidence of myocardial necrosis. - B. MI: For a complete definition, please see “MI” in the “Outcomes” section.
Number of episodes of angina in the past 24 h	Indicate the number of distinct episodes of anginal pain that occurred in the past 24 h before hospital admission.
Secondary cause of angina (yes/no)	Note whether angina was precipitated by a secondary factor such as fever, anemia, hypoxemia, tachycardia, thyrotoxicosis, or severe valvular disease as defined by Braunwald.
Cardiac arrest at first medical contact	Indicate if the patient has had an episode of cardiac arrest evaluated by EMS or ED personnel and either 1) received external defibrillation attempts (by lay responders or emergency personnel) or chest compressions by organized EMS or ED personnel or 2) were pulseless but did not receive defibrillation attempts or CPR by EMS personnel. Choose 1 of the following: • Yes • No Note: [Sudden] cardiac arrest is the sudden cessation of cardiac activity. The victim becomes unresponsive with no normal breathing and no signs of circulation. If corrective measures are not taken rapidly, this condition progresses to sudden death. Cardiac arrest should be used to signify an event as described above that is reversed, usually by CPR and/or defibrillation or cardioversion or cardiac pacing. Sudden cardiac death should not be used to describe events that are not fatal.
Height	Indicate the patient’s first recorded height in centimeters on admission/encounter to your facility.
Weight	Indicate the patient’s weight in kilograms closest to the date of admission/encounter.
Waist circumference	Indicate waist circumference based on the average of 2 measurements made while the patient is standing. Take 1 measurement after inspiration and another after expiration. Measurements should be taken at the midpoint between the lowest rib and the iliac crest. Indicate in centimeters.

ACS indicates acute coronary syndromes; CCS, Canadian Cardiovascular Society; CPR, cardiopulmonary resuscitation; ECG, electrocardiogram; ED, emergency department; EMS, emergency medical services; MI, myocardial infarction; and UA, unstable angina.

element for PCI is the type of stent used (bare metal, drug-eluting, or other) and the number of stents used. Data elements are included that provide important modifiers that may occur in the treatment of these patients, including reasons for delay in performing PCI and reperfusion contraindications. Given that other significant therapeutic approaches may occur during hospitalization, data elements are included to track any peripheral vascular or cerebrovascular interventions, requirement for

CABG surgery, use of a pulmonary artery catheter, and more advanced therapeutic techniques, including placement of an intra-aortic balloon pump, ventilator, and enhanced external counterpulsation support.

3.6. Medications Table of Data Elements

The efficacy of pharmacological therapy at symptom onset, throughout hospitalization, and at discharge from the hospital has been well established with data from both clinical

Table 4. Diagnostic Procedure Data Elements and Definitions

Element Name	Element Definition
Electrocardiography	
Rhythm	The categories of rhythm are <ul style="list-style-type: none"> • Sinus rhythm • Atrial fibrillation (or flutter) • Paced • Other rhythm (e.g., VT, supraventricular tachycardia)
Site where first ECG obtained	Indicate where the first ECG was obtained. Choose 1 of the following: <ul style="list-style-type: none"> • Prehospital (i.e., in ambulance): Check if the first ECG was obtained before arrival at your hospital, either during ground transport by EMS, air ambulance, or other method of critical care transport. • On arrival to the first hospital where the patient presented: Check if the first ECG performed after the most recent ischemic episode before hospital presentation was obtained on arrival at the first hospital where the patient presented. • Private physician office or outpatient clinic • Hospital inpatient unit
First ECG date/time	Indicate the date and time of the first ECG.
STEMI or STEMI equivalent	Indicate if there was either new or presumed new ST-segment elevation, new LBBB, or isolated inferobasal MI before any procedures and not more than 24 h after the initial presentation.
ECG evidence for STEMI or STEMI equivalent	Indicate if there was either new or presumed new ST-segment elevation, new LBBB, or isolated inferobasal (posterior) MI noted on the ECG before any procedures and not more than 24 h after the initial presentation. Choose 1 of the following: <ul style="list-style-type: none"> • New ST-segment elevation at the J point in 2 contiguous leads with the cutpoints ≥ 0.1 mV in all leads other than leads V_2 through V_3, where the following cutpoints apply: ≥ 0.2 mV in men age ≥ 40 y, ≥ 0.25 mV in men age < 40 y, or ≥ 0.15 mV in women • New isolated ST-segment depression ≥ 0.1 mV in at least 2 contiguous leads of V_1 through V_3 with upright T waves • New ST-segment elevation ≥ 0.05 mV in leads V_7 through V_9 or ≥ 0.1 mV in men age < 40 y (inferobasal [posterior] infarction) • New ST-segment elevation ≥ 0.05 mV (≥ 0.1 mV in men age < 30 y) in leads V_3R, V_4R (right ventricular infarction) • New ST-segment elevation ≥ 0.1 mV in lead aVR with concomitant ST-segment depression ≥ 0.05 mV in at least 2 contiguous leads
STEMI or STEMI equivalent noted	Indicate if a STEMI or STEMI equivalent was noted on either the first or a subsequent ECG. The subsequent ECG must be performed within 24 h of initial presentation, either to your facility or the transferring facility if a transfer patient. Choose 1 of the following: <ul style="list-style-type: none"> • First ECG • Subsequent ECG
STEMI or STEMI equivalent date/time	Indicate the date and time of the earliest subsequent ECG with ST-segment elevation, LBBB, or isolated inferobasal MI.
Other ischemic ECG findings	Indicate if other findings from the ECG were demonstrated within 24 h of the first medical contact. Choose all that apply: <ul style="list-style-type: none"> • New or presumed new ST-segment depression: Indicate if there was new or presumed new horizontal or downsloping ST depression ≥ 0.05 mV in 2 contiguous leads and/or T inversion ≥ 0.1 mV in 2 contiguous leads with prominent R wave or R/S ratio > 1. T-wave negativity may be normal in leads with predominant negative QRS complexes (see discussion) but are usually abnormal when the QRS complex is upright. • New or presumed new T-wave inversion: Indicate if there was a new or presumed new T-wave inversion of at least 0.1 mV in 2 contiguous leads. The T wave usually has a polarity of the T-wave vector similar to the QRS vector. Thus, in normal subjects, negative T waves may be observed when the QRS is negative (e.g., lead aVL with vertical axis). Juvenile T-wave patterns, marked pectus excavatum, and other conditions may also be associated with T-wave inversion that is not ischemic in origin. • Transient ST-segment elevation lasting < 20 min: Indicate if there was new or presumed new ST-segment elevation at the J point in 2 contiguous leads with the cutpoints ≥ 0.1 mV in all leads other than leads V_2 through V_3, where the following cutpoints apply: ≥ 0.2 mV in men age ≥ 40 y, ≥ 0.25 mV in men age < 40 y, or ≥ 0.15 mV in women. • Indicate if a new persistent LBBB was present. • None of the above: Indicate if the first ECG did not reveal ST-segment depression, transient ST-segment elevation, or T-wave inversion.
Location of ECG changes	The location of each type of electrocardiographic change listed below can be divided into 4 categories: <ul style="list-style-type: none"> • Inferior leads: II, III, aVF • Anterior leads: V_1 through V_6 • Lateral leads: I, aVL, • True posterior (inferobasal): (relevant only for tall wide R waves > 40 ms in leads V_1 and V_2) Consideration can be given to recording posterior ST changes, the maximal amount of ST (if applicable), and/or the number of leads with ST.
BBB and type	The presence of left or right BBB should be noted, as well as whether it is new, old, or of uncertain timing.
Follow-up ECG: new Q waves	If a follow-up ECG is performed (at least 6 h after the initial ECG), the presence or absence of new Q waves that are ≥ 0.03 s in width, in at least 2 contiguous leads, and ≥ 1 mm (0.1 mV) in depth not seen on the initial ECG should be noted, as well as the location described above.
Laboratory Tests	
LDL value	Indicate the value of the LDL cholesterol. If the value is reported using a ">" symbol (e.g., > 300), record the number only (e.g., 300). Lipids obtained within the first 24 h of this admission should take precedence. If > 24 h after admission, then enter prior values.

Table 4. Continued

Element Name	Element Definition
HDL value	Indicate the HDL-cholesterol value. If the value is reported using a ">" symbol (e.g., >300), record the number only (e.g., 300). Lipids obtained within the first 24 h of this admission should take precedence. If >24 h after admission, then enter prior values.
Triglycerides value	Indicate the value of triglycerides. If the value is reported using a ">" (e.g., >300), record the number only (e.g., 300). Lipids obtained within the first 24 h of this admission should take precedence. If >24 h of admission, then enter prior values.
Date of lipids	Indicate the date the sample was collected (not the date and time results reported) OR check either "Performed before hospitalization" or "Unknown." Lipids obtained within the first 24 h of this admission should take precedence. If >24 h after admission, then enter prior values.
When lipids were measured: other	Indicate the date and time the sample was collected (not the date and time results reported) OR check either "Performed before hospitalization" or "Unknown." Lipids obtained within the first 24 h of this admission should take precedence. If >24 h after admission, then enter prior values.
BNP/NT-proBNP value	Indicate the results from first BNP or first NT pro-BNP performed during this admission. If done, enter the numerical value and specify which assay type was done.
hs-CRP	Indicate the value of the first serum hs-CRP level and units.
Glucose	Indicate the first glucose value taken. Indicate if fasting or not.
Creatinine	Indicate the creatinine value taken at the time of admission and at the time of discharge.
Hemoglobin	Indicate the value and units for the first hemoglobin collected during this admission. Date and time of collection should also be indicated.
Hemoglobin A1c value	Indicate the percentage value for the first hemoglobin A1c collected during this admission. Date and time of collection should also be indicated.
INR	Indicate the numerical value of INR on admission. Date and time of collection should also be indicated.
Initial CK value	Indicate the results of the first CK sample obtained within the first 24 h of care, either from a transferring hospital or your hospital. If the patient was transferred into your hospital, data available from the transferring facility should take precedence.
Peak CK value	Indicate the results of the peak CK sample obtained during this admission.
CK ULN	Indicate the total CK ULN as defined by individual hospital laboratory standards. The units of CK and type of units (e.g., IU, ng/dL, kCat/L) should be noted.
Initial CK-MB value	Indicate the initial CK-MB value. The initial sample value refers to the first sample obtained within the first 24 h of care, either from a transferring hospital or your hospital. If the patient was transferred, data available from the transferring facility should take precedence.
CK-MB ULN	Indicate the initial CK-MB sample ULN for the test. If a range is given, record the highest number in the range. Examples: 1. Reference range given as 0-5: Record ULN as 5 2. ULN given as <5: Record ULN as 5 The initial sample value refers to the first sample obtained within the first 24 h of care, either from a transferring hospital or your hospital. If the patient was transferred, data available from the transferring facility should take precedence.
Peak CK-MB value	Indicate the results of the highest sample obtained during this admission. <i>Note:</i> Enter the value. If the value is reported using a "<" symbol (e.g., "<0.02"), record the number only (e.g., "0.02").
Initial troponin value	Indicate the results of the first sample obtained within the first 24 h of care, either from a transferring hospital or your hospital. If the patient was transferred, data available from the transferring facility should take precedence. <i>Note:</i> Enter the value. If the value is reported using a "<" symbol (e.g., "<0.02"), record the number only (e.g., "0.02").
Troponin type	Indicate which type: • Type T - Indicate if high sensitivity • Type I - Indicate if high sensitivity
Peak troponin value	Indicate the results of the highest sample obtained during this admission. <i>Note:</i> Enter the value. If the value is reported using a "<" symbol (e.g., "<0.02"), record the number only (e.g., "0.02").

BBB indicates bundle branch block; BNP, brain natriuretic peptide; CK, creatinine kinase; CK-MB, creatinine kinase MB isoenzyme; ECG, electrocardiogram; EMS, emergency medical services; HDL, high-density lipoprotein; hs-CRP, high-sensitivity C-reactive protein; INR, international normalized ratio; LBBB, left bundle-branch block; LDL, low-density lipoprotein; MI, myocardial infarction; NT-proBNP, N-terminal prohormone of brain natriuretic peptide; STEMI, ST-segment elevation myocardial infarction; VT, ventricular tachycardia; and ULN, upper limit of normal.

trials and ACS registries (21). Antiplatelet and anticoagulant therapies are crucial in managing the cascade of thrombotic events that occur with ACS. The complexity of the pathways involved with this cascade has led to the use of multiple therapeutic agents. Aspirin, anticoagulant agents, including heparin and bivalirudin, clopidogrel, and GP IIb/IIIa inhibitors have been established as essential for the management of patients with ACS. The writing com-

mittee determined that where possible, collection of detailed data on medications (Table 6) would provide information that is critical to evaluate patient outcomes. The group determined that the important dimensions of medication administration were the type of agent used, timing (given within the first 24 hours, during hospitalization, at discharge, and during the months after hospital discharge), dosage, duration (captured by date and time of starting and stopping

Table 5. Invasive Therapeutic Intervention Data Elements and Definitions

Element Name	Element Definition
Pacemaker implantation	If a pacemaker was placed during this admission, indicate what type of device: <ul style="list-style-type: none"> • Single chamber • Dual chamber • CRT • CRT-D • CRT-P • Biventricular • Pacer
Temporary pacemaker	Temporary pacemaker placed during this admission
ICD	An ICD may be placed for: <ul style="list-style-type: none"> • VF • Symptomatic VT • Asymptomatic VT • Other (specify) • Inducible VT/VF at electrophysiological study • Syncope • Primary prevention for patients in high-risk heart failure group The brand, model number, and serial number of the device may be recorded.
Noninvasive stress testing	Indicate if the patient underwent exercise or pharmacological stress testing with or without echocardiographic or radionuclide imaging.
Date of noninvasive stress testing	Indicate the date of exercise or pharmacological stress testing with or without echocardiographic or radionuclide imaging.
Noninvasive angiogram	Indicate if the patient underwent 1 of the following: <ul style="list-style-type: none"> • MR angiogram • Multislice CT scan
Maximum stenosis by vessel (LAD, LCx, RCA, LM, graft)	Stenosis represents the percentage occlusion, from 0% to 100%, associated with the identified vessel systems. Percent stenosis at its maximal point is estimated to be the amount of reduction in the diameter of the “normal” vessel proximal to the lesion. For the denominator, take the maximum internal lumen diameter proximal and distal to the lesion. In instances where multiple lesions are present, enter the highest percentage stenosis noted. The systems of interest are as follows and should include major branch vessels of >2 mm diameter: <ul style="list-style-type: none"> • Greatest stenosis assessed in the LAD or any major branch vessel • Greatest stenosis assessed in the LCx or any major branch vessel • Greatest stenosis assessed in the RCA or any major branch vessel • Greatest stenosis assessed in the LM • Greatest stenosis assessed in bypass graft
Maximal or submaximal stress test	Maximal stress test (symptom limited) or submaximal test (e.g., modified Bruce protocol ending with stage 1 or stage 2)
Ischemia result (positive, negative, equivocal, nondiagnostic test)	<ul style="list-style-type: none"> • Positive: new exercise-induced ischemic horizontal or downsloping ST-segment depression ≥ 0.10 mV or new ST-segment elevation ≥ 0.10 mV in a noninfarct territory, as compared with the baseline tracing (in the absence of electrocardiographic confounding such as LV hypertrophy, digoxin-induced changes, or LBBB) • Negative: normal exercise test. No significant exercise-induced ST shift or chest pain suggestive of angina and a normal hemodynamic response to exercise with adequate workload to test cardiac reserve. • Equivocal: exercise-induced chest pain considered to be angina in the absence of significant ischemic ST change. • Nondiagnostic test: negative as defined above, but level of exercise insufficient to adequately test cardiac reserve (e.g., <85% of age-predicted maximum heart rate achieved) or exercise-induced electrocardiographic changes in the presence of LBBB, LVH, or other known confounders.
LVEF assessed	Indicate whether the patient had LVEF assessed via invasive (i.e., LV gram) or noninvasive (i.e., echo, MR, CT or nuclear) testing before or during the admission.
Resting LV systolic function: global function—ejection fraction	Indicate the ejection fraction category. Choose 1 of the following: <ul style="list-style-type: none"> • Hyperdynamic: >70% • Normal: 50%–70% (midpoint 60%) • Mild dysfunction: 40%–49% (midpoint 45%) • Moderate dysfunction: 30%–39% (midpoint 35%) • Severe dysfunction: <30% Note: If no diagnostic report is in the medical record, a value documented in the medical record is acceptable.
Diagnostic coronary angiography	Indicate if the patient had diagnostic coronary angiography. This is defined as the passage of a catheter into the aortic root or other great vessels for angiography of the native coronary arteries or bypass grafts supplying native coronary arteries. This element would NOT include noninvasive CT angiography.
Diagnostic coronary angiography date/time	Indicate the date and time the patient had diagnostic coronary angiography, defined as the passage of a catheter into the aortic root or other great vessels.
Culprit artery	This is the vessel considered to be responsible for the ACS. The investigator should use his or her judgment in choosing the primary vessel. In cases in which this is difficult to determine (despite correlation of electrocardiographic changes and angiographic data), the vessel supplying the largest territory of myocardium should be selected: <ul style="list-style-type: none"> • LAD • LCx • RCA • LM • Graft • Unknown Note: “None” should be considered if there is no apparent coronary vessel lesion that could be responsible for evidence of ischemia.

Table 5. Continued

Element Name	Element Definition
Culprit artery TIMI flow	<p>TIMI grade flow in the culprit artery is defined as follows:</p> <ul style="list-style-type: none"> • Grade 0 (no perfusion): There is no antegrade flow beyond the point of occlusion. • Grade 1 (penetration without perfusion): The contrast material passes beyond the area of obstruction but “hangs up” and fails to opacify the entire coronary bed distal to the obstruction for the duration of the cineangiographic filming sequence. • Grade 2 (partial perfusion): The contrast material passes across the obstruction and opacifies the coronary bed distal to the obstruction. However, the rate of entry of contrast material into the vessel distal to the obstruction or its rate of clearance from the distal bed (or both) is perceptibly slower than its entry into or clearance from comparable areas not perfused by the previously occluded vessel (e.g., the opposite coronary artery or the coronary bed proximal to the obstruction). • Grade 3 (complete perfusion): Antegrade flow into the bed distal to the obstruction occurs as promptly as antegrade flow into the bed from the involved bed and is as rapid as clearance from an uninvolved bed in the same vessel or the opposite artery.
LM stenosis percent	<p>The best estimate of the most severe percent stenosis in the LM coronary artery. This does not include collaterals. Indicate the following:</p> <ul style="list-style-type: none"> • Percent stenosis of the LM coronary artery. • If no stenosis, then enter 0%. • If data are not available, indicate “not available.” <p>Stenosis: Stenosis represents the percent diameter reduction, from 0 to 100, associated with the identified vessel systems. Percent stenosis at its maximal point is estimated to be the amount of reduction in the diameter of the “normal” reference vessel proximal to the lesion. In instances where multiple lesions are present, enter the single highest percent stenosis noted.</p> <p>Note: If the patient only has a PCI (without a diagnostic catheterization at the same sitting), it is acceptable to use prior and recent catheterization lab visit information, even if at another institution.</p>
Proximal LAD and first diagonal branches percent stenosis	<p>Indicate the best estimate of the most severe percent stenosis in the proximal LAD and first diagonal coronary artery branches of ≥ 2.0 mm in diameter as determined by angiography. This does not include collateral circulation. Indicate the following:</p> <ul style="list-style-type: none"> • Percent stenosis of the proximal LAD and first diagonal branches. • If no stenosis, then enter 0%. • If data are not available, indicate “not available.” <p>Stenosis: Stenosis represents the percent diameter reduction, from 0 to 100, associated with the identified vessel systems. Percent stenosis at its maximal point is estimated to be the amount of reduction in the diameter of the “normal” reference vessel proximal to the lesion. In instances where multiple lesions are present, enter the single highest percent stenosis noted.</p> <p>Note: If the patient only has a PCI (without a diagnostic catheterization at the same sitting), it is acceptable to use prior and recent catheterization lab visit information, even if at another institution.</p>
Mid/distal LAD, D2, and D3 percent stenosis	<p>Indicate the best estimate of the most severe percent stenosis in the mid/distal LAD and diagonal coronary artery branches after the first diagonal of ≥ 2.0 mm in diameter as determined by angiography. This does not include collateral circulation. Indicate the following:</p> <ul style="list-style-type: none"> • Percent stenosis of the mid/distal LAD, D2, and D3. • If no stenosis, then enter 0%. • If data are not available, indicate “not available.” <p>Stenosis: Stenosis represents the percent diameter reduction, from 0 to 100, associated with the identified vessel systems. Percent stenosis at its maximal point is estimated to be the amount of reduction in the diameter of the “normal” reference vessel proximal to the lesion. In instances where multiple lesions are present, enter the single highest percent stenosis noted.</p> <p>If the patient only has a PCI (without a diagnostic catheterization at the same sitting), it is acceptable to use prior and recent catheterization lab visit information, even if at another institution.</p>
Circ, OMs, LPDA, and LPL branches percent stenosis	<p>Indicate the best estimate of the most severe percent stenosis in the Circ, OMs, LPDA, and LPL coronary artery branches of ≥ 2.0 mm in diameter as determined by angiography. This does not include collaterals. Indicate the following:</p> <ul style="list-style-type: none"> • Percent stenosis of the Circ, OMs, LPDA, and LPL branches. • If no stenosis, then enter 0%. • If data are not available, indicate “not available.” <p>Stenosis: Stenosis represents the percent diameter reduction, from 0 to 100, associated with the identified vessel systems. Percent stenosis at its maximal point is estimated to be the amount of reduction in the diameter of the “normal” reference vessel proximal to the lesion. In instances where multiple lesions are present, enter the single highest percent stenosis noted.</p> <p>If the patient only has a PCI (without a diagnostic catheterization at the same sitting), it is acceptable to use prior and recent catheterization lab visit information, even if at another institution.</p>
RCA, PDA, RPL, and AM branches percent stenosis	<p>Indicate the best estimate of the most severe percent stenosis in the RCA, PDA, RPL, and AM branches of ≥ 2.0 mm in diameter as determined by angiography. This does not include collaterals. Indicate the following:</p> <ul style="list-style-type: none"> • Percent stenosis of the RCA, PDA, RPL, and AM branches. • If no stenosis, then enter 0%. • If data are not available, indicate “not available.” <p>Stenosis: Stenosis represents the percent diameter reduction, from 0 to 100, associated with the identified vessel systems. Percent stenosis at its maximal point is estimated to be the amount of reduction in the diameter of the “normal” reference vessel proximal to the lesion. In instances where multiple lesions are present, enter the single highest percent stenosis noted.</p> <p>If the patient only has a PCI (without a diagnostic catheterization at the same sitting), it is acceptable to use prior and recent catheterization lab visit information, even if at another institution.</p>

the medication), and contraindications. Because thrombolytic therapy is an acceptable mode of reperfusion in cases where PCI is not available, detailed information is collected on type,

dosage, and timing of thrombolysis. Data collection for other medications that impact the function of the heart and the impact of coronary disease include nitrates (intravenous, oral,

Table 5. Continued

Element Name	Element Definition
Ramus percent stenosis	<p>Indicate the best estimate of the most severe percent stenosis in the ramus artery (if present) of ≥ 2.0 mm in diameter as determined by angiography. This does not include collaterals. Indicate the following:</p> <ul style="list-style-type: none"> • Percent stenosis of the ramus. • If no stenosis, then enter 0%. • If data are not available, indicate "not available." <p>Stenosis: Stenosis represents the percent diameter reduction, from 0 to 100, associated with the identified vessel systems. Percent stenosis at its maximal point is estimated to be the amount of reduction in the diameter of the "normal" reference vessel proximal to the lesion. In instances where multiple lesions are present, enter the single highest percent stenosis noted.</p> <p>If the patient only has a PCI (without a diagnostic catheterization at the same sitting), it is acceptable to use prior and recent catheterization lab visit information, even if at another institution.</p>
Catheterization contraindication	Indicate if catheterization was not performed. Contraindications may include patient refusal, advanced age, patient not a candidate for revascularization, DNR order, active bleeding, and clinical contraindications/severe comorbidities.
Reperfusion Therapy	
Reperfusion therapy: reperfusion candidate	<p>Indicate if the patient is a candidate for reperfusion therapy for treatment of STEMI. Reperfusion therapy includes thrombolysis and primary PCI. Choose 1 of the following:</p> <ul style="list-style-type: none"> • Yes • No
Reperfusion therapy: type of reperfusion	<p>If the patient received reperfusion therapy, indicate the type of reperfusion. Choose all that apply:</p> <ul style="list-style-type: none"> • Primary PCI • Thrombolytic therapy
PCI	
PCI	Indicate if the patient underwent PCI, placement of an angioplasty guidewire, balloon, or other device (e.g., stent, atherectomy, brachytherapy, or thrombectomy catheter) into a native coronary artery or CABG for the purpose of mechanical coronary revascularization.
Catheterization lab arrival date/time	Indicate the date and time the patient arrived at the catheterization lab where the PCI was being performed as documented in the medical record.
First device activation date/time	<p>Indicate the date and time the first device was activated regardless of the type of device used. Use the earliest time from the following:</p> <ul style="list-style-type: none"> • Time of first balloon inflation • Time of first stent deployment • Time of first treatment of lesion (thrombectomy/aspiration device, laser, rotational atherectomy) • If the lesion cannot be crossed with a guidewire or device (and thus none of the above apply), use the time of guidewire introduction. <p>Please note that this is a process measure about the timeliness of treatment. It is NOT a clinical outcomes measure based on TIMI flow or clinical reperfusion. It does not matter whether the baseline angiogram showed TIMI 3 flow or if the final post-PCI angiogram showed TIMI 0 flow. What is being measured is the time of the first mechanical treatment of the culprit lesion, not the time when TIMI 3 flow was (or was not) restored.</p>
PCI indication	<p>Indicate the primary reason PCI was performed or attempted. Choose 1 of the following:</p> <ul style="list-style-type: none"> • Immediate, primary PCI for STEMI • Stable following successful reperfusion or completed infarction after STEMI • Rescue PCI (after failed full-dose lytics for STEMI) • PCI for NSTEMI • Other
Nonsystem reason for delay in PCI	<p>Indicate if there is documentation of a reason for a delay in doing the first PCI after hospital arrival by a physician/advanced practice nurse/physician assistant. System reasons for delay are NOT acceptable.</p> <ul style="list-style-type: none"> • Difficult vascular access • Cardiac arrest and/or need for intubation before PCI • Patient delay in providing consent for procedure • Difficulty crossing the culprit lesion during PCI procedure • Other • None
Stent placed	Indicate if a stent was placed in the affected coronary artery.
Stent type	<p>Indicate the type of stent if a stent was placed in the affected coronary artery. Choose all that apply:</p> <ul style="list-style-type: none"> • Drug-eluting stent • Bare metal stent • Other stent
Number of stents placed	Number of stents placed. The exact type of stent should be collected.
Thrombolytics	
Thrombolytics type	<p>If the patient received reperfusion therapy with thrombolytics, indicate the type of thrombolytics used. Choose 1 of the following:</p> <ul style="list-style-type: none"> • Alteplase • Reteplase • Streptokinase • Tenecteplase • Other

Table 5. Continued

Element Name	Element Definition
Thrombolytics dose	If the patient received reperfusion therapy with thrombolytics, indicate the strength of dose of the thrombolytics. Choose 1 of the following: <ul style="list-style-type: none"> • Full dose • Reduced dose
Thrombolytics start date/time	If the patient received reperfusion therapy with thrombolytics, indicate the time of either the first bolus or the beginning of the infusion. <i>Note:</i> If the facility receives a transfer patient with ongoing infusion, record the time that the infusion was started at the transferring facility.
Nonsystem reason for delay of thrombolytics	Indicate if there is documentation of a nonsystem reason for delay in initiating thrombolytic therapy >30 min from the time of first facility arrival (including an ambulance capable of administering thrombolytic therapy). <i>Note:</i> A patient being transferred into a facility is not considered a nonsystem reason for delay.

Contraindications for reperfusion therapy

Contraindication to PCI	Indicate why PCI was not performed as reperfusion therapy. Choose 1 of the following: <ul style="list-style-type: none"> • Noncompressible vascular puncture(s) • Active bleeding on arrival or within 24 h • Quality-of-life decision • Anatomy not suitable for primary PCI • Spontaneous reperfusion (documented by catheterization only) • Patient/family refusal • DNR order in place at time of treatment decision • Prior allergic reaction to IV contrast • Facility is not a PCI center • Other
Contraindication to thrombolytics	Indicate why thrombolytics were not administered as reperfusion therapy. Choose 1 of the following: <ul style="list-style-type: none"> • Known bleeding diathesis • Recent bleeding within 4 wk • Recent surgery/trauma • Intracranial neoplasm, AV malformation, or aneurysm • Severe uncontrolled hypertension • Suspected aortic dissection • Significant close head or facial trauma within previous 3 mo • Active peptic ulcer • Traumatic CPR that precludes thrombolytics • Ischemic stroke within 3 mo except acute ischemic stroke within 3 h • Any prior intracranial hemorrhage • Pregnancy • Prior allergic reaction to thrombolytics • DNR order in place at time of treatment decision • Patient/family refusal • Other

Other Invasive Therapeutic Interventions

CABG surgery	Indicate if the patient underwent CABG surgery during this admission.
CABG surgery date/time	Indicate the date and time the patient entered the operating room suite or the first time surgery was documented on the operating room report.
IABP	Indicate if IABP was used during this admission.
Circulatory support	Indicate if circulatory support was provided during this admission and which type: <ul style="list-style-type: none"> • IABP • Tandem Heart • Impella • ECMO • LVAD • BIVAD • Other
Pulmonary artery catheter	Indicate if a pulmonary artery (Swan Ganz) catheter was used during this admission.
Ventilator	Indicate the need for intubation and respiratory support on a ventilator. Include the date and time the patient was put on and taken off the ventilator.

ACS indicates acute coronary syndrome; AM, acute marginal; AV, arteriovenous; BIVAD, biventricular assist device; CABG, coronary artery bypass graft; Circ, circumflex; CPR, cardiopulmonary resuscitation; CRT, cardiac resynchronization therapy; CRT-D, cardiac resynchronization therapy defibrillator; CRT-P, cardiac resynchronization therapy pacemaker; CT, computed tomography; D2 diagonal branch 2; D3 diagonal branch 3; DNR, do not resuscitate; ECG, electrocardiogram; ECMO, extracorporeal membrane oxygenation; IABP, intraaortic balloon pump; ICD, implantable cardioverter-defibrillator; IV, intravenous; LAD, left anterior descending; LBBB, left bundle-branch block; LCx, left circumflex; LM, left main; LPDA, left posterior descending artery; LPL left posterolateral; LV, left ventricle; LVAD, left ventricular assist device; LVEF, left ventricular ejection fraction; LVH, left ventricular hypertrophy; MR, magnetic resonance; NSTEMI, non-ST-segment elevation myocardial infarction; OM, obtuse marginal; PCI, percutaneous coronary intervention; PDA, posterior descending artery; RCA, right coronary artery; RPL, right posterolateral; STEMI, ST-segment elevation myocardial infarction; TIMI, Thrombolysis in Myocardial Infarction; VF, ventricular fibrillation; and VT, ventricular tachycardia.

and topical), beta blockers, calcium channel blockers, ranolazine therapy, warfarin/new anticoagulants, angiotensin-converting enzyme inhibitors, angiotensin receptor blockers,

aldosterone, diuretics, statins, and other lipid-lowering medications, nonsteroidal anti-inflammatory drugs, insulin, oral hypoglycemics, influenza, and pneumococcal immunizations.

Table 6. Medication Data Elements and Definitions

Element Name	Element Definition
GP IIb/IIIa blocker	Indicate if a GP IIb/IIIa inhibitor was administered during the hospital stay. If yes, indicate which of the following: <ul style="list-style-type: none"> • Eptifibatide • Tirofiban • Abciximab
GP IIb/IIIa blocker dosage	Indicate the GP IIb/IIIa blocker dose given.
GP IIb/IIIa inhibitor administered start date/time	Indicate the date and time a GP IIb/IIIa inhibitor infusion was initiated during the hospital stay.
GP IIb/IIIa inhibitor administered stop date/time	Indicate the date and time the GP IIb/IIIa inhibitor infusion was permanently discontinued during the hospital stay.
GP IIb/IIIa inhibitor contraindicated	Indicate if a GP IIb/IIIa inhibitor was contraindicated during the hospital stay.
Anticoagulant (parenteral)	Indicate if an anticoagulant was administered during the hospital stay. If yes, indicate which of the following: <ul style="list-style-type: none"> • IV unfractionated • Low molecular weight • Bivalirudin • Fondaparinux • Other
Anticoagulant dose	Indicate the anticoagulant dose given.
Anticoagulant start date/time	Indicate the date and time an anticoagulant infusion was initiated during the hospital stay.
Anticoagulant stop date/time	Indicate the date and time an anticoagulant infusion was permanently discontinued during the hospital stay.
Anticoagulant contraindicated	Indicate if an anticoagulant agent was contraindicated during the hospital stay.
IV nitrate	Nitroglycerin was administered intravenously.
Oral or topical nitrates	Oral or topical nitroglycerin was administered. Commonly prescribed agents include isosorbide dinitrate, isosorbide mononitrate, transdermal infusion system, or nitroglycerin paste. Sublingual nitroglycerin or nitroglycerin spray used on an as-needed basis only should not be noted in this category.
IV beta blocker	Indicate if IV beta blockers were administered. Some forms of IV beta blockers include atenolol, metoprolol, propranolol, timolol, esmolol, and labetalol.
Beta blocker before admission	Indicate if the patient has been taking a beta blocker routinely at home before this hospitalization. If yes, indicate which type.
Beta blocker in first 24 h	Indicate if the beta blocker was administered in the first 24 h of care provided, regardless of location of care (e.g., transferring facility or EMS). If yes, indicate which type. Medications taken at home before hospital arrival and therefore not readministered until the next day of the hospitalization should be noted.
Beta-blocker contraindications	Indicate if a beta blocker was not administered during the first 24 h of care because of a contraindication. A contraindication that is not documented explicitly by the healthcare provider but is evidenced clearly within the medical record should be noted.
Beta blocker (discharge)	Indicate if a beta blocker was continued or prescribed at hospital discharge. Indicate which type and the dose prescribed.
Beta blocker (discharge) contraindicated	Indicate if a beta blocker was discontinued or not prescribed at discharge because of a contraindication. A contraindication that is not documented explicitly by the healthcare provider but is evidenced clearly within the medical record should be noted.
Calcium channel blocker	Indicate if calcium channel blockers were administered. If yes, indicate which type. Some generic forms of calcium channel blockers are verapamil, nifedipine, diltiazem, nicardipine, nimodipine, nisoldipine, felodipine, and amlodipine.
Ranolazine before admission	Indicate if the patient has been taking ranolazine routinely at home before this hospitalization.
Ranolazine in first 24 h	Indicate if ranolazine was administered in the first 24 h of care provided, regardless of location of care (e.g., transferring facility or EMS). Medications taken at home before hospital arrival and therefore not readministered until the next day of the hospitalization should be noted.
Ranolazine (discharge)	Indicate if ranolazine was continued or prescribed at hospital discharge. Indicate which type and the dose prescribed.
Aspirin before admission	Indicate if the patient has been taking aspirin routinely at home before this hospitalization: <ul style="list-style-type: none"> • 81 mg • 162 mg • 325 mg • >325 mg • Other
Aspirin in first 24 h	Indicate if aspirin was administered in the first 24 h before or after hospital arrival, regardless of location of care (e.g., transferring facility or EMS). Medications taken at home before hospital arrival and therefore not readministered until the next day of the hospitalization should be noted.
Aspirin dose	Indicate dose of aspirin given for the first 24 h.

Table 6. Continued

Element Name	Element Definition
Aspirin contraindications	Indicate if aspirin was not administered during the first 24 h of care because of a contraindication. A contraindication that is not documented explicitly by the healthcare provider but is evidenced clearly within the medical record should be noted.
Aspirin (discharge)	Indicate if aspirin was continued or prescribed at hospital discharge.
Aspirin (discharge) dose	Indicate the daily dose prescribed. <ul style="list-style-type: none"> • 81 mg • 162 mg • 325 mg • >325 mg • Other
Aspirin (discharge) contraindicated	Indicate if aspirin was discontinued or not prescribed at discharge because of a contraindication. A contraindication that is not documented explicitly by the healthcare provider but is evidenced clearly within the medical record should be noted.
Other oral anticoagulants before admission	Indicate if the patient has been taking other oral anticoagulants (oral direct antithrombin inhibitor, e.g., dabigatran or oral direct factor Xa inhibitor, e.g., rivaroxaban, apixaban) routinely at home before this hospitalization.
Other oral anticoagulant	Indicate if other oral anticoagulant was administered in the first 24 h of care provided, regardless of location of care (e.g., transferring facility or EMS). If yes, indicate which type. Medications taken at home before hospital arrival and therefore not readministered until the next day of the hospitalization should be noted.
Other oral anticoagulant (discharge)	Indicate if other oral anticoagulant was continued or prescribed at hospital discharge. Indicate which type and the dose prescribed.
Warfarin before admission	Indicate if the patient has been taking warfarin routinely at home before this hospitalization.
Warfarin	Indicate if warfarin was administered in the first 24 h of care provided, regardless of location of care (e.g., transferring facility or EMS). If yes, indicate which type. Medications taken at home before hospital arrival and therefore not readministered until the next day of the hospitalization should be noted.
Warfarin (discharge)	Indicate if warfarin was continued or prescribed at hospital discharge. Indicate which type and the dose prescribed.
Warfarin or other oral anticoagulant (discharge) contraindication	Indicate if warfarin was discontinued or not prescribed at discharge because of a contraindication. A contraindication that is not documented explicitly by the healthcare provider but is evidenced clearly within the medical record should be noted.
Clopidogrel before admission	Indicate if the patient has been taking clopidogrel routinely at home before this hospitalization.
Clopidogrel in first 24 h	Indicate if clopidogrel was administered in the first 24 h of care provided, regardless of location of care (e.g., transferring facility or EMS). Medications taken at home before hospital arrival and therefore not readministered until the next day of the hospitalization should be noted.
Clopidogrel loading dose	Indicate the amount of the initial dose: <ul style="list-style-type: none"> • 75 mg • 150 mg • 300 mg • 600 mg • Other
Clopidogrel start date/time	Indicate the date and time the initial dose was given.
Clopidogrel contraindicated	Indicate if clopidogrel was not administered during the first 24 h of care because of a contraindication. A contraindication that is not documented explicitly by the healthcare provider but is evidenced clearly within the medical record should be noted.
Clopidogrel (discharge)	Indicate if clopidogrel was continued or prescribed at hospital discharge. Indicate which type and the dose prescribed.
Clopidogrel (discharge) contraindicated	Indicate if clopidogrel was discontinued or not prescribed at discharge because of a contraindication. A contraindication that is not documented explicitly by the healthcare provider but is evidenced clearly within the medical record should be noted.
Prasugrel before admission	Indicate if the patient has been taking prasugrel routinely at home before this hospitalization.
Prasugrel in first 24 h	Indicate if prasugrel was administered in the first 24 h of care provided, regardless of location of care (e.g., transferring facility or EMS). Medications taken at home before hospital arrival and therefore not readministered until the next day of the hospitalization should be noted.
Prasugrel start date/time	Indicate the date and time the initial dose was given.
Prasugrel contraindicated	Indicate if prasugrel was not administered during the first 24 h of care because of a contraindication. A contraindication that is not documented explicitly by the healthcare provider but is evidenced clearly within the medical record should be noted.
Prasugrel (discharge)	Indicate if prasugrel was continued or prescribed at hospital discharge. Indicate which type and the dose prescribed. DO NOT record discharge medication if patient was transferred to another acute care facility from your hospital.
Prasugrel (discharge) contraindicated	Indicate if prasugrel was discontinued or not prescribed at discharge because of a contraindication. A contraindication that is not documented explicitly by the healthcare provider but is evidenced clearly within the medical record should be noted.
Ticagrelor before admission	Indicate if the patient has been taking ticagrelor routinely at home before this hospitalization.
Ticagrelor in first 24 h	Indicate if ticagrelor was administered in the first 24 h of care provided, regardless of location of care (e.g., transferring facility or EMS). Medications taken at home before hospital arrival and therefore not readministered until the next day of the hospitalization should be noted.
Ticagrelor start date/time	Indicate the date and time the initial dose was given.
Ticagrelor contraindicated	Indicate if ticagrelor was not administered during the first 24 h of care because of a contraindication. A contraindication that is not documented explicitly by the healthcare provider but is evidenced clearly within the medical record should be noted.

Table 6. Continued

Element Name	Element Definition
Ticagrelor (discharge)	Indicate if ticagrelor was continued or prescribed at hospital discharge. Indicate which type and the dose prescribed. DO NOT record discharge medication if the patient was transferred to another acute care facility from your hospital.
Ticagrelor (discharge) contraindicated	Indicate if ticagrelor was discontinued or not prescribed at discharge because of a contraindication. A contraindication that is not documented explicitly by the healthcare provider but is evidenced clearly within the medical record should be noted.
Other oral antiplatelet medications before admission	Indicate if the patient has been taking other oral antiplatelet medications routinely at home before this hospitalization. These may include ticlopidine, dipyridamole, or cilostazol.
Other oral antiplatelet medications in first 24 h	Indicate if other oral antiplatelets were administered in the first 24 h of care provided, regardless of location of care (e.g., transferring facility or EMS). Indicate which type and the dose administered. Medications taken at home before hospital arrival and therefore not readministered until the next day of the hospitalization should be noted.
Other oral antiplatelet medications (discharge)	Indicate if other oral antiplatelet medications were continued or prescribed at hospital discharge. Indicate which type and the dose prescribed. DO NOT record discharge medication if the patient was transferred to another acute care facility from your hospital.
Other oral antiplatelet medications (discharge) contraindicated	Indicate if other oral antiplatelet medications were discontinued or not prescribed at discharge because of a contraindication. A contraindication that is not documented explicitly by the healthcare provider but is evidenced clearly within the medical record should be noted.
ACE inhibitor before admission	Indicate if the patient has been taking an ACE inhibitor routinely at home before this hospitalization.
ACE inhibitor in first 24 h	Indicate if an ACE inhibitor was administered in the first 24 h of care provided, regardless of location of care (e.g., transferring facility or EMS). Medications taken at home before hospital arrival and therefore not readministered until the next day of the hospitalization should be noted.
ACE inhibitor contraindicated	Indicate if an ACE inhibitor was not administered during the first 24 h of care because of a contraindication. A contraindication that is not documented explicitly by the healthcare provider but is evidenced clearly within the medical record should be noted.
ACE inhibitor (discharge)	Indicate if an ACE inhibitor was continued or prescribed at hospital discharge. Indicate which type and the dose prescribed. DO NOT record discharge medication if the patient was transferred to another acute care facility from your hospital.
ACE inhibitor (discharge) contraindicated	Indicate if an ACE inhibitor was discontinued or not prescribed at discharge because of a contraindication. A contraindication that is not documented explicitly by the healthcare provider but is evidenced clearly within the medical record should be noted.
ARB before admission	Indicate if the patient has been taking an ARB routinely at home before this hospitalization.
ARB in first 24 h	Indicate if an ARB was administered in the first 24 h of care provided, regardless of location of care (e.g., transferring facility or EMS). Medications taken at home before hospital arrival and therefore not readministered until the next day of the hospitalization should be noted.
ARB contraindicated	Indicate if an ARB was not administered during the first 24 h of care because of a contraindication. A contraindication that is not documented explicitly by the healthcare provider but is evidenced clearly within the medical record should be noted.
ARB (discharge)	Indicate if an ARB was continued or prescribed at hospital discharge. Indicate which type and the dose prescribed.
ARB (discharge) contraindicated	Indicate if an ARB was discontinued or not prescribed at discharge because of a contraindication. A contraindication that is not documented explicitly by the healthcare provider but is evidenced clearly within the medical record should be noted.
Diuretic	Indicate if a diuretic was continued or prescribed at hospital discharge. Aldosterone inhibitor is listed separately.
Aldosterone blocking agent (home)	Indicate if the patient has been taking an aldosterone blocking agent routinely at home before this hospitalization.
Aldosterone blocking agent in first 24 h	Indicate if an aldosterone blocking agent was administered in the first 24 h of care provided, regardless of location of care (e.g., transferring facility or EMS). Indicate which type and the dose administered. Medications taken at home before hospital arrival and therefore not readministered until the next day of the hospitalization should be noted.
Aldosterone blocking agent dose	Indicate the aldosterone blocking agent dose given.
Aldosterone blocking agent (24 h) contraindicated	Indicate if an aldosterone blocking agent was not administered during the first 24 h of care because of a contraindication. A contraindication that is not documented explicitly by the healthcare provider but is evidenced clearly within the medical record should be noted.
Aldosterone blocking agent (discharge)	Indicate if an aldosterone blocking agent was continued or prescribed at hospital discharge. Indicate which type and the dose prescribed. DO NOT record discharge medication if the patient was transferred to another acute care facility from your hospital.
Aldosterone blocking agent (discharge) contraindicated	Indicate if an aldosterone blocking agent was discontinued or not prescribed at discharge because of a contraindication. A contraindication that is not documented explicitly by the healthcare provider but is evidenced clearly within the medical record should be noted.
Statin before admission	Indicate if the patient has been taking a statin routinely at home before this hospitalization.
Statin in first 24 h	Indicate if a statin was administered in the first 24 h of care provided, regardless of location of care (e.g., transferring facility or EMS). Indicate which type of statin was administered. Medications taken at home before hospital arrival and therefore not readministered until the next day of the hospitalization should be noted.
Statin dose	Indicate the following: <ul style="list-style-type: none"> • Specific statin agent • Statin dose given

Table 6. Continued

Element Name	Element Definition
Statin contraindicated	Indicate if statin was not administered during the first 24 h of care because of a contraindication. A contraindication that is not documented explicitly by the healthcare provider but is evidenced clearly within the medical record should be noted.
Statin (discharge)	Indicate if a statin was continued or prescribed at hospital discharge. Indicate which type and the dose prescribed. DO NOT record discharge medication if the patient was transferred to another acute care facility from your hospital.
Statin (discharge) contraindicated	Indicate if statin medication was discontinued or not prescribed because of a contraindication. A contraindication that is not documented explicitly by the healthcare provider but is evidenced clearly within the medical record should be noted.
Other lipid-lowering agent (home)	Indicate if the patient has been taking another lipid-lowering agent routinely at home before this hospitalization.
Other lipid-lowering agent (discharge)	Indicate if another lipid-lowering agent was continued or prescribed at hospital discharge. Indicate which type and the dose prescribed.
Other lipid-lowering agent (discharge) contraindicated	Indicate if another lipid-lowering agent was discontinued or not prescribed at discharge because of a contraindication. A contraindication that is not documented explicitly by the healthcare provider but is evidenced clearly within the medical record should be noted.
Omega-3 fatty acid (discharge)	Indicate if a preparation of omega-3 fatty acid supplement/medication was taken at discharge.
Antiarrhythmic (discharge)	Indicate if an antiarrhythmic was administered.
Antidepressants	Indicate if the patient has been prescribed an antidepressant.
Female hormone replacement therapy	Indicate if female hormone replacement therapy was administered.
Nicotine replacement and/or suppression therapy	Indicate if nicotine replacement and/or suppression agents were administered (e.g., bupropion, varenicline).
NSAIDs	Indicate if the patient has been prescribed an NSAID. Indicate the type: <ul style="list-style-type: none"> • Nonselective • Cox-2 selective
Insulin	Indicate if the patient has been prescribed insulin.
Oral hypoglycemic agent	Indicate if the patient has been prescribed an oral hypoglycemic agent for treatment of diabetes. Specify the agent: <ul style="list-style-type: none"> • Sulfonylureas (e.g., tolbutamide, glipizide) • Biguanides (e.g., metformin, buformin) • Meglitinides (e.g., repaglinide, nateglinide) • Thiazolidinediones (e.g., rosiglitazone, pioglitazone) • Peptide analogs • DPP-4 inhibitors (e.g., vildagliptin, sitagliptin) • Alpha-glucosidase inhibitors (e.g., miglitol, acarbose) • Experimental agents
Subcutaneous hypoglycemic agent	Indicate if the patient has been prescribed a subcutaneous hypoglycemic agent for treatment of diabetes.
Influenza immunization	Indicate if the patient has received immunization for influenza or received one in the past 12 mo.
Pneumococcal immunization	Indicate if the patient has been immunized for pneumococcal pneumonia or received one in the past 12 mo.

ACE indicates angiotensin-converting enzyme; ARB, angiotensin receptor blocker; DPP, dipeptidyl peptidase; EMS, emergency medical services; GP, glycoprotein; IV, intravenous; and NSAID, nonsteroidal anti-inflammatory drug.

3.7. Outcomes Data Elements

Clinical trials on STEMI, NSTEMI, and UA patients and research published from ACS registries have established well-defined data elements that reflect clinically relevant outcomes in these patient groups. Outcome data elements (Table 7) that have been selected by the writing committee include death during hospitalization (with timing and primary cause being either cardiovascular or noncardiovascular), occurrence of reinfarction (using the universal definition of MI), heart failure, cardiogenic shock, stroke, TIMI major or minor bleeding, GUSTO bleeding, location of the bleeding event, surgical intervention required for bleeding, transfusion required, amount of blood given, thrombocytopenia, cardiac rupture, atrial fibrillation, ventricular arrhythmia, and atrioventricular block. Data elements have been included that capture discharge

status, discharge destination, and The Joint Commission discharge core measures reflecting optimal patient care. The availability of long-term outcome data on patients with ACS is essential in determining the efficacy of therapies. Data elements have been selected for patient follow-up after discharge to reflect important aspects of patient status. These include anginal status, need for cardiac catheterization, reinfarction, revascularization (either PCI or coronary artery bypass graft), readmission to the hospital and reason for readmission, important laboratory tests about risk factors (low-density lipoprotein, high-density lipoprotein, hemoglobin A1c, C-reactive protein), occurrence of heart failure and New York Heart Association class, medication use, and death (timing and cause). The timing of collection of outcomes can be determined by the specific registry or trial; for example, in-hospital outcomes versus 30 days versus 1 year.

Table 7. Outcomes Data Elements and Definitions

Element Name	Element Definition
Outcomes	
Death	The patient died during this hospitalization.
Date and time of death	Indicate the patient's date and time of death.
Acute MI	<p>The term <i>acute MI</i> should be used when there is evidence of myocardial necrosis in a clinical setting consistent with myocardial ischemia. Under these conditions, any one of the following criteria meets the diagnosis for MI:</p> <ul style="list-style-type: none"> • Detection of the rise and/or fall of cardiac biomarkers (preferably cTn) with at least 1 value above the 99th percentile and with at least 1 of the following <ul style="list-style-type: none"> - Symptoms of ischemia - New or presumed new significant ST-T changes or new LBBB - Development of pathological Q waves on the ECG - Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality - Identification of an intracoronary thrombus by angiography or autopsy • Cardiac death with symptoms suggestive of myocardial ischemia and presumed new ischemic electrocardiographic changes or new LBBB, but death occurred before cardiac biomarkers were obtained or before cardiac biomarker values would be increased. • PCI-related MI is arbitrarily defined by elevation of cTn values (≤ 5 times the 99th percentile URL) in patients with normal baseline values (≥ 99th percentile URL) or a rise in cTn values $\geq 20\%$ if baseline values are elevated and stable or falling; in addition, either symptoms suggestive of myocardial ischemia or new ischemic electrocardiographic changes or angiographic findings consistent with a procedural complication or imaging demonstration of new loss of viable myocardium or new regional wall motion abnormality • Stent thrombosis associated with MI when detected by coronary angiography or autopsy in the setting of myocardial ischemia and with a rise and/or fall of cardiac biomarker values with at least 1 value > 99th percentile URL. • CABG-related MI is arbitrarily defined by elevation of cardiac biomarker values (> 10 times the 99th percentile URL) in patients with normal baseline cTn values (≥ 99th percentile URL) plus either new pathological Q waves or new LBBB, or angiographically documented new graft or new native coronary artery occlusion, or imaging evidence of new loss of viable myocardium. • The 99th percentile is observed after the procedure in conjunction with symptoms suggestive of myocardial ischemia or new ischemic electrocardiographic changes or angiographic findings consistent with a procedural complication or imaging demonstration of new loss of viable myocardium or in patients with a preprocedure elevated biomarker that is stable or falling, a rise of biomarker values $\geq 20\%$ in conjunction with the PCI-related criteria stated above.
Recurrent MI	<p>Reinfarction occurs when there are clinical signs and symptoms of ischemia that are distinct from the presenting ischemic event and meeting at least 1 of the following criteria:</p> <ol style="list-style-type: none"> 1. Spontaneous (before or without revascularization, > 48 h after PCI, and/or after CABG) <ol style="list-style-type: none"> A. New, significant Q waves in at least 2 contiguous leads of an ECG that were not present with the presenting ischemic event B. Patients whose most recent cardiac markers drawn before reinfarction, which were normal, require an increase in CK-MB or troponin above the 99th percentile ULN, which is at least $\geq 20\%$ above the most recent value. 2. Within 48 h after PCI: <ol style="list-style-type: none"> A. Patients with normal biomarker values (preprocedure) who then develop an increase in biomarker values > 5 times the 99th percentile URL or if the baseline values are elevated and are stable or falling, a rise of cTn values $\geq 20\%$. In addition, symptoms suggestive of myocardial ischemia or new ischemic electrocardiographic changes or angiographic findings consistent with a procedural complication or imaging demonstration of new loss of viable myocardium are required. <p><i>Note:</i> Some patients presenting with ACS will not have biomarker elevations before the PCI. Elevated biomarkers after PCI in these cases do not necessarily mean a reinfarction occurred.</p> B. Stent thrombosis associated with MI when detected by coronary angiography or autopsy in the setting of myocardial ischemia and with a rise and/or fall of cardiac biomarker values with at least 1 value above the 99th percentile URL C. For patients with elevated baseline (preprocedure) cardiac biomarkers, there are 2 possible scenarios. In these scenarios, electrocardiographic changes or symptoms are not required to qualify. <ol style="list-style-type: none"> i. Patients with cardiac markers above the ULN (preprocedure) assumed to be in the midst of an acute MI ii. Patients with elevated biomarkers with a characteristic rise and fall in biomarker levels preprocedure most likely have completed their presenting infarct. Further rises in cardiac markers must be $\geq 20\%$ above the most recent value to be coded as reinfarction. D. Patients with new, significant Q waves in at least 2 contiguous leads of an ECG that were not present with the presenting ischemic event 3. Within 48 h after CABG: A CABG-related MI is defined by elevation of cardiac biomarker values > 10 times the 99th percentile URL in patients with normal baseline cTn values (≤ 99th percentile URL) plus either new pathological Q waves or new LBBB or angiographically documented new graft or new native coronary artery occlusion or imaging evidence of new loss of viable myocardium or new regional wall motion abnormality. <p><i>Note:</i> Patients with cardiac biomarkers above the ULN before CABG require the increase in biomarkers to be $\geq 20\%$ above the most recent value associated with symptoms/signs of myocardial ischemia.</p>
Reinfarction date	Indicate the date when the clinical signs and symptoms of the reinfarction first occurred.
Recurrent rest angina with electrocardiographic changes	Recurrent ischemic pain occurring at rest (and believed to be cardiac in origin) with associated electrocardiographic changes
Recurrent rest angina without electrocardiographic changes	Recurrent ischemic pain occurring at rest (and believed to be cardiac in origin) without associated electrocardiographic changes

Table 7. Continued

Element Name	Element Definition
Unstable angina requiring hospitalization	<p>Unstable angina requiring hospitalization is defined as:</p> <ol style="list-style-type: none"> 1. Ischemic discomfort (angina or symptoms thought to be equivalent) ≥ 10 min in duration occurring <ul style="list-style-type: none"> • at rest, or • in an accelerating pattern with frequent episodes associated with progressively decreased exercise capacity 2. Prompting an unscheduled hospitalization within 24 h of the most recent symptoms. Hospitalization is defined as an admission to an inpatient unit or a visit to an emergency department that results in at least a 24 h stay (or a change in calendar date if the hospital admission or discharge times are not available) 3. At least one of the following: <ol style="list-style-type: none"> a. New or worsening ST or T wave changes on resting ECG (in the absence of confounders, such as LBBB or LVH) <ul style="list-style-type: none"> • Transient ST elevation (duration < 20 min) <p>New ST elevation at the J point in 2 contiguous leads with the cut-points: ≥ 0.1 mV in all leads other than leads V2-V3 where the following cut-points apply: ≥ 0.2 mV in men ≥ 40 y (≥ 0.25 mV in men < 40 y) or ≥ 0.14 mV in women</p> • ST depression and T-wave changes <p>New horizontal or down-sloping ST depression ≥ 0.05 mV in two contiguous leads and/or new T inversion ≥ 0.3 mV in 2 contiguous leads with prominent R wave or R/S ratio > 1.</p> b. Definite evidence of inducible myocardial ischemia as demonstrated by: <ul style="list-style-type: none"> • an early positive exercise stress test, defined as ST elevation or ≥ 2 mm ST depression prior to 5 METS, or • stress echocardiography (reversible wall motion abnormality), or • myocardial scintigraphy (reversible perfusion defect), or • MRI (myocardial perfusion deficit under pharmacologic stress) and believed to be responsible for the myocardial ischemic symptoms/signs. c. Angiographic evidence of new or worse $\geq 70\%$ lesion and/or thrombus in an epicardial coronary artery that is believed to be responsible for the myocardial ischemic symptoms/signs. d. Need for coronary revascularization procedure (PCI or CABG) for the presumed culprit lesion(s). This criterion would be fulfilled if revascularization was undertaken during the unscheduled hospitalization, or subsequent transfer to another institution without interceding home discharge. 4. Negative cardiac biomarkers.
Heart failure	<p>Indicate if there is physician documentation or report of either new-onset or acute reoccurrence of heart failure.</p> <p>Heart failure is defined as physician documentation or report of any of the following clinical symptoms of heart failure described as unusual dyspnea on light exertion, recurrent dyspnea occurring in the supine position, fluid retention; or the description of rales, jugular venous distention, or pulmonary edema on physical exam. A low ejection fraction without clinical presentation does not qualify as heart failure.</p> <p>*Note: Killip class 2 is defined as rales over $\leq 50\%$ of the lung fields or the presence of an S₃. Killip class 3 is defined as rales over $> 50\%$ of the lung fields. Either class would qualify as a “yes.”</p>
Heart failure date	Indicate the date of the acute reoccurrence of heart failure.
Cardiogenic shock	<p>Indicate if the patient developed cardiogenic shock in your facility. Cardiogenic shock is defined as a sustained (> 30 min) episode of systolic blood pressure < 90 mm Hg and/or cardiac index < 2.2 L/min per square meter determined to be secondary to cardiac dysfunction and/or the requirement for parenteral inotropic or vasopressor agents or mechanical support (e.g., IABP, extracorporeal circulation, VADs) to maintain blood pressure and cardiac index above those specified levels.</p> <p>Note: Transient episodes of hypotension reversed with IV fluid or atropine do not constitute cardiogenic shock. The hemodynamic compromise (with or without extraordinary supportive therapy) must persist for at least 30 min.</p>
Cardiogenic shock date	Indicate the date when a diagnosis of cardiogenic shock was made.
Stroke	<p>Indicate whether the patient has a history of stroke, which is defined as an acute episode of neurological dysfunction caused by focal or global brain, spinal cord, or retinal vascular injury as a result of hemorrhage or infarction.</p> <p>If present, record stroke type:</p> <ul style="list-style-type: none"> • Ischemic stroke • Intracerebral hemorrhage • Subarachnoid hemorrhage • Unknown type <p>If ischemic, list the most likely etiologies:</p> <ul style="list-style-type: none"> • Large artery atherosclerosis of the extracranial vessels (e.g., carotid) • Large artery atherosclerosis of the intracranial vessels (e.g., middle cerebral artery stenosis) • Cardioembolism • Small-vessel occlusion (lacunar) • Ischemic stroke of other determined etiology (e.g., arterial dissection) • Ischemic stroke of undetermined etiology
Stroke date	Indicate the date of onset of stroke symptoms.
Type of stroke	<p>Indicate if the patient experienced a hemorrhagic or ischemic stroke with documentation on imaging (e.g., CT scan or MRI of hemorrhage in the cerebral parenchyma or a subdural or subarachnoid hemorrhage). Evidence of hemorrhagic stroke obtained from lumbar puncture, neurosurgery, or autopsy can also confirm the diagnosis.</p> <p>Note: If stroke occurs during sleep, last awake time may be used.</p>
Bleeding (TIMI major, TIMI minor, or none)	<p>An episode of bleeding is defined by the TIMI criteria as</p> <ul style="list-style-type: none"> • Major: overt clinical bleeding (or documented intracranial or retroperitoneal hemorrhage) associated with a drop in hemoglobin of ≥ 5 g/dL (0.5 g/L) or in hematocrit of $\geq 15\%$ (absolute) <p>Note: A patient who experiences an intracranial hemorrhage should be considered to have a major hemorrhage.</p> <ul style="list-style-type: none"> • Minor: overt clinical bleeding associated with a fall in hemoglobin of 3 to < 5 g/dL or in hematocrit of 9% to $\leq 15\%$ (absolute) • None: no bleeding event that meets the major or minor definition <p>Note: In calculating the fall in hemoglobin or hematocrit, a transfusion of whole blood or packed RBCs is counted as 1 g/dL hemoglobin or 3% absolute in hematocrit. This would be in addition to the actual fall in hemoglobin or hematocrit.</p>
GUSTO bleeding classification (42)	<p>Indicate the GUSTO bleeding classification:</p> <ul style="list-style-type: none"> • Severe: either intracranial hemorrhage or bleeding that causes hemodynamic compromise and requires intervention • Moderate: bleeding that requires blood transfusion but does not result in hemodynamic compromise • Mild: bleeding that does not meet the criteria for either severe or moderate bleeding

Table 7. Continued

Element Name	Element Definition
Bleeding event	Indicate if there was a bleeding event observed and documented in the medical record that was associated with a hematocrit drop of $\geq 10\%$ and/or a hemoglobin drop of ≥ 3 g/dL or that required transfusion or surgical intervention.
Location of bleeding	Indicate the location thought to be responsible for the bleeding event. Choose all that apply: <ul style="list-style-type: none"> • Access site • Retroperitoneal • GI • GU • Other
Bleeding event date	Indicate the date of the suspected bleeding event.
Surgical or procedural intervention	Indicate if the suspected bleeding event required a surgical or procedural intervention. Interventions may include surgery, protamine (heparin reversal agent), fibrin injection, transfusion of blood products, angioplasty, or stenting. Prolonged pressure does not qualify as an intervention, but ultrasonic guided compression after making a diagnosis of pseudoaneurysm does qualify.
Transfusion	Indicate if there was a nonautologous transfusion(s) of either whole blood or packed RBCs.
Units of blood given	Indicate the units of blood given.
Date of first RBC transfusion	Indicate the date of the first RBC transfusion.
RBC transfusion related to CABG	Indicate if any RBC/whole blood transfusion was related to CABG. If any units were given for reasons not related to CABG, check "No." Check "Yes" only if all transfusions given were related to CABG.
Thrombocytopenia	Platelet count dropped to either $< 50,000/\text{mm}^3$ or between 50,000 and $< 100,000/\text{mm}^3$; the level should be noted. This platelet count should be confirmed as not being pseudothrombocytopenia (i.e., platelet clumping in citrated blood).
Cardiac rupture/ventricular septal defect	Rupture of the ventricular myocardium as documented by cardiac echocardiography, ventriculography, pericardiocentesis, cardiac surgery, and/or autopsy. Rupture could be of the free wall or the ventricular septum. Included in this category is frank papillary muscle rupture.
Atrial arrhythmia	A new episode or acute recurrence of atrial fibrillation/flutter.
Supraventricular tachycardia	A new episode or acute recurrence of supraventricular tachycardia requiring treatment (supraventricular tachycardia that requires cardioversion or drug therapy, or is sustained for > 1 min).
Ventricular arrhythmia	VT or VF requiring cardioversion and/or IV antiarrhythmics.
High-degree AV block	High-level AV block defined as third-degree AV block or second-degree AV block with bradycardia requiring pacing.
Discharge	
Date of discharge	Indicate the month, day, and year the patient was discharged from acute care, left against medical advice, or died during this stay.
Discharge destination	Indicate the patient's destination after discharge. Choose 1 of the following: <ul style="list-style-type: none"> • Home • Extended care/transitional care unit • Other hospital • Nursing home • Hospice • Other
Discharge status	Discharge status: the place or setting to which the patient was discharged: <ul style="list-style-type: none"> • Discharged to home care or self-care (routine discharge) • Discharged/transferred to a short-term general hospital for inpatient care • Discharged/transferred to SNF with Medicare certification in anticipation of covered skilled care • Discharged/transferred to an ICF • Discharged/transferred to another type of institution not defined elsewhere in this code list • Discharged/transferred to home under care of organized home health service organization in anticipation of covered skilled care • Left against medical advice or discontinued care • Died • Died in a medical facility (e.g., hospital, SNF, ICF, or freestanding hospice) • Discharged/transferred to a federal healthcare facility • Hospice: home • Hospice: medical facility • Discharged/transferred to hospital-based, Medicare-approved swing bed • Discharged/transferred to an IRF, including rehabilitation distinct part units of a hospital • Discharged/transferred to a Medicare-certified LTCH • Discharged/transferred to a nursing facility certified under Medicaid but not certified under Medicare • Discharged/transferred to a psychiatric hospital or psychiatric distinct part unit of a hospital • Discharged/transferred to a CAH
Discharge status (alive versus dead)	Indicate whether the patient was alive or dead at discharge from hospitalization during which the procedure occurred. <ul style="list-style-type: none"> • Alive • Dead

The writing committee also recognizes the efforts of other groups in standardizing cardiovascular definitions, specifically, the 2012 third universal definition of MI (22) and the "Standardized Definitions for Cardiovascular and Stroke End Point Events in Cardiovascular Trials" (41) from the FDA, which is currently in development. It should also be noted that the writing committee believes that further research is needed from large observational databases to identify the actual trends

in duration of UA; however, the timing criteria for UA in this document was revised to ≥ 10 minutes to align with the FDA's Standardized Definitions for End Point Events in Cardiovascular Trials definition. Future iterations of the ACCF/AHA ACS/CAD data standards data elements and definitions will be harmonized with the work of the universal definition of MI Group, the FDA, and other groups.

Table 7. Continued

Element Name	Element Definition
Primary cause of death*	<p>Indicate the primary cause of death:</p> <ul style="list-style-type: none"> • Cardiovascular death: <ul style="list-style-type: none"> - Acute MI - Sudden cardiac death - Death due to heart failure - Death due to stroke - Death due to cardiovascular procedures - Death due to cardiovascular hemorrhage - Death due to other cardiovascular causes • Noncardiovascular death: defined as any death with a specific cause that is not thought to be cardiovascular in nature: <ul style="list-style-type: none"> - Pulmonary - Renal - GI - Hepatobiliary - Pancreatic - Infection (includes sepsis) - Inflammatory (e.g., SIRS/immune [including autoimmune]) - Hemorrhage that is neither cardiovascular bleeding nor a stroke - Noncardiovascular procedure or surgery - Trauma - Suicide - Prescription drug reaction or overdose - Nonprescription drug reaction or overdose - Neurological (noncardiovascular) - Malignancy - Other noncardiovascular cause of death • Undetermined cause of death: refers to death not attributable to either cardiovascular or noncardiovascular cause
Acute care transfer	Indicate if the patient was transferred to another acute-care center (hospital) for further management.
Date/time of transfer	Indicate the date and time the patient was transferred to another acute-care center (hospital) for further management.
Days in ICU	<p>Total number of days the patient spent in an intensive care bed at the index hospital only, either consecutively or intermittently. To count days:</p> <ul style="list-style-type: none"> • Find the ICU/CCU admit date/time and the date/time patient was transferred to another unit (telemetry or unmonitored bed) • For every 24-h period, count 1 d • For any partial day remaining, round up if ≥ 12 h and round down if < 12 h <p>In the case of an in-hospital infarct in which the patient is already in an ICU bed, record the number of days spent in ICU/CCU after the diagnosis of MI was made.</p>
Final diagnosis of the admission event	<ul style="list-style-type: none"> • STEMI is defined as an ACS in which there is cardiac marker evidence of myocardial necrosis (e.g., positive cTn or CK-MB) and new (or presumably new if no prior ECG is available) ST-segment elevation or LBBB on the admission ECG. (For a complete definition, please see “MI” in the “Outcomes” section.) • NSTEMI is defined as an ACS in which there is cardiac marker evidence of myocardial necrosis (e.g., positive cTn or CK-MB) without new ST-segment elevation. (For a complete definition, please see “MI” in the “Outcomes” section.) • BBB/uncertain type: For a complete definition, please see “MI” in the “Outcomes” section. • UA is defined as angina pectoris (or equivalent type of ischemic discomfort) with any 1 of the 3 following features: <ol style="list-style-type: none"> 1. Angina occurring at rest and prolonged, usually ≥ 10 min 2. New-onset angina of at least CCS classification III severity 3. Recent acceleration of angina reflected by an increase in severity of at least 1 CCS class to at least CCS class III <p>The patient must also not have any biochemical evidence of necrosis.</p> <p>Definite/probable UA: Patients with clinical history consistent with the diagnosis of UA as described above, in whom ischemia has been confirmed by the presence of ST changes on the initial ECG or in association with recurrent rest pain, by a positive stress test, negative cardiac biomarkers, and no evidence of acute MI.</p> <p>Possible UA is present when an acute ischemic process has not been excluded as a possible cause of the presenting symptoms or the clinical history is consistent with UA, but no diagnostic test (noted above) was performed to confirm the diagnosis.</p> • Stable CAD: The patient has a clinical diagnosis or prior history of CAD, but after evaluation in the hospital, the episode of discomfort was not thought to have represented UA. • Noncardiac chest pain: Pain in the chest, neck, arms, or abdomen (or other clinical manifestation) not clearly exertional or not otherwise consistent with pain or discomfort of myocardial ischemic origin. <p>Examples:</p> <ol style="list-style-type: none"> 1. If a patient was admitted with rest pain but had negative cardiac markers and then on day 3 developed recurrent pain, and if it was determined that an MI had occurred, the event prompting admission should be coded as “unstable angina” here. The MI on day 3 should be recorded in the “Outcomes” section as a postadmission MI. 2. If a patient was admitted with rest pain and the initial cardiac markers were negative but the enzymes drawn over the subsequent 24 h became positive, this is most consistent with an NSTEMI as the admission event.
Comfort measures only	<p>Indicate if there was physician/nurse practitioner/physician assistant documentation that the patient was receiving comfort measures only.</p> <ul style="list-style-type: none"> • Comfort measures only are commonly referred to as “palliative care” in the medical community and “comfort care” by the general public. Palliative care includes attention to the psychological and spiritual needs of the patient and support for the dying patient and the patient’s family. Usual interventions are not received because a medical decision was made to limit care to comfort measures only. • Comfort measures only are not equivalent to a DNR order, living will, no code, or no heroic measure.

Table 7. Continued

Element Name	Element Definition
Primary inpatient service	Indicate the specialty of the attending physician who primarily cared for the patient according to the most frequent and consistent notations in the medical record. Choose 1 of the following: <ul style="list-style-type: none"> • Cardiology • Internal medicine • Family practice • Hospital medicine (primary professional focus on general medical care of hospitalized patients) • Other
Clinical trial	Indicate if the patient signed an informed consent to participate in a clinical trial during his or her hospitalization, even if the investigational medication, device, or procedure was never initiated.
Smoking cessation counseling	Indicate if there was documentation in the medical record that smoking cessation advice or counseling was given during this hospital stay.
Weight management counseling	Advice is given or counseling conducted by a physician or nurse for patients who are >120% of ideal weight for height. Particular emphasis on weight loss may be given for patients with hypertension, elevated triglycerides, or elevated glucose levels.
Diet counseling	Advice is given or a discussion conducted by a physician, nurse, or registered dietitian encouraging diet counseling. This can include consumption of low-cholesterol foods; moderate restriction of sodium intake; emphasis on consumption of fruits, vegetables, and low-fat dairy products; and increased consumption of omega-3 fatty acids.
Exercise counseling	Indicate if advice was given or discussion conducted by a physician, nurse, or exercise specialist or nurse encouraging patients to engage in a minimum of 30–60 min of physical activity daily or at least 3–4 times weekly.
Cardiac rehabilitation	Indicate if advice was given or discussion conducted with the patient (by physician, nurse, or other personnel) about the importance of joining a cardiac rehabilitation program or an appointment made.
Follow-up	
Readmission	Readmission to a hospital
Readmission date	Date the patient was readmitted
Readmission reason	Reasons for admission (include all that apply): <ul style="list-style-type: none"> • MI (documented) • UA • Angina (without MI) • PCI • CABG • CHF (without MI) • Arrhythmia or conduction disturbance (without MI) • Sudden cardiac arrest • Chest pain ultimately found to be noncardiac in nature • Stroke/other cardiovascular problem • Noncardiovascular problem
BNP or NT pro-BNP	Indicate the results of BNP or first NT pro-BNP. If done, enter the numerical value and specify which assay type was done.
LDL	Indicate the value of LDL cholesterol. If the value is reported using a ">" symbol (e.g., ">300"), record the number only (e.g., "300").
HDL	Indicate the value of HDL cholesterol. If the value is reported using a ">" symbol (e.g., ">300"), record the number only (e.g., "300").
Hemoglobin A1c	Indicate value and date performed.
MI	Documented evidence of an MI. For a complete definition, please see "MI" in the "Outcomes" section.
Cardiac catheterization	Cardiac catheterization (with or without revascularization) procedure performed since the previous visit/contact
PCI	PCI performed since the previous visit/contact
CABG	CABG performed since the previous visit/contact
Angina status	CCS classes of angina: <ul style="list-style-type: none"> • Class 0: none • Class I: ordinary physical activity, such as walking or climbing stairs, does not cause angina. Angina occurs with strenuous, rapid, or prolonged exertion at work or recreation. • Class II: slight limitation of ordinary activity. Angina occurs on walking or climbing stairs rapidly, walking uphill, walking or climbing stairs after meals, or in cold, in wind, or under emotional stress, or only during the few hours after awakening. Angina occurs on walking >2 blocks on the level and climbing >1 flight of ordinary stairs at a normal pace and in normal conditions. • Class III: marked limitation of ordinary physical activity. Angina occurs on walking 1 to 2 blocks on the level and climbing 1 flight of stairs in normal conditions and at a normal pace. • Class IV: inability to perform any physical activity without discomfort—anginal symptoms may be present at rest.

Table 7. Continued

Element Name	Element Definition
NYHA functional class	<p>If heart failure is present, indicate NYHA class.</p> <p>Choose 1 of the following:</p> <ul style="list-style-type: none"> • Class I: patients with cardiac disease but without resulting limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, or dyspnea. • Class II: patients with cardiac disease resulting in a slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, or dyspnea. • Class III: patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea. • Class IV: patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms are present even at rest or minimal exertion.
Death	The patient has died since the previous visit/contact. This category includes all deaths regardless of cause of death.
Date of death	Indicate the date of death.
Primary cause of death	<p>Indicate the primary cause of death:</p> <ul style="list-style-type: none"> • Cardiovascular death: <ul style="list-style-type: none"> - Acute MI - Sudden cardiac death - Death due to heart failure - Death due to stroke - Death due to cardiovascular procedures - Death due to cardiovascular hemorrhage - Death due to other cardiovascular causes • Noncardiovascular death is defined as any death with a specific cause that is not thought to be cardiovascular in nature: <ul style="list-style-type: none"> - Pulmonary - Renal - GI - Hepatobiliary - Pancreatic - Infection (includes sepsis) - Inflammatory (e.g., SIRS/immune [including autoimmune]) - Hemorrhage that is neither cardiovascular bleeding nor a stroke - Noncardiovascular procedure or surgery - Trauma - Suicide - Prescription drug reaction or overdose - Nonprescription drug reaction or overdose - Neurological (noncardiovascular) - Malignancy - Other noncardiovascular cause of death • Undetermined cause of death: refers to death not attributable to either cardiovascular or noncardiovascular cause
Medication use	<ul style="list-style-type: none"> • Acetylsalicylic acid/antiplatelet: aspirin, clopidogrel, or ticlopidine; other (e.g., dipyridamole) • ACE inhibitors: Some common generic forms are captopril, enalapril, lisinopril, and ramipril. • Beta blocker: Some forms of IV beta blockers are atenolol, metoprolol, propranolol, timolol, esmolol, and labetalol. Some generic forms of oral beta blockers include atenolol, metoprolol, nadolol, pindolol, propranolol, timolol, acebutolol, bucindolol, bisoprolol, labetalol, and carvedilol. • Lipid lowering: Types of agents include statins (HMG Co-A reductase inhibitors), fibrates, nicotinic acid, and resin drugs (cholestyramine). Frequently prescribed drugs are cholestyramine, colestipol, probucol, gemfibrozil, lovastatin, atorvastatin, simvastatin, fluvastatin, pravastatin, and other Class I–indicated cardiovascular medication—ARB and aldosterone antagonists. <p>A complete listing of cardiac medications could also be collected.</p>

ARB indicates angiotensin receptor blocker; ACE, angiotensin-converting enzyme; ACS, acute coronary syndromes; AV, atrioventricular; BBB, bundle-branch block; BNP, brain natriuretic peptide; CABG, coronary artery bypass graft; CAD, coronary artery disease; CAH, critical access hospital; CCS, Canadian Cardiovascular Society; CCU, coronary care unit; CHF, congestive heart failure; CK-MB, creatine kinase MB isoenzyme; CT, computed tomography; cTn, cardiac troponin; DNR, do not resuscitate; ECG, electrocardiogram; GI, gastrointestinal; GU, genitourinary; GUSTO, Global Utilization of Streptokinase and Tissue Plasminogen Activator for Occluded Coronary Arteries; HDL, high-density lipoprotein; IABP, intra-aortic balloon pump; ICF, intermediate care facility; ICU, intensive care unit; IRF, inpatient rehabilitation facility; IV, intravenous; LBBB, left bundle branch block; LDL, low-density lipoprotein; LTCH, long-term care hospital; MI, myocardial infarction; MRI, magnetic resonance imaging; NSTEMI, non-ST-segment elevation myocardial infarction; NT-proBNP, N-terminal prohormone of brain natriuretic enzyme; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; RBCs, red blood cells; SIRS, systemic inflammatory response syndrome; SNF, skilled nursing facility; STEMI, ST-segment elevation myocardial infarction; TIMI, Thrombolysis in Myocardial Infarction; VAD, ventricular assist device; VF, ventricular fibrillation; VT, ventricular tachycardia; UA, unstable angina; ULN, upper limit of normal; and URL, upper reference limit.

Presidents and Staff

American College of Cardiology Foundation

William A. Zoghbi, MD, FACC, President

Thomas E. Arend, Jr. Esq., CAE, Interim Chief Staff Officer

William J. Oetgen, MD, MBA, FACC, Senior Vice President, Science and Quality

Charlene L. May, Senior Director, Science and Clinical Policy

Melanie Shahriary, RN, BSN, Director, Performance Measures and Data Standards

Erin A. Barrett, MPS, Senior Specialist, Science and Clinical Policy

*American College of Cardiology Foundation/
American Heart Association*

Maria Lizza D. Isler, BSMT, Specialist, Clinical Data Standards

American Heart Association

Donna K. Arnett, PhD, MSPH, BSN, FAHA, President
Nancy Brown, Chief Executive Officer

Rose Marie Robertson, MD, FACC, FAHA, Chief Science Officer

Gayle R. Whitman, PhD, RN, FAHA, FAAN, Senior Vice President, Office of Science Operations

Melanie Turner, MPH, Associate Science and Medicine Advisor, Office of Science Operations

REFERENCES

1. Health Insurance Portability and Accountability Act of 1996. 1996; Public Law 104-191.
2. Cannon CP, Battler A, Brindis RG, et al. American College of Cardiology key data elements and definitions for measuring the clinical management and outcomes of patients with acute coronary syndromes: a report of the American College of Cardiology Task Force on Clinical Data Standards (Acute Coronary Syndromes Writing Committee). *J Am Coll Cardiol.* 2001;38:2114-30.
3. 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). *J Am Coll Cardiol.* 2004;44:475-95.
4. Radford MJ, Arnold JM, Bennett SJ, et al. ACC/AHA key data elements and definitions for measuring the clinical management and outcomes of patients with chronic heart failure: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Heart Failure Clinical Data Standards). *Circulation.* 2005;112:1888-916.
5. Buxton AE, Calkins H, Callans DJ, et al. ACC/AHA/HRS 2006 key data elements and definitions for electrophysiological studies and procedures: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (ACC/AHA/HRS Writing Committee to Develop Data Standards on Electrophysiology). *Circulation.* 2006;114:2534-70.
6. Radford MJ, Heidenreich PA, Bailey SR, et al. ACC/AHA 2007 methodology for the development of clinical data standards: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards. *J Am Coll Cardiol.* 2007;49:830-7.
7. Hendel RC, Budoff MJ, Cardella JF, et al. ACC/AHA/ACR/ASE/ASNC/HRS/NASCI/RSNA/SAIP/SCAI/SCCT/SCMR/SIR 2008 key data elements and definitions for cardiac imaging: 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 Cardiac Imaging). *J Am Coll Cardiol.* 2009;53:91-124.
8. Rogers WJ, Canto JG, Lambrew CT, et al. Temporal trends in the treatment of over 1.5 million patients with myocardial infarction in the US from 1990 through 1999: the National Registry of Myocardial Infarction 1, 2 and 3. *J Am Coll Cardiol.* 2000;36:2056-63.
9. Granger CB. Strategies of patient care in acute coronary syndromes: rationale for the Global Registry of Acute Coronary Events (GRACE) registry. *Am J Cardiol.* 2000;86:4M-9M.
10. Cannon CP, Braunwald E, McCabe CH, et al. The Thrombolysis in Myocardial Infarction (TIMI) trials: the first decade. *J Interv Cardiol.* 1995;8:117-35.
11. Antman EM. Hirudin in acute myocardial infarction. Thrombolysis and Thrombin Inhibition in Myocardial Infarction (TIMI) 9B trial. *Circulation.* 1996;94:911-21.
12. Antman EM, McCabe CH, Gurfinkel EP, et al. Enoxaparin prevents death and cardiac ischemic events in unstable angina/non-Q-wave myocardial infarction. Results of the thrombolysis in myocardial infarction (TIMI) 11B trial. *Circulation.* 1999;100:1593-601.
13. The Global Use of Strategies to Open Occluded Coronary Arteries (GUSTO) IIb investigators. A comparison of recombinant hirudin with heparin for the treatment of acute coronary syndromes. *N Engl J Med.* 1996;335:775-82.
14. The GUSTO investigators. An international randomized trial comparing four thrombolytic strategies for acute myocardial infarction. *N Engl J Med.* 1993;329:673-82.
15. Randomised placebo-controlled and balloon-angioplasty-controlled trial to assess safety of coronary stenting with use of platelet glycoprotein-IIb/IIIa blockade. *Lancet.* 1998;352:87-92.
16. Hoekstra JW, Pollack CV, Jr., Roe MT, et al. Improving the care of patients with non-ST-elevation acute coronary syndromes in the emergency department: the CRUSADE initiative. *Acad Emerg Med.* 2002;9:1146-55.
17. American Heart Association. ACTION Registry-Get With The Guidelines. 2010. Available at: <http://www.ncdr.com/webncdr/action/default.aspx>. Accessed October 23, 2012.
18. American Heart Association. Mission: Lifeline. 2011. Available at: http://www.heart.org/HEARTORG/HealthcareResearch/MissionLifelineHomePage/Mission-Lifeline-Home-Page_UCM_305495_SubHomePage.jsp. Accessed March 22, 2011.
19. Kushner FG, Hand M, Smith SC, Jr., et al. 2009 focused updates: ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction (updating the 2004 guideline and 2007 focused update) and ACC/AHA/SCAI guidelines on percutaneous coronary intervention (updating the 2005 guideline and 2007 focused update): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol.* 2009;54:2205-41.
20. Antman EM, Hand M, Armstrong PW, et al. 2007 focused update of the ACC/AHA 2004 guidelines for the management of patients with ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Circulation.* 2008;117:296-329.
21. Anderson JL, Adams CD, Antman EM, et al. ACC/AHA 2007 guidelines for the management of patients with unstable angina/non-ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the 2002 Guidelines for the Management of Patients With Unstable Angina/Non-ST-Elevation Myocardial Infarction). *J Am Coll Cardiol.* 2007;50:e1-157.
22. Thygesen K, Alpert JS, Jaffe AS, et al. Third universal definition of myocardial infarction. *J Am Coll Cardiol.* 2012;60:1581-98.
23. Executive Summary of The Third Report of The National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, And Treatment of High Blood Cholesterol In Adults (Adult Treatment Panel III). *JAMA.* 2001;285:2486-97.
24. Lewis WR, Ellrodt AG, Peterson E, et al. Trends in the use of evidence-based treatments for coronary artery disease among women and the elderly: findings from the get with the guidelines quality-improvement program. *Circ Cardiovasc Qual Outcomes.* 2009;2:633-41.
25. Cohen MG, Fonarow GC, Peterson ED, et al. Racial and ethnic differences in the treatment of acute myocardial infarction: findings from the Get With the Guidelines-Coronary Artery Disease program. *Circulation.* 2010;121:2294-301.
26. Peterson ED, Roe MT, Mulgund J, et al. Association between hospital process performance and outcomes among patients with acute coronary syndromes. *JAMA.* 2006;295:1912-20.
27. Tricoci P, Peterson ED, Roe MT. Patterns of guideline adherence and care delivery for patients with unstable angina and non-ST-segment elevation myocardial infarction (from the CRUSADE Quality Improvement Initiative). *Am J Cardiol.* 2006;98:30Q-5Q.
28. Ellerbeck EF, Jencks SF, Radford MJ, et al. Quality of care for Medicare patients with acute myocardial infarction. A four-state pilot study from the Cooperative Cardiovascular Project. *JAMA.* 1995;273:1509-14.

Committee Member	Employer/Title	Consultant	Speaker	Ownership/ Partnership/ Principal	Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Harry P. Selker	Tufts Medical Center— Executive Director of the Institute for Clinical Research and Health Policy Studies; Tufts University—Dean of Tufts Clinical and Translational Science Institute	None	None	None	None	None	None
David M. Shahian	Massachusetts General Hospital—Associate Director of the Codman Center for Clinical Effectiveness in Surgery	None	None	None	None	None	None
Richard E. Shaw	California Pacific Medical Center— Director—Research, Quality and Education	None	None	None	<ul style="list-style-type: none"> • Duke Clinical Research Institute • Schering Plough 	None	None
Sharon Sprenger Robert Swor	The Joint Commission William Beaumont Hospital	None None	None None	None None	None None	None None	None None
James A. Underberg	NYU Langone Center for Cardiovascular Disease Prevention; Bellevue Hospital Lipid Clinic— Director	<ul style="list-style-type: none"> • Genzyme • Liposcience 	<ul style="list-style-type: none"> • Abbott • AstraZeneca • Daiichi Sankyo • DiaDexus • Eli Lilly • GlaxoSmithKline • Kowa 	None	<ul style="list-style-type: none"> • Kowa 	None	None
Frans Van de Werf	University Hospitals Leuven—Professor of Cardiology	None	None	None	None	None	None
Bonnie H. Weiner	St. Vincent Hospital Worcester Medical Center—Director of Interventional Cardiology Research	None	None	None	None	None	None
William S. Weintraub	Christiana Care Health System—Section Chief, Cardiology	<ul style="list-style-type: none"> • AstraZeneca • Bayer • Bristol-Myers Squibb • Cardionet • Eli Lilly • Pfizer • Shionogi 	None	None	<ul style="list-style-type: none"> • Abbott • AstraZeneca • Bristol-Myers Squibb • Otsuka • Sanofi-aventis 	None	<ul style="list-style-type: none"> • 2011—Oral contraceptive litigation—represented defendant for general epidemiologic testimony • 2009—Aprotinin litigation—represented defendant as an expert witness for Aprotinin

This table represents the relationships of committee members with industry and other entities that were reported by authors 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 $\geq 5\%$ of the voting stock or share of the business entity, or ownership of $\geq \$10,000$ 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. A relationship is considered to be modest if it is less than significant under the preceding definition. Relationships in this table are modest unless otherwise noted.

APPENDIX 2. PEER REVIEW RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES—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

Peer Reviewer	Representation	Consultant	Speaker	Ownership/ Partnership/ Principal	Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Robert A. Guyton	ACCF—Board of Trustees	None	None	None	• National Institutes of Health	None	• 2011—Represented defendant—aortic dissection during coronary bypass
Jafna L. Cox	ACCF—Board of Governors	• AstraZeneca • Bayer • Boehringer-Ingelheim • Sanofi-aventis	None	None	None	• Heart and Stroke Foundation of Nova Scotia	None
Lloyd Klein Biykem Bozkurt	American Heart Association ACCF/AHA Data Standards Task Force Lead Reviewer	None None	None None	None None	None • Forest Pharmaceuticals	None • Amgen • Corthera • National Institute of Health • Novartis	None None
Darice Allard	Official Reviewer—Society of Chest Pain Centers and Providers	None	None	None	None	None	None
Les R. Becker	Official Reviewer—National Association of Emergency Medical Technicians	None	None	None	None	None	None
Deborah Diercks	Official Reviewer—American College of Emergency Physicians	None	None	None	None	None	None
Robert S. Gibson	Official Reviewer—American College of Physicians	None	None	None	None	None	None
Diane Gurney	Official Reviewer—Emergency Nurses Association	None	None	None	None	None	None
Jane Nelson-Worel	Official Reviewer—Preventive Cardiovascular Nurses Association	None	None	None	None	None	None
Richard L. Prager	Official Reviewer—Society of Thoracic Surgeons	None	None	None	None	None	None
Clyde B. Schecter	Official Reviewer—American College of Preventive Medicine	None	None	None	None	None	None
David K. Tan	Official Reviewer—National Association of EMS Physicians	None	None	None	None	None	None
Shari Targum	Official Reviewer—Food and Drug Association	None	None	None	None	None	None
Michael D. Brown	Content Reviewer	None	None	None	None	None	None
Angus Jameson	Content Reviewer	None	None	None	None	None	None
Robert L. McNamara	Content Reviewer	• Boehringer-Ingelheim • Ortho-McNeill	None	None	None	None	None
Mark Menegus	Content Reviewer	None	None	None	None	None	None
Joyce L. Ross	Content Reviewer	None	None	None	None	None	None
Thomas Tsai	Content Reviewer	None	None	None	None	None	None

This table represents the relevant relationships with industry and other entities that were disclosed by reviewers at the time of peer review. It 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 \$10,000 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. A relationship is considered to be modest if it is less than significant under the preceding definition. Relationships in this table are modest unless otherwise noted. Names are listed in alphabetical order within each category of review. Participation in the peer review process does not imply endorsement of this document.