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DATA STANDARDS

ACC/AHA 2013 Methodology for Developing Clinical Data Standards

A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards

ACC/AHA Task Force on Clinical Data Standards

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TABLE OF CONTENTS

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Preamble

The use of standardized language is essential for all communication in medicine, with the ultimate goal of improved patient care. This is the driving force for enhanced use of clinical data and standardization of the lexicon of cardiovascular medicine to enhance the use of clinical data. The American College of Cardiology (ACC)/American Heart Association (AHA) Task Force on Clinical Data Standards (Task Force) is at the fulcrum of these efforts, bringing together the 2 largest professional organizations that represent the House of Cardiology.

The mission statements of the ACC ("to transform cardiovascular care and improve heart health") and the AHA ("building healthier lives, free of cardiovascular diseases and stroke") have direct relevance to the work of the Task Force. The harmonization of cardiovascular terminology enables improved clinical communication, optimizes quality assurance, enhances process improvement efforts, facilitates clinical research, and is critical to the development and analysis of registries. Therefore, the work of the Task Force supports, enables, and advances the organizations' missions, visions, and strategies of key cardiovascular organizations in improving cardiovascular health.

This document is an update of the 2007 methodology paper (1). The goals of the current publication are 1) to describe recent changes in the methods for construction of data elements, 2) to clarify the current policies of the ACC and AHA regarding the relationships of Task Force and writing group members with industry and other entities, 3) to describe the need for harmonization of data across organizations and disciplines, 4) to articulate our position on the stewardship of cardiovascular terminology and the data concepts thereof, and 5) to describe our roles and approaches to accelerating the interoperability of cardiovascular data across the clinical, research, industry, registry, regulatory, administrative, and public domains.

The processes of data standard development and the work of the Task Force are dynamic, changing to be in line with the best available science and to facilitate optimal and cost-effective care, as well as clinical research. These changes are aimed at serving the members of the ACC, AHA, other healthcare professionals, and regulatory agencies and industry. Although many groups continue to develop and define the cardiovascular lexicon, this Task Force is committed to facilitating communication among organizations and key stakeholders to promote uniformity in cardiovascular terminology through the publication of commissioned manuscripts or revision and subsequent approval of previously developed documents. The continued emphasis of the Task Force is to promote a standardized terminology and encourage the usage of this unified lexicon. This document outlines current goals and methodology and proposes a road map for potential expansion of related activities to best serve all in the cardiovascular community.

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

1.0. Introduction

The ACC and AHA support the goals of their members to improve cardiovascular care and disease prevention through professional education, promotion of research, development of guidelines, and the formation of standards for cardiovascular care. All of this is focused on optimizing patient care and outcomes.

A common, standardized vocabulary of cardiovascular data elements is essential for healthcare professionals to communicate most effectively about clinical care, as well as to conduct clinical research involving observational studies, clinical trials, and data registries. Clinical documents, including procedural reports and reports of patient encounters, must use a common language to facilitate communication and incorporation of this information into structured reports and electronic health records (EHRs). Standardization of these records, especially with widespread use of EHRs, enables sharing of consistent data between providers. Additionally, clinical studies including randomized trials and data registries may provide a wealth of information, often composed of numerous data elements collected on hundreds of thousands of patients worldwide. Comparative analysis and interpretation of these studies also requires the use of standardized data definitions. Regulatory processes and healthcare operations, including U.S. Food and Drug Administration (FDA) submissions, compliance, and billing documentation can be greatly simplified by the use of a common parlance.

The ACC and AHA recognize the importance of data standards for describing the process and outcomes of clinical care whether in randomized trials, observational studies, registries, or quality improvement initiatives. Furthermore, the ACC and AHA agree that this common language must be instituted to further integrate the use of EHRs. Broad professional agreement on a common vocabulary with clear definitions will facilitate all of these functions.

The development of quality performance measurement initiatives, particularly those for which an evaluation of providers is an implicit or explicit aim, has further raised awareness among the professional community about the importance of data standards. This includes the development and use of performance measures and other quality metrics. A wide audience, including nonmedical professionals such as payers, regulators, and consumers, may therefore draw conclusions about outcomes in care based on these standards. For a fair comparison of care patterns and outcomes, the data elements that make up the descriptions of these patterns and outcomes must be clearly

defined, be consistently used, reflect current practice guidelines and recommendations, and be properly interpreted by a broad audience.

2.0. The ACC/AHA Task Force on Clinical Data Standards

2.1. History and Charge

To further efforts aimed at standardizing data and data definitions, the Task Force was established in 2004. The charge of this Task Force is to undertake the development and publication of clinical data standards composed of data elements and corresponding definitions to describe the evaluation, treatment, and outcomes of patients. Reporting to the ACC Board of Trustees and the AHA Science Advisory and Coordinating Committee, this Task Force is charged with serving as a source of expertise on clinical data standards, with tasks involved in directing the development and maintenance of data standards and definitions for cardiovascular medicine. As such, the publication of a set of clinical data standards represents the formal position and official policy of both organizations. To achieve these goals, the Task Force was charged with the following specific tasks:

1. Specify areas in cardiovascular medicine where data standards are required for research and epidemiological assessments and for use in clinical registries and cardiovascular disease–related documents such as guidelines, appropriate use criteria, and performance measures.
2. Specify and define, as appropriate, the data elements and corresponding definitions to be used in describing patient, diagnostic, and procedural characteristics; clinical management; and outcomes.
3. Define the methodology to guide the development and maintenance of clinical data standards.
4. Develop explicit strategies and processes to promote ongoing harmonization of clinical data standards across all ACC and AHA clinical documents and initiatives and potentially with other organizations and stakeholders.
5. Optimize opportunities for sharing data across various sources to promote optimal cardiovascular care and disease prevention.
6. Collaborate with other organizations and with internal ACC and AHA committees, including, but not limited to, the ACC/AHA Task Force on Performance Measures, the ACC/AHA Task Force on Practice Guidelines, the National Cardiovascular Data Registry, the Scientific and Quality Oversight Committee, the AHA Get With The Guidelines Steering Committee, the Guideline Advantage Program of the AHA, the American Diabetes Association, and American Cancer Society, the AHA Executive Database Steering Committee, and the ACC Informatics and Health Information Technology Task Force, as appropriate, in the development, maintenance, and promotion of clinical data standards.
7. Identify strategies to promote and implement ACC/AHA clinical data standards in a wide variety of environments, including, but not limited to, EHRs.

2.2. Relationship of the Task Force on Clinical Data Standards With Other Standards Organizations

The Task Force recognizes that data standardization activities are performed by groups outside of this Task Force, both within and outside the ACC and the AHA. The Clinical Data Interchange Standards Consortium has been spearheading the formation of data elements for clinical trials and regulatory submissions. A recent initiative cosponsored by the FDA and Duke Clinical Research Institute, entitled the Standardized Data Collection for Cardiovascular Imaging Initiative, has focused on developing cardiovascular data standards for documenting the findings of imaging studies as needed for regulatory decisions. Additionally, subgroups and additional projects have been undertaken within the AHA and ACC, including, but not limited to, registries from Get With The Guidelines (2) and the National Cardiovascular Data Registry (3), such as CathPCI, ACTION Registry–Get With The Guidelines (AR-G), and Carotid Artery Revascularization and Endarterectomy (CARE). Other organizations, such as the Academic Research Consortium (ARC) (4) and its Bleeding (BARC), Peripheral (PARC), and Valve (VARC) work groups, have been involved in data element construction. Unfortunately, many of these initiatives operate independently without centralized process or output.

Although groups such as Health Level Seven (HL7) (5), Systematized Nomenclature of Medicine—Clinical Terms (SNOMED-CT), and Digital Imaging and Communications in Medicine (DICOM) emphasize data transport and interoperability, the Task Force is charged with the development, selection, and maintenance of clinical definitions as data standards. Therefore, a central role is envisioned for the Task Force in the creation and harmonization of data elements fundamental to the work of other groups focusing on accomplishing interoperability and integration aspects.

2.3. ACC/AHA Stewardship of Cardiovascular Data Standards

As the 2 largest and most broadly representative organizations in cardiovascular medicine in the United States, the ACC and AHA represent a broad coalition of professionals. It is the position of these parent organizations that the Task Force be responsible for the stewardship of

cardiovascular data standards. Furthermore, the Task Force is to work closely with other stakeholders, including other subspecialty societies such as the Society of Thoracic Surgeons, the Heart Rhythm Society, the Clinical Data Interchange Standards Consortium, as well as the FDA, in developing a uniform lexicon for cardiovascular medicine.

Over the past several years, the Task Force has demonstrated its ability to convene multiple stakeholder groups to develop and maintain data standards for a multitude of needs, including structured reporting, EHRs, clinical registries and databases, and regulatory requirements. Given this background, it is the position of the ACC and AHA that the Task Force should serve as the single coordinating body for all cardiovascular data standard efforts and initiatives. When new data sets are to be developed or specific data elements require revision, the Task Force should coordinate these activities, bringing relevant stakeholders, including noncardiology groups, into the process to reach consensus on a single, harmonized set of cardiovascular data standards and definitions. This clearinghouse approach will ultimately alleviate the confusion that currently exists when multiple groups develop data standards. Although the Task Force recognizes that it does not and should not hold a monopoly on the process of developing data standards, the Task Force is ideally suited to optimize harmonization across many efforts to develop and maintain a consistent cardiovascular lexicon. Furthermore, the Task Force is committed to maintaining a rigorous and transparent process, as detailed in this document, preserving the integrity of the data standards produced while reducing the impact of potential conflicts of interest. It is through careful peer review and public comment that the Task Force standards have their strength, as well as the fact that the data standards documents reflect the official policy statements of the ACC and AHA.

3.0. Document Development Processes

3.1. Selection of Topics

The Task Force selects potential topics for creation of clinical data standards based on the importance of the cardiovascular condition or procedure, as well as the needs of the cardiovascular community. This may also include updates or revisions of existing data standards created by the Task Force in prior years. After topic selection, which is discussed and approved by the entire Task Force, the actual work product is created by a writing committee commissioned by the Task Force. Ultimately, standards approved first by the Task Force and then by the ACC Board of Trustees and the AHA Science Advisory and Coordinating Committee are published jointly in their respective journals, *Journal of the American College of Cardiology* and *Circulation*.

3.2. Composition of the Writing Committee

Once a topic has been selected, the Task Force names a chair of the writing committee, who works with Task Force members to select the members of the writing committee. Nominations for this committee are solicited from other key organizations and representatives from the cardiovascular community. Relevant professional organizations are invited to submit nominations to provide expertise and knowledge in a particular discipline. From the nominations received, the writing committee chair, in consultation with the Task Force, selects representatives from each invited professional organization. All participating organizations are given an opportunity to review the final document and are encouraged to endorse and/or publish it in the participating organizations' scientific journals.

3.3. Relationships With Industry and Other Entities

The Task Force makes every effort to avoid actual, potential, or perceived conflicts of interest that may arise as a result of relationships with industry or other entities. All members of the writing committee, as well as those selected to serve as peer reviewers of the documents, are required to disclose all current relationships and those existing within the 12 months before initiation of the writing effort. It is also required that the writing committee chair and at least 50% of writing committee members have no relevant relationships with industry and other entities (RWI). Because clinical data standards documents do not contain recommendations for clinical care or the use of specific products, the potential to benefit a specific pharmaceutical or device manufacturer should be negligible. Therefore, the Task Force has determined that only relationships with for-profit companies that maintain or license clinical vocabularies or clinical code sets or companies that provide solutions or products related to the application of data standards, such as EHR vendors, are relevant to data standards documents. A formal policy to this effect has been adopted by both the ACC and the AHA. Any writing committee member who develops new RWI during his or her tenure on the writing committee is required to notify the data standards staff in writing. These statements are reviewed periodically by the Task Force and members of the writing committee. Author and peer reviewer relationships with industry and other entities relevant to the data standards document are also disclosed in the document. For this document, relevant relationships disclosed by writing committee members and peer reviewers are listed in Appendixes 1 and 2, respectively. Additionally, to ensure complete transparency, writing committee members' comprehensive disclosure information, including relationships not relevant to this data standards document, is available online (see Comprehensive RWI Table).

3.4. Consensus Development

The ACC/AHA data standards are intended to be consensus, team-written documents. Each writing committee member contributes his or her expertise in

constructing data elements and the components thereof. Therefore, the final document reflects the agreement of the writing committee members in the creation of a formal, recognized set of clinical data standards. The writing committee usually meets both in person and by conference call over the course of the development of a document. Consensus is reached through discussion, e-mail, formal surveys, and confidential vote.

4.0. Building the Cardiovascular Vocabulary

4.1. Selection of Data Elements

Standard clinical concepts are evaluated to identify the list of candidate data elements. To ensure consistency, previously published versions of clinical data standards that remain acceptable should be adopted whenever possible. It is recognized that some terms are well established and may not need further definition by the Task Force. In the interest of harmonization, in many instances, the Task Force or writing committee may simply adopt or refer to terms from other documents or organizations such as terminologies pertaining to demographic information, symptoms, procedural details, laboratory test results, and medical treatments unless there are compelling reasons not to do so.

4.2. Data Element Components

Previous Task Force publications on data standards have primarily included listings of the data elements and data element definitions. To provide greater clarity, particularly for users involved in data collection and data management, the Task Force is expanding data element specifications to include the following data fields: 1) data element, 2) data element definition, 3) permissible values, 4) permissible value definitions, and 5) source definitions; that is, the source of the definition of a terminology, whether derived from the published literature, controlled terminology servers, registries, or other sources. The data element "myocardial infarction," its definition, and other specifications (6) are shown in Appendix 3.

With the rapidly changing and evolving need for standardized medical nomenclature that can be used for health information exchanges, the Task Force envisions the need to also specify the data fields to include 1) permissible value data type (statistical; e.g., categorical, Boolean, ordinal, cardinal, nominal, date-time), 2) permissible value data format (computational concepts; e.g., integer, whole number, yes-no, date-time, text), and 3) for dependent variables ("daughter variable"), identification of the parent and type of dependency. The addition of these data fields may be performed by other groups, such as the ACC Informatics and Health Information Technology Task Force and external organizations to more completely include the informatics needed for effective computational use.

4.3. Comprehensive Review of the Literature and Relevant Sources

The Task Force supports gathering candidate data elements and definitions from as many relevant resources as possible. Central to the foundation of all clinical data standards is a comprehensive review of the published literature and available resources. Examples of such resources include

1. Previously published ACC/AHA data standards, guidelines, and performance measures documents, ACC appropriate use criteria documents (http://www.cardiosource.org/Science-And-Quality/Practice-Guidelines-and-Quality-Standards.aspx), and other relevant national guidelines and clinical statements;
2. ACC/AHA registries, as well as other national and international registries, such as the Society of Thoracic Surgeons;
3. Intersocietal Accreditation Commission;
4. Cardiovascular subspecialty societies;
5. Standardized healthcare coding organizations and projects, including the International Classification of Diseases, SNOMED-CT, DICOM, Logical Observation Identifiers Names and Codes, and RxNorm;
6. Government standardization initiatives, including those from the FDA, Center for Medicare and Medicaid Services, Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, and the Centers for Disease Control and Prevention;
7. Clinical trial documentation and source material;
8. Metrics related to performance measurements derived from groups such as the National Quality Forum and The Joint Commission.

4.4. Development of Data Elements and Definitions

The overriding goal in developing clinical data standards is to focus on important variables needed to assess patient characteristics, including risk factors, lifestyle, severity of disease state, diagnostic variables, treatment with medication, interventional and other therapies, and outcomes. The writing committee balances completeness with length of definition, striving to be as concise as possible to facilitate use of these variables. Standardized definitions for each variable are a key work product. The writing committee considers greater specificity of definitions against the information that can be readily and reliably obtained from a medical record to make these definitions functional in various real world settings. Data standards writing committees aim for clarity, objectivity, and consistency throughout the writing process.

A main purpose of the writing committee is to construct definitions for a topic-specific area. Once the data element

list has been refined, a draft is prepared, including definitions of those data elements. Sample definitions from a variety of existing sources are used to provide assistance to writing committee members as they draft data element definitions.

Whenever possible, data definitions are linked to clinical practice guidelines and existing registries. Existing consensus definitions, especially those that are widely adopted or previously published, are not altered unless there is a compelling reason to change a specific definition, such as a change in evidence or clinical practice. This consistency across multiple documents and organizations is critical so as to promote the interoperability of terms and linkages of various databases and report documents.

5.0. Approval and Publication

5.1. Prepublication Processes and Board Approval

These are the review and approval steps taken to prepare the data standards documents for publication (Appendix 4):

a. ***Peer Review***
Draft sets of data elements are independently reviewed by official reviewers nominated by the ACC, AHA, the Task Force, collaborating organizations, and independent content reviewers, largely composed of various members from within a variety of ACC and AHA committees.

b. ***30-Day Public Comment Period***
To provide for broad input and review, the document is posted on the Internet for a 30-day public comment period. Efforts are made to publicize the comment period to obtain external input from the widest variety of stakeholders possible for refinement and clarification of definitions of data elements and their interpretation.

c. ***Resolution of Comments Received***
After the peer review and public comments are received, the writing committee chair is responsible for comment resolution and finalization of the document, with input from the members of the writing committee as needed. The writing committee reviews and approves the final document after the chair's completed resolution of the peer review and public comments. The document is then reviewed and approved by the entire Task Force before it is submitted for organizational approval.

d. ***ACC and AHA Approval***
The final document is forwarded to the ACC Board of Trustees and the AHA Scientific Advisory and Coordinating Committee for approval before publication.

e. ***Endorsement***
After approval, the final document is sent to relevant partnering and collaborating organizations for approval and endorsement and offered for possible publication in the respective journals of these additional organizations.

5.2. Publication and Promotion of Clinical Data Standards

The introduction and definition sections of the clinical data standards document are to be published in the *Journal of the American College of Cardiology* and *Circulation*. Additional information, including revised data standards, updates, or other supplemental information may be published online.

5.3. Updates and Revisions

As with guidelines and performance measures, data standards require regular review and updates. The writing committee chair, with the writing committee members and the Task Force, reviews the clinical data standards document 12 to 24 months after publication to assess the extent to which the document requires updating. Updates may reflect changes in the medical literature or medical practice, as well as revised ACC/AHA practice guidelines or more recent efforts in the creation and promotion of data standards.

6.0. The Future: Interoperability and Informatics

The development of standardized vocabularies in medicine facilitates the exchange of clinical information across numerous domains. A necessary requirement for effective, unambiguous electronic data interchange is to achieve both syntactic interoperability (i.e., the standards-based exchange of data between computer systems), and semantic interoperability (i.e., the exchange of data with retention of the *meaning* of that data such that machine-computable logic, data federation, inferential processing, and knowledge discovery are enabled) (7,8). Efforts to develop consensus vocabularies alone, without the computational representation and modeling of the meanings, linguistics, and usage contexts of the terms that make up those vocabularies, are unlikely to accomplish the desired state of semantic interoperability (9–11).

Informatics is the discipline called on to represent clinical concepts of a vocabulary via taxonomies (i.e., the relationship of terms with other terms), as use case diagrams (i.e., flow charts documenting the context in which a term is used), and in other technical artifacts needed by the computational community to achieve semantic interoperability.

Under 2 National Institutes of Health Roadmap contracts (2006–2008), a broad multi-stakeholder public-private effort (including the ACC) defined, developed, and

tested an approach to harmonize, standardize, represent, and model clinical data elements (12). The methodology relies on collaboration between clinical domain experts and informaticians to (clinically) define, formalize, and harmonize data element specifications while characterizing with fidelity the clinical concepts via informatics-based technical models and representation artifacts. As a key exemplar, the National Institutes of Health Roadmap project resulted in the creation of a Cardiovascular Domain Analysis Model (available at http://www.hl7.org/implement/standards/product_brief.cfm?produc_id=133) of the cardiovascular vocabulary terms for EHRs prepared by the Task Force (13).

The approach delineated in the NIH Roadmap project should prove formative in defining the future state. For example, the framework incorporates thesaurus-type relations between broad and specific concepts, as well as relations between concepts and representations. This is highly relevant to the harmonizing of terms both within the ACC and AHA (e.g., for use in registries) and outside these organizations (e.g., with SNOMED-CT) because it is an effective medium for communicating detailed clinical requirements to information technology experts across healthcare domains.

The process of Domain Analysis Model development also explicitly includes the development of stakeholder consensus through open public comment periods along with balloting of the Domain Analysis Model as an HL7 informative clinical standard. The technical details included in the Domain Analysis Model are published as structured content in publically available vocabulary servers, specifically the National Cancer Institute Thesaurus (http://ncit.nci.nih.gov). This assures that the content can be consumed by any information technology solution handling cardiovascular data. It is thus anticipated that the processes and procedures collaboratively developed via the National Institutes of Health Roadmap demonstration project will serve as the basis for the methodology for the ACC and AHA to write and steward cardiovascular controlled terminologies for use by the broadest set of stakeholders of healthcare data.

7.0. Conclusions

Since the publication of the original methods paper in 2007, a number of notable changes have occurred regarding the methodology for the development, specification, and maintenance of data standards. First, policies regarding RWI have undergone significant changes and are now included in this document. Second, the method for selection of writing committee members has been slightly altered; that is, the chair and 50% of committee members are without relevant RWI. Third, and perhaps most importantly, the need for integration of data standards across many organizations and disciplines has been emphasized in this document to strive for harmonization of data elements. Finally, the Task Force believes that its members should be the stewards of cardiovascular data standards and responsible for the creation and maintenance of these data standards. This stewardship will enable the use of a common lexicon for a wide variety of applications, including incorporation into EHRs, elements for structured reports, the basis for clinical registries and data repositories, and facilitation of regulatory submissions.

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REFERENCES

1. 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.
2. American Heart Association Get With The Guidelines Web page. Available at: http://www.heart.org/HEARTORG/HealthcareProfessional/GetWithTheGuidelinesHFStroke/Focus-on-Quality-Home-Page_UCM_306348_SubHomePage.jsp. Accessed October 24, 2012.
3. American College of Cardiology - National Cardiovascular Data Registry. Available at: https://www.ncdr.com/webncdr/. Accessed October 24, 2012
4. Krucoff MW, Mehran R, van Es GA, et al. The academic research consortium governance charter. JACC Cardiovasc Interv 2011;4:595–6.
5. Health Level Seven International (HL7) Web site. Available at: http://www.hl7.org/about/index.cfm?ref=nav. Accessed October 24, 2012.

6. Thygesen K, Alpert JS, Jaffe AS, et al. Third universal definition of myocardial infarction. Circulation 2012;126:2020–35.
7. Hammond WE. eHealth interoperability. Stud Health Technol Inform 2008;134:245–53.
8. Mead CN. Data interchange standards in healthcare IT—computable semantic interoperability: now possible but still difficult, do we really need a better mousetrap? J Healthc Inf Manag 2006;20:71–8.
9. Biondich PG, Downs SM, Carroll AE, et al. Collaboration between the medical informatics community and guideline authors: fostering HIT standard development that matters. AMIA Annu Symp Proc; 2006:36–40.
10. Evans DA, Cimino JJ, Hersh WR, et al. Toward a medical-concept representation language. The Canon Group. J Am Med Inform Assoc 1994;1:207–17.
11. Rector AL, Rogers J, Taweel A. Models and inference methods for clinical systems: a principled approach. Stud Health Technol Inform 2004;107:79–83.
12. Nahm ML, Walden AC, McCourt BJ, et al. Standardising clinical data elements. Int J Funct Inform and Personal Med 2012;3:314–41.
13. Weintraub WS, Karlsberg RP, Tcheng JE, et al. ACCF/AHA 2011 key data elements and definitions of a base cardiovascular vocabulary for electronic health records: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Clinical Data Standards. J Am Coll Cardiol 2011;58:202–22.

Key Words: ACC/AHA Data Standards ■ controlled vocabulary ■ methodology ■ healthcare data interoperability.

Appendix 1. Author Relationships With Industry and Other Entities (Relevant)—ACC/AHA 2013 Methodology for Developing Clinical Data Standards

Name	Employment	Consultant	Speaker	Ownership/ Partnership/ Principal	Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Robert C. Hendel (*Chair*)	University of Miami Miller School of Medicine—Director of Cardiac Imaging and Outpatient Services	None	None	None	None	None	None
Biykem Bozkurt	Michael E. DeBakey VA Medical Center—Chief, Cardiology Section	None	None	None	None	None	None
Gregg C. Fonarow	Ahmanson–UCLA Cardiomyopathy Center Division of Cardiology—Director; Professor of Medicine	None	None	None	None	• Steering Committee—GWTG (AHA)* • Steering Committee Chair AR-G*	None
Jeffrey P. Jacobs	All Children's Hospital and Florida Hospital for Children—Cardiovascular and Thoracic Surgeon	None	None	None	None	None	None
Judith H. Lichtman	Yale School of Public Health—Associate Professor of Epidemiology	None	None	None	None	None	None
Eric E. Smith	Calgary Stroke Program Department of Clinical Neurosciences—Associate Professor of Neurology	None	None	None	None	None	None
James E. Tcheng	Duke University Medical Center—Director, Duke Translational Medicine Institute, Biomedical Informatics Core; Professor of Medicine; Professor of Community and Family Medicine	• Cardiovascular Systems, Inc.	None	None		• Duke University Medical Center—Philips Medical Systems†	None
Tracy Y. Wang	Duke University Medical Center—Associate Professor of Medicine	None	None	None	None	None	None
William S. Weintraub	Christiana Care Health System—Chief of Cardiology	None	None	None	None	None	None

This table represents the relationships of committee members with industry and other entities that were determined to be relevant to this document. These relationships were reviewed and updated in conjunction with all meetings and/or conference calls of the writing committee during the document development process. The table does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of ≥5% of the voting stock or share of the business entity, or ownership of ≥$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. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted. Please refer to http://www.cardiosource.org/Science-And-Quality/Practice-Guidelines-and-Quality-Standards/Relationships-With-Industry-Policy.aspx for definitions of disclosure categories or additional information about the ACC/AHA Disclosure Policy for Writing Committees.

According to the ACC/AHA, a person has a *relevant* relationship IF: a) The *relationship or interest* relates to the same or similar subject matter, intellectual property or asset, topic, or issue addressed in the *document*; or b) The *company/entity* (with whom the relationship exists) makes a drug, drug class, or device addressed in the *document*, or makes a competing drug or device addressed in the *document*; or c) The *person or a member of the person's household*, has a reasonable potential for financial, professional, or other personal gain or loss as a result of the issues/content addressed in the *document*.

*No financial benefit.

†Significant relationship.

ACC indicates American College of Cardiology; AHA, American Heart Association; AR-G, ACTION Registry–Get With The Guidelines; GWTG, Get With The Guidelines; and VA, Veterans Affairs.

Appendix 2. Peer Reviewer Relationships With Industry and Other Entities—ACC/AHA 2013 Methodology for Developing Clinical Data Standards

Name	Representation	Employment	Consultant	Speaker	Ownership/ Partnership/ Principal	Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
John E. Brush	ACC—Board of Trustees	Cardiology Consultants	None	None	None	None	None	None
Geetha Raghuveer	ACC—Board of Governors	Children's Mercy Hospital	None	None	None	None	None	None
Alice M. Mascette	American Heart Association	NHLBI/NIH Division of Cardiovascular Sciences—Senior Clinical Science Advisor, Office of Special Projects	None	None	None	None	None	None
Nancy Albert	Content Reviewer	Cleveland Clinic Foundation—Senior Director of Nursing Research and CNS, Kaufman Center for Heart Failure	• Gambro • BG Medicine • Medtronic	None	None	None	None	None
William B. Borden	Content Reviewer	Weill Cornell Medical College	• US Department of Health and Human Services†	None	None	• Robert Wood Johnson Foundation†	None	None
Virginia Howard	Content Reviewer	University of Alabama at Birmingham—Professor, Department of Epidemiology, School of Public Health	• Bayer Healthcare†	None	None	• NIH—Principal Investigator†	None	• Defendant, Chantix and risk of adverse events, 2012
Mark D. Huffman	Content Reviewer	Northwestern University Feinberg School of Medicine—Assistant Professor						
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*No financial benefit.

†Significant relationship.

ACC indicates American College of Cardiology; NFL, National Football League; NHLBI, National Heart, Lung, and Blood Institute; and NIH, National Institutes of Health.

Appendix 3. Sample Data Element and Definition: Myocardial Infarction (6)

Terminology Concept (Data Element)	Concept Definition	Permissible Values	Permissible Values Definitions	Additional Notes	References
Myocardial infarction, acute	Clinical syndrome where there is evidence of myocardial necrosis in a clinical setting consistent with acute myocardial ischemia	Yes			Thygesen K, Alpert JS, Jaffe AS, et al; the Writing Group on behalf of the Joint ESC/ACCF/AHA/WHF Task Force for the Universal Definition of Myocardial Infarction. Third universal definition of myocardial infarction. J Am Coll Cardiol. 2012;60:1581-98.
Myocardial infarction, acute	Type of myocardial infarction				
		Type 1: Spontaneous	Spontaneous clinical syndrome related to atherosclerotic plaque rupture, ulceration, fissuring, erosion, or dissection, with resulting intraluminal thrombus and leading to decreased myocardial blood flow or distal platelet emboli with ensuing myocyte necrosis. This classification requires a) detection of a rise and/or fall of cardiac biomarker values (preferably cTn) with at least 1 value >99th percentile of the URL and b) at least 1 of the following: – Symptoms of myocardial ischemia – New or presumed new significant ST–T changes or new LBBB on the ECG – 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	cTn—I or T—is the preferred biomarker. If a cTn assay is not available, the best alternative is CKMB (measured by mass assay). One or more coronary arteries may be involved. The patient may have underlying severe coronary artery disease but on occasion may have nonobstructive or no coronary artery disease.	
		Type 2: Ischemic imbalance	Spontaneous clinical syndrome where a condition other than coronary artery disease contributes to an imbalance between myocardial oxygen supply and/or demand (e.g., coronary endothelial dysfunction, coronary artery spasm, coronary embolism, tachy-/bradyarrhythmias, anemia, respiratory failure, hypotension, and hypertension with or without left ventricular hypertrophy). This classification requires detection of a) rise and/or fall of cardiac biomarker values (preferably cTn) with at least 1 value >99th percentile of the URL and b) at least 1 of the following: – Symptoms of myocardial ischemia – New or presumed new significant ST–T changes or new LBBB on the ECG – Development of pathological Q waves on the ECG – Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality.	cTn—I or T—is the preferred biomarker. If a cTn assay is not available, the best alternative is CKMB (measured by mass assay).	

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Appendix 3. Continued

Terminology Concept (Data Element)	Concept Definition	Permissible Values	Permissible Values Definitions	Additional Notes	References
		Type 3: Death, no biomarkers	Death where symptoms suggestive of myocardial ischemia are present and with (presumed) new ischemic changes or new LBBB on ECG but where death occurs before cardiac biomarkers can be obtained or before cardiac biomarker values could rise.		
		Type 4a: PCI related	Myocardial infarction associated with and occurring within 48 h of PCI, with elevation of cardiac biomarker values to >5× 99th percentile of the URL in patients with normal baseline values (≤99th percentile URL) or a rise of cardiac biomarker values ≥20% if the baseline values are elevated and are stable or falling. This classification also requires at least 1 of the following: – Symptoms of myocardial ischemia – New ischemic ECG changes or new LBBB – Angiographic loss of patency of a major coronary artery or a side branch or persistent slow- or no-flow or embolization – Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality.	cTn—I or T—is the preferred biomarker. If a cTn assay is not available, the best alternative is CKMB (measured by mass assay).	
		Type 4b: Stent thrombosis	Myocardial infarction associated with stent thrombosis as detected by coronary angiography or at autopsy, where symptoms suggestive of myocardial ischemia are present, and with a rise and/or fall of cardiac biomarkers values, with at least 1 value >99th percentile of the URL.	cTn—I or T—is the preferred biomarker. If a cTn assay is not available, the best alternative is CKMB (measured by mass assay).	
		Type 4c: Stent restenosis	Myocardial infarction associated with stent restenosis as detected by coronary angiography or at autopsy, occurring >48 h after PCI, without evidence of stent thrombosis but with symptoms suggestive of myocardial ischemia, and with elevation of cardiac biomarker values to >99th percentile of the URL. This classification also requires the following: – Does not meet criteria for any other classification of myocardial infarction – Presence of ≥50% stenosis at the site of previous successful stent PCI.	cTn—I or T—is the preferred biomarker. If a cTn assay is not available, the best alternative is CKMB (measured by mass assay). Type 4c is described in the Third Universal Definition of MI.	

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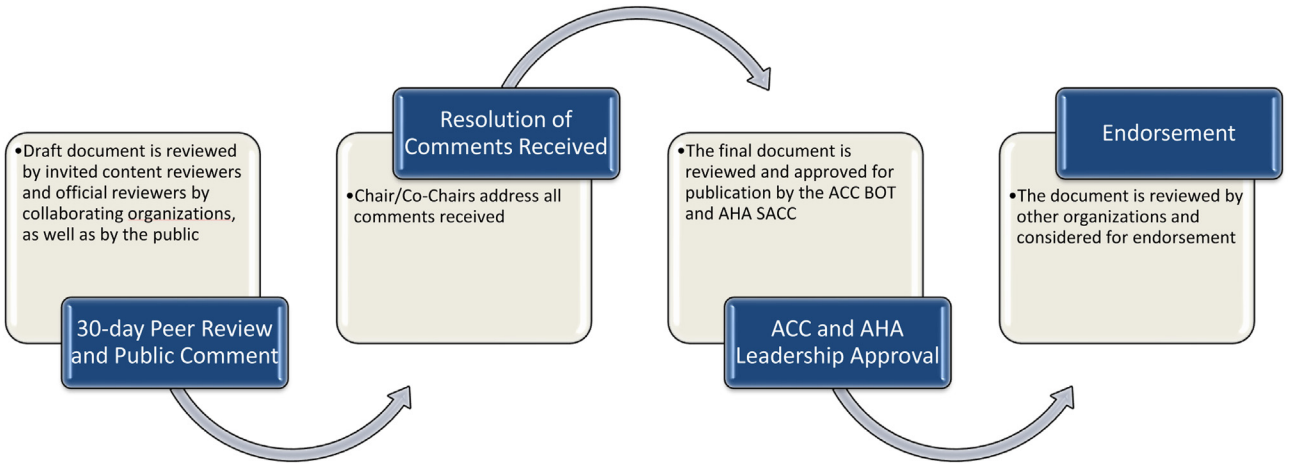
Appendix 3. Continued

Terminology Concept (Data Element)	Concept Definition	Permissible Values	Permissible Values Definitions	Additional Notes	References
		Type 5: CABG related	Myocardial infarction associated with and occurring within 48 h of CABG surgery, with elevation of cardiac biomarker values to >10× 99th percentile of the URL in patients with normal baseline cardiac biomarker values (≤99th percentile URL). This classification also requires at least 1 of the following: – New pathologic Q waves or new LBBB on ECG – Angiographic new graft or new native coronary artery occlusion – Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality.	cTn—I or T—is the preferred biomarker. If a cTn assay is not available, the best alternative is CKMB (measured by mass assay).	

ACC indicates American College of Cardiology; AHA, American Heart Association; CABG, coronary artery bypass graft; CKMB, creatine kinase MB; cTn, cardiac troponin; ECG, electrocardiogram; ESC, European Society of Cardiology; LBBB, left bundle-branch block; PCI, percutaneous coronary intervention; ST–T, ST-segment–T wave; URL, upper reference limit; and WHF, World Heart Federation.



Appendix 4. ACC/AHA Clinical Data Standards Document Approval and Publication Process

ACC indicates American College of Cardiology; AHA, American Heart Association; BOT, Board of Trustees; and SACC, Science Advisory and Coordinating Committee.