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

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

Biykem Bozkurt, MD, PhD, FACC, FAHA
Gregg C. Fonarow, MD, FACC, FAHA
Jeffrey P. Jacobs, MD, FACC
Judith H. Lichtman, PhD, MPH

Eric E. Smith, MD, MPH, FAHA
James E. Tcheng MD, FACC
Tracy Y. Wang, MD, MHS, FACC
William S. Weintraub, MD, FACC, FAHA

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Appendix 1. Author Relationships With Industry and Other Entities (Relevant) ......................... 23
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 is at the fulcrum of these efforts, bringing together the 2 largest professional organizations which represent the House of Cardiology.

The mission statements of both 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 on Clinical Data Standards. 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 on Clinical Data Standards supports, enables, and advances the 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 relationships of Task Force and Writing Group members with industry and other entities, 3) describes the need for harmonization of data across organizations and discipline, 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 Clinical Data Standards 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, as well as regulatory agencies and industry. While 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 regarding 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 paper outlines current goals and methodology, and proposes a roadmap for potential expansion of related activities, so as 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.

For healthcare professionals to most effectively communicate regarding clinical care, as well as conduct clinical research involving observational studies, clinical trials and data registries, a common, standardized vocabulary of cardiovascular data elements is essential. Clinical documents, including procedural reports and patient encounters, must utilize a common language to facilitate communication and incorporation 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 comprised 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 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 regarding 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 regarding outcomes in care based on these standards. For comparison of care patterns and outcomes to be fair, the data elements that compose the descriptions of these patterns and outcomes must be clearly defined, 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 ACC/AHA Task Force on Clinical Data Standards (Task Force) was established in 2004. The charge of this Task Force is to undertake the development and publication of clinical data standards comprised of data elements and corresponding definitions to describe the evaluation, treatment, and outcomes of patients. Reporting to the Board of Trustees of the ACC and the Science Advisory and Coordinating Committee of the AHA, 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 the aforementioned goals, the Task Force was charged with specific tasks:
1) Specify areas within cardiovascular medicine where data standards are required for research and epidemiologic 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 ongoing 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, as well as 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, Scientific and Quality Oversight Committee, the AHA Get With The Guidelines Steering Committee, The Guideline Advantage Program from the AHA, 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 co-sponsored by the U.S. Food and Drug Administration 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 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). Furthermore, other organizations such as the Academic Research Consortium (ARC) (4) and its Bleeding (BARC), Peripheral (PARC), and Valve (VARC) workgroups have been involved in data element construction. Unfortunately, many of these initiatives operate independently without a centralization of 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 the clinical definitions as data standards. Therefore, a central role is envisioned for the ACC/AHA Task Force on Clinical Data Standards in the creation and harmonization of data elements, fundamental to the work of other groups focusing on accomplishing the 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, Heart Rhythm Society, Clinical Data Interchange Standards Consortium, and the U.S. Food and Drug Administration, 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 is currently present 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 data standards development, 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, 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 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 ACC/AHA Task Force on Clinical Data Standards 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 Board of Trustees of the ACC and Science Advisory and Coordinating Committee of the AHA are
published jointly in the respective society journals, the *Journal of the American College of Cardiology*
and *Circulation*.

3.2. Writing Committee Composition

Once a topic has been selected, the Task Force selects a chair of the writing committee who
works in conjunction 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 nominations received, the writing
committee chair, in consultation with the Task Force, selects representatives from each invited
professional organization. All participating organizations are provided an opportunity to review the
3.3. Relationship With Industry and Other Entities

The ACC/AHA Task Force on Clinical Data Standards 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 prior to the initiation of the writing effort. It is also required that the writing committee chair and at least 50% of the writing committee have no relevant relationships with industry and other entities (RWI). Because clinical data standards documents do not contain recommendations regarding clinical care or the use of specific products, the potential to benefit a specific pharmaceutical or device manufacturing company 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/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/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 by 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, the writing committee member’s comprehensive disclosure information including relationships not relevant to the data standards
3.4. Consensus Development

The ACC/AHA data standards are intended to be consensus, team-written documents. Each writing committee member contributes his/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 via conference calls 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 to be further defined by the Task Force. In the interest of harmonization, in many instances, the Task Force or writing committee may simply adopt or reference terms from other documents or organizations such as terminologies pertaining to demographic information, symptoms, procedural details, laboratory results and medical therapies unless there are compelling reasons not to do so.
4.2. Data Element Components

Previous data standards publications by the Task Force 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, where the definition of a terminology is derived from whether a published literature, controlled terminology servers, registries; and so on.

Appendix 3 shows the data element myocardial infarction, its definition and other specifications (6).

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 Informatics and Health Information Technology Task Force of the ACC and external organizations to more completely include the informatics needed for effective computational use.

4.3. Comprehensive Review of Literature and Relevant Sources

The ACC/AHA Task Force on Clinical Data Standards supports gathering candidate data elements and definition from as many relevant resources as possible. Central to the foundation of all
clinical data standards is a comprehensive review of published literature and available resources.

Examples of such resources include:

a. 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;

b. ACC/AHA registries as well as other national and international registries, such as Society of Thoracic Surgeons;

c. Intersocietal Accreditation Commission, and cardiovascular subspecialty societies;

d. Standardized healthcare coding organizations and projects including: the International Classification of Diseases, SNOMED-CT, DICOM, Logical Observation Identifiers Names and Codes, and RxNorm.

e. Government standardization initiatives including those from the U.S. Food and Drug Administration, 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;

f. Clinical trial documentation and source material.

g. 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 characteristics of patients, 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: Diagram of the Approval and Publication Process):

a. Peer Review.
Draft sets of data elements are independently reviewed by official reviewers nominated by the ACC, AHA, the ACC/AHA Task Force on Clinical Data Standards, collaborating organizations, as well as independent content reviewers, largely comprised 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 Web 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 for 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 approved by the entire Task Force prior to submission for organizational approval.

d. ACC and AHA Approval

The finalized document is forwarded for approval before publication by the ACC Board of Trustees and the AHA Scientific Advisory and Coordinating Committee.
e. Endorsement

After approval, the finalized 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 in *Circulation*. Additional information, including revised data standards, updates or other supplemental information may be published online.

5.3. Updates and Revisions

Similar to guidelines and performance measures, data standards require regular review and updating. The writing committee chair in conjunction with the writing committee members along with the Task Force reviews the clinical data standards document in 12 to 24 months after publication to assess the extent to which the document requires updating. Updates may be reflective of changes in the medical literature or in 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 comprising 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 authoring of a Cardiovascular Domain Analysis Model (available at http://www.hl7.org/implement/standards/product_brief.cfm?produ_id=133) of the cardiovascular vocabulary terms for EHRs authored by the ACC/AHA Task Force on Clinical Data Standards (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) as 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 us to author 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 writing committee selection has been slightly altered; that is, a committee is composed of a chair and 50% writing committee members 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, so as to strive for harmonization of data elements. Finally, the ACC/AHA Task Force on Clinical Data Standards believes that this Task Force should be the stewards of cardiovascular data standards, responsible for the creation and maintenance of these
data standards. This stewardship will enable the use of a common lexicon to be used 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.

Staff

**American College of Cardiology Foundation**
Shalom Jacobovitz, Chief Executive Officer
Charlene May, Senior Director, Science and Clinical Policy
Melanie Shahriary, RN, BSN, Director, Performance Measures and Data Standards

**American College of Cardiology Foundation/American Heart Association**
Maria Lizza D. Isler, BSMT, Specialist, Clinical Data Standards

**American Heart Association**
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 B. Turner, MPH, Science and Medicine Advisor, Office of Science Operations
Jody Hundley, Production Manager, Scientific Publications, Office of Science Operations

**Key Words:** AHA Scientific Statements • controlled vocabulary • methodology • healthcare data interoperability.
References


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

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<thead>
<tr>
<th>Name</th>
<th>Employment</th>
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<th>Institutional, Organizational or Other Financial Benefit</th>
<th>Expert Witness</th>
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<tbody>
<tr>
<td>Robert C. Hendel (Chair)</td>
<td>University of Miami Miller School of Medicine—Director of Cardiac Imaging and Outpatient Services</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Biykem Bozkurt</td>
<td>Michael E. DeBakey VA Medical Center—Chief, Cardiology Section</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Gregg C. Fonarow</td>
<td>Ahmanson-UCLA Cardiomyopathy Center Division of Cardiology—Director; Professor of Medicine</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>• Steering Committee – GWTG (AHA)*</td>
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<td>• Steering Committee Chair AR-G*</td>
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<tr>
<td>Jeffrey P. Jacobs</td>
<td>All Children’s Hospital and Florida Hospital for Children—Cardiovascular and Thoracic Surgeon</td>
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<tr>
<td>Judith H. Lichtman</td>
<td>Yale School of Public Health — Associate Professor of Epidemiology</td>
<td>None</td>
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### ACC/AHA Data Standards Methodology

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<tr>
<td>Eric E. Smith</td>
<td>Calgary Stroke Program Department of Clinical Neurosciences—Associate Professor of Neurology</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>James E. Tcheng</td>
<td>Duke University Medical Center—Director, Duke Translational Medicine Institute, Biomedical Informatics Core; Professor of Medicine; Professor of Community and Family Medicine</td>
<td>• Cardiovascular Systems, Inc.</td>
<td>None</td>
<td>• Duke University Medical Center – Philips Medical Systems†</td>
</tr>
<tr>
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<td>Duke University Medical center—Associate Professor of Medicine</td>
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* No financial benefit.
† Significant relationship
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<table>
<thead>
<tr>
<th>Name</th>
<th>Representation</th>
<th>Employment</th>
<th>Consultant</th>
<th>Speaker</th>
<th>Ownership/Partnership/Principal</th>
<th>Research</th>
<th>Institutional, Organizational or Other Financial Benefit</th>
<th>Expert Witness</th>
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<tr>
<td>John E. Brush</td>
<td>ACC – Board of Trustees</td>
<td>Cardiology Consultants</td>
<td>None</td>
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<tr>
<td>Geetha Raghuveer</td>
<td>ACC – Board of Governors</td>
<td>Children’s Mercy Hospital</td>
<td>None</td>
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<tr>
<td>Alice M. Mascette</td>
<td>American Heart Association</td>
<td>NHLBI/NIH Division of Cardiovascular Sciences—Senior Clinical Science Advisor, Office of Special Projects</td>
<td>None</td>
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<tr>
<td>Nancy Albert</td>
<td>Content Reviewer</td>
<td>Cleveland Clinic Foundation – Senior Director of Nursing Research and CNS, Kaufman Center for Heart Failure</td>
<td>None</td>
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<tr>
<td>Name</td>
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<td>Funding</td>
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<tr>
<td>William B. Borden</td>
<td>Content Reviewer</td>
<td>Weill Cornell Medical College</td>
<td>U.S. Department of Health and Human Services†</td>
<td>None</td>
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<tr>
<td>Virginia Howard</td>
<td>Content Reviewer</td>
<td>University of Alabama at Birmingham—Professor, Department of Epidemiology, School of Public Health</td>
<td>Bayer Healthcare†</td>
<td>NIH—Principal Investigator †</td>
<td>None</td>
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<tr>
<td>Mark D. Huffman</td>
<td>Content Reviewer</td>
<td>Northwestern University Feinberg School of Medicine – Assistant Professor</td>
<td>None</td>
<td>None</td>
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</tr>
<tr>
<td>Hani Jneid</td>
<td>Content Reviewer</td>
<td>Baylor College of Medicine—Assistant Professor of Medicine; Director of Interventional Cardiology Research, Division of Cardiology</td>
<td>None</td>
<td>None</td>
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<tr>
<td>Suzanne Judd</td>
<td>Content Reviewer</td>
<td>University of Alabama at Birmingham—Associate Professor</td>
<td>None</td>
<td>None</td>
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</tbody>
</table>

† Indicates financial support or other significant relationships.
### Hendel et al.
ACC/AHA Data Standards Methodology

#### Dariush Mozaffarian
Content Reviewer
Brigham & Women’s Hospital and Harvard Medical School—Associate Physician
- Bunge, Pollock Institute, Quaker Oats, Life Sciences Research Organization, and Nutrition Impact
- Foodminds, McKinsey Health Systems Institute
- Patent*
- UpToDate
- GlaxoSmithKline, Sigma Tau, Pronova, and NIH†
- Unilever North America Scientific Advisory Board

#### Peter Tilkemeier
Content Reviewer
Warren Alpert Medical School of Brown University—Associate Professor of Medicine
None
None
None
None
None
None

#### Salim Virani
Content Reviewer
Baylor College of Medicine—Assistant Professor
None
None
None
None

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* No financial benefit
† Significant relationship
### Appendix 3. Sample Data Element and Definition – Myocardial Infarction (6)

<table>
<thead>
<tr>
<th>Terminology concept (data element)</th>
<th>Concept definition</th>
<th>Permissible values</th>
<th>Permissible values definitions</th>
<th>Additional Notes</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myocardial infarction, acute</td>
<td>Clinical syndrome where there is evidence of myocardial necrosis in a clinical setting consistent with acute myocardial ischemia</td>
<td>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 cardiac troponin (cTn)] with at least one value &gt;99th percentile of the upper reference limit (URL) and b) at least one of the following: -- symptoms of myocardial ischemia -- new or presumed new significant ST-segment–T wave (ST–T) changes or new left bundle branch block (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.</td>
<td>Cardiac troponin (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 non-obstructive or no coronary artery disease.</td>
<td>Yes</td>
<td>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. J Am Coll Cardiol 60:1-18, 2012.</td>
</tr>
</tbody>
</table>
| 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-/brady-arrhythmias, 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 cardiac troponin (cTn)] with at least one value >99th percentile of the upper reference limit (URL) and b) at least one of the following:  
-- symptoms of myocardial ischemia  
-- new or presumed new significant ST-segment–T wave (ST–T) changes or new left bundle branch block (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. | Cardiac troponin (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 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 percutaneous coronary intervention, with elevation of cardiac biomarker values to >5x 99th percentile of the upper reference limit (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 one 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. | Cardiac troponin (cTn) - I or T - is the preferred biomarker. If a cTn assay is not available, the best alternative is CKMB (measured by mass assay). |
<table>
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<tr>
<th>Type</th>
<th>Description</th>
<th>Criteria and Additional Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 4b: stent thrombosis</td>
<td>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 one value &gt;99th percentile of the upper reference limit.</td>
<td>Cardiac troponin (cTn) - I or T - is the preferred biomarker. If a cTn assay is not available, the best alternative is CKMB (measured by mass assay).</td>
</tr>
<tr>
<td>Type 4c: stent restenosis</td>
<td>Myocardial infarction associated with stent restenosis as detected by coronary angiography or at autopsy, occurring more than 48h after percutaneous coronary intervention, without evidence of stent thrombosis but with symptoms suggestive of myocardial ischemia, and with elevation of cardiac biomarker values to &gt;99th percentile of the upper reference limit (URL). This classification also requires the following: -- does not meet criteria for any other classification of myocardial infarction -- presence of a &gt;=50% stenosis at the site of previous successful stent PCI.</td>
<td>Cardiac troponin (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 text of the Third Universal Definition of MI.</td>
</tr>
<tr>
<td>Type 5: CABG related</td>
<td>Myocardial infarction associated with and occurring within 48h of coronary artery bypass graft surgery, with elevation of cardiac biomarker values to &gt;10x 99th percentile of the upper reference limit (URL) in patients with normal baseline cardiac biomarker values (&lt;99th percentile URL). This classification also requires at least one 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.</td>
<td>Cardiac troponin (cTn) - I or T - is the preferred biomarker. If a cTn assay is not available, the best alternative is CKMB (measured by mass assay).</td>
</tr>
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</table>
Appendix 4. ACC/AHA Clinical Data Standards Document Approval and Publication Process

- Draft document is reviewed by invited content reviewers and official reviewers by collaborating organizations, as well as by the public.
- Chair/Co-Chairs address all comments received.
- The final document is reviewed and approved for publication by the ACCF BOT and AHA SACC.
- The document is reviewed by other organizations and considered for endorsement.

30-day Peer Review and Public Comment
Resolution of Comments Received
ACCF and AHA Leadership approval
Endorsement
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

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<th>Research</th>
<th>Institutional, Organizational or Other Financial Benefit</th>
<th>Expert Witness</th>
</tr>
</thead>
</table>
| Robert C. Hendel      | University of Miami Miller School of Medicine Cardiac Division—Director of Cardiac Imaging and Outpatient Services | • Astellas Pharma  
• Bayer                     | None                              | None                            | None                                                                | None                                                      | None            |
| Biykem Bozkurt        | Michael E. DeBakey VA Medical Center—Chief, Cardiology Section              | None                                        | None                              | None                            | • Forest Pharmaceuticals *  
• NIH                      | None                                                      | None            |
| Gregg C. Fonarow      | Ahmanson-UCLA Cardiomyopathy Center Division of Cardiology—Director, Professor of Medicine | • Amgen  
• Gambro  
• Johnson & Johnson  
• Medtronic  
• Novartis  
• Pfizer  
• Takeda                    | None                              | None                            | • NHLBI*  
• NIH/NIAID*  
• Novartis*                | • Steering Committee – GWTG (AHA)†  
• Steering Committee Chair AR-G†  
• Steering Committee – Improve Heart Failure (Medtronic)† | None            |
| Jeffrey P. Jacobs     | All Children’s Hospital and Florida Hospital for Children—Cardiovascular and Thoracic Surgeon | None                                        | None                              | None                            | • COAST DSMB†  
• NIH Challenge Grant†                              | None                                                      | None            |
<p>| Judith H. Lichtman    | Yale University School of Public Health—Associate Professor of Epidemiology | None                                        | None                              | None                            | • NIH                                                              | None                                                      | None            |</p>
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<th>Medical Device Manufacturer</th>
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<td>Eric E. Smith</td>
<td>Calgary Stroke Program Department of Clinical Neurosciences — Associate Professor of Neurology</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>• AHA†</td>
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<tr>
<td>James E. Tcheng</td>
<td>Duke University Medical Center — Director, DTMI Biomedical Informatics Core; Professor of Medicine; Professor of Community and Family Medicine</td>
<td>• Cardiovascular Systems, Inc.</td>
<td>None</td>
<td>None</td>
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<td>William S. Weintraub</td>
<td>Christiana Care Health System— Chief of Cardiology</td>
<td>• BMS</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>• Expert Witness, Celebrex Litigation, 2008</td>
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* Significant relationship
† No financial benefit

AHA indicates American Heart Association; AR-G, Action Registry-Get With the Guidelines; BMS, Bristol-Myers Squibb; COAST DSMB, Coartation of the Aorta Stent Trial Data and Safety Monitoring Board; NHLBI, National Heart, Lung and Blood Institute; NIAID, National Institute of Allergy and Infectious Diseases; and NIH, National Institutes of Health.