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

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Preamble

The American College of Cardiology/American Heart Association (ACC/AHA) Task Force on Clinical Data Standards has undertaken the task to develop and publish clinical data standards—data elements and corresponding definitions that can be used in the measurement of patient clinical management and outcomes, and for research and epidemiological assessments. A methodology has been created that describes the formation of a diverse writing committee, guidelines for selecting and defining the standards, and achieving consensus in the development of the standards, peer review, and publication including periodic updates. A systematic approach to defining data elements is important for accurate and efficient performance of clinical research, medical record documentation, and quality assessment.

I. 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 standards for cardiovascular care, and fostering policy that supports optimal patient outcomes.

In clinical care and in research studies, caregivers communicate with each other through a common vocabulary. In the field of cardiology, large-scale clinical trials, registries, and other databases have provided a wealth of information on hundreds of thousands of patients. These data have been used to define new therapies and improve the quality of clinical care through evaluation of both care process and outcomes for patients with a range of cardiovascular conditions.

The integrity of clinical research depends in large part on firm adherence to prespecified procedures for patient enrollment and follow-up; these procedures are guaranteed through careful attention to definitions enumerated in the study design and case report forms. When data elements and definitions are standardized across studies, comparison, pooled analysis, and meta-analysis are enabled, thus deepening our understanding of individual clinical trials. This is particularly important for meta-analyses of trials where differences in data collection methods and in definitions may hamper the validity of these analyses.

II. Purpose and Scope of the ACC/AHA Clinical Data Standards

The ACC and the AHA recognize the importance of standardizing a common lexicon for describing the process and outcomes of clinical care, whether in randomized trials, observational studies, registries, or quality improvement initiatives. Broad professional agreement on a common vocabulary with common definitions will facilitate cross-study comparisons. Also, when advantageous, the combining of data across studies will improve the assessment of any project's generalizability to clinical practice.

The development of quality performance measurement initiatives, particularly those for which comparison of providers is an implicit or explicit aim, has further raised awareness among the professional community regarding the importance of data standards. For the first time, a wide audience, including non-medical professionals such as payers, regulators, and consumers, may draw conclusions about care and outcomes. For understanding and comparison of care patterns and outcomes to be fair, the data elements that compose the descriptions of these patterns and outcomes of care must be clearly defined, consistently used, and properly interpreted by a broader audience than ever before.

To further efforts aimed at standardizing such a lexicon, the ACC/AHA Task Force on Clinical Data Standards has undertaken the task to develop and publish clinical data standards—data elements and corresponding definitions that can be used in the measurement of patient clinical management and outcomes, and for research and epidemiological assessments.

The ACC and AHA recognize the importance of the use of clinical data for patient management, in the assessment of patient outcomes, and in research efforts focused on improving clinical treatment of patients. The goals that the ACC/AHA clinical data standards documents hope to fulfill by enumeration of key data elements and their standardized definitions are as follows:

1. Facilitate clinical research by driving standards for information gathered in clinical trials.
2. Improve cross-comparison of results and clinical outcomes between different trials and registries.
3. Facilitate the development and conduct of future registries, at both hospital and national levels, by providing a list of major variables, outcomes, and definitions.
4. Become the basis for a standardized medical record process with the anticipation that medical information will continue its progress to an electronic format. Data standards will provide exchange of data across different electronic medical information systems.
5. Enable seamless integration of guidelines through development of performance measures and quality assessment data collection.

III. Methodology for Developing the Clinical Data Standards

A. Selection of Topics for Developing the Clinical Data Standards

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

and/or procedure that would benefit from the creation of a set of data standards, as well as the intended purpose (see the previous listing of goals). The Task Force uses current ACC/AHA Clinical Practice Guidelines and ACC and AHA registries and quality improvement initiatives as a basis for addressing current and growing areas of interest in cardiovascular medicine. Once a topic has been selected and approved by the Task Force, the next levels of refinement are carried out by the ACC/AHA Clinical Data Standards Writing Committees. A goal of the Task Force is to publish the data standards simultaneously with the relevant ACC/AHA guideline or registry initiation.

B. Organization and Composition of a Clinical Data Standards Writing Committee

1. Writing Committee Formation

After a topic has been selected, the Task Force members select the chair of the writing committee, who then works in conjunction with Task Force members to select the writing committee members.

2. Involvement of Related Professional Organizations

When appropriate, related professional organizations are invited to submit nominations to provide expertise in specialized areas. From these nominations, the Writing Committee Chair, in consultation with the Task Force Chair, selects representatives from each invited professional organization to serve on the Writing Committee. These organizations will have an opportunity to review the final document and are encouraged to endorse and/or publish it in their own journals.

3. Relationships With Industry

The ACC/AHA Task Force on Clinical Data Standards makes every effort to avoid any actual or potential conflicts of interest that may arise as a result of an outside relationship or a personal, professional, or business interest of a member of the writing panel. Specifically, all members of the writing group are required to complete and submit a disclosure form showing all such relationships that might be perceived as real or potential conflicts of interest. These statements are reviewed by the ACC/AHA Task Force on Clinical Data Standards, reported orally to all members of the writing panel at the first meeting, and updated as changes occur. The Writing Committee members' relationships with industry are listed in Appendix A. Relationships with industry for official peer reviewers are listed in Appendix B.

C. Comprehensive Review of Relevant Resources

The ACC/AHA Task Force on Clinical Data Standards 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 published literature and available resources. Examples of these resources include:

- ACC/AHA Clinical Practice Guidelines and Other Relevant National Guidelines: Since current scientific evidence provides the basis for selection and definition of data elements, the data elements and definitions should be linked whenever possible to evidence-based national guidelines.
- Case Report Forms From Previous or Current Clinical Trials: Existing case report forms and definitions offer a context that allows Writing Committee members to visualize how the data elements can be put into practice.
- Regional, National, or International Registries: Because of their experience with various clinical trials and registries, Writing Committee members can also serve as valuable resources by sharing relevant data elements and definitions for review.
- National Quality Performance Measurement Initiatives
- Existing Clinical Data Standards and Other Sources Such as the Systematized Nomenclature of Medicine (SNOMED). Whenever possible, data standards are congruent across conditions.

D. Developing Data Element Sets

The overriding goal in developing clinical data standards is to focus on important variables needed to assess the characteristics of patients, their treatment with both medication and interventional therapies, and their outcomes. In developing the standards, the Writing Committee balances completeness with length and, thus, tries to be as concise as possible to facilitate use of these variables. Standardized definitions for each variable are provided. For these, the Writing Committee balances greater specificity of definitions against what information can readily and reliably be obtained from a medical record to make these definitions functional in the various real-world settings. Data standards writing committees strive for clarity, objectivity, and consistency throughout the writing process.

The Writing Committee pays close attention to the level of detail of the information provided about certain variables, such as timing of prior cardiovascular events, timing of procedures, exact drug names versus classes of drugs, and types of insurance. Users should understand that when undertaking a data collection effort, only a subset of these elements may be needed or, conversely, they may want to consider whether it may be necessary to collect elements that have not been included in the data standards listing. For instance, if a hospital association was examining the relationships between patient insurance status, cardiac procedure use, and outcome, the group might use more subcategorizations related to insurance status. On the other hand, if a pharmaceutical company was conducting a study to evaluate a new drug, the type of insurance might not matter and could be omitted. Data elements could also be expanded to include additional information, such as an individual listing of all of the relative contraindications for careful measurement

of quality performance. Expansion of the variables collected would also be expected in the setting of a randomized clinical trial of a new drug, for which additional information would be required regarding study procedures, therapies, and outcomes. Technical specifications related to the structure of an electronic registry or database, such as field type, parent-child relationship, and the like, are not considered part of the data standards and will be developed by those who put them to use. Thus, depending on the intended use of the variables, one could restrict or expand the number of data elements used. In either case, the definitions provided in clinical data standards documents should assist in standardizing the process.

1. General Considerations for Developing Clinical Data Standards

The following list outlines a number of considerations which to a greater or lesser degree guide all data standards writing groups:

a. **Balance Between Focus and Comprehensiveness.** In developing the data standards for a particular subject area, the Writing Committee focuses on commonly collected data elements that are thought to be most useful for the broadest set of applications. However, these data standards are not intended to be a comprehensive data element catalog encompassing every possible data need or use. Individual users will likely supplement these elements to suit their individual needs. Conversely, other users will select only a few data elements to collect.

b. **Specific Data Elements Relevant to the Topic.** When possible, the Writing Committee chooses data element names and definitions common to other ACC/AHA clinical data standards efforts. However, some elements are designed to specifically meet the needs of patients with the specific condition being addressed.

c. **Varied Clinical Presentations and Care Venues.** The data elements are intended to encompass the full range of patients with the topic condition or undergoing a topic procedure/therapy, including acute and chronic presentations and inpatient and outpatient settings, as well as scheduled and unscheduled medical care encounters.

d. **Patient-Oriented Format.** If the topic condition is chronic in nature (e.g., heart failure), the individual patient is the foundation of the data element set. This focus contrasts with other comparable efforts where the field of interest may be a procedure (e.g., cardiac catheterization) or an event (e.g., acute coronary syndrome). Thus, the format of the data elements will be designed to follow multiple events over time for each individual patient.

e. **Date and Time.** The Writing Committee recognizes the critical importance of obtaining dates (and, in some cases, times) for many data elements in order to understand the clinical course, therapy, and outcomes of the individual patient and across populations. The exact date (month, day, year) for elements, such as health care encounters, diagnostic and therapeutic procedures, or changes in therapy, should be obtained whenever possible. As the ability to obtain precise dates of prior events may be limited, a best estimate of dates should be obtained (e.g., month/year), with emphasis placed on the most current events. The operational format of date collection will vary depending on particular use.

f. **Medication Use.** Because medical therapies have such an important effect on the outcomes of patients with a certain cardiac condition, the data elements and definitions may be relatively detailed in tracking medication use for those conditions. In some instances, the Writing Committee may propose that the data on the types of medications be collected at a minimum of 3 time points: before the acute event, the first 24 hours after the event, and at hospital discharge. Furthermore, in cases in which there may be differences between drugs within a class, it is suggested that information on the specific medication within a given medication class be collected.

g. **Quality of Life.** Considerations of quality of life are particularly important in the management of certain cardiac conditions. While general health status measures may be appropriate for some programs and investigations, more focused, condition-specific measures may be important to optimize patient care and advance the state of knowledge for these conditions.

h. **Risk Adjustment.** In some instances, depending on the topic of the data standards document, the list of data elements contains factors included in published risk-adjustment models. Outcomes are adjusted for differences in patient characteristics and allow better comparisons across hospitals, treatment strategies, and subgroups of patients.

i. **Resource Utilization.** Cost-effectiveness of new and old therapies and treatment strategies is of growing importance. The data standards may include items that allow estimation of resource utilization, which will allow estimation of cardiovascular costs.

j. **Outcomes.** Many outcomes are included in the list of data elements. These are important for the evaluation of the clinical benefits and risks of medical and interventional therapies. Some outcome elements may require review by physicians (e.g., cause of death or the assessment of coronary flow at cardiac catheterization). However, most outcome elements have simple definitions that the Writing Committee believes can be abstracted from a standard medical record.

2. Selecting the Data Elements

The standard categories shown in the following outline are used when creating the list of data elements. In an effort to ensure consistency, the published versions of the clinical data standards documents all follow a similar format, which lists the key elements and definitions by category.

Standard Data Element Categories
I. Demographics
II. Medical History
a. Patient History
i. Cardiovascular
ii. Noncardiovascular
b. Family History
i. Cardiovascular
ii. Noncardiovascular
III. Patient Assessment: Current Signs and Symptoms
a. Clinical Symptoms
b. Physical Evaluation
IV. Laboratory Testing
V. Presentation to Health Care Facility
a. Admission (Inpatient)
b. Encounter (Outpatient)
VI. Diagnostic Procedures
VII. Invasive Therapeutic Procedures
VIII. Pharmacologic Therapy
a. Cardiac
b. Noncardiac
IX. Patient Education/Counseling
X. Patient Referral
XI. Follow-Up
XII. Outcomes

Based on a review of the applicable resources (described in Section C), the Writing Committee develops a comprehensive list of possible data elements relevant to the chosen topic. This initial list is aimed at capturing the universe of potential elements with the understanding that, by necessity, this set of data elements must be limited to those elements most likely to be needed in data collection efforts for research, clinical care, and quality improvement. From this initial list, the Writing Committee grades the importance of including each data element as "high," "medium," or "low." All of the data elements with an average "high" score and the majority of those with an average "medium" score are maintained in the set.

The process of writing and revising data element definitions causes many data elements to move into or out of the set for a variety of reasons. In some instances, an element that on its own ranks "low" may be necessary to complete a subset of elements pertaining to a related concept. Conversely, an element that ranks "high" may later be determined to be impossible to define in a manner that facilitates consistent data collection, or its content may be contained within another data element.

3. Defining Data Elements

The main purpose of each Writing Committee is to construct definitions for topic-specific data elements. These elements embody the collection of variables specific to the cardiovascular topic area, the definitions of which come to represent the conventional components of these variables.

Once the data element list has been refined to those deemed to have priority for the first publication of the topic data standards, members of the Writing Committee draft definitions for those data elements. Sample definitions from a variety of existing sources (see Section C) are provided to Writing Committee members as they draft the definitions for the specific data standards topic area.

Data definitions are linked whenever possible to the evidence-based national guidelines, specifically the ACC/AHA clinical practice guidelines. To ensure consistency across ACC/AHA clinical data standards, writers are required to use existing (core) ACC/AHA data standards definitions verbatim (e.g., race/ethnic origin, history of smoking) unless there is a compelling reason related to the specified topic to change that definition.

The functionality of the definitions is of key importance when developing clinical data standards. The general consideration for the level of detail and completeness of data element definitions is an evolving process. The definitions should be broad enough to be applicable in a variety of data collection settings, but specific enough that the data elements can be uniformly interpreted. Where possible, data elements are defined in a manner meant to be usable in both inpatient and outpatient settings.

The ACC/AHA recognizes that definitions cannot be written effectively without the context of their intended use. To facilitate the process of composing definitions, the Writing Committee is provided a list of data element types and specific uses for each. This list is intended to assist Writing Committee members in ensuring that the data elements and definitions are relevant to the purpose of the project. It also represents the ways in which the data standards can be operationalized and is regarded as a set of criteria that should be satisfied at this step. In most circumstances, if a data element does not fulfill at least 1 of the criteria, its value to users is questioned. Below are 5 types of data elements and 4 major environments of data collection efforts:

Data Element Types

1. *Patient Demographics:* Provides a description of the patient. Such information characterizes the patient population.
2. *Risk Assessment:* Allows appropriate identification of correlates of mortality and other outcomes, which is required for analysis of risk-adjusted outcomes. It also allows for clinical risk assessment through identification of patient characteristics associated with heightened risk for various adverse outcomes.
3. *Performance Measurement:* Allows measurement of adherence to nationally recognized clinical practice guidelines. In some circumstances, some data elements (e.g., process of care measures) could be used to construct performance measures.

4. *Procedural Description:* Describes procedures performed during the episode of care.
5. *Follow-Up and Outcomes Analysis:* Describes elements used to characterize clinical outcomes and end points after the care encounter. These may include clinical outcomes (e.g., mortality, functional status) or economic outcomes (e.g., resource utilization, length of stay).

Data Collection Environments and Use of Data Standards

Use of data standards depends on the reason clinical data is collected and the environment for data collection. Examples include:

1. *Clinical Research/Trials:* Strengthen prospective registries and randomized controlled trials by the use of clinical data standards. Growing use of data standards will bring about improved comparison of clinical outcomes between various trials and registries as well as facilitate data management.
2. *Clinical Care:* Assist in the organization and design of electronic medical information initiatives, such as electronic medical records, pharmacy databases, patient databases, or other computerized decision support tools.
3. *Health Services Research:* Enhance the systems, delivery, and outcomes of health services.
4. *Performance Measurement Initiatives:* Facilitate interpretation for non-medical users, such as payers, regulators, and consumers.

The needs of clinical researchers are frequently unique to the specific research objective. This necessitates specific data element design and definitions. The definitions proposed in a relevant data standards document may be considered as a starting point. On the other hand, quality performance measurement, particularly when quality comparison is the goal, requires standard definitions for all data elements. Discussion of the considerations for use in clinical care and quality performance measurement is as much a component of the consensus development process as the data definitions themselves.

It should be noted that clinical data standards present a model of elements which may be employed in data collection efforts, such as operating a registry, and are not functional databases in themselves.

E. Consensus Development

The ACC/AHA data standards are consensus, team-written documents that are based on judgments of experts in the field of cardiology. Writing Committee discussions and consensus building are essential to the production of the clinical data standards documents. There are several levels of refinement that the data elements undergo throughout the development of the data standards document, necessitating constant dialogue and consensus building. Each Writing Committee member contributes his or her expertise in constructing the data elements and corresponding definitions. The final document is ultimately a reflection of the agreement of the Writing Committee members on a formal, recognized set of clinical data standards.

The Writing Committee meets several times, both in person and through conference calls, over the course of the document development to define and refine the data elements. Throughout the creation of the data element set, consensus is developed through discussions (either during face-to-face meetings or conference calls), e-mails, and occasionally written votes. The process of consensus development allows for the incorporation of minority opinions in the few instances when a group consensus cannot be achieved.

F. Peer Review, Public Comment, and Board Approval

The following are the review and approval steps taken to prepare the data standards document for publication.

1. **Peer Review.** The set of data elements is independently reviewed by official reviewers nominated by the ACC and the AHA, the ACC/AHA Task Force on Clinical Data Standards, and independent content reviewers.
2. **30-Day Public Comment.** To increase its applicability further, the document is posted on the ACC Web site (www.acc.org) for a 30-day public comment period.
3. **Resolution of Comments Received.** After the peer review and the 30-day public comments are received, the Writing Committee Chair is responsible for comment resolution and finalization of the document, with input as requested from members of the Writing Committee.
4. **Final Writing Committee Approval.** After the Chair has completed the resolution of the comments in the document, the Writing Committee reviews the document and indicates their final approval.
5. **ACC and AHA Governing Body Approval.** The document must be approved for publication by the governing bodies of the ACC and the AHA.
6. **Endorsement.** At this point, the document is sent to relevant professional associations for consideration of formal endorsement.

The document will be considered current until review by the ACC/AHA Task Force on Clinical Data Standards determines that a revision is necessary (see the following section).

G. Publication and Promotion of Clinical Data Standards

The introduction, data element, and definition sections of the clinical data standards document are published in the *Journal of American College of Cardiology* and *Circulation*. Revised clinical data standards will be published on the Web.

H. 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, will review the clinical data standards document

12 to 24 months after publication to assess the extent to which the document needs to be updated. Updates may be reflective of changes in relevant medical literature, including revised ACC/AHA practice guidelines, advances in cardiovascular medicine, or changes in the feasibility of collecting data elements in practice.

IV. Conclusions

The ACC/AHA Task Force on Clinical Data Standards looks forward to the increasing use of the data standards documents and the data element definitions. The Task Force welcomes input from members and users. It is through their use, revision, and updating that clinical data standards find their place in the service and resource they offer to our ACC and AHA members and other constituencies.

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APPENDIX A. TASK FORCE RELATIONSHIPS WITH INDUSTRY—ACC/AHA 2007 METHODOLOGY FOR THE DEVELOPMENT OF CLINICAL DATA STANDARDS

Committee Member	Research Grant	Speakers' Bureau/ Expert Witness	Stock Ownership	Consultant/Honoraria/ Advisory Board/ Steering Committee
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APPENDIX B. PEER REVIEWER RELATIONSHIPS WITH INDUSTRY—ACC/AHA 2007 METHODOLOGY FOR THE DEVELOPMENT OF CLINICAL DATA STANDARDS

Reviewer	Research Grant	Speakers' Bureau/ Expert Witness	Stock Ownership	Consultant/Honoraria/ Advisory Board/ Steering Committee
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