The American College of Cardiology National Database: Progress and Challenges

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The future of medicine is increasingly in the hands of those who are effective users of clinical data. To date, this activity has been dominated by organizations with the resources and infrastructure to collect and analyze data—typically, payers, large managed care organizations and the government. The American College of Cardiology (ACC) and a handful of medical professional associations are unique in that their leadership was quick to recognize how important outcomes data sets would be in ensuring quality patient care and in establishing a place for clinicians in setting the agenda for health care.

The ACC has had a clinical database for 5 years. The process of developing a national database is not a simple one, and there have been few precedents. It is the purpose of this report to present the progress to date in the creation of the ACC National Cardiovascular Data Registry (ACC-NCDR) and the plan for future developments. Reader comments are welcome and should be addressed to William S. Weintraub, MD, FACC, the Chair of the ACC Database Committee.

Purpose of the Registry

Before even starting to describe the registry design, it is most important to articulate what the registry should accomplish. There are several possibilities. The registry could be used as a national guide for facilities management. By facilities management, we mean writing catheterization reports, managing inventory and other tasks. The registry could be used as a national standard for evaluating the efficacy of new forms of therapy. It could be used as a basis for a cooperative effort at performing clinical trials or for evaluating medical care delivery (i.e., efficacy vs. effectiveness). It is the latter purpose, effectiveness, that has driven the evolution of the ACC-NCDR.

As a national repository of data for the evaluation of cardiovascular health care delivery, the College is in a unique position to address issues that relate to the processes and outcomes of quality cardiovascular care. The size and scope of the ACC-NCDR, although fundamental to the value of this effort, will necessitate relatively slow movement into new areas and with somewhat less efficiency than other data collection efforts that are smaller in scope. Furthermore, although ideally suited for supporting the continuous quality improvement activities of its participants, the ACC-NCDR will never supplant clinical trials in addressing the efficacy of new treatments.

By virtue of the special relationship and responsibility of physicians as providers of patient care, the ACC is positioned to serve as an impartial arbiter of the quality of care. Most clinicians are only vaguely aware that insurance companies (Medical Information Bureau), large provider systems (Kaiser Permanente, Veterans Hospitals), Medicare (MEDPARS) and large health maintenance organization (HMO) providers are collecting patient or provider-identified clinical data. These efforts do not provide relevant clinical information to providers or patients at the point of care, where they might facilitate medical decisions. Clinicians and patients do not determine their structure and operation. The accuracy and analyses of their data cannot be verified. The availability of the data to “outside” purchasers and the confidentiality and security of the data are not known or controlled by clinicians or patients. The ACC is assuming a leadership role in the design and promulgation of its own high quality database that is both guided by physicians and grounded in sound scientific principles.

Registries should have several essential characteristics that include open access to participation, uniform definitions and data reporting standards, audited data, dispassionate scientific analysis and availability of specific data and comparative analyses to participating clinicians and their patients at the
point of care. Today, no existing clinical registry fully meets all of these goals. However, the closest approximations to this paradigm are the data collection efforts being organized by professional medical societies. The ophthalmology, orthopedics and medical and surgical cardiovascular societies are now devoting considerable resources to developing high quality multicenter clinical data repositories.

The Database Committee has been most interested in establishing a high quality multicenter clinical data registry that will permit the broadest assessment of cardiovascular health care delivery and effectiveness of treatment across the United States. It has been the policy of the ACC Database Committee to avoid involvement in facilities management, as this was felt to be best left to local operations and to software vendors. Thus, the ACC-NCDR has a well defined niche in the assessment of health care delivery. In addition, the ACC Database Committee has responsibilities in education concerning data collection and interpretation as well as in setting standards of what data are of greatest interest and how the data may be defined.

**Historical Development of the ACC-NCDR**

Development of what has become the ACC-NCDR was initiated in 1987 under the auspices of the ACC Computer Applications Committee (CAC) and the stewardship of Suzanne B. Knoebel, MD, FACC. Dr. Knoebel was visionary in recognizing the growing importance of outcomes research to furthering the provision of quality cardiovascular care. As originally envisioned, the purpose of the ACC clinical database effort was to demonstrate the effectiveness of specific cardiovascular procedures and practices in terms of risk-adjusted patient outcomes. This purpose was operationalized in a research perspective characterized by a comprehensive and powerful data set that could potentially resolve numerous questions pertinent to targeted procedures.

In September of 1988, a subcommittee of the CAC was formed under Dr. Knoebel's leadership to further develop a clinical angioplasty database. The scope of the subcommittee's activities was sufficiently large and complex to warrant the formation of a separate Database Committee in October of 1989. One of the first products of this new committee was a marketing study for the new angioplasty database. Database customers were expected to be institutional participants—typically, cardiac catheterization laboratories and their associated facilities. The recommendations of this study were approved by the ACC Executive Committee, and permission was given to proceed with the full-scale development of the Angioplasty Database in July of 1990. The Database Committee formed additional subcommittees to develop databases pertinent to cardiac catheterization, implantable cardioverter-defibrillators (ICDs) and radiofrequency (RF) ablation.

It was recognized that ACC would have to seek a contractor that could provide critical database software development services. A contract was eventually signed with Summit Medical Systems, Inc., of Minneapolis, to develop and market database software in February 1991. The first programs for coronary angioplasty, atherectomy and laser data collection and for cardiac catheterization data collection were released in October 1991. The ICD and RF ablation databases were released in May 1992.

An initial data "harvest" of data from catheterization laboratories and interventional centers conducted by Summit in early 1993 suggested that there were problems associated with data completion. To address this problem, the committee began an initiative to shorten the elements required for the coronary angioplasty, atherectomy and laser data collection effort. A new, shortened data collection form for this database was approved by the committee in November 1994. However, there remained multiple problems. The initial forms included data for both outcomes research and facilities management. This approach necessarily resulted in an inflexible design that incorporated many data elements that were of limited value in assessing clinical effectiveness. In addition, the database did not include patient identifiers. This created a difficult problem in assessing angioplasty because patients often have multiple procedures. Furthermore, given that the primary thrust of the ACC-NCDR is to support the provision of high quality patient care, it becomes critical to identify patients so that their outcomes may be tracked across settings and over time. Therefore, the Database Committee undertook two parallel processes to change the orientation of the ACC-NCDR from a procedure to a patient orientation and from focusing on data collection forms to the development of a core data set that would be collected by all participating institutions. This change in orientation resulted in a restructuring, combining several distinct databases into one registry, the ACC-NCDR. The change to patient orientation also creates the need for patient identifiers, which in turn results in additional requirements for confidentiality and security.

The relationship of only one company to the ACC-NCDR, no matter how responsible or capable, restricts participation. To enhance the institutional coverage of the ACC-NCDR, the Board of Trustees of the College approved promulgation of standards by which multiple companies or local institutions may develop software that will be certified and allow participation in the ACC-NCDR. These standards plus the core data elements, associated definitions and coding specifications are the foundation for all current and future participation.

**Core Data Elements**

The core data elements have been developed over a period of 2 years. This list, with associated definitions and coding specifications, reflects the combined efforts of many leading cardiovascular epidemiologists, health services researchers, interventional cardiologists and biostatisticians. The data will be patient oriented, with the Social Security Number (Social Insurance Number in Canada) as the primary key identifier. The core data elements (see Appendix) cover patient demographics, hospital admission, the procedure (cardiac catheterization or coronary intervention) and discharge. Coronary
intervention data may be further subdivided by lesion level details. The elements were selected to permit a broad assessment of intervention in the coronary arteries while not creating an overwhelming task in data collection. Besides the core elements there are extended elements. The purpose of the extended elements is to permit a more detailed assessment. For instance, the extended elements augment the core elements with information on discharge medications. Participants will be asked to collect and submit the core elements. In contrast, collection of the extended elements will be voluntary. The collection of the core elements and extended elements is expected to be with minimal missing data and will be subject to audit.

As noted above, the selection of core elements carried with it several other tasks. The accompanying data element definitions reflect a consensus process that included prior efforts by the Society of Thoracic Surgeons, the New York State Database, Emory University, Duke University and the University Hospital Consortium, to name a few. Further, modification of these definitions may become necessary as the ACC and its Database Committee work with other organizations on data standards. Coding specifications were also developed to address both coding formats and standard edit checks to be incorporated in the data collection process. Copies of the definitions and coding specifications may be obtained from Heart House.

**Registry Confidentiality and Security**

Constraining and controlling the flow of data to protect confidentiality is essential to the operation of a successful registry. Despite the tremendous potential benefits, clinical registries such as the ACC-NCDR face serious barriers to general participation, partly due to concerns regarding data confidentiality and security. While these concerns may be an outgrowth of our Hippocratic tradition, care must be taken to differentiate professional from commercial data accumulation. These concerns are not unique and also affect clinical data that are actively being aggregated into commercial databases. Patient identifiers are essential to all registries to adequately address patient outcomes, which require the ability to track patients across institutions and over time.

Confidentiality refers to the Hippocratic principle noted above, which requires physicians to protect the privacy of others. The ACC-NCDR has developed general policies regarding confidentiality based on these principles that are enunciated in forthcoming Participation Guidelines. Information that is linked with a particular patient, operator or institution will be treated as confidential and analyzed and reported confidentially to participants for use in their own quality assurance programs. The ACC-NCDR policies emphasize the participants' use of the ACC-NCDR reports as tools for physicians' continuous quality assurance programs and for direct physician to physician feedback regarding their practice patterns, practice outcomes and practice management.

There are five main steps associated with the secure treatment of reported data: 1) An ACC participant agreement shall be implemented for each participant. 2) All information shall be sent directly to the ACC Data Analysis Center at Heart House using specified data elements, data definitions, data format and encryption protocols. 3) Identifiers will be retained in separate files that will be linked via an unbreakable key to the actual patient data records. The identifier files will be kept off-line in secure storage and used only for file updates and linkages. They will be scrubbed from the system after each use. 4) Physical and electronic access to data internally at Heart House will be monitored and granted for specific purposes, such as data cleaning, feedback to participants and to discuss specific data analyses. Unauthorized or inappropriate access to data will carry specific sanctions that include dismissal and possible legal action where warranted. 5) Data reports will be routinely monitored to ensure that individual institutions, providers and patients are unidentifiable directly or indirectly. Confidential reports will not be released without a formal sign-off procedure with the receiving institution to ensure that only appropriately authorized personnel receive the reports.

Most important, since confidentiality is an evolving issue among professionals, many ACC participants may be aware of these policies and will be able to suggest amendments directly to the Database Committee.

Security refers to the specific procedures implemented by the ACC Database Committee and staff to maintain the confidentiality policy. The procedures specify the method of coding data and the transmission methods. They describe in detail the methods by which physical access and electronic access to the data are limited. They name individuals authorized to access specific classes of data. They specify the purposes of data access by these individuals and the methods by which they communicate data to others. Reviews and revision of the ACC-NCDR Security program have been delegated to the Database Committee's Subcommittee on Participant Relations and Publications in order to respond to participants' concerns.

**Standards**

Although a national registry must use standard definitions for terms, there is at present no path in clinical medicine to establish standard definitions. There has been an effort to establish a standard for correlates of coronary surgical mortality, but this has yet to be widely adopted. In June 1996, the Database Committee, with the support of several industry partners, sponsored a conference that considered standards for coronary surgery and angioplasty correlates of mortality and their definitions. Other areas considered were 1) components of a standard data element; 2) the process for establishing standards; and 3) the potential for the establishment of a permanent standards organization. The components of a standard for an element include its name, definition, coding specifications, data type, acceptable range where appropriate and cross-links to other definitions. The explicit process for establishing a standard is not well established in clinical medicine. There are organizations, such as the American Medical Association, the World Health Organization, the
National Library of Medicine and the National Institute of Standards and Technology, which have addressed a standard medical lexicon. While commendable, these efforts have not approached a level sufficient to fully characterize the processes and outcomes of cardiovascular care. The standards process must include a path that not only allows wide input but also consensus building and certification of a standard and its publication. A standards organization, once functioning, should be able to help solve each of these problems. A successful standards organization must also be able to gain wide credibility and include input from multiple sources.

**Participant Guidelines**

Each institution will receive a detailed guideline for participation in the ACC-NCDR. The guide is intended to address a number of key topics relevant to participation. These include 1) the organization and operations of the ACC Cardiovascular Data Center (the body within ACC charged with data management, analysis, and reporting); 2) a description of the products and services that will be offered to participants; 3) specifications of the qualifying terms for participation; 4) a discussion of the ACC policies and procedures pertinent to data confidentiality and the accessing of data maintained in ACC's registry; and 5) identification of points of contact for further information.

In addition, a number of detailed technical appendices will be included that provide a draft participation agreement, fee schedule, list of certified software vendors, list of core data elements and definitions, data edit and record completion specifications, data transmission specifications, data audit procedures, and the text of the ACC Cardiovascular Data Center Confidentiality Policy.

It is the intention of the ACC Cardiovascular Data Center to collect data for the registry on a quarterly basis, subject the data to automated edits and consistency checks and have each institution rectify any errors or inconsistencies. The data will be stored in a relational database. Technical support will be available during regular business hours, and annual training sessions on data collection and element definitions will be offered. The ACC will provide National Summary and Institution-Specific Reports to each contributing participant that uses certified software, that adheres to ACC standard definitions and data quality specifications and that assigns a designated database manager to work with the ACC to ensure data integrity.

**Data Audit**

Data reported from multiple sources will always be suspect in the absence of auditing. To establish auditing, two problems must be overcome: 1) expense, and 2) participant resistance. The expense can be justified if it is minimized and if the auditing enhances the credibility, and consequently, the value of the data. Participant resistance is based on the desire to minimize the intrusiveness of outsiders but can also be overcome if there is a sense that auditing is worthwhile. It is unlikely that the data will gain much acceptance in the absence of auditing. For instance, if an ACC Chapter wants to report to a state government that patients have a mortality rate that is consistent with published statistics, the state government may well reject the data in the absence of an audit. It is also the position of the Database Committee that risk adjustment in the absence of an audit is not legitimate. Thus, a participant that is compared with other institutions that were not audited may feel that they were compared with institutions whose data could not be trusted. Therefore, regular auditing becomes an indispensable part of the process. Since it is not necessary, and probably not feasible, to audit 100% of all collected data, a sampling strategy is planned. Further, current plans call for fairly extensive auditing of the process of data collection that will include testing and certification of individuals directly responsible for this activity.

**Participant and Chapter Relations**

The ACC-NCDR serves its participants and the members of the College. This represents a wide audience that subsumes clinicians, hospital administrators, nurses and technicians. The ACC Database Committee, supported by Hearst House staff, face a challenge in meeting the diverse needs of these disparate groups. The Database Committee, through the Subcommittee on Participant Relations and Publications, is working to ensure prompt two-way communication and to refine reporting appropriate to the needs of our constituencies. It is anticipated that ACC's state Chapters will be a major focal point for recruitment into the registry, given that most major clinical data collection initiatives have, to date, been state driven. The committee has established a liaison with the ACC Board of Governors to support state-based activities. A representative of the Board of Governors will sit on the Database Committee, and a member will also serve on the Subcommittee on Participant Relations and Publications. It is anticipated that grouped reporting for all participants in a state will be available to ACC state Chapters.

**Vendor and Government Relations**

It is in the interests of the College and participants in the registry to maintain the best possible relations with software vendors. As noted above, it was an express ruling of the Board of Trustees that the registry be open to participation by users of database software from multiple companies. It is the position of the Database Committee that all software companies will be treated equally, provided that they incorporate into their software a set of core elements, extended elements, definitions and coding specifications that will be identified by the ACC Database Committee. The ACC will certify software vendors as meeting these specified standards. Participants (individual physician groups, clinics or institutions) will be able to choose the software most suitable to their own needs. Separate participant agreements will be signed between the ACC and the vendor and the participant that outline the appropriate responsibilities of each party.
Several states, led by New York, have undertaken the development of clinical databases. The ACC Database Committee believes that the registry can fulfill state reporting needs regarding cardiovascular care and plans to work through its state Chapters to establish formal reporting mechanisms. This will probably be less expensive than each state undertaking the process separately and will provide uniform standards and adherence to agreed upon definitions. The ACC-NCDR will, in the near future, be able to make statements as to the quality of the data by virtue of its either passing or not passing audits. Our conversations with participants suggest that they favor data being submitted directly to the registry rather than to the state government. With the participant’s approval, ACC would fulfill their state reporting requirements. State governments may also find the process easier to implement by having a trusted and impartial organization involved in assessing the data. It is likely that the precise arrangements for data transfer and reporting will vary from state to state, and the Database Committee will depend on the involvement of the ACC state Chapters and the Board of Governors in their negotiation and establishment:

National and Local Reporting

The ACC prepares annual national summary reports based on analyses of the latest data up to a specified cutoff date. Initial results are usually presented at the ACC Annual Scientific Session. Because the most recent data submission was still procedure based, results for the 1996 report focused on summary data of 137,598 cardiac catheterizations and 124,736 coronary interventions. Copies of the 1996 National Summary Report can be obtained by contacting the ACC Cardiovascular Data Center at Heart House.

Once the ACC-NCDR is converted from a procedural to an episode-of-care orientation, national summary reports will be issued to all participants. These reports will include data on patient characteristics, characteristics of the care provided, length of stay and complication rates. Mortality and risk factor reports will be generated as well. Due to the longitudinal nature of the data, and because strict auditing criteria must be satisfied, the ACC plans to track repeat procedure status and build risk-adjusted patient outcome models.

All participants will also be provided with periodic institution-specific comparative reports. These will include tabulations on 1) data completeness; 2) volume and resource utilization; 3) procedure complications and mortality comparisons; and 4) risk-adjusted patient outcome parameters for each site. The ACC will also provide an annual written evaluation of participating site data collection efforts. This will include problem areas as well as tips on improving data gathering and decreasing missing values rates.

Links to Other Registries and Clinical Databases

Close cooperation with sister associations, including the Society for Cardiac Angiography and Interventions and the Society of Thoracic Surgeons, is expected to further develop over time. Further, the use of the Social Security Number as the primary key will permit links to other data sets, including the National Death Index and the Health Care Financing Administration (HCFA) databases. Linking to the National Death Index would allow follow-up of all patients in the registry, at least for the end point of death. Linking to the HCFA database would allow the ACC to examine the relationship of clinical variables to the cost of care. HCFA databases include hospital admission claims from the condensed hospital bill called the UB92 for most Medicare recipients. Similar Medicare data for professional billing can be obtained from the database containing the Current Procedural Technology (CPT) codes as collected on the HCFA 1500 form. Participants may be uncomfortable with the prospect of the ACC and HCFA sharing data. However, the economic data obtained through this linkage should considerably enhance the usefulness of the registry, and every effort will be taken to preserve the confidentiality of any linked data. Furthermore, the availability of appropriately audited and detailed clinical information will have a salutary effect on the quality of HCFA’s claims analyses—which should represent a major benefit to participants.

Education

Medical education is frequently deficient in providing the skills needed to collect and effectively use clinical data. The ACC Database Committee has a responsibility to the participants to offer education concerning which data to collect, how to collect the data, how to organize staff to do so, how to select software, how to transmit data to the ACC and how to interpret data. A multi-tiered educational initiative is being planned for the collectors and users of clinical data that covers classroom/lecture formats and self-learning strategies. In addition, the ACC plans to certify training programs offered by software vendors and others to participants on the appropriate submission and use of ACC-NCDR data.

Education will also be a focus of reports and publications that have been or are being developed by the ACC Database Committee. These publications, some of which were referenced above, include a regular participant newsletter, Data Basis. The ACC’s home page on the World Wide Web will become an important mechanism for both information dissemination and for receiving feedback from our various constituencies.

Additional Areas of Practice

The ACC-NCDR is currently focused on cardiac catheterization and intervention in the coronary arteries. The Database Committee will gradually move into new areas as the current efforts continue to mature. Data standardization initiatives, most recently with the Society of Thoracic Surgeons, represent an exciting way for engaging other cardiovascular subspecialties in the formation of data sets and may ultimately lead to a combined database. However, cardiology is not limited to
**PTCA Core Data Elements**

**Total Core Elements: 59 (23 repeated for each lesion)**

**Procedure Date**
- CE65. Date of PTCA Procedure

**Primary Operator**
- CE66. PTCA Operator's Name
- CE67. PTCA Operator's Social Security Number

**Indications**
- CE68. Coronary Lesion in a Major Coronary Artery (Yes/No/Unkn)
- CE69. Angina Pectoris (Yes/No/Unkn)
- CE70. Significant Residual Lesion Present Following MI (Yes/No/Unkn)
- CE71. Significant, Residual or New Lesion Present Following CABG (Yes/No/Unkn)
- CE72. Restenosis Following an Interventional Procedure Present (Yes/No/Unkn)
- CE73. Acute MI Present (Yes/No/Unkn)
- CE74. Positive Functional Tests (Yes/No/Unkn)
- CE75. Cardiogenic Shock (Yes/No/Unkn)

**Current Procedure**
- CE76. Urgency (Elective, Urgent, Emergent, Unkn)
- CE77. Cardiopulmonary Support (Yes/No/Unkn)
- CE78. IABP Sequence (Not Used, Before, During, Both, Unkn)

**In-Lab Medications**
- CE79. In-Lab Thrombolytics (Yes/No/Unkn)
- CE80. In-Lab GP 2B/3A Blockers (Yes/No/Unkn)

**Coronary Anatomy**
- CE81. Preceded by Diagnostic Catheterization (Yes/No/Unkn)
- CE82. Ejection Fraction Percent (% Unkn)
- CE83. Dominance (Left, Right, Mixed)
- CE84. Stenosis Percent—LM (%)
- CE85. Stenosis Percent—Proximal LAD (%)
- CE86. Stenosis Percent—Other LAD (%)
- CE87. Stenosis Percent—RCA (%)
- CE88. Stenosis Percent—CIRC (%)
- CE89. Valve Disease (Yes/No/Unkn)

**Procedure—Lesion Description (Complete for each lesion approached)**
- CE90. Lesion Identification Number
- CE91. Segment Number
- CE92. Pre-Stenosis Percent (%)
- CE93. Pre-Stenosis Measurement Method (Visual Reading, Caliper Reading Automated Edge Detection, Unkn)
- CE94. Post-Stenosis Percent (%)
- CE95. Post-Procedure TIMI Flow (0, 1, 2, 3)
- CE96. Previously Dilated Lesion (Yes/No/Unkn)
- CE97. In Graft to Cited Segment (Yes/No)
- CE98. Location In Graft (Aortic, Body, Distal, Unkn)
- CE99. Lesion Type (A, B1, B2, C)

**PTCA Procedure Device (Complete for each lesion approached)**

**Choices:** Balloon, DCA, Rotablator, TEC, Laser, IVUS, Stent, Other
- CE100. First Pre-Treatment Device
- CE101. Second Pre-Treatment Device
- CE102. Primary Treatment Device
- CE103. First Adjunct Treatment Device
- CE104. Second Adjunct Treatment Device
- CE105. Third Adjunct Treatment Device
- CE106. First Bailout Device
- CE107. Second Bailout Device
- CE108. Third Bailout Device

**Site Complications (Complete for each lesion approached)**
- CE109. Dissection (Yes/No)
- CE110. Acute Closure (Yes/No)
- CE111. Successful Reopening (Yes/No)
- CE112. Perforation (Yes/No)

**Procedure Summary**
- CE113. Any In-Lab Procedural Complications (Yes/No)
- CE114. Q-Wave MI (Yes/No)
- CE115. Cardiac Arrest (Yes/No)
- CE116. CVA/Stroke (Yes/No)
- CE117. Vascular Complications (Yes/No)
- CE118. Tamponade (Yes/No)
- CE119. Emergency CABG (Yes/No)
- CE120. Death In Lab (Yes/No)

**Discharge Core Data Elements (Required for All Admissions for PTCA, Even If In-Hospital Death, Not Required if the Only Procedure Was an Out-Patient Catheterization)**

**Total Core Elements: 18**

**Discharge Date**
- CE124. Date of Discharge

**Post-Procedural Medications—In-Hospital**
- CE125. Post-Procedural Heparin (Hindin, Hirulog) (Yes/No/Unkn)
- CE126. Post-Procedural GP 2B/5A Blockers (Yes/No/Unkn)

**Out-of-Lab Complications**
- CE133. Any Out-of-Lab Complications (Yes/No)
- CE134. Q-Wave MI (Yes/No)
- CE135. Congestive Heart Failure (Yes/No)
- CE136. Cardiac Arrest (Yes/No)
- CE137. CVA/Stroke (Yes/No)
- CE138. Renal Failure (Yes/No)
- CE139. Vascular Complications (Yes/No)
- CE140. Tamponade (Yes/No)

**Mortality (in Hospital)**
- CE141. Death In Hospital (Yes/No)
revascularization. Preliminary efforts are underway by the committee to establish an electrophysiology database in concert with the North American Society of Pacing and Electrophysiology (NASPE). Other areas of interest include echocardiography, nuclear cardiology, heart failure, acute myocardial infarction and outpatient management.

Appendix: ACC National Cardiovascular Data Registry—Core Element List

Enrollment Core Data Elements (Required With the First Cardiac Catheterization and PTCA Hospitalization)

Total Core Elements: 6

Patient Demographics
CE1. Patient’s Last Name
CE2. Patient’s First Name
CE3. Patient’s Middle Initial
CE4. Patient’s Social Security Number (Social Insurance Number if Canadian)
CE5. Patient’s Date of Birth (Date)
CE6. Patient’s Gender (Male, Female)

Admission Core Data Elements (Required With All Cardiac Catheterization and PTCA Hospitalizations)

Total Core Elements: 24

Admission
CE7. Facility Number
CE8. Hospital
CE9. Date of Admission

Clinical Presentation
CE10. CHF Within Six Weeks (NYHA Class I, II, III, IV, Unkn)
CE11. Angina Type (No Angina, Atypical Chest Pain, Stable, Unstable, Unkn)
CE12. Angina Class (I, II, III, IV, Unkn)
CE13. Acute or Recent Myocardial Infarction (No MI, Acute, Recent, Unkn)
CE14. Thrombolysis (Yes/No/Unkn)
CE15. Objective Evidence of Ischemia (Yes/No/Unkn)

Previous Invasive Procedures
CE16. Previous Coronary Intervention (Yes/No/Unkn)

Previous Cardiovascular Surgery
CE17. Previous Coronary Artery Bypass Graft Surgery (CABG) (Yes/No/Unkn)
CE18. Date Most Recent Previous CABG
CE19. Valvular Surgery (Yes/No/Unkn)

History/Risk Factors
CE20. Family History of CAD (Yes/No/Unkn)
CE21. History of Diabetes (Yes/No/Unkn)
CE22. Diabetic Therapy (None, Insulin, Oral, Diet, Any Combination of the Three, Unkn)
CE23. Renal Failure (Yes/No/Unkn)
CE24. Chronic Lung Disease (Yes/No/Unkn)
CE25. Cerebrovascular Disease (Yes/No/Unkn)
CE26. Peripheral Vascular Disease (Yes/No/Unkn)
CE27. Remote MI (Yes/No/Unkn)
CE28. Hypertension (Yes/No/Unkn)
CE29. Smoking History (Current, Former, Never, Unkn)
CE30. Hypercholesterolemia (Yes/No/Unkn)

Cardiac Catheterization Core Data Elements

Total Core Elements: 34

Procedure
CE31. Data of Cardiac Catheterization (Date)
CE32. Same Sitting as PTCA (Yes/No/Unkn)

Primary Operator
CE33. Catheterization Operator’s Name
CE34. Catheterization Operator’s Social Security Number

Indications
CE35. Congestive Heart Failure (Yes/No/Unkn)
CE36. Cardiogenic Shock (Yes/No/Unkn)
CE37. Valvular Heart Disease (Yes/No/Unkn)
CE38. Heart Disease of Other Etiology (Yes/No/Unkn)
CE39. Cardiac Arrest or Arrhythmia (Yes/No/Unkn)
CE40. Ischemic Heart Disease (Yes/No/Unkn)
CE41. Positive Functional Tests (Yes/No/Unkn)

Current Procedure
CE42. Urgency (Elective, Urgent, Emergent, Unkn)
CE43. IABP Sequence (Not Used, Before, During, Both, Unkn)

Cardiac Catheterization Procedure Laboratory Data
CE44. Left Ventriculogram (Yes/No/Unkn)
CE45. LV Status (Normal, Abnormal, Unkn)
CE46. Ejection Fraction Percent (%, Unkn)
CE47. Valve Disease (Yes/No/Unkn)
CE48. Pulmonary Hypertension (Yes/No/Unkn)
CE49. Severe Aortic Stenosis (Yes/No/Unkn)

Coronary Anatomy
CE50. Dominance (Left, Right, Mixed)
CE51. Stenosis Percent—LM (%) 
CE52. Stenosis Percent—Proximal LAD (%) 
CE53. Stenosis Percent—Other LAD (Distal/Diagonal) (%) 
CE54. Stenosis Percent—RCA (%) 
CE55. Stenosis Percent—CIRC (%) 

In-Lab Complications
CE56. Any In-Lab Complications (Yes/No)
CE57. Q-Wave MI (Yes/No)
CE58. Cardiac Arrest (Yes/No)
CE59. CVA/Stroke (Yes/No)
CE60. Vascular Complications (Yes/No)
CE61. Tamponade (Yes/No)

Abbreviations and acronyms: CABG = coronary artery bypass graft surgery; CAD = coronary artery disease; CHF = congestive heart failure; CIRC = circumflex coronary artery; CVA = cerebrovascular accident; DCA = directional coronary atherectomy; IABP = intraaortic balloon pump; IVUS = intravascular ultrasound; Lab = laboratory; LAD = left anterior descending coronary artery; LM = left main coronary artery; LV = left ventricular; MI = myocardial infarction; NYHA = New York Heart Association; PC = personal care; PTCA = percutaneous transluminal coronary angioplasty; RCA = right coronary artery; TEC = transluminal extraction catheter; TIMI = Thrombolysis in Myocardial Infarction; Unkn = unknown.
PTCA Core Data Elements

Total Core Elements: 59 (23 repeated for each lesion)

Procedure Date
CE65. Date of PTCA Procedure

Primary Operator
CE66. PTCA Operator's Name
CE67. PTCA Operator's Social Security Number

Indications
CE68. Coronary Lesion in a Major Coronary Artery (Yes/No/Unkn)
CE69. Angina Pectoris (Yes/No/Unkn)
CE70. Significant Residual Lesion Present, Following MI (Yes/No/Unkn)
CE71. Significant, Residual or New Lesion Present Following CABG (Yes/No/Unkn)
CE72. Restenosis Following an Interventional Procedure Present (Yes/No/Unkn)
CE73. Acute MI Present (Yes/No/Unkn)
CE74. Positive Functional Tests (Yes/No/Unkn)
CE75. Cardiogenic Shock (Yes/No/Unkn)

Current Procedure
CE76. Urgency (Elective, Urgent, Emergent, Unkn)
CE77. Cardiopulmonary Support (Yes/No/Unkn)
CE78. IABP Sequence (Not Used, Before, During, Both, Unkn)

In-Lab Medications
CE79. In-Lab Thrombolytics (Yes/No/Unkn)
CE80. In-Lab GP 2B/3A Blockers (Yes/No/Unkn)

Coronary Anatomy
CE81. Preceded by Diagnostic Catheterization (Yes/No/Unkn)
CE82. Ejection Fraction Percent (% Unkn)
CE83. Dominance (Left, Right, Mixed)
CE84. Stenosis Percent—LM (%)
CE85. Stenosis Percent—Proximal LAD (%)
CE86. Stenosis Percent—Other LAD (%)
CE87. Stenosis Percent—RCA (%)
CE88. Stenosis Percent—CIRC (%)
CE89. Valve Disease (Yes/No/Unkn)

Procedure—Lesion Description (Complete for each lesion approached)
CE90. Lesion Identification Number
CE91. Segment Number
CE92. Pre-Stenosis Percent (%)
CE93. Pre-Stenosis Measurement Method (Visual Reading, Caliper Reading Automated Edge Detection, Unkn)
CE94. Post-Stenosis Percent (%)
CE95. Post-Procedural TIMI Flow (0, 1, 2, 3)
CE96. Previously Dilated Lesion (Yes/No/Unkn)
CE97. In Grafit to Cited Segment (Yes/No)
CE98. Location In Grafit (Aortic, Body, Distal, Unkn)
CE99. Lesion Type (A, B1, B2, C)

PTCA Procedure Device (Complete for each lesion approached)
Choices: Balloon, DCA, Rotablator, TEC, Laser, IVUS, Sient, Other
CE100. First Pre-Treatment Device

CE101. Second Pre-Treatment Device
CE102. Primary Treatment Device
CE103. First Adjunct Treatment Device
CE104. Second Adjunct Treatment Device
CE105. Third Adjunct Treatment Device
CE106. First Bailout Device
CE107. Second Bailout Device
CE108. Third Bailout Device

Site Complications (Complete for each lesion approached)
CE109. Dissection (Yes/No)
CE110. Acute Closure (Yes/No)
CE111. Successful Reopening (Yes/No)
CE112. Perforation (Yes/No)

Procedure Complications
CE113. Any In-Lab Procedural Complications (Yes/No)
CE114. Q-Wave MI (Yes/No)
CE115. Cardiac Arrest (Yes/No)
CE116. CVA/Stroke (Yes/No)
CE117. Vascular Complications (Yes/No)
CE118. Tamponade (Yes/No)
CE119. Emergency CABG (Yes/No)
CE120. Death In Lab (Yes/No)

Procedure Summary
CE121. Number of Lesions Attempted
CE122. Number of Lesions Successfully Dilated
CE123. Procedure Result (Successful, Incomplete, Unsuccessful)

Discharge Core Data Elements (Required for All Admissions for PTCA, Even If In-Hospital Death, Not Required if the Only Procedure Was an Out-Patient Catheterization)

Total Core Elements: 18

Discharge Date
CE124. Date of Discharge

Post-Procedure Medications—In-Hospital
CE125. Post-Procedure Heparin (Hindin, Hirulog) (Yes/No/Unkn)
CE126. Post-Procedure GP 2B/3A Blockers (Yes/No/Unkn)

Post-Procedure Data
CE127. Number of Procedures Performed
CE128. Multiple Procedures—Same Lesion (Yes/No/Unkn)
CE129. CABG During This Admission (Yes/No)
CE130. Date of CABG During This Admission (Date)
CE131. Urgency of CABG During This Admission (Elective, Urgent, Emergent, Unkn)
CE132. Discharge Status (Home, Nursing/PC Home, Other Hospital, Death, Unkn)

Out-of-Lab Complications
CE133. Any Out-of-Lab Complications (Yes/No)
CE134. Q-Wave MI (Yes/No)
CE135. Congestive Heart Failure (Yes/No)
CE136. Cardiac Arrest (Yes/No)
CE137. CVA/Stroke (Yes/No)
CE138. Renal Failure (Yes/No)
CE139. Vascular Complications (Yes/No)
CE140. Tamponade (Yes/No)

Mortality (in Hospital)
CE141. Death In Hospital (Yes/No)