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The American College of Cardiology-National Cardiovascular Data Registry™ (ACC-NCDR™): Building a National Clinical Data Repository

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Diagnostic cardiac catheterization and percutaneous coronary interventions (PCIs) are critical components of the diagnosis and treatment of patients with coronary artery disease. As the prevalence of heart disease increases in our aging population and increasingly aggressive invasive approaches are developed for the treatment of coronary artery disease, the number of cardiac catheterization procedures performed yearly continues to rise. In the U.S., an estimated 1,194,000 in-patient cardiac catheterizations were performed in 1997 along with nearly 500,000 PCIs (1).

Since Andreas Gruentzig performed the first human angioplasty, PCI has rapidly evolved to be a highly successful strategy for achieving myocardial revascularization in patients with coronary artery disease. The PCI mortality rate has decreased in the present era to a fraction of 1%. The number of PCI procedure-related complications leading to myocardial infarction or emergent coronary artery bypass graft surgery has decreased considerably to fewer than 3% each (2). Intracoronary stenting with PCI has taken center stage at the end of the second decade of interventional cardiology. Between 1993 and 1997, stents became commonplace, leading to improved procedural success rates, decreased in-hospital complication rates, and decreased restenosis rates. With the advent of new devices and pharmacological therapies, the risk of adverse outcomes associated with PCI has further decreased. Procedural success rates and complication rates of conventional balloon angioplasty have improved with the introduction of directional coronary atherectomy, rotational atherectomy, extraction atherectomy, and other so-called niche catheter devices. New catheter devices such as filter systems and distal occlusion/aspiration systems are now being introduced. These devices help to minimize periprocedural myocardial infarctions that occur during PCI performed in diseased saphenous vein grafts associated with the release of embolic debris distally in the coronary vasculature. The major drawback of PCI, an unacceptable restenosis rate, is presently being approached with newly developing treatments such as coronary brachytherapy and the use of chemotherapy-eluting stents.

For more than 24 years, large-scale registries and databases have been used to accumulate data on PCI and, to a lesser extent, cardiac catheterizations (3). These registries have been used to study patient and procedural characteristics, post-procedure treatments, immediate in-hospital outcomes, and long-term outcomes. Many different analyses of these data have been performed in an effort to improve the quality of care that coronary patients receive. Quality improvements have come about primarily through a greater understanding of the risks and benefits of PCI, both globally for given patient populations and individually for patient procedure risk stratification. This effort has been critical for the original balloon angioplasty procedure and more importantly for the introduction of new devices and the role of PCI in myocardial infarction.

HISTORICAL DEVELOPMENT OF THE ACC-NCDR™

Among the greatest challenges of cardiovascular data analysis are the frequency of changing treatments, confusing terminology, nonstandard definitions, and the lack of applied data standards. Although some commonality of language existed, it had not been formal or rigorous. Recognizing these challenges as an opportunity for professional society leadership and guidance, the American College of Cardiology (ACC) set out in 1987 to create a database to standardize what and how information was collected for patients receiving cardiac catheterizations and PCI. This ACC initiative began with the formation of a Database Committee under the leadership of Suzanne B. Knoebel, MD, FACC. The committee explored various strategies for improving the collection and evaluation of cardiovascular data. As a result, in 1990 the ACC pursued a venture with Summit Medical Systems, Inc to distribute software that would electronically manage the collection of 411 ACC core data elements with annual data harvests to their central repository. A full description of the historical development of the ACC-NCDR™ is presented elsewhere (4). From 1991 to 1996, the ACC Data Registry and Summit Medical Systems, Inc., enrolled more than 300 hospitals and collected data on more than 301,125 cardiac catheterizations and 166,082 PCIs. The first report of aggregated data from 1991 through January 1996 was reported in late 1996.

Creation of the First Data Set: Cath Lab Module Version 1.1

In planning the original data set, the Database Committee and its Interventional Subcommittee specified that periodic revisions would be required as clinical practices changed and new information became available. In 1994, the ACC Database Committee pursued an updated version of the original catheterization laboratory core data elements that were scientifically valid and feasible in practice. This project, which soon became an integrated series of related projects, began the

arduous process of identifying which clinical variables were needed to properly characterize patients, and then developing definitions and data standards that could be used to collect and analyze these variables in a rigorous manner.

In 1997, under the leadership of William S. Weintraub, MD, FACC, the ACC Board of Trustees approved Cath Lab Module version 1.1 (v1.1), with data collection beginning in November 1998 by approximately 150 U.S. hospitals. Cath Lab Module v1.1 consists of 141 core data elements with standard definitions that focus on adult patients seen in cardiac catheterization laboratories who were undergoing diagnostic catheterization and/or PCI. This Cath Lab Module is oriented around patients rather than procedures. It allows longitudinal tracking and gives participants a way to monitor the impact of specific procedures over time or to examine the effect of multiple procedures performed on a single patient.

At the same time, the Board of Trustees approved several important strategic decisions that would propel the ACC into a new age of clinical information warehousing by drastically increasing the support and services provided to hospitals collecting and submitting clinical data. This was accomplished by the following steps:

1. Establishing the National Cardiovascular Data Registry™ (ACC-NCDR™), which would be housed at the Heart House, Bethesda, MD (ACC headquarters);
2. Allowing ACC software certification open to all viable and committed commercial vendors;
3. Hiring clinically trained personnel to support and recruit ACC-NCDR™ participants;
4. Using the ACC-NCDR™ as a data processing and data quality feedback facility;
5. Increasing the frequency of participant data submissions from annually to quarterly, allowing for more timely reporting.

In November 1998, all previous ACC Data Registry participants were required to re-enroll with the ACC-NCDR™, of which 75 did by December 1998. Approximately five new software vendors obtained ACC software certification. Simultaneously, Summit Medical Systems, Inc., announced it was no longer planning to provide clinical registry software products and support. Since the launch of the ACC-NCDR™, participant enrollment and vendor software certifications have continued to grow, with a current total of more than 350 enrolled participants and 16 certified software vendors.

The Big Revision: Cath Lab Module v2.0b

New technologies and scientific evidence in the catheterization laboratory during the past two years created the need for the ACC to update v1.1. After nearly a year of diligent planning and review, members of the Interventional Subcommittee of the ACC-NCDR™, led by H. Vernon Anderson, MD, FACC, with feedback from ACC-NCDR™ participants on the needs and clarity of specific data elements and definitions, completed the successful revision of the Cath Lab Module to version 2.0b (v2.0b) (Table 1). The Cath Lab Module v1.1 revision process was an arduous one because of the charge for the Interventional Subcommittee to have a focus and a vision to include data elements that met the following goals:

Table 1. Key Enhancements in Version 2.0

- Cardiac status—Measurement of acute coronary syndrome, angina type, and noninvasive testing.
- Adverse outcomes—Periprocedural myocardial infarction and recording of CK-MB levels, as well as capturing contrast reactions.
- Performance measures—Door-to-balloon/stent deployment time and closure devices.
- Optional follow-up elements—Vital status (alive or died, with primary cause of death), as well as readmission (including reason for readmission).

- Linkage to recommendations from the ACC/American Heart Association (AHA) Clinical Practice Guidelines, as well as anticipated Joint Commission for Accreditation of Healthcare Organizations (JCAHO) core measures to track performance measures and assess clinical outcomes.
- Consistency with other national and regional cardiovascular registries, such as the Society for Thoracic Surgeons (STS) National Data Registry, Society for Coronary Angiography and Interventions, Northern New England Cardiovascular Study Group, and National Cardiovascular Network. Of the 142 data elements in v2.0b, 43 definitions were mapped to the STS database, and up to 69 mapped to 4 other nationally recognized registries.
- Incorporation of the recently approved definition of a myocardial infarction (5).
- Inclusion of new categories to reflect recent catheterization laboratory developments, such as percutaneous closure devices and newer "niche" catheters.
- Inclusion of long-term outcomes data elements to allow assessment of the patient's clinical course after discharge from the catheterization laboratory.

Some of these modifications resulted from the growing use of glycoprotein IIb/IIIa inhibitors, increased use of stents, and the introduction of groin closure devices. Additionally, our early experience with v1.1 revealed problems with some of the data definitions (for example, the definitions of unstable angina and non–Q-wave myocardial infarction in the new era of troponin measurement). In-depth comparisons exposed discrepancies between v1.1 and other large databases. In addition, the ACC had recognized that development of practice guidelines and performance measures was a legitimate and necessary effort for professional societies to undertake to aid clinicians in promoting quality of care. The ACC-NCDR™ Cath Lab 2.0b Module was created to become a key component in collecting data elements to track such performance and outcome measures related to the catheterization laboratory.

The resulting Cath Lab Module v2.0b was approved by the ACC-NCDR™ Planning and Management Task Force

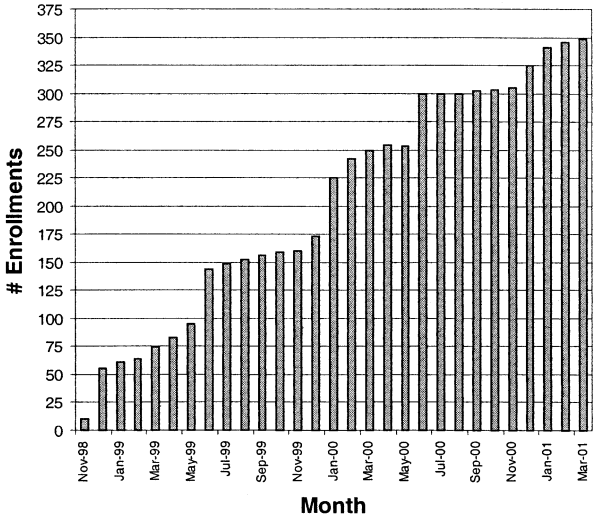

Figure 1. Cumulative enrollment by month.

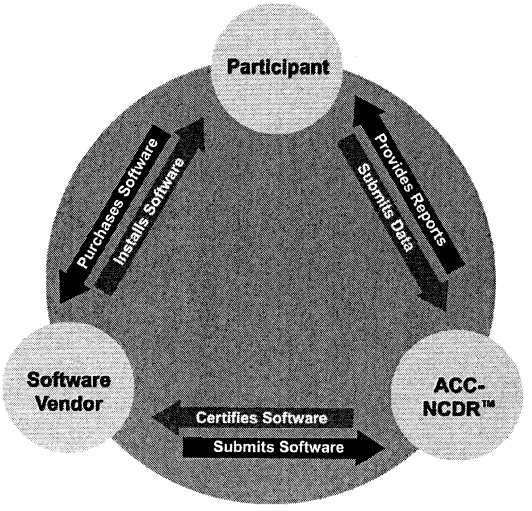

Figure 2. ACC-NCDR™ working relationships.

in March 2000. ACC-NCDR™ software vendors received v2.0 in April 2000, and participants received v2.0 in June 2000. To facilitate the transition to Cath Lab Module v2.0, the ACC-NCDR™ conducted two educational workshops for participants on the new data elements and definitions in October 2000. More than 180 ACC-NCDR™ participants and ACC certified software vendors attended the two-day workshop to learn how v2.0 was created and how it can be used for outcomes analysis, risk adjustment, and quality improvement. Additionally, attendees participated in several practice coding sessions that incorporated v2.0 definitions.

OPERATIONALIZING THE ACC-NCDR™

The main objective of the ACC-NCDR™ is to become the most comprehensive comparative database for both in-patient and out-patient cardiovascular care available in the U.S. Since institutions began enrollment in the ACC-NCDR™ in November 1998, it has grown to represent 350 participants (hospitals, free-standing laboratories, and adult cardiology practices) (Fig. 1).

In addition several international cardiology societies have begun to adopt the standards and definitions included in the Cath Lab Module v2.0. The ACC is also planning to open ACC-NCDR™ enrollment to members of the international cardiology community.

ACC-NCDR™ Contracted Software Products

The ACC-NCDR™ contracts with commercial software vendors who have agreed to provide certified software (adhering to ACC clinical and coding data standards) to interested institutions. Participating institutions obtain certified software that allows them to systematically collect data about care provided to patients undergoing diagnostic cardiac catheterization or PCIs. After obtaining certified software, participants are able to submit data to the ACC-NCDR™ (Fig. 2).

Participants receive quarterly Call for Data letters that describe in detail the process for submitting data to the ACC-NCDR™. Data are exported via certified software and either e-mailed or mailed to the ACC-NCDR™. The database uses encrypted identifiers, a system that preserves patient and physician confidentiality while permitting a longitudinal, patient-oriented view of the data. In addition, data are warehoused in a secure information system at the ACC.

ENSURING QUALITY DATA

Since 1998, the ACC-NCDR™ has received data on more than 414,000 admissions, 354,754 cardiac catheterizations, and 169,098 PCIs from institutions of various sizes and geographic locations, including both urban and rural settings, that are representative of both community and academic sites within the U.S. (Fig. 3). The ACC-NCDR™ uses a number of educational opportunities to ensure the quality of these data such as annual user group meetings, participant workshops, a participant training manual, newsletters, clinical support staff, and plans for future auditing.

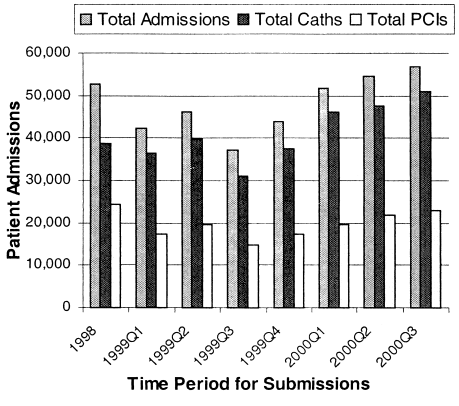

Figure 3. Total patient counts by submission period. Total admissions = 414,693; total cardiac caths = 354,754, total percutaneous coronary interventions (PCIs) = 169,098; Q = quarter.

Participants have used the ACC-NCDR™ to facilitate quality improvement activities and to provide national comparative data benchmarks. The most recent annual user group meeting was held in March 2001, with more than 180 attendees who presented oral and poster presentations on local cardiovascular quality improvement initiatives and efficient data collection systems.

The most important component of the data quality check and improvement process is the Data Quality Report (DQR), which is sent to participants after each data submission. The DQR provides feedback on the overall quality of the data submission and is used as a tool to help participants prioritize data cleaning efforts before they resubmit data. The DQR is composed of three distinct sections: 1) Inclusion Threshold Report; 2) Date Validation Report; and 3) Data Consistency Report.

Under the leadership of Dr. Richard Shaw, Chair of the Outcomes Subcommittee, inclusion thresholds were developed and implemented in 1999 to ensure data reported for the ACC-NCDR™ were complete and consistent. The Inclusion Threshold Report is based on select inclusion categories that represent core data elements that are critical for analysis of the following: Risk-adjusted mortality and patient outcomes; performance measures; outcomes analysis; patient demographics; and procedure description.

Threshold values for core data elements vary, ranging from 95% to 100%, depending on the category identified. For example, the threshold value for the core data element "discharge status (alive or expired)" is 100%. In other words, 100% of the patients in a data submission must include a valid (alive or dead) answer for this data element. If this element is left blank, the error is displayed in the DQR.

The Date Validation Report selects patient records that could contain a data entry error in the date fields. Such errors would affect the statistics calculated for age, post-procedure length of stay, and total length of stay.

The Data Consistency Report offers the participant overall information about the number of records in a data submission that were submitted compared with the number of records that were loaded into the ACC-NCDR™.

The ACC-NCDR™ began distributing the threshold component of the DQR in the fall of 1999, and the percent of data submissions meeting the threshold increased from 37% for data submissions in 1998 to 90% for data submissions in the fourth quarter of 2000 (Fig. 4).

Reports

Institutional reports are published for all enrolled participants on a quarterly and annual basis. These confidential reports compare each institution's outcomes, including risk-adjusted mortality, with the overall experience of the registry. A comparison group option (selected by each participant, e.g., all teaching hospitals or a regional hospital comparison) is being developed for upcoming reports. In each institutional report, data are displayed for patients undergoing diagnostic cardiac catheterizations and PCI.

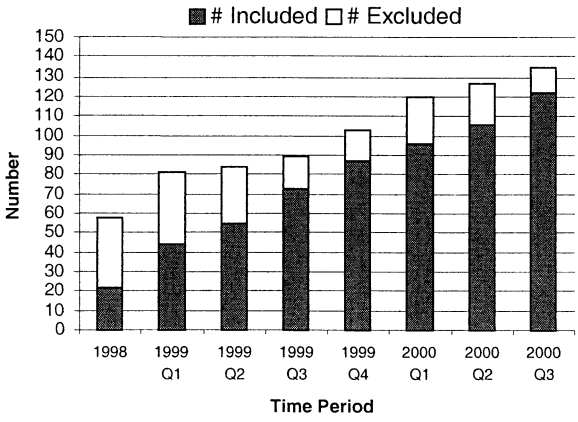

Figure 4. Data submissions meeting inclusion criteria. Q = quarter.

The profile, which focuses on PCI, presents adverse outcomes for all PCI patients and those with and without acute myocardial infarction. Additionally, adverse outcomes are stratified for patients with and without coronary artery bypass surgery during the same hospitalization.

PUBLICATION AND PRESENTATION OF ACC-NCDR™ DATA

The ACC presented more than 10 abstracts from 1999 to 2000 at national scientific meetings (AHA, ACC, and AHA/ACC Scientific Quality Forums) and plans for 10 more abstract submissions and 2 manuscript publications over the next 12 months. These activities will be facilitated by the Publications Development Subcommittee, co-chaired by John F. Williams, MD, MACC, and Ralph G. Brindis, MD, MPH, FACC. The ACC will also examine an overall access and use policy that would make aggregate ACC-NCDR™ data available to ACC members.

THE FUTURE OF THE ACC-NCDR™

The ACC-NCDR™ continues to strategically align itself with societies such as the STS, National Cardiovascular Network, and the Society for Coronary Angiography and Intervention, which share similar goals of using quality data to measure and improve patient care and outcomes. Importantly, the ACC-NCDR™ and STS continue to work closely to incorporate accepted data standards that allow for less redundant data collection for those who participate in both registries. Standardized definitions of individual data elements enable accurate comparisons to be made both for research purposes and for quality-of-care analysis. The ACC-NCDR™ will become an integral component of the catheterization laboratory continuous quality improvement (CQI) tool kit now being developed under the auspices of the ACC. Performance and outcomes measures collected through the ACC-NCDR™ will offer valuable data for application and use in the creation of future updates of ACC/AHA guidelines related to catheterization, PCI, acute myocardial infarction, unstable angina/non–ST-

elevation myocardial infarction. The ACC-NCDR™ potentially will assist ACC advocacy efforts in the promotion of improvements in individual physician catheterization laboratory performance, supporting catheterization laboratory certification and physician recredentialing.

The ACC-NCDR™ is also considering the introduction of additional modules for conditions such as acute coronary syndromes, heart failure, and atrial fibrillation in upcoming years. Copies of the data elements and definitions for Cath Lab Module v1.1 and v2.0b can be downloaded from the ACC-NCDR™ Web site (www.acc.org).

In summary, the ACC-NCDR™ has made significant strides in collecting and reporting meaningful and complete diagnostic catheterization and PCI patient data. The ACC-NCDR™ continues to be a leader in the quest to capture quality catheterization laboratory data in 2001 and beyond and is the most comprehensive comparative database for diagnostic catheterization and PCI in the U.S.

For more information on the ACC-NCDR™, visit www.acc.org, send an e-mail message to ncdr@acc.org, or call 800-253-4636, extension 451.

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APPENDIX 1. ACC-NCDR™ CARDIAC CATH LAB MODULE VERSION 2.0B ELEMENT LIST

ADMINISTRATIVE
1 Transmission Number
2 Software Vendor
3 Software Version
4 NCDR Version
5 Participant ID
6 Participant Name

DEMOGRAPHICS
7 Unique Patient ID
8 Patient Last Name
9 Patient First Name
10 Patient Middle Initial
11 Patient SSN/Country Code
12 Gender
13 Race
14 Patient DOB

ADMISSION/DISCHARGE
15 Date of Admission
16 Date of Discharge
17 Admission Status
18 Insurance Payor
19 Number of PCI Lab Visits
20 Multiple PCI—Same Lesion
21 CABG During this Admission—Status
22 CABG During this Admission—Date
23 Discharge Status
24 Date of Death
25 Primary Cause of Death
26 Location of Death

HISTORY AND RISK FACTORS
27 Height
28 Weight
29 Family History of CAD
30 CHF
31 Diabetes
32 Renal Failure
33 Chronic Lung Disease
34 Cerebrovascular Disease
35 Peripheral Vascular Disease
36 Previous MI
37 Hypertension
38 Smoking History
39 Hypercholesterolemia

PREVIOUS INTERVENTIONS
40 Previous PCI
41 Previous PCI—Date
42 Previous CABG
43 Previous CABG—Date
44 Previous Valvular Surgery
45 Previous Valvular Surgery—Date

CARDIAC STATUS
46 CHF—Prior Procedure
47 NYHA
48 Noninvasive Test—Ischemia
49 Angina Type
50 Canadian Clinical Classification
51 ACS Time Period

CATH LAB VISIT
52 Date of Procedure
53 Procedure Number
54 Procedure Type
55 Fluoroscopy Time (min)
56 Cath/PCI Same Lab Visit

CATH LAB VISIT—MEDICATIONS
57 Thrombolytics
58 IIb/IIIa Blockade
59 Heparin
60 Aspirin
61 Clopidogrel/Ticlopidine

CATH LAB VISIT—HEMODYNAMIC SUPPORT
62 IABP
63 Cardiopulmonary Bypass

CATH LAB VISIT—LV STATUS
64 Left Ventriculogram
65 Left Ventricular Wall Motion

CATH LAB VISIT—EF STATUS
66 EF Testing
67 Ejection Fraction Percent

CATH LAB VISIT—CORONARY ANATOMY
68 Dominance
69 Stenosis Percent—LM
70 Stenosis Percent—Proximal LAD
71 Stenosis Percent—Mid/Distal LAD
72 Stenosis Percent—RCA/PDA if Right or MI Dominant
73 Stenosis Percent—CIRC

CATH LAB VISIT—PERCUTANEOUS ENTRY
74 Percutaneous Entry Location
75 Closure Device

DIAGNOSTIC CATH PROCEDURE
76 Catheterization Operator's Name
77 Catheterization Operator's SSN
78 Cardiac Cath Status

DIAGNOSTIC CATH PROCEDURE—INDICATIONS
79 Cardiogenic Shock
80 Valvular Heart Disease
81 Arrhythmia
82 Ischemic Heart Disease
83 Positive Functional Tests
84 Heart Disease of Other Etiology

DIAGNOSTIC CATH PROCEDURE—FINDINGS
85 Pulmonary Hypertension
86 Valve Disease—Mitral
87 Valve Disease—Tricuspid
88 Valve Disease—Aortic
89 Valve Disease—Pulmonic

PCI PROCEDURE
90 PCI Primary Operator's Name
91 PCI Operator's SSN
92 PCI Status

PCI PROCEDURE—INDICATIONS
93 Coronary Lesion ≥50% in a Major Artery
94 Acute MI Present
95 ST Elevation Onset
96 Balloon/Stent Deployment Time
97 Cardiogenic Shock Indication

PCI PROCEDURE—SUMMARY
98 Number of Lesions Attempted
99 Number of Lesions Successfully Dilated
100 Procedure Result

PCI PROCEDURE—LESION INFORMATION
101 Lesion Identification Number
102 Segment Number
103 Guidewire
104 Pre-Stenosis Percent
105 Post-Stenosis Percent
106 Pre-Procedure TIMI Flow
107 Post-Procedure TIMI Flow
108 Previously Dilated Lesion
109 In Graft to Cited Segment
110 Location in Graft
111 Lesion Risk
112 Device Number
113 Intracoronary Devices Used
114 Primary Intracoronary Device Indicator
115 Dissection in Segment
116 Acute Closure
117 Successful Reopening
118 Perforation

ADVERSE OUTCOMES
119 Periprocedural MI
120 CK-MB ULN
121 CK-MB Baseline
122 CK-MB Peak
123 Cardiogenic Shock
124 Arrhythmia
125 CVA/Stroke
126 Tamponade
127 Vascular Complications—Bleeding
128 Vascular Complications—Occlusion
129 Vascular Complications—Loss of Distal Pulse
130 Vascular Complications—Dissection
131 Vascular Complications—Pseudoaneurysm
132 Vascular Complications—AV Fistula
133 Contrast Reaction
134 Congestive Heart Failure
135 Renal Failure
136 Emergency PCI
137 Unplanned CABG

OPTIONAL PCI FOLLOW-UP
138 Date of Follow-Up
139 Vital Status
140 Primary Cause of Death
141 Readmission
142 Readmission Reason