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Standardized Cardiovascular Data for Clinical Research, Registries, and Patient Care:

A Report from the Data Standards Workgroup of the National Cardiovascular Research Infrastructure Project. A collaboration of the Duke Clinical Research Institute and the American College of Cardiology – National Cardiovascular Data Registry

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Abstract

Relatively little attention has been focused on standardization of data exchange in clinical research studies and patient care activities. Both are usually managed locally using separate and generally incompatible data systems at individual hospitals or clinics. In the past decade there have been nascent efforts to create data standards for clinical research and patient care data, and to some extent these are helpful in providing a degree of uniformity. Nevertheless these data standards generally have not been converted into accepted computer-based language structures that could permit reliable data exchange across computer networks. The National Cardiovascular Research Infrastructure (NCRI) project was initiated with a major objective of creating a model framework for standard data exchange in all clinical research, clinical registry, and patient care environments, including all electronic health records. The goal is complete syntactic and semantic interoperability. A Data Standards Workgroup was established to create or identify and then harmonize clinical definitions for a base set of standardized cardiovascular data elements that could be used in this network infrastructure. Recognizing the need for continuity with prior efforts, the Workgroup examined existing data standards sources. A basic set of 353 elements was selected. The NCRI staff then collaborated with the two major technical standards organizations in healthcare, the Clinical Data Interchange Standards Consortium and Health Level 7 International, as well as with staff from the National Cancer Institute Enterprise Vocabulary Services. Modeling and mapping were performed to represent (instantiate) the data elements in appropriate technical computer language structures for endorsement as an accepted data standard for public access and

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use. Fully implemented, these elements will facilitate clinical research, registry reporting, administrative reporting and regulatory compliance, and patient care.

1. Introduction

Clinical research studies are usually organized as separate and distinct efforts conducted locally at independent individual sites. Clinical information used in patient care also typically is managed locally using separate, distinct, and generally incompatible data systems at each individual institution. There has been relatively little attention focused on data exchange both in the clinical research and patient care domains. Although some limited clinical data standards exist and can be helpful in standardizing certain aspects of clinical data and providing a certain amount of uniformity, for the most part these have not been converted into accepted computer-based language structures that could be used interchangeably across computer networks. So while clinicians in different locations may think, act, and talk alike in their activities, the basic computer systems which they use to store and retrieve data locally do not, and for the most part cannot, transmit, receive, combine, analyze, and use shared data as information. As a consequence, a robust infrastructure for conducting clinical research using commonly defined and electronically exchangeable data derived directly from clinical sources does not exist in the United States.

In 2009, the National Cardiovascular Research Infrastructure (NCRI) project was initiated by the Duke Clinical Research Institute (DCRI) and the American College of Cardiology Foundation (ACCF) in order to create a model infrastructure for clinical research, clinical registries, and patient care. (1) Initial funding was provided by a grant through the American Recovery and Reinvestment Act (ARRA). The four goals of NCRI are: 1) replace the repetitive assembly and disassembly of short-lived clinical investigator networks with a stable and enduring operational infrastructure for clinical research; 2) standardize and harmonize cardiovascular data to achieve complete syntactic and semantic interoperability throughout the network; 3) coordinate and facilitate the transfer of selected, standardized cardiovascular data into existing and future national registries; 4) develop an enduring library of content for education and training of clinical investigators and site personnel. The NCRI seeks to overcome limitations of current approaches, including the absence of streamlined, one-time data collection activities at each independent site, lack of common data terms used by all, and the inability to transmit, receive, combine, analyze, and use shared data in comparable and interchangeable formats (interoperability).

One critical aspect of NCRI is establishing a universal vocabulary of cardiovascular data elements. This includes establishing all the formal technical features that are required of a controlled vocabulary that can operate on multiple computer networks in the healthcare environment, achieving both syntactic interoperability (format, packaging, transmission) as well as semantic interoperability (unambiguous shared meanings). (2, 3) This also includes disseminating widely the selected data elements and their definitions, and then eliciting feedback from, and facilitating acceptance by, all relevant parties, including investigators, sponsors, regulatory bodies, clinicians, policymakers, payors, and the general public. We describe here the methodology and principal results of the project to identify and harmonize clinical definitions of a base set of standardized cardiovascular data elements applicable to clinical research, registries, and patient care. We also seek to engage the community in efforts to absorb and integrate this distinct advance. Our work continues and expands upon recent work by the American College of Cardiology Foundation/American Heart Association (ACCF/AHA) Task Force on Clinical Data Standards that previously established a base cardiovascular vocabulary of key data elements and definitions for electronic health records (EHR). (4) That initiative identified 99 key terms that should be

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available in every general purpose EHR, terms that are interoperable and applicable to every cardiovascular subspecialty EHR, and which have maximal utility across the widest spectrum of clinical settings, including clinical care and clinical research, as well as in local institutional, state, regional, and national registries and all data interchange environments. The NCRI Data Standards Workgroup followed these same principles in its efforts to build upon that foundation.

2. Methodology

2.1 Workgroup Composition

The principal investigators of NCRI collaborated with ACCF leadership to identify appropriate members for a Data Standards Workgroup charged with undertaking this project. The 8 members selected have overlapping expertise in clinical research and clinical care, information technologies, informatics, clinical registries, data standards development, and statistical analyses. The present document was composed and written by the Workgroup.

2.2 Relationships With Industry and Other Entities

The ACCF, DCRI, NCRI, and their committees, task forces, workgroups, and other bodies all make every effort to avoid actual or potential conflicts of interest. Specifically, all members of a workgroup are required to file statements disclosing current and recent relationships that may be perceived as relevant real or potential conflicts of interest, and the same is required of all peer reviewers of a document. These disclosures for members of this Workgroup are listed in Appendix 2. Comprehensive disclosure information is available online at: www.cardiosource.org/ACC/About-ACC/Leadership/Guidelines-and-Documents-Task-Forces.aspx.

2.3 Review of Literature and Existing Data Elements

This Workgroup identified several tasks involved in establishing the library of core universal cardiovascular concepts (i.e. vocabulary) to be developed for this project. The first task was identifying key clinical terms from among the many available data element concepts. To begin, the Workgroup examined the data dictionaries of the ACCF National Cardiovascular Data Registry (NCDR) and the Society of Thoracic Surgeons (STS) Adult Cardiac Surgery Registry, and then systematically examined all the current existing cardiovascular data dictionaries and standards documents published by these and other professional societies. (4–11) Criteria for inclusion of a specific term (data element) from these sources was that the key clinical concept embodied in the term had the broadest utility and therefore would be collected commonly in cardiovascular clinical research investigations, including both randomized clinical trials and registries. Selection of terms from these sources was achieved by consensus of the group after review and discussion. In general, basic (simple, singular, or atomic) terms were preferred over composite terms. Once selected, all data elements were grouped into standard categories as previously outlined. (4, 12) These categories indicate the clinical context in which the data element is expected to be obtained or collected, and reflect the usual workflow organization of information in typical clinical settings for a single episode of care. Categories are: Personal History and Family History, Physical Examination (Clinical Condition) at the time of the encounter, Laboratory Values, Diagnostic Procedures, Therapeutic Procedures, Adverse Events, Medications, Discharge Information, and Outcomes.

2.4 Data Element Definitions and Consensus Development

The second task of the Workgroup was to harmonize the definitions of elements selected, making certain that unambiguous definitions resulted. This task was intentionally focused on

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the needs of both the clinical care and clinical research communities, as one objective of NCRI is to promote and foster cross-domain compatibility (clinical and research) while accomplishing semantic interoperability. Nearly all clinical terms considered had multiple source definitions. However, upon closer examination many source element definitions were the same or very nearly so. This reflects prior work harmonizing the NCDR registries and the STS adult cardiac surgery registry with existing clinical data standards. Where differences remained the Workgroup used a hierarchical approach to select a final definition. Preference was given to sources as follows (sources shown in Table 1):

1) ACCF/AHA Adult Cardiovascular Vocabulary for EHR; (4) 2) NCDR-STS harmonized data elements; (8) 3) other ACCF/AHA Task Force on Clinical Data Standards endorsed elements, (4–9) 4) other published data standards. (10, 11) The ACCF/AHA Adult Cardiovascular Vocabulary for EHR (containing 99 elements) was given highest priority because it is the most recently completed data standardization effort and was developed specifically for EHR systems. Nevertheless, this hierarchy was not absolute and rigid; definitions were selected for best unambiguous structure and wording in the judgment of the Workgroup, regardless of source. Every element from every source was thoroughly reviewed and discussed. When inconsistencies, discrepancies, inaccuracies, ambiguity, or other substantive issues were discovered in existing data elements or definitions, the Workgroup proposed resolutions for consideration by the ACCF/AHA Task Force on Clinical Data Standards.

The Workgroup was assisted by informatics staff of ACCF and DCRI, with additional help from two other organizations (further described below): the Clinical Data Interchange Standards Consortium (CDISC) and Health Level 7 International (HL7) (13, 14). Staff members provided technical informatics support for the project, including representation of elements and terms in a standard machine readable information model developed according to the specifications in the National Cancer Institute (NCI) Data Standards Repository (caDSR). (15) Materials were assembled by staff and circulated by email. The work was conducted in a series of telephone conference calls and email exchanges beginning in June 2010 and concluding in October 2011. In addition, there was one face-to-face meeting held during the ACC Scientific Sessions in March 2011.

2.5 Relations to Other Standards

As described above, the Workgroup reviewed available published data standards and current national registry data elements. From these source materials a circumscribed set of data elements along with single best definitions was selected to serve as an initial cardiovascular data standard for computer network implementation in clinical research, clinical registries, and patient care activities.

2.6 Technical Development for Endorsement as a Recognized Data Standard

The final task for the Workgroup and supporting staff was to represent (instantiate) the selected vocabulary within accepted EHR technical language standards and publish it in a publicly available data library. (16, 17) The NCRI leadership and staff therefore contacted and collaborated with CDISC and HL7 as the two relevant international standards organizations working in this segment of the healthcare environment. Although likely not widely known among clinicians, the CDISC and HL7 technical standards are broadly accepted and have been generally adopted within the information technology platforms of both the patient care and clinical research communities. (13, 14) For example, the HL7 Reference Information Model (RIM), along with its clinical documents standards and EHR functional profile, are widely recognized as the international technical standard for clinical information systems. The CDISC Study Data Tabulation Model (SDTM) and the Clinical

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Data Acquisition Standards Harmonization (CDASH) are technical standards used for clinical research data collection and exchange between different organizations, for data comparisons across different clinical trials, and for electronic data submission to regulatory agencies. (10, 18) The SDTM accommodates metadata (data format and content tags), which facilitate interoperability and data exchange. The United States Food and Drug Administration (FDA) endorses submission of clinical data in this standard for regulatory review purposes. The NCRI staff therefore created a Unified Modeling Language representation of elements as a Cardiovascular Domain Analysis Model, mapping the model to the specifics required for CDISC SDTM and HL7 RIM. The NCRI data elements were then matched with concept codes assigned by NCI Enterprise Vocabulary Services (EVS). The entire set of cardiovascular concepts will be published in the NCI EVS for public access and use. (19) The data model will be imported into the NCI caDSR and linked with the metadata tags required for full and complete semantic interoperability. This means that these 353 selected cardiovascular data elements should be fully exchangeable across computer networks and within EHR structures, something that previously has not been possible.

2.7 Peer Review and Approval

Drafts of this report and the core set of cardiovascular data elements (excluding the technical representations required for CDISC and HL7 endorsement), were reviewed by the ACCF/AHA Task Force on Clinical Data Standards, and discussed at the Task Force Meeting at the ACC Scientific Sessions in March 2012, with comments transmitted back to the Workgroup. The final version was reviewed and approved by the Chairs of the Research and Publications Committees of the NCDR registries, and also by the Chair of the Science and Quality Oversight Committee. The Workgroup fully acknowledges and anticipates that these standardized data elements and definitions will require regular review and updating, as occurs with all other published guidelines, data standards, performance measures, and appropriateness criteria. NCRI staff will monitor and receive feedback, and periodically review the controlled vocabulary work product to ascertain whether modifications should be considered.

2.8 Intended Use

Adoption and implementation of the cardiovascular data standards presented here should improve interoperability, accuracy, and efficiency in all domains: administrative, regulatory, clinical research, and patient care. Dependable and reliable data exchange should reduce errors caused when multiple transcriptions occur, with the same data being entered into several systems. At the local site level, this will facilitate efforts to extract and review local data, and to transmit data to other entities, for example the large national registries. Combining uniform data from multiple sites for larger scale analyses will also be possible. Linkages of extracted data with administrative and long-term data records will facilitate longitudinal follow-up of specific patient groups of interest. Such linkages with outside data sources may have advantages over the direct clinical follow-up of patients, and may be more efficient and more complete, especially for larger patient groups and for very long term analyses. The Center for Medicare and Medicaid Services (CMS) Medicare Provider Analysis and Review (MEDPAR) datafiles are an example of external data linkages that might be made. Linkages with longitudinal databases may provide opportunities to assess long term mortality, hospital readmissions, subsequent procedures, and various other outcomes of interest. This is likely to enhance the study of long term safety and efficacy of drugs and devices in widespread clinical practice after initial drug or device approval. Furthermore, clinical effectiveness and patient-centered outcomes research comparing a variety of options could be conducted, and evidence-based practice recommendations developed and validated. (20, 21) Such efforts align with other national efforts to improve the clinical patient care domain, specifically the implementation of clinical decision-support

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tools, with the compilation and return of patient-specific, clinician-specific, and institution-specific data back to the point of care where it originates. These efforts furthermore are significant steps toward achieving the goals of the CMS 'Meaningful Use' program, including the use of certified EHR technologies for the purposes of exchanging health information to improve patient care. (22) All of this is consistent with the policies of the national professional societies, and conforms to the recent policy statement from the AHA on expanding the applications of existing and future clinical registries. (23)

3. National Cardiovascular Research Infrastructure Data Elements

From the various sources examined the Workgroup assembled a final list of 353 elements, including a number that are intended to exist as parent-child relationships. Elements that were judged to be the most commonly used in cardiovascular clinical research and clinical care were selected, including all 99 of the previously developed elements for the Adult Cardiovascular EHR. The Workgroup was also keenly aware of the need for parsimony. While this initial list is meant to be comprehensive, we recognize that it may not be adequate for all purposes. Furthermore, any list of data elements will always need ongoing review, with outdated ones deleted and new ones added. The underlying concepts leading to element formation also will change over time and periodic revisions are intended.

3.1 Data elements by category

The elements and their source reference locations are shown in Table 2. Only the element names along with the sources of element values and definitions are listed. Complete element specifications and definitions can be found in an online appendix (Appendix 3), as well as the NCRI website (www.ncrinetwork.org) and the HL7 website (www.hl7.org). Most of these elements were selected from existing data sources. However, nine new data elements of a minor nature were adopted by the Workgroup. These nine new elements and their definitions are shown in Table 3.

3.2 Example representation of data elements

Representation of the data elements was done according to the caDSR implementation of the ISO 11179 metamodel. (15) An example of this representation for the physical examination assessment of Killip Class is shown in Figure 1. More details can be found in the online Appendix 3. A description of the cardiovascular domain analysis model (CV_DAM) is available at the HL7 website (http://www.hl7.org/implement/standards/product_brief.cfm?product_id=133

4. Discussion

Clinical research in the United States is an enormous enterprise of great value to the nation's health. Yet the remarkable advances achieved over the past 80 years have been accomplished largely as a series of separate, organizationally distinct and disconnected efforts undertaken by individual public and private sponsors. For the most part these were done using data management procedures unique to each specific endeavor. Even when ultimate sponsorship has been through the federal enterprise (the National Institutes of Health and other agencies) the individual projects themselves have been dispersed and uncoordinated, and with little effort or attention focused on data interchange. There does not yet exist in the United States, Europe, or elsewhere a robust and sustainable unifying infrastructure that spans the entire translational research, clinical research, regulatory, and clinical practice continuum. Arguably, this absence leads to inefficiencies, delays, and increased costs, all of which have called into question the foundations upon which our clinical research enterprise is built. (24–26) In some instances the increasing globalization of

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clinical research has allowed new techniques and therapies, including some that are federally funded, to become available first to other regions of the world.

It is noteworthy that the multiple available methods of data collection, storage, and transmission, mostly remain generally incompatible with one another, even though they are parts of the same system involving administrative functions, patient care, clinical research, and regulatory reporting and compliance. Lack of full integration with clinical EHR systems has especially constrained efforts to coordinate information transfer, despite the fact that all the functional areas mentioned have become increasingly interdependent. Development of standard data elements with clear and unambiguous definitions and that are compatible with EHR systems holds great promise for addressing the current absence of interoperability. The EHR thus becomes the definitive repository of valid and fully verifiable clinical data, as well as the substrate for facilitating extraction and exchange of data across multiple systems in both the clinical research and patient care domains. Properly constructed, this substrate will enable a broadly distributed yet interconnected network to facilitate information exchange with semantic interoperability among geographically dispersed sites. In order to begin, a single authoritative set of interoperable data elements are needed as the basis for a unified nationwide infrastructure useful simultaneously in both clinical research and patient care. This portion of the NCRI project addresses that need.

Ideally, all clinical data captured via integrated clinical workflows into EHRs eventually will be subject to data standards, including those endorsed by ACCF, AHA, SCAI, STS, and other organizations. However, the task is twofold. First, the relevant clinical data standards have to be created by the appropriate clinical workgroups. Then, these clinical terms and concepts must be converted into syntactically and semantically compatible computer language structures to make them interoperable across networked computer information systems. Implementing such structures for all existing clinical data standards is a daunting task and cannot be accomplished all at once. The NCDR and STS registries together contain approximately 2,400 data elements in current use. When other officially approved data elements are added, the total could grow by hundreds and possibly thousands more. The costs of fully developing the technical specifications and obtaining endorsement for all potential data elements will be quite large. Therefore, some selectivity is required initially in order to establish the core elements for a baseline data standard that can be put into place and then periodically modified. That was the task of this Workgroup. Ultimately, the NCRI project is intended to evolve into permanent stewardship by ACCF of a fully accepted cardiovascular vocabulary. This stewardship will include mechanisms for constant oversight and periodic formal review and updating in response to research, development, and new discoveries. There will be continuing opportunities for engagement and involvement of all stakeholders. For one thing, much more work is needed to harmonize even these initial standardized cardiovascular data elements with other recognized administrative data formats, such as the Systematized Nomenclature for Medicine (SNOMED/CT), the International Classification for Diseases (ICD 9/10), the Logical Observation Identifiers Names and Codes for laboratory values (LOINC), and RxNorm for drugs and pharmacy systems. (27 – 30)

In conclusion, the NCRI Data Standards Workgroup has assembled a set of 353 cardiovascular data elements with definitions that is designed to serve as a foundation of a national cardiovascular clinical and research infrastructure. The vast majority of elements were identified from already existing sources. This work builds upon earlier efforts to establish a base cardiovascular vocabulary for electronic health records, and it includes all the technical developments required for adoption as an international standard. Once fully adopted and implemented these elements will be useful in facilitating clinical research,

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registry reporting, administrative reporting and regulatory compliance, and all aspects of patient care.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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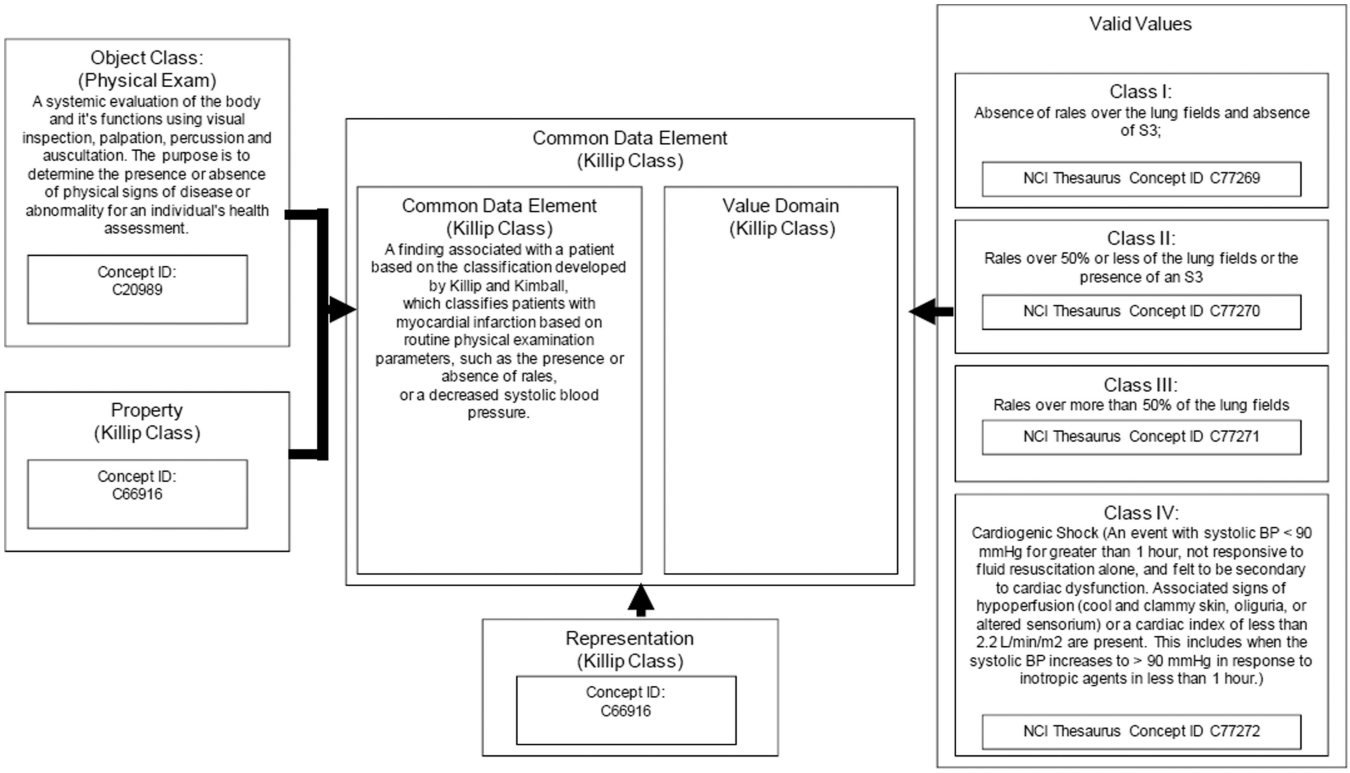

Figure 1.

A simplified view of a Common Data Element (CDE) in the National Cancer Institute Data Standards Repository (caDSR) Implementation of the ISO 11179 metamodel. This example is for a CDE that describes the physical examination assessment of Killip Class constrained to an enumerated list of values as presented by the HL7 Acute Coronary Syndrome Domain Analysis Model, Release 1. Modified from Komatsoulis et al. (15).

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Table 1

Data sources reviewed.

Title	Reference
ACC-NCDR Registries:	
CathPCI Registry	www.ncdr.com/WebNCDR/elements.aspx#1
ICD Registry	www.ncdr.com/WebNCDR/ICD/elements.aspx
ACTION-GWTG Registry	www.ncdr.com/WebNCDR/ACTION/elements.aspx
CARE Registry	www.ncdr.com/WebNCDR/carotidstent/elements.aspx
Society of Thoracic Surgeons Adult Cardiac Surgery Data Registry	www.sts.org/national-database/database-managers/adult-cardiac-surgery-database (Ref. 8)
ACC/AHA Data Standards documents:	
Adult Cardiovascular HER	Weintraub WS, et al. JACC 2011;58:202 (Ref. 4)
Cardiac Imaging	Hendel RC, et al. JACC 2009;53:91 (Ref. 5)
Electrophysiology	Buxton AE, et al. JACC 2006;48:2360 (Ref. 6)
Acute Coronary Syndromes	Cannon CP, et al. JACC 2001;38:2114 (Ref. 7
ACS and Coronary Artery Disease	Cannon CP et al. (in press) (Ref. 9)
Other data standards:	
Clinical Data Interchange Standards Consortium (CDISC): Clinical Data Acquisition Standards Harmonization (CDASH)	www.cdisc.org/cdash (Ref. 10)
National Quality Forum (NQF) – Quality Data Model (QDM)	www.qualityforum.org/QualityDataModel.aspx#t=1&s=&p (Ref. 11)

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Table 2

National Cardiovascular Research Infrastruture Data Elements

Element Name	Source	Element Name	Source	Element Name	Source
Personal history					
Hypertension	ACC/AHA CV EHR	Transient Ischemic Attack	ACC/AHA CV EHR	Hemodynamic Instability assoc. with Ventricular Tachycardia	NCDR (ICD)
Diabetes Mellitus	ACC/AHA CV EHR	Ischemic Stroke	ACC/AHA CV EHR	ICD	NCDR (ICD)
Diabetes Therapy	NCDR (ACTION-GWTG)	Hemorrhagic Stroke	ACC/AHA ACS	Initial ICD reason is Cardiac Arrest/ arrhythmia Etiology Unknown	NCDR (ICD)
Dyslipidemia	ACC/AHA CV EHR	Undetermined Stroke	New	Initial ICD reason is Not Documented	NCDR (ICD)
Tobacco Use	ACC/AHA CV EHR	Syndromes at risk for sudden death	NCDR (ICD)	Initial ICD reason is Spontaneous Sustained VT	NCDR (ICD)
Tobacco Use-Smoked Tobacco Type	New	Sudden death syndrome type	NCDR (ICD)	Initial ICD reason is Syncope with High Risk Characteristics	NCDR (ICD)
Smokeless Tobacco	New	Syncope	ACC/AHA CV EHR	Initial ICD reason is Syncope with Inducible VT	NCDR (ICD)
Heart Failure	STS Adult Cardiac	Syncope Date	ACC/AHA CV EHR	Initial ICD reason is Ventricular Fibrillation	NCDR (ICD)
Heart Failure Hospital Timeframe	NCDR (ICD)	Syncope-Frequency of Episodes	ACC/AHA CV EHR	Structural Abnormality Type - Amyloidosis	NCDR (ICD)
CHF Hospitalization	NCDR (ICD)	Syncope-Number of Episodes	ACC/AHA CV EHR	Structural Abnormality Type - Atrial Septal Defect	NCDR (ICD)
Prior cardiac transplant	NCDR (ICD)	Sleep Apnea	ACC/AHA EP	Structural Abnormality Type - Chagas Disease	NCDR (ICD)
Heart transplant waiting list	NCDR (ICD)	Sleep Apnea-Sleep Study Diagnosis	New	Structural Abnormality Type - Common Ventricle	NCDR (ICD)
NYHA Class	ACC/AHA CV EHR	Aorta Disease	ACC/AHA CV EHR	Structural Abnormality-Type - Ebstein's Anomaly	NCDR (ICD)
Chronic Kidney Disease	ACC/AHA CV EHR	Peripheral Arterial Disease	ACC/AHA CV EHR	Structural Abnormality Type - Giant Cell Myocarditis	NCDR (ICD)
Dialysis	ACC/AHA CV EHR	Renal Artery Disease	ACC/AHA CV EHR	Structural Abnormality Type - Hypertrophic Cardiomyopathy	NCDR (ICD)
Chronic Lung Disease	ACC/AHA CV EHR	Deep Venous Thrombosis	ACC/AHA CV EHR	Structural Abnormality Type - Left Ventricuar Aneurysm	NCDR (ICD)
Chronic Lung Disease-Home Oxygen Therapy	New	Venous thromboembolism	ACC/AHA CV EHR	Structural Abnormality Type-LV Non-compaction Syndrome	NCDR (ICD)
Coronary artery disease	ACC/AHA CV EHR	Pulmonary Embolism	ACC/AHA CV EHR	Structural Abnormality Type - Other	NCDR (ICD)

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Element Name	Source	Element Name	Source	Element Name	Source
One epicardial artery > = 70% confirmed by angiography	NCDR (ICD)	Primary Valvular Disease	ACC/AHA CV EHR	Structural Abnormality Type - Right Ventricular Dysplasia (ARVD)	NCDR (ICD)
Myocardial Infarction	ACC/AHA CV EHR	Prior Valve Surgery/Procedure	NCDR (CathPCI)	Structural Abnormality Type - Sarcoidosis	NCDR (ICD)
Myocardial Infarction timeframe	NCDR (ICD)	Sinus Node Function	ACC/AHA EP	Structural Abnormality Type - Transposition of Great Vessels	NCDR (ICD)
PCI	NCDR (CathPCI)	Permanent Pacemaker	NCDR (ICD)	Structural Abnormality Type - Tetralogy of Fallot	NCDR (ICD)
CABG Surgery	NCDR (CathPCI)	Atrial arrhythmias	ACC/AHA CV EHR	Structural Abnormality Type - Ventricular Septal Defect	NCDR (ICD)
Cardiac Arrest	ACC/AHA CV EHR	Atrial Fibrillation	NCDR (ICD)	Depression	ACC/AHA CV EHR
Cardiac Arrest Date	ACC/AHA CV EHR	Atrial Fibrillation Classification	NCDR (ICD)	HIV Infection	ACC/AHA CV EHR
Cardiac Arrest Due to Arrhythmia	NCDR (ICD)	Atrial Flutter	NCDR (ICD)	Illicit Drug Use	ACC/AHA CV EHR
Previous ICD Implant site	NCDR (ICD)	Bradycardia arrest	NCDR (ICD)	Illicit Drug Use Type-Cocaine Use	NCDR (ICD)
Previous ICD reason	NCDR (ICD)	Ventricular arrhythmias	ACC/AHA CV EHR	Patient Life Expectancy of > = 1 year	NCDR (ICD)
Previous ICD type	NCDR (ICD)	Ventricular Tachycardia	NCDR (ICD)	Clinical Trial	NCDR (ICD)
Cardiogenic Shock	STS Adult Cardiac	Ventricular Tachycardia Type	NCDR (ICD)		
Cerebral Artery Disease	ACC/AHA CV EHR	VT/VF Arrest	NCDR (ICD)		
Family history					
Coronary artery disease	ACC/AHA CV EHR	Sudden Cardiac Death	ACC/AHA CV EHR		
Physical exam					
Height	ACC/AHA CV EHR	Heart Rate	ACC/AHA CV EHR	Anginal classification	ACC/AHA CV EHR
Weight	ACC/AHA CV EHR	Heart Rate Date/Time	ACC/AHA CV EHR	Anginal Classification Date	ACC/AHA CV EHR
Systolic Blood Pressure	ACC/AHA CV EHR	Waist Circumferance	ACC/AHA CV EHR	Killip Class	ACC/AHA ACS
Diastolic Blood Pressure	ACC/AHA CV EHR	Chest Pain: Angina or Anginal Equivalent	ACC/AHA CV EHR	New York Heart Association Class	ACC/AHA CV EHR
Laboratory values					
Blood Urea Nitrogen	CDISC-CDASH	Total Cholesterol	CDISC-CDASH	Sodium	CDISC-CDASH
Creatinine	CDISC-CDASH	LDL Cholesterol	CDISC-CDASH	Potassium	CDISC-CDASH
Hematocrit	CDISC-CDASH	HDL Cholesterol	CDISC-CDASH	Creatine Kinase (CK)	CDISC-CDASH
Hemoglobin	CDISC-CDASH	Triglycerides	CDISC-CDASH	Creatine Kinase MB (CK-MB)	CDISC-CDASH
Glucose, any	CDISC-CDASH	Brain Naturetic Peptide (BNP)	CDISC-CDASH	Troponin	CDISC-CDASH

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Element Name	Source	Element Name	Source	Element Name	Source
Glucose, fasting	ACC/AHA CV EHR	NT-proBNP	CDISC-CDASH	Troponin I	CDISC-CDASH
Hemoglobin A1c	CDISC-CDASH	Prothrombin Intl. Normalized Ratio (INR)	CDISC-CDASH	Troponin T	CDISC-CDASH
Diagnostic Procedures					
Cardiac diagnostic procedure	ACC/AHA CV EHR	Cardiac Rhythm-Sinus Rhythm	NCDR (ICD)	PR Interval	NCDR (ICD)
Date of cardiac diagnostic procedure	ACC/AHA CV EHR	Cardiac Rhythm-Atrial Tachycardia	NCDR (ICD)	PR Interval not obtainable	NCDR (ICD)
12 Lead ECG	NCDR (ICD)	Cardiac Rhythm-Junctional	NCDR (ICD)	Cardiac Rhythm-Second Degree Heart Block	NCDR (ICD)
12 Lead ECG Date/Time	NCDR (ICD)	Cardiac Rhythm-Idioventricular	NCDR (ICD)	Cardiac Rhythm-Third Degree Heart Block	NCDR (ICD)
ECG (any)	NCDR (ICD)	Cardiac Rhythm-Afib/Flutter	NCDR (ICD)	Abnormal Intraventricular Conduction	NCDR (ICD)
ECG (any) Date/Time	NCDR (ICD)	Cardiac Rhythm-Paced	NCDR (ICD)	Abnormal Intraventricular Conduction Type - Delay, Nonspecific	NCDR (ICD)
ECG Timing with STEMI or STEMI Equivalent	NCDR (ACTION GWTG)	Pacing Type	NCDR (ICD)	Abnormal Intraventricular Conduction Type - Left Anterior Fascicular Block	NCDR (ICD)
ECG Findings for NSTEMI	NCDR (ACTION-GWTG)	Underlying Atrial Rhythm	NCDR (ICD)	Abnormal Intraventricular Conduction Type - Left Posterior Fascicular Block	NCDR (ICD)
ECG Findings for STEMI	NCDR (ACTION-GWTG)	Only Ventricular Paced QRS Complexes	NCDR (ICD)	Abnormal Intraventricular Conduction Type - Left Bundle Branch Block	NCDR (ICD)
Electrophysiology Study	NCDR (ICD)	QRS Duration (Non-ventricular Paced Complexes)	NCDR (ICD)	Abnormal Intraventricular Conduction Type - Right Bundle Branch Block	NCDR (ICD)
Ventricular Arrhythmias Induced	NCDR (ICD)	Ventricular Paced QRS Duration	NCDR (ICD)	Abnormal Intraventricular Conduction Type - Ventricular Paced Rhythm	NCDR (ICD)
Non-Invasive Stress Testing	NCDR (ACTION-GWTG)	Stress Echo Imaging Results	NCDR (CathPCI)	Cardiac CTA	NCDR (CathPCI)
Stress Test Result	ACC/AHA CV EHR	Risk/Extent of Ischemia (Stress Echo)	NCDR (CathPCI)	Cardiac CTA Results	NCDR (CathPCI)
Exercise Stress Test Results	NCDR (CathPCI)	Stress Test with CMR Imaging Results	NCDR (CathPCI)	Pre-test probability of coronary artery disease	ACC/AHA CV EHR
Spect/MPI Imaging Results	NCDR (CathPCI)	Risk/Extent of Ischemia (Stress Test with CMR)	NCDR (CathPCI)		
Risk/Extent of Ischemia (Spect/MPI)	NCDR (CathPCI)				
Left Ventricular Ejection Fraction (qualitative)	ACC/AHA CV EHR	Left atrium size (quantitative)	ACC/AHA CV EHR		
Left Ventricular Ejection Fraction (quantitative)	ACC/AHA CV EHR	Aortic valve stenosis severity	ACC/AHA CV EHR	Mitral valve stenosis severity	ACC/AHA CV EHR

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Element Name	Source	Element Name	Source	Element Name	Source
Left ventricle size, end-diastole (quantitative)	ACC/AHA CV EHR	Aortic valve area	ACC/AHA CV EHR	Mitral valve area	ACC/AHA CV EHR
Left ventricle size, end-systole (quantitative)	ACC/AHA CV EHR	Aortic valve regurgitation severity	ACC/AHA CV EHR	Mitral valve regurgitation severity	ACC/AHA CV EHR
Diagnostic Catheterization	NCDR (CathPCI)	Reason for Diagnostic Catheterization_Cardiac Transplantation	NCDR (CathPCI)	Intravascular Ultrasound (IVUS)	NCDR (CathPCI)
Diagnostic Catheterization Status	NCDR (CathPCI)	Reason for Diagnostic Catheterization_Cardiac Transplant Evaluation Type	NCDR (CathPCI)	Fractional Flow Reserve Reserve Ratio	NCDR (CathPCI)
Left Heart Catheterization	NCDR (CathPCI)	Reason for Diagnostic Catheterization_Cardiomyopathy or Left ventricular systolic dysfunction evaluation	NCDR (CathPCI)	Fractional Flow Reserve Ratio	NCDR (CathPCI)
Diagnostic Coronary Angiography	NCDR (CathPCI)	Reason for Diagnostic Catheterization_Pre-operative evaluation for non-cardiovascular surgery	NCDR (CathPCI)		
Coronary Anatomy Dominance	NCDR (CathPCI)				
Coronary artery: number of diseased vessels (excludes left main disease)	ACC/AHA CV EHR				
Stenosis location	NCDR (CathPCI)				
Stenosis severity	NCDR (CathPCI)				
Therapeutic Procedures					
Cardiac Therapeutic Procedure	ACC/AHA CV EHR	Percutaneous Coronary Intervention	NCDR (CathPCI)	Primary reason reperfusion therapy not indicated-Urgent Cardiac Surgery	NCDR (ACTION-GWTG)
Date of Cardiac Therapeutic Procedure	ACC/AHA CV EHR	PCI Indication	NCDR (CathPCI)	Non-system reason for Delay in PCI	NCDR (CathPCI)
Coronary Artery Bypass Graft Surgery	NCDR (CathPCI)	PCI Status	NCDR (CathPCI)	Culprit Lesion	NCDR (CathPCI)
Coronary Bypass Graft Surgery Status	NCDR (CathPCI)	Coronary lesions treated	NCDR (CathPCI)	Pre-Procedure TIMI Flow	NCDR (CathPCI)
Coronary graft anastomoses	ACC/AHA CV EHR	Lesion Complexity Description	NCDR (CathPCI)	Post-Procedure TIMI Flow	NCDR (CathPCI)
Stent Placed in affected coronary artery	NCDR (CathPCI)	Bifurcation Lesion	NCDR (CathPCI)	Percent Stenosis	NCDR (CathPCI)
Stent placed in previous lesion	NCDR (CathPCI)	Chronic Total Occlusion	NCDR (CathPCI)	Lesion Length	NCDR (CathPCI)
Stent Placed in Previous PCI	NCDR (CathPCI)	Lesion in Graft	NCDR (CathPCI)	Guidewire Across Lesion	NCDR (CathPCI)

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Element Name	Source	Element Name	Source	Element Name	Source
Stent Type	NCDR (CathPCI)	Location in Graft	NCDR (CathPCI)	Intracoronary Device Used	NCDR (CathPCI)
Previously Treated Lesion	NCDR (CathPCI)	Intra-aortic Balloon Pump (IABP)	NCDR (CathPCI)	Device Deployment	NCDR (ICD)
Previous treatment type_Stent	NCDR (CathPCI)	Intra-aortic Balloon Pump (IABP) Timing	NCDR (CathPCI)	Device Diameter	NCDR (ICD)
Reason for current treatment of previously treated lesion_In-stent Restenosis	NCDR (CathPCI)	Mechanical Ventricular Support-Other	NCDR (CathPCI)	Device Length	NCDR (CathPCI)
Reason for current treatment of previously treated lesion_in-stent Thrombus	NCDR (CathPCI)	Mechanical Ventricular Support–Other, Timing	NCDR (CathPCI)	Contrast Volume	NCDR (CathPCI)
Arterial Access Site	NCDR (CathPCI)			Fluoroscopy Dose	NCDR (CathPCI)
Arterial Access Closure Method	NCDR (CathPCI)			Fluoroscopy Time	NCDR (CathPCI)
Electrophysiology Procedure	NCDR (ICD)	VT Ablation Performed	NCDR (ICD)		
ICD	NCDR (ICD)	ATP or Shock Therapy Appropriate	NCDR (ICD)	Lead Abnormality_Oversensing with Shock or ATP	NCDR (ICD)
ICD Procedure Indication	NCDR (ICD)	ATP or Shock Therapy Delivered	NCDR (ICD)	Lead Abnormality_Oversensing with out Shock or ATP	NCDR (ICD)
Device Implanted	NCDR (ICD)	ATP Therapy Successful	NCDR (ICD)	Lead Abnormality_Defibrillation Issues	NCDR (ICD)
Device Explanted	NCDR (ICD)	Shock Therapy Successful	NCDR (ICD)	Lead Abnormality_Extracardiac Stimulation	NCDR (ICD)
Device Manufacturer	NCDR (ICD)	CS/LV Lead Successful	NCDR (ICD)	Lead Abnormality_Failure to Capture	NCDR (ICD)
Device Model Name	NCDR (ICD)	Reason CS/LV Lead Not Implanted	NCDR (ICD)	Lead Abnormality_Failure to Pace	NCDR (ICD)
Device Model Number	NCDR (ICD)	Battery Voltage	NCDR (ICD)	Lead Abnormality_Oversensing	NCDR (ICD)
Device Returned to Manufacturer	NCDR (ICD)	Conductor Failure	NCDR (ICD)	Lead Abnormality_Undersensing	NCDR (ICD)
Device Serial Number	NCDR (ICD)	Defribillation Threshold/Lowest Energy Tested	NCDR (ICD)	Lead Dislodgement Requiring Reposition/Reoperation	NCDR (ICD)
Lead Returned to Manufacturer	NCDR (ICD)	Upper Limit of Vulnerability	NCDR (ICD)	Lead Erosion	NCDR (ICD)
Manufacturer Advisory/Recall	NCDR (ICD)	Failed to Shock with Inadequate DFT Safety Margin	NCDR (ICD)	Lead Infection	NCDR (ICD)
Non-lead Related Medical/ Surgical Procedure	NCDR (ICD)	Faulty Connector Header	NCDR (ICD)	Lead Perforation	NCDR (ICD)
Reason for Malfunction	NCDR (ICD)			Lead Location	NCDR (ICD)
Reason(s) for Reimplant	NCDR (ICD)			Existing Lead Dislodgement	NCDR (ICD)
				Existing Lead Status	NCDR (ICD)
				Existing Lead Function	NCDR (ICD)

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Element Name	Source	Element Name	Source	Element Name	Source
Clinical/Adverse Events					
Significant Coronary Dissection	NCDR (CathPCI)	Myocardial infarction	NCDR (CathPCI)	Pneumothorax	NCDR (ICD)
Coronary Artery Perforation	NCDR (CathPCI)	Urgent cardiac surgery	NCDR (CathPCI)	Hemothorax	NCDR (ICD)
Coronary Thrombus	NCDR (CathPCI)	Cardiac Tamponade	NCDR (CathPCI)	Peripheral Embolus	NCDR (ICD)
Coronary Venous Dissection	NCDR (ICD)	Luminal/Carotid Thrombus	NCDR (CARE)	Peripheral Nerve Injury	NCDR (ICD)
Cardiac Valve Injury	NCDR (ICD)	Venous Obstruction	NCDR (ICD)	Infection Requiring Antibiotics	NCDR (ICD)
Chamber Thrombus	ACC/AHA EP	Hematoma at Access Site	NCDR (CathPCI)	Set Screw Problem	NCDR (ICD)
Conduction Block	NCDR (ICD)	Hematoma Size	NCDR (CathPCI)	Drug Reaction/Serious Substance-related Adverse Event	NQF-QDM
Cardiac Perforation	NCDR (ICD)	Hematoma Requiring Re-op	NCDR (CathPCI)	Drug/Substance Allergy	NQF-QDM
Pericardial Effusion	NCDR (ICD)	Red blood cell or whole blood transfusion	NCDR (CathPCI)		
Medications					
At Home Medications	New	Medication Timepoint	CDISC-CDASH	Prophylactic Antibiotics Within 1 hour of procedure start time	NCDR (ICD)
Aspirin in First 24 hours	NCDR (ACTION-GWTG)	Medications Held or Discontinued	New	Diuretic	ACC/AHA CV EHR
Clopidogrel in First 24 hours	NCDR (ACTION-GWTG)	Blinded	New	Direct renin inhibitor	ACC/AHA CV EHR
Prasugrel in First 24 hours	NCDR (ACTION-GWTG)	Contraindication	New	Alpha blocker	ACC/AHA CV EHR
Ticlipodine in First 24 hours	NCDR (ACTION-GWTG)	Anticoagulant	ACC/AHA CV EHR	Steroid, systemic	ACC/AHA CV EHR
Beta Blocker in First 24 hours	NCDR (ACTION-GWTG)	Cyclo-oxygenase 2 inhibitor	ACC/AHA CV EHR	Nonsteroidal anti-inflammatory	ACC/AHA CV EHR
ACE Inhibitor in First 24 hours	NCDR (ACTION-GWTG)	P2Y12 inhibitor	ACC/AHA CV EHR		
Angiotensin Receptor Blocker in First 24 hours	NCDR (ACTION-GWTG)	Beta-Blockers	CDISC-CDASH		
Statin in First 24 hours	NCDR (ACTION-GWTG)	GP IIb/IIIa Inhibitor	CDISC-CDASH		
Non-Statin Lipid Lowering in First 24 hours	NCDR (ACTION-GWTG)	Lipid Lowering Statin Medications	CDISC-CDASH		
Aldosterone Blocking Agent in First 24 hours	NCDR (Action-GWTG)	Non Statin Lipid Lowering Medications	CDISC-CDASH		
Discharge					
Vital Status	NCDR (CathPCI)	Dietary Counseling	NCDR (ACTION-GWTG)	Transfer for Procedure	NCDR (CathPCI)
Comfort Measures	NCDR (ACTION-GWTG)	Exercise Counseling	NCDR (ACTION-GWTG)	Transfer for Procedure Location	NCDR (CathPCI)
CMS Comfort Measures Timing	NCDR (ACTION-GWTG)	Smoking Counseling	NCDR (ACTION-GWTG)		
CMS Discharge Disposition	NCDR (ACTION-GWTG)	Cardiac Rehabilitation Referral	NCDR (ACTION-GWTG)		

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Element Name	Source	Element Name	Source	Element Name	Source
Outcomes					
Death	ACC/AHA CV EHR				
Date of death	ACC/AHA CV EHR				
Cause of death	NCDR (CathPCI)				
Cardiac death	ACC/AHA CAD				
Death During Procedure	NCDR (CathPCI)				

ACC/AHA ACS = ACC/AHA Acute Coronary Syndromes Data Standard (Ref. 7).
ACC/AHA CV EHR = ACC/AHA Cardiovascular Vocabulary for Electronic Health Records Data Standard. (Ref. 4).
ACC/AHA CAD = ACC/AHA Coronary Artery Disease Data Standard (Ref. 9).
CDISC-CDASH = Clinical Data Interchange Standards Consortium - Clinical Data Acquisition Standards Harmonization (Ref. 10).
STS Adult Cardiac = Society of Thoracic Surgeons Adult Cardiac Surgery Data Registry (Ref. 8).
NCDR (ACTION-GWTG) = NCDR ACTION-GWTG Registry (see text and Table 1).
NCDR (CARE) = NCDR CARE Registry (see text and Table 1).
NCDR (CathPCI) = NCDR CathPCI Registry (see text and Table 1).
NCDR (ICD) = NCDR ICD Registry (see text and Table 1).
NQF-QDM = National Quality Forum-Quality Data Model (Ref. 11).

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Table 3

Newly defined NCRI Data Elements.

Element name	Definition	Value Domain
Chronic lung disease – Home oxygen therapy	Indicate if, the patient has been receiving home oxygen therapy for treatment of chronic lung disease.	Yes No
Sleep apnea – sleep study diagnosis	Indicate if the sleep apnea was diagnosed by a sleep study.	Yes No
Smoked tobacco type	Indicate the type of smoked tobacco.	Cigars Cigarettes Pipes
Smokeless tobacco	Indicate the use of smokeless tobacco.	Yes No
Undetermined stroke	Defined as a stroke with insufficient information to allow categorization as an ischemic or hemorrhagic stroke.	Yes No
At-home medications	Indicate if the medication was taken or started at home.	Yes No
Blinded	Indicate if the medication use was blinded.	Yes No
Contraindicated	Indicate if the medication was contraindicated.	Yes No
Medications held or discontinued	Indicate if the medication was held or discontinued.	Yes No