

ACC/AHA/SCAI 2014 Health Policy Statement on Structured Reporting for the Cardiac Catheterization Laboratory

A Report of the American College of Cardiology Clinical Quality Committee

Developed in Collaboration With the American Association for Critical-Care Nurses, Asian Pacific Society of Cardiology, Canadian Cardiovascular Society, Health Level Seven International, Inter-American Society of Cardiology, Integrating the Healthcare Enterprise, Society of Thoracic Surgeons, and Society for Vascular Surgery (any subsequent endorsements will be reflected in print publication)

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Table of Contents

Preamble	5
Executive Summary	6
1. Introduction.....	7
1.1. Document Development Process.....	7
1.1.1. Writing Committee Organization	7
1.1.2. Document Development and Approval	8
1.2. Background and Rationale	8
2. Principles of Structured Reporting	12
2.1. General Principles	12
2.2. Integration of Data Acquisition with Workflow.....	12
2.3. Capture of Information as Data Rather than Prose.....	14
2.4. Role of the Physician in Authoring the Structured Procedure Report.....	15
2.5. The Best Practice Model	16
3. Catheterization Procedure Reporting: Anticipating 2 Different Reports	17
3.1. The Procedure Log Report.....	18
3.2. The Physician-Authored Structured Procedure Report	19
4. The Prototype Formatted, Tabular, Structured Procedure Report.....	20
4.1. Front Page Summary: Highest Value Information	21
4.2. Graphics and Images Section	21
4.3. Report Body: Details.....	22
4.3.1. Administrative Information	22
4.3.2. History and Risk Factors	23
4.3.3. Procedure Details.....	24

4.3.4. Diagnostic Results	25
4.3.5. Intervention.....	25
4.3.6. Final Diagnoses	26
4.3.7. Operators, titles, regulatory attestation.....	26
4.4. Procedure-Specific Content.....	26
4.4.1. Cardiac Catheterization (Right, Left, Coronary Intervention).....	27
4.4.2. Peripheral Vascular Catheterization	29
4.4.3. Cerebrovascular Catheterization.....	30
4.4.4. Valvular Heart Disease: Transcatheter Aortic Valve Replacement.....	30
4.4.5. Congenital and Structural Heart Catheterization.....	31
4.4.6. Combination Procedures	33
4.5. Structured Report Style Guide.....	33
4.6. Data Export.....	35
4.7. Paradigm Expansion.....	36
5. Adoption and Implementation	36
6. Extending the Structured Reporting Use Case	39
ACC President and Staff	41
References.....	42
Appendix 1. Author Relationships With Industry and Other Entities (Relevant).....	48
Appendix 2. Peer Reviewer Relationships With Industry and Other Entities (Relevant)	53
Appendix 3. Abbreviations.....	62

Preamble

This document has been developed as a health policy statement (HPS) by the American College of Cardiology (ACC). HPSs are intended to promote or advocate a position, be informational in nature, and offer guidance to the stakeholder community regarding the stance of the ACC and other contributing organizations on healthcare policies and programs. HPSs are not intended to offer clinical guidance and do not contradict existing ACC clinical policy. They are overseen by the ACC Clinical Quality Committee (CQC), the group responsible for developing and implementing all HPS policies and procedures related to topic selection, commissioning writing committees, and defining document development methodologies. The CQC brings together various areas of the College such as the Advocacy Committee, the National Cardiovascular Data Registry (NCDR), the ACC/American Heart Association (AHA) Task Forces on Guidelines and Performance Measurement, and the ACC Appropriate Use Criteria (AUC) Task Force.

The CQC recommended the development of this HPS to document the ACC's official position on structured reporting of cardiac catheterization procedures. A number of organizations were invited to co-author this statement with the goal of sharing a unified message on this important topic. Structured reporting is believed to be foundational to the provision of high quality care for patients undergoing procedures in the cardiac catheterization laboratory. As such, the intended audience for this document includes third party payers; electronic health record (EHR) and clinical software vendors; accrediting and certifying organizations; and regulators whose areas of responsibility include electronic health data.

To avoid actual, potential, or perceived conflicts of interest that may arise as a result of industry relationships or personal interests among the writing committee, all members of the writing committee, as well as peer reviewers of the document, are asked to disclose all current healthcare-related relationships, including those existing 12 months before initiation of the writing effort. The CQC reviews these disclosures to determine what companies make products (on market or in development) that pertain to the document under development. Based on this information, a writing committee is formed to include a majority of members with no *relevant* relationships with industry and other entities (RWI), led by a chair with no *relevant* RWI. Authors with *relevant* RWI are not permitted to draft initial text or vote on recommendations pertaining to their RWI. RWI is reviewed on all conference calls and updated as changes occur. Author and peer reviewer RWI pertinent to this document are disclosed in Appendices 1 and 2, respectively. In addition, to ensure complete transparency, authors' *comprehensive disclosure information*—including RWI not pertinent to this document—is available as an [online supplement](#) to this document

http://jaccjacc.cardiosource.com/DataSupp/2014_Cathlab_COMPREHENSIVE_RWI_DISCLOSURE_TABLE.pdf). Disclosure information for the ACC CQC is also available online at www.cardiosource.org/ACC/About-ACC/Leadership/Guidelines-and-Documents-Task-Forces.aspx, as well as the ACC disclosure policy for document development at www.cardiosource.org/Science-And-Quality/Practice-Guidelines-and-Quality-Standards/Relationships-With-Industry-Policy.aspx. The work of the writing committee was supported exclusively by the ACC without commercial support. The writing committee members volunteered their time to this effort. Conference calls of the writing committee were confidential and attended only by committee members.

Joseph P. Drozda, Jr., MD, FACC
Chair, ACC Clinical Quality Committee

Executive Summary

The final report is an essential component of every invasive and operative procedure. This vital document records key data used to assess indications and appropriateness of care, details technical aspects of the procedure, describes findings and observations, lists results and calculations, provides the interpretation of the study, and conveys patient care recommendations. In addition to providing essential information to the entire team of care providers, the final report is utilized in billing and inventory management, process and performance improvement, outcomes analysis, teaching and education, and as a data source for registries (1). The final report is a legal medical record document and should be of the highest quality so as to optimize both patient outcomes and institutional operational efficiencies. A structured report generated by a structured reporting process is the most suitable vehicle for these goals, but this approach is only slowly being adopted despite prior recommendations and endorsements. This HPS is intended to provide a general model for structured reporting for invasive and interventional cardiovascular procedures and thus catalyze and accelerate implementation of structured reporting. Through endorsement of this document, the cardiovascular community recognizes the critical importance of structured reporting and calls for its uniform adoption.

The general principles of structured reporting in cardiovascular imaging are well established. Information should be captured as data rather than prose; these data should flow bi-directionally to and from the EHR for subsequent presentation and analysis. The final report should be clear, concise, organized, consistent, reproducible, understandable, and in a format that is flexible to accommodate evolutionary procedural changes and documentation requirements.

Key considerations for generating a structured report are discussed in detail, with a structured procedure report prototype included for modeling purposes. The prototype final report is segmented into three principal sections. The first section (front page) is a single (physical) page that contains the highest value clinical information. Since angiography is inherently visual, the second section is dedicated to the graphical representations of the findings and (optionally) images imported into the report. The body (third section) contains all of the remaining data presented as a series of structured, formatted tables. Procedure-specific content is outlined for diagnostic cardiac catheterization, percutaneous coronary intervention (PCI), peripheral vascular and cerebral vascular procedures, valvular heart disease including transcatheter aortic valve replacement (TAVR), structural and congenital heart disease (CHD), and combination procedures. The concepts enumerated in this HPS are applicable to nonsurgical endovascular procedures performed in a cardiac catheterization laboratory, hybrid catheterization/operating room suite, and interventional/neuroradiology suite.

Universal adoption of structured reporting for invasive cardiovascular imaging procedures requires the acknowledgement of its potential benefits and acceptance of the responsibilities entailed. In order to stimulate structured reporting implementation, key groups including physician operators, catheterization laboratory personnel, the software vendor community, and leadership of registries must be on the forefront of advocating the adoption of structured reporting. The ACC/AHA/Society for Cardiovascular Angiography and Interventions Foundation (SCAI) recognize that the development and deployment of structured reporting will be an ongoing process and, therefore, strongly encourage the view that structured reporting be considered one component of the overall quality improvement imperative for cardiovascular care.

1. Introduction

1.1. Document Development Process

1.1.1. Writing Committee Organization

The writing committee consists of a broad range of members from the ACC as well as the following societies: American Association of Critical-Care Nurses (AACN), AHA, Asian Pacific Society of Cardiology (APSC), Canadian Cardiovascular Society (CCS), Digital Imaging and Communications in Medicine (DICOM), Health Level Seven International (HL7), Inter-American Society of Cardiology (IASC), Integrating the Healthcare Enterprise (IHE), International Society for Adult Congenital Heart Disease (ISACHD), SCAI, Society of Interventional Radiology (SIR), Society of Thoracic Surgeons

(STS), and Society for Vascular Surgery (SVS). Representatives from these societies included those with expertise in cardiothoracic surgery, interventional cardiology, interventional radiology, general cardiology, echocardiography, and cardiac nursing. Along with these specialties, specific knowledge in the areas of TAVR, carotid and cerebrovascular disease, vascular medicine, structural heart disease, patient outcomes, data interoperability, and catheterization laboratory workflows were also reflected in the workgroup to provide an appropriate balance of perspectives. Geographically, the writing committee included both domestic and international members. Relationships with EHR companies and software vendors active in cardiovascular medicine were deemed relevant to this writing effort. This writing committee met the College's disclosure requirements for RWI as described in the Preamble.

1.1.2. Document Development and Approval

The writing committee convened by conference call and e-mail to finalize the document outline, develop the initial draft, revise the draft per committee feedback, and ultimately approve the document for external peer review. Each participating organization provided peer reviewers, resulting in 32 reviewers representing 410 comments. To increase its applicability further, the document was posted on the (<https://services.acc.org/formsubmit/cathlabhps/form.htm>) for a 3-week public comment period, resulting in 4 people providing 19 comments. These additional comments were used to develop the final version. All comments were reviewed and addressed by the writing committee. A member of the ACC CQC served as lead reviewer to ensure that all comments were addressed adequately. Both the writing committee and CQC approved the version of the final document sent for board review. The ACC Board of Trustees, The ACC Board of Governors, The ACC CQC, AHA, SCAI, AACN, DICOM, HL7, IHE, CCS, APSC, IASC, ISACHD, STS, SIR, SVS, ACPC Council, Cardiovascular Care Team, ISC, CCCOA, Surgeon, Scientific Council, Imaging Council, Informatics Committee, Advocacy Steering Committee, NCDR Management Board, EP Committee, PCI GL chairs, Cath Lab Standards ECD chair, Patient Radiation Safety ECD chair, Provider Radiation Safety ECD chair, TF on Performance Measures, and the AUC reviewed the document, including all peer review comments and writing committee responses, and approved the document in February 2014. The AACN, AHA, APSC, CCS, HL7, IASC, IHE, SCAI, STS, SVS, endorsed the document in March 2014. This document is considered current until the CQC revises or withdraws it from publication.

1.2. Background and Rationale

A final procedure report is essential and required for all cardiovascular catheterization procedures. The procedure report documents key data used to assess indications and appropriateness of

care, details technical aspects of the procedure, describes findings and observations, lists results and calculations, provides the interpretation of the study, and conveys patient care recommendations. It is a vital means of communication between the physician operator and the team of care providers. Additionally, it is utilized in billing and inventory management, process and performance improvement, patient outcomes analysis, teaching and education, and participation in data registries. The final procedure report is a legal medical record document often accessible to patients via internet portals and personal health records. Patient education, enablement, and participation in their health care are augmented by unambiguous information returned to the patient, a movement that is facilitated by better procedure reporting. Accordingly, it is imperative that complete reports of the highest quality are authored. Elements of quality achieved through structured reporting include clarity and completeness of documentation, consistency in the organization and presentation of information, and fulfillment of requirements for quality reporting, regulatory compliance, coding and billing, all while reducing the time devoted to documentation and improving operator efficiency. Furthermore, structured reporting creates the potential for patient-specific risk prediction (e.g., bleeding, restenosis, mortality) and other types of clinical decision support at the point of care.

The concept of a structured procedure report is not new (2,3). In 2006, a multi-stakeholder group recommended the use of structured reports as a key component to achieving quality in cardiovascular imaging (4). The subsequent “2008 ACCF/ACR/AHA/ASE/ASNC/HRS/NASCI/RSNA/SAIP/SCAI/SCCT/SCMR HPS on Structured Reporting in Cardiovascular Imaging” articulated the framework for structured reporting for cardiovascular imaging procedures (5). Structured reporting was again endorsed in the 2012 ACCF/SCAI Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update as the instrument for documenting cardiac catheterization laboratory procedures (6). Nonetheless, adoption of structured reporting has been slow, and even today the majority of catheterization reports are dictated and transcribed in unstructured formats. Even when structured reporting is used, there is a lack of consistency from laboratory to laboratory, and from vendor to vendor. This suggests several reasons for the failure to universally adopt structured reporting: insufficient understanding of the specifics of structured reporting, inadequate guidance to both the clinical community and administrative management as to exactly what to demand; and an absence of sufficient economic, professional and regulatory motivation to adopt structured reporting as a "requirement." This HPS addresses these dimensions, leveraging advances in standards (such as the HL7 Consolidated Clinical Document Architecture [C-CDA] (7) and the Integrating the Healthcare Enterprise Cath Report Content [IHE CRC] profile) (8) to provide explicit technical specifications while articulating the clinical, scientific, social, economic, and regulatory advantages of structured reporting in the cardiovascular catheterization suite.

It is critical to differentiate the narrow concept of the “structured report” from the more comprehensive process of “structured reporting.” Structured reporting begins with the explicit use of standardized, controlled vocabularies of clinical data elements, integrates workflow and documentation processes, and achieves data interoperability among information technology systems as a natural and intended result. The authoring of formatted, structured catheterization procedure reports in a coherent, consistent, and clinically relevant manner is perhaps the most valuable outcome of a structured reporting environment. However, this HPS purposefully expands beyond the narrow concept of the structured report to include the entire data acquisition and reporting process.

Controlled vocabularies are selected lists of words and phrases (standardized data elements) with explicit definitions that convey specific (human interpretable) meaning while achieving computational interoperability. Controlled vocabularies are foundational to structured reporting as they enable the computational assessment of systems, processes, performance, and outcomes. The consistent use of controlled vocabularies among disparate encounters allows organizations to assess procedure appropriateness and determine compliance with practice guidelines of professional societies (9-15). While standardized data can improve care within an individual organization, the larger impact occurs when the data are shared externally for analysis and reporting. Specifically, this standardization facilitates the extraction, transmission, and analysis of the data via registries such as the ACC NCDR (16). At the clinician level, the use of controlled vocabularies, coupled with report formats that are consistent in key elements, improves understanding of report content critical to direct patient care. Analysis of datasets comprising uniformly defined data elements can be returned to the clinician to identify opportunities for care improvement and, encourage lifelong professional learning activities. For patients, data terminology standards facilitate a better understanding of the documents that describe their process. For society, the capability of aggregating data in a semantically meaningful way enables device and drug surveillance, including comparative effectiveness research that strives to best understand the risks and benefits of treatments and alternatives.

On February 17, 2009, the United States federal government enacted the Health Information Technology for Economic and Clinical Health (HITECH) Act of the American Recovery and Reinvestment Act of 2009 legislation (17). A key goal of HITECH is to achieve interoperability of standardized, structured data. Interoperability is the capacity of information technology systems and software applications to communicate and exchange data accurately, effectively, and consistently as well as to use the information that has been exchanged meaningfully (18). Achieving true *semantic interoperability*, which refers to the interchange of data while retaining the meaning of the contained information, is the ultimate goal. In health care, semantics are represented in controlled vocabularies such

as Systemized Nomenclature of Medicine – Clinical Terms (SNOMED CT), with the semantic relationships among terms modeled in the Unified Medical Language System (UMLS) (19,20). However, the SNOMED CT vocabulary set is substantially limited by not including many of the detailed findings required for the completion of a typical cardiac catheterization procedure report, signaling the necessary development of additional data standards in the cardiovascular arena. For cardiovascular procedures, the NCDR data dictionary provides a comprehensive list of many of the terms critical to a complete cardiovascular catheterization report (21), as does the CCS (22). In addition, the ACC and AHA both have a methodology (23) and ongoing projects to formalize and harmonize the vocabularies of cardiovascular medicine with relevant professional societies and the U.S. Food and Drug Administration, including an imaging lexicon (24). Importantly, the informatics formalisms to achieve semantic interoperability of these terms are still under development—in other words, many of the above efforts are better described as the authoring of clinical dictionaries rather than the development of the specifics required for semantically interoperable controlled vocabularies. Despite the absence of a formal controlled vocabulary for cardiovascular catheterization procedures, it is nonetheless believed that the structured reporting principles (including the structured report format construct described herein) can be adopted by the clinical and vendor communities.

In the healthcare environment, data interoperability through controlled vocabularies will ultimately allow us to achieve a “collect once, verify often, use many times” approach to data, rather than the manual, inefficient, repetitive, and potentially inaccurate acquisition of data (and the corresponding entry and reentry of that data into information systems) that characterizes healthcare operations today. However, the work required to achieve this interoperability is extensive and complex. Data standardization goes beyond simply defining the data elements (the packets); these electronic elements must be delivered, received, and opened across the information technology systems found in our complex healthcare ecosystem. The American Health Information Management Association lists 16 standards development organizations and 45 groups working on structure and content standards, functional EHR standards, technical and interoperability standards and vocabulary, along with terminology and classification systems (25). This only serves to highlight the complexities of positioning and aligning this structured reporting initiative within the larger context of healthcare information management.

This HPS is intended to provide a general model for structured reporting for invasive and interventional cardiovascular procedures. Of note, the principles and practices espoused by this HPS are also applicable to nonsurgical endovascular procedures performed in a cardiac catheterization laboratory, hybrid catheterization/operating room suite, and interventional/neuroradiology suite given the similarities in workflows. Use of controlled vocabularies coupled with formatted reporting will facilitate quality

improvement activities and provide the ability to interact with data registries for data exchange. All healthcare providers will find catheterization reports easier to understand when they are presented in a consistent format using defined and standardized terminologies. Comparisons between studies performed by other operators or at other institutions will be facilitated by following structured reporting principles.

Implementation of structured reporting is thus both a clinical practice and healthcare policy imperative. Through the creation and endorsement of this document, the organizations involved recognize the critical importance of structured reporting and call for its uniform adoption. This includes the collection of standardized data via controlled vocabularies in all cardiovascular procedure settings, the use of structured reports for the reporting of these procedures by all physicians, and adherence to standards for data interoperability, transfer, and communications (1).

2. Principles of Structured Reporting

2.1. General Principles

The general principles of structured reporting in cardiovascular imaging have been published previously and remain current, relevant, and applicable (5). The key characteristics of a proper structured report are as follows: 1) it must be inclusive of all information relevant to both clinical care and operational administration; 2) it should be clear, concise, organized, and reproducible as well as straightforward to cognitively assimilate and comprehend, while being sufficiently flexible to accommodate evolutionary changes in procedures and documentation requirements; 3) it should contain all the required elements for documenting procedure indications and assessing appropriateness per local coverage determination rules and/or published AUC (9-11); 4) a consistent minimum data set should be included in the content of each report, anticipating clinical, operational, regulatory, and financial uses of the data therein; and 5) the report should be devoid of extraneous content and be brief yet thorough.

2.2. Integration of Data Acquisition with Workflow

The processes of structured reporting extend the emphasis from structure and format of the report to the integration of data acquisition with workflow, maximizing the accuracy, completeness, and efficiency of procedure report generation. In this paradigm, complete and accurate documentation occurs at every step of the workflow; the responsibility for data acquisition is shared by the entire healthcare team. Ideally, proper system design will enable this tight coupling, resulting in a final structured procedure report within minutes of procedure completion.

Typical steps that comprise a cardiovascular catheterization procedure encounter are depicted in Figure 1 (http://jaccjacc.cardiosource.com/DataSupp/2014_Cathlab_HPS_Figure_1.png). In a structured reporting environment, the opportunity for data gathering begins with the request to the scheduling office. This includes requesting the capture of demographic information and procedures. Additional clinical information such as a basic history, medications, allergies, risk factors, previous procedures, and laboratory data should be available at this juncture. The idealized workflow imports (or otherwise) captures these data before the patient presents for the procedure. Ideally, data should flow bidirectionally to and from the EHR.

This basic paradigm—using optimized technology solutions to accomplish data collection by the individuals handling the data when the information becomes available—is then extended to the other steps involved in a catheterization procedure, with the data aggregated and stored for subsequent presentation and analysis (Figure 2 – http://jaccjacc.cardiosource.com/DataSupp/2014_Cathlab_HPS_Figure_2.png). The need to establish specific responsibilities and accountability of the individuals for specific sets of data is an implicit step at every point in the process. No single individual is to be overburdened with responsibility. The form factor used to record information is to be optimized for both user and task, with the user interface designed from a usability perspective. Again, data are captured simultaneously and in real time, as delayed or retrospective data entry creates an opportunity for recall errors.

For intraprocedural data, structured reporting requires an individual be assigned the responsibility of entering data into a procedure logging system. Typically this individual also has the responsibility for simultaneously monitoring patient clinical data such as cardiac rhythms and hemodynamic status. In order for this approach to work effectively, it is incumbent upon the physician operator, nursing staff, and technologists to articulate every procedure detail relevant to the individual documenting the details. In turn, the monitoring individual has the responsibility of assuring the accuracy of data as they are collected. Functionally, multiple individuals (technologists, nursing staff and physician operators) should be able to enter data such as hemodynamics, medications and findings simultaneously. This approach to data capture in the catheterization laboratory is required not only to generate the procedure log report (see the separate Cath Report Style Guide data supplement - http://jaccjacc.cardiosource.com/DataSupp/2014_Cathlab_HPS_CathReportStyleGuide.pdf) but also to provide source data for populating the final structured procedure report.

Unfortunately, inaccurate or inconsistent data entry does occur and requires a systematic means of identification and correction (26,27). The data management system should include range, data format, validation checks, and other verification features to augment data accuracy at the point of entry. Even

with a rich set of validation checks, the system must also allow updates, edits, and corrections as needed. Data entry should be ascribable to the individual entering the information in the event that an investigation of data provenance is needed. Default values should be used sparingly, or only when appropriate.

2.3. Capture of Information as Data Rather than Prose

The first tenet of structured reporting is that the entire process requires the capture of information as discrete, defined, computable, and reusable data elements instead of dictated or typed (free text) prose. In a structured report, prose is purposefully limited to those circumstances where capture of the information as data is unwieldy or inefficient. These limited circumstances could include a brief history, details of complex procedures not otherwise adequately represented by the data, and the final impressions and recommendations. For a structured report to be successful, the permissible values of the structured data elements of the controlled vocabulary must be anticipated *a priori*, but the system must also have sufficient flexibility to capture *ad hoc* values where appropriate, as frustration can foster nonadherence and overuse of free-form data fields.

A second tenet is that all phases of data acquisition utilize the same controlled vocabulary. At a minimum, a controlled vocabulary consists of clinical data element concepts, definitions of those data elements, and notations regarding the format specific to each data type (e.g., text, integer, yes/no, date/time, or alphanumeric) along with permissible (or allowed) values. Typically, data standards committees, such as the ACC/AHA Task Force on Data Standards (23), oversee this process on behalf of many stakeholders, with the technical representation of the data elements made available via an authoritative International Organization for Standardization 11179-compliant reference resource, such as the National Cancer Institute Enterprise Vocabulary Server system (28). As of the time of this publication, the data standards for catheterization procedure reporting remain a work in progress, anticipated for completion within the next several years. In lieu of a completely modeled and vetted controlled vocabulary for catheterization procedure reports, the ACC NCDR and the CCS data dictionaries provide a comprehensive list of the majority of the requisite data element concepts to provide a basis on which to begin structured reporting today (21,22).

A third tenet is the augmentation of the completeness of data capture, a natural consequence of structured reporting. Systematic, template-based documentation reduces errors of omission while accruing a more complete set of information compared with text-based procedure reporting. More complete and consistent structured reporting reduces ambiguity and the effort required to extract the information necessary to support other activities such as billing, quality improvement, and clinical research. Note that

this should not be interpreted as a call for exhaustive data capture; instead, the guiding principle is data parsimony. For structured reporting to be successful, all members must recognize that they are contributing to the creation of the final structured procedure report while not being burdened with redundant and/or unnecessary data capture.

2.4. Role of the Physician in Authoring the Structured Procedure Report

A structured reporting process succeeds only if the integrity of both the structure and meaning of the data are maintained. The physician operator is primarily responsible for interpretation, description, and documentation of results and findings (i.e., the “meaning” of the data). The physician also validates (and assumes responsibility for) data that others have entered throughout the sequence of events related to the catheterization. In this construct, the structure of the data is largely the province of the information technology solution used to manage the data. With all parties contributing, the procedure report is then produced automatically based upon reporting templates populated by the entirety of the data. Additionally, the data can be exported into standard (machine-interpretable) file formats such as an .xml representation, a Clinical Document Architecture (CDA) file, or a Clinical Data Interchange Standards Consortium (CDISC) file for machine-to-machine data transfer and subsequent analysis.

By shifting data collection (and data quality) responsibilities to others involved in the process of care, physician time devoted to repetitive recapture and redocumentation of data is reduced while a more complete set of data in the report is ensured. Optimally, this reduced workload translates into time saved, as the required responsibility for the physician operator is focused on interpretation and results documentation. Preliminary findings may even be entered by experienced catheterization laboratory staff, fellows, or Advanced Practice Practitioners (APPs) to further reduce physician operator time. Of note, the responsible physician must directly review, edit, or amend the data, an essential component of the data management system, as a well-designed and orchestrated structured reporting process will promote an accurate, efficient, and timely final catheterization report.

Since angiography is inherently visual, documentation of angiographic findings may be provided by graphical vascular tree and structural anatomy diagrams as well as by the inclusion of images in the report. The capture of this data in a graphical or image format is a highly accurate mechanism for representing angiographic findings. While the use of a graphical vascular tree program is strongly encouraged, the specifications for vascular tree programs are beyond the scope of this document. Finally, it is recognized that there is both a paucity of data, and conflicting evidence regarding best practices in data collection and presentation. The idea that a structured report in the catheterization suite can deliver on the promises outlined in this HPS is perhaps most strongly supported by the success of the Veterans

Administration Clinical Assessment, Reporting, and Tracking System for Cath Labs (CART) program (29). The CART program is embedded in the Veterans Administration's EHR system and used in place of dictation and typing following principles of the structured reporting process. Analysis of the CART system has demonstrated excellent data quality, marked improvements in timeliness in reporting, and the ability to use the data for quality improvement and registry reporting. So while the recommendations presented herein are largely based on expert consensus, the existing evidence base does support the structured reporting approach endorsed by this HPS as state of the art, evidence based, and patient centered.

2.5. The Best Practice Model

Building a best practice model for the cardiac catheterization laboratory begins with an understanding of the temporal sequence of events associated with the procedure (Figure 1 – http://jaccjacc.cardiosource.com/DataSupp/2014_Cathlab_HPS_Figure_1.png) and identifying the data, systems, and individuals associated with each step of the sequence (Figure 3 – http://jaccjacc.cardiosource.com/DataSupp/2014_Cathlab_HPS_Figure_3.png). Events that typically occur in the context of a catheterization procedure include the following:

1. Scheduling of the procedure
2. Preprocedure evaluation and consent by an operator or designee
3. Nursing preprocedure evaluation
4. Catheterization procedure
5. Documentation and interpretation of findings, analysis, and procedure report generation
6. Finalization and distribution of the report and report data

At the initiation of a procedure request, administrative patient data (e.g., patient identifiers, demographics) are obtained from source systems such as the EHR and combined with clinical information to schedule the procedure. The IHE Cardiac Catheterization Workflow (CATH) profile integrates ordering and scheduling of cardiac catheterization procedures and ensures the accurate transfer of patient identification data (8). In subsequent steps, these data, coupled with other sources of information (e.g., laboratory results, previous procedure findings), are further collected and again converted into data. In informatics modeling terms, *actors* are the individuals responsible for capturing the information, with the mechanism for capturing the information as data determined by the information systems being used by that individual. The best practice model specifies that the form factor (e.g., workstation, mobile tablet, hemodynamic monitoring station) is optimized to the actors and their respective workflows and operational logistics. A portion of the data populates subsequent downstream information systems.

Regarding the data themselves, the preprocedure evaluation, consent and nursing preprocedure evaluation steps capture demographic, history, physical, laboratory, and medications data. The cardiac catheterization procedure utilizes these data and adds new data: hemodynamic information, administered medications, inventory utilization, as well as angiography findings, therapeutic interventions, results, and complications. Combined with the final analysis and interpretation, report generation merges and incorporates the new data recorded, calculated, and captured during the procedure into the final structured procedure report. Catheterization reports are distributed across the enterprise for clinical care, and the data are extracted and analyzed for inventory management, process assessment, quality improvement, billing, and other administrative purposes. Combined with in-hospital and follow-up information, the data are also packaged for transmission to data registries. The IHE Cross Enterprise Document Sharing (XDS) profile exists to ensure that reports (and images) can be effectively exchanged within and between entities (30). The ultimate goal of modeling best practice in the cardiac catheterization laboratory is to explicitly identify and specify the processes, systems, and personnel that are required to interact smoothly as a coordinated entity. This creates an environment in which the interaction of the clinical team and the patient is the focus, with information and data sources available to each actor in whatever form factor will distract the least from the clinician-patient interaction. At any stage of the procedure, data are readily available to any actor while data systems remain “invisible” to the actors and unobtrusive to their patient care focus. This model allows quality and process efficiency to be the primary drivers of the structured reporting process.

3. Catheterization Procedure Reporting: Anticipating 2 Different Reports

While the focus of this HPS is the final (physician-authored) structured procedure report, a second complementary procedure log report is also created for each procedure via the same structured reporting process. The structured reporting process is thus designed with both of these critical reports in mind – the catheterization procedure log report and the final procedure structured report – as integrated, seamless, consistent and intrinsic to the catheterization procedure. As a final step, both of these reports should be uploaded into the EHR system, occurring automatically once electronic signature attestation has been completed.

3.1. The Procedure Log Report

The procedure log is the documentation record of the events (as time-stamped entries) occurring during a catheterization procedure, from patient entry to exit from the catheterization suite.

Documentation of these events is the responsibility of the individual monitoring the procedure and is accomplished using the database of a hemodynamic monitoring system. Most vendors are already producing the procedure log report in a tabular (table-based) format, albeit without standardized definitions or structure. This detailed procedure log report is an integral part of the medical record, reflecting the chronological occurrence of events during a procedure.

While there may be substantial overlap with the physician-authored procedure report, the procedure log report is constrained to the duration of the procedure, largely reflecting nursing and technologist responsibilities. As the monitoring individual transcribes events on behalf of the entire team (including the physician operator), communication among the team members is essential for accurate and complete documentation. The procedure log report should reflect the temporal occurrence of events, including documentation of the preprocedure “time-out,” the preprocedure immediate reassessment required by The Joint Commission (31), vital signs, levels of consciousness, oxygen saturations, and other assessments and measurements performed over the course of a procedure. In addition, recording of procedural personnel, procedures performed, equipment used, medications administered, contrast volume, and radiation exposure parameters should be included. To reduce variability in the format of the data being captured, it is highly recommended that macros, drop-down lists, coded phrases, or other structured approaches be utilized in accordance with the underlying controlled vocabulary data element specifications. This practice improves both accuracy and efficiency for the monitoring recorder. Ideally, data interfaces should be implemented to automatically export data from ancillary modalities and other external equipment (e.g., fractional flow reserve, intravascular ultrasound) into the procedure documentation system.

The data collected via the procedure logging process form the foundation for the procedural data section of the physician-authored structured procedure report. A degree of data transformation is needed to convert data recorded chronologically into the summary representation more appropriate for the physician-authored report. For example, a medications tally is needed in the structured procedure report, rather than a more simplistic time-stamped listing of a medication administration record. For interventions, implanted devices are associated with lesions, along with the respective device parameters (e.g., stent size, maximum balloon inflation pressure); a time-stamped listing of the actual events is of much less value. As noted previously, the extraction and transformation of these data from the procedure

log should be as automated as possible to reduce the workload on the physician, allowing the physician to focus on the accuracy of the documentation itself.

3.2. The Physician-Authored Structured Procedure Report

The physician-authored final catheterization procedure report fulfills the long-standing requirements for an operator-authored synthesis and summary document of the salient points of an operative or invasive procedure. In the United States, content requirements are stipulated in state and federal statutes as well as guidance provided by The Joint Commission (31). It is recommended that these content requirements (e.g., documentation of indications for the procedure, procedures performed, results, complications, and recommendations; logistical, operational, and administrative information) serve as the foundation of catheterization structured reporting around the world. Of note, what is not specified by regulation is how to accomplish the specifics: whether to even use a computerized information system, the capture of data versus prose, and the format and structure of the reports themselves. This HPS fills that gap, developing the base regulatory requirements into an explicit reference standard. Specifically, Section 4.0 describes the specifics of the prototype formatted, tabular, structured procedure report.

Intentionally, it is recommended that the report should avoid listing the absence of a finding in certain situations. Specifically, the absence of disease in the coronary arteries (and other vascular territories) is denoted by describing the primary vessels (left main, left anterior descending, left circumflex, and right coronary artery) as “normal” without further listing the absence of pathology in the terminal branches. Conversely, when coronary disease is present, only the segments with disease are listed (i.e., the term “normal” is not printed with vessels and segments free of disease). Similarly, the lack of occurrence of an adverse event is summarized by the word “none,” rather than denoting that every possible adverse event (e.g., ventricular fibrillation, cardiopulmonary resuscitation, or death) did not occur. The concept of pertinent positives also extends to the listing of risk factors on the procedure report. When a risk factor is not present, the report should not list “no” (as in “no hypertension” in the patient who is normotensive). This allows the clinician to rapidly understand what is known to be abnormal while implicitly accepting as absent (or unknown) what is not otherwise mentioned or described. Of note, depending on the specifications of a secondary consumer of the data (e.g., NCDR registry), there may be a requirement for acquisition of the data as either a “yes” or “no” response. Regardless of the data in the database, on the report itself, only the pertinent positives are to be listed. While it is acknowledged that this representation is incomplete (i.e., it does not differentiate negation from the absence of information), this HPS endorses “charting by exception” as a mechanism to reduce

clutter and maximize readability, and because there are essentially no differences in terms of analytics among the various representations of “no” and “null.”

4. The Prototype Formatted, Tabular, Structured Procedure Report

The 2008 HPS on Structured Reporting in Cardiovascular Imaging provides a general procedure report framework for all cardiovascular imaging modalities (5). Given the additional documentation requirements for invasive and operative procedures, coupled with the variability and volume of data acquired across the spectrum of cardiovascular catheterization procedures, extensions to this general framework are necessary to handle cardiovascular catheterization reports. The need to restructure data from multiple sources into the final report, and the desire for consistency across procedures also influences this framework. These factors collectively contribute to the rationale for the organization and formatting of catheterization procedure reports using the schema described next. A key concept is that each section of the procedure report has specific content and composition attributes that remain relatively constant from one procedure type to the next.

The final catheterization procedure report is to be organized into three primary sections, with each containing section-specific content (Table 1 – http://jaccjacc.cardiosource.com/DataSupp/2014_Cathlab_HPS_Table_1.pdf). The first section—ideally a single page of text—is an easily understood, focused summary of the salient points, that is directed to the clinical community. All clinicians (spanning the spectrum from the highly technical procedural cardiologists to nurses and other members of the clinical care team) should not need to look further than this first page to ascertain the procedures performed, diagnostic findings, and recommendations. The second section is focused on images, including a computerized depiction of the observed anatomy, findings, and results. Optionally, captured images (with or without annotations) are included in this section. Finally, the third section includes the details of the procedure. This includes administrative data, the preprocedure history (particularly information captured as structured data), most of the procedural detail, free text descriptions of technical details, and other content relevant to the final procedure report. In addition to the content included in the published version of this HPS, additional resource information such as a sample procedure report and accompanying style guide are available at - http://jaccjacc.cardiosource.com/DataSupp/2014_Cathlab_HPS_CathReportStyleGuide.pdf).

4.1. Front Page Summary: Highest Value Information

The front page is explicitly intended to be a single (physical) page that contains the highest value clinical information. The purpose of this page is to communicate the key findings, interpretation, and patient care recommendations from the physician operator to the clinical care providers of the patient. The objective is for this front page summary to include all of the information needed by providers to understand the context of the procedure, what was performed, the relevant findings, and the recommendations for care. As such, it replaces (and largely mimics) the preliminary procedure note.

For all catheterization procedures, the front page summary includes the following information in the header: facility information, patient identifiers (name, date of birth, and medical record number), date of procedure, referring physician(s) and physician operator(s). In the first part of the body of the summary page, the primary indication for the procedure by International Classification for Diseases (ICD) code and a brief prose history describe the circumstances leading to the procedure. Recognizing that structured data will never substitute for the richness of language, a short description (1 to 3 sentences) of the patient's presentation is endorsed as the most efficient mechanism to convey the clinical context. (The remaining structured data obtained during the preprocedure history and physical—such as the cardiovascular risk factors, noninvasive test findings, past procedure history, and medications—are placed in the third “Report Body” section). The prose history is then followed by a tabular listing of the composite procedures performed along with their corresponding CPT procedure codes.

The next section of the front page summary describes the key findings of the procedure, with the content of this section specific to the actual procedure(s) performed. This is to include vascular access site details, type and size of sheath, key hemodynamic and diagnostic findings and measurements, intervention results, devices implanted, as well as medication and contrast totals, listed in a summary tabular format. The findings of diagnostic procedures are presented as a sequence of modular tables, listing only key findings. The complete listing of all findings is included in the third section of the report. Interventions are organized by the treatment target, which includes a listing of the equipment, implanted devices, and results in association with the target lesion. A listing of complications and estimated blood loss (or acknowledgement of the absence of complications) follows this procedure-specific information section.

4.2. Graphics and Images Section

The second section of the structured report is optional as it is dedicated to images, including graphical representations of the findings or images imported into the report. The vascular “tree” diagram

should include a representation of the vascular anatomy specific to the patient, including graphics depicting vascular abnormalities, anomalies, disease, and interventions. While vendors have developed a number of different systems to depict cardiovascular anatomy, the key criterion is the accurate depiction of the vessels in a manner that facilitates the rapid understanding of the major features of the anatomy, including the 3-dimensional relationships of key vascular structures. As such, accuracy as to the curves and squiggles of a vessel are much less important than the distribution of major and minor branches of that same vessel. Unfortunately, there is currently no unifying data schema that allows the vascular tree created by 1 vendor to be exported and reproduced by the vascular tree program of a second. It is hoped that an effort to standardize this will occur in the near future to facilitate the exchange and interoperability of graphical data. For now, the vascular tree graphics will be conveyed necessarily from provider to provider and system to system as images, rather than data. Nonetheless, the computerized graphical vascular tree representation is felt to be a critical element of the structured catheterization procedure report given its utility in communicating procedure findings and results. Similarly, a graphical description of the anatomy with structural heart disease is also a critical element. Finally, in addition to the graphical depictions generated by computerized vascular tree programs, other images can be critical to capture in the structured procedure report. These include hemodynamic tracings, angiographic still frames, ultrasound images, and other potential image types. These images are also housed in the second section of the report. Annotation of these images should be allowed.

4.3. Report Body: Details

The body (third section) of the structured procedure report contains all of the remaining data accrued during the procedure not listed on the Front Page Summary. As nearly all of the information reproduced in the body of the report can be expected to be data, the layout of this section is a series of structured, formatted tables. In sequential order, the information in the body is included in the following subsections.

4.3.1. Administrative Information

The capability of information systems to meaningfully interoperate requires context, starting with the administrative data uniquely identifying the patient and procedure. Accuracy along with the ability to share data across systems is critical not only for clinical care but also for supply chain management, charging and billing, laboratory administration, quality assessment, and performance and outcomes analyses. Patient demographics provide personal information and unique patient identifiers to link the patient to the report. Demographic elements include the full name of the patient at the time of the

procedure, medical record number, date of birth, gender, and race. All of these should be included to provide sufficient information to correct errors and to allow comparison of data over time and across providers. Special care must be taken in the identification of fetal and newborn patients, as names and other identifiers may change following birth. Insurance information or other payer information may be included. In most healthcare organizations, all of these data are available electronically through the relevant admission-discharge-transfer and order management data streams, and it is highly recommended that these data streams be used to initialize and populate the catheterization laboratory modality, hemodynamic, and procedure reporting systems. Populating these systems with data from the hospital database limits errors and facilitates bidirectional information interchange.

Information identifying the healthcare organization, laboratory, operators, and staff are key administrative data included in this section of the body of the report. The facility name, address and other contact information, and the specific laboratory (if there are multiple laboratories in the facility) are noted. Accreditation status and entity are included given the increasing importance of accreditation of cardiac catheterization laboratories. Along with the physician operator, the report lists the name and identifiers of all individuals involved in the study, including the names and credentials of the nurses, technologists, APPs, trainees, and all others involved in the performance of the procedure. The list of referring providers, consisting of not only the requestor of the procedure but also the primary care and referring cardiologist, facilitates distribution of the final report.

An objective of the HITECH Act of 2009 is to improve communication of the specifics of consultation requests, and the catheterization procedure environment presents a prime opportunity to leverage the functionalities being added to EHR systems to fulfill this objective (17). A fully formed EHR procedure request describes the clinical situation, question, and study indication as well as identifies the provider requesting the procedure. The request also includes the date and time of the order, study priority (elective, urgent, or emergency), and special handling instructions such as a call back number. Inclusion of this study referral information should be anticipated for the near future as these data become electronically available by direct data transfer.

4.3.2. History and Risk Factors

Two complementary sets of history information are to be captured for documentation purposes. As described in Section 4.1, because the complexities and nuances of patient history are unlikely to be adequately conveyed using a structured data construct, a brief sentence history (1 to 3 sentences) is to be included on the Front Page Summary. However, this analog history is largely unusable for purposes other than human cognitive interpretation. This necessitates the structured capture of key elements of the

history (typically the class of symptoms, including limited details regarding the acuity of those symptoms) along with risk factors, medications, and previous procedures. The structured data are to be included in the body of the report. As data, these elements are used in coverage determinations as well as in the assessment of appropriateness per the relevant AUC and other practice guideline recommendations for invasive and interventional procedures. Of note, AUC criteria are being developed for additional procedures, which will expand the requirements for the collection of history and risk factor information as data.

Historical data are typically first available from the referring physician requesting the procedure. Personnel involved in the scheduling of procedures are positioned to capture this data, with those on the clinical team evaluating the patient prior to catheterization (particularly APPs or the actual physician operator) then being in the position to confirm and validate these data. While some translation may be required (e.g., free text information found in the EHR), the ideal workflow accommodates even this issue by having all individuals upstream of the actual procedure participate in the process of converting information into data.

4.3.3. Procedure Details

The capture of procedure details is largely the responsibility of the laboratory nursing and technologist staff. From the time of laboratory entry to departure, all relevant events are to be captured in a time-stamped log, typically via the hemodynamic monitoring system of the laboratory. This includes the component parts of the procedure as it is being performed, patient status and hemodynamics, name and doses of medications, observations and measurements, and other pertinent actions and events.

The conversion of the events from a time-stamped log database structure into the format of a structured report requires summarization and transformation of that data. This postprocessing necessarily impacts database design, as the database must support direct data conversion, preferably in real time. Aside from the medication log, a time-stamped log of the other events is generally not useful in the final procedure report. Instead, the information is arranged in a fashion that makes the most clinical sense, grouping and organizing related information in a clinically cogent manner. This applies to the detailed list of the individual (component-level) procedures performed, logistics, consent and other required documentation, vascular access and disposition, details regarding ancillary hemodynamic support, total volume and name of contrast agent(s), radiation exposure parameters (fluoroscopy time, cumulative air kerma, and dose area product), as well as intraprocedural findings, measurements, observations, and results. In this paradigm, data entered by staff into the documentation system are converted from individual time-stamped line items into aggregate information ready for the final (physician-authored)

structured procedure report. Done properly, the summary data are directly imported into the structured procedure report without further physician processing or handling. This in turn further reduces the time required of the physician to review the data and complete the final report. To improve patient safety, the cumulative contrast volume and radiation dose for all diagnostic and interventional procedures should be recorded and incorporated into the electronic medical record as readily accessible data elements.

4.3.4. Diagnostic Results

Study findings will vary substantially depending on the study performed, and therefore specifics by procedure are covered in much greater detail in the sections to follow (Table 2 – http://jaccjacc.cardiosource.com/DataSupp/2014_Cathlab_HPS_Table_2.pdf). At a general level, for the reporting of procedure results, the layout paradigm common to the diagnostic results section is to group all quantitative measurements, qualitative assessments, and calculated data with a given anatomic structure and/or physiologic function, beginning the grouping with an appropriate label. For example, under a header of “left ventricle,” the findings include left ventricular size, dilation, ejection fraction, segmental wall motion, and end-diastolic pressure. Groupings are presented successively in a logical anatomic or physiologic sequence established by the conventions of medicine. Measurements should be properly referenced to norms for body size, gender, and age. Abnormal or inappropriate physiologic and hemodynamic changes observed during the procedure, whether spontaneous or in response to stress or other interventions, are also included. Reported data should be based upon standardized data elements for anatomic, morphologic, physiologic, and functional findings as developed and recommended by relevant data standards groups.

4.3.5. Intervention

Similar to the Diagnostic Results section, the Intervention section will vary substantially depending on the procedure performed (Table 3– http://jaccjacc.cardiosource.com/DataSupp/2014_Cathlab_HPS_Table_3.pdf). A dedicated section for interventions explicitly separates diagnostic components from interventional procedures, with reporting in the intervention section organized by the anatomic treatment target of the intervention. The common layout paradigm of the intervention section is to describe the treatment target first, followed by the equipment used, parameters of that equipment, and the results of the intervention. Pre and postprocedure results are described in sufficient detail to determine procedure success or failure. As free-text notes are occasionally needed to further characterize the intervention, a limited free-text section (a few sentences)

may be associated with each treatment target. Again, the specific data to be reported by procedure are covered in much greater detail in the sections to follow.

4.3.6. Final Diagnoses

With respect to the interpretation of the results and the final recommendations thereof (impressions and recommendations), this set of information is included on the summary (front) page. As described previously, the relatively short Impressions and Recommendations sections on the summary page are concise free-text descriptions of the findings, comparison to prior studies (where applicable), impressions and conclusions, immediate care recommendations, and the long-term management plan. The original question for which the study was performed should be explicitly answered.

In the final diagnoses section of the Report Body, a list of the ICD encoded diagnoses reflecting the final interpretation of the procedure is included (largely for billing and regulatory purposes). While discouraged, if a traditional dictated note is created, it is included at the end of the body of the structured report.

4.3.7. Operators, Titles, Regulatory Attestation

The e-signature process embeds the date and time of the finalization of the procedure report and identifies the signatory. If any portion of the procedure is performed by a trainee, an attestation clause is added stating that the supervising physician operator was present for the entire procedure or key parts of the procedure. Finally, amendments to a finalized report must include the date and time of the change, along with the identification of the individual making the change, per the processes and policies of the healthcare organization.

4.4. Procedure-Specific Content

As listed in Table 1 (http://jaccjacc.cardiosource.com/DataSupp/2014_Cathlab_HPS_Table_1.pdf), the structured cardiac catheterization report uses a modular approach, with the report consisting of content created via the same workflow processes regardless of the type of catheterization procedure. The only portion where data content varies substantially from procedure to procedure on the Front Summary Page is the information in the Procedure Details section, where summary data specific to the actual procedures performed is included. Similarly, the Report Body (details) section of the report recapitulates this modular approach. Specifically, the 2 portions entitled (1) Diagnostic Findings and (2) Intervention will necessarily have data content in subsections of each portion specific to the procedures performed, while the remaining sections will have a high degree of overlap as they are derived from the same workflow

processes across all procedure types. The following text describes the variable, procedure-specific portions by type of procedure.

4.4.1. Cardiac Catheterization (Right, Left, Coronary Intervention)

The hemodynamic data acquired during right heart cardiac catheterization provides an assessment of cardiac performance along with the physiologic impact of a number of cardiac structural abnormalities. Data imported from a hemodynamic monitoring system must be easily edited and corrected in the reporting system. Critically, despite advances in the computerized algorithms for automated detection and measurement of hemodynamics, all data obtained during a right heart catheterization should not just be accepted as an import or pass-through from the hemodynamic recording system but must be reviewed, verified, and corrected by the physician operator. Substantive discrepancies between what is automatically determined by the hemodynamic recording system and more relevant measurements identified manually by the physician operator can be present and result in major errors of interpretation or incomplete conclusions.

An extensive set of data can be acquired during a right heart catheterization, particularly if a shunt run is performed, an assessment of a therapeutic intervention is conducted (e.g., nitric oxide challenge, exercise, volume challenge, intra-aortic balloon pump placement), or a structural defect is present. Right heart catheterization results to be reported on the summary page should reflect the key findings, focusing on mean filling pressures, pulmonary pressures and resistance, cardiac performance (cardiac output and index), responses to intervention (if conducted), and summary calculations (e.g., valve area or shunt magnitude). On the other hand, the complete set of data, such as the fraction of inspired oxygen (FiO₂), end-expiratory phasic pressures, oxygen content and saturations measurements, dose of nitric oxide administered, and formal calculations are to be reported in the Report Body section. In the evaluation of restrictive cardiomyopathy, constriction, and valvular abnormalities, the qualitative and quantitative assessment and comparison of multiple simultaneous waveforms is to be reported, including pertinent negatives. On the summary page, the findings are to be reported in the interpretation section, with representative tracings included in the second (graphics and images) section that support the qualitative interpretation of the waveforms.

While the formal term “left heart” catheterization implies placement of a catheter in the left ventricle, the more generic concept of left heart catheterization includes coronary angiography, left ventriculography, and transvalvular hemodynamics for the assessment of valvular abnormalities. The summary page is to convey a sufficient amount of information for the clinician to understand the anatomy visualized during left heart catheterization. This includes a notation regarding the number of diseased

vessels, coronary dominance, coronary anomalies, and summary findings related to bypass graft anatomy. Optionally, a listing of the hemodynamically significant lesions organized by coronary (or graft) segment location can be listed on the summary page. If left heart catheterization is performed, left ventricular end diastolic pressure (LVEDP) and mean aortic valve gradient (if a gradient is present) should be reported on the summary page. If left ventriculography is performed the ejection fraction and mitral regurgitation grade should also be reported on the summary page.

The complete details of left heart catheterization are to be reported in the third (Report Body) section, including a description of the coronary anatomy and branches, dominance, anomalies, a listing of all coronary lesions with corresponding anatomic location, and additional qualitative terms that further describe the extent and type of disease. Of note, the reporting of coronary disease is by exception—reporting of “0% stenosis,” “no disease,” or other similar approaches denoting the absence of disease—of no real utility and increases clutter. The simultaneous hemodynamic measurements of the aorta and left ventricle are reported, including peak-peak and mean differences between pressure measurements. For left ventriculography, in addition to the ejection fraction, regional wall motion is described as normal, hyperkinetic, hypokinetic, akinetic, or dyskinetic by specific wall segment. Quantitative regurgitant volume or percent by volumetric analysis of the left ventriculogram versus forward cardiac output is included (and labeled as such) if performed. Other observations such as calcification and other findings are reported in sufficient detail to meaningfully contribute to the overall interpretation of the study.

Key data reported regarding PCI include identification and description of the lesion(s), equipment used, equipment parameters (e.g., balloon type and nominal balloon diameter, stent type, nominal stent diameter and length, maximum inflation pressures), technical details if exceptional (e.g., retrograde crossing of a chronic total occlusion) along with the angiographic results (32). On the summary page, this information is concatenated into a single line of text, listing the lesion, stent information, notation of the type of intervention if stent implantation is not performed, and the pre and post results. In the Report Body section, parameters associated with each device are recorded. If an invasive evaluation is performed of an intermediate lesion, the details of the findings are reported. In the case of fractional flow reserve, the specific value should be reported along with the coronary segment(s) interrogated. Similar results from intravascular ultrasound, including intraluminal diameter (33), extent of calcification, evidence of prior stent placement, and presence or absence of dissection or thrombus, are listed. The current role for optical coherence tomography is unclear, but if performed, pertinent findings should be described in detail.

4.4.2. Peripheral Vascular Catheterization

The performance of peripheral vascular catheterization often requires different techniques, tools, and implantable devices from those required for cardiac catheterization. The scope of this HPS covers peripheral vascular procedures for atherosclerotic occlusive disease. Thus, renal, aorto-iliac, femoro-popliteal and tibial catheterization and intervention are included. Endovascular aneurysm repair of the thoracic aorta, endovascular aneurysm repair of the abdominal aorta, and all venous procedures (inferior vena cava filters, thrombolysis for deep vein thrombosis, venous intervention, etc.) are purposefully not modeled via this initiative, although extensions to include these procedure types may be added in the future.

The history, physical, and vascular anatomic descriptions for peripheral vascular disease reporting are target-lesion specific; use of the anatomic lexicon published by the American College of Cardiology Foundation/American Heart Association Task Force on Clinical Data Standards (writing committee to develop Clinical Data Standards for peripheral atherosclerotic vascular disease) (34) or the TransAtlantic Inter-Society Consensus is recommended (35,36). Vascular access for peripheral catheterization is much more varied than for cardiac catheterization and can include femoral retrograde, femoral antegrade, brachial, axillary, radial, popliteal, and other access sites. As with cardiac catheterization, the summary page is to convey summary information sufficient for the clinician to understand the approach used and the anatomy visualized. For lower extremity disease, analogous to coronary disease, this includes notation regarding the “number” of diseased vessels per leg, using aorto-iliac, femoro-popliteal, and tibial-crural groupings as equivalents to the coronary concept of a “vessel,” along with summary findings of bypass graft anatomy. This section can optionally include a listing of hemodynamically significant lesions. A summary of interventions and results is included, patterned after the approach used for the reporting of coronary interventions.

In the Report Body, the anatomy visualized is matched with the specific diagnostic catheter type and shape. The findings of arteriography are reported via a formatted table, inclusive of lesion segment location, maximum percent stenosis, and qualitative descriptors of the disease where appropriate. If abnormal, the condition of previously deployed devices (e.g., migrated, fractured, stenosed) is described. The details of endovascular intervention including the technique for crossing a lesion (true lumen versus subintimal or 0.035” versus 0.014” wire, recanalization adjuncts), and the sequence, types, and parameters of endoluminal treatment (e.g., balloon size, length, dilation pressures) are listed. Alternative endoluminal treatments are noted (e.g., plaque debulking, atherectomy, cryoplasty, scoring balloon

thrombolysis). When a stent is deployed, the stent type (e.g., balloon-expandable versus self-expanding) and size parameters are listed in conjunction with the target lesion and the final residual percent stenosis.

4.4.3. Cerebrovascular Catheterization

Catheterization of the cerebrovasculature includes the aortic arch, brachiocephalic branches, carotid, and vertebral artery territories. The scope of this HPS covers cerebrovascular procedures for atherosclerotic occlusive and other types of obstructive disease and specifically excludes intracranial disease including aneurysms. Imaging and intervention of intracranial arteriovenous aneurysm, fistula, and venous anatomy are not modeled in this initiative, although extensions to include these procedure types may be added in the future.

Given the variability of anatomy of the vessels of the aortic arch, the actual arch and great vessel anatomy are documented on the Front Page Summary as are the specialized catheters required to study the cerebrovasculature. Similar to the cardiac and peripheral vascular catheterization use cases above, description of cerebrovascular intervention should be displayed as a single concatenated line of text, listing the lesion, stent data, notation of the type of intervention if stent implantation is not performed, and the pre and post results.

Full details of the cerebrovascular catheterization procedure are to be included in the Report Body. In addition to documentation of vascular disease—for extracranial and intracranial imaging—the carotid system, cerebral system, Circle of Willis and cross-filling of hemispheric blood flow are described. For carotid stenting, the time interval between the deployment of an embolic protection device in the internal carotid artery and the carotid intervention is noted in addition to the standard documentation regarding the equipment used, devices deployed, and the parameters thereof.

4.4.4. Valvular Heart Disease: Transcatheter Aortic Valve Replacement

TAVR for the treatment of severe symptomatic aortic stenosis has been shown to be a viable therapy for patients deemed at high or extreme risk for conventional surgical aortic valve replacement (AVR) (37,38). Due to the complexity of these patients and their significant medical comorbidities, the concept of the multidisciplinary heart team (MHT) has been accepted and embraced by the respective professional societies (39). Furthermore, the complexity of the cases and the requirement of the expertise of the multiple specialties have resulted in the general acceptance that these procedures should be performed in a hybrid operating room/catheterization laboratory setting, with full and engaged participation of the entire MHT. Therefore, the structured procedure report must reflect this genuine multispecialty collaboration among the subspecialties.

On the Front Page Summary, vascular access information, anesthesia, circulatory support, and a summary of the TAVR procedure and results (concatenated preprocedure stenosis severity, device implanted, and final result) are listed. However, most of the actual data of a TAVR procedure is reported in the Report Body (Table 3 –http://jaccjacc.cardiosource.com/DataSupp/2014_Cathlab_HPS_Table_3.pdf). This begins with a listing of all of the physicians and healthcare providers contributing to the performance of the TAVR procedure, including anesthesiologists, neurologists, sonographers, and other imaging specialists, nurses, and technologists. As recently mandated by the coverage decision of the U.S. Centers for Medicare and Medicaid Services, at least 1 surgeon and 1 interventional cardiologist must be present for the procedure. These individuals (and their respective specialities) are identified as the operators of the procedure.

Data in the report history to substantiate the decision of the MHT to perform TAVR instead of surgical AVR are listed as discrete data elements. The rationale for TAVR, however, is documented for each patient via the free-text History on the Front Page Summary.

From a procedural standpoint, routes of vascular access (i.e., transfemoral, transapical, transaortic, or subclavian) as well as method of access (i.e., percutaneous, surgical cutdown, or vascular conduit) for TAVR are documented in the respective sections of both the summary page and procedure details section. For percutaneous access, the type and number of closure devices used are also listed. For surgical cutdown, the location of the incision is listed.

If right heart catheterization is performed, the data are reported as described in the right heart catheterization section above. Specifics related to positioning and rapid ventricular pacing are captured as data. At the completion of deployment, the final TAVR positioning, function of the prosthesis, and evidence of paravalvular leak are essential data of the report.

Complication management and bailout maneuverers are often required in TAVR procedures. If cardiopulmonary bypass is required for hemodynamic support, duration of bypass time as well as technique, route, and size of cannulation are recorded. Open conversion to sternotomy and conventional AVR or surgical repair of complications, such as aortic dissection or access vessel complications, should be included and details provided clearly. If a second TAVR is needed due to malpositioning or paravalvular leak, the valve-in-valve procedure is described in the details. The method and success of hemostasis are also documented, including details regarding surgical repair, if needed.

4.4.5. Congenital and Structural Heart Catheterization

Few fields cover as much variety in every aspect of anatomy, history, presentation, physical exam, physiology, diagnostic and interventional approaches, procedural technique, and follow-up events

as CHD. Nonetheless, these procedures share sufficient commonalities with the other procedures described above to utilize the structured reporting construct of this HPS. Compared with adult cardiac catheterization, however, the clinical drivers of invasive assessment and intervention in this population emanate from first principles quite different from those applicable to adult acquired heart disease, and there is a paucity of quality outcomes analyses related to these procedures. Substantial work has been completed in developing pediatric nomenclatures, particularly the International Paediatric and Congenital Cardiac Code vocabulary (40,41); these are to be used as the foundation of CHD structured catheterization procedure reports. Use of consistent terminology across the myriad of procedures performed to evaluate and treat CHD will in turn help advance understanding of the principles and practice of cardiac catheterization in this arena.

While the specifics are much more varied than the other types of cardiovascular catheterization described above, the organization of the structured report and sections are more similar than different. The clinical question resulting in referral for catheterization is captured, along with a brief (prose) history, sufficiently broad to convey the context of the referral. This complements details of the history captured as data specific to the disease state and procedure being performed. Details of sedation, medication administration, anesthesia, and vascular support are captured in the corresponding sections of the structured procedure report. Short- and long-term clinical plans as modified by the outcome of the procedure are included in the impressions and recommendations sections.

Compared with adult cardiovascular disease, there are a greater number of modules (and much more overlap of those modules) in the congenital space. The diagnostic procedures include standard right and left heart cardiac catheterization as well as angiography of other vascular structures (Table 2 - http://jaccjacc.cardiosource.com/DataSupp/2014_Cathlab_HPS_Table_2.pdf). On the summary page, pertinent summary findings are to be listed, while a more complete tabular listing in the Report Body (details) section reflects the combination of anatomy, findings, and technical approach. This includes documentation of the conditions under which hemodynamics are obtained (with the recording of hemodynamics, such as the pressures and oximetry from cardiac chambers and vascular passages), together with unique aspects of hemodynamics.

For reporting congenital intervention, a series of templates is needed, given that intervention is used to open stenoses, close defects, and variations thereof (Table 3 – http://jaccjacc.cardiosource.com/DataSupp/2014_Cathlab_HPS_Table_3.pdf). Specific documentation regarding devices used, the anatomic and physiologic targets of the intervention, technical success, and physiologic measurements (pre and post) is included. In addition, specific and customizable diagrams that

reflect unique physiologies, anatomic variants, structural abnormalities, and the interventions thereof are crucial to the graphics/images section of the report.

The principles described above (and throughout this HPS) similarly apply to reporting on structural heart disease and other catheterization procedures. These procedures include (but are not limited to) percutaneous valve implantation (in addition to TAVR), balloon valvuloplasty, percutaneous repair of mitral valve regurgitation, atrial appendage occlusion, and alcohol ablation of the septum in hypertrophic obstructive cardiomyopathy. We believe the examples described above and modeled in the prototypes (Tables 2 and 3) provide a template sufficient to create structured reports consistent with this HPS and have, therefore, not further represented these procedures in the report prototype tables.

4.4.6. Combination Procedures

The performance of multiple procedures in a single case setting occurs frequently in the catheterization laboratory. From a structured reporting perspective, the modular approach to organizing the collection and reporting of data in segments corresponding to the procedures performed allows for straightforward construction of a final, single, organized, and cogent procedure report. This “stacking” of report modules should logically follow the temporal sequence of the events that occurred in the catheterization visit. Note that this is not to facilitate “drive by” procedures; just being in the lab for one procedure is not an indication for a second. Instead, this modular approach is to facilitate the complete reporting of all that transpired during a catheterization visit. Indeed, indications for all procedures performed need to be present in the final procedure report. Complex procedures also raise issues including radiation exposure and radiographic contrast media volume that must be carefully managed by the physician operator(s).

One comprehensive report should be generated for the entire case so as to avoid confusion that could arise if multiple individual procedure reports are generated from a single patient visit to the catheterization suite. Reporting of these procedures must follow the standards set for the individual procedures being performed as described in the previous sections. The front page should clearly reflect the performance of each separate procedure within the total case. Demographics, history, and indications that support each procedure are required. Impressions and recommendations should reflect the entire set of procedures performed.

4.5. Structured Report Style Guide

The capture of structured data via structured reporting processes serves little utility if that same data cannot be presented in a format easily understood by human readers. Optimally, structured data are

coupled with standardized templates to produce structured reports that require the least amount of cognitive processing to comprehend and assimilate. To accomplish this goal, this HPS calls for a certain degree of cross-vendor conformity with respect to the appearance and organization of catheterization procedure reports. Within this general framework, specifics of formatting (e.g., conventions for indentation, alignment and justification, even font size) further reduce the cognitive burden, particularly when reading reports created by differing software solutions. To this end, a style guide has been created that articulates formatting recommendations for the final structured procedure report. A copy of this guide can be downloaded at [<http://www.cardiosource.org/xxxx>] (see the separate Cath Report Style Guide attachment -

http://jaccjacc.cardiosource.com/DataSupp/2014_Cathlab_HPS_CathReportStyleGuide.pdf).

The style guide builds on the content recommendations of the previous sections to detail the specifications for presentation of that content. The style recommendations focus on the consistency needed to improve the readability and usability of the (printed) physician-authored, final structured procedure report. A degree of consistency and reproducibility reduces the effort required to find specific pieces of information. A specific emphasis is the presentation of data in a tabular (table-based) formatted layout. This includes right justification to align labels and left justification to align data where feasible. For example, the layout of the pressure readings of a right heart catheterization might appear in text as the following:

Right Heart Catheterization

RA: a=6 v=4 mean=3 (If a wave is absent in atrial fibrillation, suggest N/A or -)

RV: 30/7, EDP 11

PA: 30/13, mean=18

PCW: a=14 v=12 mean=10

Δ AVO₂: 4.3 vol%

CO: 4.4 L/min

CI: 2.5 L/min-m²

The overall construct is to present information in a label: finding format. Inconsistent with structured reporting is presenting data as prose, whether the prose is created via dictation or a computerized conversion of data into a phrase. The sentence “The results of the right heart catheterization are as follows: RA a=6, v=4, and mean=3; RV 30/7, EDP 11; PA 30/13, mean=18; and PCW a=14, v=12, mean=10, AV O₂ difference of 4.3 volume percent, cardiac output of 4.4 L/min, and cardiac index of 2.5 L/min per m²” includes all the data; however, none of the prosaic elements (including the words added to

create the sentence and the structure of the sentence itself) add anything to the meaning of the data. In fact, the prose substantially reduces the efficiency of comprehending and retaining the data as information.

As noted previously, report layout is purposefully modular. Certain sections are universal regardless of the procedure being performed. For example, a brief (prose) history, a tabular listing of the procedures performed, and the impressions and plans (prose) section appearing on the Front Page Summary are universal to all procedures, as is the medications log in the Report Body. Depending on the actual procedures performed, the other sections of the report—history and physical data relevant to the procedure and the underlying disease state, procedural details, findings, interpretation, and recommendations—follow in the same general order regardless of the procedure. What varies is the content within each modular section, with the content specific to the procedure actually performed. Institutional preference for the use of a vendor-based or a “home-grown” standardized reporting system should be viewed in the context of the requirements of this HPS and compatibility with national registries and other reporting mechanisms. Finally, the choice of design and layout should also consider the distribution and forwarding of the report to the patient, referring physician, and primary care physician as an expected standard practice.

4.6. Data Export

A key objective of the capture of structured data is the interchange of the same data among information systems. To convert structured data into a printed format suitable for interpretation, the typical solution is to use a report writer application that converts the data stored in a database into a formatted layout that is pleasing to the human eye and understandable to the human mind. Similarly, to accomplish interoperability among information systems, the data in a database must be first converted into a file format suitable for data transfer, with labeling and organization of the data content following a specific set of rules so that the receiving system can interpret the file and convert the content back into consumable data.

The general specification endorsed by this HPS for this purpose is the HL7 Consolidated Clinical Document Architecture (C-CDA) standard, which is the standard for the electronic transfer of clinical information per the standards and certification for Stage 2 Meaningful Use of EHR (7). This specification has been further developed into a Cath Report Content (CRC) profile by the organization IHE and successfully balloted by HL7, inclusive of the specifications and discrete data elements for the CDA-format report for a PCI procedure (42). While a detailed discussion of the specifics of the C-CDA standard and the supporting IHE CRC profile is well beyond the scope of this HPS, a requirement of

conformance with this HPS is the ability of the system to export and import C-CDA documents specific to the cardiovascular catheterization procedures covered herein. Finally, it is anticipated that as the C-CDA becomes the electronic *standard* for the interoperable exchange of information, this format will become the standard for the transmission of data to registries such as the ACC NDCR CathPCI registry.

4.7. Paradigm Expansion

This ACC/AHA/SCAI HPS summarizes the rationale, principles, processes, and components of structured reporting in cardiac catheterization laboratories. The resulting structured procedure reports will be clear, concise, and practical. Compared with dictated reports, they will be readily interoperable among clinical information systems. We believe this basic paradigm to be easily extensible to other areas of cardiology, such as electrophysiology, and ultimately scalable to all procedure types, particularly those performed under semi-sterile conditions without routine general anesthesia. Of note, the workflows and data flows of the operating room environment are substantially different from the “laboratories” where cardiac catheterization and other semi-sterile procedures are typically performed, and thus the framework presented here will likely have less applicability to open surgical procedures. As medicine moves into the era of EHRs, standardized structured reporting will ensure completeness of the capture of the data elements representing the key components of these procedures and operations.

5. Adoption and Implementation

Universal adoption of structured reporting processes for invasive cardiovascular catheterization requires both acknowledgement of benefits and acceptance of responsibilities by key groups. In order to stimulate the implementation of structured reporting, it is critical to articulate these aspects as they directly affect physician operators, catheterization laboratory management and personnel, and the software vendor community.

For physician operators, the key benefit is that structured reporting is inherently more thorough, complete, and accurate than other approaches, particularly dictation. Both the quality and quantity of the information are enhanced, reducing potential compliance, regulatory, and legal liabilities. A complete set of data is captured that conveys the information needed to optimize care of the patient. Nonetheless, 3 concerns are typically expressed by physicians transitioning from dictation to structured reporting: 1) the time required to directly input data into a computer compared with dictation, 2) the additional learning and cognitive effort required to use computerized solutions, and 3) the difficulty of capturing complexity as data. While dictation is admittedly time efficient, the actual amount of time required to enter data into

a well-engineered, high-usability system can be approximately the same or less than that required to dictate, review, correct, and sign a dictated report. Furthermore, creation of a final procedure report within minutes of completing the procedure eliminates the need for a preliminary handwritten or hand-typed report (and the time required thereof). The communication of standardized findings and technical details to referring clinicians via the EHR will be faster, more efficient and more accurate. The systematic collection of standardized procedural data elements provides high-quality data for process and performance improvement, comparative effectiveness and other types of clinical research, and drug and device surveillance. It can also be used to populate state and national registries, inform health services research, and generate the foundation for feedback-based lifelong learning and maintenance of certification opportunities.

For catheterization laboratory staff, a period of transition and adaptation to new structured reporting processes will be followed by greater coordination of activities with less redundancy and repetition, thus allowing the staff to focus more attention and energy on the delivery of care. Given the degree of coordination required to optimize a structured reporting environment, education and training of staff is critical in accomplishing a smooth transition; therefore, a budget for training programs must be anticipated prospectively. Unquestionably, structured data collection offers the potential to achieve operational efficiencies and inventory management gains as well as optimized catheterization laboratory workflows. By using well-defined data standards, operational insights can be shared among institutions and across systems to develop and refine best practice workflows. Additionally, ongoing monitoring of performance measure data will foster an environment based on individual accountability and identify areas for potential improvement.

The success of structured reporting is highly dependent upon the software vendor community. While the most obvious and visible product of a structured reporting approach is the structured report itself, this is only one aspect of the totality of requirements and responsibilities of vendors (Table 4). The structured reporting system must recognize the sources of information, data to be captured, the actors (personnel handling the data), and data output at each step of the process of a catheterization procedure, starting with the scheduling of the patient through the generation of the final procedure report (see the separate Cath Report Sample attachment - http://jaccjacc.cardiosource.com/DataSupp/2014_Cathlab_CathReportSample.pdf). In other words, the focus should be on the tasks and the way the tasks are accomplished, with the technology solutions designed to support the task flow. In this model, the input devices (e.g., tablets and workstations) are optimized to the data management requirements of each step. The data model of the database must be both robust and flexible to not only capture data associated with a specific episode of care, but also span

multiple episodes. The human interfaces used to capture the data must be maximally efficient and effective, built using principles of human factors and ergonomics. A key metric of success—perhaps singularly the most powerful criterion of all—is the capability to generate the final procedure report within a few minutes of the completion of the catheterization procedure. Anything less will mean that the potential of structured reporting has not been realized. Furthermore, it is anticipated that the vendor community will have a key role in teaching best-practice structured reporting processes to healthcare enterprises.

As the expertise that must be brought together to create an integrated structured reporting environment is spread across multiple disciplines, partnership between the professional societies and the vendor community is required to identify best practices, specify requirements, evaluate solutions, iteratively improve systems, and promulgate structured reporting processes. To this end, the ACC/AHA/SCAI anticipates that the development and deployment of structured reporting in the catheterization suite will be an ongoing process for some period of time. The expectation is that the physiologic monitoring, procedure reporting, and EHR vendor communities will respond quickly to create linkages between the wealth of information entered into the physiologic recorder and the format requirements specified herein. Accomplishing the desired state defined in this HPS requires the careful coordination of all of these groups. Given the complexities, implementation of the recommendations of this HPS may need to occur in stages. An absolute requirement is the procedure documentation and reporting system, along with interfaces for the exchange of data (e.g., orders and results messages). Changes to workflows and responsibilities are not trivial and demand careful orchestration. Planning (including budgeting) to achieve a structured reporting environment must therefore be coordinated among these groups, including catheterization laboratory and cardiovascular service line administrations and enterprise information systems management.

Ultimately, it is our patients who have the most to gain. Understanding the risks, benefits, and alternatives of any medical intervention requires a foundation of evidence-based knowledge. To easily convey this knowledge to patients, the data must be available, reliable, and relevant. The widespread implementation and adoption of structured reporting will build this indispensable foundation.

Table 4. Vendor Responsibilities

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- Usability: interfaces designed and built for maximum efficiency (human factors design)
 - Input devices: specific to use case (e.g., workstations, tablets, interfaces with hemodynamic and administrative systems)
 - Input handling: use of controlled vocabulary with specific permissible values, range checking, consistency checking, other types of data validation on input
 - Database: based on a patient-centric (not procedure-centric) data model, use of a controlled vocabulary
 - Outputs: structured report per specifications of this HPS including health information exchanges for a full report and reporting to registries such as the NCDR for subset data.
 - Interoperability: adherence to the IHE Cath Report Content (CRC) profile (42), which specifies catheterization report content; the IHE Cardiac Cath Workflow (CATH) profile (43), which specifies the basic patient data flow of catheterization procedures; and ACC/AHA Task Force on Data Standards key data elements for cardiac imaging documents (44)
 - Partnership with professional societies in developing the structured reporting environment
 - Dissemination of best practices in structured reporting to the user community
 - Report exchange: seamless movement of procedure reports between procedure reporting systems and EHR systems
 - Graphics: software solution for the graphical depiction of anatomic findings and treatment results
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ACC indicates American College of Cardiology; AHA, American Heart Association; HPS, Health Policy Statement; IHE, Integrating the Healthcare Enterprise; and NCDR, National Cardiovascular Data Registry.

6. Extending the Structured Reporting Use Case

Professional societies active in the cardiovascular field have critical roles in defining and establishing the guidelines and performance metrics for cardiovascular procedures. Comprising voluntary representatives, societies have the responsibility for determining standards, norms, and expectations of professionalism of their members. No one is better positioned to understand the issues involved. As developers and shapers of clinical guidelines, performance measures, AUC, and educational and training programs that produce the specialists trained in these procedures, professional societies must lead the efforts to establish standards in reporting.

As described in this document, 1 critically important task in this effort is establishing a controlled vocabulary or terminology of relevant data elements for catheterization procedures. The individual terms selected for inclusion in this controlled vocabulary must be clinically appropriate and relevant to the patient and the procedure, and have precise and mutually agreed upon definitions so that the elements have unambiguous shared meanings (i.e., semantic interoperability). Closely aligned with data element specification is determination of the data structures that combine individual elements into meaningful statements. It is the combination of a controlled vocabulary and a data structure that provides semantic interoperability. Although these concepts may seem obtuse to clinicians, they are crucially important for ensuring that data can be transmitted, received, and used as real information.

In order to obtain compatibility with EHRs and operate across computer networks, the standardized data elements and structures must meet technical language standards for data interchange. The primary technical standard for procedure report data structures is the HL7 CDA, with terminology encoded using recognized vocabulary standards such as the SNOMED/CT, the ICD-9 and ICD-10, the Logical Observation Identifiers Names and Codes for laboratory values, and RxNorm for drugs and pharmacy systems. However, these lexicons are relatively incomplete for representing the depth and breadth of cardiovascular procedure terminology, so stewardship of the controlled vocabulary of standardized data elements is required of the cardiovascular professional societies. As the primary performers, interpreters, and users of the procedures, these societies must maintain close supervision of the specialized vocabulary. Other data element terminology coding systems will have to be mapped and cross-referenced with the professional society system in order to ensure appropriate correspondences and eliminate confusion. This necessarily entails collaboration to help establish and maintain the formal technical features required of a controlled vocabulary compatible with EHRs and operating on multiple computer networks in the healthcare environment. An example of this is the International Society for Pediatric and Congenital Heart Disease (ISPCHD). Founded in 2000, the ISPCHD is a multinational and multisocietal group composed of cardiologists, cardiac surgeons, cardiac pathologists, and morphologists. Since the group was founded, it has been tasked with developing a common and harmonized hierarchical coding structure of terms and definitions identified as the International Pediatric and Congenital Cardiac Code (IPCCC) (40,41). The IPCCC has been endorsed or adopted by a number of pediatric specialty societies in Europe and the United States. The challenge and also the opportunity are that constant interaction among all the groups, with constant review and periodic revision, will be necessary.

In the past, catheterization laboratory accreditation standards did not mandate structured reporting. However, this is changing. In the recently published 2012 Expert Consensus Document on Cardiac Catheterization Laboratory Standards, the recommendation is made that a structured report using standardized data should be finalized in a timely fashion following procedure completion (6). The ACC- and SCAI-endorsed Accreditation for Cardiovascular Excellence program (www.cvexcel.org) specifies the generation of structured reports as a criterion for accreditation, similar to criteria established by the respective Intersocietal Commissions in echocardiography, nuclear cardiology, and cardiac magnetic resonance imaging (www.intersocietal.org). In short, structured reporting must be considered 1 component of the overall quality improvement imperative for cardiovascular care.

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Figure Legends

Figure 1. Sequence Diagram for Cardiovascular Catheterization Procedures.

This schematic illustrates the temporal relationships and dependencies among the events, individuals, and actions that occur from the point of requesting/scheduling a catheterization procedure through the data outputs arising from the procedure. The diagram depicts the sequence of the Duke University Hospital Catheterization Laboratory; modification may be needed to represent the sequence of other catheterization laboratories. Time is nonlinear and is oriented along the horizontal axis in this depiction.

Cath Lab indicates Catheterization Laboratory; H&P, History and Physical; HIS, Hospital Information System; HER, Electronic Health Record; MRN, Medical Record Number; OP, Outpatient; PA, Physician Assistant; NP,– Nurse Practitioner; IT, Information Technology; PACS, Picture Archiving and Communication System; RN, Registered Nurse; Tech, Technologist; IV, Intravenous; IP, Inpatient; Hemo, Hemodynamic; ACC NCDR, American College of Cardiology National Cardiovascular Data Registry; CathPCI, Cardiac Catheterization and Percutaneous Coronary Intervention (registry); IMPACT, Improving Pediatric and Adult Congenital Treatment (registry); ACTION-GWTG, Acute Coronary Treatment and Intervention Outcomes Network-Get With the Guidelines (registry) and STS CT Surgery, Society of Thoracic Surgeons Cardiothoracic Surgery (registry).

Figure 2. Data Flow Diagram for Cardiovascular Catheterization Procedures.

This diagram identifies sources, contributors, outputs, and users of data associated with cardiovascular catheterization procedures.

Figure 3. Process-Interaction Matrix for Cardiovascular Catheterization Procedures.

This chart maps the processes (across the top) that occur to accomplish a catheterization procedure and the contributions of the constituent components (left side of figure) to be coordinated with each process.

Cath Lab indicates Catheterization Laboratory and EHR, Electronic Health Record.

Committee Member	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
	Associate Chief of Cardiovascular Surgery please						
Bonnie Weiner	St. Vincent Hospital Worcester Medical Center—Training Director	None	None	None	None	None	None
William Weintraub	Christiana Care Health System—Section Chief, Cardiology	None	None	None	None	None	<ul style="list-style-type: none"> • 2012, Defendant, Celebrex Litigation • 2011, Defendant, Oral Contraceptive Litigation
John Windle	University of Nebraska Medical Center Cardiology Section—Professor and Chief, Internal Medicine Division of Cardiology	None	None	None	None	None	None

1 This table represents the relationships of committee members with industry and other entities that were determined to be relevant to this document. These
2 relationships were reviewed and updated in conjunction with all meetings and/or conference calls of the writing committee during the document development
3 process. The table does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a
4 business if the interest represents ownership of $\geq 5\%$ of the voting stock or share of the business entity, or ownership of $\geq \$10,000$ of the fair market value of the
5 business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. Relationships that exist
6 with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted.

7
8 According to the ACC, a person has a *relevant* relationship IF: a) The *relationship or interest* relates to the same or similar subject matter, intellectual property
9 or asset, topic, or issue addressed in the *document*; or b) **The company/entity (with whom the relationship exists)** makes a drug, drug class, or device addressed
10 in the *document*, or makes a competing drug or device addressed in the *document*; or c) **The person or a member of the person's household**, has a reasonable
11 potential for financial, professional or other personal gain or loss as a result of the issues/content addressed in the *document*.

12

1 *Significant relationship.

2 †No financial benefit.

3

4 ACC indicates American College of Cardiology; AHA, American Heart Association; SCAI, Society for Cardiovascular Angiography and Interventions.

1 **Appendix 2. Peer Reviewer Relationships With Industry and Other Entities (Relevant)—ACC/AHA/SCAI 2014 Health Policy Statement on Structured**
 2 **Reporting for the Cardiac Catheterization Laboratory**

Peer Reviewer	Representation	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Deepak L. Bhatt	Official Reviewer— CQC Lead Reviewer	Brigham and Women's Hospital Heart and Vascular Center; Harvard Medical School— Executive Director of Interventional Cardiovascular Programs; Professor of Medicine	None	None	None	• Medtronic†	None	None
Gregory Dehmer	Official Reviewer— ACC BOT	Texas A&M College of Medicine, Scott & White Clinic Cardiology Division— Professor of Medicine; Director of Cardiology	<ul style="list-style-type: none"> • Clinical Advisory Group, Maryland Health Care Commission • Society for Cardiovascular Angiography and Interventions* • U.S. Food & Drug Administration 	None	None	None	None	None
Jacqueline Kreutzer	Official Reviewer— AHA	Children's Hospital of Pittsburgh— Director, Cardiac Catheterization	<ul style="list-style-type: none"> • Medtronic • St Jude Medical 	None	None	None	None	None

Peer Reviewer	Representation	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
		Laboratory						
Sunil Rao	Official Reviewer—SCAI	Duke Cardiology—Associate Professor of Medicine	None	None	None	None	None	<ul style="list-style-type: none"> Defendant, Catheterization related complications, 2011
Rose Shaffer	Official Reviewer—AHA	Thomas Jefferson University Hospital—Cardiology Nurse Practitioner	None	None	None	None	None	None
Barry Uretsky	Official Reviewer—SCAI	University of Arkansas Medical Sciences—Clinical Professor of Medicine	None	None	None	None	None	None
Robert Vincent	Official Reviewer—IASC	Children's Healthcare of Atlanta—Co-Medical Director, Heart Transplant Program; Director, Cardiac Catheterization Lab; Pediatric Cardiologist	None	None	None	None	AGA*	None
Tom Dolan	Organizational Reviewer—DICOM	Philips Healthcare—Director Interoperability	<ul style="list-style-type: none"> Integrating the Healthcare Enterprise* 	None	None	None	None	None

Peer Reviewer	Representation	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
		Department of Preventive Medicine						
Glenn Levine	Content Reviewer—PCI GL	Baylor College of Medicine; Michael E. DeBakey Medical Center— Professor of Medicine; Director, Cardiac Care Unit	None	None	None	None	None	None
Marian Limacher	Content Reviewer— Provider Radiation Safety ECD	University of Florida Division of Cardiovascular Medicine— Suncoast Endowed Professor of Cardiovascular Medicine Research	None	None	None	NIH†	None	None
Howard C. Lewin	Content Reviewer— Imaging Council	Positron Imaging Partners in Los Angeles— Medical Director	None	None	None	None	None	• Plaintiff, interpretation of perfusion scan, 2012
Ehtisham Mahmud	Content Reviewer—ISC	University of California San Diego, School of Medicine— Chief of Cardiovascular Medicine	• Medtronic	• Medtronic	None	None	None	None

Peer Reviewer	Representation	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
		—Cardiologist; Director of Catheterization Lab						

1 This table represents the relationships of reviewers with industry and other entities that were disclosed at the time of peer review and determined to be relevant to
2 this document. It does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business
3 if the interest represents ownership of $\geq 5\%$ of the voting stock or share of the business entity, or ownership of $\geq \$10,000$ of the fair market value of the business
4 entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. A relationship is considered to
5 be modest if it is less than significant under the preceding definition. Relationships that exist with no financial benefit are also included for the purpose of
6 transparency. Relationships in this table are modest unless otherwise noted. Names are listed in alphabetical order within each category of review. Please refer
7 to <http://www.cardiosource.org/Science-And-Quality/Practice-Guidelines-and-Quality-Standards/Relationships-With-Industry-Policy.aspx> for definitions of
8 disclosure categories or additional information about the ACC Disclosure Policy for writing committees.
9

10 According to the ACC, a person has a *relevant* relationship IF: a) The *relationship or interest* relates to the same or similar subject matter, intellectual property
11 or asset, topic, or issue addressed in the *document*; or b) The *company/entity* (with whom the relationship exists) makes a drug, drug class, or device addressed in
12 the *document*, or makes a competing drug or device addressed in the *document*; or c) The *person or a member of the person's household*, has a reasonable
13 potential for financial, professional or other personal gain or loss as a result of the issues/content addressed in the *document*.
14

15 * No financial benefit.

16 †Significant relationship.

17
18 ACC indicates American College of Cardiology; AACN, American Association for Cardiac-Care Nurses; ACPC, Adult Congenital and Pediatric Cardiology;
19 AHA, American Heart Association; APSC, Asian Pacific Society of Cardiology; BOG, Board of Governors; BOT, Board of Trustees; CCS, Canadian Cardiology
20 Society; CQC, Clinical Quality Committee; CV, Cardiovascular; DICOM, Digital Imaging and Communications in Medicine; ECD, expert consensus document;
21 EP, electrophysiology; HL7, Health Level Seven; IASC, Inter-American Society of Cardiology; ISACHD, International Society of Adult Congenital Heart
22 Disease; ISC, Interventional Scientific Council; PCI GL, percutaneous coronary intervention guideline; PVD, peripheral vascular disease; SCAI, Society for
23 Cardiovascular Angiography and Interventions; SIR, Society of Interventional Radiology; STS, Society of Thoracic Surgeons; SVS, Society for Vascular
24 Surgery.

1 **Appendix 3. Abbreviations**

- 2 AACN – American Association for Cardiac-Care Nurses
- 3 ACC – American College of Cardiology Foundation
- 4 AHA – American Heart Association
- 5 APP – Advanced Practice Practitioners
- 6 APSC – Asian Pacific Society of Cardiology
- 7 AUC– appropriate use criteria
- 8 AVR – aortic valve replacement
- 9 CART – Clinical Assessment, Reporting, and Tracking System for Cath Labs
- 10 C-CDA – Consolidated Clinical Document Architecture
- 11 CCS – Canadian Cardiovascular Society
- 12 CDA – Clinical Document Architecture
- 13 CDISC – Clinical Data Interchange Standards Consortium
- 14 CHD – congenital heart disease
- 15 CQC – Clinical Quality Committee
- 16 CRC – cath report content
- 17 DICOM – Digital Imaging and Communications in Medicine
- 18 EHR – electronic health record
- 19 HITECH – Health Information Technology for Economic and Clinical Health
- 20 HL7 – Health Level Seven, Incorporated
- 21 HPS – health policy statement
- 22 IASC – InterAmerican Society of Cardiology
- 23 ICD – International Classification for Diseases
- 24 IHE – Integrating the Healthcare Enterprise
- 25 IPCCC – International Pediatric and Congenital Cardiac Code
- 26 ISACHD – International Society of Adult Congenital Heart Disease
- 27 ISPCHD – International Society for Pediatric and Congenital Heart Disease
- 28 MHT – multidisciplinary heart team
- 29 NCDR – National Cardiovascular Data Registry
- 30 PCI – percutaneous coronary intervention
- 31 RWI – relationships with industry and other entities
- 32 SCAI – Society for Cardiovascular Angiography and Interventions
- 33 SIR – Society of Interventional Radiology
- 34 SNOMED CT – Systemized Nomenclature of Medicine – Clinical Terms
- 35 STS – Society of Thoracic Surgeons
- 36 SVS – Society for Vascular Surgery
- 37 TAVR – transcatheter aortic valve replacement
- 38 UMLS – Unified Medical Language System
- 39 XDS – Cross Enterprise Document Sharing
- 40