Conflict of Interest

H. Vernon Anderson, MD has no real or apparent conflicts of interest to report.

James E. Tcheng, MD, has the following relationships with industry.

- Consulting Fees: Philips Medical Systems
- Contracted Research: Philips Medical Systems
Learning Objectives

• Recognize barriers to clinician adoption of the structured report, using cardiac cath procedure reporting as an archetype

• Identify use cases advantaged by structured data and the structured report, spanning clinical, patient-centric, performance improvement, payer, regulatory, and research domains

• Discriminate structured reporting as a process from the structured report as a document

• Define the multidisciplinary, workflow-oriented principles of structured reporting for efficient and high-quality data capture and management, from point of order entry through interoperable data reporting to the EHR, national data registries, and other entities

• Summarize the roles and responsibilities of the HIT vendor community in accomplishing best-practice structured reporting in the cardiac cath lab
## Value STEPS™ of Cath Procedure SR

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Satisfaction</td>
<td>effective &amp; efficient communication of information among providers, pts, administration</td>
</tr>
<tr>
<td>Treatment / Clinical</td>
<td>accurate &amp; complete documentation of procedures performed, inventory used, findings &amp; results, interpretations, care recommendations</td>
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<td>Savings</td>
<td>reducing FTE resources for data management, reducing physician documentation burden, improving efficiency and effectiveness</td>
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</table>

http://www.himss.org/ValueSuite
Structured Reporting in the Cath Lab

• How did we get here?
• The need for data
  • Healthcare delivery, quality measurement, performance improvement, device surveillance
• Structured reporting - what and why?
• ACC/AHA/SCAI Health Policy Statement on Structured Reporting
• Details, details, details
• Perspectives
<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1860</td>
<td>Florence Nightingale (English social reformer and statistician): systematic collection and publication of hospital death data.</td>
</tr>
<tr>
<td>1893</td>
<td>Jacques Bertillon (French physician, statistician and demographer): Bertillon Classification of Causes of Death; adapted in Europe.</td>
</tr>
<tr>
<td>1898</td>
<td>American Public Health Association recommends adoption of Bertillon Classification.</td>
</tr>
<tr>
<td>1948</td>
<td>United Nations (UN) and the World Health Organization (WHO). Extends ICD.</td>
</tr>
<tr>
<td>1965</td>
<td>Systematized Nomenclature of Pathology (SNOP).</td>
</tr>
<tr>
<td>1974</td>
<td>Systematized Nomenclature of Medicine (SNOMED).</td>
</tr>
</tbody>
</table>
Percutaneous Coronary Intervention (PCI)
It’s first “world registry” – circa 1979-80
The Last 20 Years in CV Medicine ...

<table>
<thead>
<tr>
<th>Time Period</th>
<th>Key Events</th>
</tr>
</thead>
</table>
| Mid 1990’s  | - Beginning of conversion from film, VCR tape to digital PACS → proliferation of individual, modality-specific PACS  
- Beginning of dedicated commercial procedure reporting systems → largely replicated the dictation paradigm  
- Rise of randomized clinical mega-trials → evidence generation, guidelines |
- Emergence of multi-modality CVIS (PACS + reporting) systems |
| 2009        | - ARRA HITECH Act → catalyst for migration to EHR  
- C-Suite response: use EHR to replace dedicated CVIS |
| 2015        | - Where’s the data?  
  - Failure of the EHR model (i.e., replicates dictation; ↑copy & paste)  
  - Minimal adoption of structured reports, structured reporting  
  - Little data exchange, mostly manual data collection (i.e., RCT model) to supply data for performance metrics, registries, etc. |
Put to the Test: Cath Lab Reporting Systems

• Cardiovascular information systems (CVIS) invented when HIS, EMR, PACS, laboratory reporting systems, could not meet cardiology needs

• But CVIS systems now viewed as unwelcome “information islands” - hospital information ecosystem now the EHR

• Declining demand for CVIS systems; some CVIS vendors have abandoned support for aging software

• 30% of current cath reporting products at end-of-life; cath labs at risk of system failure, leaving no alternative but to rip out and replace existing systems
Put to the Test: Cath Lab Reporting Systems

• BUT: cath lab workflow integration is paramount, every feature must be secondary to the workflow – and cath lab is a data-rich environment

• CVIS model inherently accomplishes data interoperability much more effectively and efficiently than EHR model

• Interoperability should make it possible to blend enterprise (EHR) and cardiology-specific data & ensure data consistency

• Facilitates clinical expression of the same findings in a compatible way, regardless of the source of the findings; positions healthcare to take advantage of the benefits of data
We believe the need for outcome measurement is even greater today than when we began this work. Health care systems around the world are still struggling with the intractable problems of high costs and suboptimal quality, and are looking for new answers. We believe value-based health care, with systematic outcomes measurement as its underpinning ...
DATA NEEDS

RECOMMENDATION 1: Acting on behalf of all relevant data-gathering agencies in the U.S. Department of Health and Human Services, the National Institutes of Health and the National Center for Health Statistics should join with an international partner (such as the OECD or the World Health Organization) to improve the quality and consistency of data sources available for cross-national comparisons. The partners should establish a data harmonization working group to standardize indicators and data collection methodologies. This harmonization work should explore opportunities for relevant U.S. federal agencies to add questions to ongoing longitudinal studies and population surveys that include various age groups—especially children and adolescents—and to replicate validated questionnaire items already in use by other high-income countries.
Grand Challenge: Multiple Masters

- Government
- Public Health
- Payers
- Regulators
- Patients
- Industry
- Research
- Lawyers
- Oh yes … clinicians

Recipients

Producers
Digital technologies have grown exponentially in speed, capacity and adoption.

The transition of cell-phones from 2G to 4G enabled a speed improvement of 12,000 times.

10 years ago: A genome sequence took 9 months and cost $100 million.

Today: 24 hours and ≈ $1,000.
‘Big Data’

- Volume. Volume. Volume …
  - megabyte, gigabyte, terabyte, petabyte, exabyte, & bigger!
- Velocity … faster and faster!
- Variety … both structured data and unstructured information (e.g., analog text / audio / video)
- Variability … quality / veracity, quantity, timing

Converted to:

- Value … targets operational insight (e.g., individual patient care)

Endless Variety

Genomic

Other ‘Omics

Imaging

Phenotypic

Exposure

Clinical
Big Data Meets The Real World

Measuring the *interactions* of biology, sociology, environment and decision-making that affect individual and population health.

Health and disease are the product of the interactions of genes, multiple biological systems, environment, social context, and personal decisions, we tend to look only at one or a few at a time.

K. Newby, MD – The Baseline Study
THE ESSENTIAL ISSUE

The “Tower of Babel” of language from common usage, medical literature, and multiple independent clinical trials.

Without data standards and controlled vocabulary we are lost in the age of computers and networks!
Clinician Desired State

- **Best approach** for the task – based on usability, efficiency and effectiveness – not regulation!
  - Even if this means disruptive change
  - Marry technical approach to best-practice workflow
  - Consistency at the task level (e.g., procedure reporting), rather than the system level (e.g., EHR) – one size does NOT fit all

- Capture **information as data** – but only where “data” are actually useful (e.g., conveying clinical / administrative info, risk calculation / stratification, predictive modeling)

- Procedure reporting naturally lends itself to structured reporting
Documentation Directions

• Create **structured reports** where there is inherently structured content (e.g., **procedure notes**)
  – Data (not words) populate report
  – Data acquisition, management by all members of the team

• Create (only) **elements** of structure in documents not inherently structured (e.g., **clinic / hospital notes**)
  – (Limited) data – summative assessments (e.g. CCS class)
  – (Limited) lexicon (<100 critical data elements for cardiology)
  – Data management by all members of the team

• ↑SPEED, efficiency, effectiveness, quality, productivity, ↓repetition / redundancy
What is **Structured Reporting**?

- Data management integrated into workflow
- Data acquisition by those closest to (handling) the data → also improves data quality
- Multiple authors contribute to procedure report
- Reducing MD time to procedure report completion
- Improving clinical communication with care team, physicians, patients
- Collect once, use many times (e.g., clinical report, PI analysis, data to registries)
What is Needed for **Structured Reporting?**

- **Vocabulary & data interoperability standards**
  - Inclusive of SDOs through registries

- **Best-practice workflows** *(industrial engineering)*
  - From cath order through data submission to registries

- **Professionalism expectations of CV clinicians**
  - Conversion from dictation model to structured data model
  - Expected content and format
    - Procedure documentation *(technical / procedure log)*
    - Physician report *(structured report)*

- **IT systems (vendors)**
  - Information model, systems aligned with clinical model
CV Informatics

• ACC/AHA “Top 100” EHR Terminology
  – Weintraub WS et al., JACC 2011; 5:202-22

• NCRI Cardiology Clinical Trials Terminology
  – Anderson HV et al., JACC 2013; 61:1835-46

• ACC/AHA/SCAI Cardiac Cath Structured Reporting
  – Sanborn TA et al., JACC ePup: 28 March 2014
  – IHE Cath Report Content (CRC-technical supplement)
    • http://www.ihe.net/Technical_Frameworks/#cardiology

• ACC/AHA/FDA CV Endpoints Terminology
  – Hicks KA et al., JACC 2014 Dec (epub ahead of print)

• Coming soon:
  – Echo controlled vocabulary, HRS Health Policy Statement on EP
    Structured Reporting, NCDR Consolidated Data Dictionary
Standardized Cardiovascular Data for Clinical Research, Registries, and Patient Care

A Report From the Data Standards Workgroup of the National Cardiovascular Research Infrastructure Project

H. Vernon Anderson, MD,* William S. Weintraub, MD,† Martha J. Radford, MD,‡ Mark S. Kremer, MD,§ Matthew T. Roe, MD, MHS,‖ Richard E. Shaw, PhD,¶ Dana M. Pinchotti, BS,# James E. Tcheng, MD‖

Houston, Texas; Newark, Delaware; New York, New York; Charlotte and Durham, North Carolina; San Francisco, California; and Washington, DC

CV vocabularies – NCRI
Balloted via HL7
Available on NCI-EVS
Example of a Common Data Element contains structured data + metadata tags

Object Class: (Physical Exam)
A systemic evaluation of the body and its functions using visual inspection, palpation, percussion and auscultation. The purpose is to determine the presence or absence of physical signs of disease or abnormality for an individual's health assessment.

Concept ID: C20969

Property (Killip Class)

Concept ID: C66916

Common Data Element (Killip Class)
A finding associated with a patient based on the classification developed by Killip and Kimball, which classifies patients with myocardial infarction based on routine physical examination parameters, such as the presence or absence of rales, or a decreased systolic blood pressure.

Concept ID: C66916

Value Domain (Killip Class)

Valid Values

Class I:
Absence of rales over the lung fields and absence of S3.

- NCI Thesaurus Concept ID: C77269

Class II:
Rales over 50% or less of the lung fields or the presence of an S3.

- NCI Thesaurus Concept ID: C77270

Class III:
Rales over more than 50% of the lung fields.

- NCI Thesaurus Concept ID: C77271

Class IV:
Cardiogenic Shock: An event with systolic BP < 90 mmHg for greater than 1 hour, not responsive to fluid resuscitation alone, and felt to be secondary to cardiac dysfunction. Associated signs of hypoperfusion (cool and clammy skin, oliguria, or altered sensorium) or a cardiac index of less than 2.2 L/min/m² are present. This includes when the systolic BP increases to > 90 mmHg in response to inotropic agents in less than 1 hour.

- NCI Thesaurus Concept ID: C77272
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

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William S. Weintraub, MD, FACC, FAHA  
John R. Windle, MD, FACC*

<table>
<thead>
<tr>
<th>Process</th>
<th>Information Sources</th>
<th>Information Captured as Digital Data</th>
<th>Actors</th>
<th>Information Systems</th>
<th>Form Factor (for Actors)</th>
<th>Data Output</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schedule Patient for Cath Procedure</td>
<td>History &amp; Physical Other documents Laboratories</td>
<td>Patient identifiers Demographics Diagnosis Laboratories</td>
<td>Physician requestor</td>
<td>Registration system Scheduling app Electronic Health Record</td>
<td>Desktop workstation</td>
<td>Schedule – to scheduling app Orders – to Electronic Health Record (EHR) system</td>
</tr>
<tr>
<td>Physician Pre-Procedural Evaluation and Consent</td>
<td>Existing clinical data History &amp; Physical Other documents Laboratories</td>
<td>Patient identifiers Demographics History Physical Exam Previous studies Laboratories Diagnosis</td>
<td>Advanced Practice practitioners Physician operator</td>
<td>Electronic Health Record Procedure Reporting system</td>
<td>Mobile tablet</td>
<td>Clinical data – to procedure reporting system (history section) Patient status – to scheduling system → electronic schedule Orders – to EHR</td>
</tr>
<tr>
<td>Nursing Pre-Procedural Evaluation</td>
<td>History &amp; Physical Other documents Laboratories Consents</td>
<td>Patient identifiers Height, weight, vital signs Medications</td>
<td>Outpatient / inpatient nurses</td>
<td>Electronic Health Record</td>
<td>Bedside workstation</td>
<td>Nursing documentation – to EHR Patient status – to scheduling system → electronic schedule</td>
</tr>
<tr>
<td>Cardiac Catheterization Procedure</td>
<td>Pre-procedure evaluation packet Hemodynamics Catheterization images</td>
<td>Patient identifiers Procedures Hemodynamics Findings Measurements Medications Inventory</td>
<td>Physician operator Cath lab nurses Cath lab technologists</td>
<td>Procedure Reporting system</td>
<td>Desktop workstation</td>
<td>Multiple workstations: Radiography Modality Hemodynamic Monitoring Procedure Documentation</td>
</tr>
<tr>
<td>Analysis and Report Generation</td>
<td>Hemodynamics Catheterization images Measurements Calculations</td>
<td>Patient identifiers Cath results Interpretation Tree diagram</td>
<td>Physician operator</td>
<td>Procedure reporting system</td>
<td></td>
<td>Procedure results – to procedure reporting system (results section) structured procedure report</td>
</tr>
</tbody>
</table>

[Diagram showing flow of information and actors involved in different processes.]
Pre-Procedure

• Who
  – Ordering physician
  – Pre-procedure evaluation by operator

• What information
  – Patient demographics, requested procedure, scheduling logistics, procedure indications, clinical history

• What information as data
  – Demographics, ICD-9 indications, structured history

• Output
  – Structured H&P
• **Who**
  – CV Technologist / Nurse

• **What information**
  – Procedure log, procedure findings

• **What information as data**
  – Hemodynamics, medications, procedures performed, devices used / implanted, medications – basically everything

• **Output**
  – Structured procedure data (in tables)
Analyse and Recompile

• Who
  – Physician (with the aid of the computer)

• What information
  – Findings and interpretations (physician)

• What information as data
  – Compiled H&P, procedure data
  – Structured findings

• Output
  – Procedure log
  – Procedure report
Cardiac Catheterization Procedure Report

SUMMARY

Procedures
- Left heart catheterization
- Percutaneous coronary intervention: prox LAD, mid-distal RCA
- Intra-aortic balloon pump

History
A 57-year old man with hyperlipidemia, hypertension, and a positive family history who presents with typical chest discomfort with exertion relieved with rest. A stress echocardiogram was positive for ischemia in the anterior and inferior distributions.

Encounter category
Elective cath, possible PCI
Key diagnostic findings

Right heart
- RA: 10 (mean)
- PA: 42/18, 26 (mean)
- Wedge: 16
- AV O2 Δ: 4.5 vol\%
- CO: 4.5 L/min
- CI: 2.5 L/min-m2

Coronary artery disease (significant)
- Left dominant
- Prox LAD: 90%
- Mid-distal RCA: diffuse 80%
- OM3: 60%
- Left ventricle
  - EF: 48%
  - EDP: 12
  - Wall motion: mod anterior hypokinesis, mild inferior hypokinesis
  - MR: 1+ mild

Interventions
1. 90% prox LAD: Integrity 3.0mm x 20mm stent (bare metal)
2. 80% mid-distal RCA: Xience 3.0mm x 28mm stent (drug eluting)

Complications
- Ventricular fibrillation

Notes
- Anterior takeoff of the RCA, unable to seat JR catheter, required AL1 guide. VE with cannulation of conus branch with AL1 guide. RCA lesion opened at 18 ATM. Successful PCI x2, recommend thienopyridine indefinitely.

Catheters
- JL 4, JR4, Pigtail, Amplatz 1, XB 3.5

Signature / eSignature / attestation
Native Diagnostic Summary

<table>
<thead>
<tr>
<th>Right Coronary Artery</th>
<th>Left Circumflex Artery</th>
<th>Left Anterior Descending</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prox RCA</td>
<td>QM, LPL1, LPL2, LPDA</td>
<td>Mid LAD</td>
</tr>
<tr>
<td>30% Tubular</td>
<td>small</td>
<td>30% Tubular</td>
</tr>
<tr>
<td>30% Tubular</td>
<td>small</td>
<td>D2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>D3</td>
</tr>
</tbody>
</table>

Comment: distal LAD with intramyocardial segment
Patient demographics
Healthcare facility information
Operators, staff
Referring care provider information
History and physical (categorical) data
Previous procedures
High risk allergies (e.g., contrast)
Laboratory data
ICD diagnoses
AUC indications

Procedures performed
Logistics (e.g., time in, time out)
Baseline data (e.g. height, weight, eGFR)
Vascular access details
Hemodynamic support
... and the rest of the details ...
• Health Policy Statement
  – Informatics and Health IT Committee
  – Clinical Quality Committee

• Prototype procedure report

• Style guide

• IHE profile
CVIS – Future State?

Enterprise Information Systems

Clinical Data Repository (EHR)

Decision Support Repository

Registration (ADT), Accounts, Scheduling, Labs, Pharmacy, CPOE, Inventory, Interfaces …

Integration Broker

Meta-data / resources

Cardiovascular Information System

OP → Admission → Discharge → OP
History, ECG, medications, events

ALL Modality Management
Measurements
Analysis
Reports
Image processing

DATA

Consistent MD experience
Pre-cert / LCD / Appropriate use
Clinical decision support
Scheduling / “White Board”
Registry / quality reporting
Modality “Plug and Play”

CPACS - Enterprise
HIT Vendors

Roles and Responsibilities

- Best practice: data handling integrated with workflow; team-based documentation
- Usability: interfaces designed and built for maximum efficiency and effectiveness (human factors design)
- Input devices: specific to role (e.g. mobile devices, workstations, hemo system interfaces)
- Graphics: graphical input and display of anatomic findings and treatment results
- Data management: use of controlled vocabularies including permissible values, range / consistency / validation checking; patient-centric (not procedure-centric) data model
HIT Vendors

Roles and Responsibilities

- **Outputs**: structured report per specifications of this HPS
- **Interoperability**: adherence to the IHE Cath Report Content (CRC) profile, Cardiac Cath Workflow (CATH) profile, and ACCF/AHA Task Force on Data Standards key data elements for cardiac imaging documents
- **Partnership**: with professional societies on developing the structured reporting environment
- **Point person role**: dissemination of best practices in structured reporting to the clinical community
# The World is Changing …

What Will the Next Decade Hold for Cardiology?

<table>
<thead>
<tr>
<th><strong>Was</strong></th>
<th><strong>Will Be</strong></th>
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</thead>
<tbody>
<tr>
<td>Modality / lab centric</td>
<td>Images everywhere</td>
</tr>
<tr>
<td>Paper / dictation</td>
<td>Optimized IT form factors</td>
</tr>
<tr>
<td>Data definitions by vendor</td>
<td>International data standards</td>
</tr>
<tr>
<td>Locked-in data</td>
<td>Interoperable data</td>
</tr>
<tr>
<td>Niche / possessive data use</td>
<td>Open, overlapping data use</td>
</tr>
<tr>
<td>Invasive maintenance</td>
<td>Zero footprint</td>
</tr>
<tr>
<td>Local data</td>
<td>HIE / cloud</td>
</tr>
<tr>
<td>Post-care reporting</td>
<td>Point-of-care data</td>
</tr>
<tr>
<td>acquisition</td>
<td>Informatics model</td>
</tr>
<tr>
<td>Clinical trials model</td>
<td>Teamwork is dreamwork</td>
</tr>
<tr>
<td>Individual is the weakest link</td>
<td></td>
</tr>
</tbody>
</table>
### Review of Benefits (Value STEPS™)

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http://www.himss.org/ValueSuite
Questions?

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