Cardiovascular Data Standards

James E. Tcheng, MD, FACC, FSCAI
Professor of Medicine (Cardiology)
Professor of Informatics
Duke University, Durham, NC
james.tcheng@duke.edu

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Healthcare Data Ecosystem

Clinical Vocabularies

Terminology (CDE) Standards, Data Models (CDM), Model Library (e.g. Graphite, NLM)

Model Translation Process

HL7 FHIR Resources, FHIR Profile Library

Enterprise Systems

- Interoperability Platform
  - Terminology Standards (Vocabulary) Service
  - Data Management (Data Model) Service

Apps Platform

- Internal Applications, Purchased Applications, Registries

Shared data, trusted environment

EHR
HIT
Registry vendor

Societies
Consortia
Registries

open source

proprietary

 Courtesy of Stan Huff, MD
It Starts with Good Data

**Clinical data**
- (standardized data elements and definitions)

**Other data**
- (administrative, EHR, etc)

**Database**

**Evidence Generation**

**Quality Improvement**

**Technology Assessment**

**Meaningful role in clinical practice**

How Registries Solve the Data Capture Problem

Standardized NCDR data elements and processes

- Patient demographics for diagnostic coronary angiography and percutaneous coronary intervention (PCI) procedures
- Patient history/risk factors, cath lab visit indications and coronary lesion information
- Provider and facility characteristics
- PCI Indications, lesion information, intracoronary device utilization and intra/post-procedure events
- 30-day and 1-year follow-up information on patients who had PCI

The registry supports a variety of data entry and submission options including certified third-party vendors and secure web-based entry. Data collection options

The FHIR Specification Provides:

- Healthcare domain resources (content framework)
- Infrastructure for exchanging resources (RESTful API)
- Descriptive and ontological narrative describing relationships
- Framework for determining conformance (testing and safety)
- Resources for management workflows

- References between resources build up the record
Search Term: myocardial infarction
Returns 308 matches in 2.33 seconds
Terms defined by pathologic, anatomic relationships
No clinical definition

SNOMED-CT
End to End Native Data Interoperability?

- Identify, define core clinical concepts
- Capture core clinical concepts as data (not text)
- Specify representation of data as data elements in database systems (physical data model)
- Integrate data capture with clinical workflow
- Target direct data transfer (while respecting ETL / boundary-based interoperability)
- Capture once, use many times ...
Cardiovascular data eXchange
Why CardX?

Cardiovascular medicine is rich in consensus, evidence-based guidelines and practice models proven to reduce cardiovascular morbidity and mortality.

**DATA STANDARDS**

**ACCF/AHA 2011 Key Data Elements and Definitions of a Base Cardiovascular Vocabulary for Electronic Health Records**

A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Clinical Data Standards

J Am Coll Cardiol. 2011; 58:202-22
Circulation. 2011; 124:103-23

**Clinical Practice Guideline**


A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines

J Am Coll Cardiol. 2018; 71:e127-e248
Circulation. 2018; 138:e484-e594
Evidence-Based Medicine

- What is mature?
  - Epidemiology, science – we understand the problems & have solutions
  - Pharmacology, devices – we have therapeutics that improve outcomes
  - Guidelines, policies – we have agreement about what needs to be done

- What is incomplete (or missing)?
  - Guidelines written per computational constructs
  - **Device standards**: that enables “plug and play” (e.g., home BP devices)
  - **Data standards**: clinical concepts expressed as (universal) data elements
  - Patient-facing IT: high usability systems that enable patients (e.g., medication reconciliation, guided BP management)
Potential CardX Use Cases

Foundation: core, interoperable cardiovascular lexicon

- Home-based management of hypertension
- Quality and performance measures assessment
- Registry submission
- Medical device assessment and surveillance
- Clinical decision support
- Research and discovery
- ...
CardX – Cardiovascular Data eXchange

A set of common data elements for cardiovascular care that is standardized, computable, clinically applicable and available in every electronic health record for patients with a cardiovascular diagnosis

A standard health record for cardiology
Builds on the methods and technologies of mCODE

An expert validated set of data elements applicable to all cardiovascular conditions, and collected for:

Standardized information exchange
Use-case driven and targeted use

Cardiology data element domains: patient, disease, treatment, outcomes, device, lab/vital

mCODE STU2: http://hl7.org/fhir/us/mcode/
Hypertension Use Case

Problem
• Hypertension affects 115 million adults in America
• Lack of adherence to clinical guidelines to diagnose, treat, and manage hypertension
• Home BP monitoring is the standard for hypertension management, however there are no data exchange standards

Solution
• Integrated standard that enables interoperable, scalable, and accessible HTN management both at home and clinic

Desired Impact
• Provide patients, physicians, APPs, nurses, medical assistants, pharmacists, and dieticians with the tools needed to adhere to hypertension guidelines
• Increase data liquidity between blood pressure measurements captured at home with those captured in the clinic
Hypertension Use Case

Clinic
- Clinician
- Decision Support
- EHR
- Quality Measures
- Payers

Home
- Patient
- Patient Guidance Engine
- Personal Health Record
- Personal Health Devices
- Device Gateway

CardX
Clinician Encounter (Outpatient) (e.g., cardiology, internal medicine, family medicine)

EHR
- Demographics
- Vitals
- Diagnoses
- Prescriptions
- Labs
- Social history
- Care plan

ASCVD Risk Calculator
American College of Cardiology

Clinical Decision Support, Guidelines
- HTN management
- Performance measures
- Clinical documentation

Home Monitoring (asynchronous, semi-autonomous)

PHR
- BP / Health Management Portfolio

@Home BP Measurement

RESTful API

Patient

FHIR BP1 (EHR to PHR: both push to and call from PHR)
- Demographics: patient ID, DOB, MRN, sex, race, ethnicity
- Vitals: SBP, DBP, HR, height, anatomic location, measurement location
- Diagnoses: HTN, DM, CKD, kidney transplant, pregnancy, comorbidities ...
- Assessment: EtOH, diet, nicotine, activity, stress
- Labs: cholesterol, HDL
- Meds: ASA, statin, HTN rx, HTN aggravating rx, RxClass (as prescribed)
- Non-pharm rx: diet, tobacco, exercise, stress reduction
- Care plan: HTN target, care plan components, education

FHIR Personal Medical Device
- Patient ID
- Device ID
- Vitals: SBP, DBP, HR, anatomic location
- Measurement location (home)
- Date and timestamp

FHIR BP2 (episodic PHR to EHR: BP data, clinician messaging)
- Demographics: patient ID, DOB, MRN
- Vitals: SBP, DBP, average BP, HR, anatomic location, measurement location, weight
- Meds: ASA, statin, HTN rx, HTN aggravating rx, RxClass (as taken)
- Social: diet, tobacco, EtOH, exercise, behavioral
- Patient-reported outcome measures (PROM)

KEY
Purple: not in scope
Orange: our responsibility to define
Dark blue: collaboration with stakeholders at data exchange & implementation levels
Light blue: high level data content
Technical Approach

- Map and disambiguate Guidelines and Performance Measures (ACC/AHA, AAFP, NQF, etc.) into core concepts and corresponding data elements
- Identify sources of data in context of processes and workflows
- Specify, build FHIR profiles and implementation guides
  - From device or device gateway, self-monitored BP data will be exchanged with a Patient Data Manager (PHR)
  - Separate FHIR-based exchanges will connect the Patient Data Manager / PHR with the EHR
Stakeholder Opportunities and Contributions
Linking Clinicians, Patients, Health Systems, Vendors, and Government

Opportunity
- Lower barriers to evidence-based practice
- Reduce burden of data collection
- Facilitate actionable data to inform treatment

Contribution
- Enable data liquidity through FHIR
- Support development of next generation care models for patients with HTN
- Focus on the user experience

Opportunity
- Reduce death and disability due to HTN
- Decrease healthcare costs
- Increase scalability, efficiency, and effectiveness of HTN management

Contribution
- Demonstrate proof of use of FHIR-based interoperability
- Validate value of FHIR Accelerator model in improving HTN management
Thank You!

james.tcheng@duke.edu

Visit the Pew Project website:

https://dcri.org/registry-data-standards