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Clinical Data Registries: Solving for Interoperability

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COMMITMENT

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Conflict of Interest

Seth Blumenthal, MBA

Has no real or apparent conflicts of interest to report

Agenda

- What is a clinical registry
- Segmentation of registries and the need for standardization
- Registries on FHIR: an approach to increasing semantic interoperability
- Q&A

Learning Objectives

- Explain interoperability concepts, how they apply to registries, why registry interoperability needs to be improved and what is being done about it
- Describe an interoperability solution process and discuss how organizations can use it to carry out interoperability demonstration projects
- Classify potential focus areas for good interoperability demonstration projects that have wide applicability and can contribute to the general health IT infrastructure that supports interoperability
- Interpret the current state of registry interoperability, particularly where the barriers are and how numerous conflicting stakeholder incentives can be aligned to overcome them
- Express how you can become involved in this work and contribute to solution building

What is a clinical registry

Clinical Data Registries

- 100+ clinical registries in the United States; many more around the world
- Most U.S. registries stewarded by medical specialty and health care professional societies and associations
- Some registries support multiple databases e.g., for subspecialties
- Structured data from EHRs, data warehouses and other clinical information systems (CIS) are extracted and loaded into registries
- Data that cannot be captured in this way are hand-abstracted
- Data are structured and standardized to a degree within a single registry, but usually not across registries

AHRQ defines a clinical registry as:

“...an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves predetermined scientific, clinical, or policy purpose(s).”

[Source: Registries for Evaluating Patient Outcomes: A User's Guide: 3rd Edition](#)

Registries are BIG

American Academy of Allergy, Asthma & Immunology
American Academy of Dermatology
American Academy of Neurology
American Academy of Ophthalmology
American Academy of Orthopaedic Surgeons
American Academy of Otolaryngology - Head and Neck Surgery
American Association of Cardiovascular and Pulmonary Rehabilitation
American Association of Neurological Surgeons
American Board of Family Medicine
American College of Cardiology
American College of Emergency Physicians
American College of Gastroenterology & American Society for Gastrointestinal Endoscopy
American College of Physicians
American College of Radiology
American College of Rheumatology
American College of Surgeons
American Congress of Obstetricians and Gynecologists
American Gastroenterological Association
American Heart Association
American Optometric Association
American Orthopaedic Association
American Physical Therapy Association
American Society for Reproductive Medicine
American Society of Anesthesiologists
American Society of Clinical Oncology
American Society of Nuclear Cardiology
American Society of Plastic Surgeons
American Urogynecologic Society
American Urological Association
Americas Hernia Society Quality Collaborative
Anesthesia Business Group
Arthrex
Arthritis Foundation
ASPIRE (Anesthesiology Performance Improvement and Reporting Exchange)
Bivarus
Boston Advanced Analytics
CDC
Childhood Arthritis and Rheumatology Research Alliance (CARRA)
CODE Technology (Clinical Outcomes and Data Engineering Technology)
Consortium for Universal Health System Metrics

Corrona, Inc.
CreakyJoints®
Cystic Fibrosis Foundation
DARTNet Institute
Emory University and the Centers for Disease Control (CDC)
ePreop
gEHRiMed
Hawkins Foundation, Center for Effectiveness Research in Orthopaedics and SunCostRHIO
Heart & Vascular Outcomes Research Institute
ICLOPS
ImproveCareNow
InVivoLink
Kaiser Permanente®
Massachusetts Eye and Ear Infirmary, Harvard Medical School and the National Institute on Deafness and Other Communication Disorders (NIDCD)
MedAmerica
Mednax
NARCOM
National Cancer Institute
National Institutes of Health (NIH)
National Osteoporosis Foundation / National Bone Health Alliance
North American Spine Society
OBERD
Office of Rare Diseases Research
Oncology Nursing Society
PatientsLikeMe
Pediatric Rheumatology Care and Outcomes Improvement Network
Premier
Press Ganey
Renal Physicians Association
ReportingMD
Society for Vascular Surgery
Society of Gynecologic Oncology
Society of Interventional Radiology / American College of Radiology
Society of Thoracic Surgeons
Society of Transplant Surgeons
Spine IQ
University of Massachusetts Medical School
US Hereditary Angioedema Association
US Wound Registry
Wellcentive
westhealth™ institute
Wisconsin Collaborative for Healthcare Quality (WCHQ)
Wound Care Quality Improvement Collaborative

A partial listing of
U.S. registry steward
organizations

[Source: PCPI registry inventory \(2016\)](#)

The Role of Registries

- Registries capture clinical data that matter to clinicians, patients and others
- Registries capture data from multiple organizations on their patients who have similar reasons for seeking care
- Information from registries allow accurate performance measurement and feedback on a national level
- This information is used to improve patient health outcomes

Supportive Characteristics

- Registry data models are designed for specific purposes
- Data are captured from multiple patient encounters across provider organizations and care settings
- Registry data governance ensures the consistency and validity of data captured from different individuals, data sources and organizations
- Registries track patient care delivered over varying periods of time as patients move between organizations

Registry Landscape Survey

- Surveyed 152 societies and associations about registry programs: governance, # of registries, purpose, data collection, expenses, funding and interoperability
- 52% response rate. Registries are generally self-funded with smaller budgets. 39% <\$1mil/yr.
- Most registries collected demographics, treatments, practitioner information and comorbidities; 53% captured PROs
- 88% used manual data entry; 18% linked to external secondary data sources
- Cost, interoperability were barriers to continued registry development

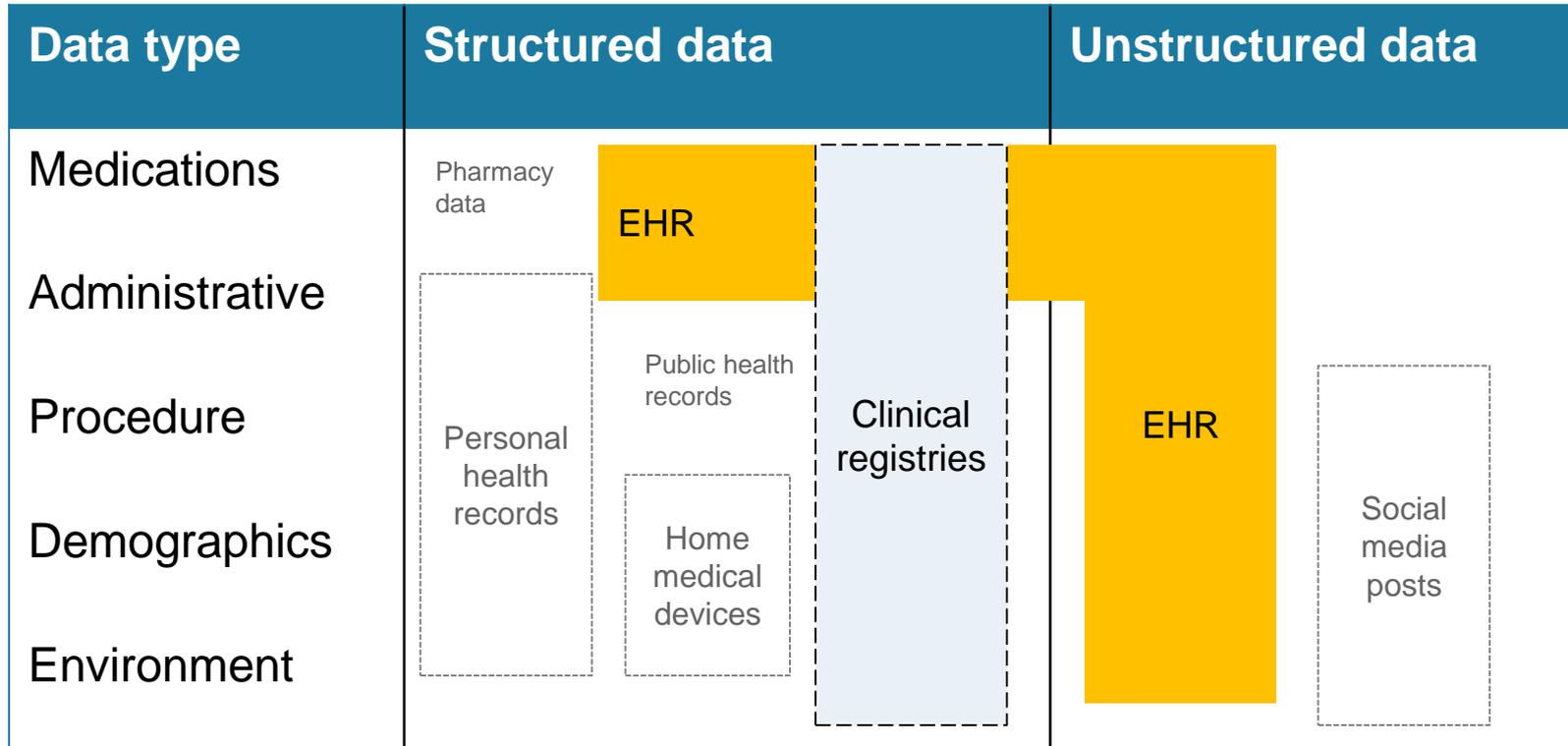
Registry Purposes and Uses

Purpose	Response
Quality improvement	94%
Benchmarking	86%
Clinical effectiveness	59%
Safety or harm	44%
Comparative effectiveness research	37%
Cost effectiveness	24%
Device surveillance	18%
Population surveillance	17%
Public health	4%

Use	Response
Clinical decision support development	61%
Education development	54%
Measure development	53%
Qualified Clinical Data Registry (QCDR)	39%
Guideline development	35%
Certification	29%
Public reporting	26%
Payment	17%
Population management	15%
Other	5%
Licensure	1%

Source: Blumenthal S. The Use of Clinical Registries in the United States: A Landscape Survey. eGEMs (Generating Evidence & Methods to improve patient outcomes). 2017;5(1):26. DOI: <http://doi.org/10.5334/egems.248>

Registries in the health IT landscape



Registries collectively capture data on a cross section of data types from multiple organizations
Need to ease sharing of clinical content across organizational and clinical silos

Registry Information Flow



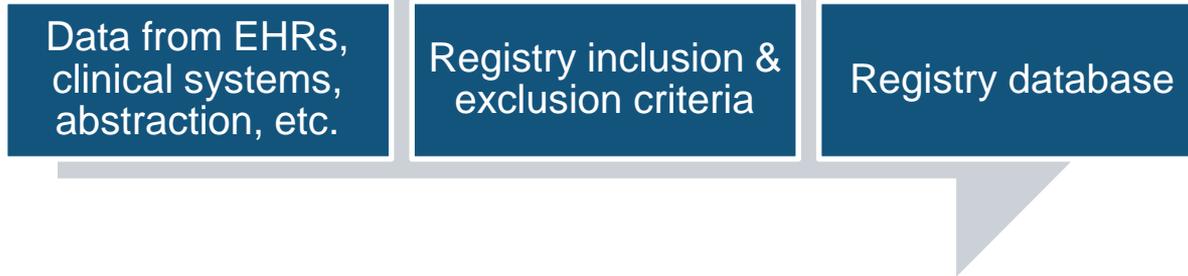
Registry Data Capture Models

EHRs	Other CIS	Patients
<ul style="list-style-type: none">• Push• Pull• Certification model• Chart abstraction (manual data capture)	<ul style="list-style-type: none">• Linking with external databases e.g., for public health data• As with EHRs, interface with clinical & departmental information systems	<ul style="list-style-type: none">• Direct data entry from patient facing apps• Data feed from patient devices

[Source: PCPI Registry FAQ](#)

Some level of adoption of data standards at various levels
Some specialties have or are developing data standards for clinical content;
adoption is currently low

Registry Data Intake



Typical broad data categories

EHR

- Problem list
- Orders
- Encounters

Clinical info system

- Specialty-specific data
- Diagnosis

Registry data model

- Clinical finding
- Device
- Disorder
- Encounter
- Entity
- Intervention
- Patient
- Procedure
- Etc...

Source: HL7 Common Clinical Registry Framework Domain Analysis Model

Registries are big because...

Their ability to capture structured, standardized, valid high quality data on large real-world populations across care settings, organizational boundaries and over varying periods of time...

Has made them useful for:

- Clinician performance measurement on a national level
- Benchmarking, QI, research
- Driving value-based payment models

They have been given an expanded role in the Quality Payment Program

Segmentation of registries and the need for standardization

Making value-based payment a reality

To move from partial to full risk

Organizations for which value-based care is still a fairly new phenomenon are slowly being incentivized to take on more risk:

- The CMS Quality Payment Program
- Medicare Readmissions Reduction Program

Other organizations have started utilizing models such as:

- Bundled payments
- Advanced alternative payment models (APMs) in the CMS Quality Payment Program

Models such as global capitation, system owned health plan are on the rise

We need...

Data aggregation and analysis

- The right tools to capture the right set of data and measures to assess against

Care coordination and population health improvement

Administrative and financial

Patient engagement

- Engage patients outside the episode of care

Clinical engagement

- Success dependent on clinicians being on board with a value-based care strategy and comfortable using any necessary tools.

So what is the problem

- Emphasis on measuring health outcomes requires longitudinal, multispecialty data collection
- E.g.: looking at a complete picture of care in a chronic disease. It's hard to find all the data one needs in a single registry
- **Data are not standardized across registries**
- Linking registries to create a unified view is hard
- Provider organizations are participating in multiple registries; interfacing (in all dimensions – technical, legal, etc.) is a lot of work and must be repeated for each registry
- Much needed registry data are still entered manually due to their lack of structure and standardization in EHRs
- **The status quo is not sustainable...**

Information models in registries vary

Challenges

- Many different clinical specialties
- Registries collect very detailed, specific, highly structured data to suit particular purposes
- Some data are common across many specialties, but even those are described differently in each registry
- Some stewards developing their own standards but vendors don't want to implement 30+ different specialty standards
- Hard to obtain highly structured, standardized data from EHRs

Opportunities

- Need a convener to bring the registry steward / clinical community together with SDOs, platforms, vendors
- Demand is increasing for single view of care across clinical specialty domains
- HL7 FHIR® is a good platform for standardizing clinical content in exchanged between registries and source data systems
- The registry community, convened through registry networks such as the PCPI's NQRN program and MDEpiNet, an FDA public private partnership, is nimble and a good place to pilot standards and interoperability efforts
- Significant cost savings and burden reduction possible if >% structured data capture and easier data sharing

Why Interoperability Matters

- Value-based payment driving measurement that crosses boundaries
- Current lack of interoperability of health care data impairs ability to realize better value for populations & patients
- Clinicians and patients need pertinent data from all sources to make decisions
- Technical interoperability allows access to data; semantic interoperability preserves the meaning of the information in the data so it can reliably be used in decision-making
- Improved semantic interoperability is expected to result in significantly reduced data acquisition costs as well as better data quality

Opportunity for Registries

- Industry has mostly focused on technical interoperability
- Semantics, or the way information or meaning is represented in data, vary widely between specialties, institutions and throughout the industry
- Registries collectively capture much important clinical data with validity & specificity that allow for national measurement & analysis
- Opportunity in registries to standardize definitions of common data elements, reducing need for abstraction & data mapping
- Registry community networks such as NQRN and MDEpiNet well-suited to drive consensus on these kinds of standards and demonstrate the hypothesis that the work is value-added.

What do we need to do?

Because registries:

- Capture structured, specific clinical data for most clinical specialties
- Are relatively small in number and coordinated through registry networks

They are a good platform for data standards & interoperability work

We need to standardize semantics in a way that represents a voluntary, clinician-driven consensus. If clinical stakeholders across the specialties and professions can agree on standardizing common clinical data, burdens and barriers to adoption will be lowered.

Theory: this work will lower data acquisition burden to a greater extent than the cost of making the changes in registries and source data systems. It might also improve data quality.

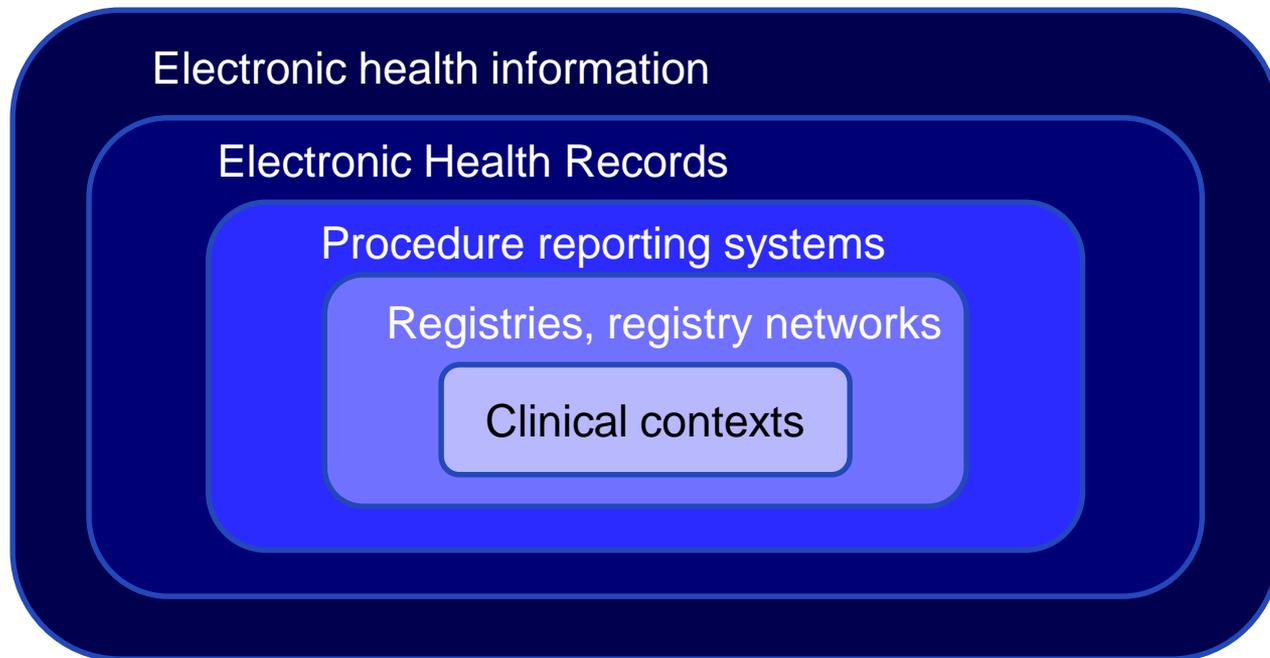
Registries on FHIR: an approach to increasing semantic interoperability

The Foundational Issue



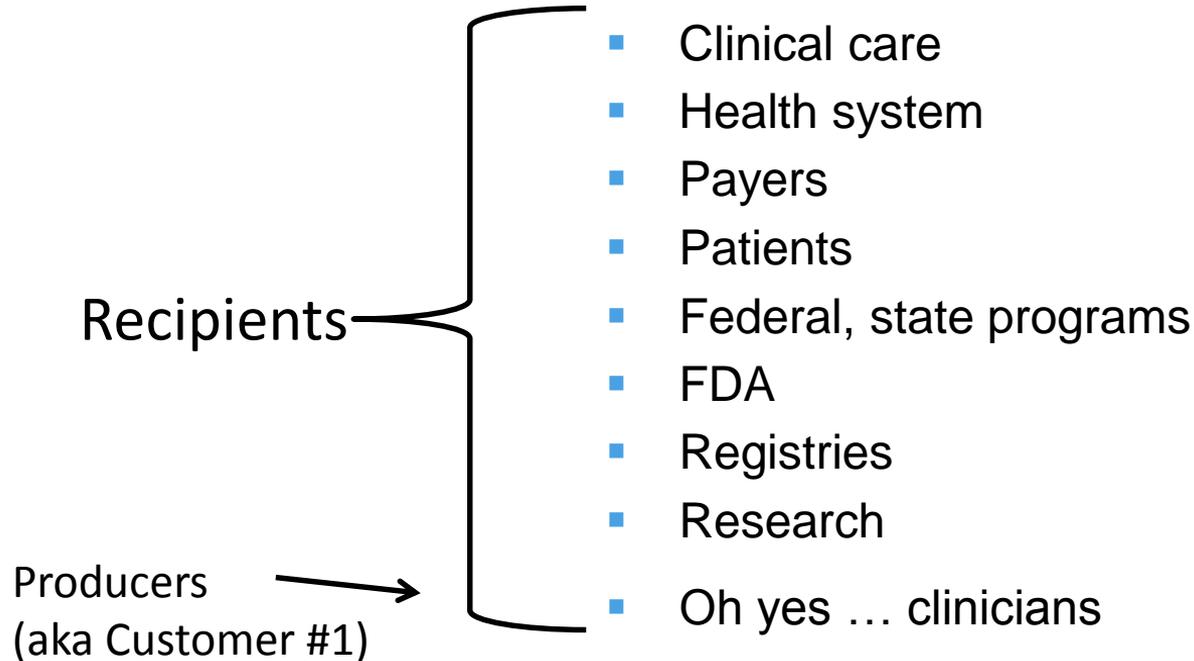
Tower of Babel
*Pieter Bruegel the Elder and
Pieter Bruegel the Younger, 1563*

The Foundational Solution



Native,
Interoperable Data
Standardization

Data Challenge: Multiple Masters



Customer #2: Database Developer

So you want to build a database ...

- Database field label (i.e., what do you call the data element, aka the “address” of the data in the database)
- Data type / format (e.g., text string, integer, date, constrained list, ...)
- Business rules (e.g., range limits, consistency checks, ...)

Key CDE Metadata

1. Clinical concept label e.g., human prompt for CRF, data entry screen
2. Database field label: all caps, no spaces, underscores only, limited chars ...
3. Clinical definition of the concept, synonyms thereof
4. Data type / format e.g., free text, constrained list, integer, ...
5. Allowed values aka permissible values; value set; VSAC
6. Allowed values definitions
7. Business rules e.g., range or edit checks, consistency, validation
8. SDO binding(s)
9. Published reference(s)

Question or
prompt
*May have associated
controlled terminology*

Value, result or
answer
*May have associated
controlled terminology*

HCV status:

Common Clinical Data Elements

- Demographics, administrative data (ONC)
- Vital signs, tobacco use history (ONC)
- Procedure codes (CPT)
- Laboratory data (LOINC)
- Medications (RxNorm)
- UDI and reference device data (GUDID)

Clinical concepts shared across clinical, research, and regulatory contexts NOT unique to the discipline and that already have bindings to standardized terminologies:

HL7 FHIR Common Data Element Specification

- ...
 - Identifier
 - Based on
 - Status
 - Category
 - Code
 - Subject
 - Context
 - Effective period
 - Issued
 - Performer
 - Value Codable Concept
- Data Absent Reason
 - Interpretation
 - Comment
 - Body Site
 - Method
 - Specimen
 - Device
 - Reference Range
 - Reference Range ID
 - Reference Range Extension
 - ...



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C:\Users\tchen\Desktop\FHIR...
Find: element id Previous Next Options 66 matches
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  <definition value="A coded value that represents the result of an observation, assessment, or evaluation."/>
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From Concepts to Action

- MDEpiNet Projects (RAPID, BUILD, CATNIP, EP PASSION, etc.) – identify domain-specific CDEs
 - Clinical concept label, db label, etc.
 - Re-populate GUDID, create AUDI
- NQRN – identify common clinical CDEs
 - Leverage FHIR for vetted content
 - Create simplified technical representation to accelerate implementation across NQRN registries
- Informatics – model representations
 - CIIC process, CIMI repository

Creating the ecosystem ...

What is NQRN doing to help registries improve interoperability?

- NQRN identified interoperability as a priority in 2016
- Registries on FHIR project launched bringing registries, vendors and informaticists together
- Completed information-gathering campaign and submitted paper to AMIA 2018 Informatics Summit
- Currently scoping first project – to demonstrate value of common data elements in lowering registry data acquisition cost and/or improving data quality
- Collaborating with the MDEpiNet and the Duke Clinical Research Institute. Initial pilot registries – NCDR, Vascular Quality Initiative

2017 Fact-finding

- A registry interoperability needs survey was conducted in June 2017 using SurveyMonkey. The survey was sent to all 2018 QCDRs where a contact email address was found; emails were located for 50 QCDRs.
- Interviews were conducted with registries and registry vendors participating in Registries on FHIR
- Interviews were conducted with informaticists, including those affiliated with SDOs, trade groups and consultants.
- We asked respondents for their views on how to solve interoperability problems from a registry perspective.

Results

- 16% (8/50) of the QCDRs responded to the survey, and an additional 4 were interviewed, for a total of 24% of the 2018 QCDRs.
- 6 registry vendors were interviewed. Registries reported the greatest level of interest in solving problems related to their specific workflows, and a secondary interest in general interoperability problems.

Registry Interoperability Priority Areas

Area	Reporter
Develop common data elements for data used in many registries e.g., demographics, vitals, pain	Registries and registry vendors
Develop standardized information models that support needs common across many registries e.g., QCDR measures, measure sets needing harmonization, cross-cutting measures	Registries and registry vendors
Develop nationally-accepted specialty-specific data standards e.g., for pathology specimen collection, and make them generally available	Registries
Develop HL7 FHIR implementation guides that incorporate existing data standards i.e., American College of Cardiology data standards	Registries
Improve patient matching	Registry vendors
Identify a system to standardize the way things are identified in registries	Registry vendors

Getting it done: three projects

- **MDEpiNet Project RAPID:** developing a set of common clinical data elements, beginning with the ONC Common Clinical Data Set and FHIR resources
- **Registries on FHIR:** implement these CDEs in two registries: NCDR/CathPVI and SVS VQI. Measure impact in data acquisition cost/data quality
- **HL7 Common Clinical Registry Framework work group:** Update CCRF Domain Analysis Model (DAM) to incorporate these CDEs, then work to create a general registry FHIR profile that incorporates those CDEs. Collaborate with NQRN to push for adoption in registries.

Questions

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