Comparative Effectiveness Research and Data Interoperability

Why MU and EHRs are Insufficient for Evidence Based Medicine (EBM) and Comparative Effectiveness Research (CER)

By Shahid N. Shah, CEO
Who is Shahid?

- 20+ years of software engineering and multi-site healthcare system deployment experience
- 12+ years of healthcare IT and medical devices experience (blog at http://healthcareguy.com)
- 15+ years of technology management experience (government, non-profit, commercial)
- 10+ years as architect, engineer, and implementation manager on various EMR and EHR initiatives (commercial and non-profit)

Author of Chapter 13, “You’re the CIO of your Own Office”
# Commonly Used Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>AHRQ</td>
<td>Agency for Healthcare Research and Quality</td>
</tr>
<tr>
<td>CDISC</td>
<td>Clinical Data Interchange Standards Consortium</td>
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<tr>
<td>CCHIT</td>
<td>Certification Commission for Healthcare Information Technology</td>
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<tr>
<td>CDS</td>
<td>Clinical Decision Support</td>
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<tr>
<td>CIO</td>
<td>Chief Information Officer</td>
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<tr>
<td>CISO</td>
<td>Chief Information Security Officer</td>
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<tr>
<td>CMS</td>
<td>Centers for Medicare and Medicaid Services</td>
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<tr>
<td>CONNECT</td>
<td>NHIN gateway</td>
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<tr>
<td>CPRS</td>
<td>Computerized Patient Record System</td>
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<tr>
<td>EHR</td>
<td>Electronic Health Record</td>
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<tr>
<td>EMR</td>
<td>Electronic Medical Record</td>
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<tr>
<td>FHA</td>
<td>Federal Health Architecture</td>
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<tr>
<td>HHS</td>
<td>Department of Health &amp; Human Services</td>
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<tr>
<td>HIE</td>
<td>Health Information Exchange</td>
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<tr>
<td>HIT</td>
<td>Health Information Technology (Health IT)</td>
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<tr>
<td>HIMSS</td>
<td>Healthcare Information Management Systems Society</td>
</tr>
<tr>
<td>HIPAA</td>
<td>Health Insurance Portability and Accountability Act</td>
</tr>
<tr>
<td>HL7</td>
<td>Health Level 7</td>
</tr>
<tr>
<td>JCAHO</td>
<td>Joint Commission on Accreditation of Healthcare Organizations</td>
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<tr>
<td>MU</td>
<td>Meaningful Use</td>
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<tr>
<td>NHIN</td>
<td>Nationwide Health Information Network</td>
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<tr>
<td>ONC</td>
<td>Office of the National Coordinator (preferred abbreviation for ONCHIT)</td>
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<tr>
<td>ONCHIT</td>
<td>Office of the National Coordinator for Health Information Technology</td>
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<tr>
<td>PQRI</td>
<td>Physician Quality Reporting Initiative</td>
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<tr>
<td>SNOMED</td>
<td>Systematized Nomenclature of Medicine</td>
</tr>
<tr>
<td>VistA</td>
<td>Veterans Health Information Systems and Technology Architecture</td>
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</tbody>
</table>
EBM and CER are not new

Success factor: large well-designed effectiveness studies with mountains of data
Medicare and Medicaid are paying more 50% of the nation’s healthcare costs but doing so as *fees for services without regard* to what treatments, medications, or tests *really work*.

The evidence-based research that goes into figuring out what works and what doesn’t is the foundation of CER.
Congress allocated $1.1 billion to The Department of Health and Human Services (HHS) to “provide information on the relative strengths and weakness of various medical interventions”


The Council will specifically make recommendations for the $400 million allocated to the Office of the Secretary for CER.

Source: http://www.hhs.gov/recovery/programs/cer
AHRQ’s definition of CER

• Comparative effectiveness research is designed to inform health-care decisions by providing evidence on the effectiveness, benefits, and harms of different treatment options.

• The evidence is generated from research studies that compare drugs, medical devices, tests, surgeries, or ways to deliver health care.

Source: http://effectivehealthcare.ahrq.gov/index.cfm/what-is-comparative-effectiveness-research1/
AHRQ’s definition of CER evidence

• Researchers **review evidence** about the benefits and harms of each choice for different groups of people from **existing** clinical trials, clinical studies, and other research.

• Researchers **conduct studies** that generate **new** evidence of effectiveness or comparative effectiveness of a test, treatment, procedure, or health-care service.

AHRQ’s definition of CER process

1. Identify new and emerging clinical interventions.
2. Review and synthesize current medical research.
3. Identify gaps between existing medical research and the needs of clinical practice.
4. Promote and generate new scientific evidence and analytic tools.
5. Train and develop clinical researchers.
6. Reach out to stakeholders via a citizens forum.
7. Translate and disseminate research findings to diverse stakeholders.

CER is about the patient

• CER sounds like it’s all about the government and evidence-based medicine to contain healthcare costs but ultimately it’s about providing treatment comparison choices to help make informed decisions.

• Healthcare professionals must deliver tools to the patient that can help the patient and their families select the right treatment options.
MEANINGFUL USE MAKES CER POSSIBLE BUT IS NOT ENOUGH
Where is all the data coming from?

The Federal Government believes collecting healthcare data is so important that “Meaningful Use” of health IT is a national $20 billion priority.
How does Meaningful Use (MU) fit with CER?

“Enable significant and measurable improvements in population health through a transformed delivery system.”

- Improving quality, safety, and efficiency as well as reducing health disparities.
- Engage patients and families in their health care.
- Improve care coordination.
- Improve population and public health.
- Ensure adequate privacy and security protections for health information.
Hospitals are serious about MU

AHA survey found that 81 percent of hospitals are going after MU incentive payments and 65 percent may enroll during Stage 1 (by 2012)

What problems can data help solve?

- Cost per patient per procedure / treatment going up but without ability to explain why
- Cost for same procedure / treatment plan highly variable across localities
- Unable to compare treatment effectiveness across patients
- Variability in fees and treatments and lack of data sharing promotes fraud
- Lack of data sharing and visibility of entire patient record causes medical errors
- Lack of data sharing prevents evidence-based care to drive policy
MU implementations will generate enormous amounts of data

Stage 1: 2011
Capture/share data
- Medication Orders entered by licensed healthcare professionals
- Core clinical documentation
- E-copies of health information to patients
- Quality and immunization reporting
- Drug-drug, drug-allergy, drug-formulary checks; medication lists/reconciliations
- Lab results delivery
- Patient reminders
- E-prescribing

Stage 2: 2013
Advanced care processes with decision support
- Health summaries for continuity of care
- Registry reporting and reporting to public health
- Populate PHRs
- CPOE for all order types
- Evidence-based order sets
- Clinical decision support at point of care
- All clinical documentation in EHR
- Claims and eligibility checking

Stage 3: 2015
Improved outcomes
- Minimal levels of performance on quality, safety and efficiency measures
- Clinical decision support for national high-priority conditions
- Access comprehensive data from all available sources
- Experience-of-care reporting
- Medical device interoperability
- Dynamic/ad hoc quality reports
- Real-time surveillance
- Multimedia support (e.g. X-rays) Patients have access to self-management tools
- Use of epidemiologic data
- Clinical dashboards
- Provide patients with accounting of treatment, payment, and healthcare operations disclosures (upon request)
MU Will Create Data Deluge

- Ambulatory Care Environment
- Outcomes Management System
- Emergency Department
- Labor and Delivery
  - Bar Coding
  - Patient Accounting
  - Electronic Charge Capture System
  - Radiology
  - Clinical Lab Information System
  - Cardiology
- Dictation/Transcription
- Inpatient Pharmacy Services
- Pathology
- Electronic Medication Administration Records
Thousands of healthcare data islands

CER data sources

- Hospitals, Health Systems
- Research & Labs
- Physician Groups
- Pharmacists
- Clearinghouses
- Payers
- Medicare / Medicaid
- Public Health (e.g. CDC)
- Patients
- HIEs & RHIOs
- Regulatory Agencies
EHRs are not the only applications that generate data

Clinical Enterprise
- Advanced Clinical (CPOE, interdisciplinary doc, advanced decision support, knowledge management)
- Clinical Data Repository (data warehouse, results reporting)

Departmental
- Departmental Clinical (PACS, cardiology, perinatal, perioperative, anesthesia)
- Ancillary Clinical (lab, pharmacy, radiology IS)

Administrative Enterprise
- Patient Management (registration, discharge management, accounting)

Financial Systems
- A/P, A/R, materials management, general ledger, reporting
- Payroll, personnel

Physician Office
- EMR
- Practice Management (billing, scheduling)
HIT systems that generate evidence

- Clinical systems
- Consumer and patient health systems
- Core transaction systems
- Decision support systems (DSS and CPOE)
- Electronic medical record (EMR)
- Managed care systems
- Medical management systems
- Materials management systems
- Clinical data repository
- Patient relationship management
- Imaging
- Integrated medical devices
- Clinical trials systems
- Telemedicine systems
- Workflow technologies
- Work force enabling technologies
COMPUTABLE CLINICAL DATA
Computable Clinical Data is the Goal

Complete Solution
Conversion of Electronic Medical Data into Information

Semantic Interoperability

Extraction, Transformation, & Loading

Health Information Exchange

Database Technology

Ontology Engineering

Natural Language Processing
Gartner Hospital Technology View
Gartner Hospital Technology Cycle

On the Rise
• Healthcare-Assistive Robots
• Consent Management
• Digital Pathology Scanners
• NHIN Direct
• Semantic Web Tools/Healthcare

At the Peak
• HIPAA/HITECH
• Bluetooth Medical Device Profile
• IT GRCM Tools
• GS1 Healthcare (GDSN)
• Unified Communications
• openEHR/CEN-EN 13606
• Standards-Based Medical Device Management

Climbing the Slope
• Enterprise Content Management
• IHE
• SNOMED-CT
• Strong Authentication for Enterprise Access
• Service-Oriented Architecture
• Strong Authentication for Remote Access
• Distributed Antenna Systems
• Speech Recognition (Once and Done)
• User Provisioning
• Natural-Language Processing
• UMDB
• Tablet PCs for Healthcare

Source: Gartner; “Hype Cycle for Healthcare Provider Applications and Systems, 2010”
Gartner’s Data Formats Predictions

Benefit and Years to Mainstream Adoption for Selected Healthcare Provider Technologies & Standards

<table>
<thead>
<tr>
<th>Level of Benefit</th>
<th>Less than 2 Years</th>
<th>2 to 5 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td></td>
<td>6 Natural Language Processing (Text to Facts)</td>
</tr>
<tr>
<td>Moderate</td>
<td>5 HL7 CDA R2</td>
<td>2 CCR/CCD</td>
</tr>
<tr>
<td></td>
<td>7 Natural Language Processing (Clinical Concepts)</td>
<td>1 ICD-10 CM (U.S.)</td>
</tr>
</tbody>
</table>

Years to mainstream adoption
Use NLP for Unstructured Structure

Natural Language Processing
Convert Free Text into Structured Data

Tagged content

Tobacco use: None
Alcohol use: Occasional
Penicillin: 250 mg, 1/day
Hydroxyurea: 500 mg, 2/day

Transcript of physician’s words

Negative for tobacco use, but likes to have a glass of wine on occasion.
On admission he was on penicillin 250mg a day and hydroxyurea 500mg twice a day.
EBM AND CER MANDATE DATA INTEROPERABILITY
Evidence-based Medicine Vision

- **Simplify & Unify**: Come up with novel and innovative techniques to capture clinical data as a byproduct of care instead of specific documentation entered by practitioners.
- **Embrace, Adopt, Extend**: Take data being created by all clinical or IT systems (medical devices, labs, etc), add value by repurposing it, and make it immediately available for better clinical care.

**Operational Systems** ➔ **Analytical Systems**

*Analytics must create new insight (such as patient value and safety prediction) and feed it back to the operational systems (the applications)*
When does Evidence Become Available?

<table>
<thead>
<tr>
<th>Responsiveness</th>
<th>Proactive</th>
<th>Reactive</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPOE Operations</td>
<td>HIS / EHR</td>
<td>Scheduled Reports</td>
</tr>
<tr>
<td>Financial Labs</td>
<td>Automated Analysis</td>
<td>Manual Analysis</td>
</tr>
<tr>
<td>Meds</td>
<td>Alerts</td>
<td>Response</td>
</tr>
</tbody>
</table>

Time Elapsed:
- Minutes: 1 Day/Week
- Minutes: 1 Month

Source: Informatica Corporation
How is Evidence Shared?

- The ability for data elements to be shared *syntactically* as well as *semantically* at the transactional and analytical levels across different products.
  - *Syntactic* sharing simply requires the data to be in the same general format (text, numeric, date, etc) in all our applications.
  - *Semantic* sharing requires that the data mean the same thing in all our applications using the same units, terminology, and temporal ranges (this is the hard part).
What is the Impact of Non-sharable Evidence?

- Applications come and go but should data live on forever. Without interoperability, it doesn’t.
- We can not gain long-term value and generate multiple revenue streams (make money on data collection via applications and then again from analytical use or other repurposing) without interoperability.
- Unable to deliver a consistent view of our data across different customer touchpoints and interactions which means lower customer satisfaction.
- *We need an accurate, timely, and complete view of the patient across different sources of patient data in multiple application systems and databases.*
Data Exchange Formats that Allow Evidence Sharing

- HL7
- HL7 RIM
- CDISC
- SEND
- CCD
- CCR
- RDF
- ATOM Pub
Clinical Data Exchange Models

- Federated model with peer-to-peer network + shared repositories
- Federated model with peer-to-peer network + real-time, request/delivery of clinical data
- Federated model with peer-to-peer network + clinical data pushed from sending organization
- Federated model with peer-to-peer network—no real-time clinical data sharing
- Non-federated peer-to-peer network (co-op model)
- Centralized clinical database or data warehouse

Health data claims bank
Clinical data exchange cooperative
### Content Standards

<table>
<thead>
<tr>
<th>Item</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Summary Record</td>
<td>HL7 CDA Release 2 CCD or ASTM CCR</td>
</tr>
<tr>
<td>Electronic Prescribing</td>
<td>NCPDP SCRIPT Version 8.1 or 10.6</td>
</tr>
<tr>
<td>Electronic Submission of Lab Results to Public Agencies</td>
<td>HL7 2.3.1 or HL7 2.5.1</td>
</tr>
<tr>
<td>Electronic submission to immunization registries</td>
<td>HL7 2.3.1 or HL7 2.5.1</td>
</tr>
<tr>
<td>Quality Reporting</td>
<td>The CMS Physician Quality Reporting Initiative (PQRI) 2009 Registry XML Specification</td>
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</table>
## Vocabulary Standards

<table>
<thead>
<tr>
<th>Item</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Problem List</td>
<td>ICD9-CM or SNOMED CT 2009</td>
</tr>
<tr>
<td>Procedures</td>
<td>CPT-4</td>
</tr>
<tr>
<td>Laboratory test results</td>
<td>LOINC 2.27</td>
</tr>
<tr>
<td>Medications</td>
<td>Any source vocabulary that is included in RxNorm</td>
</tr>
<tr>
<td>Immunizations</td>
<td>HL7 Standard Code Set CVX - Vaccines Administered, July 30, 2009 version</td>
</tr>
<tr>
<td>Race and Ethnicity</td>
<td>OMB Statistical Policy Directive No. 15</td>
</tr>
<tr>
<td>Item</td>
<td>Standard</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Encryption and decryption of electronic health information</td>
<td>NIST FIPS 140-2</td>
</tr>
<tr>
<td>Record actions related to electronic health information</td>
<td>The date, time, patient identification, and user identification must be recorded when electronic health information is created, modified, accessed, or deleted; and an indication of which action(s) occurred and by whom must also be recorded</td>
</tr>
<tr>
<td>Verification that electronic health information has not been altered in transit</td>
<td>SHA-1 or higher (NIST FIPS PUB 180-3)</td>
</tr>
<tr>
<td>Record treatment, payment, and health care operations disclosures</td>
<td>The date, time, patient identification, user identification, and a description of the disclosure must be recorded for disclosures for treatment, payment, and health care operations, as these terms are defined at 45 CFR 164.501</td>
</tr>
<tr>
<td>Transport</td>
<td>Flexible (i.e. REST or SOAP, SMTP, etc.)</td>
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</table>
The following steps can be used to begin sharing information from the bottom-up based on app-specific requirements without necessarily utilizing a centralized DW approach. However, a DW will provide more analytical capabilities and extensibility.

1. **Transport**
   - Getting the data from one application to another is the first problem to solve. SOA, ETL, hub-and-spoke and other mechanisms can be a good start.

2. **Transform**
   - Once an application can send and receive information information, it needs to transform it into a manner it can understand. This means structural, format, and units may need to be translated.

3. **Match & Link**
   - Depending on the complexity of information identifiers and other important data may need to be matched and linked across applications. This is where we manage data quality.

4. **Analyze & Predict**
   - As soon as data has been matched and linked we can start using it for analytics and prediction.

5. **Utilize and Enhance**
   - Once we have predictive and analytics available we can use the information back within our applications or just for dashboards/reports.
Questions?

THANK YOU