Caveats and Recommendations for Use of Operational Electronic Health Record Data for Research and Quality Measurement

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Caveats and Recommendations for Use of Operational Electronic Health Record Data for Research and Quality Measurement

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Outline

- Opportunities for secondary use or re-use of clinical data for research and other purposes
- Caveats of using operational clinical data
- Recommendations for using operational clinical data
- Need for standards and interoperability
- Role of informatics professionals

US has made substantial investment in health information technology (HIT)

"To improve the quality of our health care while lowering its cost, we will make the immediate investments necessary to ensure that within five years, all of America's medical records are computerized … It just won't save billions of dollars and thousands of jobs – it will save lives by reducing the deadly but preventable medical errors that pervade our health care system."
January 5, 2009

Health Information Technology for Economic and Clinical Health (HITECH) Act of the American Recovery and Reinvestment Act (ARRA) (Blumenthal, 2011)

- Incentives for electronic health record (EHR) adoption by physicians and hospitals (up to $27B)
- Direct grants administered by federal agencies ($2B, including $118M for workforce development)

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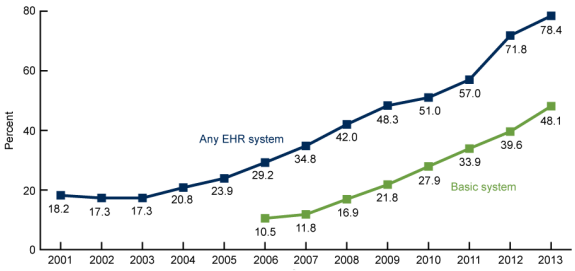
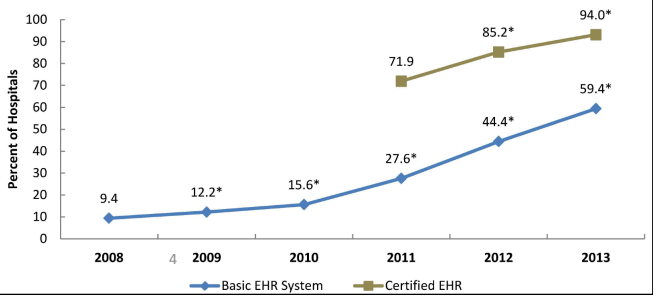
Which has led to significant EHR adoption in the US



(Hsiao, 2014)

(Charles, 2014)



Providing opportunities for "secondary use" or "re-use" of clinical data

- (Safran, 2007; SHARPn, Rea, 2012)
- Using data to improve care delivery
- Healthcare quality measurement and improvement
- Clinical and translational research
- Public health surveillance
- Implementing the learning health system

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Using data to improve healthcare

- With shift of payment from "volume to value," healthcare organizations will need to manage information better to provide better care (Diamond, 2009; Horner, 2012)
- Predictive analytics is use of data to anticipate poor outcomes or increased resource use – applied by many to problem of early hospital re-admission (e.g., Gildersleeve, 2013; Amarasingham, 2013; Herbert, 2014)
- A requirement for "precision medicine" (Mirnezami, 2012) and "personalized medicine" (Altman, 2012)

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Quality measurement and improvement

- Quality measures increasingly used in US and elsewhere to make care more "accountable"
  - Used more for process than outcome measures (Lee, 2011), e.g., Stage 1 meaningful use
- In UK, pay for performance schemes achieved early value but fewer further gains (Serumaga, 2011)
- In US, some quality measures found to lead to improved patient outcomes (e.g., Wang, 2011), others not (e.g., Jha, 2012)
- Desire is to derive automatically from EHR data, but this has proven challenging with current systems (Parsons, 2012; Pathak, 2013; Barkhuysen, 2014)

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Clinical and translational research

- Led in part by activities of NIH Clinical and Translational Science Award (CTSA) Program (Mackenzie, 2012)
- One of largest and most productive efforts has been eMERGE Network – connecting genotype-phenotype (Gottesman, 2013; Newton, 2013)
  - http://emerge.mc.vanderbilt.edu
  - Has used EHR data to identify genomic variants associated with atrioventricular conduction abnormalities (Denny, 2010), red blood cell traits (Kullo, 2010), white blood cell count abnormalities (Crosslin, 2012), thyroid disorders (Denny, 2011), etc.

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Clinical and translational research (cont.)

- Other successes include replication of clinical studies, e.g.,
  - Randomized controlled trials (RCT)
    - Women's Health Initiative (Tannen, 2007; Weiner, 2008)
    - Other cardiovascular diseases (Tannen, 2008; Tannen, 2009) and value of statin drugs in primary prevention of coronary heart disease (Danaei, 2011)
  - Observational studies
    - Metformin and reduced cancer mortality rate (Xu, 2014)
- Much potential for using propensity scores with observational studies as complement to RCTs
  - Often but not always obtain same results as RCTs (Dahabreh, 2014)

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Public health

- "Syndromic surveillance" aims to use data sources for early detection of public health threats, from bioterrorism to emergent diseases
- Interest increased after 9/11 attacks (Henning, 2004; Chapman, 2004; Gerbier, 2011)
- Ongoing effort in Google Flu Trends
  - http://www.google.org/flutrends/
  - Search terms entered into Google predicted flu activity but not early enough to intervene (Ginsberg, 2009)
  - Performance in recent years has been poorer (Butler, 2013)
  - Case of needing to avoid "Big Data hubris" (Lazer, 2014)

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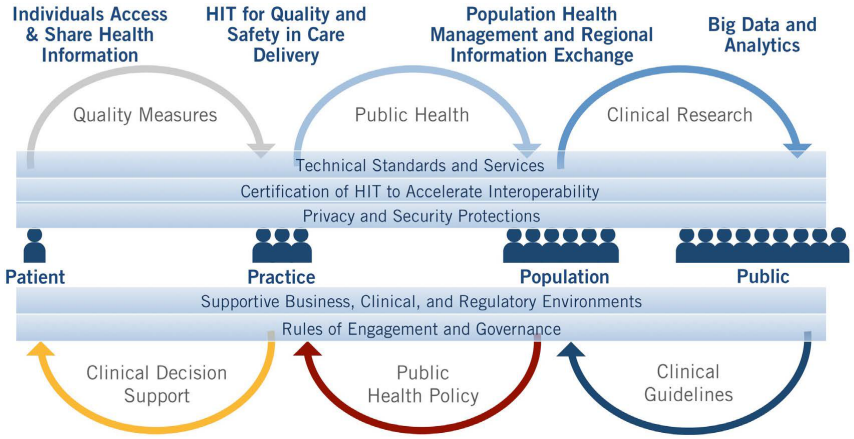
Implementing the learning healthcare system (ONC, 2014)



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Caveats for the Use of Operational Electronic Health Record Data in Comparative Effectiveness Research

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Operational clinical data may be (Medical Care, 2013):

- Inaccurate
- Incomplete
- Transformed in ways that undermine meaning
- Unrecoverable for research
- Of unknown provenance
- Of insufficient granularity
- Incompatible with research protocols

(*Med Care* 2013;00: 000–000)

Health Information Technology (ONC) through the Strategic Health IT Advanced Research Projects (SHARP) Program,

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Inaccurate

- Documentation not always a top priority for busy clinicians (de Lusignan, 2005)
- Analysis of EHR systems of four known national leaders assessed use of data for studies on treatment of hypertension and found five categories of reasons why data were problematic (Bayley, 2013)
  - Missing
  - Erroneous
  - Un-interpretable
  - Inconsistent
  - Inaccessible in text notes

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Incomplete

- Not every diagnosis is recorded at every visit; absence of evidence is not always evidence of absence, an example of a concern known by statisticians as *censoring* (Zhang, 2010)
- Makes tasks such as identifying diabetic patients challenging (Miller, 2004; Wei, 2013; Richesson, 2013)
- Undermine ability to automate quality measurement
  - Measures under-reported based on under-capture of data due to variation in clinical workflow and documentation practices (Parsons, 2012)
  - Correct when present but not infrequently missing in primary care EHRs (Barkhuysen, 2014)

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"Idiosyncrasies" of clinical data (Hersh, 2013)

- "Left censoring" – First instance of disease in record may not be when first manifested
- "Right censoring" – Data source may not cover long enough time interval
- Data might not be captured from other clinical (other hospitals or health systems) or non-clinical (OTC drugs) settings
- Bias in testing or treatment
- Institutional or personal variation in practice or documentation styles
- Inconsistent use of coding or standards

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Overcoming the caveats: recommendations for EHR data use

- (Hersh, 2013)
- Assessing and using data
- Adaptation of "best evidence" approaches to use of operational data
- Need for standards and interoperability
- Appropriate use of informatics expertise

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Approach: adapt rules of evidence-based medicine (EBM)?

- Ask an answerable question
  - Can question be answered by the data we have?
- Find the best evidence
  - In this case, the best evidence is the EHR data needed to answer the question
- Critically appraise the evidence
  - Does the data answer our question? Are there confounders?
- Apply it to the patient situation
  - Can the data be applied to this setting?

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INFORMATICS PROFESSOR

THIS BLOG MAINTAINS THE THOUGHTS ON VARIOUS TOPICS RELATED TO BIOMEDICAL AND HEALTH INFORMATICS BY DR. WILLIAM HERSH, PROFESSOR AND CHAIR, DEPARTMENT OF MEDICAL INFORMATICS & CLINICAL EPIDEMIOLOGY, OREGON HEALTH & SCIENCE UNIVERSITY.

SATURDAY, SEPTEMBER 6, 2014

Unscrambling Eggs and the Need for Comprehensive Data Standards and Interoperability

Two local informatics-related happenings recently provided teachable moments demonstrating why a comprehensive approach to standards and interoperability is so critical for realizing the value of health IT. Fortunately, the Office of the National Coordinator for Health IT (ONC) has prioritized interoperability among its activities moving forward, and other emerging work on standards provides hope that the problems I will described that occurred locally (and I know occur many other places) might be avoided in the future.

INFORMATICS PROFESSOR

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WEDNESDAY, MAY 15, 2013

Universal EHR? No. Universal Data Access? Yes.

A recent blog posting calls for a "universal EMR" for the entire healthcare system. The author provides an example and correctly laments how lack of access to the complete data about a patient impedes optimal clinical care. I would add that quality improvement, clinical research, and public health are impeded by this situation as well.

However, I do not agree that a "universal EMR" is the best way to solve this problem. Instead, I would advocate that we need universal access to underlying clinical data, from which many different types of electronic health records (EHRs), personal health records (PHRs), and other applications can emerge.

WILLIAM HERSH

http://www.billhersh.info/

Uptake of health information exchange (HIE) less than adoption of EHRs

- Hospitals 62% with outside organizations (Swain, 2014)
- Physicians 38% with outside providers (Furukawa, 2014)
- Costs and technical challenges still undermine sustainability of HIE organizations (eHI, 2014)

Challenges to EHRs and HIE have spurred focus on interoperability

- Office of National Coordinator for Health IT (ONC) developing interoperability road map for 10-year path forward (ONC, 2014)
- Emerging approaches include
  - RESTful architectures for efficient client-server interaction
  - OAuth2 for Internet-based security
  - Standard application programming interface (API) for query/retrieval of data
    - Need for both documents and discrete data
    - Emerging standard is Fast Health Interoperability Resources (FHIR) – http://wiki.hl7.org/index.php?title=FHIR_for_Clinical_Users

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ONC draft interoperability roadmap (Galvez, 2014)

2017	2020	2024
Providers and individuals send, receive, find, use a basic set of essential health information	Granular information access Expanded sources and users of information Improved quality and reduced cost Increased (and scalable) automation	Longitudinal information Ubiquitous precision medicine Reduced time from evidence to practice Virtuous learning cycle (learning health system)

Core technical standards and functions

Certification to support adoption and optimization of health IT products & services

Privacy and security protections for health information

Supportive business, clinical, cultural, and regulatory environments

Rules of engagement and governance

Interoperability goals for 2017?

- RESTful architecture with OAuth2 security
- FHIR APIs with some specified data standards
  - For documents
    - Consolidated Clinical Document Architecture (CCDA) with standard metadata including document and section type names
  - For discrete data
    - Use of mature terminology sets for diagnoses (ICD, SNOMED), tests (LOINC), medications (RxNorm/RXTerms)
    - National Library of Medicine Value Set Authority Center (VSAC) for quality and other measures – https://vsac.nlm.nih.gov

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Also need to develop clinical data research networks

- Established
  - HMO Research Network – facilitates clinical research
    - www.hmoresearchnetwork.org
  - FDA Mini-Sentinel Network – safety surveillance
    - www.mini-sentinel.org
- New
  - PCORnet – www.pcornet.org
    - Clinical data research networks (CDRNs) – 11 networks aggregating data on >1M patients each
      - (Fleurence, 2014; Collins, 2014; and other papers in JAMIA special issue)
    - Common Data Model for subset of data

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Another need: contributions of a competent informatics workforce

- Many roles for diverse professionals (Hersh, 2010)
- Opportunities
  - Estimated need for 41,000 additional HIT professionals as we moved to more advanced clinical systems (Hersh, 2008)
  - Actual numbers hired were even higher (Furukawa, 2012; Schwartz, 2013)
  - Well-paying jobs! (HealthITJobs.com, 2014)
- Shortages
  - 71% of healthcare CIOs said IT staff shortages could jeopardize an enterprise IT project, while 58% said they would affect meeting meaningful use (CHIME, 2012)
  - More recent surveys paint continued picture of healthcare organizations and vendors having challenges recruiting and maintaining staff (HIMSS, 2014)

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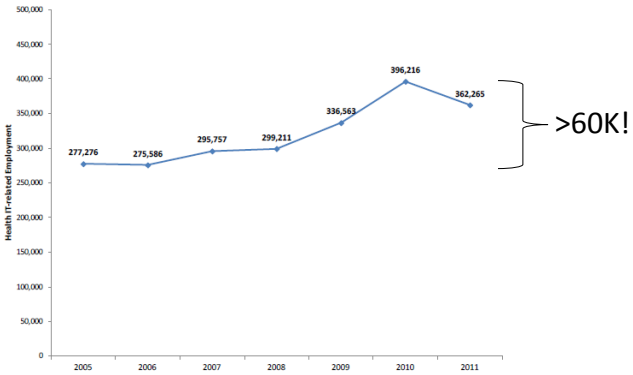
Job growth and salaries are high

Employment in health IT-related occupations in the health delivery system: 2005-2011 (Furukawa, 2012)



Opportunities for physicians: clinical informatics subspecialty

- History
  - 2009 – American Medical Informatics Association (AMIA) develops and publishes plans for curriculum and training requirements
  - 2011 – American Board of Medical Specialties (ABMS) approves; American Board of Preventive Medicine (ABPM) becomes administrative home
    - Subspecialty open to physicians of all primary specialties but not those without a specialty or whose specialty certification has lapsed
  - 2013 – First certification exam offered by ABPM
    - 455 physicians pass (91%)
  - 2014 – ACGME fellowship accreditation rules released
    - Four programs accredited nationwide, including OHSU

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Clinical informatics subspecialty (cont.)

- Following usual path of five years of "grandfathering" training requirements to take certification exam before formal fellowships required
- Two paths to eligibility for exam in first five years
  - Practice pathway – practicing 25% time for at least three years within last five years (education counts at half time of practice)
  - Non-traditional fellowships – qualifying educational or training experience, e.g., NLM, VA, or other fellowship or educational program (e.g., master's degree)

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Clinical training model presents some challenges

- Fragmentation and funding challenges (Detmer, 2014)
- Clinical fellowship model has some aspects of "fitting square pegs into round holes" (Hersh, 2014)
- Requirement of two-year, full-time fellowship for board certification may limit career paths
  - Many clinicians pursue informatics in mid-career
- Many concerned about sustainability of funding
  - Fellows may practice but CMS rules do not allow them to bill
- Informatics is not only for physicians – AMIA exploring certification for others in informatics
  - http://www.amia.org/advanced-interprofessional-informatics-certification

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Conclusions

- There are plentiful opportunities for secondary use or re-use of clinical data
- We must be cognizant of caveats of using operational clinical data
- We must implement best practices for using such data
- We need consensus on approaches to standards and interoperability
- There are opportunities for rewarding careers for diverse professionals

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