Effectiveness Research Using EHRs: 
*Gold Mine or Tower of Babel?*

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Outline

- Goal: reuse EHR clinical data for effectiveness research and clinical trials as a byproduct of care
- Requested focal topics:
  - Can EMRs be used to generate evidence? Are the data available? Easy to access?
  - Do the leading provider-systems have the capability of doing these analyses now? in five years? Can we incorporate EMR system into RCTs or pragmatic clinical trials?
  - What are some of the concerns of researchers (e.g., ability to access data, pool data across organizations)?

Vision for Delivering Quality Care
*“Do the Right Thing”*

- Shape quality patient-care decisions in real time…
  - … at the point of care
- As a byproduct of delivering care:
  - Measure quality performance
  - Provide physicians feedback to facilitate spread and sustained performance
  - Support public health reporting
  - Facilitate clinical and effectiveness research

Data Reuse
*Sweet Spot*

Decision Support Tools

Impact of Using Administrative Data for Clinical Quality Reporting

*Comparing Claims-Based Methods with EHR-Based Methods*

Fund by CMS
**Methods**

- Randomly selected charts of Medicare patients reviewed for presence of diabetes by 3 methods
  - Gold standard chart review (to identify 125 diabetics)
  - Claims-based definitions used in CMS DOQ project (2 visits with encounter diagnosis of diabetes)
  - Query of coded information in EHR
    - Problem list, medication list, lab results (and not progress notes)
- Apply DOQ quality measures using standard definition vs. clinical definition

**Results**

- 98% of gold-standard diabetics identified using EHR coded data (sens=97.6%, spec=99.6%)
  - 94% identified using problem list alone
- Using only administrative claims-based definition (2 encounters with diabetes diagnosis):
  - 25% of gold-standard confirmed diabetics “missed”
- Statistically significant difference for ½ of diabetic performance measures when comparing those identified using administrative definition vs. those missed by administrative definition

**Implications**

**Claims-Based Measures**

- Underestimates target population (denominator)
- Biased toward spuriously higher scores (self-fulfilling prophecy)
- Subject to “gaming” (no clinical downside)
- Potential to misdirect quality-improvement efforts

**EHR-Based Measures**

- Accurately identifies target population (subject to policies)
- More accurate, though lower scores may disincent EHR adoption
- Clinical record less subject to “gaming” due to clinical reuse
- More accurate tool to manage clinical QI initiatives and conduct effectiveness research

**NQF’s HIT Expert Panel**

*Measuring the Quality of Data*

**HITEP Charge**

*From AHIC Quality Work Group*

- Accelerate current efforts to identify a set of common data elements to be standardized in order to enable automation of a prioritized set of AQA and HQA measures through EHRs
### Measure Development Framework

**Data Quality Criteria**

1. **Authoritative source/accuracy:** Is the entry in the EHR from an authoritative data source? What is the accuracy of the data element in EHRs? [Weight 5]
2. **Use of data standards:** Does the data element use standardized data elements for coding? [Weight 5]
3. **Fit workflow:** Does capture of the data element by the most appropriate healthcare professional fit the typical EHR workflow for that user? [Weight 4]
4. **Availability in EHRs:** Is the data element currently available within EHRs? [Weight 4]
5. **Auditable:** Can the data be tracked over time to assess accuracy? [Weight 2]

Scale: 1-5; Weight (out of 5)

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### Measure Development Framework

**Analysis of Quality Measure Clusters (DM)**

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<th>Data class-type name</th>
<th>Completeness</th>
<th>Accuracy</th>
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<th>Exclusion</th>
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“Devil in the Details”

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### Pareto Analysis

**Quality Measure Exclusion Data Types Used**

![Pareto Chart]

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### Deriving Evidence from EHRs

**Traditional Approach**

1. What data are available?
2. Are they standardized and combinable?
3. What important effectiveness questions can you answer with the available data?

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### Deriving Evidence from EHRs

4. What are the high priority effectiveness research questions?
3. What *critical* data do you need to answer the important effectiveness questions?
2. Are they standardized and combinable?
1. Can they exist in EHRs?
Sample Data in the EHR

- Problem list
- Encounter diagnoses
- Medications
- Past medications
- Allergies
- Family history
- Past medical history
- Past surgical history
- Vital signs
- Chief complaint
- Progress notes
- Lab test results

(Mostly) Standardized Data in the EHR

Mapping Required to Exchange

- Problem list
- Encounter diagnoses
- Medications
- Past medications
- Allergies
- Family history
- Past medical history
- Past surgical history
- Vital signs
- Chief complaint
- Progress notes
- Lab test results

Interoperable Data in the EHR

No Mapping Required

- Problem list
- Encounter diagnoses
- Medications
- Past medications
- Allergies
- Family history
- Past medical history
- Past surgical history
- Vital signs
- Chief complaint
- Progress notes
- Lab test results

Example Data Issue

Clinical Classification of Asthma

Implications for Treatment

Rx with controller meds
ICD Classification of Asthma

**ICD9-CM**

- 493.00 Extrinsic asthma, unspecified
- 493.01 Extrinsic asthma, with status asthmaticus
- 493.02 Extrinsic asthma, with (acute) exacerbation
- 493.10 Intrinsic asthma, unspecified
- 493.11 Intrinsic asthma, with status asthmaticus
- 493.12 Intrinsic asthma, with (acute) exacerbation
- 493.20 Chronic obstructive asthma, unspecified
- 493.21 Chronic obstructive asthma, with status asthmaticus
- 493.22 Chronic obstructive asthma, with (acute) exacerbation
- 493.81 Exercise induced bronchospasm
- 493.82 Cough variant asthma
- 493.90 Asthma, unspecified
- 493.91 Asthma, unspecified, with status asthmaticus
- 493.92 Asthma, unspecified, with (acute) exacerbation

**ICD10-CM**

- J45.20 Mild intermittent asthma, uncomplicated
- J45.21 Mild intermittent asthma with (acute) exacerbation
- J45.22 Mild intermittent asthma with status asthmaticus
- J45.30 Mild persistent asthma, uncomplicated
- J45.31 Mild persistent asthma with (acute) exacerbation
- J45.32 Mild persistent asthma with status asthmaticus
- J45.40 Moderate persistent asthma, uncomplicated
- J45.41 Moderate persistent asthma with (acute) exacerbation
- J45.42 Moderate persistent asthma with status asthmaticus
- J45.50 Severe persistent asthma, uncomplicated
- J45.51 Severe persistent asthma with (acute) exacerbation
- J45.52 Severe persistent asthma with status asthmaticus
- J45.90 Unspecified asthma, uncomplicated
- J45.91 Unspecified asthma with (acute) exacerbation
- J45.92 Unspecified asthma with status asthmaticus
- J45.991 Unspecified asthma with (acute) exacerbation
- J45.992 Exercise induced bronchospasm
- J45.990 Cough variant asthma
- J45.995 Other asthma

Inhaled Corticosteroids in Asthma

**Quality / Research Example**

- Quality / research reporting requirements
  - Denominator (patients with persistent asthma)
  - Numerator (getting ICS)
- Interoperable data standards available?
  - Denominator (none)
  - Numerator (none, RxNorm)

Asthma Quality Measure

**Clinical Guideline vs. Quality Measure**

**Clinical Guideline for Use of Controller Medication**

- Components of severity
  - Symptom
  - Exacerbation
  - Work, school, family, leisure
  - Impact on daily activities

**NCQA Measure of Controller Use**

**Implications**

- Denominators determined by administrative data biased for populations already under active treatment
- Affects clinical trial:
  - Recruitment
  - Analysis
  - Data aggregation
  - Tracking
  - Reporting

Reusing Data as a Byproduct of Care

**Implications for EHR Design**

- Clinically meaningful – used directly for care by physicians
- Efficient workflow
- Structured data – not too little, not too much
- Enter once by the right professional; reuse many

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EHR Data Support of Clinical Trials

- Prioritize clinically important problems (For MD: patient care, public health, research)
- Leverage care delivery workflow when capturing data
  - Make use of reusable data
  - Make data reusable
- Ensure that critical data elements are on standards development roadmap
- Work with EHR vendors (through customers and CCHIT) to ensure that EHRs capture clinical trials data as part of user workflow

Summary

Gathering Evidence in EHRs

- Use of EHRs provide significant opportunity to efficiently conduct effectiveness research (half full)
- But, to use EHR data in effectiveness research, we need to:
  - Design EHRs to capture relevant research data that is useful and reusable to clinicians
  - Capture key data using standardized codes (and advocate for better standards (e.g., ICD 10, SNOMED))
  - Harmonize critical data needs with clinical care and quality measurement