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

Paul Tang, MD

VP, Chief Medical Information Officer
Palo Alto Medical Foundation
Consulting Associate Professor
*Stanford University*

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

Effectiveness Research

Clinical Guidelines

Decision Support Tools
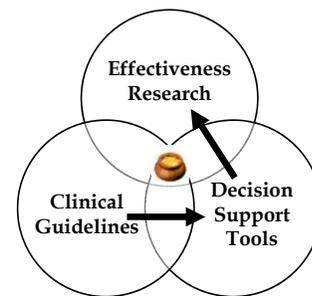
Lessons from Quality

Impact of Using Administrative Data for Clinical Quality Reporting

Comparing Claims-Based Methods with EHR-Based Methods

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 <u>identified</u> using administrative definition vs. those <u>missed</u> by administrative definition

Tang PC, et al. J Am Med Inform Assoc. 2007;14:10 –15.
http://www.jamia.org/cgi/reprint/14/1/10

Results
Performance Result Differences in Subgroups

Table 5 ■ DOQ Diabetes Measures Calculated From Expert Review Data for all Patients Identified as Having Diabetes: Comparison of Patients With Two Visits for Diabetes Vs. Patients With Zero or One Visit

Measure (Probability, Fisher's Exact Test)	Zero or One Visit For Diabetes N (%)	D	Two visits For Diabetes N (%)	D*
DM1: HbA1c Management (p<.001)	21 (67.7%)	31	91 (96.8%)	94
DM2: HbA1c Management Control (measure of poor control) (p=0.27)	0 (0.0%)	21	6 (6.6%)	91
DM3: Blood Pressure Management (p=0.05)	14 (45.2%)	31	57 (60.6%)	94
DM4: Lipid Measurement (p=(0.06)	22 (71.0%)	31	78 (83.9%)	94
DM5: LDL Cholesterol Level (p=0.23)	21 (95.5%)	22	69 (88.5%)	78
DM6: Urine Protein Testing (p<.001)	17 (54.8%)	31	80 (85.1%)	94
DM7: Eye Exam (p=0.03)	12 (41.4%)	29	55 (61.8%)	89
DM8: Foot Exam (p=0.13)	2 (7.1%)	28	15 (16.5%)	91

Implications

Claims-Based Measures	EHR-Based Measures
- Underestimates target population (denominator)	- Accurately identifies target population (subject to policies)
- Biased toward spuriously higher scores (self-fulfilling prophesy)	- More accurate, though lower scores may disincent EHR adoption
- Subject to "gaming" (no clinical downside)	- Clinical record less subject to "gaming" due to clinical reuse
- Potential to misdirect quality-improvement efforts	- 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]
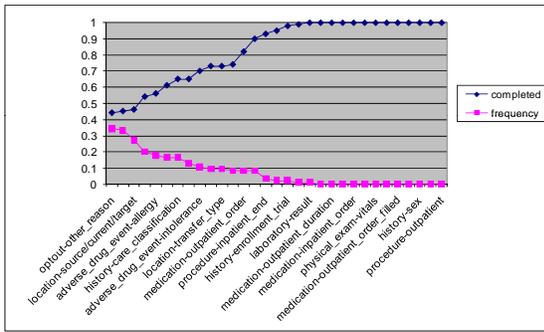
Scale: 1-5; Weight (out of 5)

Measure Development Framework
Analysis of Quality Measure Clusters (DM)

example: Diabetes

Data class-type name	Quality Score	Freq %	HbA1C, checked	HbA1C, at goal	BP, checked	Lipids, checked	Lipids, at goal	Eye exam, screen	Eye exam, severity
history-birth_date	100	53	●	●	●	●	●	●	●
physical_exam-vitals	95	1			▲				
laboratory-result	91	13	▲	▲		▲	▲	▲	
diagnosis-inpatient	86	71	● ×	● ×	● ×	● ×	● ×	● ×	
medication-outpatient_order_filled	76	10	●	●	●	●	●	●	▲
medication-outpatient_order	72	19	●	●	●	●	●	●	▲
diagnostic_study-result	59	33						▲	▲
procedure-consult_result	55	6						▲	▲
diagnosis-outpatient (billing)	47	26	● ×	● ×	● ×	● ×	● ×	● ×	●
optout-other_reason	20	38				×			×

● - denominator
✖ - exclusion
▲ - numerator

Pareto Analysis
Quality Measure <u>Exclusion</u> Data Types Used

- completed
- frequency

x-axis labels: optout-other_reason, location-source/current/target, adverse_drug_event-allergy, history-care_classification, adverse_drug_event-intolerance, location-transfer_type, medication-outpatient_order, procedure-inpatient_end, history-enrollment_trial, laboratory-result, medication-outpatient_duration, medication-inpatient_order, physical_exam-vitals, medication-outpatient_order_filled, history-sex, procedure-outpatient

---

What's in those EHRs?

"Devil in the Details"

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?

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
- Diagnostic test results
- Test images/tracings
- Immunizations
- Procedures
- Drawings
- Scanned documents
- Level of service
- Drug interactions
- Alerts
- HM Reminders
- Patient instructions

(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**
- Diagnostic test results
- Test images/tracings
- Immunizations
- **Procedures**
- Drawings
- Scanned documents
- **Level of service**
- Drug interactions
- Alerts
- HM Reminders
- Patient instructions

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
- Diagnostic test results
- Test images/tracings
- Immunizations
- Procedures
- Drawings
- Scanned documents
- **Level of service**
- Drug interactions
- Alerts
- HM Reminders
- Patient instructions

Example Data Issue

Clinical Classification of Asthma
Implications for Treatment
Rx with controller meds

| | Classification of asthma severity (≥12 years of age) | | | |
| | | Persistent | | |
Components of severity	Intermittent	Mild	Moderate	Severe
Symptoms	≤2 days/week	>2 days/week but not daily	Daily	Throughout the day
Nighttime awakenings	≤2x/month	3-4x/month	>1x/week but not nightly	Often 7x/week
Short-acting beta$_2$-agonist use for symptom control (not prevention of EIB)	≤2 days/week	>2 days/week but not daily, and not more than 1x on any day	Daily	Several times per day
Interference with normal activity	None	Minor limitation	Some limitation	Extremely limited
Lung function	• Normal FEV$_1$ between exacerbations • FEV$_1$ >80 percent predicted • FEV$_1$/FVC normal	• FEV$_1$ ≥80 percent predicted • FEV$_1$/FVC normal	• FEV$_1$ >60 but <80 percent predicted • FEV$_1$/FVC reduced 5 percent	• FEV$_1$ <60 percent predicted • FEV$_1$/FVC reduced >5 percent
Exacerbations requiring oral systemic corticosteroids	0-1/year (see footnote)	≥2/year (see footnote)		
	Consider severity and interval since last exacerbation			
	Frequency and severity may fluctuate over time for patients in any severity category			
	Relative annual risk of exacerbations may be related to FEV$_1$			

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

NO "PERSISTENT" CODE

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)

ICD Classification of Asthma
ICD10-CM

> J45.20 Mild <u>intermittent</u> asthma, uncomplicated
> J45.21 Mild <u>intermittent</u> asthma with (acute) exacerbation
> J45.22 Mild <u>intermittent</u> asthma with status asthmaticus
> J45.30 Mild <u>persistent</u> asthma, uncomplicated
> J45.31 Mild <u>persistent</u> asthma with (acute) exacerbation
> J45.32 Mild <u>persistent</u> asthma with status asthmaticus
> J45.40 Moderate <u>persistent</u> asthma, uncomplicated
> J45.41 Moderate <u>persistent</u> asthma with (acute) exacerbation
> J45.42 Moderate <u>persistent</u> asthma with status asthmaticus
> J45.50 Severe <u>persistent</u> asthma, uncomplicated
> J45.51 Severe <u>persistent</u> asthma with (acute) exacerbation
> J45.52 Severe <u>persistent</u> asthma with status asthmaticus
> J45.901 Unspecified asthma with (acute) exacerbation
> J45.902 Unspecified asthma with status asthmaticus
> J45.909 Unspecified asthma, uncomplicated
> J45.990 Exercise induced bronchospasm
> J45.991 Cough variant asthma
> J45.998 Other asthma

Asthma Quality Measure
Clinical Guideline vs. Quality Measure

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

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 resusable 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