Making learning health care a standard(s) activity

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September 15, 2014
“We seek the development of a learning health system that generates and applies the best evidence for the collaborative health care choices of each patient and provider; drives … discovery as a natural outgrowth of patient care; and ensures innovation, quality, safety, and value in health care.”

(Roundtable Charter)
“The increased complexity of health care requires a sustainable system that gets the right care to the right people when they need it, and then captures the results for improvement. The nation needs a healthcare system that learns.”
Every day, patients and doctors face common questions for which we have no solid evidence:

- “For ‘short cervix’ does bed rest prevent early labor?”
- “Should I take my daily blood pressure medicine in the morning or at night?”
- “How can I help my 87 year old patient with multiple myeloma decide which chemotherapy option is best?”
- “What are the benefits and risks of giving medication to my child with ADHD?”
Which Treatment is Best for Whom?  
High-Quality Evidence is Scarce: < 15% of guideline recommendations are supported by high quality evidence

ORIGINAL CONTRIBUTION

Scientific Evidence Underlying the ACC/AHA Clinical Practice Guidelines

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Context  The joint cardiovascular practice guidelines of the American College of Cardiology (ACC) and the American Heart Association (AHA) have become important documents for guiding cardiology practice and establishing benchmarks for quality of care.

Objective  To describe the evolution of recommendations in ACC/AHA cardiovascular guidelines and the distribution of recommendations across classes of recommendations and levels of evidence.

Data Sources and Study Selection  Data from all ACC/AHA practice guidelines issued from 1984 to September 2008 were abstracted by personnel in the ACC Science and Quality Division. Fifty-three guidelines on 22 topics, including a total of 7196 recommendations, were abstracted.
When could we have suspected a link?
A Vision For A National Patient-Centered Research Network
Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health
National Workshop to Advance the Use of Electronic Data in Patient-Centered Outcomes Research
July 2, 2012

www.pcori.org/assets/2-Collins-Slides-Network.pdf
Quality

National Healthcare Safety Network (NHSN)

Tracking Infections in Acute Care Hospitals/Facilities

NHSN is the HAI surveillance gold standard. The system (and its predecessors) started years ago helping a few hundred healthcare facilities; today, more than 11,000 healthcare facilities use NHSN as the cornerstone of their HAI elimination strategies. Specifically, facilities use NHSN to:

- Access NHSN enrollment requirements for CMS Hospital Inpatient Quality Reporting Program,
- Obtain baseline HAI rates,
- Compare rates to CDC’s national data,
- Participate in state or national HAI prevention collaboratives,
- Devise and implement HAI elimination strategies,
- Evaluate immediate and long-term results of elimination efforts,
- Refocus efforts as needed, or advance to different areas.

CLABS - Surveillance for Central Line-associated Bloodstream Infections
- Training
- Protocols
- Forms
- Support Materials
- Analysis Resources
- FAQs

CAUTI - Surveillance for Catheter-associated Urinary Tract Infections
- Training
- Protocols
- Forms
- Support Materials
- Analysis Resources
- FAQs

CLIP - Surveillance for Central Line Insertion Practices Adherence
- Training
- Protocols
- Forms
- Support Materials
- Analysis Resources
- FAQs

SSI - Surveillance for Surgical Site Infections
- Training
- Protocols
- Forms
- Support Materials
- Analysis Resources
- FAQs
Digital platform

Selected themes
• Services and research embedded in a digitally-based learning loop
• Strong trust fabric

Issues for further attention
• The public case
• Governance and coordination
• Functionality standards
FDA's Mini-Sentinel Program
Mini-Sentinel

- Congress mandated FDA develop electronic record based safety surveillance system

Mini-Sentinel:

- Develops operational capacity for active medical product safety surveillance in existing automated healthcare data systems
- Develops and evaluates scientific methods
- Offers FDA the opportunity to evaluate safety issues
- Assesses barriers and challenges
Mini-Sentinel Partner Organizations

Lead – HPHC Institute

Data and scientific partners

Scientific partners
Mini-Sentinel Distributed Database*

- Populations with well-defined person-time for which most medically-attended events are known
- 358 million person-years of observation time
- 48 million people currently accruing new data
- 4 billion dispensings
- 4.1 billion unique encounters
  - 42 million acute inpatient stays
- 30 million people with >1 laboratory test result

*As of July 2014
Mini-Sentinel’s Data Sources

- **Administrative data**
  - Enrollment
  - Demographics
  - Outpatient pharmacy dispensing
  - Utilization (encounters, diagnoses, procedures)

- **EHR data**
  - Height, weight, blood pressure, temperature
  - Laboratory test results (selected tests)

- **Registries**
  - Immunization
  - Birth certificates

- **Full text records** (small number to confirm selected exposures and outcomes)
Mini-Sentinel’s Common Data Model

<table>
<thead>
<tr>
<th>Enrollment</th>
<th>Person ID</th>
<th>Birth date</th>
<th>Sex</th>
<th>Race</th>
<th>Etc.</th>
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<td>Person ID</td>
<td>Dates of service</td>
<td>Provider seen</td>
<td>Type of encounter</td>
<td>Facility</td>
</tr>
<tr>
<td>Dispensing date</td>
<td>Person ID</td>
<td>Dates of order, collection &amp; result</td>
<td>Test type, immediacy &amp; location</td>
<td>Procedure code &amp; type</td>
<td>Test result &amp; unit</td>
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<tr>
<td>Vital Signs</td>
<td>Person ID</td>
<td>Date &amp; time of measurement</td>
<td>Height</td>
<td>Weight</td>
<td>Diastolic &amp; systolic BP</td>
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<tr>
<td>Death</td>
<td>Person ID</td>
<td>Cause of death</td>
<td>Diagnosis code &amp; code type</td>
<td>Source</td>
<td>Confidence</td>
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<td>Cause of Death</td>
<td>Person ID</td>
<td>Date</td>
<td>Principal diagnosis flag</td>
<td>Encounter type &amp; provider</td>
<td>Diagnosis code &amp; type</td>
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</tr>
</tbody>
</table>

Also:
- Vaccine table
- Birth certificate table
- Blood components table

Common Data Model Standards

- The data set uses the data source’s original codes whenever possible.
- For each variable, the model captures both the value AND coding system, e.g., ICD-9-CM, SNOMED, CPT, HCPCS, LOINC.
Ensuring Data Privacy
Share Info Not Data!
Mini-Sentinel Distributed Analysis

1- User creates and submits query (a computer program)
2- Data partners retrieve query
3- Data partners review and run query against their local data
4- Data partners review results
5- Data partners return results via secure network
6- Results are aggregated
Mini-Sentinel Operations Center

- Reporting
- Project Management
- Policies and Procedures
- Query Fulfillment
- ETC...

Mini-Sentinel DRN Secure Portal

Knowledge Management System
Cross project lessons learned, query tracking, meta-data capture, search functions, etc

Projects
- Utilization trends
- Modular programs
- Protocol based assessments

Analytic Tools
- Modular programs
- Summary tables
- Query interface
- Menu-driven query
- Data checking tools
- Reporting tools

Administration
- Security \ Access control
- File \ Query repository
- User administration
- Workflow management

Data Partner 1

Data Partner 2

... 

Data Partner 18
Dabigatran vs warfarin and stroke / bleeding

- Goal: Compare ischemic and hemorrhagic stroke and gastrointestinal bleeding rates among new users of dabigatran or warfarin therapy who have atrial fibrillation/flutter
New User Cohort Design

- Look back XX days
- Inclusion/exclusion condition

Index Date

Start Date

Start of new treatment episode

End Date

Need all dispensings and days’ supply from any pharmacy to determine treatment duration

Need all diagnoses at any ED or hospital

Need all inpatient, ED, ambulatory diagnoses / procedures from every provider

Outcome(s)
- Optional: blackout days
- Optional: extension days

Start of new treatment episode

Time

Need all dispensings from any pharmacy in the prior X months

Need all diagnoses at any ED or hospital

info@mini-sentinel.org
Dabigatran vs warfarin and stroke / bleeding

- Analysis: A standard, reusable, SAS program
- Inputs:
  - Population: Patients with pre-existing atrial fibrillation,
  - Exposures: New users of dabigatran or warfarin (no prior exposure to either in preceding 183 days).
  - Outcomes: First diagnoses of gastrointestinal (GI) or intracerebral hemorrhage in inpatient or ED settings. (No event in the 183 days prior to initiating therapy.)
  - Period: 10/19/2010 to 12/31/2011
- Results:
  - Counts of eligible patients and days under observation
  - Counts of new users of dabigatran and warfarin, dispensings, total days supplied, treatment episodes,
  - Counts of first GI or intracerebral hemorrhage diagnoses

Dabigatran vs warfarin: Data sources

- **Administrative files:**
  - Demographic data
  - Eligible person time (periods when both presence and absence of events is reliably known)

- **Dispensing data:**
  - Outpatient medications, including dosage form and days supply

- **Claims:**
  - Diagnoses, ambulatory and inpatient
  - Procedures, ambulatory and inpatient
Dabigatran vs Warfarin: Data sharing

- No person-level data is shared!
- Count data only is shared
GI bleeding after warfarin or dabigatran

Figure 1a. New Events of GIH per 100k Days at Risk in the MSDD between October 19, 2010 and December 31, 2011, by Drug, Incidence Criteria, and Washout Period for Individuals with a Pre-Existing Condition of Atrial Fibrillation


info@mini-sentinel.org
“Bleeding rates associated with new use of Pradaxa do not appear to be higher than bleeding rates associated with new use of warfarin.”
“we are now conducting two protocol-based assessments, using claims data from Mini-Sentinel and other claims databases, in which adjustments will be made for confounding factors”
PCORnet’s Goal

Improve the nation’s capacity to conduct rapid, efficient, and economical comparative effectiveness research.
PCORnet’s Vision:
The world will be different

- Clinical trials and observational studies
- Multi-center studies
- Greater comparability
- Research priorities evolve

Modified from Beth McGlynn, 2014
PCORnet’s Top 5 Needs

- Engaged clinical organizations and patients
- Collaboration framework
- Analysis-ready complete longitudinal standardized data with strong privacy protections
- Ability to embed research in care settings
- Regulatory oversight that protects patients without unnecessary burdens
11 Clinical Data Research Networks and 18 Patient Powered Research Networks

Numbers indicate the number of networks active in each state
57 of 62 CTSAAs are affiliated with a PCORnet network
11 Clinical Data Research Networks

Integrated Delivery Systems

Clinical & Translational Science Awardees

Health Information Exchanges

Safety Net Clinics

Academic Health Centers
Goals for Clinical Data Research Networks

- Establish **analysis-ready datasets with complete longitudinal data covering ≥1 million people**
- Develop capability to embed clinical trials into healthcare operations
- Involve patients, clinicians, and health system leaders in all aspects
18 Patient Powered Research Networks
Goals for Patient-Powered Research Networks (PPRNs)

- Enroll >0.5% of those with the condition in the U.S. (~50 to 50,000)
- Patient-reported data for ≥80% of cohort
- Patients involved in governance
- Standardized data able to respond to queries
PCORnet DRN Operations Center

- Reporting
- Project Management
- Policies and Procedures
- Query Fulfillment
- ETC...

PCORnet DRN Secure Portal

Knowledge Management System
Cross project lessons learned, query tracking, meta-data capture, search functions, etc

Projects
- Utilization trends
- Observational studies
- Pragmatic and clinical trials

Analytic Tools
- Modular programs
- Summary tables
- Query interface
- Menu-driven query
- Data checking tools
- Reporting tools

Administration
- Security / Access control
- File / Query repository
- User administration
- Workflow management

CDRN 1
- Data Partner A
- Data Partner B
- Data Partner C
- Data Partner D

CDRN 2
- Data Partner A
- Data Partner B
- Data Partner C
- Data Partner D

CDRN 11
- Data Partner A
- Data Partner B
- Data Partner C
- Data Partner D

PPRN 1
PPRN 2
PPRN 18
Other data resources
The NIH Collaboratory: Complementary development of health care systems research capabilities

Millions of people. Strong collaborations. Privacy first.
Multiple Networks Sharing Infrastructure
Multiple Networks Sharing Infrastructure
Multiple Networks Sharing Infrastructure
Each organization can participate in multiple networks

Each network controls its governance and coordination

Networks share infrastructure, data curation, analytics, lessons, security, software development
In theory there is no difference between theory and practice. In practice there is.

Yogi Berra (and others)
What “complete” data means

If a person received a diagnosis or treatment we care about:
- Would we observe it?
- In what data source?
One person's data can be in different places

Data in claims

Data in inpatient EHRs

Data in ambulatory EHRs

Care public health clinic

Prescription fills paid out of pocket
What “complete” data means

If a person received a diagnosis or treatment we care about:
- Would we observe it?
- In what data source?

Completeness might depend on:
- The specific conditions, treatments, and outcomes of interest
- Health system structure
- Insurance coverage
- Geographic region within health system
- Referral patterns
Data Visualization: After 7th refresh, partner A
Data Visualization: After 8\textsuperscript{th} refresh, partner A

New time period

New data problem in old time period
Data Visualization: After 8\textsuperscript{th} refresh fixed
Will EHR data be better / easier?
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<th>TH/UL</th>
<th>X10(3)</th>
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<td>THOUC/MM</td>
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<td>k/cm</td>
<td>thou/cm</td>
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<td>X10 3</td>
<td>K/B5L</td>
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Percent of KPCO Visits Due to Syndromic Surveillance ILI by Week, Noting Mid-October RI Values of Interest - Fall 2003

Date

Percent of Visits

10/12, RI = 526
10/19, RI = 500
ESPnet enables medical practices and hospitals to provide automated, timely information to public health departments about notifiable conditions, influenza-like illness and chronic diseases.

Practices can use ESPnet to query their own data and allow queries from state Departments of Public Health, returning de-identified summary reports.

ESPnet uses information in electronic health records. These records remain under the full control of the practice or hospital at all times.
### CPT to LOINC Map - Challenges

<table>
<thead>
<tr>
<th>Test Name</th>
<th>CPT</th>
<th>COMPONENT</th>
<th>LOINC</th>
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<td>CHLAMYDIA PCR, URINE (MALES)</td>
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<td>835</td>
<td>16601-7</td>
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</tbody>
</table>

- **Proprietary code**
- **Multiple codes for same test**
- **Incorrect code (gonorrhea test)**
- **Obsolete code**

M Klompas
Welcome to Mini-Sentinel

Mini-Sentinel is a pilot project sponsored by the U.S. Food and Drug Administration (FDA) to create an active surveillance system - the Sentinel System - to monitor the safety of FDA-regulated medical products. Mini-Sentinel uses pre-existing electronic healthcare data from multiple sources. Collaborating institutions provide access to data as well as scientific and organizational expertise. Mini-Sentinel is part of the FDA's Sentinel Initiative, which is exploring a variety of approaches for improving the Agency's ability to quickly identify and assess safety issues.

Most Mini-Sentinel activities focus on assessments, methods, or data. Visit the following links to learn more about each type of activity:

- Assessments
- Methods
- Data
- Communications
- All Reports

ESPnet

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PCORnet: The National Patient-Centered Clinical Research Network

PCORnet is a national network of organizations that includes researchers, patient advocates, providers, payers, and others. The goal of PCORnet is to conduct and disseminate research that helps people and their healthcare providers make better-informed decisions about prevention, diagnosis, treatment, and end-of-life care.
ON A CLEAR DAY (YOU CAN SEE FOREVER)

The Learning Health System
Thank you!