turning knowledge into practice

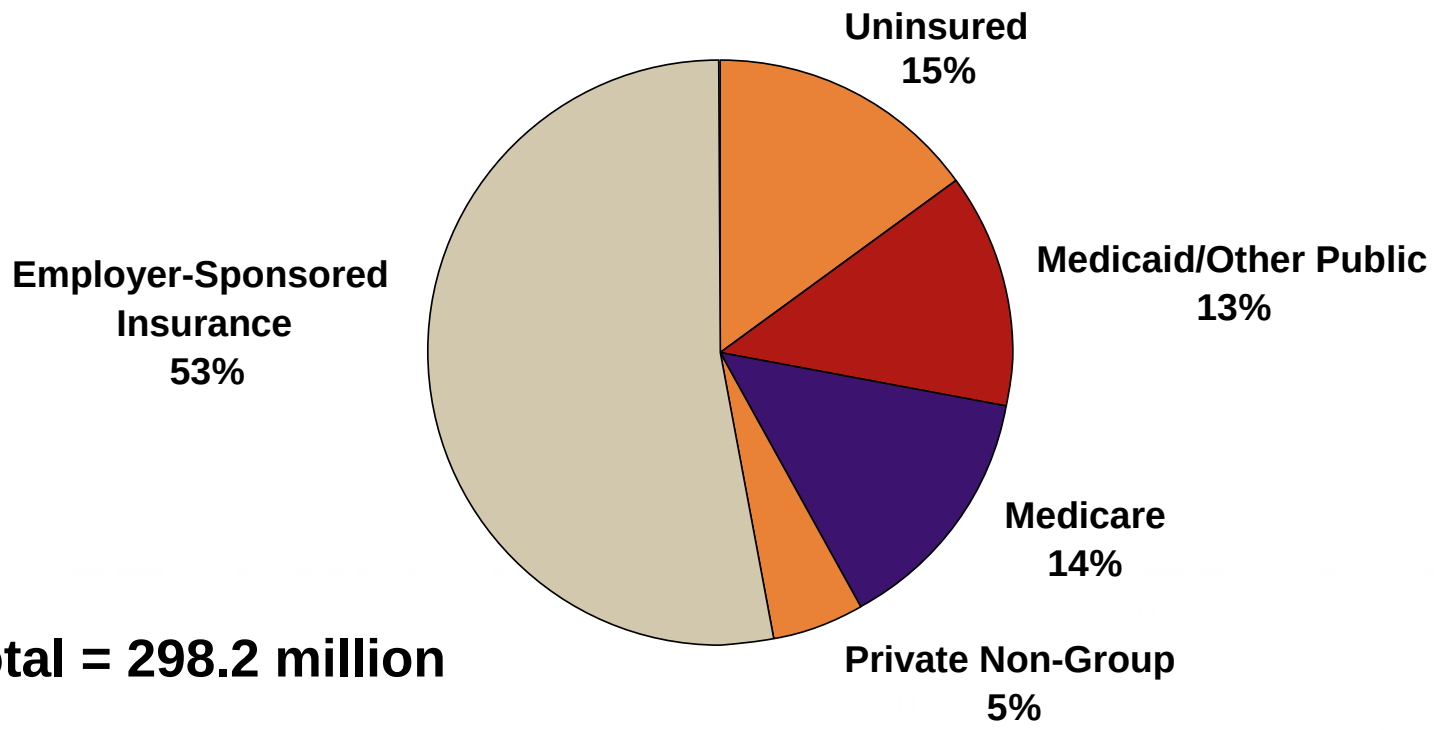
Using Electronic Data for Research, Surveillance, and Quality Assessment

Suzanne L. West, MPH, PhD
Senior Public Health Researcher
RTI International
and
Adjunct Associate Professor
Department of Epidemiology
Gillings School of Global Public Health
The University of North Carolina at Chapel Hill

Topics

- Health insurance data
- Electronic health record data
- Use of electronic data for research, surveillance, and quality assessment
- Research challenges
- Conclusions

Health Insurance Coverage in the U.S., 2007



NOTE: Includes those over age 65. Medicaid/Other Public includes Medicaid, SCHIP, other state programs, and military-related coverage. Those enrolled in both Medicare and Medicaid (1.7% of total population) are shown as Medicare beneficiaries.
SOURCE: Kaiser Commission on Medicaid and the Uninsured/Urban Institute analysis of March 2008 CPS

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Health Insurance Data

- Data arises from *billing claims* generated by insured patients
- Many different insurers but formats are similar
- Some health insurance data available for purchase

Typical Information Available in Health Insurer Databases

MEMBERSHIP DATA

Member identifier
Date of birth
Gender
Date of enrollment
Date of disenrollment
Benefit plan number

PHYSICIAN SERVICES

Member identifier
Provider identifier
Date of service
ICD-9-CM codes
CPT-4 procedure codes

OUTPATIENT PHARMACY CLAIMS

Member identifier
Pharmacy identifier
NDC code/ATC code
Generic code
Drug strength
Dosage form
Quantity dispensed
Days supply
Prescribing physician ID
Date filled

NDC: National Drug Code
ATC: Anatomical Therapeutic Chemical Classification

HOSPITAL SERVICES

Member identifier
Provider identifier
Date of admission
Date of discharge
DRG code
ICD-9-CM codes
Length of stay

LABORATORY SERVICES

Member identifier
Provider identifier
Date of service
ICD-9-CM, CPT-4, and HCPCS codes

Electronic Health Records

- Data arises from *clinicians* in the delivery of care to patients
- Many different EHR products available
  - Size of the practice
  - Features and upgrades
- EHRs are costly; adoption is slow
  - Learning curve

EHR Data Available in Vendor Databases

PATIENT DATA
Patient identifier
Gender
Race
Age
Zip code
State
Date of enrollment
Date of first encounter
Date of last encounter
Type of insurance
Provider specialty

ACTIVITY
Patient identifier
Patient age
Encounter type
Date

PRESCRIPTION
Patient identifier
Rx date
Paper/fax/phone Rx
Formulary status
Patient age
Number of refills
Quantity of pills
Generic name & strength
Dosage form
Route of administration
Quantity dispensed
Days supply
Therapeutic class

Rx=prescription

OBSERVATION
Patient identifier
Clinical measure (BP)
Laboratory test results
Date of observation
Patient age

PATIENT PROBLEMS
Patient identifier
Date of service
ICD-9-CM codes*
Patient age
**New/history/rule out*

ORDERS
Patient identifier
Date of service
Procedure codes (CPT)
Patient age

Research Using Electronic Data

- Comparative effectiveness research (CER)
- Epidemiology studies
- Drug safety

CER Question

How do drugs and “watchful waiting” compare with surgery as a treatment for leg pain that results from blockage of the arteries in the lower legs?

Designing a CER Study

	Insurer Claims	EHR
Identifying patients	• Diagnosis of peripheral arterial disease or intermittent claudication • *Procedure codes* (present/absent) - Doppler - Arteriography - MRI	• Diagnosis of peripheral arterial disease or intermittent claudication • Doppler pressures for computing ankle brachial index (ABI) where ABI ≤ 0.95 • Arteriography indicating ≥50% stenosis or occlusion • Magnetic resonance angiography indicating ≥50% stenosis or occlusion
Treatments received	• Medications (statins, antiplatelets, platelet-aggregation inhibitor/ arterial vasodilator) • Surgery (angioplasty, revascularization, reconstruction) • No medications, no surgery (watchful waiting)	

Designing a CER Study (cont)

	Insurer Claims	EHR
Outcomes	Diagnoses: • Skin ulcer • Limb amputation • *Procedure codes* (present/absent) - Doppler - Arteriography - MRI	Diagnoses: • Skin ulcer • Limb amputation • ***Procedure results*** - Doppler: ABI - Arteriography % occlusion - MRI: % occlusion

Epidemiology Studies

	Insurer Claims	EHR
Epidemiology & survival	• First diagnosis of immune thrombocytopenic purpura • Blood work done	• First diagnosis of immune thrombocytopenic purpura • Platelet counts
Prevalence	• Numerator: # with a diabetes • Denominator: # insured	• Numerator: # with a diabetes • Have to estimate a denominator
Medication use & patterns	• Years on a particular oral diabetes medication before switching to insulin	• How well the diabetes was controlled (HbA1c <8%) on an oral diabetes medication before being switched to insulin
	• Type of antihypertensive medications in children	• Same study except grouped by severity of blood pressure
	• Medication use in pregnancy	• Same study except gestational age at exposure assessed more accurately

Drug Safety

- Food and Drug Administration's (FDA) passive adverse event reporting system (AERS)
- Active surveillance via the Sentinel Initiative

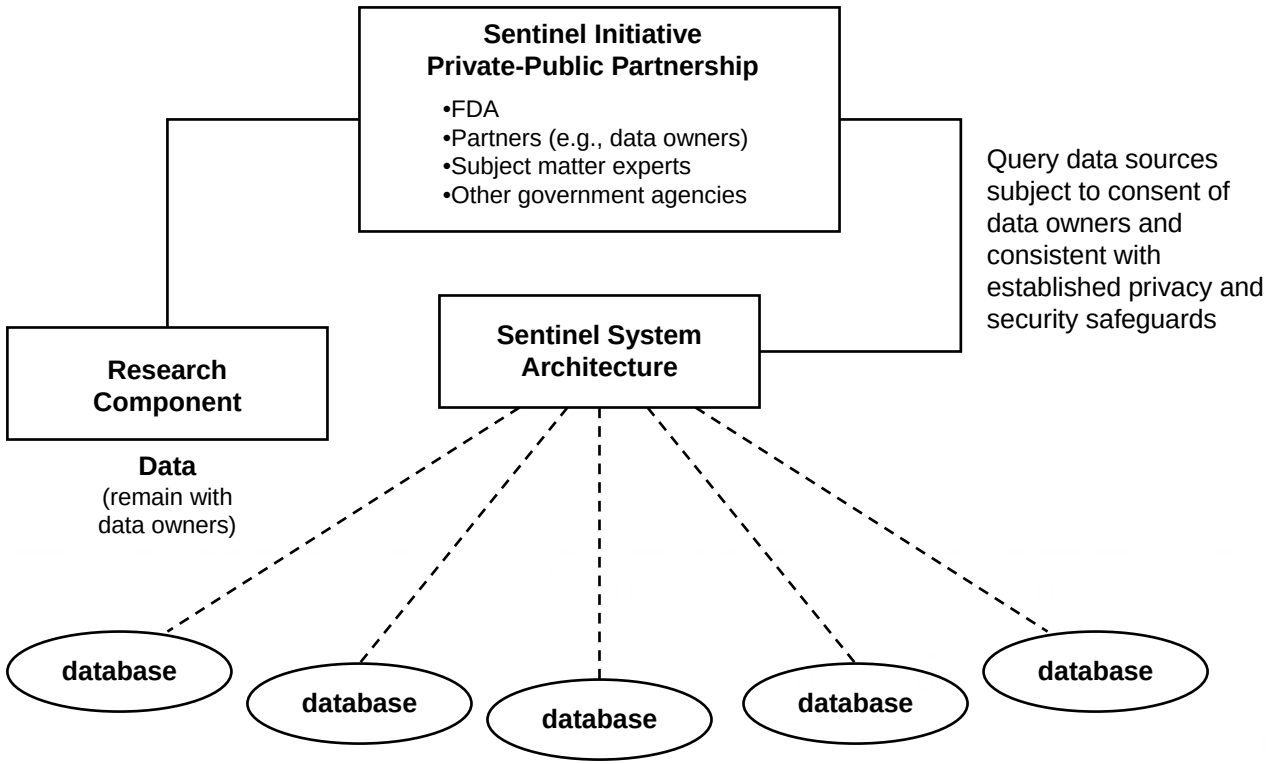
* http://www.fda.gov/oc/initiatives/advance/reports/report0508.html

FDA's Sentinel Initiative*

- Use health insurer and EHR data from 25 million patients by July 2010 and 100 million patients by July 2012
- Query distributed, de-identified, insurer and EHR data *quickly* and *securely* for product safety information
- Electronic data from multiple sources will *not* be aggregated into one large dataset

* http://www.fda.gov/oc/initiatives/advance/reports/report0508.html

Potential Organizational Structure for the Sentinel Initiative / System



The Sentinel Initiative National Strategy for Monitoring Medical Product Safety Department of Health and Human Services. U.S. Food and Drug Administration. Office of Critical Path Programs. May 2008 www.fda.gov/oc/initiatives/criticalpath/

Health Care Quality for Diabetes

	Insurer Claims	EHR
HbA1c	• Test done	• Test results ≤ 7%
Lipids	• Low-density lipoprotein cholesterol (LDL-C) test done	• Low-density lipoprotein cholesterol (LDL-C) <130 mg/dL
Micro-albuminuria	• Test done	• No evidence of protein in urine
Blood pressure	• Measured on at least two occasions (presumably at provider visits)	• <140/90 mm/Hg
Foot exam	• Not listed as a separate billing code	• Normal sensory testing of foot
Eye exams	• Billing data indicating a dilated eye exam was done	• Normal eye exam (no microaneurysms)

Research Challenges with Electronic Data

- Fragmentation of health care
- Type of data available
- Access/cost
- HIPAA

Fragmentation of the Health Care System

- Employer-based health insurance
- No “gatekeeper”
- No national health ID
- Many different electronic medical record vendors
- Little or no interoperability between systems

Types of Available Data

- Standardization of coding systems
  - Diagnosis
  - Laboratory
- Text data
  - Some electronic health records are only text based with no standard codes
  - Visit transcriptions are text, often with identifiers
- Data are “messy” and require considerable cleaning before use

Access and Cost Issues

Electronic health data

- are costly to maintain
- valuable to researchers

➔ Very costly to purchase

➔ Insurers developing internal research capabilities so less likely to “sell” data

HIPAA Privacy Rule

45 CFR 164.502

- Enacted because the Common Rule (historical ethics practices) did not adequately cover privacy of electronic data
- Original version was not “research friendly”
- August 2002 version
  - Individual authorization obtained from each patient to access his/her PHI for a research study
  - The research must qualify for an exemption otherwise individual consent will be required

Most Common Exemption Used in Research

Limited use data set 45 CFR 164.514

- Remove 16 identifiers (e.g., Names, Medical record #s, Social security #s, E-mails, URLs, license #s)
- Dates and geographic location allowed
- Implement a data use agreement with adequate:
  - Plan to protect the identifiers from improper use and disclosure
  - Plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research
  - Written assurances that the PHI will not be reused or disclosed to any other person or entity

IOM: Enhancing Privacy Improving Health Through Research*

- Recommended changes to the HIPAA Privacy Rule, to enable greater use of electronic data for research purposes:
  - Develop a new approach to protecting privacy that would apply uniformly to all health research
  - Exempt health research from HIPAA
  - HHS should develop guidance materials to facilitate more effective use of existing data and materials
  - HHS and researchers should take steps to provide the public with more information and health research

* *Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research*. Washington, DC: The National Academies Press 2009.

Conclusions

- Research Based on Electronic Medical Data
  - has played a vital role in advancing public health and medical knowledge
  - will become even more valuable as larger, more effective records linkage systems are implemented and more detailed information from EHRs becomes available
  - must be exempted from the HIPAA Privacy Rule to facilitate research
- Researchers need to do a better job explaining
  - the benefits of research using electronic data
  - how individual privacy and data security will be protected

Contact Information

Suzanne L. West, MPH, PhD
3040 Cornwallis Rd
Research Triangle Park, NC 27709
919.541.7048
swest@rti.org