Improving Quality requires "Uniform Effort and Standardized Data"

Community Care of North Carolina

"Medical Homes and Community Networks"

L. Allen Dobson, Jr. MD FAAFP
President -Community Care of NC
Vice President- Carolinas Health Care System

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Uniform Effort

- Requires provider engagement
- Focus on local care delivery and coordination
- Additional resources may be necessary
- For chronic disease management and prevention- primary care enhancement is the key
- Focused changes applied broadly can produce significant results

Standardized Data

- Standardized (multi-payer) quality measures/reporting required (claims data may be best first source)
- Need for timely and actionable data delivered to the provider
- Community and practice level reporting a first step
- Transparency (accountability) will produce a “new level” of competition (and collaboration) among providers

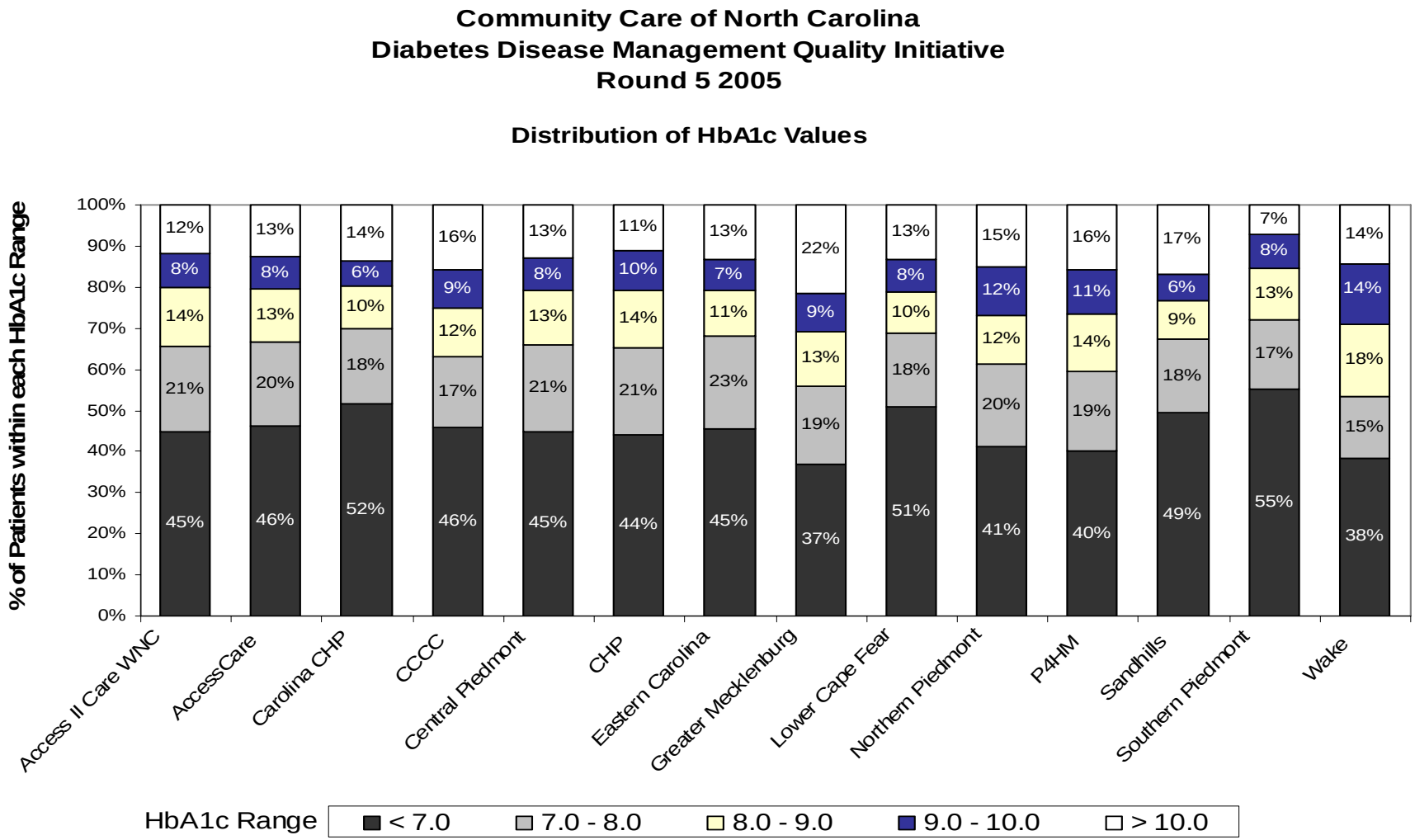
Community Care of NC
Now in 2009

- Focuses on improved quality, utilization, and cost effectiveness (Medicaid program)
- 14 Networks with more than 4,200 primary care physicians (1,350 medical homes) plus all health systems, hospitals and public providers
- Over 975,000 Medicaid enrollees
- Now inclusion of aged, blind, and disabled, and SCHIP

Current State-wide Disease and Care Management Initiatives

- Asthma
- Diabetes
- Pharmacy Management
- Dental Screening and Fluoride Varnish
- Emergency Department Utilization Management
- Case Management of High Cost – High Risk Patients
- Congestive Heart Failure (CHF)

Diabetes—Network Comparisons



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Key Results

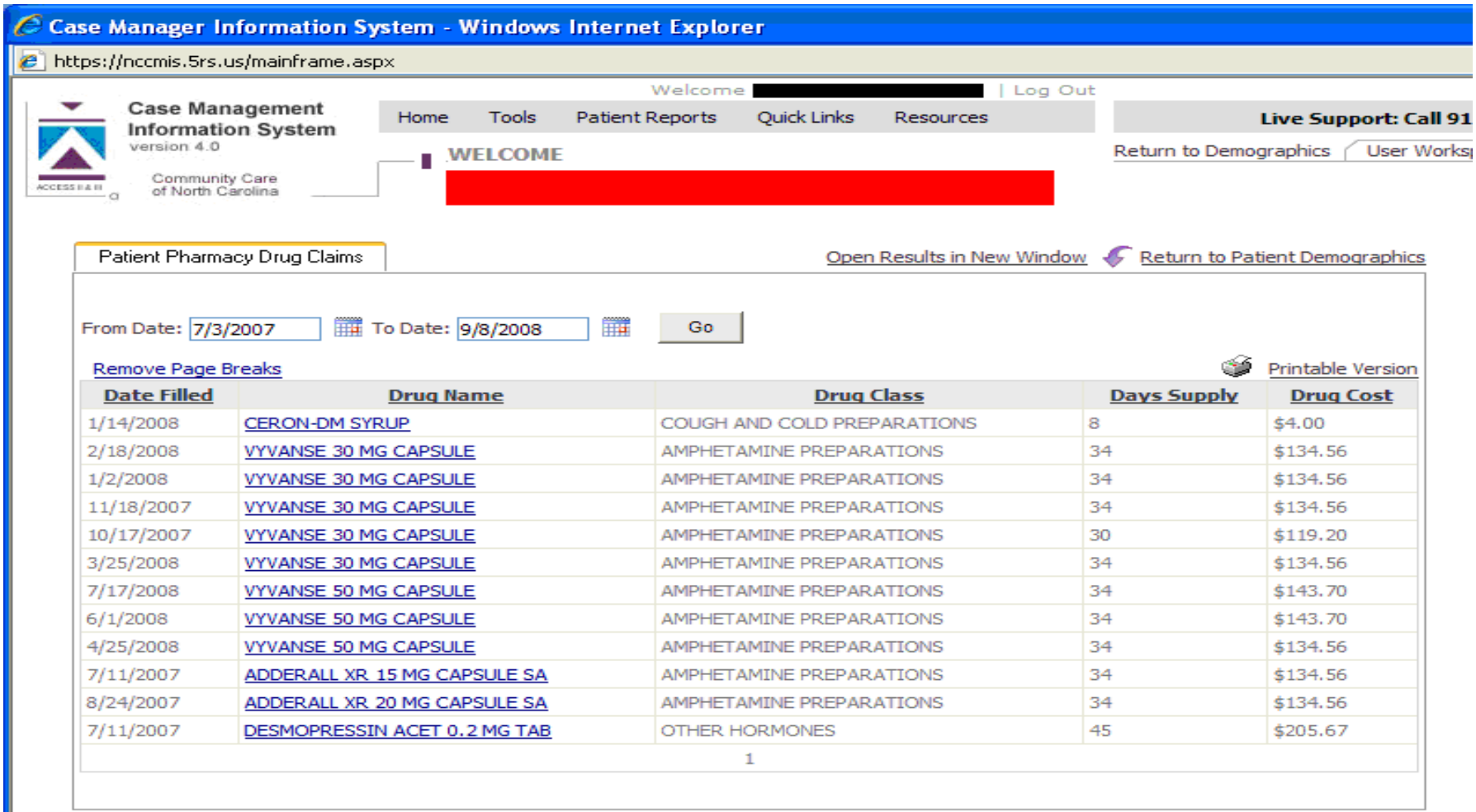
Asthma

- 34% lower hospital admission rate
- 8% lower ED rate
- average episode cost for children enrolled in CCNC was 24% lower
- 93% received appropriate inhaled steroid

Diabetes

- 15% increase in quality measures

Patient Clinical Information – Pharmacy Claims



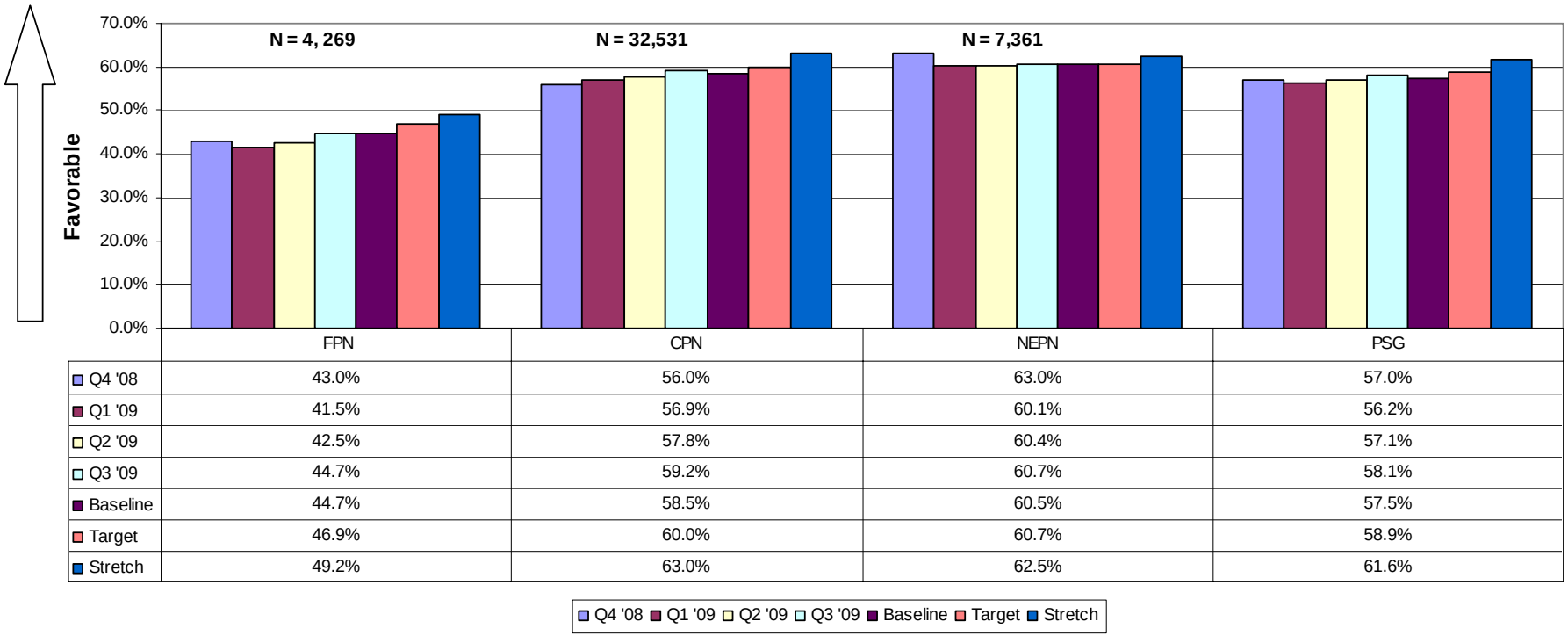
Date Filled	Drug Name	Drug Class	Days Supply	Drug Cost
1/14/2008	CERON-DM SYRUP	COUGH AND COLD PREPARATIONS	8	$4.00
2/18/2008	VYVANSE 30 MG CAPSULE	AMPHETAMINE PREPARATIONS	34	$134.56
1/2/2008	VYVANSE 30 MG CAPSULE	AMPHETAMINE PREPARATIONS	34	$134.56
11/18/2007	VYVANSE 30 MG CAPSULE	AMPHETAMINE PREPARATIONS	34	$134.56
10/17/2007	VYVANSE 30 MG CAPSULE	AMPHETAMINE PREPARATIONS	30	$119.20
3/25/2008	VYVANSE 30 MG CAPSULE	AMPHETAMINE PREPARATIONS	34	$134.56
7/17/2008	VYVANSE 50 MG CAPSULE	AMPHETAMINE PREPARATIONS	34	$143.70
6/1/2008	VYVANSE 50 MG CAPSULE	AMPHETAMINE PREPARATIONS	34	$143.70
4/25/2008	VYVANSE 50 MG CAPSULE	AMPHETAMINE PREPARATIONS	34	$134.56
7/11/2007	ADDERALL XR 15 MG CAPSULE SA	AMPHETAMINE PREPARATIONS	34	$134.56
8/24/2007	ADDERALL XR 20 MG CAPSULE SA	AMPHETAMINE PREPARATIONS	34	$134.56
7/11/2007	DESMOPRESSIN ACET 0.2 MG TAB	OTHER HORMONES	45	$205.67

1

Carolinas Healthcare System Physician Networks

Diabetic Patients: A1C < 7

% Diabetic Patients A1C < 7



	FPN	CPN	NEPN	PSG
Q4 '08	43.0%	56.0%	63.0%	57.0%
Q1 '09	41.5%	56.9%	60.1%	56.2%
Q2 '09	42.5%	57.8%	60.4%	57.1%
Q3 '09	44.7%	59.2%	60.7%	58.1%
Baseline	44.7%	58.5%	60.5%	57.5%
Target	46.9%	60.0%	60.7%	58.9%
Stretch	49.2%	63.0%	62.5%	61.6%

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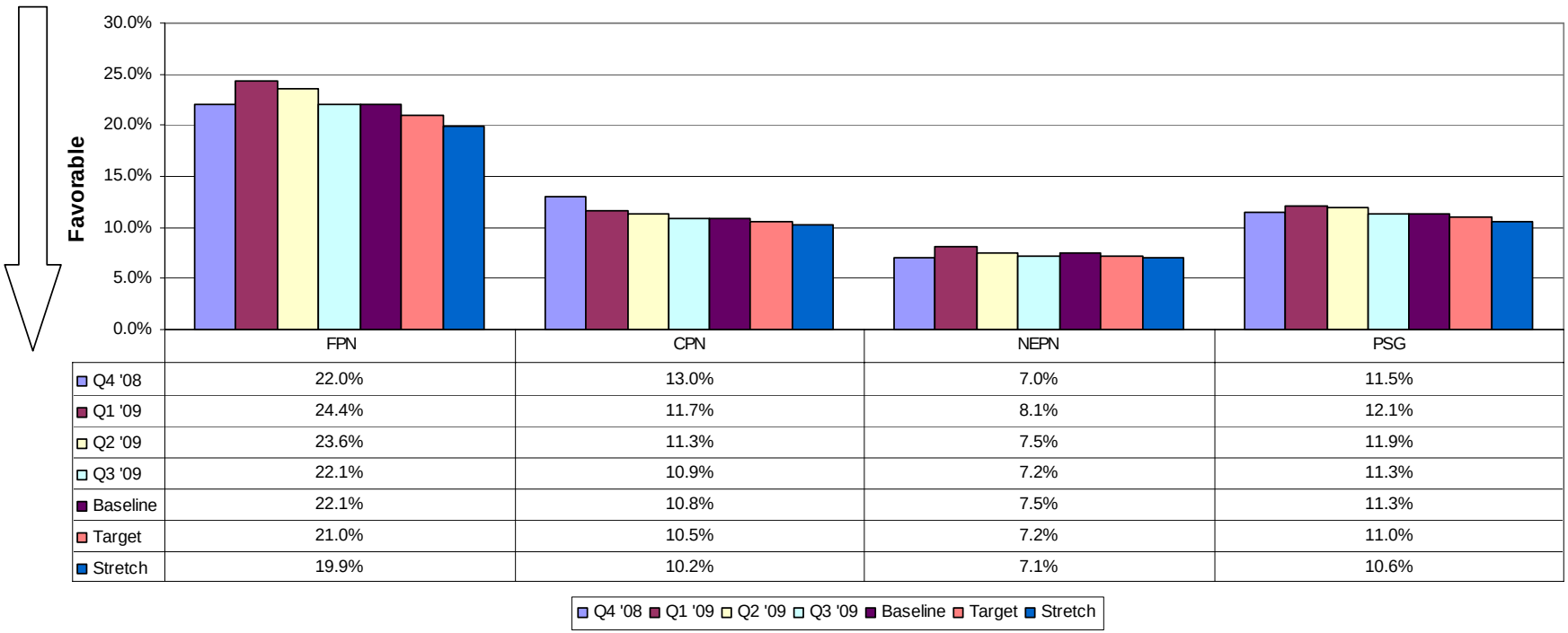
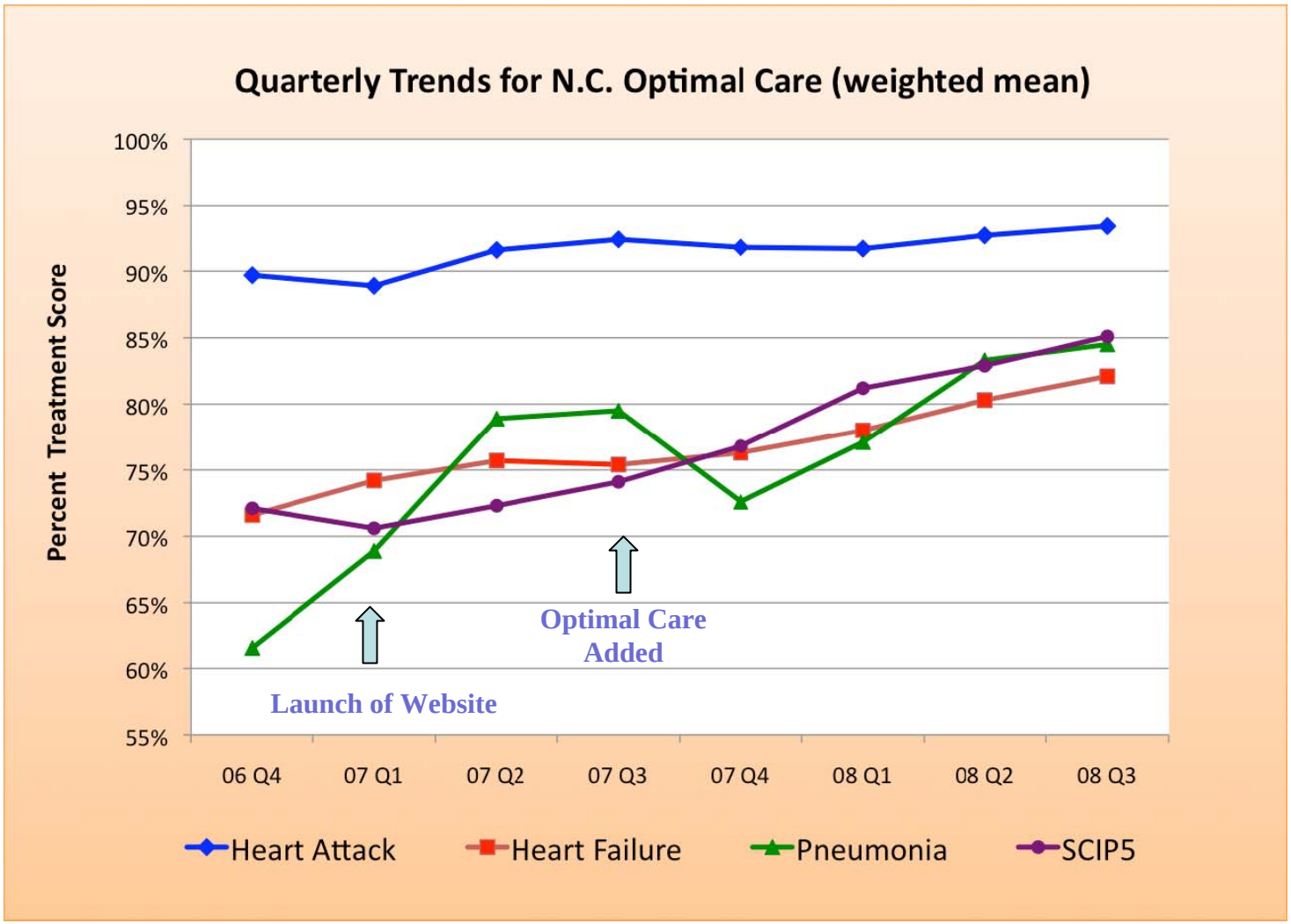
Diabetic Patients: A1C > 9



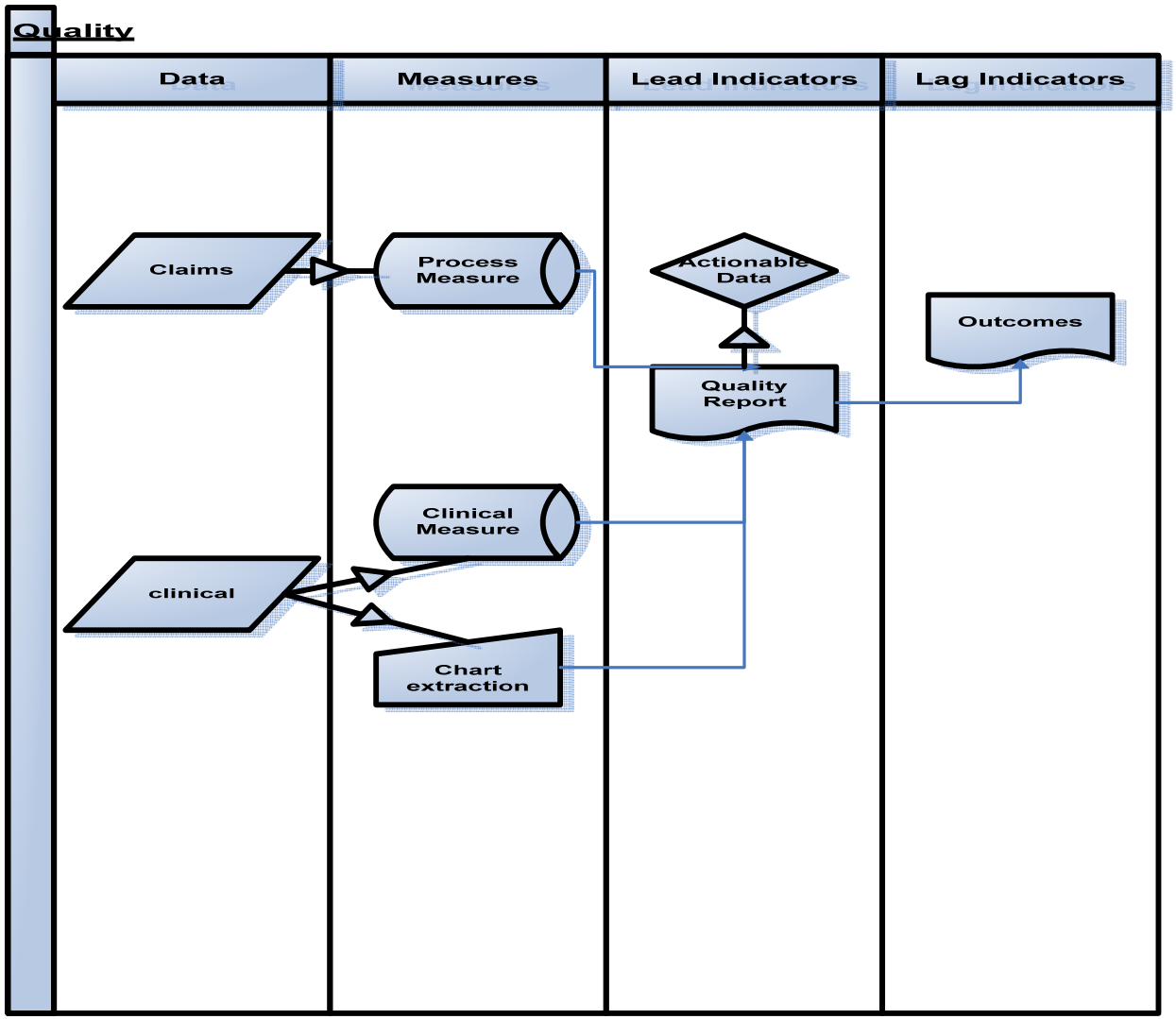
	FPN	CPN	NEPN	PSG
Q4 '08	22.0%	13.0%	7.0%	11.5%
Q1 '09	24.4%	11.7%	8.1%	12.1%
Q2 '09	23.6%	11.3%	7.5%	11.9%
Q3 '09	22.1%	10.9%	7.2%	11.3%
Baseline	22.1%	10.8%	7.5%	11.3%
Target	21.0%	10.5%	7.2%	11.0%
Stretch	19.9%	10.2%	7.1%	10.6%

N.C. Center for Hospital Quality and Patient Safety



Important Data Elements to Inform Quality Improvement

- Patient-level data
  - May help to identify gaps in care that need to be addressed
  - Identify opportunities for good transitions; or
  - Avoid readmissions
- Provider performance summary data
  - Provide complete, standardized and objective data on provider performance compared to the average



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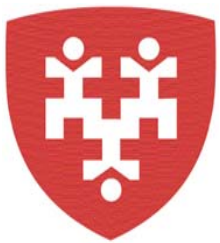
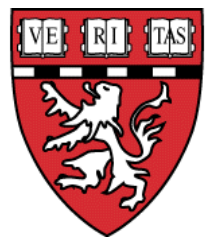
Final Comments

- There is little “system” in the US healthcare system
- HIT alone can not fix the quality problem
- The primary care system in the US is underdeveloped and undervalued- will need additional resources to move quality
- Uniform effort and standardized data required
- In addition to aggregate data, actionable patient level data needed
- Transparency will foster a new level of competition around quality

Public health uses of electronic health data:
medical product safety and other public health reporting

Richard Platt, MD, MSc
Harvard Medical School and
Harvard Pilgrim Health Care Institute





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The opportunity

- Current technology can identify and report:
  - Some drug and vaccine adverse events
  - Cases of individually notifiable diseases
  - Influenza-like illness and other syndromes
  - Conditions of public health interest, e.g., diabetes and pre-diabetes

Drugs: Designated medical events

- ✓ Congenital anomalies
- ✓ Acute respiratory failure
- ✓ Seizure
- ✓ Aplastic anemia
- ✓ Toxic epidermal necrolysis
- ✓ Acute liver failure or necrosis
- ✓ Anaphylaxis
- ✓ Acute renal failure

- ✓ = accomplished with electronic data + chart review

- Agranulocytosis
- Sclerosing syndromes
- Pulmonary hypertension
- Pulmonary fibrosis
- Ventricular fibrillation
- Torsades de pointe
- Malignant hypertension
- Transmission of infectious agent
- Endotoxin shock

Modified from www.fda.gov/OHRMS/DOCKETS/98fr/03-5204.pdf

Drugs: Selected other events

- ✓ Myocardial infarction
- ✓ Gastrointestinal bleeding
- ✓ Rhabdomyolysis
- ✓ Hypoglycemia
- ✓ Urticaria
- ✓ Irritable bowel syndrome
- ✓ Churg Strauss syndrome
- ✓ Gout
- ✓ Arrhythmia
- ✓ Mortality

- OMOP's outcomes
  - Angioedema
  - Aplastic anemia
  - Acute liver injury
  - Bleeding
  - GI ulcer hospitalization
  - Hip fracture
  - Hospitalization
  - Myocardial infarction
  - Mortality after MI
  - Renal Failure

H1N1 vaccine safety outcomes: VSD and PRISM

- ✓ Guillain-Barré Syndrome (GBS)
- ✓ Central nervous system demyelinating diseases
- ✓ Neuropathies
- ✓ Seizures
- ✓ Encephalitis
- ✓ Bell's palsy
- ✓ Myocarditis
- ✓ Ataxia
- ✓ Anaphylaxis
- ✓ Spontaneous abortion
- ✓ Pre-eclampsia

VSD = Vaccine Safety Datalink
PRISM = Post-licensure Rapid Immunization Safety Monitoring system

Vaccines: Selected other Vaccine Safety Datalink outcomes

- ✓ Ataxia
- ✓ Cranial nerve disorders
- ✓ Thrombocytopenia
- ✓ Appendicitis
- ✓ Stroke
- ✓ Venous thromboembolism
- ✓ Syncope
- ✓ Intussusception
- ✓ Gram negative sepsis
- ✓ Arthritis

Other conditions of public health interest

- Individually
  - ✓ Hepatitis A / B / C
  - ✓ Tuberculosis
  - ✓ Chlamydia
  - ✓ Gonorrhea
  - ✓ Syphilis
  - ✓ Pelvic inflammatory disease
  - – 50+ other conditions
- In the aggregate
  - – Influenza-like illness
  - – Diabetes / pre-diabetes
  - – Unusual illness clusters

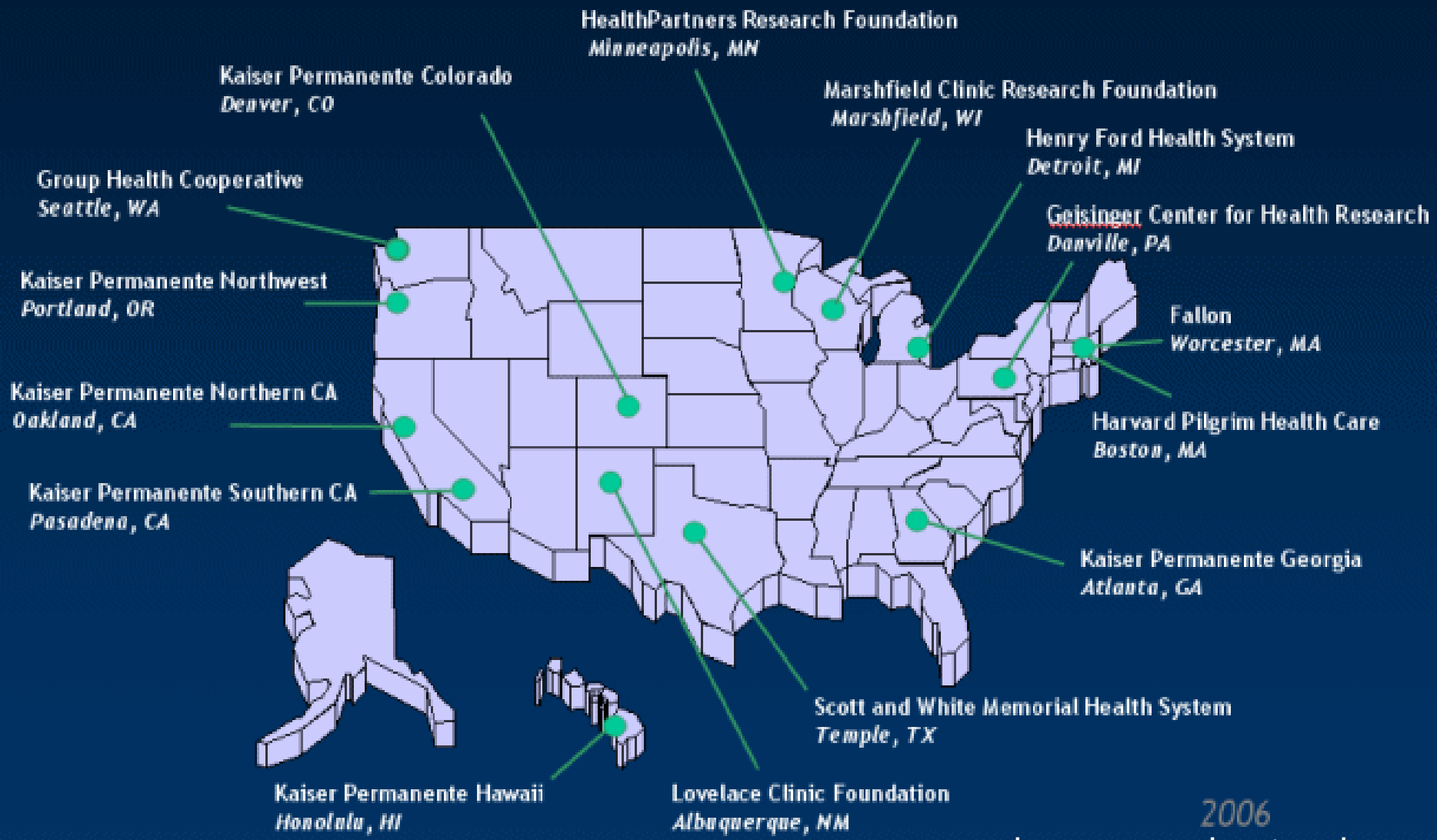
Electronic data sources for medical product safety assessment

- Usually necessary
  - Enrollment: dates and type of coverage
  - Demographics
  - Claims – inpatient, outpatient
  - Pharmacy dispensing
  - Access to full text medical records
- Sometimes necessary
  - Electronic medical records
  - Linkage to external registries, e.g., birth, death certificates, immunization

Electronic data sources for other public health reporting

- Often sufficient
  - Demographics
  - Electronic medical records
    - Vital signs, diagnoses, laboratory tests, treatments prescribed
- Sometimes necessary
  - Diagnoses and procedures from care outside the medical practice
  - Treatments dispensed
  - Linkage to selected external registries, e.g., birth, death certificates, immunization

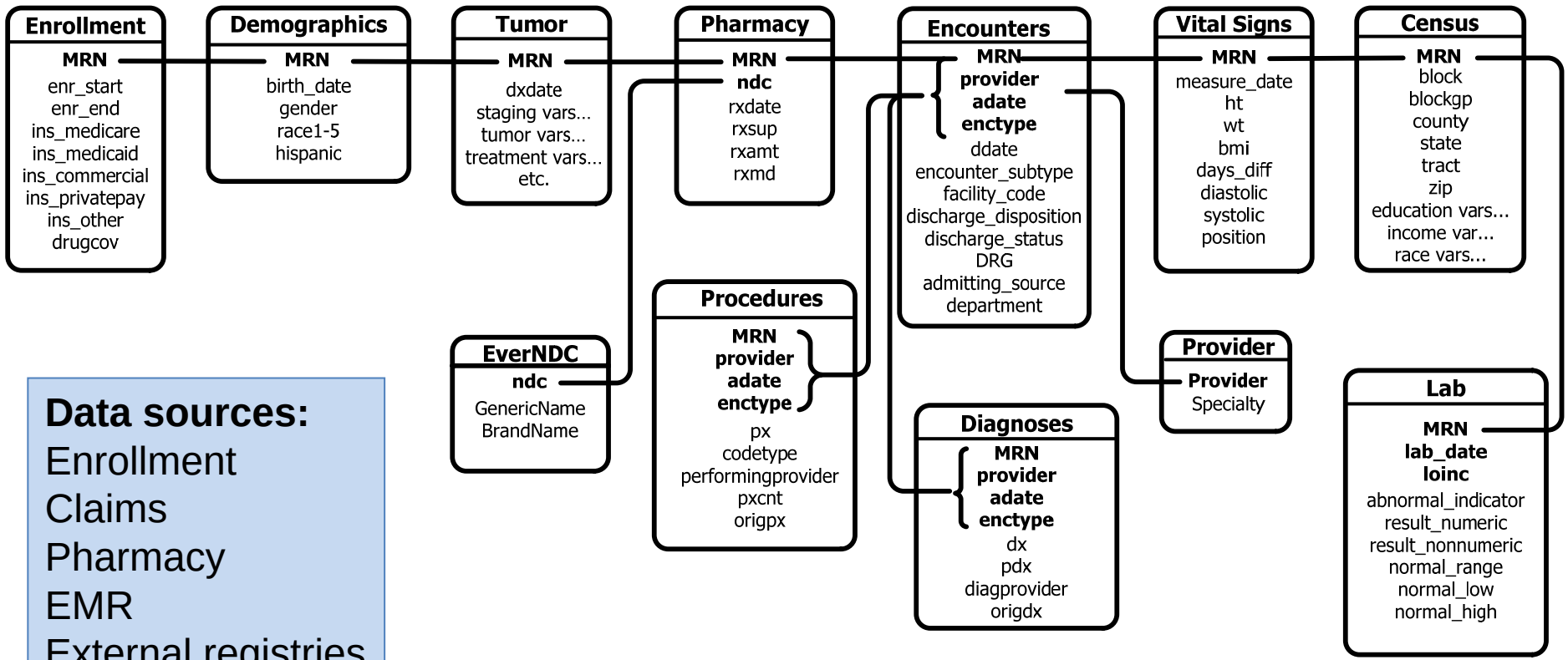
HMO Research Network Members



2006

www.hmoresearchnetwork.org

HMO Research Network
Virtual Data Warehouse



Data sources:
Enrollment
Claims
Pharmacy
EMR
External registries

http://hmoresearchnetwork.org/resources/collab_toolkit.htm#linked_index

HMO Research Network programs that use its Virtual Data Warehouse

- Post-marketing drug safety programs (FDA mini-Sentinel, CDER, CBER)
- Center for Education and Research on Therapeutics (AHRQ CERT)
- Developing Evidence to Inform Decisions about Effectiveness Center (AHRQ DEcIDE)
- Multicenter Diabetes Research Consortium (AHRQ)
- Cancer Research Network (NIH)
- CardioVascular Research Network (NIH)

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MMWR Weekly

March 14, 2008 / 57(10);258-260

Update: Recommendations from the Advisory Committee on Immunization Practices (ACIP) Regarding Administration of Combination MMRV Vaccine

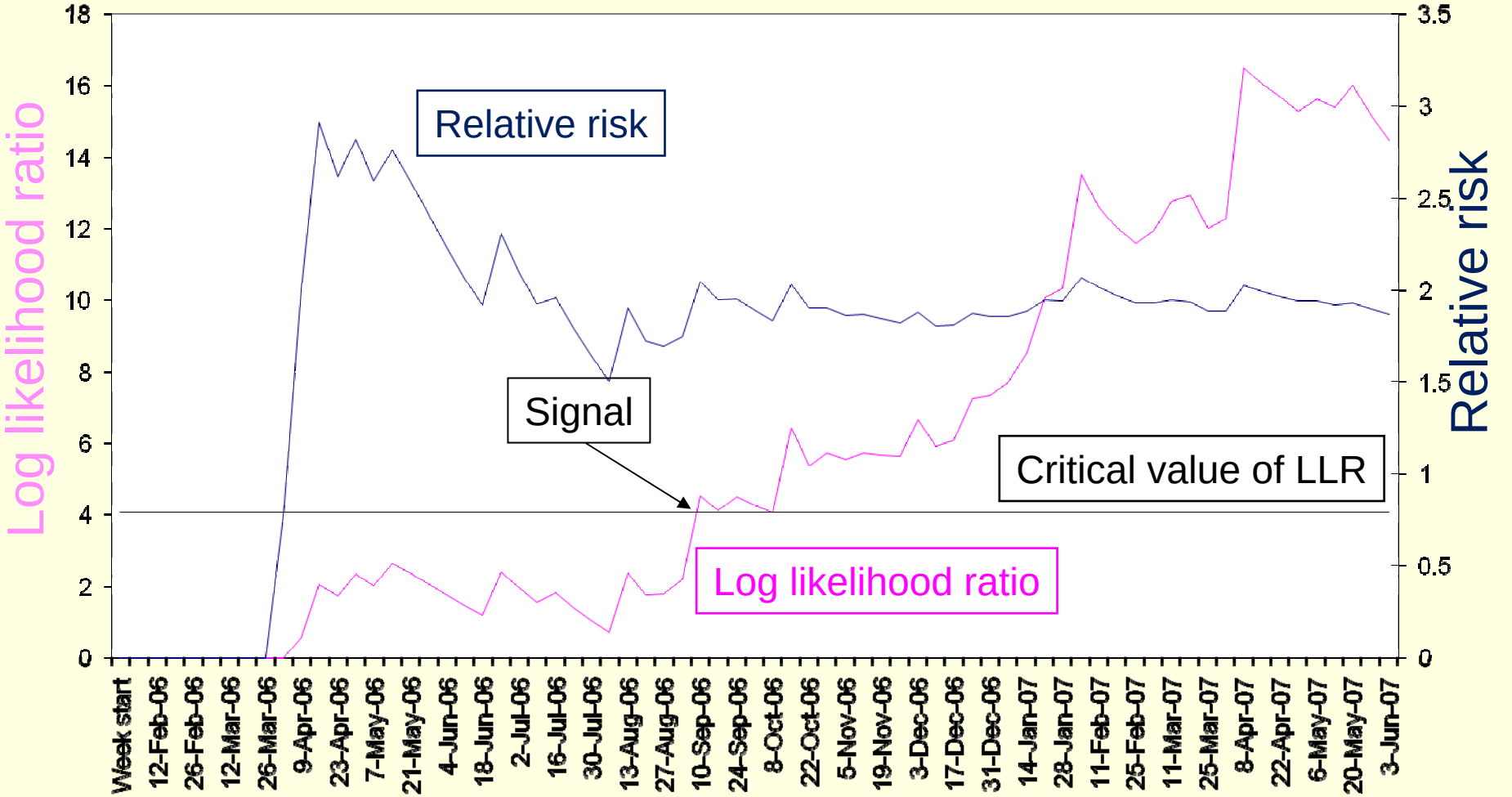
On February 27, 2008, new information was presented to the Advisory Committee on Immunization Practices (ACIP) regarding the risk for febrile seizures among children aged 12--23 months after administration of the combination measles, mumps, rubella, and varicella (MMRV) vaccine (ProQuad®, Merck & Co., Inc., Whitehouse Station, New Jersey). This report summa… knowledge regarding the risk for febrile seizures after MMRV vaccination and presents updated ACIP recommendations that were issued after presentati… updated recommendations remove ACIP's previous preference for administering combination MMRV va… varicella vaccine).

"…new information was presented…regarding the risk ….for febrile seizures after MMRV"

The combination tetravalent MMRV … months--12 years (*1*). MMRV vaccine … dose vaccine policies for prevention of measles, mumps, rubella, and varicella (*1*,*2*). The first vaccine dose is recommended at age 12--15 months and the second at age 4--6 years.

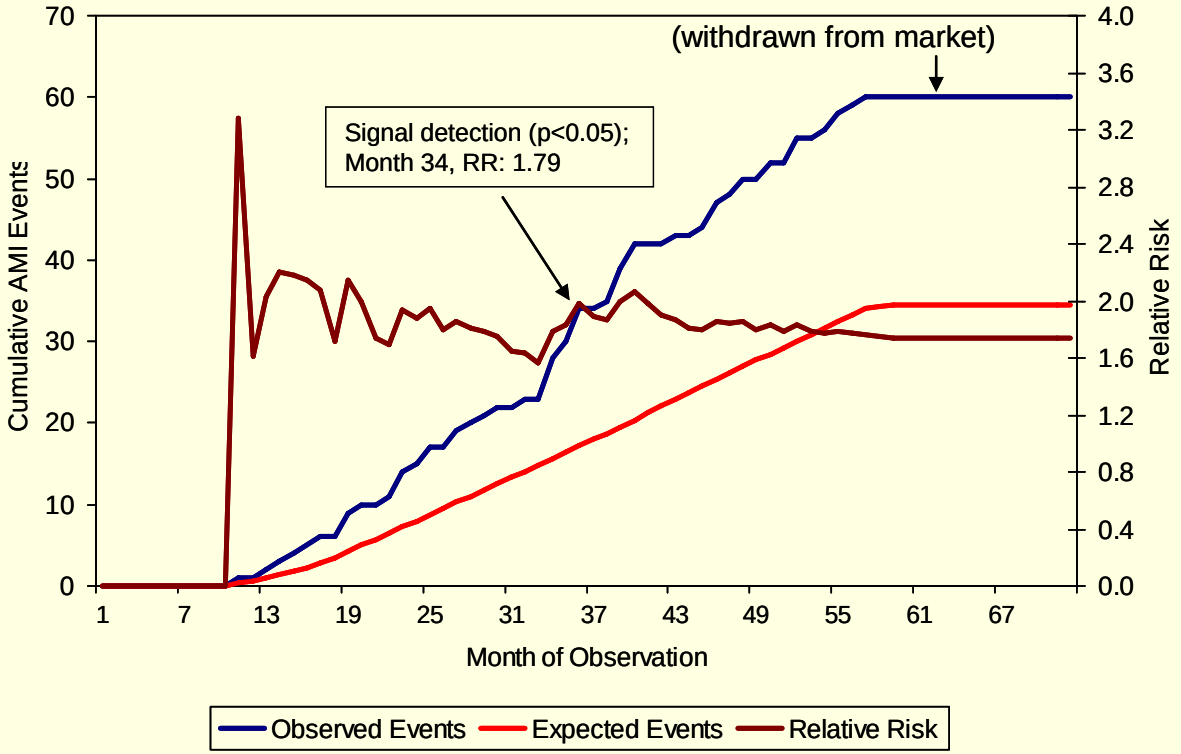
In MMRV vaccine prelicensure studies, an increased rate of fever was observed 5--12 and 0--42 days after the first vaccine dose, compared with administration of MMR vaccine and varicella vaccine at the same visit (*3*,*4*). Because of the known association between fever and febrile seizures (*5*), CDC and Merck initiated

MMRV and Seizures



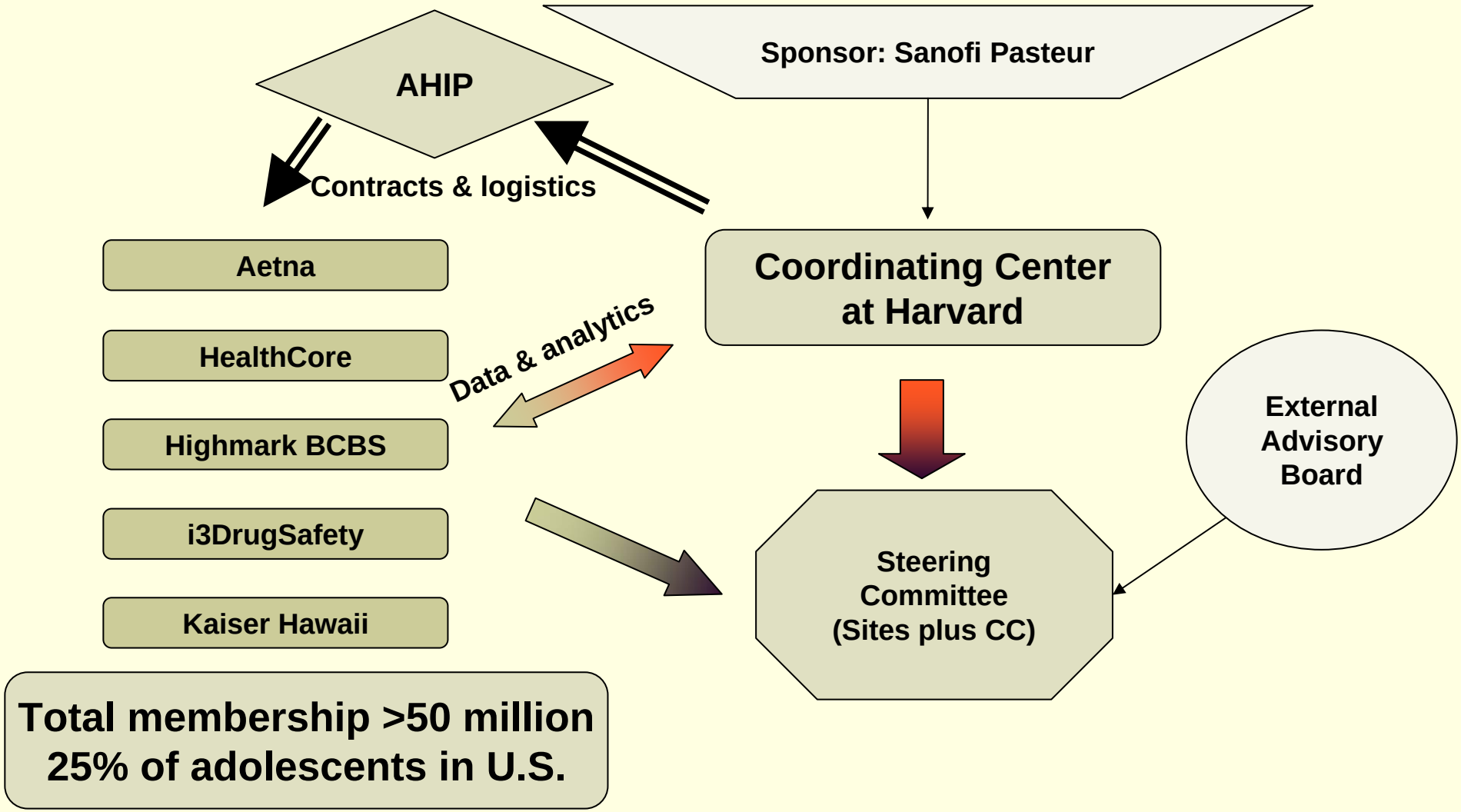
Observed and expected events for rofecoxib versus naproxen users: 2000-2005

- Signal occurred after 28 heart attacks among new users of drug.
- Would have occurred by 2nd or 3rd month if 100 million people had been observed.



Brown *et al*. (2007) PDS; Adjusted for age, sex, health plan. Outcome: AMI.

Meningococcal Vaccine Study



CDC Center of Excellence in Public Health Informatics (Boston)

- Harvard Medical School / Harvard Pilgrim Health Care Institute Department of Population Medicine
- Children's Hospital Informatics Program
- Massachusetts Department of Public Health
- Harvard Vanguard Medical Associates (for Atrius Health)
- Brigham and Women's Hospital Channing Laboratory
- Cambridge Health Alliance

Electronic Support for Public health (ESP)

- Software and architecture to automate detection and reporting of EMR-based data
- Current applications
  - ✓ ESP Notifiable diseases (Hepatitis A/B/C, STDs, TB)
  - ✓ ESP:VAERS Vaccine adverse events
  - ✓ ESP:ILI ILI surveillance
  - ✓ ESP:HZ Herpes zoster surveillance
- New focus on chronic disease
  - ✓ ESP:DM Diabetes and pre-diabetes
- ESP source code is freely available

http://esphealth.org
JAMIA 2009;16:18-24
MMWR 2008;57:372-375
Advances Disease Surveillance 2007;3:3

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MMWR Weekly

April 11, 2008 / 57(14);373-376

Automated Detection and Reporting of Notifiable Diseases Using Electronic Medical Records Versus Passive Surveillance --- Massachusetts, June 2006--July 2007

Electronic medical record (EMR) systems have the potential to improve reporting of notifiable diseases beyond either traditional clinician-initiated or automated laboratory-based reporting systems. Traditional clinician-initiated passive surveillance is burdensome to clinicians and often incomplete and delayed (*1,2*). Electronic laboratory reporting addresses these limitations (*3,4*) but often lacks information needed for public health purposes (e.g., patient signs and symptoms, prescribed treatments, and pregnancy status). Laboratory systems also do not integrate multiple laboratory tests to satisfy a case definition. Many EMRs, however, contain this information and store it in a form that is amenable to electronic analysis and reporting. Consequently, EMR-based reporting has the potential to provide active notifiable disease surveillance that is more timely, complete, and clinically detailed. This report summarizes findings from a pilot EMR-based electronic surveillance system in Massachusetts, which documented increases of 39% in reported chlamydia and 53% in reported gonorrhea for the period June 2006--July 2007, compared with the existing passive surveillance system. Eighty-one instances of pregnancy not identified by passive surveillance were reported by the electronic system in patients with chlamydia or gonorrhea. In addition, the electronic system identified 20 cases of pelvic inflammatory disease and four cases of acute hepatitis A, compared with none and one, respectively, reported via the passive system. Improved reporting can help public health departments better allocate limited resources for targeted investigations and interventions.

Manual versus electronic reporting

Atrius Health, June 2006 - July 2007

- Electronic reporting:
  - ✓ 12-fold increase in reports of chlamydia / gonorrhea patients with concurrent pregnancy
  - ✓ 16% increase in reports with treatment information
  - ✓ Elimination of transcription errors from case reports (6% error rate in manual reports)

MMWR 2008;57:372-375

Our experience has taught us…

- Many safety, effectiveness, and quality questions can be answered using relatively few items in electronic health data systems
  - No need to deal with entire content of claims and EMR systems
- Distributed data networks work
  - Avoids need to pool large amounts of confidential and proprietary data
- Distributed networks depend on common data models
  - Models can be modified as data availability increases and needs evolve

A way forward

- Develop a core common data model
  - Standardize definition and format of elements useful for at least two disciplines (safety, effectiveness, quality)
  - Each discipline assumes responsibility for elements unique to its work
  - Elements may be simpler than those needed to support delivery of care or payment

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VA Palo Alto Health Care System

STANFORD HEALTH POLICY
Center for Health Policy/FSI
Center for Primary Care and Outcomes Research/SOM

LEARNING ABOUT COMPARATIVE EFFECTIVENESS FROM HEALTH CARE DATABASES

December 2, 2009
Brookings Institution

Compelling advantages of observational studies

- Cost
- Size
- Speed
- Real-world
- Databases assembled from electronic health records offer detailed clinical information
- In some circumstances, statistical methods can adjust for bias

Observational analysis not always suitable

- When placebo effects are substantial
- When relevant outcomes aren't routinely measured
- When selection effects are important
- Hard to do intention to treat analysis in the context of an observational study

When observational analysis is essential

- When randomization is unethical
- When treatment adherence is particularly important
- When "real-world" treatment differs from treatment rendered in formal trials (e.g., complex surgery)
- When trial would need to be prohibitively large or long-lasting to answer question (e.g., diagnostic test)

How results of randomized trials and observational studies compare

- What is direction of bias, if any, in observational studies?
- Are differences between results of RCTs and of observational studies larger than differences between results of different RCTs?

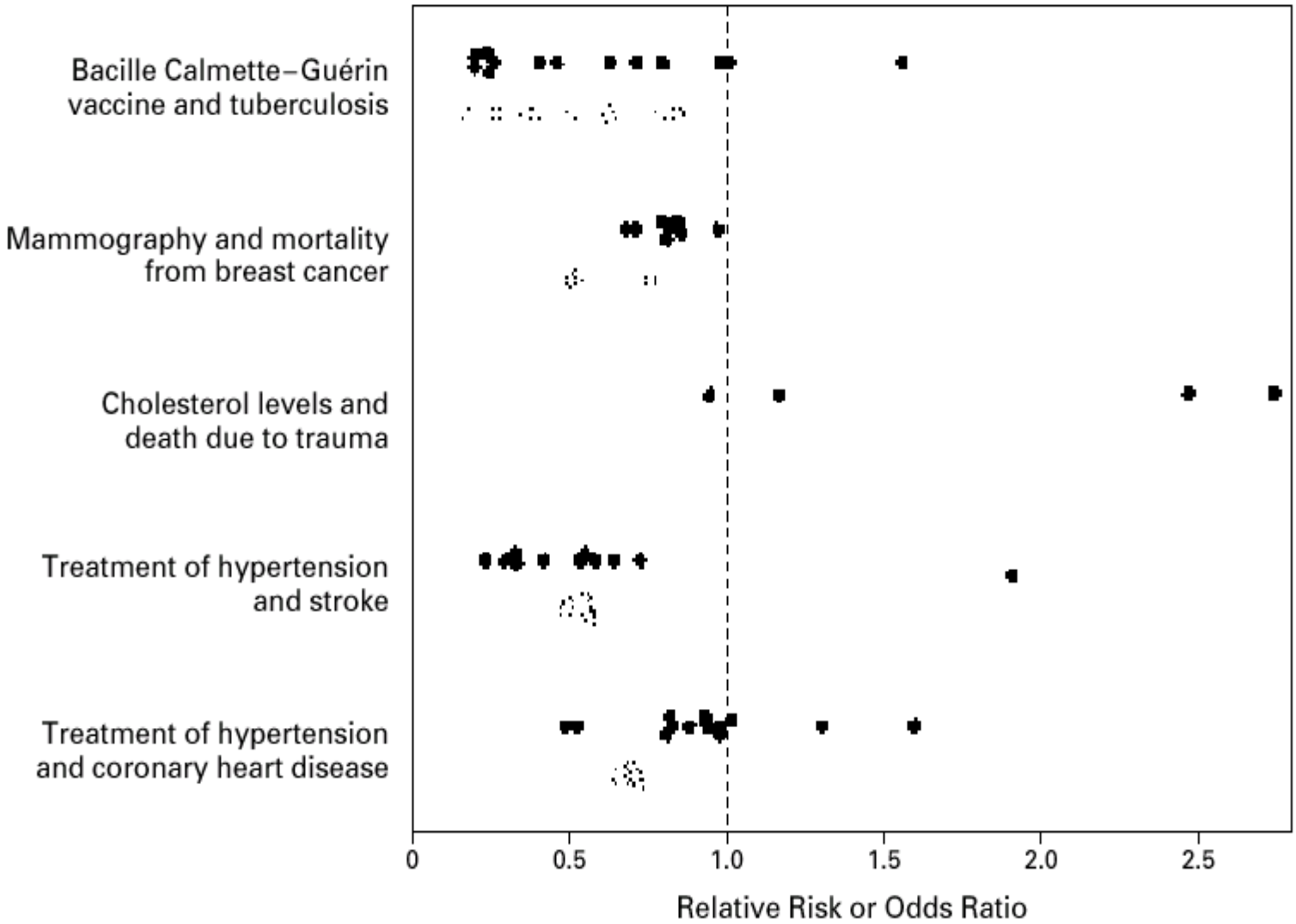

Figure 1. Range of Point Estimates According to Type of Research Design.

Dark spots represent RCTs, light spots represent observational studies

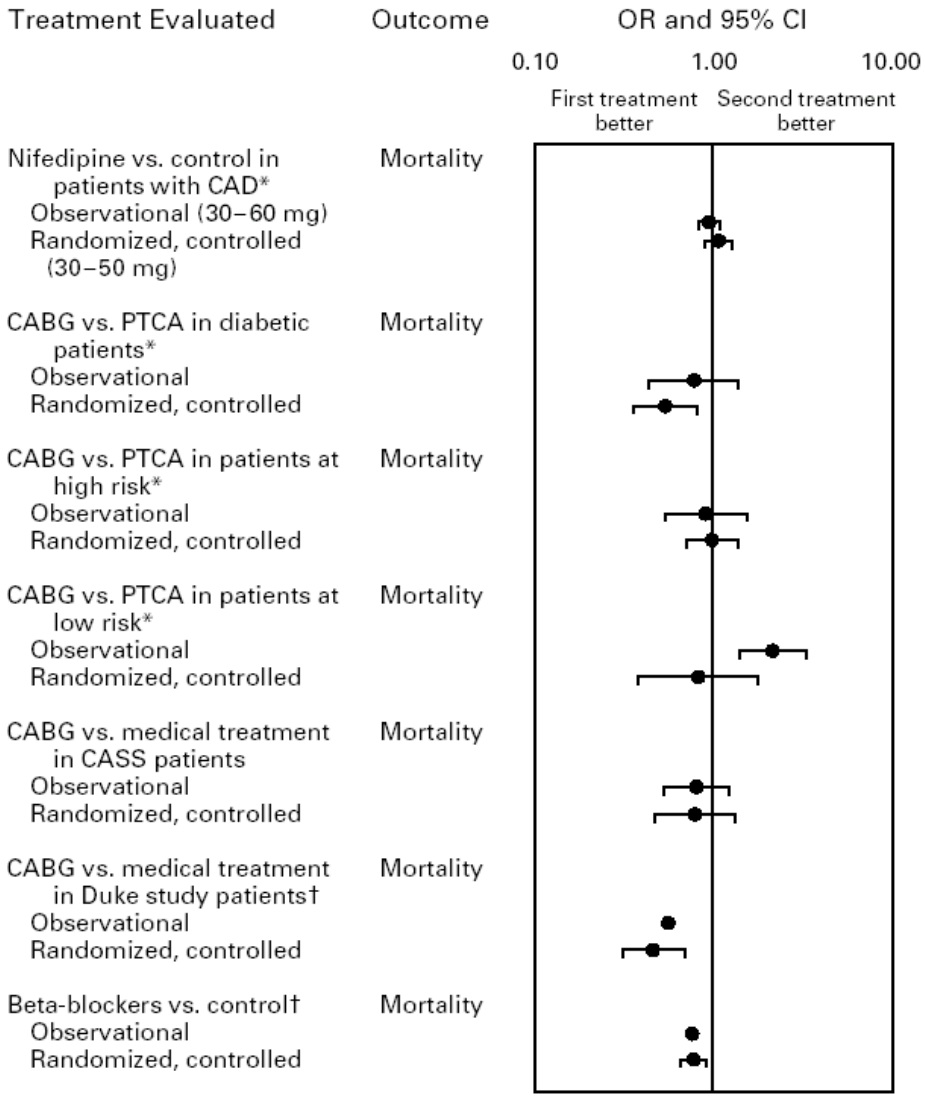

Figure 1. Results of Observational Studies and Randomized, Controlled Trials of Cardiologic Treatments.

The figure is based on data from eight articles.[13-20] Some articles contain data from more than one study. OR denotes odds ratio, CI confidence interval, CAD coronary artery disease, CABG coronary-artery bypass graft surgery, PTCA percutaneous transluminal coronary angioplasty, CASS Coronary Artery Surgery Study, and Duke the Duke University Cardiovascular Disease Databank. Asterisks indicate studies that reported relative risks rather than odds ratios. Daggers indicate studies that reported neither a confidence interval nor a P value for the odds ratio.

Details needed for good observational studies

- Results of diagnostic tests
  - laboratory tests
  - diagnostic imaging
- Diagnoses
- Disease severity measures
- Treatments administered
- Outcomes

With good observational databases, can gain unique insights

TABLE 5. RISK OF DEATH FROM HEART DISEASE AND OF ANY HEART DISEASE EVENT IN RELATION TO THE HOSPITAL ANGIOGRAPHY RATE BEFORE (MODEL I) AND AFTER (MODEL II) ADJUSTMENT FOR UNDERGOING ANGIOGRAPHY IN THE SUBGROUPS IN WHICH ANGIOGRAPHY WAS DEEMED NECESSARY OR NOT NECESSARY.*

OUTCOME	ANGIOGRAPHY NECESSARY	ANGIOGRAPHY NOT NECESSARY
	MODEL I	MODEL I
	hazard ratio (95% confidence interval)	
Death from heart disease		
Hospital with higher rate of angiography vs. one with lower rate	0.67 (0.40–1.12)	0.85 (0.59–1.21)
Angiography vs. no angiography	—	—
Any heart disease event		
Hospital with higher rate of angiography vs. one with lower rate	0.72 (0.54–0.95)	0.90 (0.72–1.17)
Angiography vs. no angiography	—	—

*Model I is a proportional-hazards model that includes age, sex, race, Charlson comorbidity score, congestive-heart-failure score, history of prior infarction, and type of hospital (higher rate of angiography vs. lower rate). Model II also includes the time-dependent covariate indicating whether the patient underwent angiography.

†P=0.09 for the comparison of the association of angiography with outcome between subgroups.

‡P<0.001 for the comparison of the association of angiography with outcome between subgroups.

Table 2. Incidence of Death or Acute Myocardial Infarction Among Patients With Acute Coronary Syndrome Medically Treated or Treated With Percutaneous Coronary Intervention (PCI) After Stopping Treatment With Clopidogrel

	Medically Treated Patients			PCI-Treated Patients		
	No. at Risk	No. of Events	Incidence Rate per 1000 Patient-Days (95% CI)	No. at Risk	No. of Events	Incidence Rate per 1000 Patient-Days (95% CI)
Period, d[a]						
0-90	1568	163	1.31 (1.12-1.53)	1569	73	0.57 (0.45-0.72)
91-180	1212	57	0.69 (0.53-0.89)	1279	29	0.33 (0.23-0.47)
181-270	582	26	0.64 (0.44-0.94)	630	8	0.19 (0.09-0.37)
271-360	363	5	0.19 (0.08-0.45)	366	5	0.18 (0.08-0.44)
361-450	238	8	0.46 (0.23-0.93)	237	4	0.24 (0.09-0.63)

Abbreviation: CI, confidence interval.
[a] There were 9 events and 5 events in the medically treated and PCI-treated groups, respectively, in the time interval of more than 450 days.

Promise of observational databases

- Complement to formal randomized trials
- Many more questions can be addressed
- Tie research more directly to quality improvement
- Rapid implementation
- Costs likely to fall