Distributed Data Networks
Brookings Institute
November 23, 2009

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Northwest | Hawaii | Southeast

Center for Health Research

- KP has established a Center for Effectiveness and Safety Research (CESR) which is intended to be a powerful partner to the Sentinel Initiative and other CER work.
- CESR is the front-door for SI.
- KP's CESR Steering Committee will set priorities for participation in studies and ground rules for our participation.

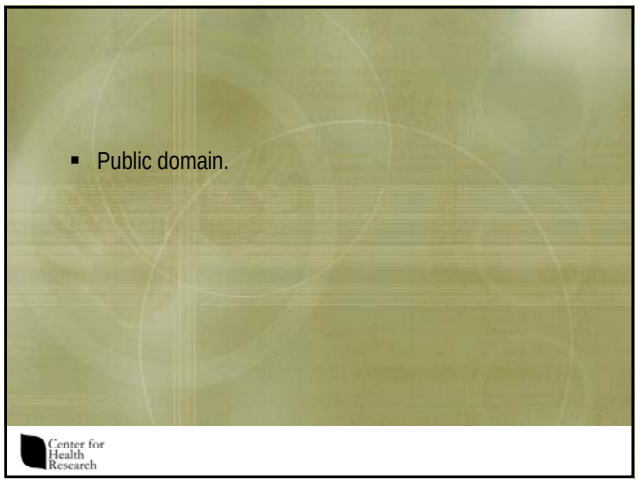
Center for Health Research

- The purpose of CESR is to present a more unified Kaiser face to the CER research/funding community while maintaining the success and autonomy of our regional research centers.
  - A federated data model with a VDW front-end.
  - OPT IN/OPT OUT.
  - Simplified IRB.
  - PrepTo Research (PTR).

Center for Health Research

- KP will not necessarily provide resources to conduct the actual research.

Center for Health Research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Knowledge as a By-Product of Care: Drug & Device Surveillance in Large Health Systems (Opportunities & Challenges)

Think Tank: Distributed Data Networks for Active Medical Product Surveillance

Engelberg Center for Health Care Reform

The Brookings Institution

Washington, DC – November 23, 2009

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Overview:

- Opportunities & Challenges
  - Technology
  - Business / Proprietary Interests
  - Privacy & Security
  - Clinical Practice
- Proof-of-Concept Examples
  - VA (Drug Surveillance, Blood Pressure Control & Blood Glucose)
  - HCA (Influenza Surveillance & H1N1Vaccines)
- Summary & Policy Points

Technology & Domain Challenges

Goal: Ability to share data as “transparent by-product of care”

- Challenges:
  - Variable standards for storing data and transmitting data
  - Where electronic, different representation of same clinical between/within organizations (e.g., lack of semantic interoperability)
    - Domain complexity (conceptual complexity) contributes to IT complexity
  - Encoding of use patterns incomplete
    - Usually have med start & stop and allergies, but not . . .
      - Non-allergy reason for stopping medication
      - Consistent documentation of patient response
      - Genetic information or other molecular bio-markers
  - No monolithic “master database”
    - Data are distributed in multiple data sets, in multiple organizations
      - Some resident at organization, some outside (e.g., PBM, pharmacy, etc.)
    - Most care in small practices; most hospitals independent or small systems

Technology & Domain Challenges

Goal: Ability to share data as “transparent by-product of care”

- Opportunities:
  - Use HITECH as organizing principle for data requirements
    - “Meaningful Use” interoperability requirements to drive semantic interoperability
    - ePrescribing requirements extend trail of data across organizations
  - Larger systems, federations may be more wired, thus good starting point
    - Offer capacity to address urgent issues (i.e., novel H1N1 flu or vaccine)
  - Create incentives to drive drug/device database development and/or data submission
    - Opportunities for exploration of public data sets for business development?
      - Opportunities for “first use” or new use
      - Mandate for reporting of adverse events at earliest detection
        - » May require analytic algorithms
  - Attach data requirements to FDA “Expanded Access” programs

Business / Proprietary Interests

Goal: Participation by private-sector health care community

- Challenges:
  - Necessary data are typically not produced for routine operations
    - Necessitates changing clinical data capture process (real costs)
    - Necessitates developing, aggregating databases (real costs)
  - Data have inherent value; unrealistic to expect health providers to pay to compete against own financial interests
    - Hospital/health systems may be developing datasets for research use or as productive asset for business with pharma, device, investors, etc.
- Opportunities:
  - Use HITECH to reduce financial barriers (e.g., reward participation)
  - Provide or subsidize software to support desired data development
  - Reward participants through positive recognition
  - Link participation to CMS program participation or “bonuses”

Privacy & Security

Goal: Maintaining Privacy & Security of PHI

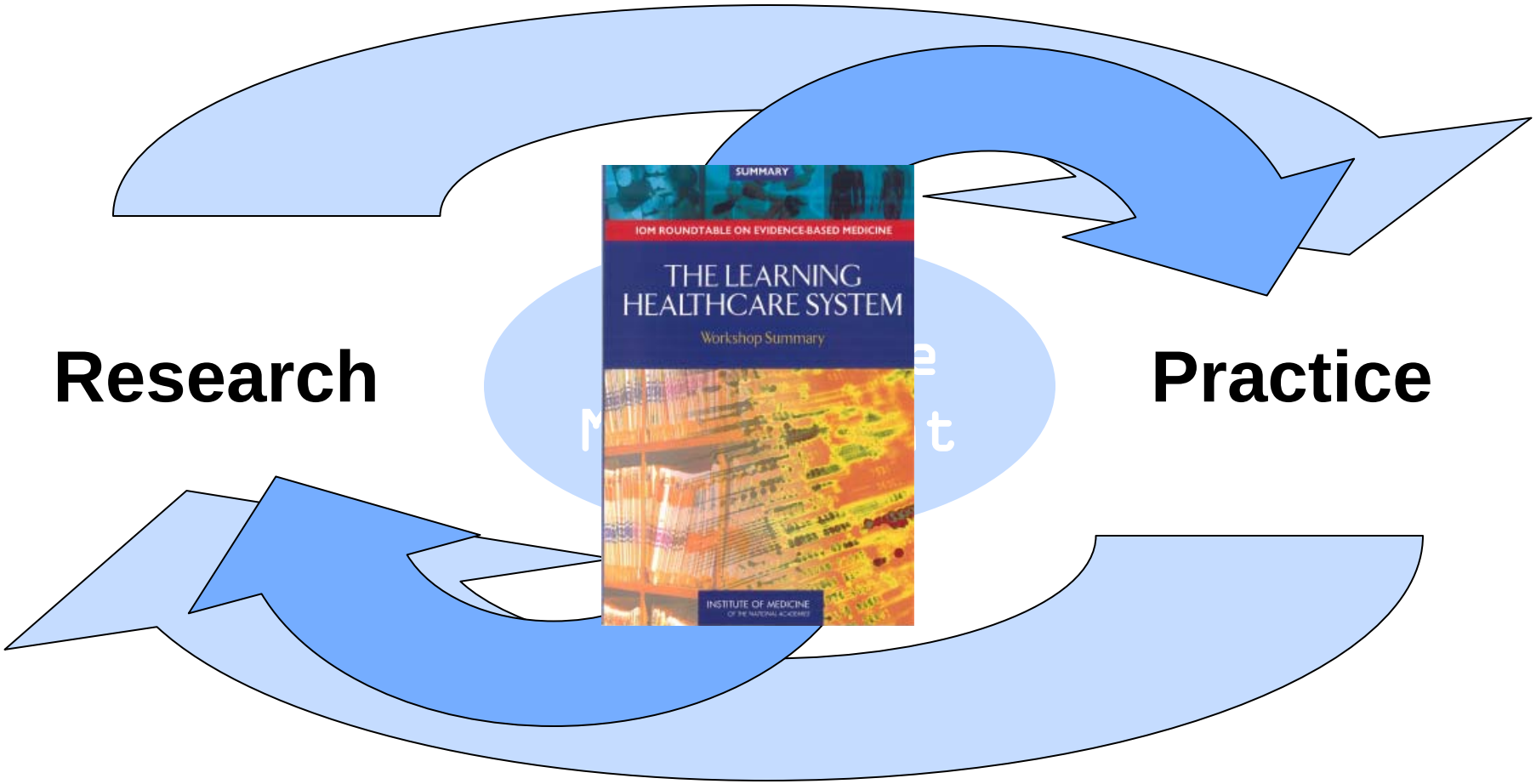
- Challenges:
  - HIPAA compliance
  - Liability of data aggregation
    - Database loss is larger threat
  - Cost of de-identification, potential need to create a data replicate
  - Public perception about personal data use & privacy
- Opportunities:
  - Simplification of Business Associate Agreement for this purpose
  - Provision of de-identification standards, software
  - Education that de-identified data is a public good

Clinical Practice

Goal: Clinicians don't see surveillance as professional obligation

- Challenges:
  - Currently, drug (device) safety is perceived responsibility of FDA
    - Obligation to safe drug/device use around prescription, adverse events
    - Detailed recording of effectiveness & reason for stopping is not routine
  - Drug use not consistently associated with bio-markers, certainly not molecular bio-markers
    - While physiologic markers for hypertension control evident, biomarkers for who may be most/least responsive to particular antihypertensive neither clear, nor routine
- Opportunities:
  - Education: Prescriptive privileges obligate activity beyond Rx
  - Reimbursement for "prescription" visits, calls (CMS)
  - Partnership with NIH (NCI, NHGRI, etc.) to advance biomarker associations

New Knowledge as a Transparent By-Product of Care: *From "TRIP" (Translating Research into Practice) to "TPIR" (Translating Practice into Research)*

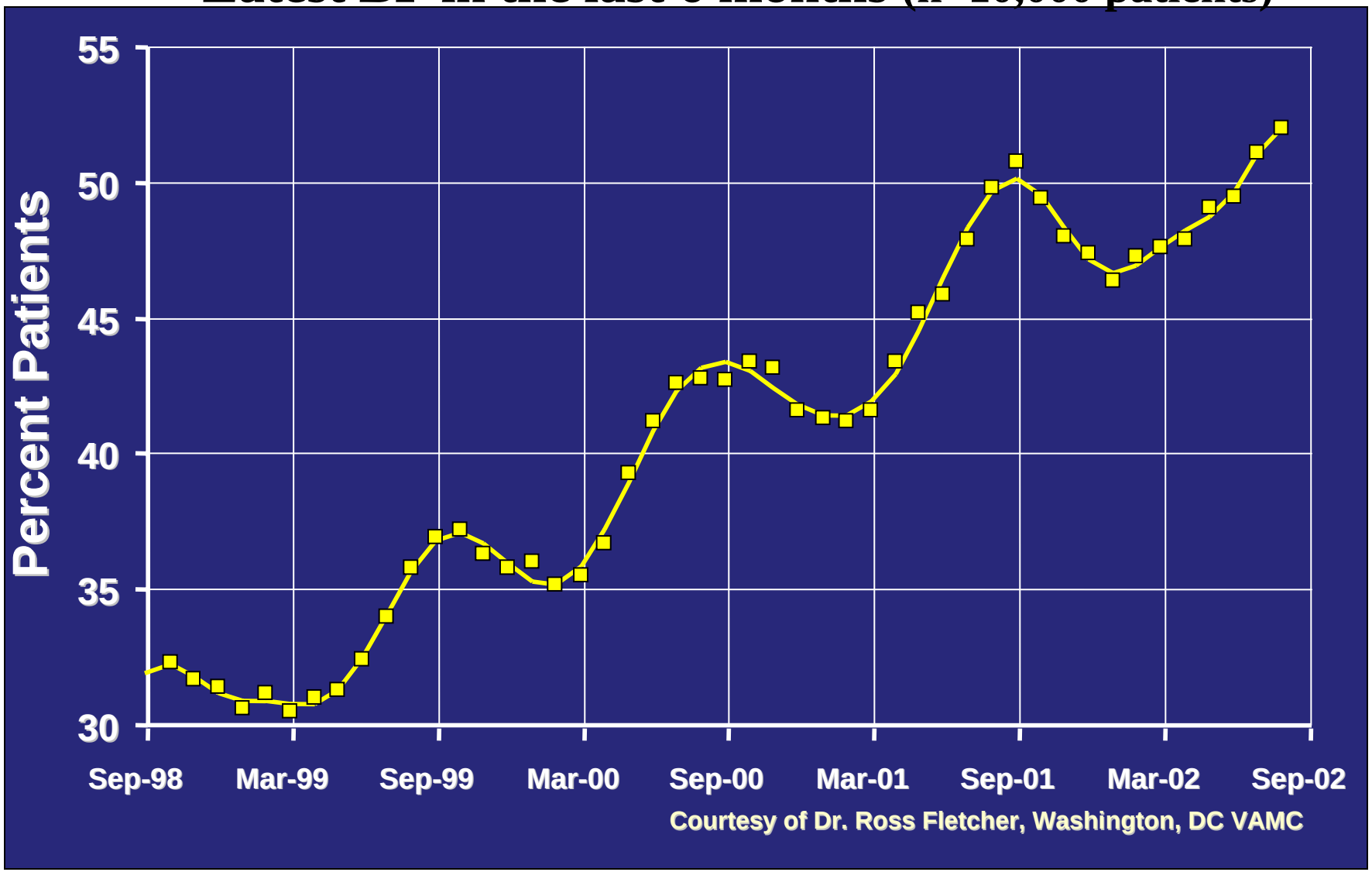


VA Experience in Post-Marketing Surveillance

- Trovan® (Trovafloxicin) – hepatotoxicity
  - Early data in VA
- Atypical Antipsychotics – weight gain, hyperglycemia, diabetes
  - Early data in VA
- Baycol® (Cerivastatin) – rhabdomyolysis
  - Reported in DoD data; not added to VA formulary

Discovery: Seasonal Variation in Blood Pressure of Hypertensive Patients Returning to < 140 / < 90

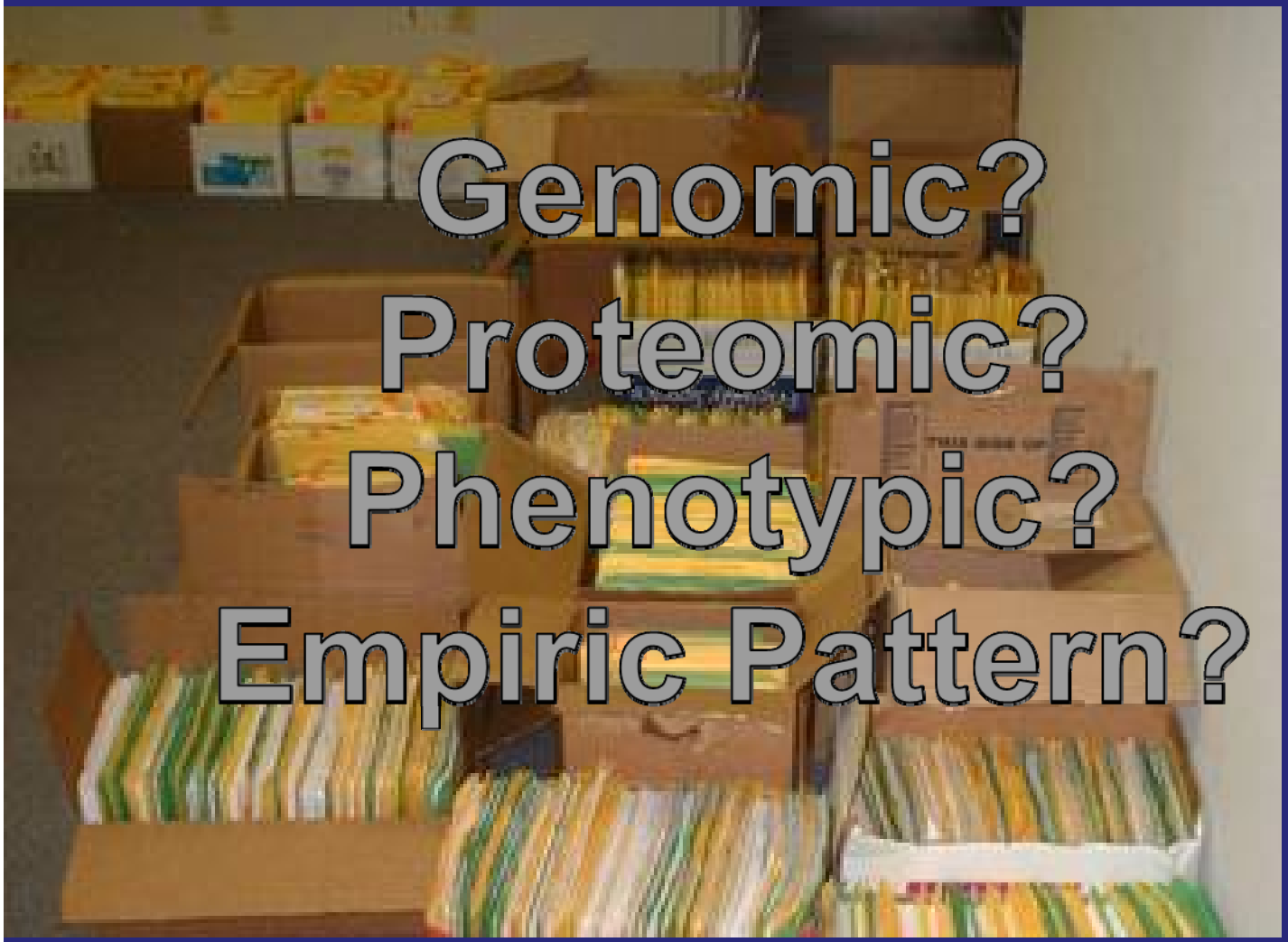
Latest BP in the last 6 months (n=10,000 patients)

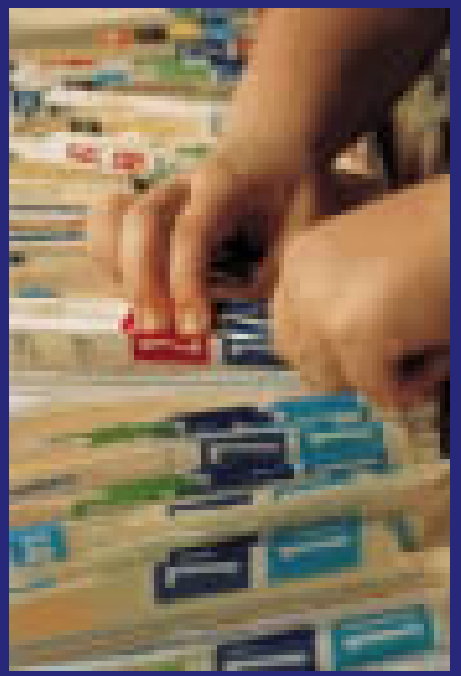


Any Differences Between Panels (Patients)?

1) None, 2) One to Two, 3) Three to Four, 4) Five or more

Challenge One: Pattern Recognition Here ?

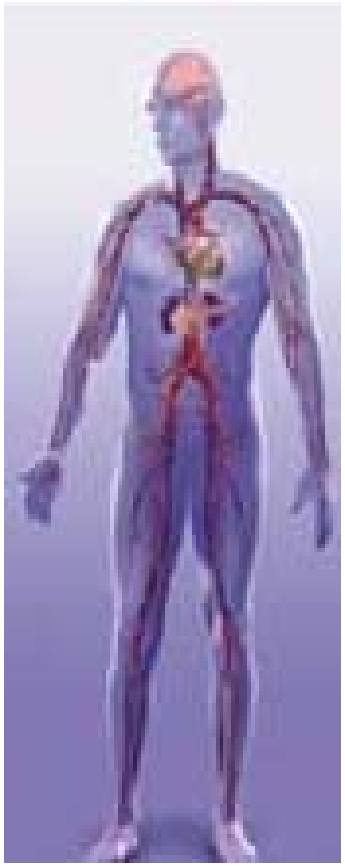




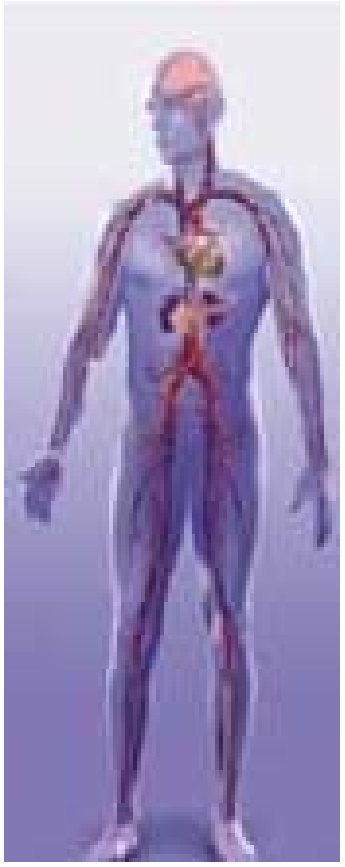
Lazarus List

- CTX + B6

Applying the Evidence



- Two ICU Patients
  - Both Hyperglycemic
    - BG > 300 mg/dl
  - One: Diabetic
  - One: No Prior Diagnosis of DM
- Who is at greater risk?
  - Could do a RCT
    - Practical?
    - Ethical?
    - Timely?



Adjusted Odds Ratios for Mortality (2002-05) in VA ICU's

Mean Glucose is Independently Associated with Increased Mortality

	Odds Ratio (95% CI)			
	Mean Glucose (mg/dl)			
	111-145	146-199	200-300	> 300
Entire cohort	1.3 (1.2-1.3)	1.7 (1.6-1.8)	2.0 (1.9-2.1)	2.6 (2.3-2.9)
No DM	1.3 (1.2-1.4)	1.9 (1.8-2.0)	2.7 (2.4-2.9)	3.8 (3.1-4.6)
+ DM	1.1 (1.0-1.3)	1.4 (1.2-1.6)	1.8 (1.5-2.0)	2.4 (2.0-2.9)

HCA Represents Approximately 5% of Inpatient Services in the US

Admission Category	HCA	National	HCA as % of National
Deliveries	220,221	4.3M	5.12%
Inpatient Cardiac Cath	26,691	490,285	5.44%
CABG	12,518	266,072	4.70%
CHF	44,775	1,012,404	4.42%
Joint Replacement	31,128	504,686	6.17%
Total Inpatients	1,765,704	37,067,877	4.76%

*12 Months ending June 30, 2006.

Centers for Disease Control and Prevention

- In May 2009, 11 healthcare industry representatives were asked to participate in the Influenza Medical Surge Group
- HCA was asked by the CDC to share information on influenza
  - 14,000-16,000 daily ED visits (>18,000/day with novel H1N1)
  - 1,300 daily influenza tests (since 9/09)
- Working with CDC leadership, the following daily reports were requested:
  - Emergency Department total visits by age group
  - Emergency Department influenza visits by age group
  - Rapid influenza tests performed with results
  - 2009 H1N1 tests performed with results

Centers for Disease Control and Prevention

- Emergency department data elements
  - Date of visit
  - Zip code of emergency department
  - Patients age in years (0-4, 5-24, 25-49, 50-64, >65)
  - Number of emergency department patients
  - Number of patients with influenza like illness (ILI)
    - Defined by fever >100°F, with cough and/or sore throat

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		AgeGrp1 0-4 Yrs		AgeGrp2 5-24 Yrs		AgeGrp3 25-49 Yrs		AgeGrp4 50-64 Yrs	
ER Arrival Date	Facility Zip	Patients In ER	Patients with ILI Symptoms	Patients In ER	Patients with ILI Symptoms	Patients In ER	Patients with ILI Symptoms	Patients In ER	Patients with ILI Symptoms
11/4/2009	[redacted]	7	1	24	1	42	3	7	0
11/4/2009		5	3	14	4	25	1	6	0
11/4/2009		4	1	18	8	25	6	10	0
11/4/2009		1	0	19	0	23	4	6	0
11/4/2009		15	5	25	6	37	6	17	0
11/4/2009		44	23	79	14	90	7	27	4
11/4/2009		10	3	37	4	62	1	34	1
11/4/2009		5	1	22	2	36	1	7	0
11/4/2009		2	1	23	5	13	1	6	1
11/4/2009		4	2	10	2	25	0	17	1
11/4/2009		0	0	9	5	16	1	6	0
11/4/2009		5	2	12	2	12	1	6	0
11/4/2009		3	0	12	0	7	0	3	0
11/4/2009		29	6	36	1	41	2	14	0
11/4/2009		6	0	22	0	32	0	8	0
11/4/2009		28	4	29	1	9	0	0	0
11/4/2009		5	0	13	0	20	0	4	0
11/4/2009		8	2	22	1	34	1	8	0
11/4/2009		11	0	29	1	40	0	19	0
11/4/2009		5	2	12	0	21	0	6	0
11/4/2009		4	0	34	1	59	1	23	0
11/4/2009		1	0	4	0	11	1	6	0
11/4/2009		4	1	13	1	23	2	6	0

Centers for Disease Control and Prevention

- Laboratory data elements
  - Date of laboratory test
  - Zip code of hospital laboratory
  - Rapid influenza tests ordered
  - Rapid influenza tests positive
  - Rapid influenza tests negative
  - 2009 H1N1 tests ordered
  - 2009 H1N1 tests positive
  - 2009 H1N1 tests negative

Centers for Disease Control and Prevention

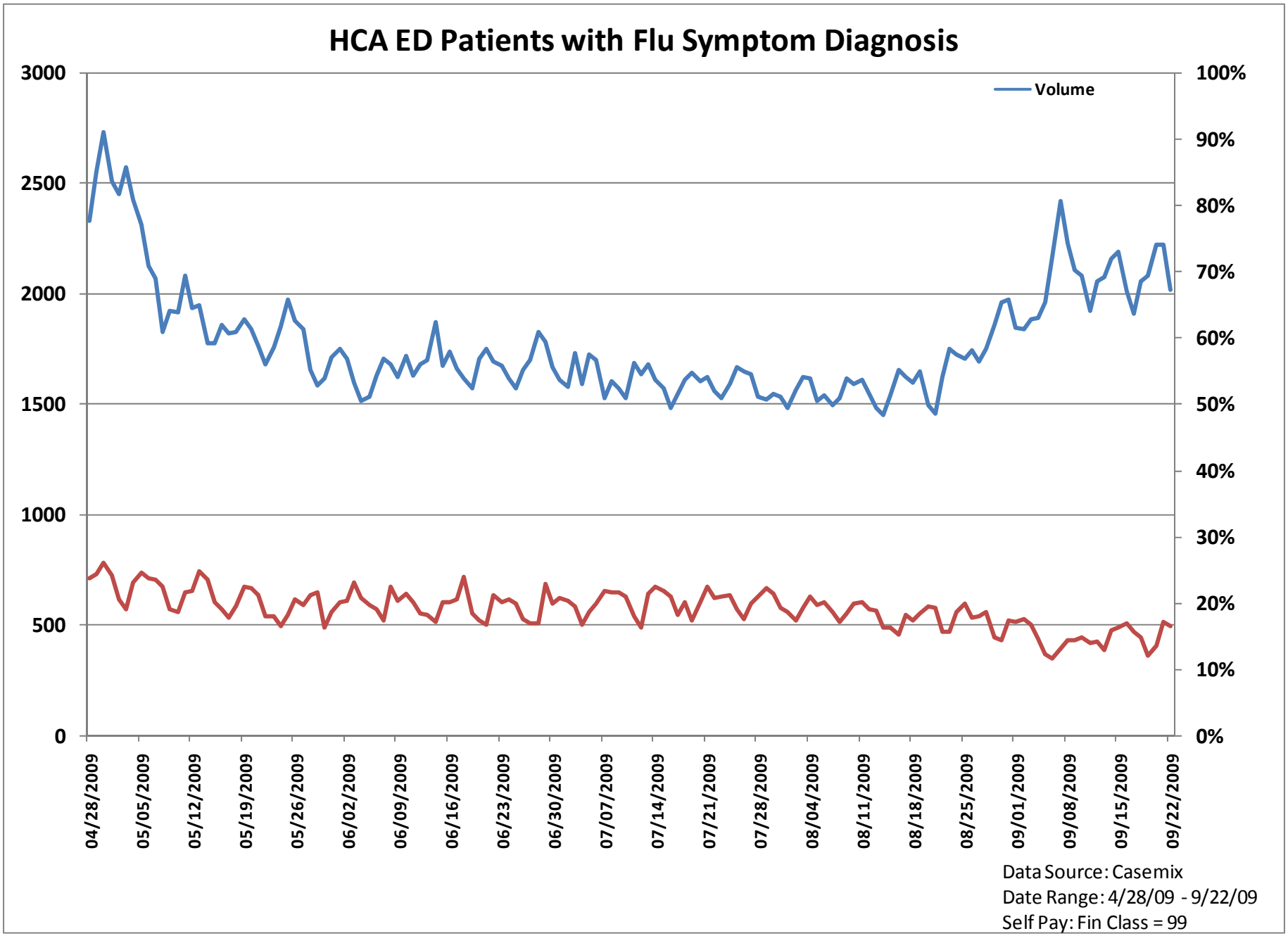
Date	facility zip	Influ A Rapid Tests Ordered	Influ A Rapid Tests Positive	Influ A Rapid Tests Negative	H1N12009 Confirm Tests Ordered	H1N12009 Confirm Tests Positive	H1N12009 Confirm Tests Negative
11/4/2009	[redacted]	24	0	24	0	0	0
11/4/2009	[redacted]	35	5	32	0	0	0
11/4/2009	[redacted]	2	0	2	0	0	0
11/4/2009	[redacted]	1	1	0	3	3	0
11/4/2009	[redacted]	24	2	21	0	0	0
11/4/2009	[redacted]	0	0	0	0	0	0
11/4/2009	[redacted]	0	0	0	0	0	0
11/4/2009	[redacted]	0	0	0	0	0	0
11/4/2009	[redacted]	4	1	4	0	0	0
11/4/2009	[redacted]	6	1	5	0	0	0
11/4/2009	[redacted]	9	1	8	0	0	0
11/4/2009	[redacted]	14	1	13	0	0	0
11/4/2009	[redacted]	3	1	2	0	0	0
11/4/2009	[redacted]	13	0	12	0	0	2
11/4/2009	[redacted]	7	2	6	0	0	0
11/4/2009	[redacted]	28	1	28	0	0	0
11/4/2009	[redacted]	2	0	2	0	0	0
11/4/2009	[redacted]	8	1	7	0	0	0
11/4/2009	[redacted]	6	0	6	0	0	0
11/4/2009	[redacted]	1	0	1	0	0	0
11/4/2009	[redacted]	19	1	18	0	0	0
11/4/2009	[redacted]	6	0	5	0	0	0
11/4/2009	[redacted]	5	2	4	0	0	0
11/4/2009	[redacted]	2	0	3	0	0	0

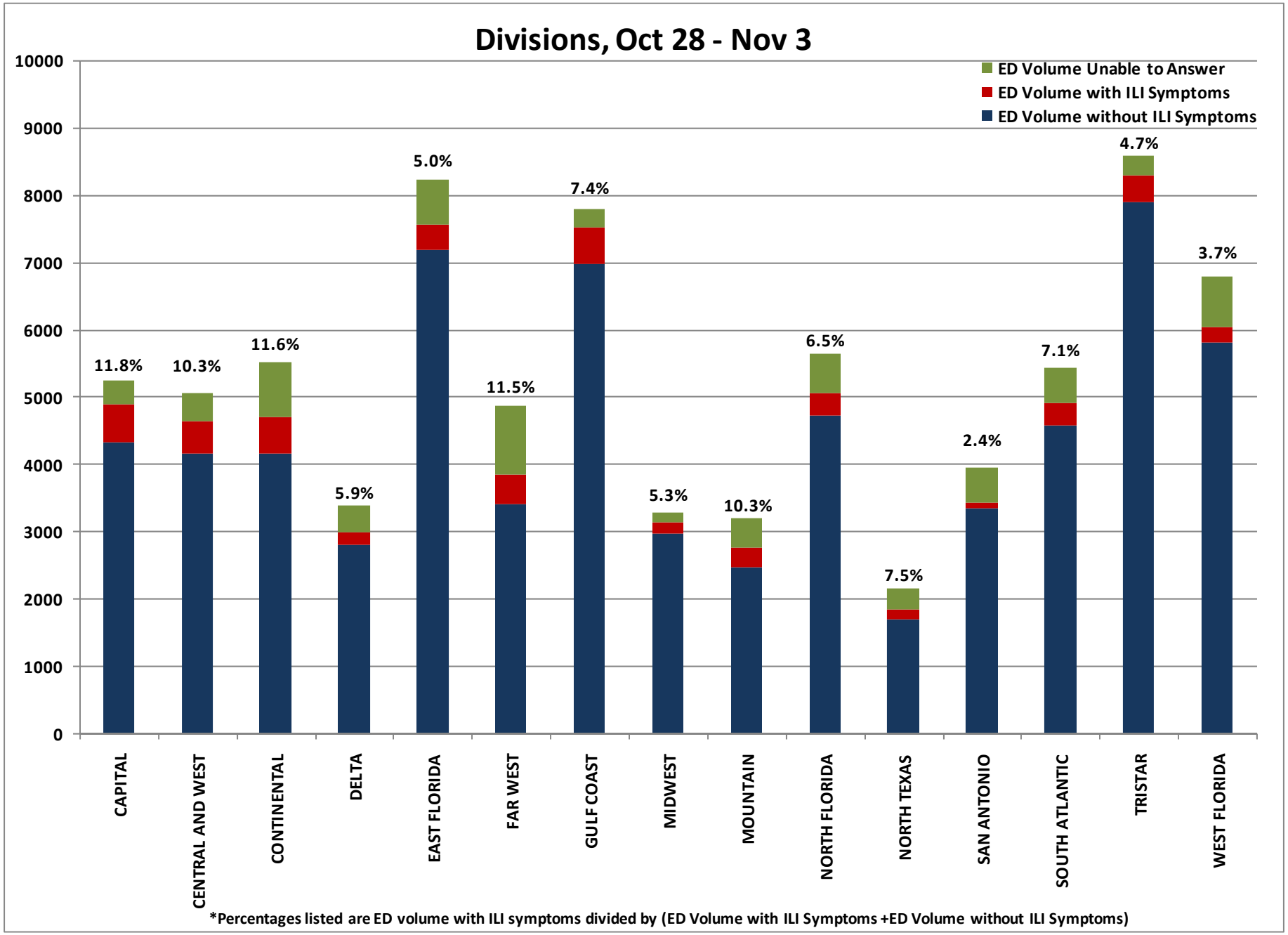
Centers for Disease Control and Prevention

- A Memorandum of Understanding (MOU) was developed for the collaboration
- The work required each hospital to make changes to their electronic record systems to standardize how information was entered and reported
- Work was completed in less than 2 weeks
- An inpatient report is currently under development

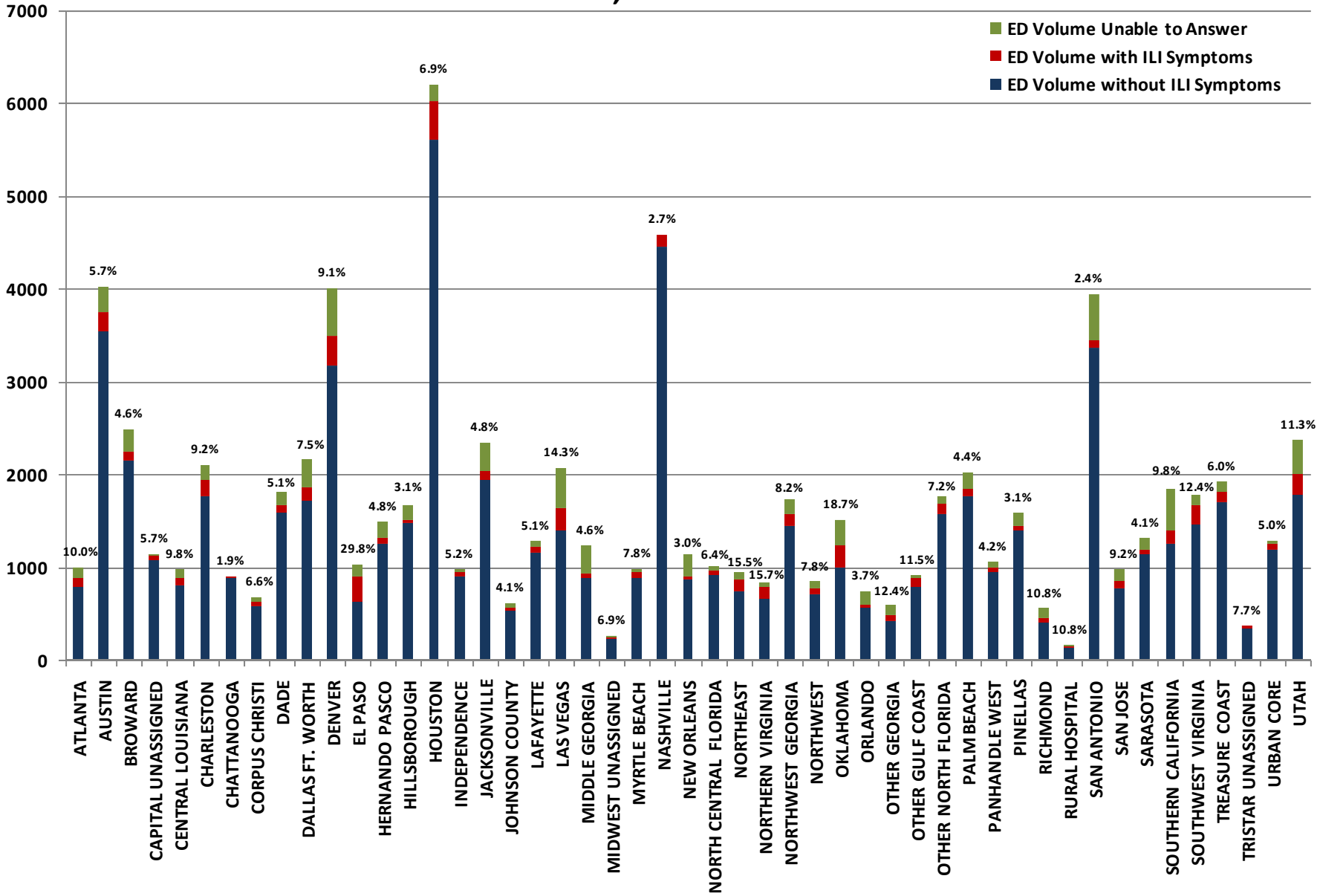
Centers for Disease Control and Prevention

- Reports are sent to the CDC 7 days a week
- CDC Weekly Influenza Report data lags 7-10 days
- HCA data is current within 48 hours
- Data is utilized by HCA Management Team to for resource allocation, staffing assistance, and pandemic management


HCA ED Patients with Flu Symptom Diagnosis
Volume
3000
2500
2000
1500
1000
500
0
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
04/28/2009
05/05/2009
05/12/2009
05/19/2009
05/26/2009
06/02/2009
06/09/2009
06/16/2009
06/23/2009
06/30/2009
07/07/2009
07/14/2009
07/21/2009
07/28/2009
08/04/2009
08/11/2009
08/18/2009
08/25/2009
09/01/2009
09/08/2009
09/15/2009
09/22/2009
Data Source: Casemix
Date Range: 4/28/09 - 9/22/09
Self Pay: Fin Class = 99


Divisions, Oct 28 - Nov 3
ED Volume Unable to Answer
ED Volume with ILI Symptoms
ED Volume without ILI Symptoms
10000
9000
8000
7000
6000
5000
4000
3000
2000
1000
0
11.8%
10.3%
11.6%
5.9%
5.0%
11.5%
7.4%
5.3%
10.3%
6.5%
7.5%
2.4%
7.1%
4.7%
3.7%
CAPITAL
CENTRAL AND WEST
CONTINENTAL
DELTA
EAST FLORIDA
FAR WEST
GULF COAST
MIDWEST
MOUNTAIN
NORTH FLORIDA
NORTH TEXAS
SAN ANTONIO
SOUTH ATLANTIC
TRISTAR
WEST FLORIDA
*Percentages listed are ED volume with ILI symptoms divided by (ED Volume with ILI Symptoms +ED Volume without ILI Symptoms)

Markets, Oct 28 - Nov 3

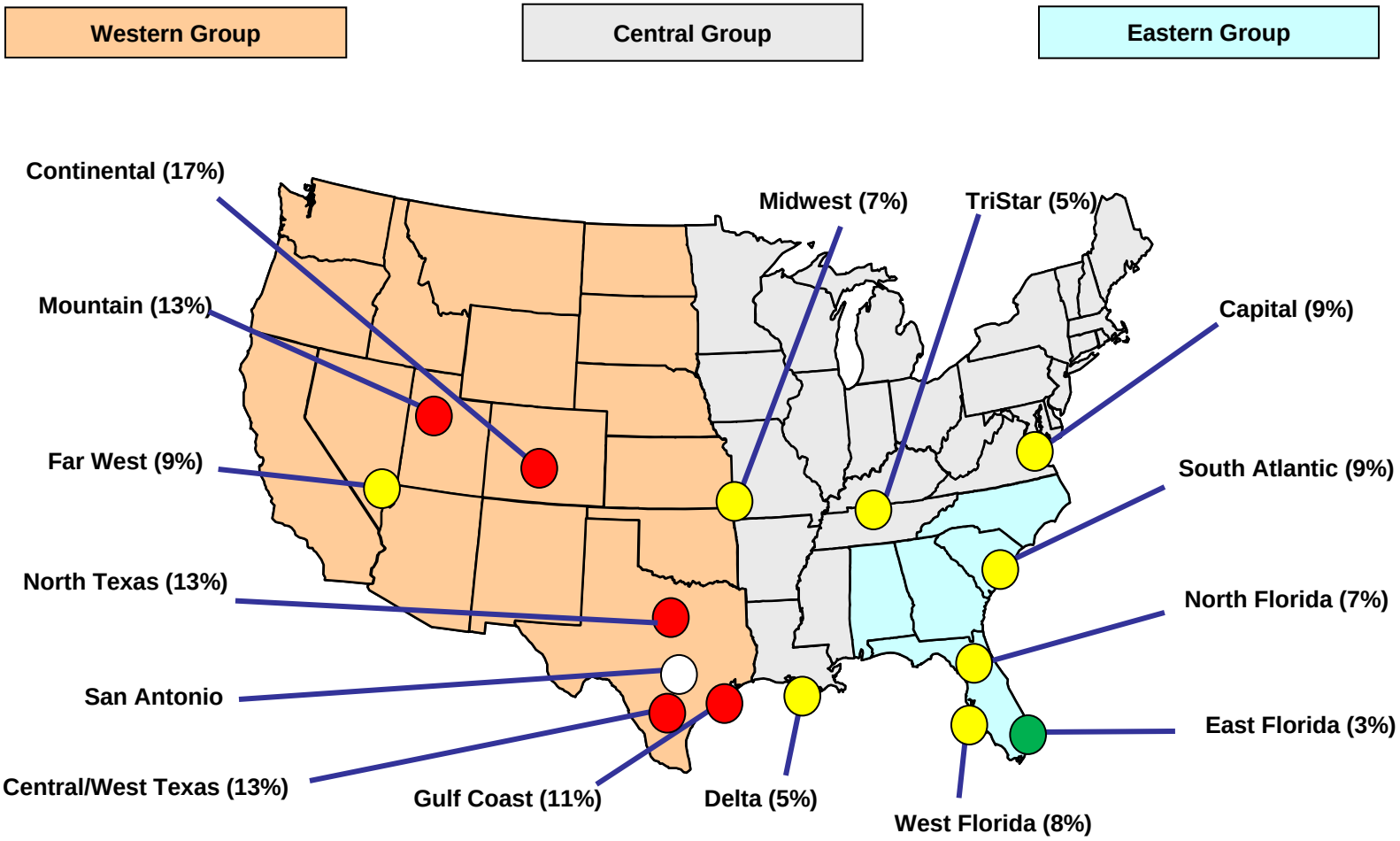


*Percentages listed are ED volume with ILI symptoms divided by (ED Volume with ILI Symptoms +ED Volume without ILI Symptoms)

HCA clinical services group

Surveillance

ILI ED Visits as Percentage of Total ED Volume, Oct. 7-13

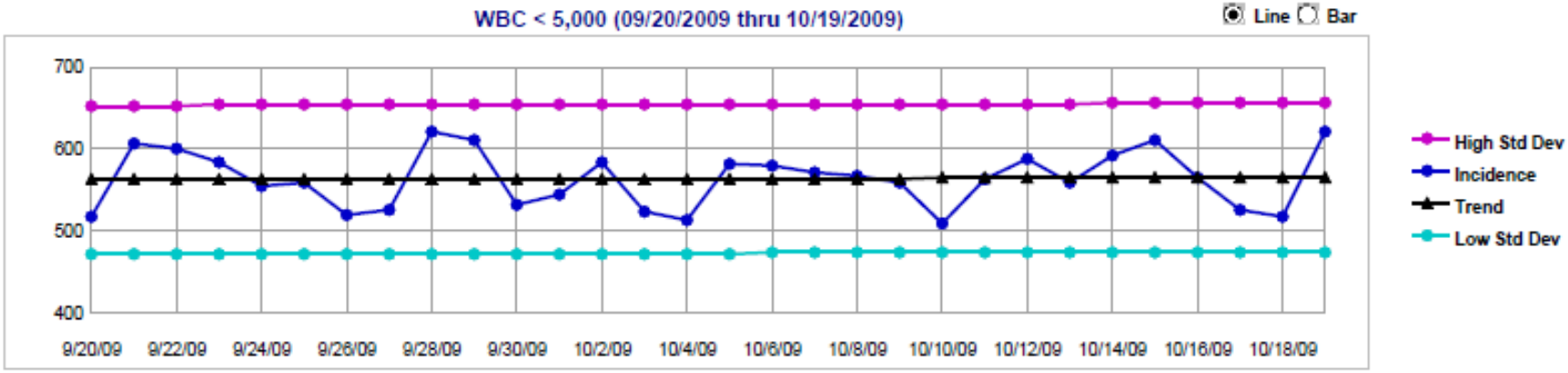


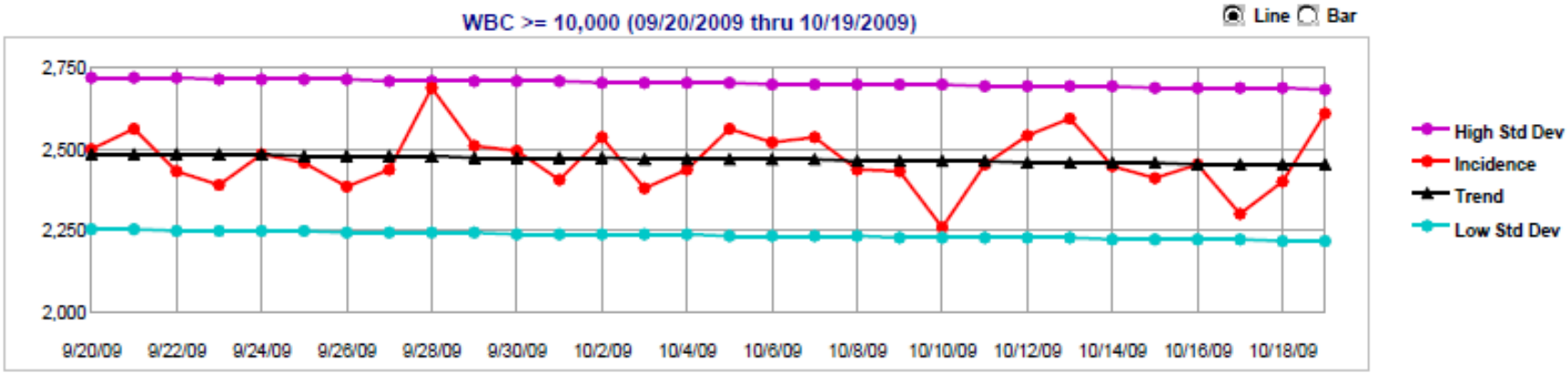
Green: Less than 5% of ED Visits are ILI patients
Yellow: 5-9 % of ED visits are ILI patients
Red: 10% or greater of ED visits are ILI patients
White: Division data excluded-lack of compliance
* Division data may be incomplete due to hospitals excluded from the data set due to lack of compliance

HCA clinical services group

Surveillance: WBC Tests

Organization	Start Date	End Date
HCA, INC.	09/20/2009	10/19/2009





Date	10/16/09	10/17/09	10/18/09	10/19/09
<5K	565	525	517	621
>=10K	2,453	2,303	2,402	2,608

HCA clinical services group

Policy & Concluding Points . . .

- Product Surveillance: Voluntary or mandatory?
  - If voluntary, are there incentives to offset cost and/or create the business case (including opportunity to benefit from discovery)

- Variety of Challenges & Opportunities:
  - Technology
  - Business & Proprietary Interests
  - Privacy & Security
  - Clinical Practice

  } None Insurmountable - All nuanced & complex; Requires "customer-friendly" approach

- There is a compelling national value proposition:
  - Opportunity for earlier detection of adverse events, new uses, utilization patterns & strategic investments

Distributed Data Networks for Active Medical Product Surveillance

Barriers and Solutions to Private Sector Participation in Active Surveillance Networks

23 November 2009

The company of specialists.

Overview

- i3 Drug Safety has been conducting medical product safety surveillance research projects for years
- We've worked closely with our parent company(ies) and legal counsel to address items pertaining to privacy, intellectual property, data transfer, and data ownership
- FDA's Sentinel Initiative, plus the changing regulatory environment, present some new challenges for potential private sector participants

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Policy: PHI and De-identification

- When possible, studies should be conducted using de-identified data
  - But for safety surveillance, dates are critical in establishing a temporal relationship between exposures and outcomes
- Pursuant to state and federal laws, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA), use of protected health information (PHI) in research studies is limited and subject to certain restrictions and protections
  - Need IRB or Privacy Board waiver or patient authorization
  - Use minimum amount necessary for the research
- PHI should not be transferred
  - Data would remain with each holder of the data
  - Each company would conduct its portion of the research behind its firewall
  - Results could be distributed

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Policy: PHI and De-identification

- We say 'distributed data networks' and work is done 'behind the firewalls' to mitigate privacy concerns
  - May need to share datasets
    - Datasets might be requested to validate analytic results (especially when regulatory action is impending)
    - Datasets might be requested to support combined analyses by the coordinating center of a multisite study
      - "… a cohort study may require extensive project-specific data transferred for analysis" (Defining and Evaluating Possible Database Models to Implement the Sentinel Initiative. US Food and Drug Administration; Contract No. HHSF223200831315P)
    - Any dataset transferred should be de-identified or a limited dataset
- Recommendation: More clarity around what we mean by a 'distributed data network' from a data transfer and data sharing perspective

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Policy: Changing Regulatory Environment

- American Recovery and Reinvestment Act of 2009 (ARRA) signed into law on 17 February 2009
- The Health Information Technology for Economic and Clinical Health Act (HITECH Act) was included as part of ARRA and imposes new requirements under HIPAA
  - New patient privacy rights
  - Breach notification
  - Guidance on the "minimum necessary" standard
  - Prohibitions on sale of PHI
  - Increased enforcement and penalties
- There may be additional guidance or regulations issued under ARRA with respect to the sale of PHI, marketing, minimum necessary, and de-identification
- Recommendation: Continued monitoring of changes. A formal review and interpretation relative to Sentinel Initiative database models used (to ensure compliance with changing privacy and security rules) would be helpful.

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Policy: Adverse Event Reportability

- 21 CFR 314.80 defines responsibilities for reporting postmarket adverse drug experiences
- What if a Sentinel Initiative project uncovers adverse events?
  - Are individual adverse events or aggregate safety issues identified through Sentinel Initiative research reportable under expedited safety reporting regulations?
  - What are the responsibilities of the data holder and their investigators to report adverse events? Who is obliged to report?
  - If not reported, are the data holder and their investigators liable if a significant public health issue is later uncovered?
- Recommendation: A formal review and interpretation of responsibilities of the data holder and their investigators relative to the reporting of adverse events would be helpful.

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Policy: Data Ownership

- Pursuant to state and federal laws, certain information provided to state or federal entities may be provided to the public upon request under the Freedom of Information Act (FOIA) or similar laws
- Data holders would want to protect their data from becoming publicly available or losing ownership rights to the data
  - If any data are transferred, is it owned if the analytic dataset was developed under performance of a contract?
  - Can data be used for purposes beyond the originally intended research?
  - How long are data retained?
  - What about mis-use of the data (due to lack of expertise or different motivation?)
- Recommendation: A formal review and interpretation of whether data used for the Sentinel Initiative may become publicly available would be helpful.
  - Whether provided to a federal entity (e.g. FDA) or to a coordinating center that may be subject to state laws (e.g. university),

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Economic

- Our business model includes consulting services and observational study design, execution, and reporting that often leverages our proprietary automated healthcare data. Will participation in Sentinel limit our revenue opportunities?
  - Current 'distributed data networks' implementation model frequently relegates all but 1 site/investigator to a 'data holder' role, limiting revenue opportunities for the other participating sites/investigators
  - Sentinel in the future: With 100 million+ subjects, would commercial companies even need to run independent safety surveillance studies using automated healthcare data?

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Economic

- Our business has invested heavily
  - Building and maintaining a data warehouse for research purposes
  - Hardware, and proprietary software, to optimize using the data warehouse for research purposes
  - Substantial IP (tools and algorithms) developed
  - Thought leaders who are expert in conducting pharmacoepidemiologic research that leverages automated healthcare data resources
- Public perception of commercial firm bias serves as a barrier for the Sentinel Initiative to leverage these private investments
  - This may limit the ability for substantial private sector participation in active medical product surveillance
  - Evidence that public may favor 're-inventing the wheel' (this may not be the best use of public funds)

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Economic

- Concerns about losing IP may serve as a barrier to some private sector participants
- Internal processes to develop and maintain methods to ensure compliance with privacy regulations adds cost and time both from an overhead perspective, but also to conduct specific research studies
  - Data holders may take a conservative stance, limiting their participation or what they make available externally to ensure compliance
- Recommendations: Business model may need to change. Leverage available private sector expertise to optimize the development and maintenance of Sentinel.

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Questions?

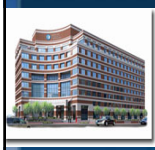
Barriers and Solutions to Private Sector Participation:
NCDR Perspective

November 23, 2009

Janet Wright, MD FACC
Sr Vice President Science and Quality
American College of Cardiology

NCDR Overview

American College of Cardiology Mission:



"… to foster optimal cardiovascular care and disease prevention through professional education, promotion of research, leadership in the development of standards and guidelines and the formulation of health care policy."

NCDR™ mission is to:

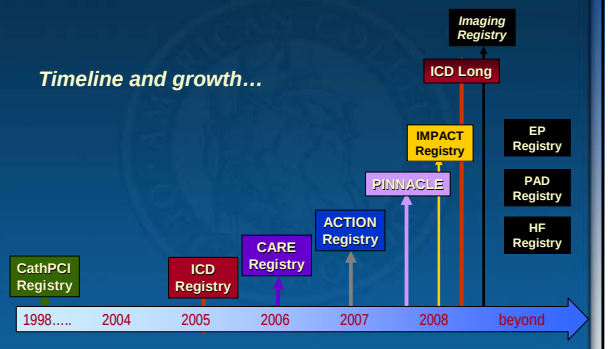
"… to improve the quality of cardiovascular patient care by providing information, knowledge and tools; implementing quality initiatives; and supporting research that improves patient care and outcomes.

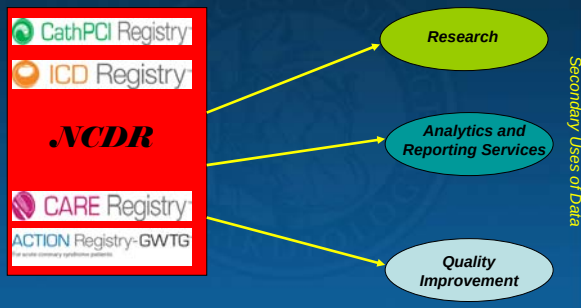
What is the NCDR?

- Suite of Clinical Registries
- 15 years in Evolution
- Benchmarks and Quality Improvement
  - Standardized, evidence-based data collection
  - Quarterly benchmark reports
- Supports P4P and Pay for Reporting Programs
- Platform for Outcomes Research
- Solution of Post-Market Surveillance
- Performance Measurement Tool

National Cardiovascular Data Registry

Timeline and growth…





NCDR and Post Market Surveillance

Post-Market Registry Goals

Medical Device Performance and Patient Outcomes

- Develop a network of hospitals and clinics
  - Careful sampling to reflect reference population
- Measure device performance and recall or remove devices that perform poorly
  - Provide a method to monitor real world application that preserves reasonable approval cycles but assures immediate removal when new problems may arise
  - Removal goal: No device should be on the market if an available alternative is superior
- Measure device efficacy/effectiveness
  - Confirm pre-market assumptions
  - Detect off-label trends to initiate new studies
- Detect new AEs and estimate known AE rates
  - Addresses long-term durability and effect concerns

Pre-Market

Post-Market

NCDR™ National Cardiovascular Data Registry

Phase 1	Phase 2	Phase 3	Phase 4: Post-Approval	Phase 4: Post-Market	Registries
• Safety is primary endpoint • Small sample Size (n < 20) • Highly selected population (must meet several selection criteria) • Short duration	• Safety and efficacy are primary endpoints • Limited sample size (n ~ 25-50) • Highly selected population • Short duration	• Safety and efficacy are primary endpoints • Larger sample size to test hypotheses (n ~ 150-250) • Selected population • Pivotal studies (randomized controlled trial, RCT) • Longer duration	• FDA driven and negotiated • Centers defined • Generally a Phase 3 continuance • Sample size pre-determined • Study interval defined	• Sponsor driven • Generally RCT or Claims based • Direct product comparisons • Costs collected • Sample size pre-determined • Study interval defined	• Collect product performance and safety data • Effectiveness is the primary endpoint • Hypothesis generating • Very large and usually undefined sample size • Real world population (no selection criteria beyond device, disease, or exposure) • Continuous duration • Treatment not assigned

Case Study: Hemostasis Device and Local Adverse Events

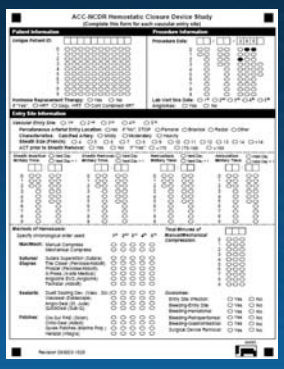
Issue

- **FDA reports in late '90s of serious injuries and deaths**
- **Gender?**

Process

- **Phase I- 214 hospitals; 2001**
- **>166,000 procedures… found HCDs to be protective against complications**

Tavris et al. , J Invasive Cardiol 2005; 17:644-650


ACC-NCDR Hemostatic Closure Device Study

- Developed and implemented new data collection form
  - Time to hemostasis
  - Time to ambulation
  - Sheath size
  - Methods of hemostasis
  - Other adverse outcomes
- Recruited among 150 sites in 2003
- 90 initially….59 sites completed
- Collected 1 quarters data…>13k procedures

Findings…

- Women had 2x risk of men for local complications… adjusted OR 1.73 "any vascular comp"
- VasoSeal demonstrated higher risk of "any vascular comp" compared to manual compression….

Risk of adverse events following PCI by type of hemostasis

Variable	Type Hemostasis	Odds Ratio	95%CI
Any Vascular Complication	Perclose	0.86	0.62-1.18
	VasoSeal	2.38	1.47-3.85
	Angio-Seal	0.99	0.77-1.28
	Chito-Seal	0.63	0.35-1.12
	Syvek Patch	1.10	0.66-1.83
	Mechanical Compression	0.84	0.59-1.18

Tavris et al. , J Invasive Cardiol 2005; 17:644-650

Vasoseal Taken Off Market !

EDITORIAL COMMENT

Arteriotomy Closure Devices—The FDA Perspective

Risk of local adverse events by gender following cardiac catheterization

A Original Contribution

Risk of Local Adverse Events following Cardiac Catheterization by Hemostasis Device Use — Phase II

Challenges/Solutions for Participation

Goals of Distributed Network-Active Surveillance

- Accuracy
- Acuity
- Efficiency
- Speed

……Clinical registries can be used as a component of an elegant system of event detection……

Challenges

- Accessing data from disparate sources
  - Lack of harmonization of data elements and definitions
    - CCHIT, NIH Roadmap, LOINC, etc
  - Lack of device bar coding to facilitate accuracy of data collection
  - Electronic medical records vs clinical registries- HIT conundrum
- Solution: Opportunity through this project to establish and **implement** standards

Challenges

- Legal issues accessing and using data
  - Hospitals own their own data
  - ACC owns aggregated data
- Solution: Only make available limited, de-identified dataset

Challenges

- Legal, privacy and security issues in tracking events across health care settings
  - De-identified patient level data. Difficult to re-identify for purposes of event tracking
    - State confidentiality laws growing issue
  - Privacy and security issues prevail
  - Balance between research and surveillance
- Solution: IRB review required if structured safety surveillance program

Challenges

- Analytical complexities in combining data
  - De-identified patient level data
  - Need to have same protocol
  - Appropriate statistical methods
- Solution: Use agreed upon probabilistic matching methods; Use same protocol for extracting data

Challenges

- Legal and Privacy complexities combining data sets
  - De-identified patient level data. Difficult to re-identify for purposes of event tracking
    - State confidentiality laws growing issue
  - Ownership of data at hospital level, not at professional society
- Solution: Establish firewall; Data must stay within it; PHI can't be shared

Challenges

- Flexibility in data capture
  - Web-based platform easier to capture data on new devices vs software vendors
    - CathPCI Registry 22 certified vendors... Can be done, but painful
- Solution: Implement extensible data collection fields to readily capture new devices, meds

Challenges

- Accuracy and adjudication of events
  - Validating events critical to assessing causality
  - Data quality varies
    - Clinical registries often focused on QI. Different standard of data quality than needed for PMS
- Solution: Relies upon achieving levels of data quality- completeness, consistency, and accuracy; Implementing data standards

Thank you

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Transforming Health Plan Raw Materials into Assets for Knowledge Generation

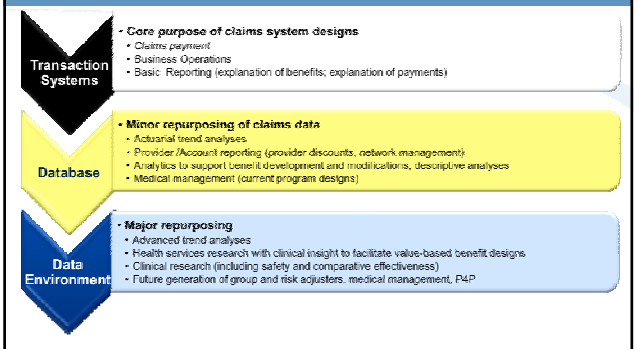
Marcus Wilson, Pharm.D.

November 23, 2009

Key Concerns

- Patient privacy and data security
- Accuracy

Expanding the Uses of Health Plan Electronic Data



Key Concerns

- Patient privacy and data security
- Accuracy
- Speed
- Liability
- Conflict of interest
- Disintermediation