

Starting a Successful Career in QCOR:

The Role of Health IT in Effective Cardiovascular Care Delivery and Research

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Tufts
UNIVERSITY

School of
Medicine



Health IT Impacts QCOR....

Everywhere

The End



Health IT Impacts QCOR...

- **Patient Care:**
 - Clinical Records (EHR)
 - Imaging – storage, distribution (PACS)
 - Clinical Decision Support (CDS)
 - Prescribing, communication, scheduling, billing
- **Population Health Management:**
 - Quality metrics – adherence, benchmarking
 - Levels: Physician, Practice, Hospital, System, Region
 - Measuring resource utilization, patient satisfaction
- **Health Outcomes Research:**
 - Outcomes measurement and associations
 - Comparative Effectiveness (CER, CEA)
 - Surveillance: Syndromic, Medication, Device Safety



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Clinical Decision Support Tools

The **NEW ENGLAND** **JOURNAL** *of* **MEDICINE**

ESTABLISHED IN 1812

MARCH 10, 2005

VOL. 352 NO. 10

Electronic Alerts to Prevent Venous Thromboembolism among Hospitalized Patients

Nils Kucher, M.D., Sophia Koo, M.D., Rene Quiroz, M.D., M.P.H., Joshua M. Cooper, M.D.,
Marilyn D. Paterno, B.S., Boris Soukonnikov, M.S., and Samuel Z. Goldhaber, M.D.

Study Design:

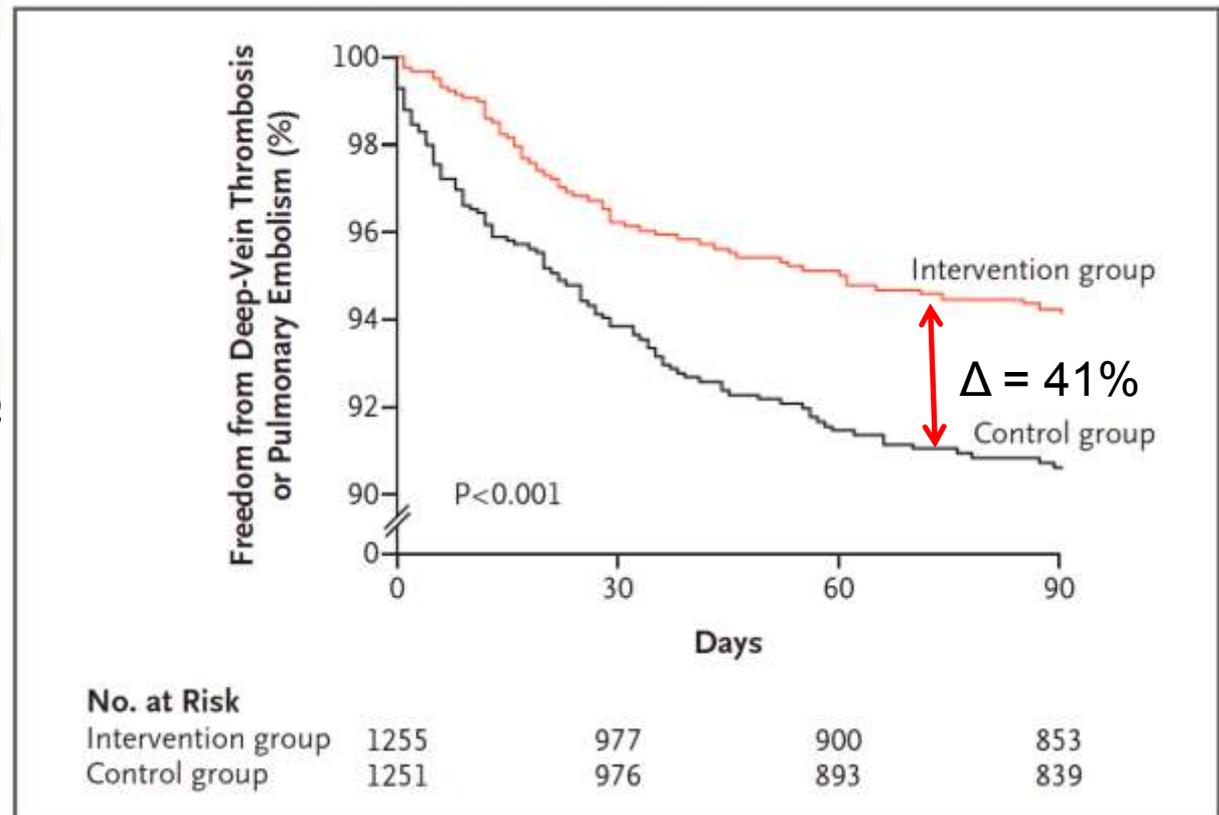
- Randomized interns to receive automated CDS messages regarding VTE prophylaxis for all hospitalized patients at increased risk for DVT or PE.
- Measured proportion of patients treated with prophylaxis as well as clinical events.
- Over 2,500 patients between 200-2005 included.



Clinical Decision Support Tools

Table 2. Prophylactic Measures against Venous Thromboembolism.

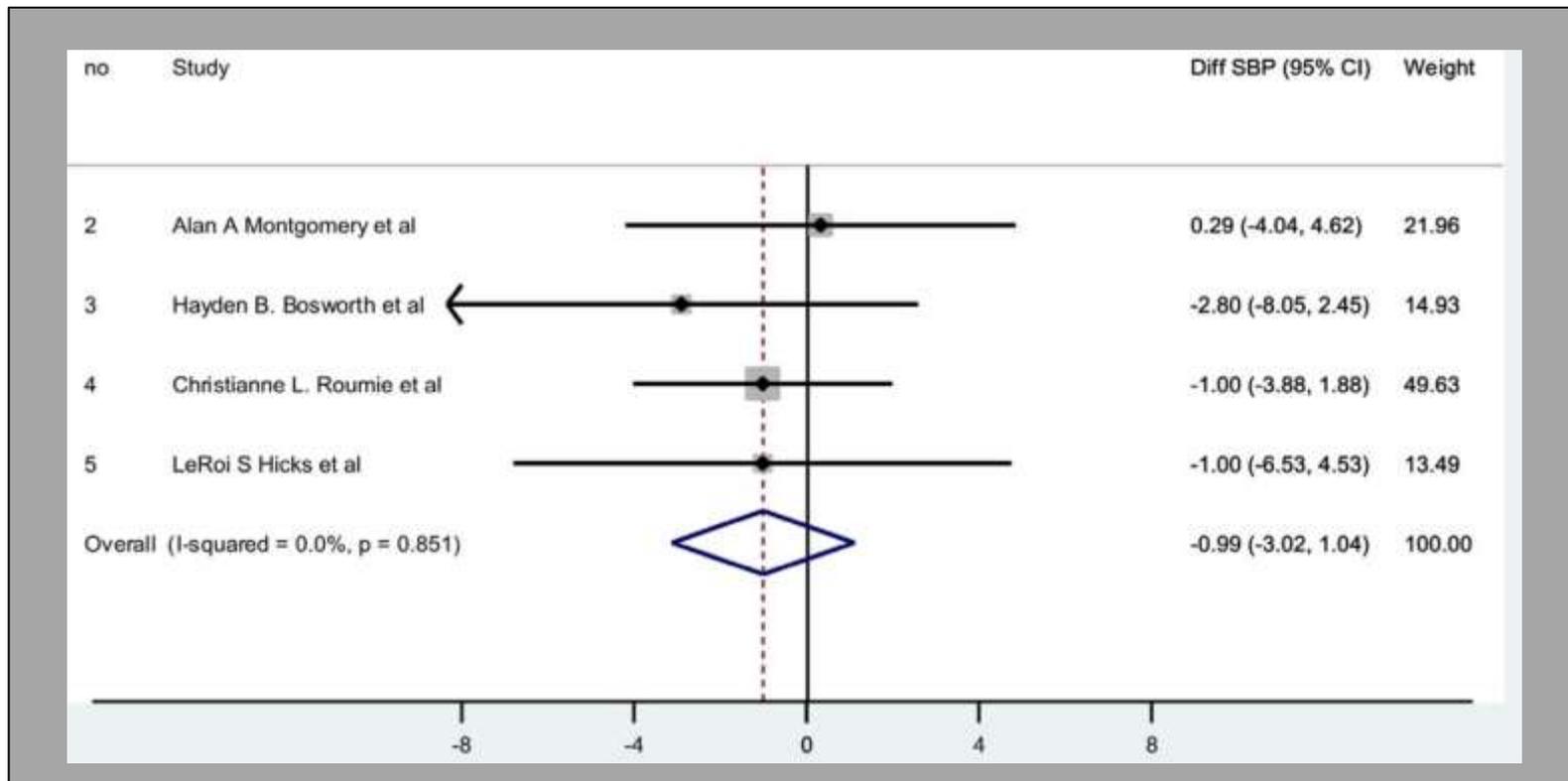
Measure	Intervention Group (N=1255) no. of patients (%)	Control Group (N=1251) no. of patients (%)	P Value
Mechanical			
Compression stockings			
Pneumatic boots			
Pharmacologic			
Unfractionated heparin			
Warfarin			
Enoxaparin			





Clinical Decision Support Tools

A recent meta-analysis of studies of CDS tools for control of BP demonstrated only a marginal trend toward improved BP control with CDS as compared with traditional clinical management.

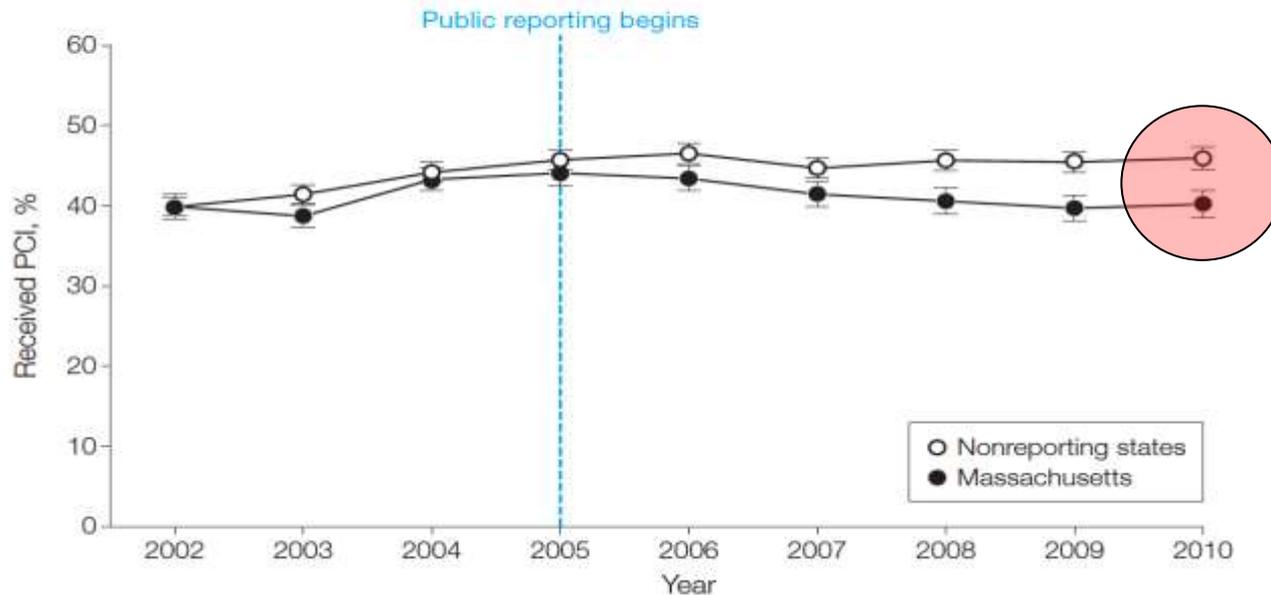




Population Health: Policy Impact

Association of Public Reporting for Percutaneous Coronary Intervention With Utilization and Outcomes Among Medicare Beneficiaries

Figure 1. Change in Rates of Percutaneous Coronary Intervention for Acute Myocardial Infarction After Public Reporting, Massachusetts vs Nonreporting States



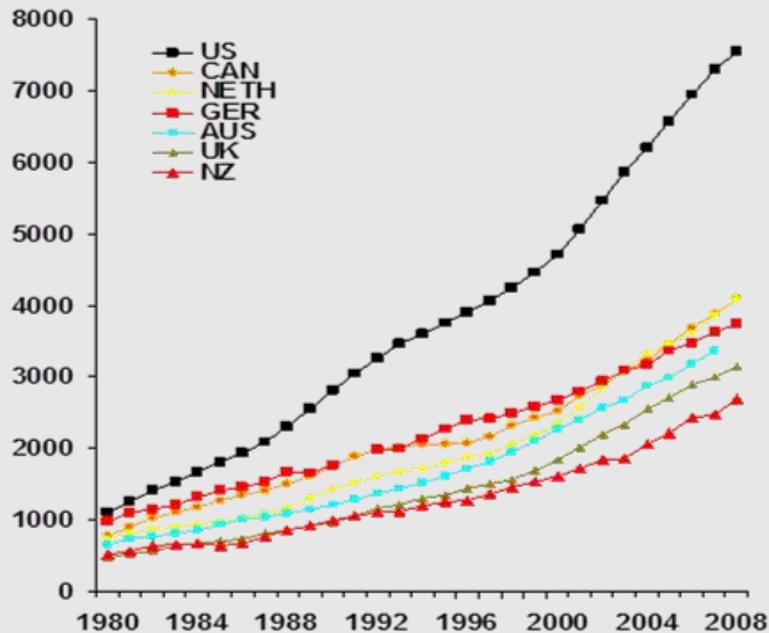
MI indicates myocardial infarction; PCI, percutaneous coronary intervention. Error bars indicate 95% CIs.



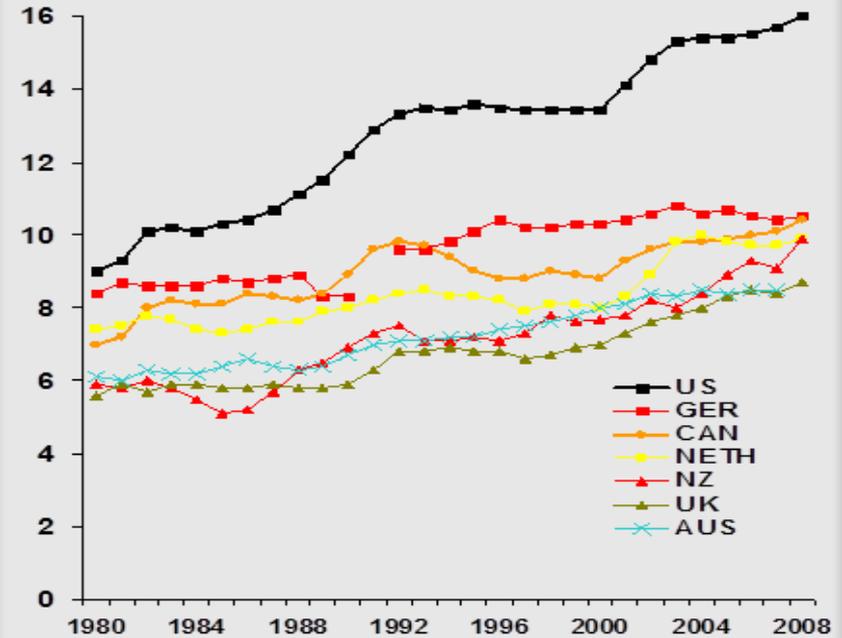
Population Health Studies: Reducing CV Readmissions

The U.S. spends substantially more on healthcare per capita, and as a percent of GDP than other developed nations.

Average Spending on Health per Capita (\$US PPP)¹



Total Expenditures on Health as Percent of GDP



Note (1): \$US PPP = purchasing power parity.

Source: Organization for Economic Cooperation and Development, *OECD Health Data 2010* (Paris: OECD, October 2010).



Population Health Studies: Reducing CV Readmissions

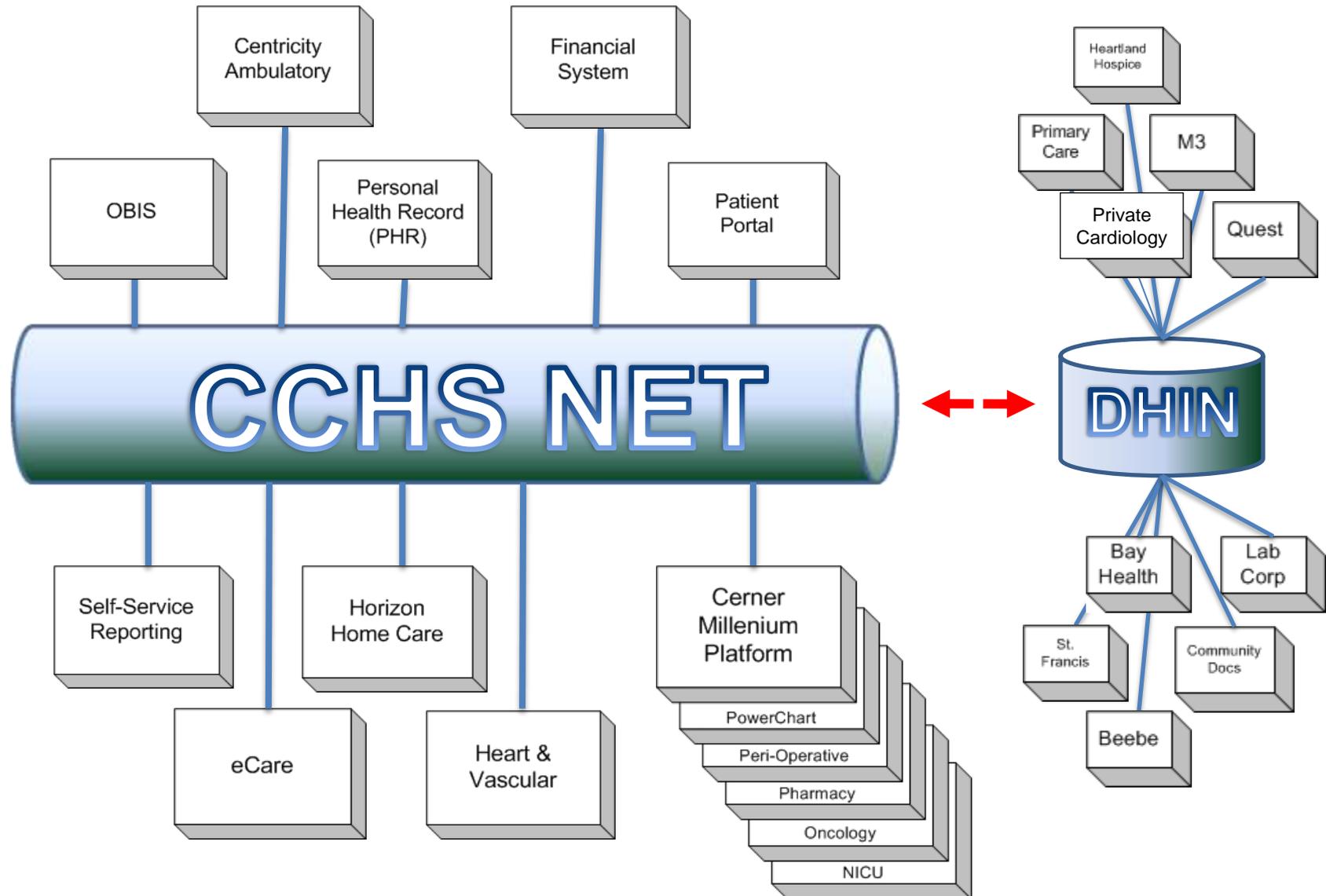
Led by Dr. William Weintraub, Christiana Care Health System (DE) was awarded a CMS contract to improve quality and reduce the cost of care following revascularization for CAD - The **Bridges** Program.

BRIDGING THE DIVIDE – ENROLLMENT AND EVALUATION

- **The Population:** Patients with acute myocardial infarction with PCI, CABG
- **Primary outcomes measures:**
 - **Health:** LDL cholesterol below 70 mg/dl, BP below 140/90
 - **Healthcare:** Reduction in readmissions to the hospital and ED visits
 - **Costs:** Reduction in 1 year costs after the initial hospitalization



Population Health Studies: Reducing CV Readmissions

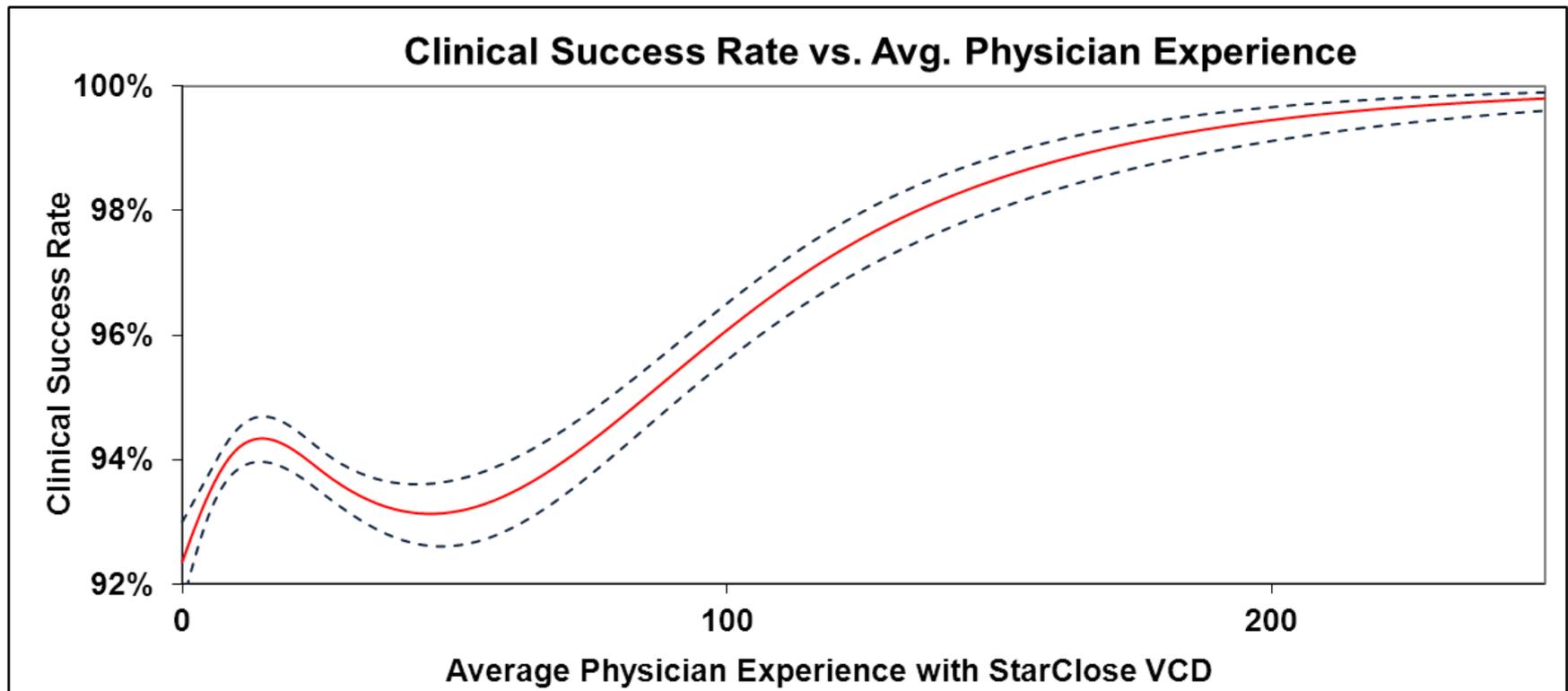




Registries for Methodology Development: Device Learning Curve

An evaluation of 107,000 consecutive new VCD deployments in the national NCDR CathPCI dataset demonstrates a clear learning curve in the use of these devices.

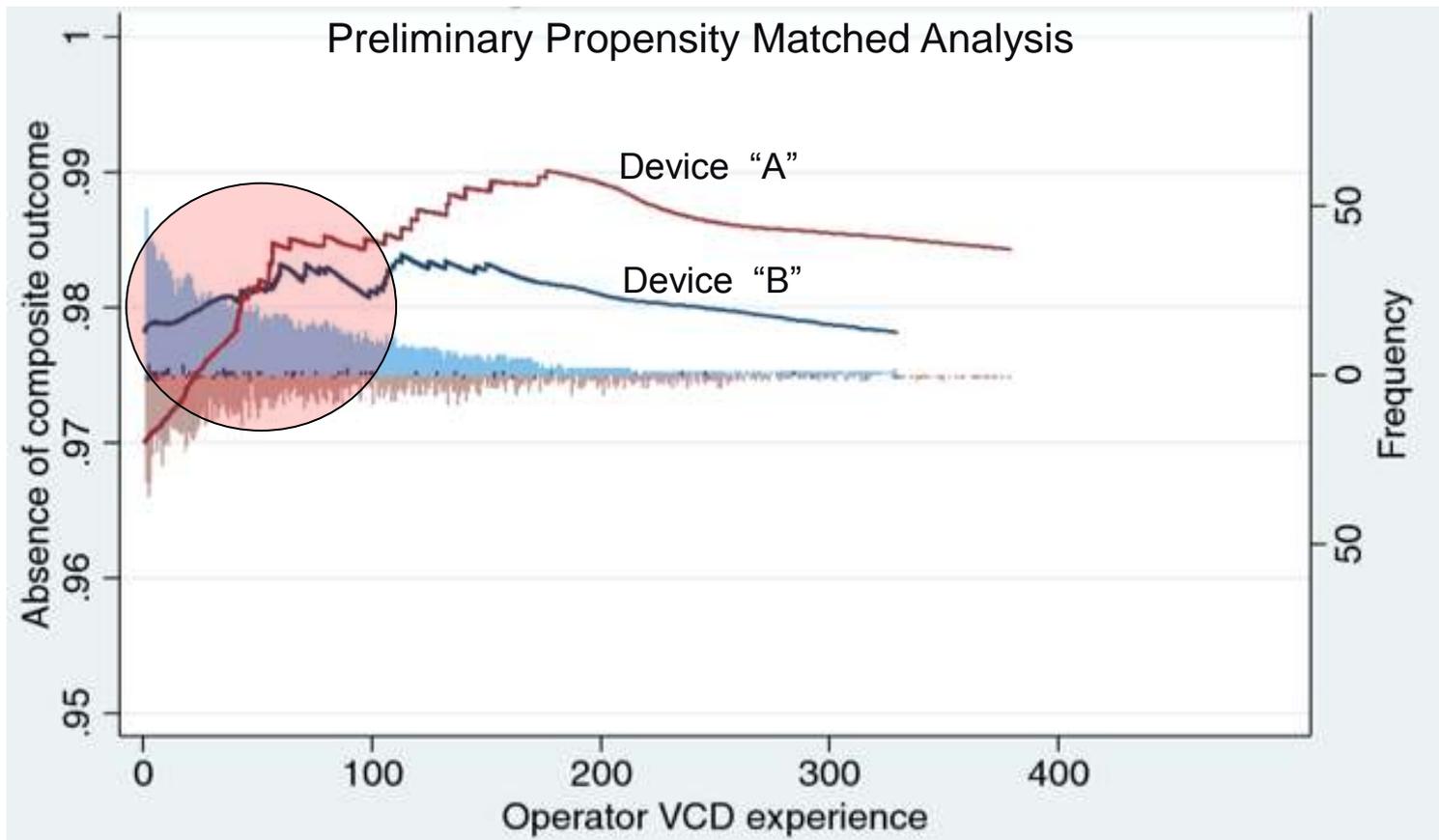
Figure 2: GEE Modeled Learning Curve from 107,000 Deployments of Novel VCD





Registries for Methodology Development: Device Learning Curve

.... And provides insights into training/learning differences with specific devices as well as “steady-state” performance and safety.





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Basic Truth: No Medical Device is Perfectly Safe

The New York Times

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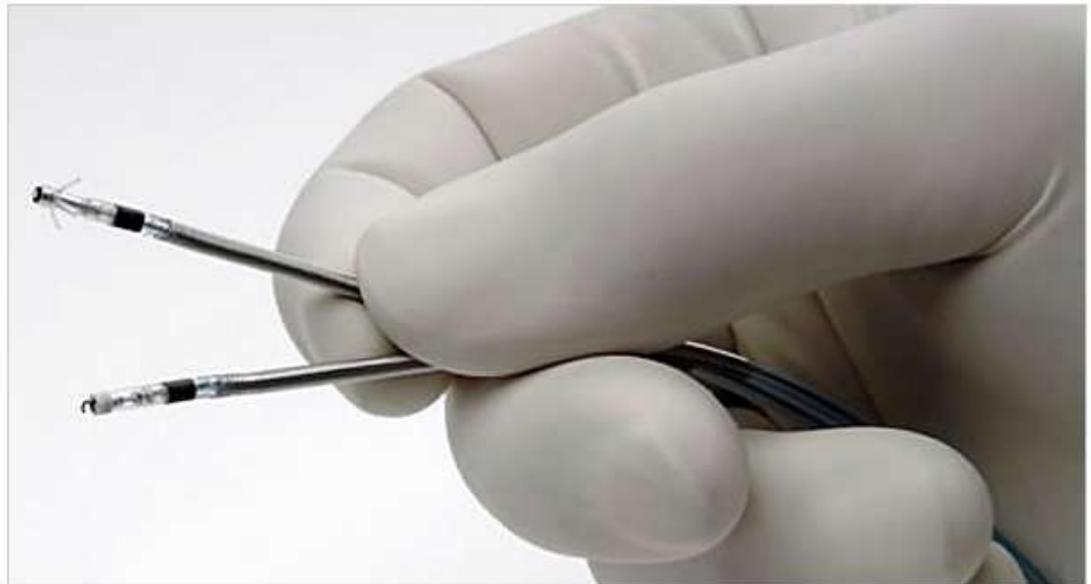
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In Data for Heart Devices, Parts Are a Blind Spot



Medtronic

Experts say there is a dearth of information about the performance of the wires that connect defibrillators to the heart.

By BARRY MEIER

Published: October 16, 2007

Medtronic's decision to stop selling a widely used part for implanted heart devices underscores the dearth of safety monitoring of such

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Device Adverse Event Reporting Today

- Primary responsibility of healthcare facilities to report medical device failures and complications to manufacturers. Must report all related deaths.
 - FDA receives >300,000 reports per year
 - GAO estimates <0.5% events reported
- Major Failures of Adverse Reporting Today:
 - No “denominator” information
 - Lack of (implemented) unique device identification
 - Poor quality reports; not interpretable
 - Influenced by media reports, publicity as much as by clinical and safety concerns



Key Differences Between Drugs and Medical Devices



Medications:

- Exposure: NDI uniform documentation; available in claims records
- Outcomes: general clinical conditions, rare diagnoses
- Often suitable for population based surveillance

Devices:

- Exposure: No uniform identification; ? claims requirement for UDI.
- Variable documentation of implant procedure
- Multiple failure modes of interest
- Learning curve; procedural quality
- Rapid Iteration / Life Cycle



Automated Safety Surveillance Systems

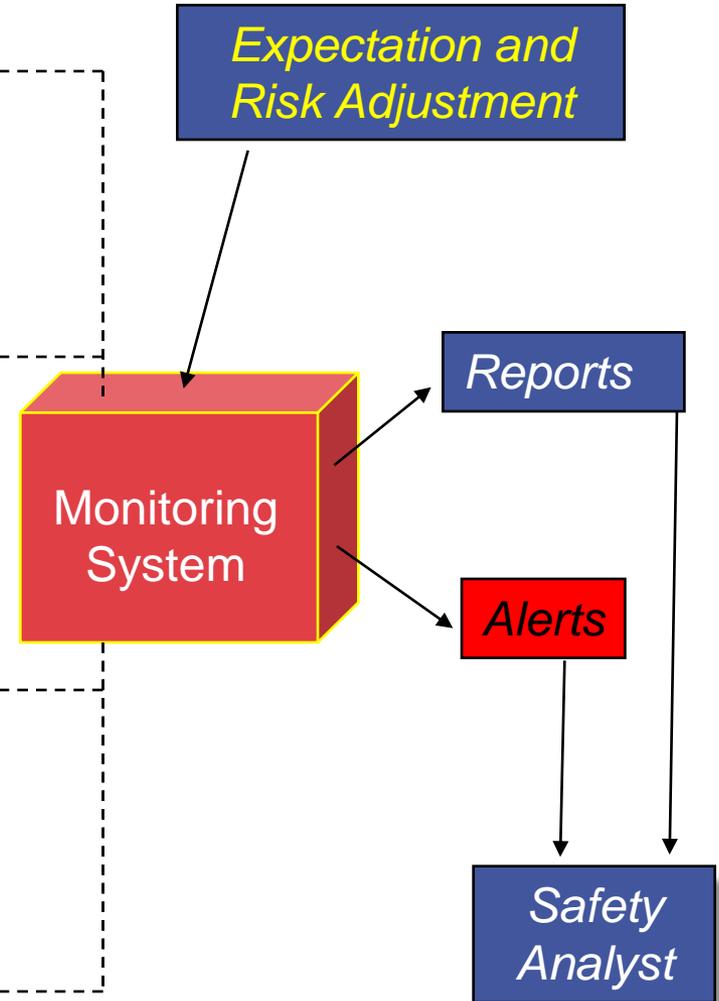




Idealized Safety Monitoring System

Monitoring System

- Continuously updated
- Array of statistical analytic options
- Monitor multiple analyses simultaneously
- Flexible Alert notification
- Generic structure
- Widely accessible – feedback to source sites



Distributed Data Ownership

DELTA

Data Extraction and Longitudinal Time Analysis System

Welcome to DELTA

Data Extraction and Longitudinal Time Analysis System

Engineered to support dynamic safety monitoring in healthcare utilizing various statistical methods.

Supported by grant R01-LM08142 from the National Library of Medicine.

Developed by Coping Systems, Inc.
Delta Version V3.0.1.19a

Links

- [Frederic S. Resnic, MD, MSc, FACC](#)
- [Michael Matheny, MD, MS, MPH](#)
- [Lucila Ohno-Machado, MD, PhD](#)
- [Coping Systems, Inc.](#)
- [DELTA2 Documentation Wiki](#)



DELTA LOGIN



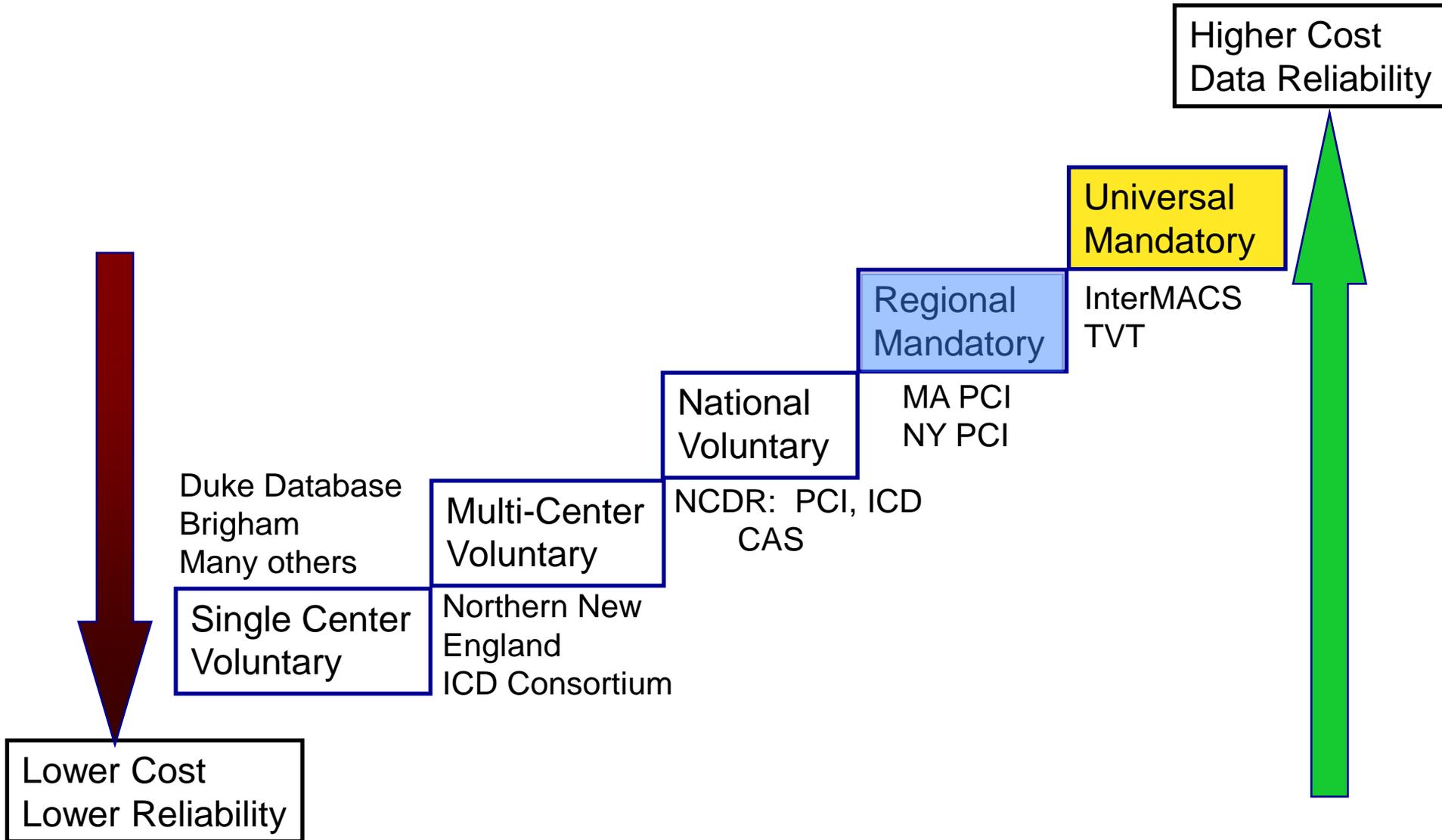
Username

Password

Login >



Data Sources: Clinical Registries for Surveillance and Outcomes Research



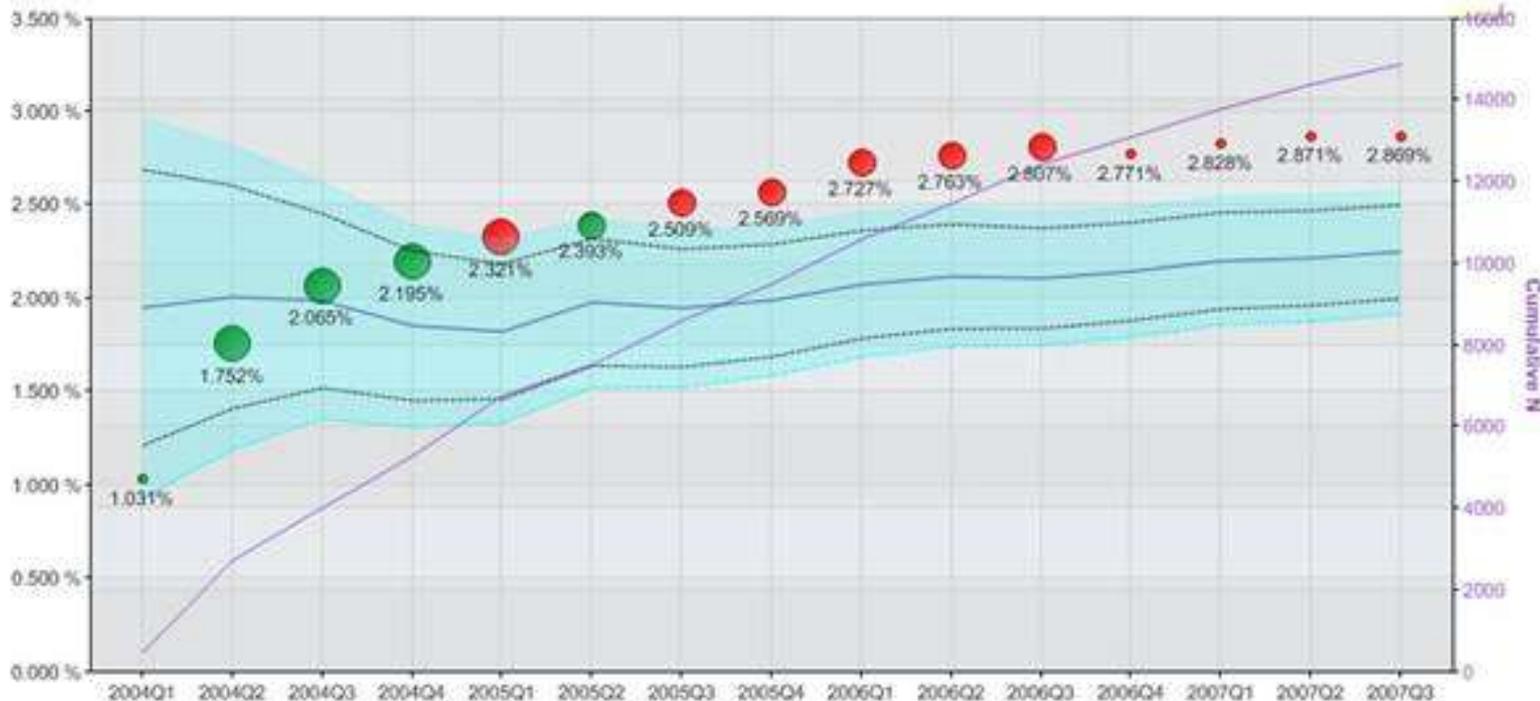


DELTA Automated Surveillance: Retrospective Cohort Registry Analysis

Using the MA state-wide PCI device dataset, we explored the **cumulative** post-procedure myocardial infarction rate for new drug eluting stent as compared with propensity matched control DES.

Using 38 clinical variables in propensity match a total of 81.5% of 18,277 new stents were analyzed.

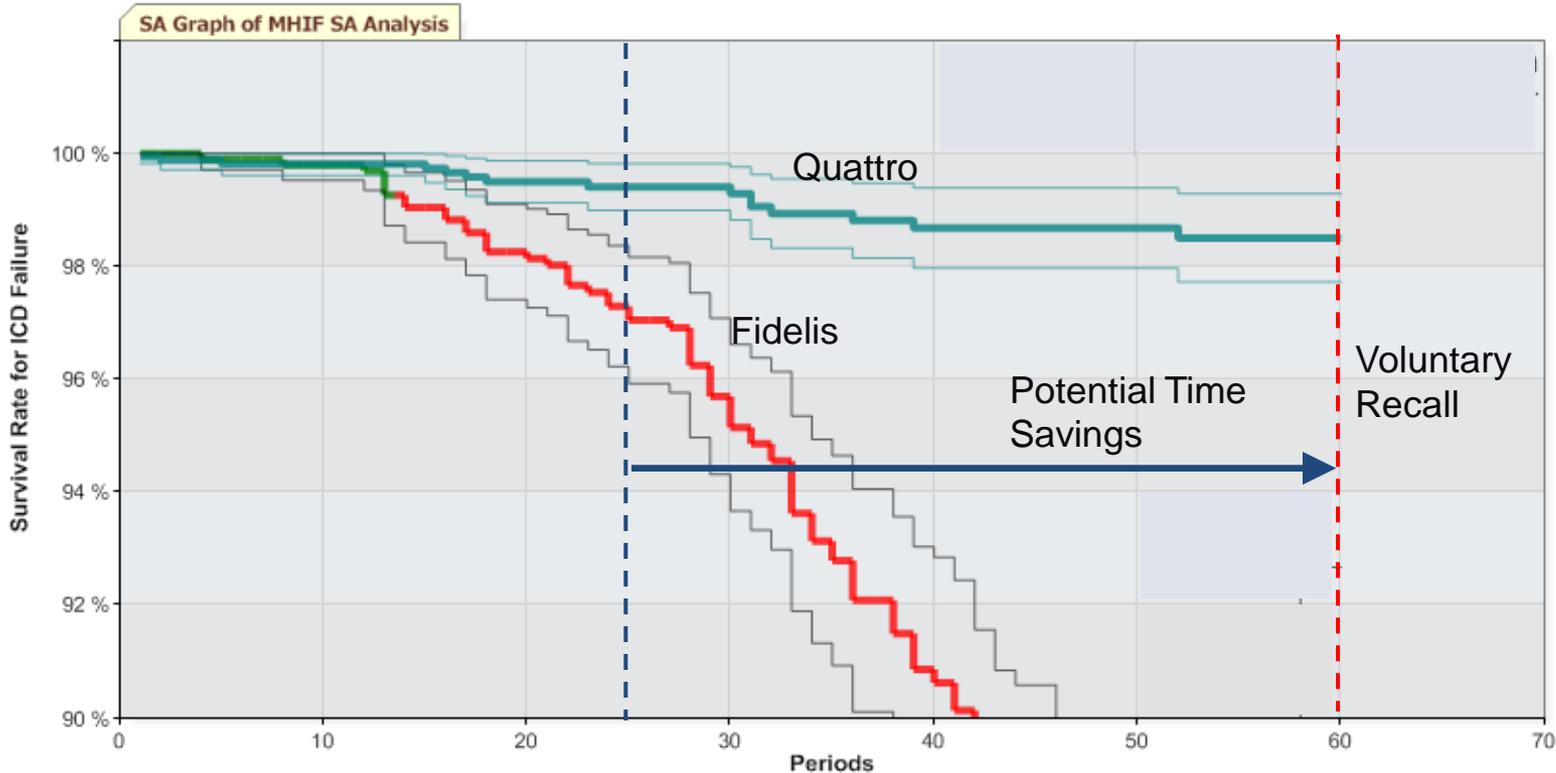
MA Experience 2004-2007: Post Procedure MI Rates – Taxus Express vs. Cypher DES





DELTA Automated Surveillance: Hospital Registries and Time Savings

Using pooled data from *three* high volume centers, DELTA performed a propensity matched analysis of 859 Fidelis lead implants versus traditional leads. By 25 months of analysis (dashed line) 3% of Fidelis leads had fractured (red line) whereas only 0.1% (1 of 859) alternative ICD leads had fractured.





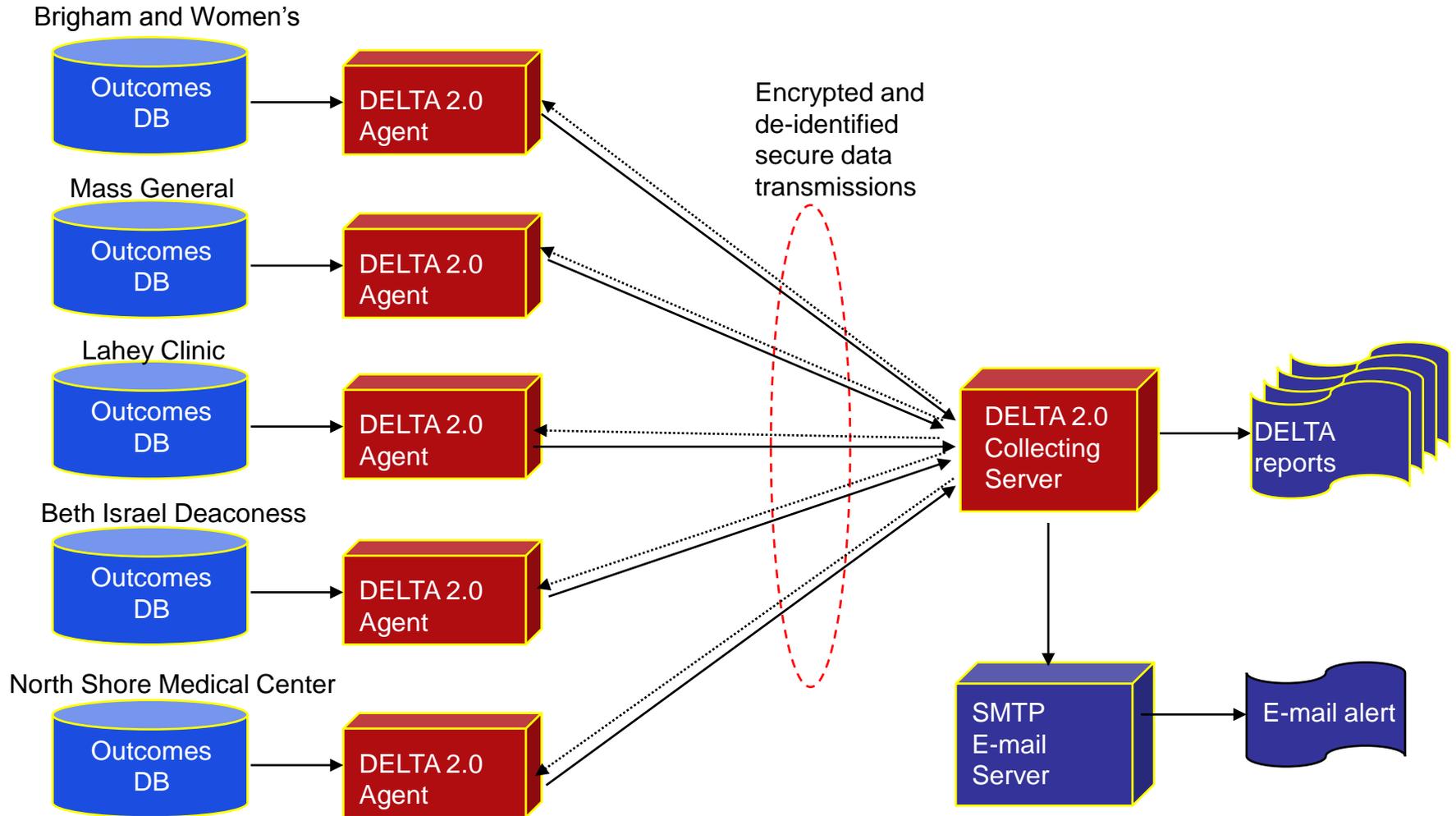
DELTA Automated Surveillance: Hospital Registries and Time Savings

.... Those 25 months of delayed recognition led to 70,000 patients in the U.S. receiving the defective ICD lead AFTER we should have known that they were dangerous. 70,000 people is....



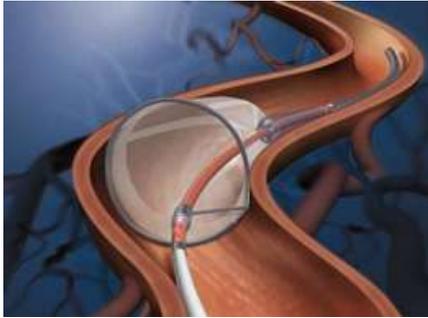


DELTA Automated Surveillance: Prospective Surveillance Network Pilot

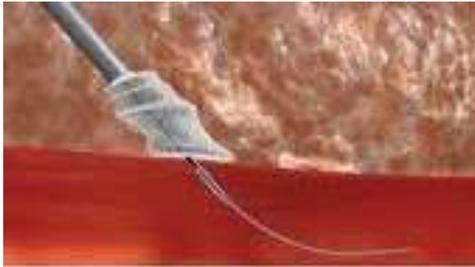




Ongoing DELTA Surveillance Projects



- VA Healthcare System – Catheter safety during complex coronary stenting procedure



- ACC-NCDR Pilots: Vascular Closure Devices and Thrombectomy Devices



- Kaiser-Permanente: Artificial Hip implant safety

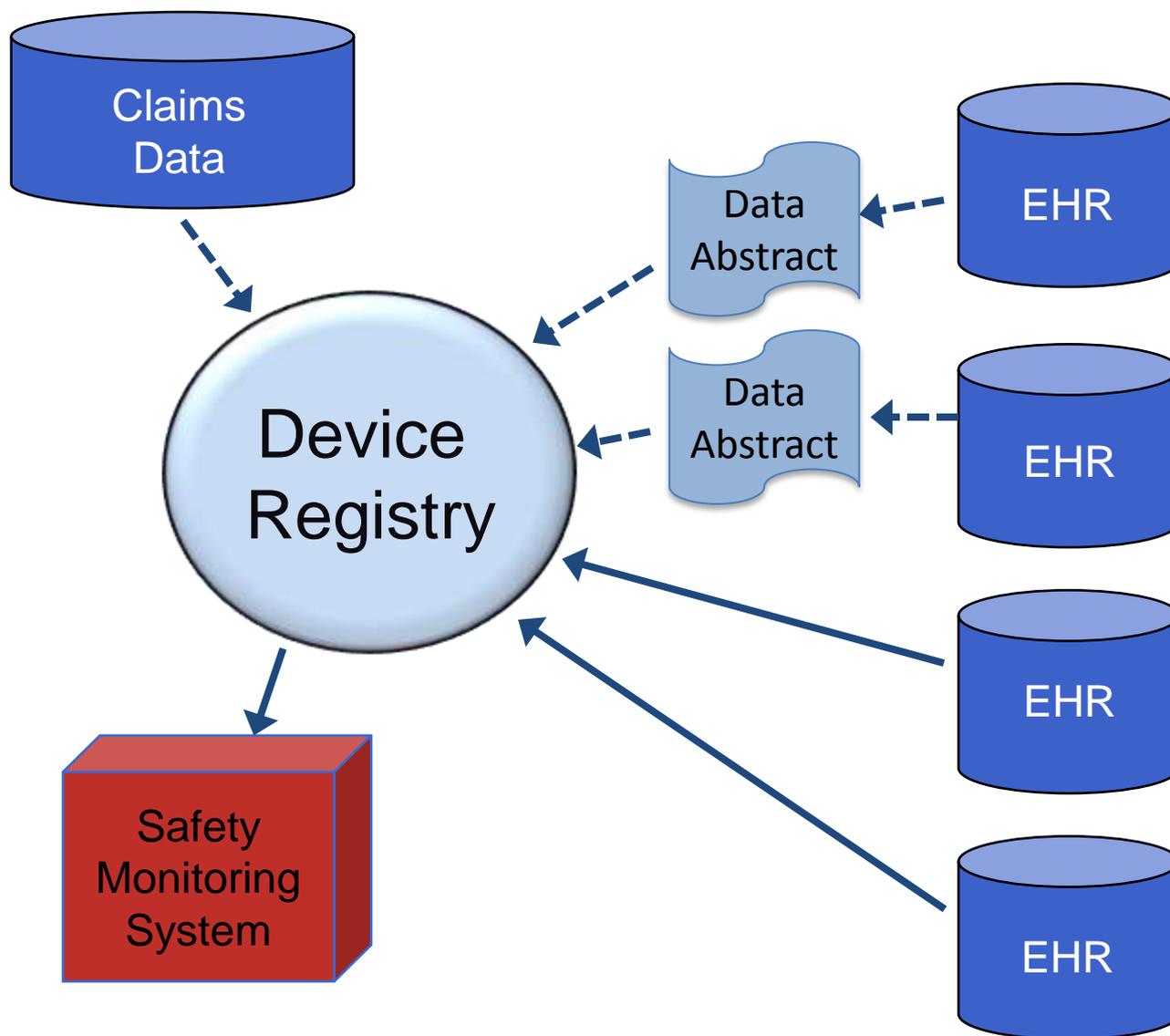


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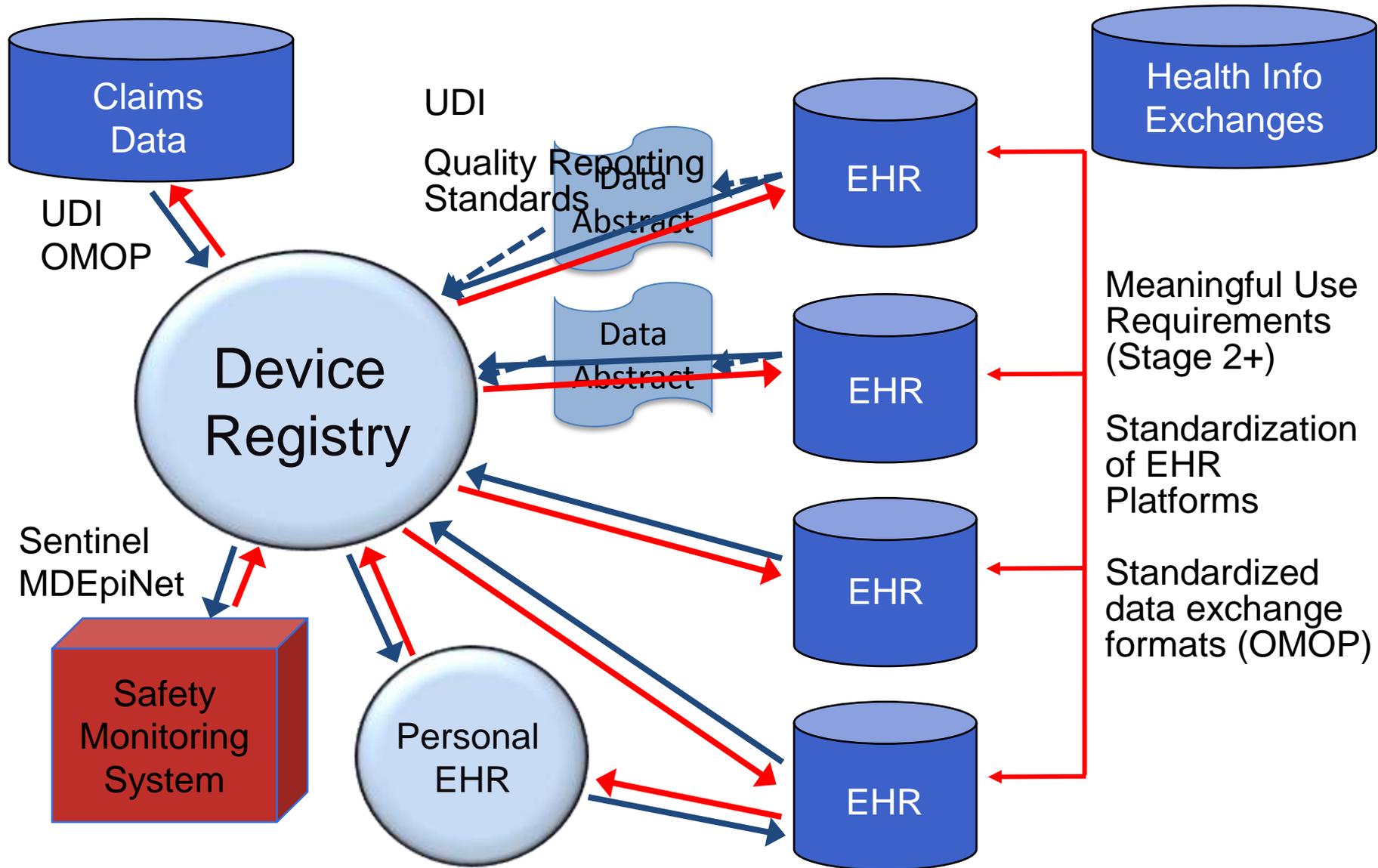


Device Registries: Today





Device Registries: 2020





Thank You!!

Lahey Clinic

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FDA CDRH

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Coping Systems, Inc.

Richard Cope

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DELTA Automated Surveillance: Retrospective Cohort Registry Analysis

Propensity matching selected as primary analysis as a strategy to reduce treatment selection bias based on ability to communicate to public and policy makers.

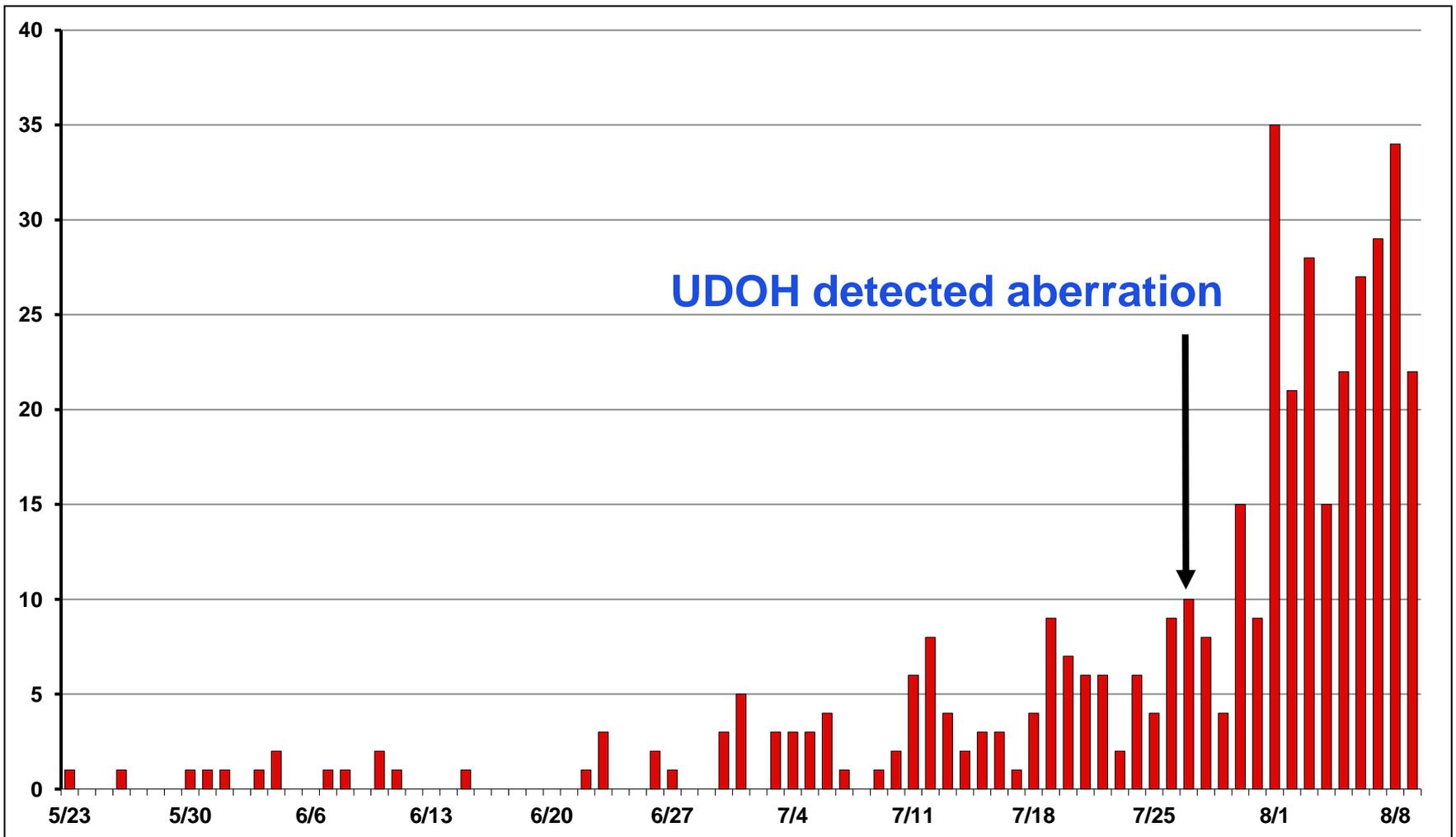
Table 2. Distribution of Clinical Covariates in Patients Receiving Taxus Express2 or Alternative Drug-Eluting Stents

Covariate	%								
	Total Study Population			Propensity Matched			Unmatched Patients ^a		
	Taxus Express2 (n = 18 277)	Alternative (n = 28 327)	Standard Difference ^b	Taxus Express2 (n = 14 893)	Alternative (n = 14 893)	Standard Difference ^b	Taxus Express2 (n = 3384)	Standard Difference ^b	
Age, mean (SD), y	64.6 (12.2)	64.8 (12.6)	1.60	64.6 (12.2)	64.3 (12.3)	2.40	64.4 (12.2)	1.60	
Women	31.0	30.1	2.00	30.9	30.1	1.70	31.7	1.70	
History of diabetes	30.6	30.2	0.90	30.1	30.3	0.40	33.0	6.20	
History of MI	27.8	29.3	3.30	28.6	29.6	1.80	24.2	10.40	
Current smoker	21.6	20.4	2.90	21.4	20.9	1.20	22.9	3.60	
History of renal insufficiency	5.26	6.25	4.30	5.23	5.46	1.00	5.36	0.60	
History of PAD	13.5	13.7	0.60	13.7	13.8	0.30	13.0	2.00	
Ejection fraction <30%	41.9	43.8	3.80	41.2	41.6	0.80	44.6	6.90	
Emergent procedure	16.2	15.1	3.00	16.1	15.5	1.60	16.7	1.60	
Acute MI on presentation	36.3	35.3	2.10	36.4	36.3	0.20	35.9	1.00	
Left main vessel disease >50%	5.91	6.27	1.50	6.20	6.15	0.20	4.63	6.90	
Vein graft lesion	5.08	6.20	4.90	5.28	5.67	1.70	4.20	5.10	
Glycoprotein IIb/IIIa antagonist	29.3	34.5	11.10	28.4	27.4	2.20	33.3	10.60	
Final stent diameter, mean (SD), mm	3.15 (0.52)	3.22 (0.49)	13.90	3.16 (0.53)	3.23 (0.54)	0.70	3.11 (0.55)	9.30	
Maximum lesion length, mean (SD), mm ^c	17.8 (9.9)	17.1 (9.7)	7.10	17.6 (9.7)	18.4 (10.3)	8.00	18.2 (10.6)	5.90	



Cryptosporidiosis Outbreak

Utah 2008



Source: Staes K. Woods Hole Symposium 2010

Notifiable Condition Reporting

National Electronic Disease Surveillance System

- Open source base system used by 16 states, Java based system
- Slow adoptions, from inception in 2001 to 2008, only 38 states and DC were fully integrated.
- (2008) : Last 12 States still need to achieve compliance with one or more of the three NEDSS criteria; an integrated data repository (IDR), electronic lab-result (ELR) messaging, and Web based accessibility.
 - Alaska, Minnesota, Mississippi: **IDR and Web support**
 - Arizona, Arkansas, Iowa, Kansas, New Hampshire, Wyoming: **ELR**
 - California, Connecticut, Utah: **All three**

Notifiable Condition Reporting

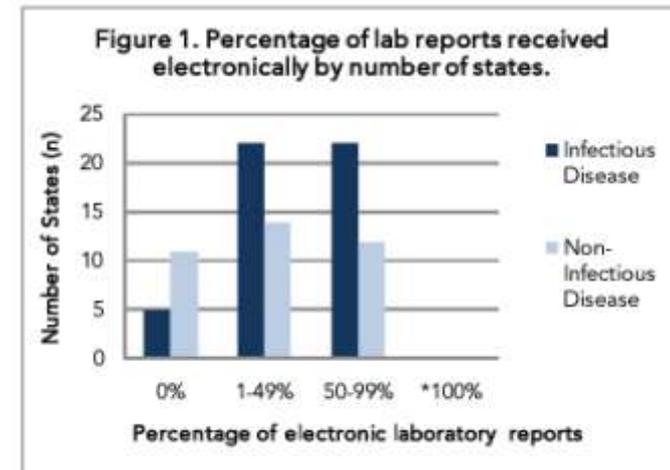
National Electronic Disease Surveillance System

Table 1. Characteristics of operational and implemented NEDSS modules/components for data that are being sent to CDC: No. (%)

	COTS*	State-developed	CDC-developed	State hybrid**	N/A	Total States
General Communicable Disease	12 (24)	15 (30)	15 (30)	8 (16)	0 (0)	50
HIV Surveillance	4 (8)	1 (2)	32 (65)	8 (16)	4 (8)	49
STD Surveillance	7 (14)	11 (22)	20 (41)	9 (18)	2 (4)	49
Lead Surveillance	1 (2)	15 (35)	14 (33)	5 (12)	8 (19)	43
Vectorborne/Zoonotic Disease Surveillance	10 (21)	12 (26)	14 (30)	11 (23)	0 (0)	47
Animal Disease Surveillance	8 (18)	12 (27)	9 (20)	6 (13)	10 (22)	45
Environmental Disease Surveillance	2 (5)	12 (30)	2 (5)	6 (15)	18 (45)	40
Poisoning Surveillance	2 (5)	12 (30)	3 (8)	4 (10)	19 (48)	40
Cancer Surveillance	9 (21)	8 (19)	8 (19)	6 (14)	12 (28)	43
Injury Surveillance	3 (8)	6 (16)	3 (8)	1 (3)	25 (66)	38
Occupational Disease Surveillance	0 (0)	7 (18)	4 (11)	3 (8)	24 (63)	38
Other Chronic Disease Surveillance	2 (5)	6 (16)	1 (3)	3 (8)	25 (68)	37

* COTS: Commercial-off-the-shelf

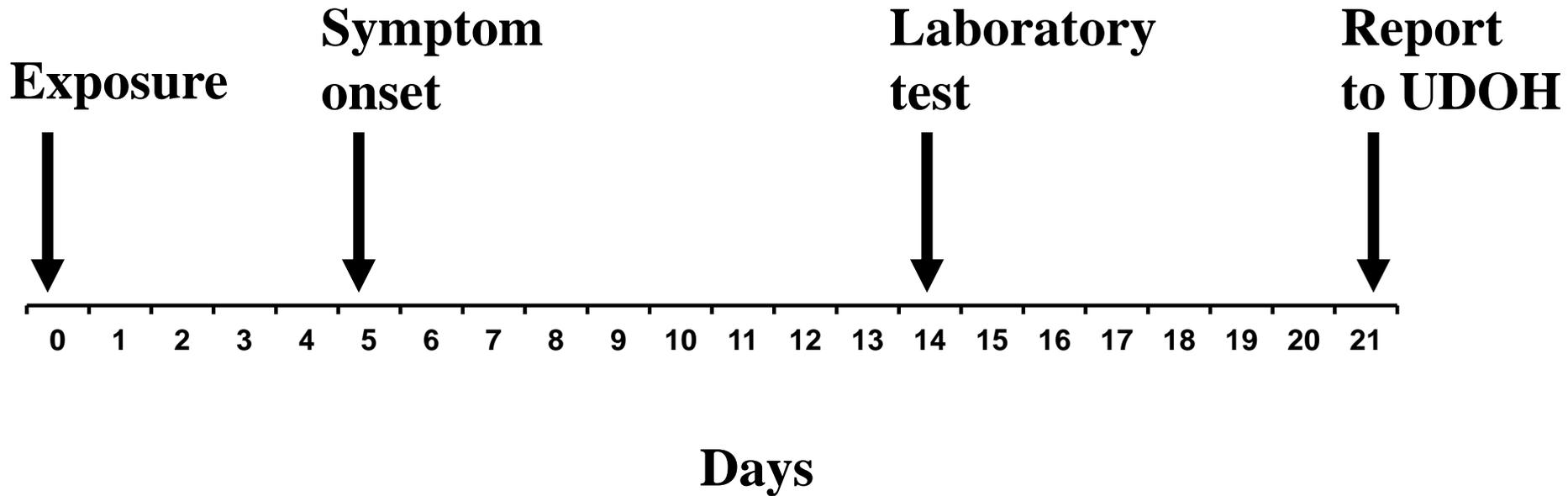
**State hybrid: systems that are combinations of State and COTS systems or State and CDC developed systems



* No state reported receiving 100% of laboratory reports electronically for infectious or non-infectious diseases.



Situational Awareness



Outbreak Statistics

- 1,902 *confirmed cases*
- Median age: 9 years (range: <1–101 years)
- 8% hospitalized (97 / 1,144)
- No reported deaths
- Morbidity, lost time from work, swimming pools closed

Electronic Laboratory Reporting

Meaningful Use Criteria

- Messaging Standard: HL7 2.5.1
- Message Vocabulary: LOINC version 2.27
- Capability to submit electronic data on reportable lab results (as required by state or local law) to public health agencies and actual submission in accordance with applicable law and practice.
- Measure: perform at least one test of certified EHR technology capacity to provide electronic submission of reportable lab results to public health agencies and follow-up submission[s] if the test [is] successful
- Stage 2 Measure: Successful ongoing submission of reports from EHR to public health agencies for entire reporting period
- Final rule: just hospitals have to do final submission (not providers)
- Legally, both provider and hospital required to report