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National Cardiovascular Disease Registries:
Current Practices in Moving From Evidence to Decision

Institute of Medicine
Workshop on Systems for Research and Evaluation for Translating Genome-Based Discoveries for Health

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February 12, 2009

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Presenter Disclosure Information

National Cardiovascular Disease Registries

Disclosure Information…
The following relationships exist related to this presentation:

Ralph Brindis, MD, MPH, FACC

“ No relationships to disclose”

What is the American College of Cardiology (ACC)?

Helping Cardiovascular Professionals Learn. Advance. Heal.

Chartered as a teaching institution in 1949 now serves more than 37,000 cardiologists, nurses, and PAs.

ACC headquarters

2400 N. Street, NW

Washington D.C.

1-800-257-4737

Bill Weintraub: NCDR Founding Father, CV Epidemiologist, Clinical Trialist and Outcomes Thought Leader

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"Science tells us what we can do;

Guidelines what we should do;

Registries what we are actually doing."

The Cycle of Clinical Effectiveness

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What is the NCDR?

- Suite of Hospital and Office-Based Quality Improvement Programs focused on CV disease
  - measure and quantify outcomes
  - Identify gaps in the delivery of quality cardiovascular patient care
- Our Mission is to:
  - improve patient care
  - Provide knowledge and tools
  - Implement quality initiatives
  - Support research

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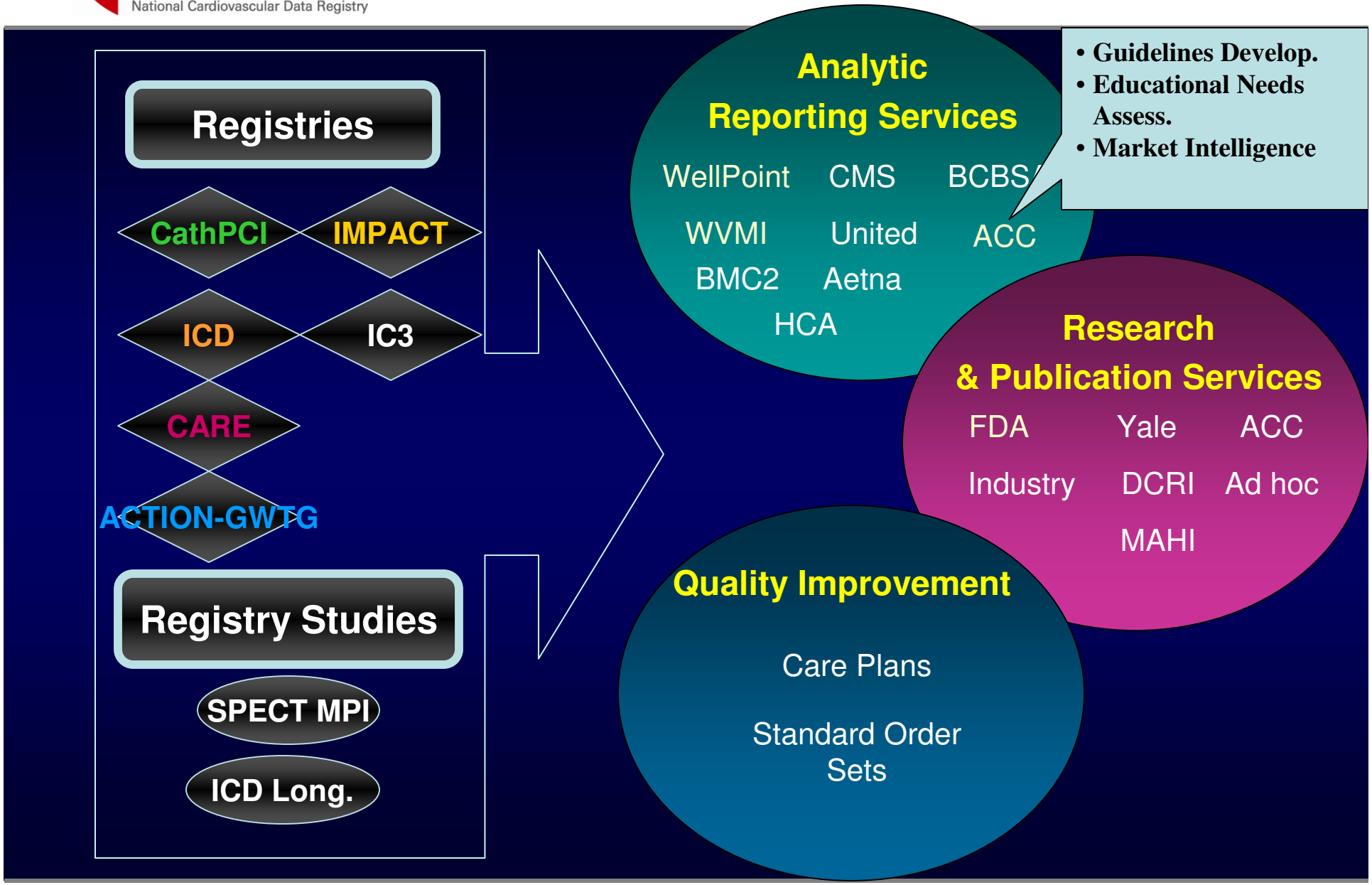
How is NCDR Used

ACC	• Educational Needs Assessment • Scientific Insights • Research and Publications
Health Plans	• Participation requirements for preferred provider programs. • Performance Tracking Tool
Researchers	• Outcomes Research • Post Market Surveillance
Hospitals & Physician Practices	• Quality Improvement • Performance Measurement Reporting • Utilization Review

What is the National Cardiovascular Data Registry?



ACTION Registry-GWTG™ CARE Registry™ CathPCI Registry™ ICD Registry™ IC³ Program™ IMPACT Registry™

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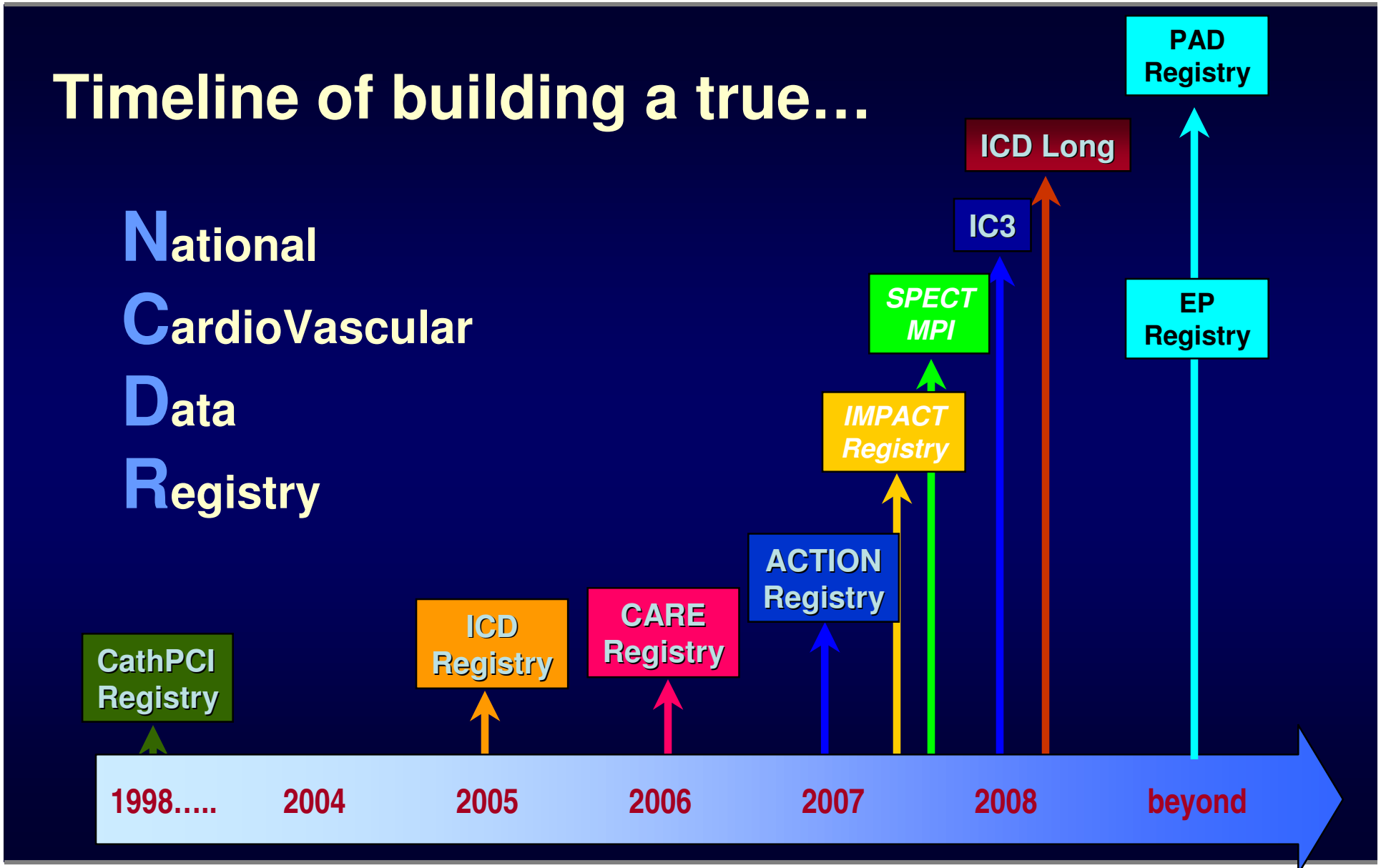
Timeline of building a true…

National
CardioVascular
Data
Registry



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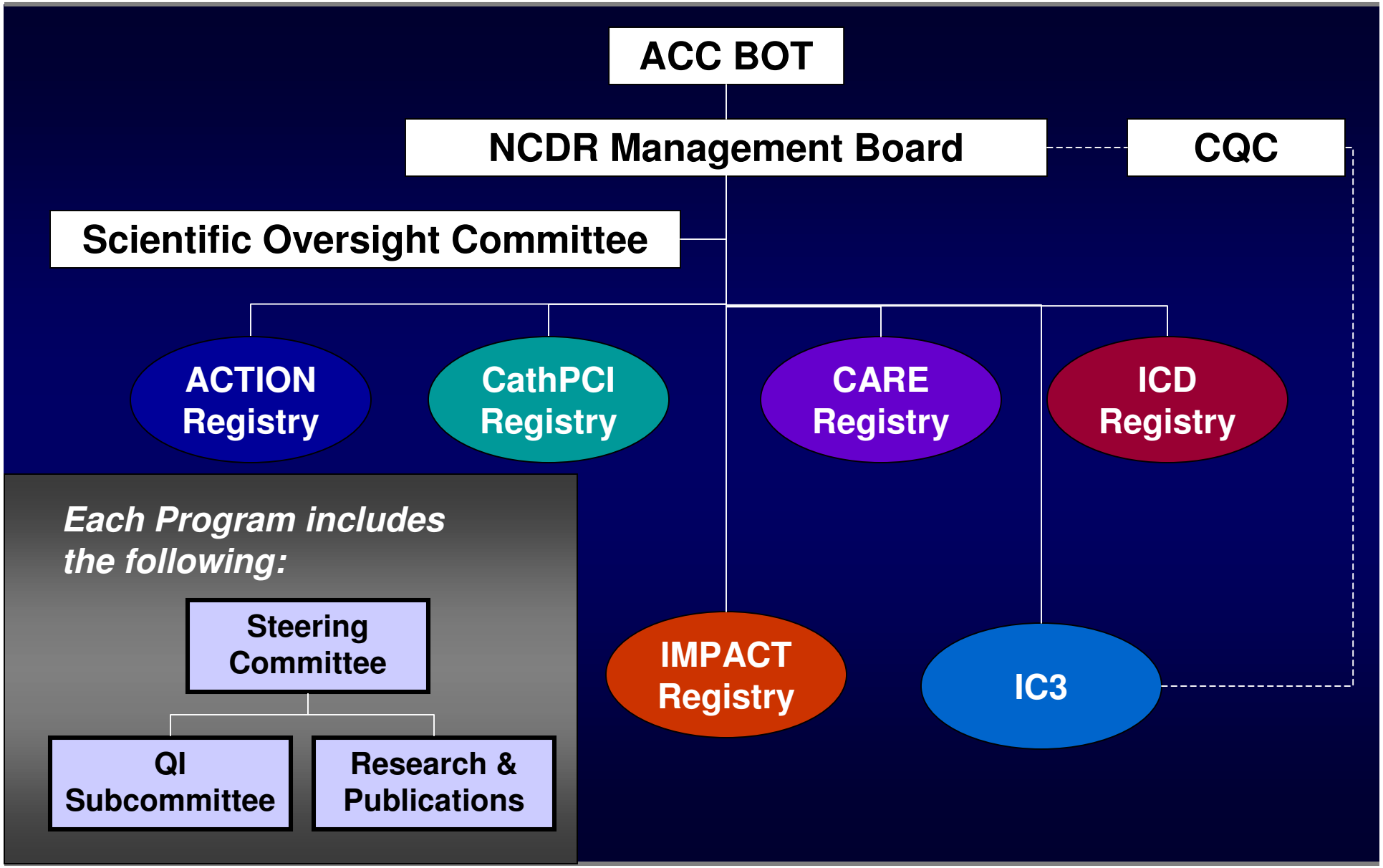

ACTION Registry-GWTG™ CARE Registry™ CathPCI Registry™ ICD Registry™ IC³ Program™ IMPACT Registry™

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Data Quality Program

- Online field checks for completeness and consistency
- Electronic Data Quality Reports
- National On-Site Audit Program
  - Annual
  - Nurse abstractors go on-site to audit charts

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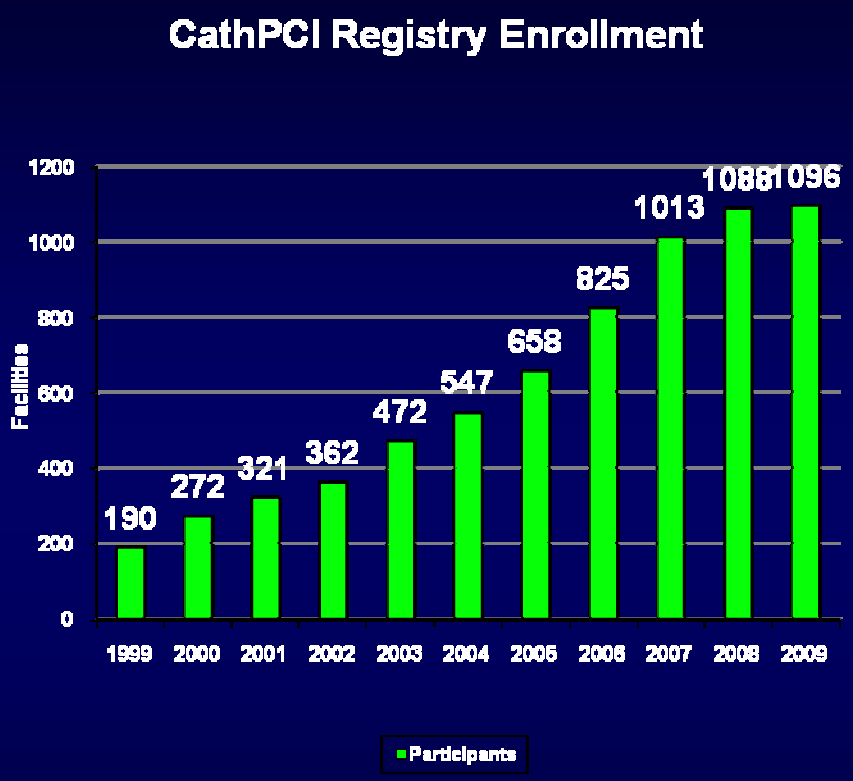
CathPCI Registry™

Registry/QI
- 1100 participants
- 8.2 million patient records
- 2.91 million PCI records

Analytic & Reporting Services
- States – MA, WV, MI
- Payers – United, BCBSA, WellPoint

Research and Publications
- DCRI analytic center
- Manuscripts
  - –30 published
  - – 4 in press
  - –16 in development
- 17 abstracts ’08



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ACTION Registry®-GWTG™

Registry

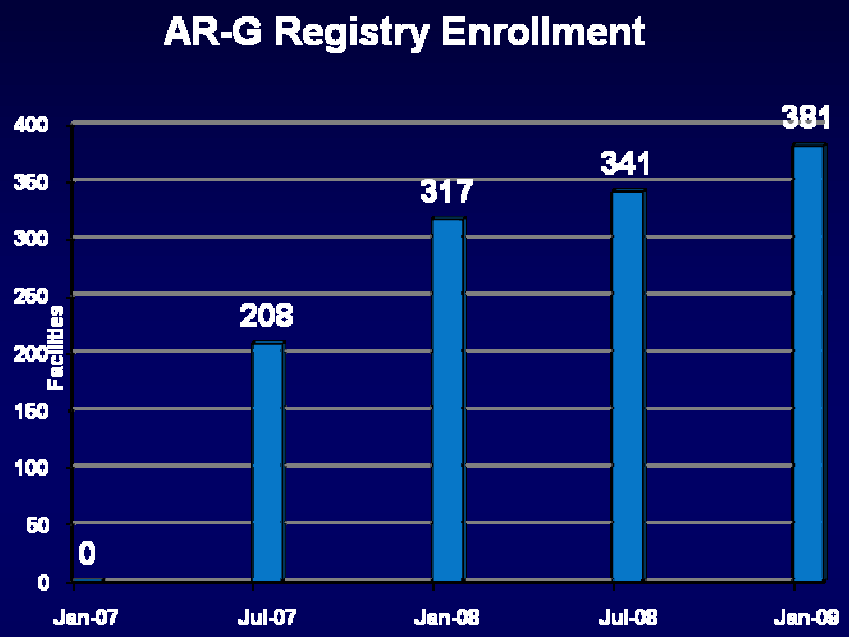
- 100,000 Patient Records
- Merger with American Heart Association GWTG-CAD
- Certified Vendor - Outcome Inc.,
- Pending Vendors - Quantros, Lumedx
- Linked to CathPCI v.4 (launch mid 2009)

Data Sharing

- Early discussions with payers

Research and Publications

- DCRI analytic center
- 9 Abstracts accepted ACC'09



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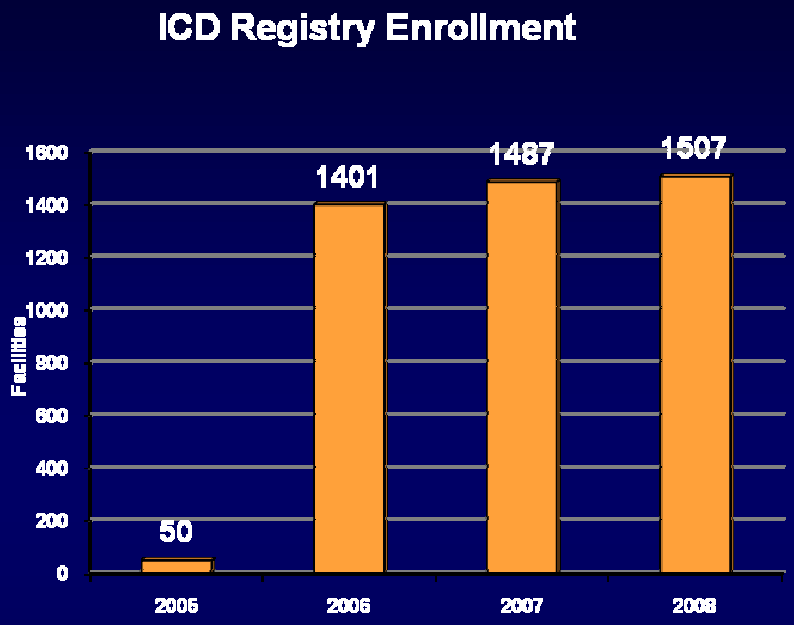
ICD Registry™

Registry

- 1,507 enrolled
- 330,00 patient records
- 76% of participants submit all ICD patients
- Version 2.0 - Peds and Leads (2010)



Analytic & Reporting Services

- Provide data to CMS for reimbursement

Research

- **ICD *Lo*ngitudinal Study**
- **Atrial Fibrillation Ablation Registry ?**
- Perform analysis for FDA

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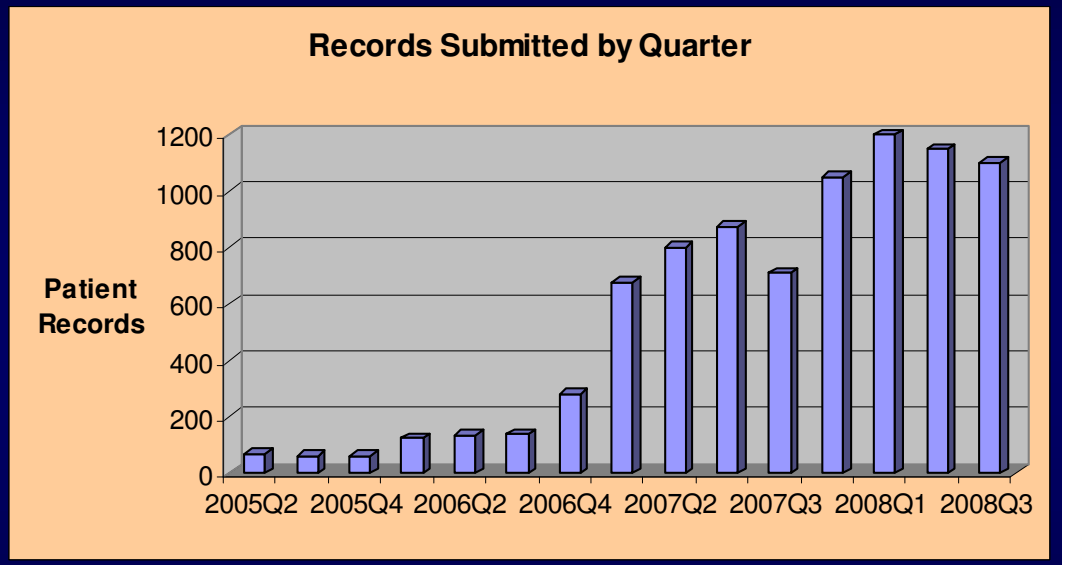
CARE Registry™

Registry
- 178 Participants
- CAS Patient Records in Transactional Database – 6,244
- CEA Patient Records in Transactional Database – 3,629
- Online data entry tool

Software Vendors
- Cedaron Medical Inc.
- Heartbase
- LUMEDX

Research & Publications
- Mid America Heart Institute (MAHI)
- Oral Abstract Presented at AHA'08
- Poster Abstract Accepted for ACC'09

Data Extract Feature
- CAS Procedure
- CAS Adverse Events
- CAS Medication
- CAS Lesion Data
- CAS Stents Implanted
- CAS Embolic Protection Device
- CAS Closure Method
- CEA Procedure
- CEA Adverse Events
- CEA Medication



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ImpactRegistry_cmyk

- **IM**proving **P**ediatric and **A**dult **C**ongenital **T**reatment (IMPACT)
- **Phase I: 2007-2009**
  - Steering Committee and governance
  - Develop registry protocol, data collection tool, data elements & definitions
  - Initially Cath lab/procedure focused
  - Identify and recruit 10 pilot CHD centers
  - Develop data quality reports, outcome reports, and data delivery system

NCDR™ Executive Summary Performance Metrics

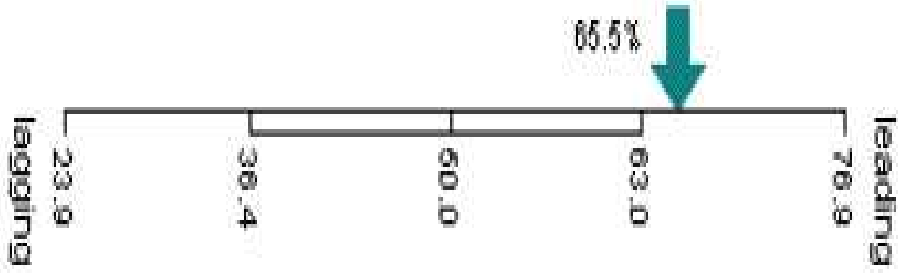
National Cardiovascular Data Registry

PCI Quality Measures

1. Proportion of STEMI Pts with DBT <= 90"

My Hospital: 65.5% (Rank: 87 of 389, Rank Percentile: 78)

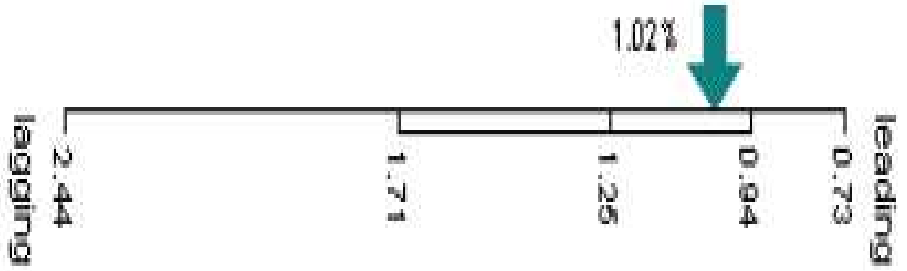
The proportion of primary PCI patients with DBT (door to balloon time) <= 90 minutes. The goal is to have a DBT of <= 90 minutes for all non-transferred patients pts having an ST elevated MI and having primary PCI. [Detail Line: 1767]



2. Risk Adjusted Mortality

My Hospital: 1.02% (Rank: 118 of 366, Rank Percentile: 68)

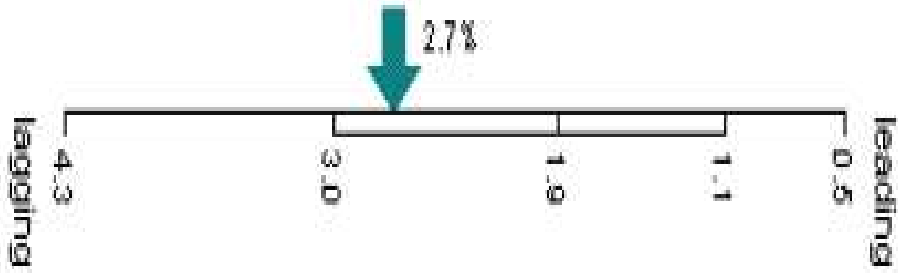
Your hospital's PCI mortality rate adjusted using the ACC-NCDR® risk adjustment model [Detail Line: 1732]



3. Incidence of Vascular Complications

My Hospital: 2.7% (Rank: 286 of 401, Rank Percentile: 30)

Includes procedures with at least one vascular complication. [Detail Line: 2029]



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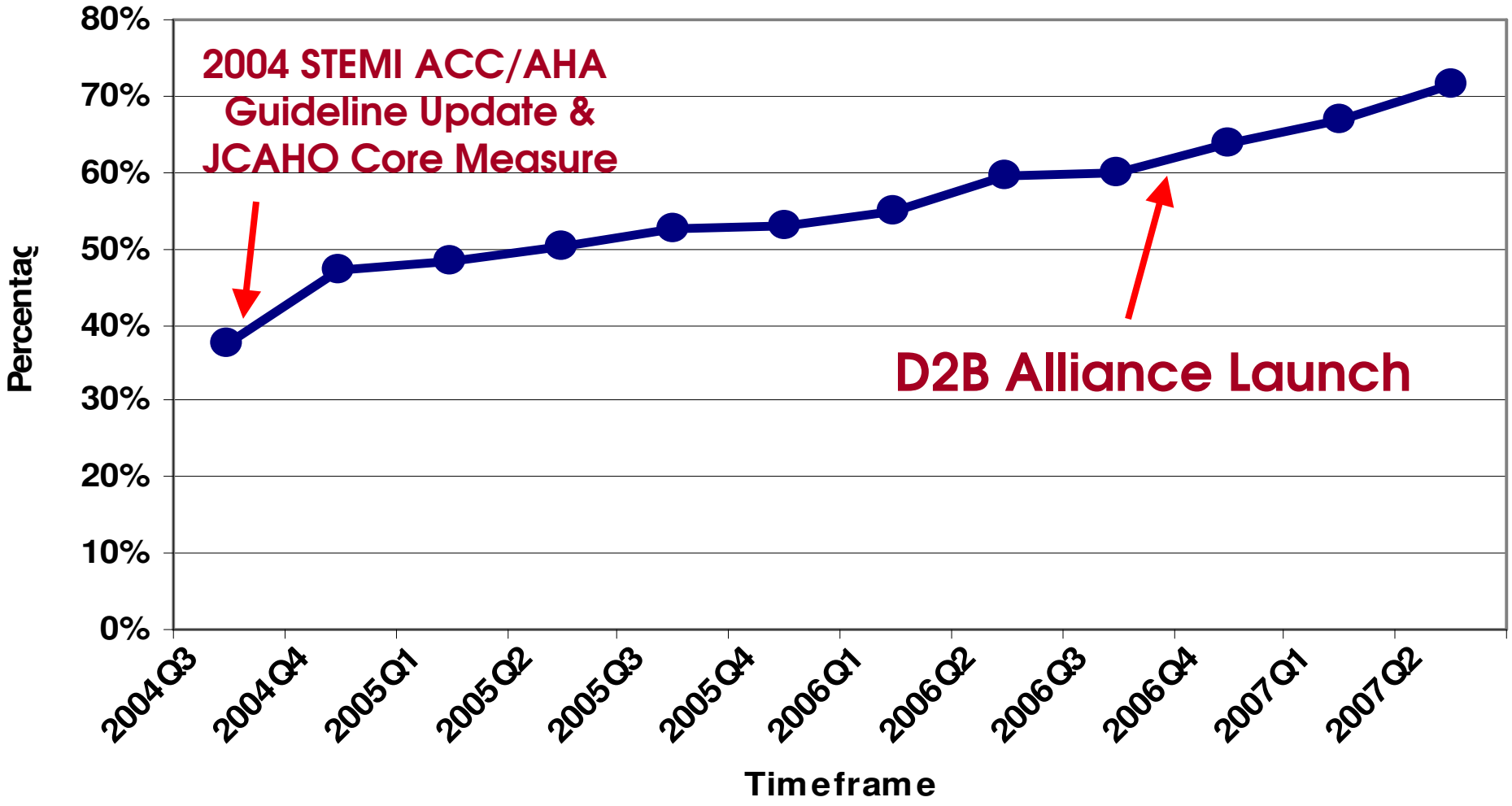
Percentage of Primary PCI with D2B <= 90 minutes

NCDR CathPCI v3



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Pre-CathPCI Risk Models

	Full Model †				Precath Simple Model			
Label	O.R.	95% CI		Wald Chi-Square	O.R.	95% CI		Wald Chi-Sq
Age (for age<=70) ‡	1.55	1.44	1.69	115.33	1.52	1.40	1.64	107.92
Age (for age>70) ‡	1.71	1.57	1.88	125.80	1.76	1.60	1.91	150.93
Previous History - CHF	1.29	1.13	1.47	13.85	1.75	1.54	1.98	77.25
Peripheral Vascular	1.53	1.35	1.74	42.39	1.67	1.48	1.89	67.78
Chronic Lung Disease	1.48	1.31	1.66	43.04	1.52	1.36	1.71	52.87
GFR for stemi ‡	0.77	0.74	0.80	181.90	0.77	0.75	0.78	377.55
Cardiogenic Shock at Admission	8.35	7.40	9.44	1168.28	12.19	10.86	13.68	1804.73
NYHA Class IV for STEMI	1.21	1.05	1.39	6.74	1.61	1.46	1.79	81.71
Urgent PCI Status- STEMI §	1.09	0.64	1.83	0.09	1.25	0.748	2.07	0.71
Emergency PCI Status-STEMI §	2.07	1.30	3.31	9.24	2.65	1.68	4.18	17.58
Salvage PCI Status-STEMI §	14.55	8.39	25.21	91.08	21.45	12.57	36.61	126.36

† Full model also includes Previous PCI, PreOp IABP, Ejection Fraction, Coronary Lesion >= 50%: Subacute Thrombosis (Y/N), Highest Risk Pre-Procedure TIMIFlow = none, Diabetes/Control, Highest Risk Lesion: SCAI Lesion Class 2 or 3, BMI for STEMI/non STEMI, Previous Dialysis for STEMI/non STEMI, Highest Risk Lesion Segment Category for STEMI/non STEMI. ‡ Per 10 unit increase. § Versus Elective

NCDR - Elective PCI
PCI Volume with Mortality

NCDR Centers (n= 403) 2001 - 2004

Annual PCI Volume	# of Sites	Number of Patients (%)	Mortality (%)	Odds Ratio (95% CI) (vs. volume ≥801)
0-200	43	6,305 (1.3)	0.49	1.17 (0.81 - 1.71)
201-400	85	42,039 (8.7)	0.49	1.12 (0.96 - 1.31)
401-800	132	116,116 (24.0)	0.45	1.10 (0.99 - 1.22)
≥801	139	318,500 (65.9)	0.39	ref.

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Percutaneous Coronary Interventions in Facilities without On-Site Cardiac Surgery: A Report from the National Cardiovascular Data Registry (NCDR)

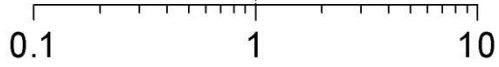
ACC/SCAI – i2 Summit

Late Breaking Clinical Trials

March 29, 2008

Risk Adjusted Outcomes

Outcome	Total N	Favors On-Site	Favors Off-Site	Odds Ratio (95% CI)	p-value
Mortality - overall	308,105			1.08 (0.86 - 1.35)	0.507
Mortality - primary PCI pts	33,002			1.02 (0.79 - 1.31)	0.881
Mortality - non-primary PCI pts	275,089			1.12 (0.84 - 1.50)	0.444
Emergency CABG	308,124			1.59 (1.00 - 2.52)	0.049
Mortality - pts not requiring emergency CABG	306,961			1.05 (0.84 - 1.32)	0.671



Odds Ratio (OR): outcomes for patients at On-Site (vs. Off-Site) facilities adjusting for site correlations and potential confounding variables

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Outcomes of Patients > 85 years undergoing PCI ACC-NCDR® 2001-2004

	Mortality	Emerg. CABG
• Chronic CAD (n=14,077)	1.4%	0.2%
• STEMI (n=2,941)	15.6%	0.3%
• Non-STEMI (4,316)	5.1%	0.2%

- *Total PCI procedures= 666,415 from 409 institutions*
- *%>85 years old = 2.9% CAD, 3.2% STEMI, 4.7% NSTEMI*

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Risk of Local Adverse Effects Following Cardiac Catheterization by Hemostasis Device and Gender

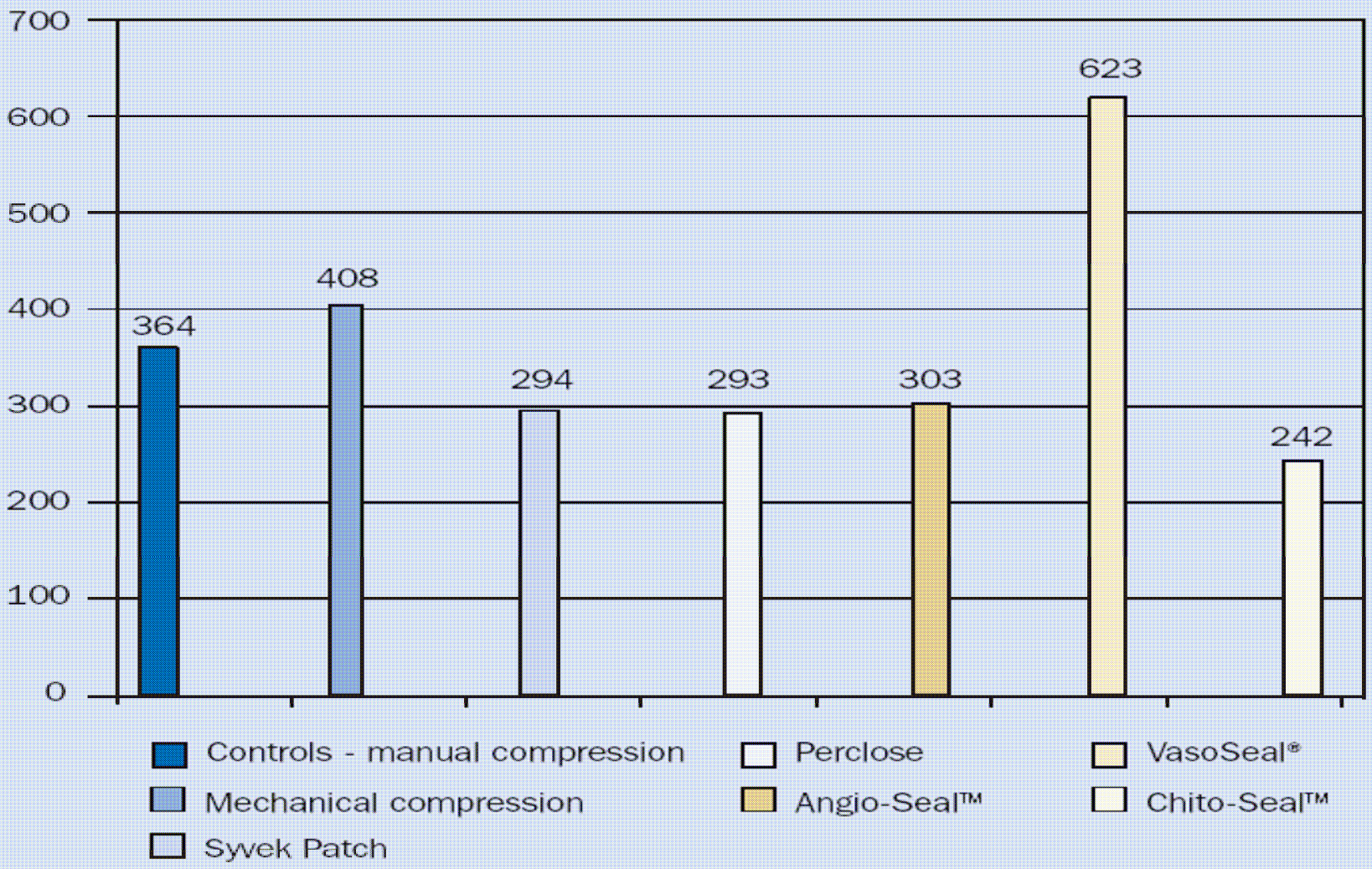
A Report from the NCDR in
Partnership with the FDA

Dale Tavris, Syamal Dey, Albrecht Gallauresi, Richard Shaw,
William Weintraub, Kristi Mitchell, Ralph Brindis

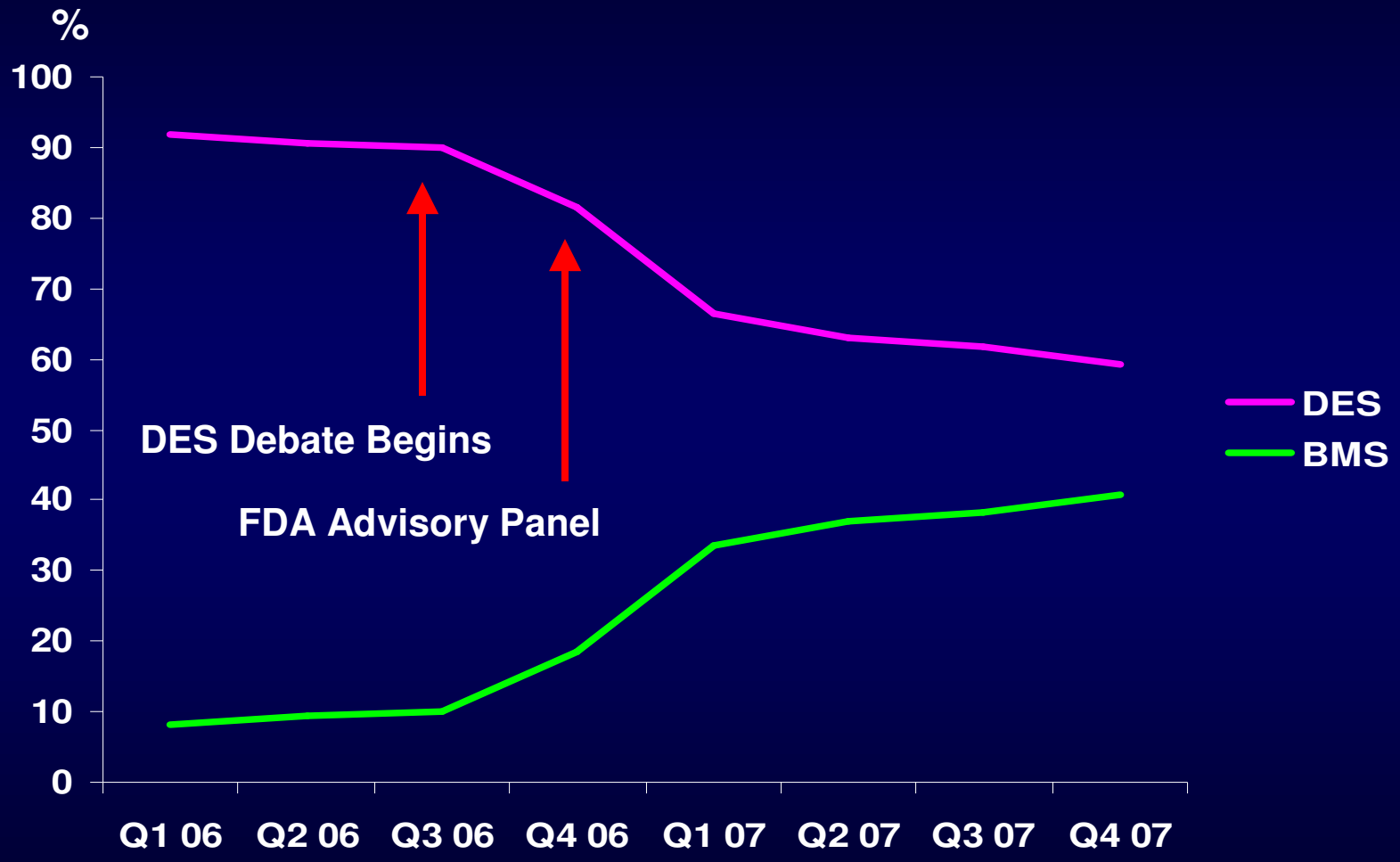
Grant from Office of Women's Health, Food and Drug Administration

Rate per 10,000 of Local Vascular Complications by Type Hemostasis (Univariate Analysis) - Year 2003

N=13,878



Trends in DES vs. BMS Use for PCI for NSTEMI



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Present Focus for National Registries

- Achieve data standardization
- Streamline data collection-100% EHR integration
- Unique Patient identifier – Legislative Approach
- Linkage of relevant Registries
- Longitudinal strategies – develop viable business cases

- **GOAL: Convert procedural or episodic hospital based Registries to "disease state" patient-centric registries**

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CMS- Yale- NCDR- ACC
Public Performance Measure Development

- Initial effort - NCDR CathPCI outcomes measures
  - 30 day mortality following PCI
  - 30 day readmission following PCI
- Linkage with CMS claims data for 30 day longitudinal assessment
  - Probabilistic Matching –unique patient admission by hospital, admission date, age, gender
  - HIPAA Compliant

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NCDR Data Merging Partnerships

- Society of Thoracic Surgery
  - Opportunity to merge CathPCI and CABG Databases
  - Understand practice patterns and longitudinal outcomes
  - Cross match patients with CMS data
  - Cross match patients with Health Plan data
    - Wellpoint, Aetna, BCBS, UnitedHealthcare:
      - Hospital, longitudinal, and pharmacy data
  - Funded Longitudinal projects:
    - Symptoms/Quality of Life Assessment via SAQ

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AHRQ/FDA Long-term Outcomes of Coronary Stents Study

- Clinical Effectiveness and Long-term Outcomes of Stents in PCI
- Duke Center of the AHRQ funded DEcIDE Network

Study Goal

To determine the comparative effectiveness of drug eluting stents (DES) versus bare metal stents (BMS) in both early and long term patient outcomes.

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NCDR Data Merging Partnerships

AHRQ- DEcIDE Collaborative with DCRI

- NCDR patients as AHRQ-DEcIDE database source
- Linkage of NCDR with complete Medicare files
  - Creating a longitudinal database
- Linkage with HMORN (Regional Network)
  - Kaiser patient data-pharmacy, costs, and longitudinal results
- Real world assessment tracking DES use/outcomes

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AHRQ- DEcIDE Collaborative with DCRI

- Advantages of NCDR large patient base
  - Assess low frequency adverse events
  - Subgroup patients of interest:
    - Women
    - Minorities
    - Diabetes
    - Acute coronary syndromes
    - Very elderly (>80years)
    - Renal failure

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Key Principles of National Clinical Registries

A. Patient-Centric
   A. Seamless
   B. EHR Integrated
   C. Patient-focused
B. Interoperable
C. Transparent
D. Efficient- operate in real time
E. High Data Quality

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Uses of Registry Data

A. Quality Improvement
B. Clinical Practice Guidelines
C. Post-Market Surveillance
D. Informed Decision Making in Real Time
E. Maintenance of Certification & Privileging
F. Meet Regulatory Needs
G. Pay for Participation, Reporting, and Performance
H. Clinical Research

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Registry Standards

A. Standardized Data Elements and Definitions
B. Evidence-based Performance Measures
C. Quality and Performance Key Metrics
D. Risk-adjusted Outcomes, Process and Structural Measures
E. Appropriateness & Effectiveness Measures
F. Financial Data

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Principles of National Clinical Registries
Coordination of Key Players

- Medical Professional Societies
- Hospital Organizations and Leaders
- Payers (CMS and Private)
- AMA Consortium
- NQF
- AQA, SQA
- FDA
- NHLBI, NIH
- AHRQ, CDC
- And more

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NCDR Research

- Informing Public policy
  - Evidence-based reimbursement
  - State regulations/CON
- Growing interest to assess patient quality of life and functional status
  - Linking with SAQ
- Intense interest in assessing efficiency, ROI,
  - linking with administrative data (CMS, health plans)

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NCDR Research

- Effectiveness and Translational Research
  - role for planned Institute of CER
  - Diffusion of new technologies
- Post Market Surveillance
  - Adverse/sentinel events
  - Identify device performance trends,
  - Inappropriate off-label use,
  - Hypotheses for follow up studies
- Quality Improvement
  - Effectiveness of P4P
  - Guideline adherence
  - Performance measure development, implementation, validation

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Legal/Regulatory Implications

A. Unique patient identifiers
B. HIPAA challenges –
   - Stimulus Package, IT legislation
   - active lobbying needed!!
C. IRB issues (QI vs Research)
D. Longitudinal data
E. Linkage of databases

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GENOMICS: Clinical Translation & Registries

- Conversion of a QI model to Longitudinal study
  - IRB approval, Patient consent, HIPAA compliant
- Linkage with DNA banks, genomic/bio markers
  - Financial models – Registry versus "Study" (time limited)
  - Opportunity: industry & public/private financing models
    - Biomarker companies, pharmaceuticals
  - Long term viability

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What kind of uses of genetics are considered by the NCDR ?

What evidence do you need to make decisions about these uses?

– Just beginning to think about connecting “the dots”

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What kind of process is used to make the decisions?

- NCDR prioritizes all opportunities considering:
  - The Science
  - The Political Landscape and Potential Partners
  - NCDR Heart House Operational Resources
  - Business Case

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NCDR & Professional Society: Genomic Translation

Infrastructure built on Partnerships with:

- Academic Centers
- Analytical Centers
- Health Plans
- CROs
- Merged data from other relevant Registries and payer data (administrative, pharmacy, national death data, etc

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