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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“No relationships to disclose”
What is the American College of Cardiology (ACC)?

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
“Science tells us what we can do; Guidelines what we should do; Registries what we are actually doing.”
The Cycle of Clinical Effectiveness

- Concept
- Clinical Trials
- Outcomes
- Guidelines
- Performance Indicators
- QUALITY & Effectiveness

NCDR: ACTION Cath PCI & STS
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
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?

Registries
- CathPCI
- IMPACT
- ICD
- IC3
- CARE
- ACTION-GWTG

Registry Studies
- SPECT MPI
- ICD Long.

Analytic Reporting Services
- WellPoint
- CMS
- BCBS
- WVMI
- United
- ACC
- BMC2
- Aetna
- HCA

Research & Publication Services
- FDA
- Yale
- ACC
- Industry
- DCRI
- Ad hoc
- MAHI

Quality Improvement
- Care Plans
- Standard Order Sets

- Guidelines Develop.
- Educational Needs Assess.
- Market Intelligence
Timeline of building a true... National Cardiovascular Data Registry

1998..... 2004 2005 2006 2007 2008 beyond
Each Program includes the following:

- Steering Committee
- QI Subcommittee
- Research & Publications

NCDR Management Board

Scientific Oversight Committee

- ACTION Registry
- CathPCI Registry
- IMPACT Registry
- IC3 Program

CQC

ACC BOT
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
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
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

Founding Sponsors
Bristol-Myers Squibb and Sanofi Partnership and Schering Plough Corporation
Registry

- 1,507 enrolled
- 330,000 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 Longitudinal Study
- Atrial Fibrillation Ablation Registry
- Perform analysis for FDA
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
IMproving Pediatric and Adult Congenital Treatment (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
# Executive Summary Performance Metrics

## PCI Quality Measures

<table>
<thead>
<tr>
<th>Measure</th>
<th>Worse</th>
<th>Better</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Proportion of STEMI Pts with DBT ≤ 90&quot;</td>
<td></td>
<td>65.5%</td>
</tr>
<tr>
<td>My Hospital: 65.5% (Rank: 87 of 389, Rank Percentile: 78)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Risk Adjusted Mortality</td>
<td></td>
<td>1.02%</td>
</tr>
<tr>
<td>My Hospital: 1.02% (Rank: 118 of 366, Rank Percentile: 68)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Your hospital’s PCI mortality rate adjusted using the ACC-NCDR® risk adjustment model [Detail Line: 1732]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Incidence of Vascular Complications</td>
<td></td>
<td>2.7%</td>
</tr>
<tr>
<td>My Hospital: 2.7% (Rank: 286 of 401, Rank Percentile: 30)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Includes procedures with at least one vascular complication. [Detail Line: 2029]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Percentage of Primary PCI with D2B <= 90 minutes

NCDR CathPCI v3

- 2004 STEMI ACC/AHA Guideline Update & JCAHO Core Measure
- D2B Alliance Launch

Timeframe:
- 2004Q3
- 2004Q4
- 2005Q1
- 2005Q2
- 2005Q3
- 2005Q4
- 2006Q1
- 2006Q2
- 2006Q3
- 2006Q4
- 2007Q1
- 2007Q2
## Pre-CathPCI Risk Models

<table>
<thead>
<tr>
<th>Label</th>
<th>Full Model ‡</th>
<th></th>
<th></th>
<th>Precaht Simple Model</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>O.R.</td>
<td>95% CI</td>
<td>Wald Chi-Square</td>
<td>O.R.</td>
<td>95% CI</td>
<td>Wald Chi-Sq</td>
</tr>
<tr>
<td>Age (for age&lt;=70) ‡</td>
<td>1.55</td>
<td>1.44</td>
<td>1.69</td>
<td>1.52</td>
<td>1.40</td>
<td>1.64</td>
</tr>
<tr>
<td>Age (for age&gt;70) ‡</td>
<td>1.71</td>
<td>1.57</td>
<td>1.88</td>
<td>1.76</td>
<td>1.60</td>
<td>1.91</td>
</tr>
<tr>
<td>Previous History - CHF</td>
<td>1.29</td>
<td>1.13</td>
<td>1.47</td>
<td>1.75</td>
<td>1.54</td>
<td>1.98</td>
</tr>
<tr>
<td>Peripheral Vascular</td>
<td>1.53</td>
<td>1.35</td>
<td>1.74</td>
<td>1.67</td>
<td>1.48</td>
<td>1.89</td>
</tr>
<tr>
<td>Chronic Lung Disease</td>
<td>1.48</td>
<td>1.31</td>
<td>1.66</td>
<td>1.52</td>
<td>1.36</td>
<td>1.71</td>
</tr>
<tr>
<td>GFR for stemi ‡</td>
<td>0.77</td>
<td>0.74</td>
<td>0.80</td>
<td>0.77</td>
<td>0.75</td>
<td>0.78</td>
</tr>
<tr>
<td>Cardiogenic Shock at Admission</td>
<td>8.35</td>
<td>7.40</td>
<td>9.44</td>
<td>12.19</td>
<td>10.86</td>
<td>13.68</td>
</tr>
<tr>
<td>NYHA Class IV for STEMI</td>
<td>1.21</td>
<td>1.05</td>
<td>1.39</td>
<td>1.61</td>
<td>1.46</td>
<td>1.79</td>
</tr>
<tr>
<td>Urgent PCI Status- STEMI ‡</td>
<td>1.09</td>
<td>0.64</td>
<td>1.83</td>
<td>0.09</td>
<td>1.25</td>
<td>0.748</td>
</tr>
<tr>
<td>Emergency PCI Status-STEMI ‡</td>
<td>2.07</td>
<td>1.30</td>
<td>3.31</td>
<td>2.65</td>
<td>1.68</td>
<td>4.18</td>
</tr>
<tr>
<td>Salvage PCI Status-STEMI ‡</td>
<td>14.55</td>
<td>8.39</td>
<td>25.21</td>
<td>21.45</td>
<td>12.57</td>
<td>36.61</td>
</tr>
</tbody>
</table>

‡ 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

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

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

Odds Ratio (OR): outcomes for patients at On-Site (vs. Off-Site) facilities adjusting for site correlations and potential confounding variables
### Outcomes of Patients > 85 years undergoing PCI

**ACC-NCDR® 2001-2004**

<table>
<thead>
<tr>
<th></th>
<th>Mortality</th>
<th>Emerg. CABG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic CAD (n=14,077)</td>
<td>1.4%</td>
<td>0.2%</td>
</tr>
<tr>
<td>STEMI (n=2,941)</td>
<td>15.6%</td>
<td>0.3%</td>
</tr>
<tr>
<td>Non-STEMI (4,316)</td>
<td>5.1%</td>
<td>0.2%</td>
</tr>
</tbody>
</table>

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

DES Debate Begins
FDA Advisory Panel

Q1 06 Q2 06 Q3 06 Q4 06 Q1 07 Q2 07 Q3 07 Q4 07

DES
BMS
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
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
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
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.
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
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 (>80 years)
    - Renal failure
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
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
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
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
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)
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
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
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
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”
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
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)