National Cardiovascular Data Registry

Young and Early Career Investigators
ACC/AGS/NIA Multimorbidity in Older Adults with Cardiovascular Disease Workshop

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Mission of NCDR

To improve the quality of cardiovascular patient care by providing knowledge and tools; implementing quality initiatives; and supporting research that improves patient care and outcomes.
>2,500 hospitals
>3,500 cardiologists
>35 million clinical records
That was Then...  
...This is Now

1997...
- Launched 1997
- 1 registry
- Focused on quality patient care

2007...
- More than 2,200 hospitals and 700 practices
- Health plans and government regulator adoption
- Industry uses for market research, clinical research
- FDA uses NCDR data for post market assessment
- EHR Integration

2015...
- Patient centric
- Value-based reimbursement reporting tool
- Global
- Platform for clinical trials and CER
- Post approval studies/IDEs
- MOC/MOL tool
- QI tools and initiatives
<table>
<thead>
<tr>
<th>Name</th>
<th>Disease or Device</th>
<th>Facility</th>
<th>Sites</th>
<th>Patient Records</th>
</tr>
</thead>
</table>
| CathPCI            | Percutaneous coronary interventions
Diagnostic catheterizations           | Cath Lab                   | 1,683 | 17,000,000      |
| ICD                | Implantable cardioverter defibrillators                                         | EP Lab                     | 1,770 | 1,500,000       |
| ACTION-GWTG        | Acute coronary syndrome
STEMI and NSTEMI                      | Emergency                  | 985   | 920,000         |
| CARE/PVI           | Carotid artery revascularization
Lower extremity                    | Cath Lab, Surgical
Radiology                      | 205   | 340,000
(CAS & CEA)               |
| IMPACT             | Congenital heart disease
Pediatric and Adult                 | Cath Labs w/ Congenital
Service                        | 92    | 40,000          |
| PINNACLE           | Coronary artery disease, heart failure, atrial fibrillation,
hypertension, diabetes, peripheral
arterial disease               | Outpatient                 | 2,684 | 15,000,000      |
| STS/ACC TVT        | Transcatheter Valve Therapy                                                      | Hybrid Surgical or Cath Lab
Cath Lab                       | 354   | 28,000          |
NCDR Collaborations
How is ACC’s registry data used?

- Health plan reimbursement
- Research:
  - Evidence based medicine
  - Surveillance
- Health system / practice monitoring
- State and federal quality improvement
- Facilitates public reporting
NCDR: A Community of Quality

Data Standards
Guidelines
Performance Measures
Appropriateness Criteria
Risk Models
NCDR Data Acquisition

- Software Vendors
- Home grown systems
- ACC’s web tool
- EHR
- Longitudinal Administrative Databases
- Benchmark Reporting
- Quality Improvement
- Clinical Research

Helping Cardiovascular Professionals
Common Data Sections

- Demographics
- Episode of Care
- History and Risk Factors
- Procedure information
- Lesions and Devices
- Labs
- Post Procedure Events
- Discharge
- Follow up module
Outcome Reporting

Executive Summary

Section III: Quality Metrics

Detail Section
NCDR Research
Traditional Clinical Research Studies

<table>
<thead>
<tr>
<th>Benefits</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Industry “Gold Standard”</td>
<td>- Expense</td>
</tr>
<tr>
<td>- Rigorous</td>
<td>- Strict inclusion/exclusion criteria</td>
</tr>
<tr>
<td>- Controlled and Monitored</td>
<td>- Often restricted to “research ready” specialized study centers and</td>
</tr>
<tr>
<td>- Levels of randomization</td>
<td>experienced Investigators known as “thought leaders”</td>
</tr>
<tr>
<td>- High Data Quality</td>
<td>- Lengthy timeframe</td>
</tr>
<tr>
<td>- Regulatory Requirements</td>
<td>- Often requires industry sponsorship</td>
</tr>
<tr>
<td>- Useful tool for investigating new drugs and devices</td>
<td>- Increasing number of visits, procedures and data collection requirements</td>
</tr>
<tr>
<td></td>
<td>- Difficult to identify low frequency safety signals</td>
</tr>
</tbody>
</table>
NCDR used for PAS, PMS, IDEs

Pre-Market

Phase 1  Phase 2  Phase 3

Post-Market

Role for New Generation of Clinical Registries

Phase 4

Post-Approval  Post-Market  Registries
## Current Post Market Studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Sites/Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ASCERT SYNTAX Study</strong></td>
<td>60 CathPCI sites</td>
</tr>
<tr>
<td><strong>TRANSOLVE</strong></td>
<td>171 CathPCI sites</td>
</tr>
<tr>
<td><strong>SAFE PCI for Women</strong></td>
<td>50 high volume radial CathPCI sites</td>
</tr>
<tr>
<td><strong>ICD Longitudinal Study</strong></td>
<td>10 ICD sites</td>
</tr>
<tr>
<td><strong>Edwards PAS / IDEs</strong></td>
<td>1st 5,000 patients in the STS/ACC TVT Registry</td>
</tr>
<tr>
<td><strong>Boston Scientific Corporation</strong></td>
<td>Use data captured via the ICD Registry</td>
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</table>

*Helping Cardiovascular Professionals
Learn. Advance. Heal.*
New PINNACLE® Registry
Research Alliance

- American College of Cardiology (ACC)
- Leverages PINNACLE Registry
  - 25k physician-patient encounters/day
- Addresses lack of diverse patient pool
- Facilitates patient recruitment
- Drives down screening and recruitment costs

NCDR.com/PinnacleAlliance
Approximately 1 in 4 PCIs done in the U.S. are on patients >75 years old.
Presentation: ≥75 versus <75 years

- Elective PCI: 47% (vs. 45%)
- Asymptomatic: 15% (vs. 11%)
- NSTEMI: 19% (vs 17%)
- STEMI: 12% (vs. 17%)
  - Primary PCI: 10% (vs. 14%)
NCDR Home

Data Powering Performance

The NCDR® is the American College of Cardiology’s suite of cardiovascular data registries helping hospitals and private practices measure and improve the quality of care they provide.

Cardiology’s most established, comprehensive registry offering, the NCDR consists of five hospital based registries, one outpatient registry and two multispecialty registries. Learn about the NCDR’s suite of registries.

NCDR participation benefits individual providers, care teams and administrators. The NCDR offers the most relevant data elements and metrics, actionable reports and opportunities to do even more with your data through quality improvement programs. Learn about the benefits of participating.

Make the Most of Your NCDR Experience

Quality Improvement for Institutions

Advertisement

Save Time & Improve Efficiency
with LUMEDX
The #1 Independent Provider of Registry Software
Providing Answers That Advance Cardiovascular Care

About NCDR Research

The NCDR is positioned to examine critical questions pertaining to cardiovascular healthcare and its delivery. The NCDR's substantial participant base comprising hospitals and outpatient practices, coupled with a growing patient population, have allowed for the creation of a vast repository of clinical data invaluable to those wishing to conduct cardiovascular research. The NCDR's robust datasets hold answers to complex questions by collecting relevant clinical information such as patient risk factors and outcomes, procedure and treatment trends, guidelines adherence, and device, facility and provider characteristics.

How to Participate in NCDR Research

Offering two distinct opportunities for engagement in research, the NCDR allows individuals and organizations to submit hypothesis-driven research requests based on analysis of NCDR data. For information, visit our Research & Publications page.

In addition, the NCDR offers hospitals, practices and cardiac care facilities opportunities to participate in a growing number of government and privately funded NCDR research projects. These projects can be focused on outcomes research, comparative effectiveness research, longitudinal studies and surveys. For information, visit our Research Studies page.
The NCDR's Research and Publications process allows investigators to submit research proposals based on analysis of limited datasets from the registries. This robust investigator-lead research program is an important component of the NCDR's quality improvement efforts. Submitted proposals are reviewed for scientific merit and undergo a competitive approval process for NCDR funding, which is used to support analysis conducted by an NCDR-contracted data analytic center. The NCDR does not release limited datasets to individual investigators or organizations.

Research & Publications Process

Research proposals are intended for hypothesis-driven studies based upon secondary analysis of NCDR data, with the intent to develop manuscripts suitable for peer-reviewed publication. These studies require the completion of a formal research proposal application (RPA) and will undergo a careful review process. When an investigator submits an RPA, the proposed project enters the NCDR Research and Publications (R&P) pipeline. This includes:

1. Proposal review, approval and prioritization by the appropriate NCDR Research and Publication Subcommittees
2. Analysis by an NCDR-designated analytic center
3. Oversight of manuscript and abstract preparation and submission

Patient, hospital and physician confidentiality is always protected. All projects are supervised by NCDR R&P committees to ensure adherence to NCDR data access and use policies and procedures, as well as relevant regulations.

Submitting Research Proposals:

1. All applications must be submitted online via the online management system. Review the brief
Submitting Research Proposals

1. Review “Intro. to NCDR Research Management System”
2. NCDR Research Calendar- for submission deadlines
3. “Applications Instructions and Author Guidelines”
4. Choose Appropriate Registry
5. Check for Overlap
   - NCDR Manuscripts and Abstracts by Registry and current unpublished projects
CATHPCI Registry and the Elderly

• Patterns of stress testing and diagnostic catheterization after coronary stenting in 250,350 medicare beneficiaries. Circ Cardiovasc Imaging 2013

• Bleeding-Avoidance Strategies and Outcomes in Patients >80 Years of Age With ST-Elevation Myocardial Infarction Undergoing Primary Percutaneous Coronary Intervention (NCDR® CathPCI Registry®). AJC 2013

• Downstream testing and subsequent procedures after coronary computed tomographic angiography following coronary stenting in patients ≥65 years of age. AJC 2013

ICD Registry and the Elderly

- QRS duration, bundle-branch block morphology, and outcomes among older patients with heart failure receiving cardiac resynchronization therapy. JAMA. 2013 Aug 14; 310(6):617-26


- Primary Prevention Implantable Cardioverter Defibrillators and Survival in Older Women. JACC Heart Fail. 2014
CARE Registry

In Preparation

ICD:
• Geriatric Conditions and Multimorbidity in Older Adults Undergoing Defibrillator Implantation for Primary Prevention of Sudden Cardiac Death: Prevalence and Impact on Mortality.
• CRT in the Elderly: Benefit and Long-Term Outcome.

CathPCI Registry:
• Safety and Clinical Effectiveness of Drug-Eluting Stents for Saphenous Vein Graft Stenting in Older Individuals: Results from the Medicare-linked National Cardiovascular Data Registry® CathPCI Registry® (2005-2009).
• PCI in Older Patients with Syncope and Obstructive Coronary Artery Disease.

CARE Registry:
In Preparation

ACTION:

• Interaction between MI type and Revascularization Use During the Index Hospitalization on Short- and Long-Term Outcomes Among Elderly patients
• Post-Hospital Outcomes for Elderly Survivors of Acute Myocardial Infarction Complicated by Shock: Findings from the NCDR® ACTION Registry-GWTG
• Long-term outcomes in elderly survivors of acute coronary syndrome complicated by out-of-hospital cardiac arrest

TVT:

• Outcomes of Treatment of Nonagenarians with Severe Aortic Stenosis
NCDR Research & Publications

NCDR Research & Publications (R&P) Application Instructions and Author Guidelines
National Cardiovascular Data Registry’s (NCDR®) Research and Publications (R&P) Program

Introduction to the NCDR Research Management System
Background

A web-enabled tracking system that:

• Manages the R&P process, from RPA submission through journal publication

• Allows various users a centralized location for accessing files and information, and reviewing documents

• Allows investigators to submit research proposals based on analysis of limited datasets from the registries
Background (cont.)

• Studies require the completion and submission of a formal research proposal application (RPA) using this system

• Approved research proposals are expected to produce manuscripts suitable for peer-reviewed journal publication

• Abstracts and manuscripts developed from the approved RPAs must be reviewed by co-authors, analytic centers, and relevant committees
Key Features of the System Include:

• Online RPA entry and submission, as well as abstract and manuscript submission for committee review
• Ability for investigators to view status of RPAs, abstracts, and manuscripts
• Ability for committee members to review RPAs, abstracts and manuscripts online
• Enhanced communication capabilities with data analytic centers
• Enhanced tracking and reporting capabilities
Technical Details & Accessibility

• Preferred browsers are Microsoft Internet Explorer and Google Chrome.
  – Mozilla Firefox or Safari/Mac are not recommended for use with this system.

• The online system may be accessed at: http://rp.acc.org
Technical Details & Accessibility

• A CardioSource ID and password are required to access the system.
  – For customer assistance regarding a CardioSource log in, please call: 800-253-4636 ext. 5603 (Toll Free US & Canada, 202-375-6000 ext. 5603); or send an email to resource@acc.org.
  – Please ensure your current or preferred email address is updated in CardioSource. The system sends automated emails to your primary email address in CardioSource. Users are asked to use the same email for CardioSource as well as the NCDR’s Online Research Management System.
Online Dashboard

- Dashboard divided into sections for different tasks
- Tasks will vary by user; you may not need to use every section

![Online Dashboard Screenshot]

- Your New RPAs
- Your Approved RPAs
- RPA-related Review Tasks (e.g., committee members)
- Abstract/Manuscript Review Tasks (e.g., committee members)
Completing Tasks

- Users will be asked to complete tasks as the R&P process progresses.
- When there is a task to complete, the system will send you an email.
- You can also find the task listed on your dashboard.

Click here to return to the “home” page.

Tip: Refreshing your browser page will clear any tasks that you may have recently completed, but are still showing on your task list.
Contact Information/Help

- Email: NCDRresearch@acc.org
- Phone: (800) 257-4737
- System Website: http://rp.acc.org
- R&P Website: http://www.NCDR.com
- Login assistance: 800-253-4636 ext. 5603 (Toll Free US & Canada, 202-375-6000 ext. 5603) or send an email to resource@acc.org.)