Registry Design & Reporting: The NCDR

ACC/AGS/NIA Multimorbidity in Older Adults with Cardiovascular Disease Workshop

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Clinical Professor of Medicine
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We Have Robust Evidence & Guidelines—Why Registries?

Evidence -> Guidelines

The New England Journal of Medicine

ACCF/AHA/HRS Practice Guideline

The diagram illustrates the relationship between evidence, guidelines, and clinical practice. The text indicates the importance of registries in supporting robust evidence and clinical practice guidelines.
Challenges in Evidence Based Medicine

Karen Alexander, DCRI
Clinical Registries: Not Just Observational Studies

Data elements and definitions

Clinical Data

Observational Database

Quality Assessment

Quality Improvement

Clinical Research

NCDR: Research to Motivate Change

Non–Evidence-Based ICD Implantations in the United States

Sana M. Al-Khatib, MD, MHS
Anne Hellkamp, MS
Jeptha Curtis, MD
Daniel Mark, MD, MPH
Eric Peterson, MD

Context Practice guidelines do not recommend use of an implantable cardioverter-defibrillator (ICD) for primary prevention in patients recovering from a myocardial infarction or coronary artery bypass graft surgery and those with severe heart failure symptoms or a recent diagnosis of heart failure.

Objective To determine the number, characteristics, and in-hospital outcomes of patients who receive a non–evidence-based ICD and examine the distribution of these patients in the United States over a 10-year period.

Conclusion Among patients with ICD implants in this registry, 22.5% did not meet evidence-based criteria for implantation.

Sara M. Gault, MD
Stephen Hammill, MD

Several randomized controlled trials have proven the efficacy of the implantable cardioverter-defibrillator (ICD) at preventing sudden cardiac death in patients with advanced systolic heart failure. These trials excluded patients who were in the acute phase of a myocardial infarction (MI), had recent coronary revascularization, had New York Heart Association (NYHA) class IV symptoms, or had newly diagnosed heart failure. In other clinical trials, survival benefit from ICD therapy could not be demonstrated in patients recovering from myocardial infarction.

Main Outcome Measure In-hospital outcomes.

Results Of 111,707 patients, 25,145 received non–evidence-based ICD implants (22.5%). Patients who received a non–evidence-based ICD compared with those who received an evidence-based ICD had a significantly higher risk of in-hospital death (0.57% [95% confidence interval (CI), 0.48%-0.66%] vs 0.18% [95% CI, 0.15%-0.20%]; P<.001) and any postprocedure complication (3.23% [95% CI, 3.01%-3.45%] vs 2.41% [95% CI, 2.31%-2.51%]; P<.001). There was substantial variation in non–evidence-based ICDs by site. The rate of non–evidence-based ICD implants was significantly lower for electrophysiologists (20.8% [95% CI, 20.5%-21.1%]) than nonelectrophysiologists (24.8% [95% CI, 24.2%-25.3%] for nonelectrophysiologist cardiologists; 36.1% [95% CI, 34.3%-38.0%] for thoracic surgeons; and 24.9% [95% CI, 23.8%-25.9%] for other specialties) (P<.001 for all comparisons). There was no clear decrease in the rate of non–evidence-based ICDs over time (24.5% [6908/28233] in 2006, 21.8% [7395/33965] in 2007, 22.0% [7245/32960] in 2008, and 21.7% [3597/16549] in 2009; P=.94 for trend from 2006-2009 and P=.94 for trend from 2007-2009).

Conclusion Among patients with ICD implants in this registry, 22.5% did not meet evidence-based criteria for implantation.

JAMA. 2011;305(1):43-49
Completing the Cycle of Medical Knowledge

Data Powering Performance

>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>
<tbody>
<tr>
<td>CathPCI</td>
<td>Percutaneous coronary interventions</td>
<td>Cath Lab</td>
<td>1,683</td>
<td>17,000,000</td>
</tr>
<tr>
<td></td>
<td>Diagnostic catheterizations</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICD</td>
<td>Implantable cardioverter defibrillators</td>
<td>EP Lab</td>
<td>1,770</td>
<td>1,500,000</td>
</tr>
<tr>
<td>ACTION-GWTG</td>
<td>Acute coronary syndrome STEMI and NSTEMI</td>
<td>Emergency</td>
<td>985</td>
<td>920,000</td>
</tr>
<tr>
<td>CARE/PVI</td>
<td>Carotid artery revascularization Lower extremity</td>
<td>Cath Lab, Surgical Radiology</td>
<td>205</td>
<td>340,000 (CAS &amp; CEA)</td>
</tr>
<tr>
<td>IMPACT</td>
<td>Congenital heart disease Pediatric and Adult</td>
<td>Cath Labs w/ Congenital Service</td>
<td>92</td>
<td>40,000</td>
</tr>
<tr>
<td>PINNACLE</td>
<td>Coronary artery disease, heart failure, atrial fibrillation, hypertension, diabetes, peripheral arterial disease</td>
<td>Outpatient</td>
<td>2,684</td>
<td>15,000,000</td>
</tr>
<tr>
<td>STS/ACC TVT</td>
<td>Transcatheter Valve Therapy</td>
<td>Hybrid Surgical or Cath Lab</td>
<td>354</td>
<td>28,000</td>
</tr>
</tbody>
</table>
NCDR Data Acquisition

Software Vendors

Home grown systems

ACC’s web tool

EHR

Longitudinal Administrative Databases

Benchmark Reporting

Quality Improvement

Clinical Research
Data Quality

- **Training and Clinical Support Team**
  - Orientation webinars
  - Online FAQs
  - Live customer support
  - Email
  - Monthly webinars
  - Annual meeting with case reviews, etc.

- **Data Entry Integrity**
  - Software value checks
  - Field level range parameters
  - Parent:Child fields

- **Data Completeness**
  - Completeness monitoring reports

- **Data Accuracy**
  - Up to 650 records audited annually.

- **Adjudication**

NCDR.14 over 1,000 attendees
National Audit Program (NAP)

Methodology
- Data submitted the previous year
- Subset of data elements (rotating each year)
- Hybrid of random and targeted selection of sites
- Remote and onsite review
- Stratified selections for records
- Blinded data abstraction from medical charts
- Inter-rater Reliability Assessment
- Adjudication Phase

Scope
- 6 onsite review (Targeted) + 267 remote reviews
- 2,850 records
- Review of hospital’s medical records
- Assessment of submission completeness
**NCDR Data Quality Brief**

- **Self reported**

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**The National Cardiovascular Data Registry (NCDR) Data Quality Brief**

The NCDR Data Quality Program in 2012

John C. Messenger, MD,* Kalon K. L. Ho, MD, MSc,† Christopher H. Young, PhID,‡ Lara E. Slattery, MHS,§ Jasmine C. Draoui, MS,¶ Jeptha P. Curtis, MD,§ Gregory J. Dehmer, MD,|| Frederick L. Grover, MD,¶ Michael J. Mirro, MD,# Matthew R. Reynolds, MD, MSc,** Ivan C. Rokos, MD,†† John A. Spertus, MD, MPH,‡‡ Tracy Y. Wang, MD, MHS, MSc,§§ Stuart A. Winston, DO,¶¶ John S. Rumsfeld, MD, PhID,¶¶ Frederick A. Masoudi, MD, MSPh,* on behalf of the NCDR Science and Quality Oversight Committee Data Quality Workgroup

_Aurora and Denver, Colorado; Boston, Massachusetts; Washington, DC; New Haven, Connecticut; Temple, Texas; Fort Wayne, Indiana; Los Angeles, California; Kansas City, Missouri; Durham, North Carolina; and Ann Arbor, Michigan_

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In the 2010 audits, the participant average raw accuracy of data abstraction for the CathPCI Registry, ICD Registry, and ACTION Registry-GWTG were, respectively, 93.1% (range, 89.4% minimum, 97.4% maximum), 91.2% (range, 83.7% minimum, 95.7% maximum), and 89.7% (range, 85% minimum, 95% maximum).
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 experienced Investigators known as “thought leaders”</td>
</tr>
<tr>
<td>• Levels of randomization</td>
<td>• Lengthy timeframe</td>
</tr>
<tr>
<td>• High Data Quality</td>
<td>• Often requires industry sponsorship</td>
</tr>
<tr>
<td>• Regulatory Requirements</td>
<td>• Increasing number of visits, procedures and data collection requirements</td>
</tr>
<tr>
<td>• Useful tool for investigating new drugs and devices</td>
<td>• Difficult to identify low frequency safety signals</td>
</tr>
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</table>
National Cardiovascular Research Infrastructure (NCRI)

- Initiated in 2009 by DCRI and ACCF
- Four goals to improve cardiovascular research

| Replace the repetitive assembly and disassembly of short-lived clinical investigator networks with a stable and enduring operational infrastructure for clinical research; | Standardize and harmonize cardiovascular data to achieve complete syntactic and semantic interoperability throughout the network; | Coordinated and facilitate the transfer of selected, standardized cardiovascular data into existing and future national registries; and | Develop an enduring library of content for education and training of clinical investigators and site personnel. |
Using a National Clinical Registry as a platform for research

- Economical
- Reduces data entry burden
- Real world population
- Consecutive patients

- Larger patient volumes
- Can use central randomization mechanism
- Ongoing data capture
NCDR Research is Scalable

### Traditional Approach

- **Recruitment**: $$$ Longer
  - select among existing participants
- **Site Training Support**: build upon existing training structures
- **IRB/Informed Consent**: traditional
- **Site Monitoring**: onsite and remote monitoring
- **Data Capture**: registry + more
- **Adjudication**: clinical event committee

### Novel Approach

- **Recruitment**: $ Shorter
  - select among existing participants
- **Site Training Support**: build upon existing training structures
- **IRB/Informed Consent**: modified
- **Site Monitoring**: registry completeness & select audits
- **Data Capture**: registry only
- **Adjudication**: algorithmic
## An example... SAFE-PCI for Women

<table>
<thead>
<tr>
<th><strong>In a nutshell...</strong></th>
<th><strong>Programmatic outcomes...</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• NCRI proof of concept</td>
<td>• $750 per patient reimbursement</td>
</tr>
<tr>
<td>• First multicenter randomized trial comparing radial with femoral access in U.S.</td>
<td>• ~ $5 million budget</td>
</tr>
<tr>
<td>• First randomized trial comparing interventional strategies in women</td>
<td>• Study start up time cut in half</td>
</tr>
<tr>
<td>• Sponsored by DCRI</td>
<td>• Included research naive sites</td>
</tr>
<tr>
<td>• Used NCDR CathPCI Registry platform</td>
<td>• Wider enrollment spread</td>
</tr>
<tr>
<td>• Estimated 65% per patient workload reduction</td>
<td>• 90% sites enrolled at least 1 patient</td>
</tr>
<tr>
<td></td>
<td>• &gt; 70% sites enrolled at least 10 patients</td>
</tr>
</tbody>
</table>
NCDR used for PAS, PMS, IDEs

Pre-Market  Phase 1  Phase 2  Phase 3

Post-Market Post-Approval Post-Market Registries

Role for New Generation of Clinical Registries

Phase 4
## Current Post Market Studies

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

- American College of Cardiology (ACC)
- Leverages PINNACLE Registry – 25k physician-patient encounters/day
- Addresses lack of diverse patient pool
- Facilitate 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%)
Who is Undergoing TAVR in the USA?

Demographics: Age, Sex, Race, Ethnicity

The Baby Boomers are Coming and US Demographics are Shifting in Race/Ethnicity
Women

What Does the STS-ACC TVT Registry Show?
(N= 7710 Patient Records)

Expected
Percentage of TAVR Patients Who are Predicted to be Women Based on US Census, TAVR Age Data, and Assumed Disease Frequency

61.9%

Actual
Percentage of TAVR Patients Who are Women

49.1%

WHY the difference?
Black-African/Americans
What Does the STS-ACC TVT Registry Show?
7710 Patient Records

Expected
Percentage of TAVR Patients Who are Predicted to be Black Based on US Census, TAVR Age Data, and Assumed Disease Frequency

9%

Actual
Percentage of TAVR Patients Who are Black

3.6%

WHY the difference?
The Outcomes of Transcatheter Aortic Valve Replacement in Patients with End-stage Renal Disease: A Report from the STS/ACC TVT Registry


For the TVT Registry
Conclusions

• Outcomes at 30 days and one year in patients with ESRD are significantly worse than in patients without renal disease
• TAVR outcomes are not clearly any better than historical outcomes of surgical AVR
• Functional and longer term outcomes are necessary
• Based on this data, TAVR should be used sparingly in select patients (STS PROM <15%) with aortic stenosis and ESRD without significant co-morbidities
Research and Publications

- January 2014 the R & P Committee accepted investigator research proposals for using the TVT Registry data
- 80 proposals already received!

“Outcomes of Rx of Nonagenarians with Severe Aortic Stenosis”

“Geriatric Conditions and Multimorbidity in Older Adults Undergoing Defibrillator Implantation (ICD) for Primary Prevention of Sudden Cardiac Death: Prevalence and Impact on Mortality”
Outcomes from TAVR and Surgical AVR

Is Consumer Level Reporting Coming?

Surgical Aortic Valve Replacement vs Transcatheter Aortic Valve Replacement
A Consumer’s Perspective Regarding Data Education and Transparency of Hospitals

Invited Commentary

A Consumer’s Pursuit of Health Care Outcomes Daunting Even With a Guardian Angel!

Michael Mack, MD
Assuming
1. Patients, Families, and Clinicians Have Access to TAVR and sAVR
2. Sites Have Outcomes That Are at Least as Good as Expected

How Can The TVT Registry Be Used to Help Patients, Families, and Clinicians in Key Patient-Centric Decisions?

Should they undergo TAVR, sAVR, or neither?
Do they have a reasonable choice between the approaches or is one treatment much better for them?
What are the patient-specific risks and benefits of different treatments?
“Optimizing Health Outcomes in Patients with Symptomatic Aortic Valve Disease.”

PICORI Grant Awarded Late 2013

Matthew Brennan, MD
Principle Investigator
DCRI
Research Goal:
Help patients make informed treatment decisions that incorporate their preferences and outcomes of interest

1. Creation and assessment of statistical prediction models
   - accurate and valid patient-level predictions of outcomes for patients with severe aortic stenosis treated with SAVR vs. TAVR.

2. Creation of decision assistance tools suitable for use by patients
   - Surgical candidates
   - A second tool for patients who have surgically inoperable disease.

3. Dissemination of these tools into clinical practice using a web-based platform coupled with a pilot evaluation of their effectiveness
The ASCERT II Study

American College of Cardiology Foundation - The Society of Thoracic Surgeons Collaboration on the Comparative Effectiveness of Revascularization Strategies

Fred H. Edwards, MD

William S. Weintraub, MD

The initial ASCERT project described herein was supported by Award Number RC2HL101489 from the National Heart, Lung, and Blood Institute. This award was issued under the American Recovery and Reinvestment Act of 2009.
ASCERT II OVERVIEW

Observational Study

Comparing Long-term Outcomes of Coronary Artery Bypass Grafting (CABG) with Percutaneous Catheter Intervention (PCI)

for Patients with Stable Coronary Artery Disease
ASCERT II OVERVIEW

- **STS Database**
- **ACC Database**

CMS

Probabilistic Linkage

- **Study Population**
To assess the effect of pre-procedure frailty and patient-reported health status on the clinical outcomes of CABG or PCI

- Assess the contribution of pre-procedure frailty and health status to subsequent mortality and major cardiovascular events after CABG or PCI

- Compare changes in patient-reported health status following CABG or PCI, adjusted for baseline status, in the entire population and in key subgroups
Significance of Frailty

ASCERT II will reflect the importance of patient frailty as a predictor of outcomes

- Frailty not recorded in observational studies and randomized clinical trials, but likely affects choice of treatment and outcome
- Few studies effectively measure the impact of frailty
- ASCERT II leadership includes a nationally-recognized expert in the study of frailty
Significance of Patient Perceptions

ASCERT II will tailor multiple PROM instruments for patients undergoing coronary revascularization.

**EQ-5D**
- Mobility
- Self-Care
- Activities
- Pain
- Anxiety

**PROMIS**
- Physical Function
- Emotional Distress
- Pain
- Fatigue
- Global Health

**Seattle Angina Questionnaire**
- Range of limitation experienced for seven different typical activities

**Patient Reported Outcome Measures**
ASCERT II Study Design

- PROM:
  - EQ-5D
  - PROMIS
  - SAQ

- Frailty:
  - 5m walk test
  - Weight loss

Frailty & Health Status Impact on Outcome

Site Recruitment
Positioning the NCDR Registry to Better Assess the CV Elderly

• Increase Data Elements of Co-Morbidities
• Employ Frailty/Cognitive Data Element(s)
• Promote QOL/PROM Data Collection
• “Surgical Turn down” Data Element?
• Coronary Calcium Element
• Harness the EMR- merge “big data” with NCDR
• Promote/expand the NCDR as a key research infrastructure engine
Tiered Center Certification*  

ST/S/ACCF  

Strengthening the Clinical Trial Enterprise

**Criteria**
- Dataset Needs/Capabilities
- Research Infrastructure
- IRB/Contracting Efficiency
- Clinical Infrastructure/Case mix
- Volume and Outcomes

**Databases/Registries**
- TVT Aortic
- TVT Mitral
- PINNACLE
- STS Adult
- CathPCI
- PVI
- ACTION-GWTG

**Subscription**

*Sites apply for certification level desired in each database. Free to use certification level for each database in marketing.*