ICD Registry
Highlights to Date

- 1,438 hospitals
- >195,000 implants
- 56% are primary prevention CMS patients
- 88% of implants from hospitals entering all patients (1° and 2° prevention, all ages)

Getting to this point and moving forward

- Longitudinal registry developed (CED)
- Research and publications in progress
ICD Registry
Developing the Baseline Registry

9/28/04: CMS published proposed NCD

- Following SCD-HeFT release
- National data base proposed
- HRS asked to chair the Working Group to develop the registry
National ICD Registry Working Group

HRS, chair Medtronic
ACC Guidant
HFSA St Jude
STS Biotronik
FDA (observer)
CMS (observer)
At large experts: Robert Califf, Catherine Detre, Bernard Gersh, William Groh, David Malenka
ICD Registry
Developing the Baseline Registry

9/28/04: CMS published proposed NCD
  • Following SCD-HeFT release
  • National data base proposed
  • HRS asked to chair the Working Group to develop the registry

11/22/04: Working Group recommendations sent to CMS
  • Purpose of the registry
  • Patients to be enrolled
  • Patient and device data elements to be collected
  • Defining providers as competent and qualified to implant ICDs
ICD Registry
Developing the Baseline Registry

1/27/05: CMS published final NCD
- Expanded ICD indications
- CED process described
- Data collection using QNet
  Temporary data collection tool
What does CMS hope to gain from the Registry?

CMS’s goal is to determine whether primary prevention ICD’s are appropriate for the Medicare beneficiaries who meet the clinical conditions identified in the agencies NCD of 1/27/05.

Coverage with evidence development (CED)

Hammill, Phurrough, Brindis. HeartRhythm, 2006
CED
Coverage with evidence development

“Develop evidence on what works best in clinical practice . . . explicit, rapid, evidence based on a process that is predictable with transparency . . . to improve the knowledge base by which patients and providers can make better treatment decisions.”

Mark McClellan
Administrator, CMS
2/14/05 Conference call
ICD Registry
Developing the Baseline Registry

1/27/05: CMS published final NCD
  • Expanded indications
  • CED process described
  • Data collection using QNet
    Temporary data collection tool

3/05: HRS asked to reconvene the Working Group
  • Define questions that should be answered
  • Define the core characteristics of a national clinical registry

5/19/05: Recommendations sent to CMS
ICD Registry
Developing the Baseline Registry

10/27/05: CMS selected the ICD Registry developed by ACC and HRS based on the NCDR

1/1/06: All data submitted to ICD Registry; QNet phased out 4/1/06

• Hospitals encouraged to submit data on all patients
  SCD-HeFT – median age 60 yrs
  Medicare – median age 74 yrs

4/07: Quarterly benchmarking reports sent to hospitals

• DQR process
• Random auditing
“Observational registries can quickly accumulate large amounts of data on real-world practice and effectiveness of new treatments and procedures. Physicians and hospitals can use these data to further QI efforts at a local level and physician associations can evaluate data to determine the effectiveness of existing clinical guidelines.”

http://effectivehealthcare.ahrq.gov/reports
# National ICD Registry 2006

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (yr)</td>
<td>68</td>
</tr>
<tr>
<td>Male/female (%)</td>
<td>74/26</td>
</tr>
<tr>
<td>Race (%)</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>83</td>
</tr>
<tr>
<td>Black/African American</td>
<td>12</td>
</tr>
<tr>
<td>Hispanic</td>
<td>5</td>
</tr>
<tr>
<td>Asian</td>
<td>1</td>
</tr>
<tr>
<td>American Indian/Alaska Native</td>
<td>0.3</td>
</tr>
<tr>
<td>Native Hawaiian</td>
<td>0.2</td>
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<tr>
<td>Other</td>
<td>4</td>
</tr>
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</table>

Hammill et al: Heart Rhythm, 2007
### National ICD Registry 2006

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total implants (no.)</td>
<td>108,341</td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>72</td>
</tr>
<tr>
<td>Diabetes (%)</td>
<td>36</td>
</tr>
<tr>
<td>Chronic lung disease (%)</td>
<td>22</td>
</tr>
<tr>
<td>Ischemic heart disease, no. (%)</td>
<td>67</td>
</tr>
<tr>
<td>Non-ischemic dilated cardiomyopathy, no. (%)</td>
<td>30</td>
</tr>
<tr>
<td>Hx of cardiac arrest, no. (%)</td>
<td>10</td>
</tr>
<tr>
<td>Hx of CHF, no. (%)</td>
<td>77</td>
</tr>
<tr>
<td>NYHA class II-III (%)</td>
<td>80</td>
</tr>
<tr>
<td>QRS duration (ms)</td>
<td>129</td>
</tr>
<tr>
<td>Ejection fraction (%)</td>
<td>27</td>
</tr>
</tbody>
</table>

**Hammill et al: Heart Rhythm, 2007**
## National ICD Registry 2006

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total implants (no.)</td>
<td>108,341</td>
</tr>
<tr>
<td>Single chamber ICD (%)</td>
<td>23</td>
</tr>
<tr>
<td>Dual chamber ICD (%)</td>
<td>39</td>
</tr>
<tr>
<td>Biventricular ICD (%)</td>
<td>38</td>
</tr>
<tr>
<td>Adverse procedure-related event (%)</td>
<td>3.63</td>
</tr>
<tr>
<td>Death in laboratory</td>
<td>0.02</td>
</tr>
<tr>
<td>Cardiac perforation</td>
<td>0.08</td>
</tr>
<tr>
<td>Hematoma</td>
<td>1.27</td>
</tr>
<tr>
<td>Lead dislodgement</td>
<td>1.01</td>
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<tr>
<td>Hemo/pneumothorax</td>
<td>0.60</td>
</tr>
<tr>
<td>Transient ischemic attack/stroke</td>
<td>0.09</td>
</tr>
<tr>
<td>Other</td>
<td>0.56</td>
</tr>
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</table>

Hammill et al: Heart Rhythm, 2007
National ICD Registry 2006

Total implants (no.) 108,341

ICD indication, no. (%)

- Primary prevention 79
- Secondary prevention 21

Primary insurance payer (%)

- Medicare/medicaid 70
- Other payer 30

Hammill et al: Heart Rhythm, 2007
### National ICD Registry 2006

3,249 Physicians  
108,341 implants

<table>
<thead>
<tr>
<th>Training category</th>
<th>Physicians</th>
<th>Implants performed by category</th>
</tr>
</thead>
<tbody>
<tr>
<td>EP fellowship + Boards</td>
<td>53%</td>
<td>76%</td>
</tr>
<tr>
<td>EP fellowship only</td>
<td>6%</td>
<td>7%</td>
</tr>
<tr>
<td>Surgery residency</td>
<td>11%</td>
<td>3%</td>
</tr>
<tr>
<td>Pediatric EP fellowship</td>
<td>0.2%</td>
<td>0.10%</td>
</tr>
<tr>
<td>HRS ICD Guidelines</td>
<td>15%</td>
<td>9%</td>
</tr>
<tr>
<td>None of the above</td>
<td>15%</td>
<td>6%</td>
</tr>
</tbody>
</table>

*11/07 -- 3663 MDs; 195,000 patients*

Hammill et al: Heart Rhythm, 2007
Developing the Longitudinal Registry to Answer the CED Questions
“It is particularly important that these factors (ICD firing data and survival) be determined in the actual population receiving ICDs, who are older and present more comorbidities than represented in the trial populations. Fortunately, these key factors will be tracked in the ICD Registry”

Lynne Warner Stevenson, MD
Circulation. 2006;114:101
3/8/06: HRS asked to reconvene the Working Group

- Working Group expanded
- Refine the CED questions (group B questions)
- Develop the Longitudinal Registry

Study design
National ICD Registry Working Group
Expanded

HRS, chair  ACC
HFSA        AHA
Medtronic   Biotronik
Guidant     St Jude
BCBS        NCDR
United HealthCare  Aetna
Am Hlth Ins Plans  AHRQ
FDA         Am Hosp Assoc
CMS         At large members
Longitudinal Registry
Task Force #1: Refine the Group B Questions

Members
Lynne Warner Stevenson, Chair
Stephen Hammill (HRS)
Gillian Sanders (Duke)
Eric Fain (St. Jude)
Neil Jenson (Health Partners)
Marcel Salive (CMS)
Joel Harder (HRS)
B1: Do patient outcomes differ for patients with ejection fractions above and below 30%?

Final

B1: What are the rates of device therapies during the first 3 years after implantation for patients with LVEF 31-35% and patients with LVEF \( \leq 30\% \)?
Longitudinal Registry

Task Force #1: Refine the Group B Questions

NCD

B2: Do patient outcomes differ for patients with nonischemic CHF based on time from diagnosis?

Final

B2: What are the rates of device therapies during the first 3 years for patients with a diagnosis of nonischemic dilated cardiomyopathy for <9 months and patients with diagnosis ≥9 months?
Longitudinal Registry

Task Force #1: Refine the Group B Questions

NCD

B3: Do patient outcomes differ for patients with Class IV CHF?

Final

B3: What are the rates of device therapies during the first 3 years for patients who are NYHA Class IV at the time of implantation of a CRT-D device and for patients who are Class III at the time of CRT-D placement?
Interpretation of findings

No threshold of device therapies or survival that would be pre-specified to be clinically meaningful

Results compared to the Baseline ICD Registry population to determine the appropriateness of ICD therapy in the 3 CED groups
Longitudinal Registry
Task Force #2: Develop the Methodology to Obtain Device Therapy Data

Members

Peter Bach, Chair
Stephen Hammill (HRS)
Alan Kadish (Northwestern)
Steve Pearson (AHIP)
Mark Grant (BCBS)
Bob Thompson (Medtronic)
Marcel Salive (CMS)
Kristi Mitchell (NCDR)
Jeptha Curtis (Yale)
Harlan Krumholz (Yale)
Joel Harder (HRS)
Longitudinal Registry
Study Design

- Yale CORE – Data analytic center
- NCDR – Data collection and coordination center
- HRS – Physician recruitment and oversight
- Eligible patients
  CMS beneficiaries receiving a primary prevention ICD
Longitudinal Registry
Study Design

• **Primary endpoint**
  First delivery of an appropriate ICD therapy (shock, ATP)

• **Secondary endpoint**
  Survival probability at 3 and 5 years
  Death from CV cause
  Total # and rate of device therapies
  Ratio of inappropriate to total device therapies
Longitudinal Registry
Study Design

- 350 randomly selected implanting MDs
- 3,500 patients followed 3 years for events and 5 years for survival
  
  Based on 10\% rate of appropriate therapy at 3 years (15\% at 3 years in SCD-HeFT)
  
- Device therapy follow-up
  
  Every 3 months for a minimum of 3 years

Adjudication process

Data combined with NDI and Medicare claims data
Longitudinal Registry Study Design

• Funding – $3.5 million needed
  - Received
    - $1.5 million from industry
    - $1.0 million from AHIP

Wellpoint provided a $500,000 grant to the Baseline Registry
**Longitudinal Registry Study Design—Problems**

- Funding – $3.5 million needed for 3500 patient study
- $2.5 million received
- Reduce study size to 2000 patients?
- Confidence intervals change
  - Based on 10% event rate at 3 years:
# Longitudinal Registry

## Study Design—Problems

Reducing the study size from 3500 to 2000 pts

<table>
<thead>
<tr>
<th>Category</th>
<th>#/3500</th>
<th>CI</th>
<th>#/2000</th>
<th>CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>EF 31-15%</td>
<td>315</td>
<td>6.9-13.8</td>
<td>180</td>
<td>6.0-15.5</td>
</tr>
<tr>
<td>NYHA IV</td>
<td>180</td>
<td>6.0-15.5</td>
<td>100</td>
<td>4.9-17.6</td>
</tr>
<tr>
<td>NIDCM</td>
<td>260</td>
<td>6.7-14.2</td>
<td>150</td>
<td>5.7-16.0</td>
</tr>
<tr>
<td>&lt;9 mo</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
ICD Registry

Next Steps

• Develop version 2.0

• Research and publications

• Hospital responsible for Registry payment

• QI and P4P programs
  
  CMS physician performance measures (PQRI)

  United Health Care Premium Cardiac Specialty Center (established 5/24/07)
ICD Registry
Version 2.0 – Updating the Registry

- Redefine the registry purpose, goals and target audience; add leads
- Enhance the data collection forms and data collected
- Meet public policy
- Make the registry a performance reporting tool (Guidelines)
- Post market surveillance (Sentinal Network)
- Coordinate with longitudinal data
ICD Registry
Research and Publications

• Research requests are reviewed and prioritized by Research and Publication Subcommittee

25+ requests to date

• ICD-Registry provides financial support for data analysis

• Yale CORE assists with data analysis

• 6 AHA abstracts, 11/07
ICD Registry
Research and Publications

Sample research proposals

• How do the baseline characteristics of patients receiving ICD therapy in the general population (“real world”) compare with the characteristics of patients enrolled in randomized clinical trials of ICD therapy?

• Are patient outcomes such as morbidity and mortality affected by patient baseline clinical characteristics such as ejection fraction, QRS duration, NYHA class, gender, age, and race?
Sample research proposals

• What are the characteristics of the physicians implanting ICDs regarding training, experience, and volume; and how does this relate to implantation outcomes?

• Does age, race, and sex distribution of patients undergoing ICD implantation differ among different regions of the country and different size of hospitals?
Why a Registry?

Science tells us what we can do; Guidelines what we should do; and Registries what we are actually doing.

Lukas Kappenberger MD
HRS ICD Policy Conference
Washington DC, 9/16/05