

# **Optimizing Information Under CED**

## **ICD Registry**

**The Health Industry Forum**

**Washington, DC**

**October 24, 2007**

**Stephen Hammill, MD**

# ICD Registry Highlights to Date

- 1,438 hospitals

- >1

***Getting to this point  
and moving forward***

- 88% of hospitals (including all patients) (ages)

- 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**

**ACC**

**HFSA**

**STS**

**FDA (observer)**

**CMS (observer)**

**At large experts: Robert Califf, Catherine Detre, Bernard Gersh, William Groh, David Malenka**

**Medtronic**

**Guidant**

**St Jude**

**Biotronik**

# ICD Registry

## Developing the Baseline Registry

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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)***

# **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**

# ICD Registry

## A “Quality Improvement Tool” AHRQ

***“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.”***

Registries for Evaluating Patient Outcomes:  
A User’s Guide.

<http://effectivehealthcare.ahrq.gov/reports>

# National ICD Registry 2006

<b>Age, mean (yr)</b>	<b>68</b>
<b>Male/female (%)</b>	<b>74/26</b>
<b>Race (%)</b>	
<b>White</b>	<b>83</b>
<b>Black/African American</b>	<b>12</b>
<b>Hispanic</b>	<b>5</b>
<b>Asian</b>	<b>1</b>
<b>American Indian/Alaska Native</b>	<b>0.3</b>
<b>Native Hawaiian</b>	<b>0.2</b>
<b>Other</b>	<b>4</b>

Hammill et al: Heart Rhythm, 2007

# National ICD Registry 2006

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

**Hammill et al: Heart Rhythm, 2007**

# National ICD Registry 2006

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

# National ICD Registry 2006

<b>Total implants (no.)</b>	<b>108,341</b>
<b>ICD indication, no. (%)</b>	
<b>Primary prevention</b>	<b>79</b>
<b>Secondary prevention</b>	<b>21</b>
<b>Primary insurance payer (%)</b>	
<b>Medicare/medicaid</b>	<b>70</b>
<b>Other payer</b>	<b>30</b>

# National ICD Registry 2006

3,249 Physicians  
108,341 implants

**Implants  
performed by  
category**

**Physicians**

<b>Training category</b>	<b>%</b>	<b>%</b>
• EP fellowship + Boards	53	76
• EP fellowship only	6	7
• Surgery residency	11	3
• Pediatric EP fellowship	0.2	0.10
• HRS ICD Guidelines	15	9
• None of the above	15	6

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



# ***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**

# **ICD Registry**

## **Developing the Longitudinal Registry**

**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**

**HFSA**

**Medtronic**

**Guidant**

**BCBS**

**United HealthCare**

**Am Hlth Ins Plans**

**FDA**

**CMS**

**ACC**

**AHA**

**Biotronik**

**St Jude**

**NCDR**

**Aetna**

**AHRQ**

**Am Hosp Assoc**

**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)**

# Longitudinal Registry

## Task Force #1: Refine the Group B Questions

### NCD

**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  $\geq 9$  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?**



# **Longitudinal Registry**

## **Study Design**

### **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

Category	#/3500	CI	#/2000	CI
EF 31-15%	315	6.9-13.8	180	6.0-15.5
NYHA IV	180	6.0-15.5	100	4.9-17.6
NIDCM <9 mo	260	6.7-14.2	150	5.7-16.0



# 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?

# ICD Registry

## Research and Publications

### 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**