

ICD Registry™

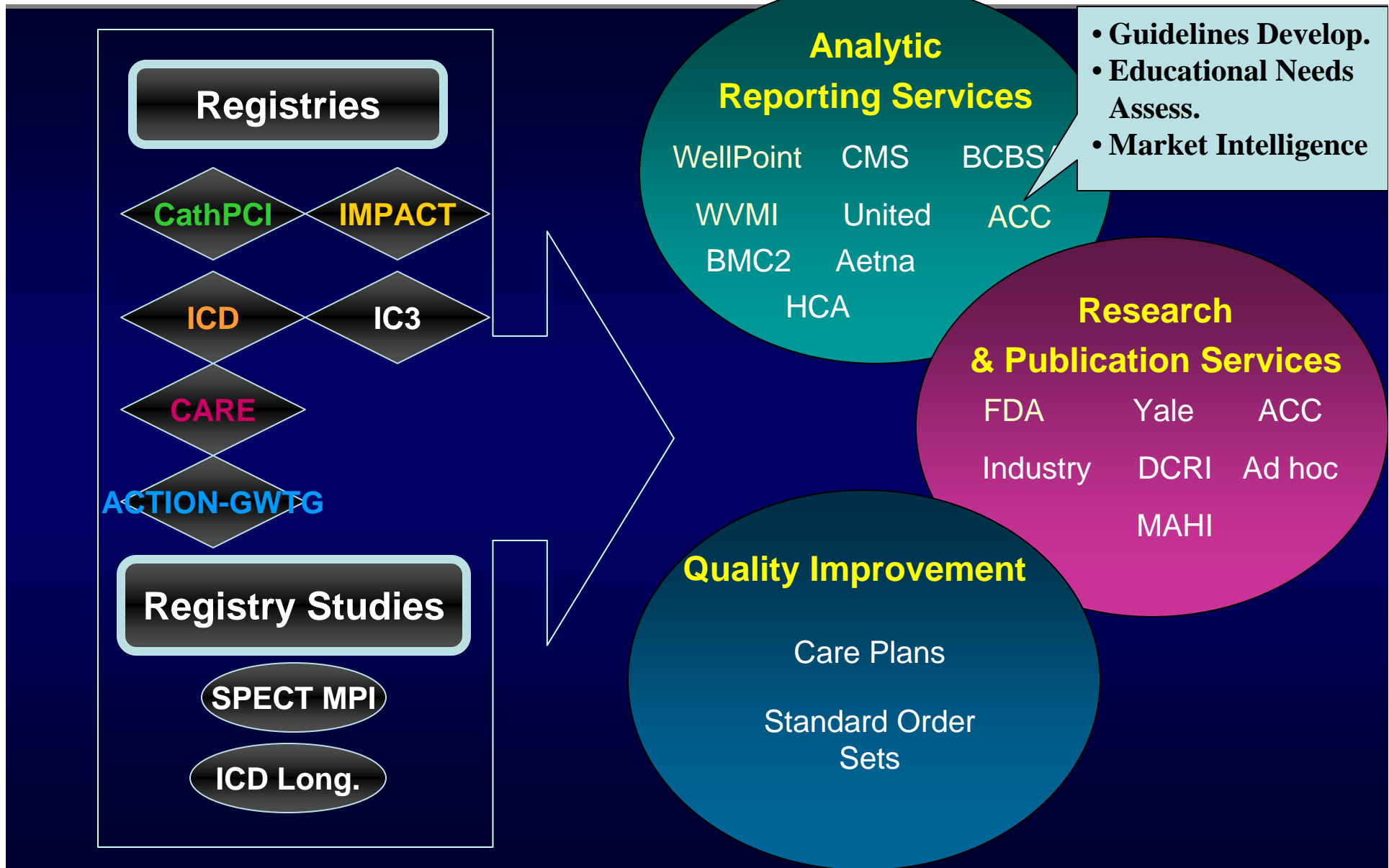
Impantable
Cardioverter
Defibrillator:

Overview of the ICD Registry

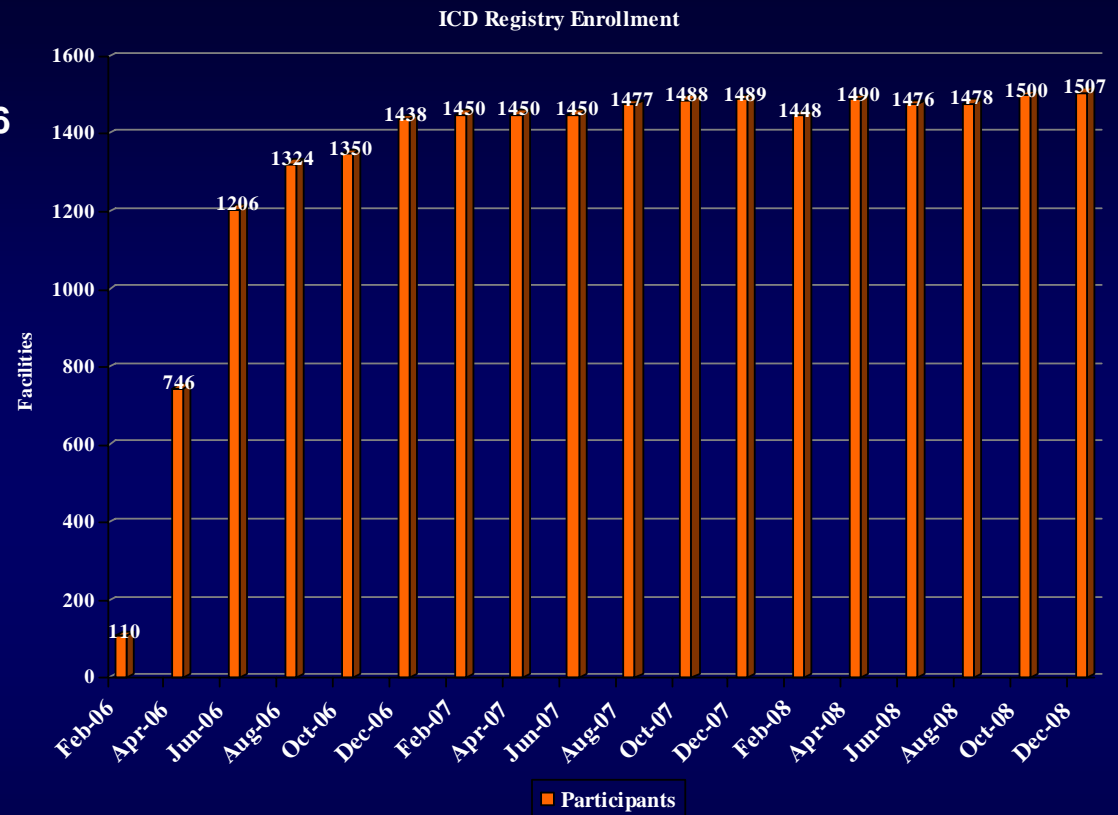
Jeptha P. Curtis, MD
Assistant Professor of Medicine
Yale University School of Medicine
April 27, 2009

**“Science tells us what we can do;
Guidelines what we should do;
Registries what we are actually doing.”**

What is the National Cardiovascular Data Registry?



- Registry
- Created in response to CED
- Mandatory for payment for CMS
- 1,507 hospitals enrolled since 2006
- >330,00 patient records
- % ICD-Premier Submissions:76%
- Version 2.0
- To Include Peds and Leads 2010
- Funding
- Startup funds from industry, payers
- Hospital fee \$3,395.00
- Analytic & Reporting Services
- In May UHC added ICD Registry participation for sites with EP Labs
- Discussions underway with BCBSA
- Provide data to CMS for reimbursement
- Research
- ICD Longitudinal Study
- Perform analyses for FDA



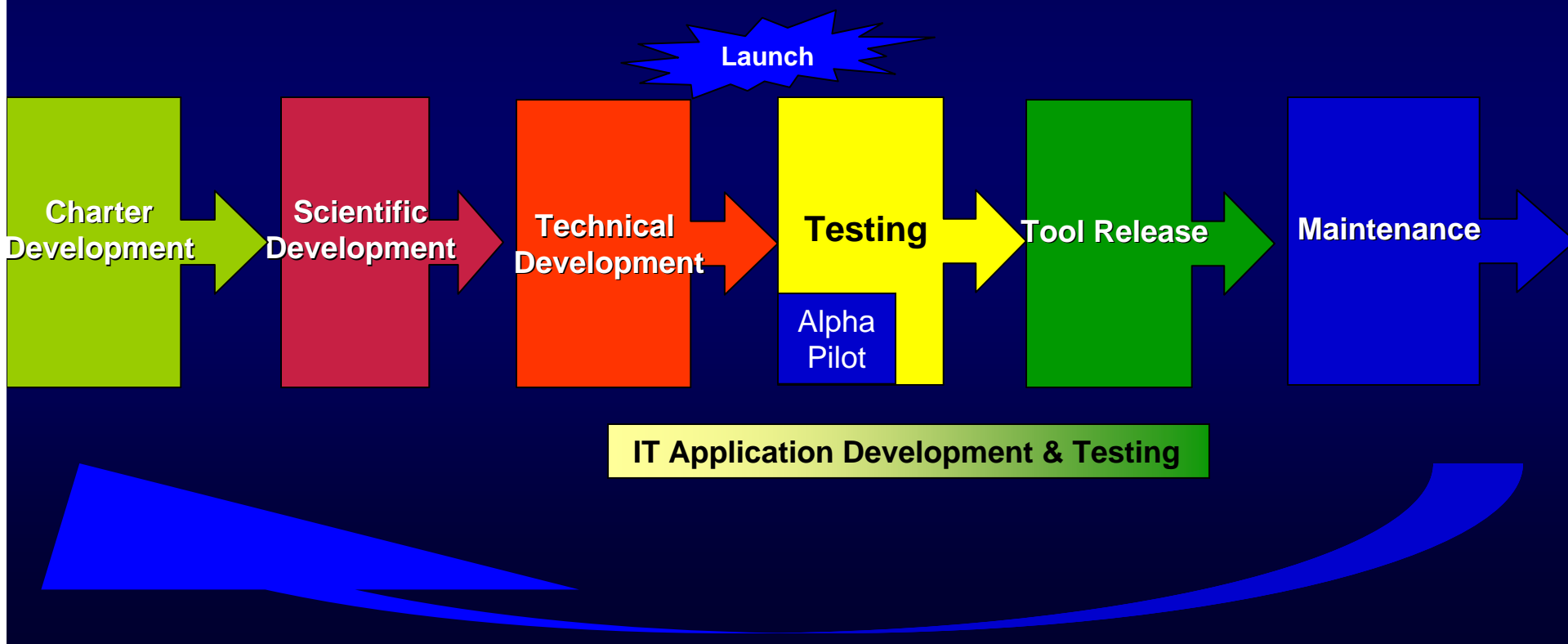
NCDR Research

- Effectiveness
 - 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 and Translational Research
 - Effectiveness of P4P
 - Guideline adherence
 - Performance measure development, implementation, validation

NCDR Research

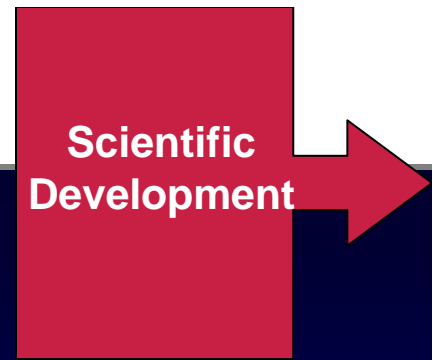
- Informing Public policy
 - Evidence-based reimbursement
- Intense interest in assessing efficiency, ROI,
 - linking with administrative data (CMS, health plans)

ICD Registry V1.08 Development Timeline



Scientific Development: Data Elements

1. Based on Hypothesis and Executive Summary Metrics
2. Use existing Clinical Data Standards derived from ACC/AHA Electrophysiology Data Standards.
3. Review clinical trials, practice guidelines, performance measures, existing registries
4. Include fields for patient, device, facility and provider information, disease process.



ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antitachycardia Devices

COMMITTEE MEMBERS

TASK FORCE MEMBERS

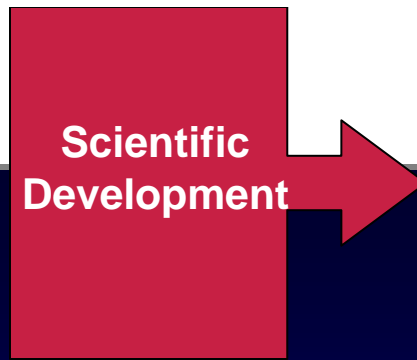
TABLE OF CONTENTS

AHA/ACC Scientific Statement

From the American Heart Association Council on Clinical Cardiology, Cardiovascular Nursing, Cardiovascular Disease in the Young, and Stroke, and the Quality of Care and Outcomes Research Interdisciplinary Working Group and the American College of Cardiology Foundation

Table of Contents





ICD Registry Key Outcomes Measures: Incidence of Lead Dislodgement

Incidence of Lead Dislodgement	Numerator	Number of occurrences of Lead Dislodgement ^{ae008} as an Adverse Event. May occur more than once during a single procedure.
	Denominator	Total number of procedures.
	Inclusion/ Exclusion Criteria	It is possible to have a value greater than 100% if there are more occurrences of Lead Dislodgement ^{ae008} than the number of procedures performed.
	Clinical Rationale/ Recommendation	<ol style="list-style-type: none"> Lead dislodgement is problematic for the patient following ICD implantation. The rate for lead dislodgement can be an indicator of technical operator performance or a manufacturer issue; and, is also influenced by patient characteristics (such as weight, compliance with movement restrictions, etc.). Monitoring and analyzing the causes of lead dislodgement can result in the development of policies, procedures, and future education aimed at risk minimization. "Lead Displacement" is defined as a Data Element in the Adverse Events section of the 2006 ACC/AHA Data Standard.[€]

Executive Summary
Implantable Cardioverter Defibrillator Procedures
National Outcomes Report (099007) compared to Rolling Four Quarters (R4Q) for the Registry Aggregate - 2007Q4

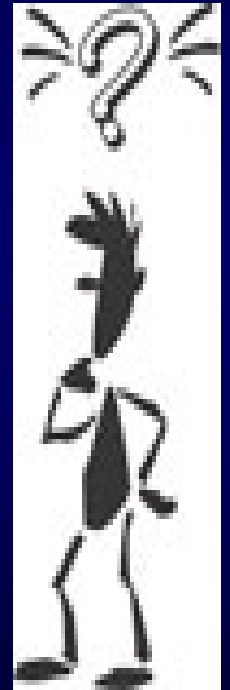
Registry Metric	My Hospital	Registry Aggregate Percentiles						
		5th	10th	25th	50th (Median)	75th	90th	95th
1. Incidence of Any Adverse Event The proportion of procedures with an incidence of one or more Adverse Events, including any deaths. [Detail Line: 1270]		0.0%	0.0%	0.0%	2.4%	4.6%	7.1%	11.1%
2. Incidence of Hematoma The number of occurrences per procedure of Hematomas (requiring transfusion or reoperation) as indicated by an Adverse Event. [Detail Line: 1284]		0.0%	0.0%	0.0%	0.0%	1.1%	2.5%	3.8%
3. Incidence of Lead Dislodgement The number of occurrences per procedure of Lead Dislodgement as indicated by an Adverse Event. [Detail Line: 1291]		0.0%	0.0%	0.0%	0.0%	1.2%	2.4%	3.4%
4. Beta-Blocker Prescribed with EF<=40% The proportion of patients with LVEF <=40% admitted only for the procedure with any beta-blocker prescribed at discharge, excluding patients with contraindications. [Detail Line: 1342]		50.0%	66.8%	81.8%	88.2%	94.1%	100.0%	100.0%
5. ACE-I/ARB Prescribed with EF<=40% The proportion of patients with LVEF <=40% with any ACE-I or ARB prescribed at discharge, excluding patients with contraindications. [Detail Line: 1332]		50.0%	59.8%	70.0%	78.1%	85.1%	91.5%	97.0%

Utilization Metric	My Hospital	Registry Aggregate Percentiles						
		5th	10th	25th	50th (Median)	75th	90th	95th
1. Type of ICD - Single Chamber The proportion of patients implanted with a Single Chamber implantable cardioverter defibrillator device. [Detail Line: 1264]		0.0%	2.7%	9.3%	20.0%	34.5%	48.8%	57.6%
2. Type of ICD - Dual Chamber The proportion of patients implanted with a Dual Chamber implantable cardioverter defibrillator device. [Detail Line: 1265]		15.2%	21.2%	29.3%	40.9%	51.0%	63.8%	76.5%
3. Type of ICD - Biventricular The proportion of patients implanted with a Biventricular implantable cardioverter defibrillator device. [Detail Line: 1266]		0.0%	6.8%	23.9%	34.0%	45.0%	54.5%	62.4%
4. Total Length of Stay Mean total length of hospital stay (in days) for patients having an ICD implanted during admission. [Detail Line: 1360]		1.5	2.0	2.7	3.7	5.0	6.7	8.0
5. Post-Implant Length of Stay Mean total length of hospital stay (in days) for all patients following an implant procedure. [Detail Line: 1358]		1.0	1.0	1.3	1.6	2.1	2.7	3.1

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Rev. 5 Aggregation Date: 10 Apr 2008

Maintenance Phase- Evaluation

- Quarterly Outcome Reports
- Participant FAQ's for clarification
- Feedback from Committees
 - Steering Committee
 - Research and Publications Committee
- Metric change
- Literature Review
- Guideline Recommendations
- Audit



ICD Registry Data Quality Program

National Onsite Audit Program

- Annual review
 - 10% random sample of eligible sites
 - 10% random sample of patient records (minimum 50) based on ICD volume
 - Comparative analysis of audit findings and site's original data submission

ICD Registry Successes

- Rapid development of a procedure-specific registry
 - Leveraging experience
 - Scientific Rigor
 - Successfully managing multiple stakeholders
- Buy-in from hospitals as QI tool
- Responsive
 - Lead information
- Generating new knowledge

ICD Registry Challenges

- Funding
 - Unfunded mandate
 - Shifting cost to sites
 - Longitudinal study
- Maintaining focus on mission
 - Quality Improvement or Research
- Data Quality
 - Accuracy
- Linking Data
 - HIPPA
 - Business Associate Agreements
 - Feasibility