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# ICD Registry™

**Program Summary**  
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**Christine Lang, RN, MSN**  
*Associate Director*

Heart House  
2400 N Street, NW  
Washington, DC 20037  
(800) 257-4737

## TABLE OF CONTENTS

1.	Background.....	3
2.	ICD Registry™ Description .....	4
3.	Purpose of the ICD Registry .....	4
4.	Objectives of the ICD Registry.....	5
5.	ICD Registry Audience.....	5
6.	How to Participate in the ICD Registry .....	5
7.	ICD Registry Case Inclusion/Exclusion Criteria.....	6
8.	ICD Registry Data Collection .....	6
8.1	Web-Based Data Capture.....	6
8.2	Vendor-Based Data Capture.....	6
9.	Collection of Existing Recorded Data, Privacy, and Ethical Considerations .....	6
10.	ICD Registry Data Quality .....	7
10.1	Data Completeness.....	7
10.2	Data Consistency and Accuracy .....	7
11.	ICD Registry Reporting, and Data Analysis.....	7
12.	Use of ICD Registry Data for Physician Maintenance of Certification (MOC) .....	7
13.	Ongoing ICD Registry Participant Support.....	8
13.1	Participant Training and Orientation .....	8
13.2	Regional Group Meetings .....	8
14.	ICD Registry Governance.....	8
14.1	ICD Registry Steering Committee .....	8
14.2	ICD Registry Research and Publications Committee.....	9
14.3	ICD Registry Clinical Support Team.....	9
15.	ICD Registry Operations Oversight.....	9
16.	ICD Registry Sponsorship .....	9

## 1. Background

The published randomized controlled trials present convincing evidence that ICDs (implantable cardioverter defibrillators) are effective for primary and secondary prevention of sudden cardiac death. The ICD Registry™ is designed to assess ICD implantations as they extend beyond the confines of controlled trials.

On September 28, 2004, CMS released its proposed National Coverage Determination (NCD) for implantable defibrillators in response to a request to expand coverage consistent with the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT). That decision proposed a national database as a condition of coverage of ICDs for primary prevention.

As part of the process of finalizing that decision, CMS requested that the Heart Rhythm Society (HRS) form the ICD Registry Working Group, which met in the fall of 2004, and submitted recommendations to CMS on the purpose of, and the questions that can be answered by, the registry. Members of the Working Group included representatives from HRS, American College of Cardiology (ACC), Heart Failure Society of America, Biotronik, Guidant, Medtronic, St. Jude, at-large members with special expertise in databases, along with observers from CMS and the FDA.

Based upon recommendations from the Working Group, CMS published the national coverage decision on January 27, 2005, which expanded the indications for ICD implantation and outlined the initial steps to develop the registry. A temporary data collection tool was operated by the Iowa Foundation for Medical Care (IFMC), a quality improvement organization which supported the tool using QNet (Quality Network Exchange).

CMS then requested HRS to re-convene the ICD Registry Working Group, which added representatives from the American College of Cardiovascular Administrators, American Heart Association, American Hospital Association, Kaiser Permanente, Society of Thoracic Surgeons, and Wellpoint.

This Working Group met in the spring of 2005 and submitted final recommendations to CMS on May 19, 2005. The group proposed the following four questions that could be answered by a national registry:

1. **Who is receiving the device?** Beyond ensuring that patient characteristics qualify them for an ICD for primary prevention, it would be important to understand how case mix in the real world compares to case mix in the randomized trials that provide the data supporting the coverage decision. In particular, are patients who stand to benefit the most receiving the majority of devices, or is it patients for whom the benefit is more questionable? Data elements would include individual patient demographics, comorbidities, cardiac history, cardiac surgery, symptoms, and left ventricular function.
2. **Who is implanting the device?** Physicians implanting the device will have varying degrees of formal training and practical experience and this might demonstrate differences related both to appropriateness of implanting the device and to patient outcomes. Data elements would include physician and hospital identifiers as well as information on their training and expertise (e.g., board certification).
3. **What device is being implanted and how is it programmed?** It is unknown if outcomes differ by specific devices. Data elements would include manufacturer, device type, unique device identifier, and programming.
4. **What are the in-hospital outcomes?** This is an important metric of physician and hospital quality. It would be informative to relate provider characteristics (e.g., physician level of training, physician and hospital volume) to in-hospital outcomes. It would also be informative to relate patient and device characteristics to outcomes.

The Working Group went on to define the core characteristics of a national clinical registry, which include the following:

- Organizational Structure: Multifunctional, unbiased, HIPAA-compliant, and representative.
- Evidence-based Science: Standardized data elements and definitions; input and consensus among national experts; built-in quality indicators and performance measures; and national benchmarking.
- Data Quality and Accuracy: Quality checks, onsite audit, training and education of the data abstracters, and consecutive patients entered into the registry
- Research: Statistical support, open data access, and publication.

On October 27, 2005, CMS announced that the ICD Registry, developed by ACC and HRS based on the NCDR<sup>®</sup> CathPCI Registry<sup>®</sup>, would become the sole-source data repository for information for the 1,400 hospitals nationwide that perform ICD implantation procedures.

The ICD Registry replaced the temporary QNet data collection tool as of April, 2006, and all hospitals implanting primary prevention ICDs in Medicare beneficiaries have been federally mandated to submit the required data elements to this Registry. Importantly, hospitals will have the option to enter only CMS beneficiaries receiving ICDs for primary prevention indications or, preferably, all patients receiving ICDs.

## **2. ICD Registry Description**

On June 30, 2005, NCDR launched the ICD Registry, allowing cardiovascular facilities to benchmark quality care when implanting defibrillators. Developed in partnership with the HRS, the ICD Registry helps facilities meet requirements from The Centers for Medicare and Medicaid Services (CMS). CMS mandated that facilities implanting ICDs provide data on patient outcomes and more. The ICD Registry tracks all CMS-required fields in addition to extended information.

Participants send their data to the registry using a secure, Web-based data entry tool. The ICD Registry provides online dashboards, quarterly benchmark reports, annual reports and more, tracking —

- Patient, facility and provider characteristics
- Device type and characteristics
- Device interrogation for firing data
- In hospital patient outcomes

Data fields are based on standardized definitions derived from ACC/American Heart Association/Heart Rhythm Society Electrophysiology Data Standards.

The purpose, objectives, audience, and scope of the ICD Registry are far-reaching.

## **3. Purpose of the ICD Registry**

The published, randomized, controlled trials present convincing evidence that ICDs are effective for primary and secondary prevention of sudden cardiac death. The ICD Registry is designed to assess ICD implantations as they extend beyond the confines of controlled trials.

The ICD Registry seeks to determine if the findings in randomized controlled trials can be applied to the general population. CMS uses the registry data to determine if the ICD implantation was appropriate for each Medicare beneficiary. In addition, the Registry data will be used to assess different outcome measures, such as:

- In-hospital complications
- Length of stay
- Device implant indications for each hospital and provider

The results will then be compared with the findings from randomized trials such as SCD-HeFT (4). In SCD-HeFT the median patient age was 60 years. If hospitals confine the patients enrolled in the ICD Registry to only Medicare beneficiaries, the median age will approach 70-75 years. The outcomes will most likely be different in the older cohort of Medicare beneficiaries compared to the outcomes in patients in the randomized controlled trials who were significantly younger. Therefore, it is advantageous to the hospital to enroll all patients who receive ICDs to allow more accurate comparison with the published randomized trials and national benchmarking.

The ICD Registry also tracks the relationship of physician training to outcomes. In the final coverage decision released on January 27, 2005, CMS commented, "As with any invasive procedure, physicians who insert ICDs must be appropriately trained and fully competent to perform the implantation. CMS strongly encourages credentialing and certification of physicians who insert ICDs by appropriate national organizations such as the Heart Rhythm Society (HRS) or Boards of Medical Specialties to ensure the safety of Medicare beneficiaries. CMS also believes that provider credentialing and certification should be tracked and included in any and all registries and data collection systems." The ICD Registry also collects information on the providers' training.

#### **4. Objectives of the ICD Registry**

In January, 2005, Medicare (CMS) expanded their coverage based on the results of three major, randomized controlled trials. However, there were certain patient populations that Medicare felt required more data:

- Patients with an ejection fraction between 31-35 percent
- Patients with a diagnosis of nonischemic cardiomyopathy of less than 9 months' duration
- Patients receiving a resynchronization device to treat Class IV heart failure

The ICD Registry was designed to collect additional data and, in the process, help determine if the trial findings can be applied to the general population. CMS' goal for the ICD Registry is to determine whether primary prevention ICD implantation procedures are appropriate for the Medicare beneficiaries who meet the clinical conditions identified in the Agency's national coverage policy.

#### **Sample questions the ICD Registry can answer:**

- How do the characteristics of patients and implanting physicians compare between those involved in randomized trials and those receiving and placing the device following approval?
- What are the characteristics/competencies of the individual implanting the ICD?
- What are the indications for the ICD?
- What are the in-hospital, procedure-related complications?
- What are the relative outcomes within the registry population?

#### **5. ICD Registry Audience**

Clinicians (electrophysiologists, cardiologists, emergency medicine physicians, hospitalists, primary care physicians, nurses, physician assistants, nurse practitioners), pharmacists, case managers, allied health care personnel, hospital quality improvement personnel and administrators, professional organizations, accrediting organizations, regulatory agencies, payers, pharmaceutical and device industry, and clinical research organizations.

#### **6. How to Participate in the ICD Registry**

First steps include registering at the NCDR ICD Registry Website, [www.ncdr.com](http://www.ncdr.com). An ICD Registry Support Specialist will contact you after registration with the forms you'll need to complete your enrollment, including the Business Associate Agreement.

## 7. ICD Registry Case Inclusion/Exclusion Criteria

- Cardiac arrest due to VF, not due to a reversible cause (effective 1991)
- Spontaneous or induced VT, not associated with an acute MI or reversible cause (effective 1999)
- Familial conditions at high risk such as LQTS, HCM (effective 1999, (Registry required)
- CAD, prior MI, EF 35% or less, inducible sustained VT (EP test and ICD implant >4 weeks after MI, (Registry required)
- Documented prior MI, EF 30% or less (Registry required)
- IDCM, prior MI, Class II-III, EF 35% or less (Registry required)
- Non-IDCM, >3 months, Class II-III, EF 35% or less (Registry required)
- CRT candidates, Class IV (Registry required)

## 8. ICD Registry Data Collection

NCDR registry products, including the ICD Registry, are created under the leadership of clinical experts with critical input from NCDR participants regarding the feasibility of implementation and the burden of data collection. The ICD Registry collects data on primary and secondary prevention patients who meet the registry's inclusion criteria. Data are collected, validated, and submitted under the responsibility of a designated Registry Site Manager at each participating institution.

### 8.1 Complimentary Web-Based Data Entry Tool

Information collected on Data Collection Forms (DCFs) may be entered by participating facilities via a secure, password-protected Website managed by NCDR. Participation in the ICD Registry is required to be able to enter and access data.

### 8.2 Vendor-Based Data Capture

The ICD Registry has contracted with a variety of software vendors that offer a large range of software products. NCDR reviews and certifies each software application prior to its distribution to verify it meets the strict data collection standards and export requirements as defined by NCDR. Since many of the vendors' software applications do much more than collect and export ICD Registry data, participants should consider their own software requirements when reviewing vendor product information. NCDR provides a brief description of each vendor as well as a summary of their product information at [www.ncdr.com](http://www.ncdr.com).

## 9. Collection of Existing Recorded Data, Privacy, and Ethical Considerations

The American College of Cardiology Foundation (ACCF) does not require Institution Review Board review and approval as a condition of participation in NCDR. However, the ACCF does require that all participating facilities abide by the policies and procedures of their facility. Please consult with your facility for guidance in participation in quality improvement activities. This program summary for the registry may be used for presentation to your IRB if required by your facility policies.

Registry data is collected based on the registry specific inclusion criteria. Data collected in the registry are collected using existing medical record data. The registry does not require participating facilities to contact individual patients.

The ACCF takes reasonable safeguards to protect the data collected through the registry including physical, technical and administration safeguards required of a Business Associate under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as amended by the HITECH ACT. All facilities participating in the registry are required to sign a Business Associate Agreement with the ACCF which stipulates permitted and restricted data uses.

The registry requires collection of direct identifiers allowing data captured in multiple registries to be interoperable, hence reducing the data collection burden of participating facilities. The Business Associate Agreement also stipulates permitted disclosures and secondary uses of registry data. Please note that the ACCF is only permitted to disclose a Limited Data Set to third parties for very restrictive purposes. The only permitted disclosure of direct identifiers is to entities who actively act as sub-contractors of the ACCF. Such sub-contractors are bound by contract under the same requirements stipulated in the Business Associate Agreement as required by HIPAA. Additionally, ACCF may release data to entities where a Participant has authorized the release of such information.

## **10. ICD Registry Data Quality**

The NCDR Data Quality Program (DQP) is designed to meet the requirements needed for a comprehensive health information management system. The Onsite Data Audit Program is a component of this effort. The overall purpose of the DQP is to ensure that data submitted to NCDR are complete, consistent, and accurate - ultimately improving the overall quality of the CARE Registry.

### **10.1 Data Completeness**

In keeping with established NCDR data quality procedures, participant data submissions are reviewed to establish overall completeness prior to analyzing and developing reports for any given quarter. The Data Quality Report (DQR) process assesses the overall completeness of a participant's data submission, and provides feedback to the participating hospitals. The DQR provides participants with a confidential analysis of their data completeness, and is used by the participant to help prioritize data "cleaning" efforts.

### **10.2 Data Consistency and Accuracy**

Each year, participating sites will be randomly selected to be audited. Trained nurse abstractors will conduct medical record reviews and blind data abstraction of randomly selected patient medical records at each site. Audit results will be analyzed for overall accuracy by comparing audit findings against data originally submitted from each site. The participants that are selected for audit will receive a confidential report which will display their audit score and individual accuracy for each data element.

## **11. ICD Registry Reporting and Data Analysis**

ICD Registry participants receive access to comprehensive, timely information about measuring quality of care for their ICD patients in the form of quarterly and annual comparative benchmark reports. These institution-specific reports are comprised of evidence-based elements that correspond to the ICD Registry data elements, facilitating continuous monitoring of quality improvement efforts and enabling facilities to compare, on a blinded basis, their institution's practice patterns to national averages and volume-based peer comparison groups. Participants can use this information for reducing complications in ICD procedures, improving patient care, supporting local quality-improvement programs, and communicating with regulatory and contracting organizations.

As a result, the ICD Registry provides a potent research tool that permits focused analysis of clinical treatment, procedures, and outcomes of patients with ICDs. Data collected through the ICD Registry can be analyzed to assess determinants of practice guideline implementation, to assist in medical decision-making, to assess the appropriateness of medical care provided to patients who have ICD devices implanted for primary or secondary prevention, and to provide clinical evidence to help support CMS in their National Coverage Decision.

## 12. Using ICD Registry Data to Meet Physician Board Maintenance of Certification (MOC) Requirements

All physicians who are board-certified and have a time-limited certification must complete a Maintenance of Certification (MOC) process to renew their certification. For example, ABIM-certified physicians have 10 years to complete the process, which includes self evaluation of practice performance. NCDR ICD Registry data can be used to earn up to 80 points out of the 100-point total required by ABIM. This practice performance requirement is referred to as MOC Part IV. Visit [www.cardiosource.com/moc](http://www.cardiosource.com/moc) for more information.

There are several Web-based tools offered by ABIM to complete MOC Part IV called Practice Improvement Modules (PIMs). The ABIM self-directed PIM allows physicians to use ABIM-approved data sources to complete the module. The NCDR is an approved data source for completing the ABIM self-directed PIM for physicians whose patient records are submitted to the CARE Registry. Completion of the ABIM self-directed PIM is also recognized by a number of insurance companies and Pay for Performance programs. For more information, visit <http://www.abim.org/moc/healthcare/healthplans/default.aspx>.

## 13. Ongoing ICD Registry Participant Support

The ICD Registry provides "help desk" support to all participants from 9 am to 5 pm (ET) on regular business weekdays. This includes telephone and email support for participants who have questions or need assistance with any facet of the registry operations.

### 13.1 Participant Training and Orientation

Training and orientation are critical functions to ensure data quality and, ultimately, a high-quality registry. In addition to the "help desk" functions described above, training and orientation also include:

- **Introductory Calls and Webcasts**

ICD Registry participants are invited on a routine basis to join calls and/or Webcasts where registry staff provide an overview to the ICD Registry program and answer questions. Participants can sign up for these bi-weekly classes via the ICD Registry Website at [www.ncdr.com](http://www.ncdr.com).

### 13.2 Regional Group Meetings

NCDR registry participants, in many cases, have organized themselves into regional training and networking groups. Educational meetings and/or teleconferences may include presentations regarding recent findings from ICD Registry data analyses, strategies for ensuring successful collaboration between various hospital specialties and departments in support of the quality improvement process, question and answer sessions or case studies, and other topics of interest.

## 14. ICD Registry Governance

The mission of NCDR is to improve the quality of cardiovascular patient care by providing information, knowledge, and tools; implementing quality initiatives; and supporting research that improves patient care and outcomes. Oversight of NCDR is provided by the NCDR Management Board.

### 14.1 ICD Registry Steering Committee

The ICD Registry Steering Committee reports to the NCDR Management Board. The Steering Committee provides strategic direction for the ICD Registry and monitors research and clinical activities to include the following:

- Sets a high level agenda for the strategic direction of the ICD Registry
- Advocates, promotes and influences key groups regarding ICD Registry activities

- Assures activities conducted by the ICD Registry Research and Publications Committee and Clinical Support Team are congruent with NCDR methodologies and policies
- Identifies new opportunities and strategies to further promote utilization of the ICD Registry
- Establishes working groups as needed to support specific projects.

#### **14.2 ICD Registry Research and Publications Subcommittee**

This committee oversees all activities related to research and publications for the ICD Registry including:

- Oversees all research activities, including the evaluation, improvement, approval, and prioritization of investigational, industry and government research proposals
- Oversees the production of analytical and/or descriptive abstracts, poster presentations, and manuscripts
- Selects secondary reviewers for abstract and manuscript development

#### **14.3 ICD Registry Clinical Support Team**

The ICD Registry Clinical Support Team provides ad hoc clinical expertise as needed to respond to questions from participating hospitals regarding data elements and data collection. The team consists of clinical experts on the ICD Registry patient population.

### **15. ICD Registry Operations Oversight**

NCDR oversees all activities associated with the ICD Registry, including the NCDR Information Technology and Research and Innovation departments that provide all technology management, data coordinating, report generation, and statistical functions for the ICD Registry.

### **16. ICD Registry Sponsorship**

There is no outside funding for the ICD Registry.