



ACC-NCDR®

National ICD Registry

An American College of Cardiology Foundation and the Heart Rhythm Society collaboration.

Frequently Asked Questions

What is the ACC-NCDR®?

ACC-NCDR® stands for the ACC-Nat'l Cardiovascular Data Registry. The ACC-NCDR® is a confidential quality measurement program for cardiovascular specialists and hospital administrators, who are committed to measurement, improvement, and patient care excellence. Currently the ACC-NCDR® operates three Nat'l registries:

- Cath Lab (diagnostic cardiac catheterization and percutaneous coronary intervention)
- ICD (implantable cardioverter defibrillator implantation)
- Carotid Stenting

For each of its registries the ACC-NCDR® provides comparison of a participant's practice patterns and outcomes to Nat'l and peer group results. Participants can use this information as a benchmark for improving quality of care, for supporting local quality improvement programs, and for communicating with regulatory and contracting organizations.

The ACC-NCDR® allows longitudinal analysis and uses standardized data elements. The program is multicentered, voluntary, Nat'l in scope, outcome-oriented, patient-based, secure, and strictly confidential.

What is the Nat'l ICD Registry?

Scheduled for launch mid summer 2005, the Nat'l ICD Registry is being developed through a collaboration between the American College of Cardiology Foundation (ACCF) the Heart Rhythm Society (HRS). Scientific experts from both organizations have developed core data elements and definitions needed to accurately measure patient outcomes and patient care track trends.

What role does the Center for Medicare and Medicaid Services (CMS) play in the Nat'l ICD Registry?

In early 2005 the Center for Medicare and Medicaid Services (CMS) issued a statement that has created an urgent need for a Nat'l ICD registry. *See attached summary of coverage for implantable cardioverter defibrillators (ICDs).*

What is QNET?

At present, CMS currently provides a data entry tool which is called "QualityNet" or "QNet" this default registry takes advantage of a data submission mechanism already in place for Medicare participating hospitals to submit data to the Iowa quality improvement organization. This application is a bare bones registry, collecting data on all patients receiving ICDs as a primary prevention for sudden cardiac death. Participation in this database is available at no charge to hospitals. Relevant patient information is collected and stored, but CMS does not provide any benchmark reports or any clinical support to the participants.

How have the ACC and HRS Partnered

ACCF) and HRS represent two leading organizations whose mission is to guide and support optimal cardiovascular patient care, have joined together to create the ACC/HRS ICD Registry Working Group. ACCF and HRS strongly believe the efforts of this Working Group will provide CMS the information it needs to support its expanded coverage for implantable cardioverter defibrillators (ICDs), as well as, provide an invaluable tool for healthcare providers to measure and improve the care they provide to patients with ICD implantation.

What is the purpose of the Nat'l ICD Registry?

- The purpose of the registry is to assess and improve the care of patients receiving ICDs for primary prevention therapy.
- To ensure that Hospitals and providers are certified as competent in the ICD implantation.
- Participating hospitals and providers report data on all patients undergoing ICD implantation for primary prevention.
- Hospitals and providers who do not comply with the data collection requirements are removed from the system.
- The data set includes elements with the following characteristics:
 - Baseline patient characteristics
 - Device type and characteristics
 - Facility and provider characteristics
 - Extent of disease progression
 - Periodic device interrogation for firing data
 - Long term patient outcomes

What questions will the Nat'l ICD Registry 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 characteristics of the patient?
- What are the indications for the ICD?
- What are the in-hospital procedure related complications?
- What are the reasons for subsequent hospitalization for procedure or device-related complication and care?
- What are the relative outcomes within the registry population?

What are the benefits of the Nat'l ICD Registry?

When you enroll in the Nat'l ICD Registry you'll receive access to the most comprehensive, timely information available for measuring quality of care for ICD patients. As a Nat'l ICD Registry member, you'll benefit from

- "Apples to apples" comparisons. Quarterly benchmark reports are based on input from active participants, all of whom use certified software with standardized data elements and definitions.
- Expert oversight. Scientific experts guide the ACC-NCDR® through both scientific and operational committees.
- Guaranteed confidentiality and data protection. We protect your data through procedures, technology, and contractual agreements. All patient, physician, and institution data are treated confidentially, and only anonymous aggregated data are reported for benchmarking purposes.
- A detailed manual and clinically experienced support staff. Our materials help you set up your data collection program, and our support staff is carefully trained to assist you in any problems you encounter.
- Comprehensive annual reports. These reports comprise a year's worth of data on evidence-based elements that correspond to current ACC/AHA/HRS Electrophysiology Clinical Guidelines.
- Quarterly newsletters that catalyze change. Newsletters include subscriber profiles and detail best practices for leveraging ACC-NCDR® programs. These publications also offer interviews with health care experts and the latest news on software and core data elements.
- Discounted registration for the ACC-NCDR® Quality Conference. This meeting is held each spring for health care leaders focused on improving patient care.
- Data quality reports. These Web-accessible reports make it easy to ensure that data submitted are complete and consistent.

When will the Registry be launched?

In the third quarter of 2005, participating hospitals will have immediate access to an online data entry tool and receive quarterly comparative benchmark reports to assist them with quality improvement.

- Scheduled to go live June 30, 2005, the Nat'l ICD Registry will initially focus on reporting demographic and quality indicators to meet Medicare and Medicaid's recommendations.
- In mid October 2005 ACC/HRS will host an educational workshop for participants and institutions interested in becoming enrolled in the Nat'l ICD Registry.

What are my responsibilities as a participant?

In order to ensure the integrity of your and the Nat'l ICD Registry data, participants must—

- On a quarterly basis, submit complete data on adult patients who have undergone ICD implantation for primary prevention.
- Review Data Quality Reports for data completeness and resubmit if necessary; and
- Review quarterly comparative Institutional Reports.

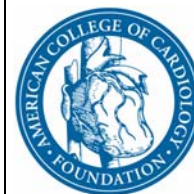
How can I be sure that my data are kept in strict confidence?

The ACC has established a one-to-one relationship with each participant, as well as with a variety of software vendors. Initially the ACC-NCDR® will offer a web based data entry tool, with eventual roll out to third party software vendors. *Participants submit data directly to the ACC—there is no third party involved.* The ACC certifies only those software vendors that meet the College's rigorous quality standards. When an ACC-NCDR® participant purchases software from one of the certified vendors, the vendor installs it for the participant. The participant then uses that software to submit its data to the ACC on a quarterly basis.

How do I enroll in the ACC-NCDR®?

Contact the ACC to begin the enrollment process. E-mail Christie Lang RN, MSN at clang@acc.org, and include your name, institution, address, phone, and fax number.

For more information contact:



Christine Lang RN, MSN
Associate Director, Nat'l ICD
Registry

800-253-4636, ext. 457
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Expanded ICD COVERAGE for Primary Prevention

Implementation Details Now Available

Dear Heart Rhythm Society Member:

On January 27, the Centers for Medicare and Medicaid Services (CMS) announced its expanded ICD coverage decision for primary prevention ICD therapy. Immediately, coverage for primary prevention was expanded to include most SCD-HeFT patients and an expanded MADIT II population. Along with this expanded coverage, CMS also implemented an ICD registry requirement. Details of this expanded coverage, including the QNET registry requirement have now become available.

Implementation of Expanded Implantable Defibrillator Coverage:

CMS has revised and expanded ICD coverage as indicated in the ICD national coverage determination. This expanded coverage is in addition to already indicated patients. A new ICD Registry through your hospitals QNET system has also been established. This ICD Registry requirement is for primary prevention ICD patients only as indicated below.

View the summary of coverage that includes the revised [National Coverage Determination \(NCD\)](#).

This revised expanded coverage in the January decision includes the following indications :

1. Documented episode of cardiac arrest due to ventricular fibrillation (VF), not due to a transient or reversible cause (effective July 1, 1991). **(These patients are not required to be entered into the registry, secondary prevention)**
2. Documented sustained ventricular tachyarrhythmia (VT), either spontaneous or induced by an electrophysiology (EP) study, not associated with an acute myocardial infarction (MI) and not due to a transient or reversible cause (effective July 1, 1999). **(Not required to be entered into the registry, secondary prevention)**
3. Documented familial or inherited conditions with a high risk of life-threatening VT, such as long QT syndrome or hypertrophic cardiomyopathy (effective July 1, 1999). **(REGISTRY REQUIREMENT)**
4. Coronary artery disease with a documented prior MI, a measured left ventricular ejection fraction (LVEF) ≥ 0.35 , and inducible, sustained VT or VF at EP study. (The MI must have occurred more than 4 weeks prior to defibrillator insertion. The EP test must be performed more than 4 weeks after the qualifying MI.) **(MADIT I patients, REGISTRY REQUIREMENT)**
5. Documented prior MI and a measured LVEF $\geq 30\%$; **(MADIT II patients, Class I, REGISTRY REQUIREMENT)**
6. Patients with ischemic dilated cardiomyopathy (IDCM), documented prior myocardial infarction (MI), New York Heart Association (NYHA) Class II and III heart failure, and measured left ventricular ejection fraction (LVEF) $\leq 35\%$; **(SCD-HeFT patients, REGISTRY REQUIREMENT)**
7. Patients with nonischemic dilated cardiomyopathy (NIDCM) > 9 months, NYHA Class II and III heart failure, and measured LVEF $\leq 35\%$; **(SCD-HeFT patients, REGISTRY REQUIREMENT)**
8. Patients who meet all current CMS coverage requirements for a cardiac resynchronization therapy (CRT) device and have NYHA Class IV heart failure; **(COMPANION patients, no national coverage decision exists for CRT, coverage may vary by Medicare carrier, REGISTRY REQUIREMENT)**
9. Patients with NIDCM > 3 months and < 9 months, NYHA Class II or III heart failure, and measured LVEF $\geq 35\%$ at this time are only covered by Medicare if these patients are enrolled in either an FDA-

approved category B IDE clinical trial (42 CFR §405.201), a trial under the CMS Clinical Trial Policy (NCD Manual §310.1), or a prospective data collection system. ***These patients cannot be enrolled in the current ICD Registry through QNET. Therefore, these patients do not have a covered Medicare indication unless this patient is enrolled in a FDA-approved category B IDE clinical trial or an IRB clinical investigation. A subsequent ICD Registry is being developed that will enroll this subset of patients. The Heart Rhythm Society will notify HRS members as soon as this becomes available.***

NOTE: The QRS duration is no longer a requirement for any patients receiving an ICD under the expanded coverage for ICD therapy. However, CRT therapy still requires a QRS of 120 MS or greater.

The following additional criteria for all of the above patients must also be met:

a. Patient must be able to give an informed consent;

b. Patient ***must not*** have:

- Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm;
- Had a coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) within the past 3 months;
- Had an acute MI within the past 40 days; ***[NOTE: This requirement has changed from previous coverage which required an acute MI within the past month]***
- Clinical symptoms or findings that would make them a candidate for coronary revascularization;
- Irreversible brain damage from preexisting cerebral disease;
- Any disease, other than cardiac disease (e.g. cancer, uremia, liver failure), associated with a likelihood of survival less than one year;

NOTE: All primary prevention ICD replacements for Medicare patients must also be included in the Registry.

Diagnosis Codes for ICD Patients

ICD-9 codes are important in this expanded coverage and determining which patients should and should not be included in the registry. A claim with a diagnosis of 427.1 ventricular tachycardia as ***secondary prevention***, does not need to be included in the registry. However, a claim with this same diagnosis 427.1 ventricular tachycardia as ***primary prevention*** as in MADIT I or MUST patients (post-EP study) should be included in the registry. The important difference in these two claims is the determination that the patient is considered primary or secondary prevention. Other diagnosis codes that may identify patients with previous arrhythmias (secondary prevention) are:

- 427.1 Ventricular tachycardia
- 427.41 Ventricular fibrillation
- 427.42 Ventricular flutter
- 427.5 Cardiac arrest
- 427.9 Cardiac dysrhythmia, unspecified

Read more detailed information on [diagnosis](#) coding related to ICD patients.

QR Modifier "C What the Clinician Needs to Know

Beginning April 1st 2005 the physician must include modifier QR on the primary procedure code for the ICD implant for patients receiving primary prevention therapy. ***Prior to April 1st, claims should be submitted without the modifier.***

ICD Registry Requirement "C Using the QNET System

The data collection requirement for patients with indications #3 - 8 above is met by your hospital submitting data through the ICD Abstraction Tool through QualityNet Exchange.

All of the resources necessary for your hospital to comply with this new requirement can be found on the [QualityNet Exchange](#) website.

For detailed information related to this new data collection requirement for ICDs, click here for an QNET ICD [Q&A](#).

For any problems encountered with the use of the QualityNet Exchange web site, or questions/problems related to ICDA, please contact the QualityNet Help Desk for support.

Phone: 866-288-8912 (7 a.m. - 7 p.m. CT Monday through Friday)

Fax: 888-329-7377

Email: qnetsupport@ifmc.sdps.org

ICD Registry Worksheet/Required Data Elements

Some hospitals and EP labs find it useful to use the [worksheet](#) found here to use with every ICD implant. This worksheet is not a CMS requirement but is useful to determine which patient's medical record will need to be included in the ICD Registry and which does not. More importantly, this ICD Registry Worksheet/Data Elements Checklist also indicates to the implanting physician which data fields must be complete in the patient record for the ICD-QNET system to function properly. It is the physician's responsibility that these data elements on the attached [worksheet](#) be complete in the patient's record and/or that this data element checklist be completed and appended to the patient record.

Certification Status Information Will be Collected

During this past year, the Heart Rhythm Society encouraged CMS require providers be certified as competent in ICD implantation. The Heart Rhythm Society's goal was to ensure patient's access to this life saving therapy and access to qualified implanters. This new ICD Registry requirement through the QNET system will collect data on physician certification. CMS included the following statement in the final [coverage decision](#). *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. This information is valuable for informing patients as part of effective clinical decision-making and will provide useful data on procedural outcomes associated with different levels of provider training and expertise .*^{1±}

The QNET system is collecting data on the certification status of physicians. At this time, physicians are being asked to indicate if they are certified in electrophysiology. According to the help screen provided in the ICDA QNET tool, electrophysiology certification includes physicians with board certification in Clinical Cardiac Electrophysiology by the American Board of Internal Medicine or physicians that are certified by passing [NASPExAM](#).

In the second phase of the registry, definitions of certification and qualifications will be expanded and further defined. This data will need to be either present in the patient's medical record or indicated on the data element [worksheet](#) .

The Heart Rhythm Society will continue to provide information regarding ICD coverage and reimbursement to the membership as it becomes available. Please contact the Heart Rhythm Society (Amy Melnick or Brian Outland at 202.464.3400 or amelnick@hrsonline.org or boutland@hrsonline.org if you have questions regarding implementation of these new policies.

Sincerely,

Stephen C. Hammill, MD
President
Heart Rhythm Society