November 22, 2004

Sean Tunis, MD
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Dear Sean and Steve:

I want to thank you for allowing the Heart Rhythm Society (HRS) the opportunity to form the National ICD Registry Working Group and to work with CMS as the ICD Registry is developed. The Working Group has completed its review of the initial issues surrounding the registry and this letter describes our recommendations concerning the ICD registry.

Background

On September 29, 2004, CMS published its Draft Decision Memo for Implantable Defibrillators which included the following information concerning the ICD Registry:

> *In addition, CMS has determined that the use of ICDs for primary prevention of sudden cardiac death (SCD) is reasonable and necessary only if the beneficiary receiving the ICD implantation is enrolled in either an FDA approved Category B IDE Clinical Trial or a qualifying national database (registry). A registry must include criteria that ensure:*
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> 1. *Hospitals and providers are certified as competent in the ICD implantation.*
> 2. *Participating hospitals and providers report data on all patients undergoing ICD implantation for primary prevention.*
> 3. *Hospitals and providers who do not comply with the data collection requirements are removed from the system.*
> 4. *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*

5. *Specific hypotheses are addressed*

CMS convened a meeting October 7 attended by the Heart Rhythm Society, American College of Cardiology (ACC), Heart Failure Society of America (HFSA), Guidant, St. Jude, and Medtronic, during which the concept and purpose of the registry were discussed. At the conclusion of the meeting, CMS asked the Heart Rhythm Society to organize a working group to determine the questions that should be answered by the registry, the data elements required, funding, and certification requirements for providers.

The Heart Rhythm Society then formed the National ICD Registry Working Group with the following charge:

- Review the purpose and merits of a national registry and recommend to CMS a plan for establishing a national registry to follow Medicare patients receiving an ICD for primary prevention therapy.

Members of the Working Group

- HRS: Stephen Hammill, MD, chair; Bruce Lindsay, MD, alternate
- ACC: Ralph Brindis, MD; Kristi Mitchell, Kathleen Hewitt, staff
- HFSA: Marvin Konstam, MD; Robert Bourge, MD, alternate; Cheryl Yano, staff
- Biotronik: Mark Johnson
- Guidant: Joseph Smith, MD
- Medtronic: Dan Schaber, PharmD; Aida Cicic, MD, alternate
- St. Jude: Andra Thomas, RN
- At large members: Robert Califf, MD (Duke University); Catherine Detre, MD (University of Pittsburgh); Bernard Gersh, MBChB DPhil (Mayo Clinic); William Groh, MD (Indiana University); and David Malenka, MD (Dartmouth Medical School).
- CMS Observer: Marcel Salive, MD, MPH
- FDA Observer: Mitchell Shein

The Working Group met on three occasions: conference calls on October 19, 2004 and October 28, 2004; and an in-person meeting on November 8, 2004. The Working Group reviewed the following:

1. Purpose of the registry and main question(s) to be answered.
2. Patients enrolled: all CMS covered patients or selected population
3. Patient and device data elements collected
4. Defining providers as competent and qualified to implant ICDs
5. Registry management
6. Registry funding

National ICD Registry Working Group Comments and Recommendations

Purpose of the Registry

The Working Group discussed the purpose and merits of the registry. The majority of the Working group supported the concept of a registry.

However, a minority of the Working Group questioned the need for and appropriateness of a registry for ICDs. This group indicated that the purpose of the registry remains unclear in view of the many randomized controlled clinical trials that support ICD therapy. Additionally, the high cost associated with data collection in the absence of clear questions to be answered and the concerns with linking a registry to reimbursement were articulated.

The National ICD Registry should be based upon the following principles:

- The primary focus of the registry is measuring outcomes and quality in a non-punitive environment leading to improvement of the care of patients receiving ICDs for primary prevention therapy.
- A competent national ICD registry should have the following qualities:
    - Assurance of data quality which includes training and education of individuals entering the data, clinical and technical support at the provider hospital, assessment of completeness of data entry, consistency of data evaluation, on-site auditing to assure accurate data submission.
    - Use of a nationally recognized set of data standards and data definitions such as the ACC/AHA data set elements and standard definitions for electrophysiology.
    - Use of a nationally recognized quality measure
    - Professionally driven

Questions to be Answered by the Registry: A Framework for Progress through Data Analysis

- How do the characteristics of the patients and implanting physicians compare between those involved in the randomized trials and those receiving and placing the device following approval?
- Are there differences in outcomes as a function of the characteristics/competencies of the individual implanting the ICD?
- Are there differences in outcomes as a function of the characteristics of the hospital where the ICD is implanted?
- Are the indications for the ICD similar to those in the randomized trials?
- Are the in-hospital procedure related complications similar to those in the randomized trials?
- What are the reasons for subsequent hospitalization for procedure or device-related complication and care?

Data Elements to be Collected

The Working Group discussed and reviewed possible data elements to be collected. The Working Group concluded that the Centers/Organizations competing to manage the Registry should develop the specific data elements.

The Working Group believes that routine patient follow-up data including ICD shock information obtained every 3-6 months is too expensive a task for the registry to undertake in the initial phase. Verification of the heart rhythm at the time of a shock would require an oversight group to review each intracardiac electrogram which would markedly increase the registry cost and burden. This type of data may be added in a later phase, once better computer based methods are developed to allow transfer of data from the device interrogation programmer to the Registry Coordinating Center.

However, follow-up data at the time of re-hospitalization(s) could be obtained in the initial phase of the Registry. This would allow documentation of information such as device related complications, need for ICD upgrade, and date of routine ICD replacement.

Defining Providers and Hospitals as Competent in ICD Implantation

The majority of the Working Group supported CMS's requirement that *"Hospitals and providers are certified as competent in the ICD implantation"* although additional discussion of this issue at a national level is recommended. The Working Group discussed that physician certification would be achieved by the following approaches:

- American Board of Internal Medicine Clinical Cardiac Electrophysiology Board Certification
- Completion of ACC COCAT Criteria (Josephson et al, Hayes et al) during a cardiology fellowship for device implantation. This should then be followed by successfully passing NASPExAM or another suitable nationally recognized examination . NASPExAM has been administered by the National Board of Medical Examiners since 1986 and tests physician competency to manage patients receiving cardiac pacemakers and implantable defibrillators.
- Completion of the ICD implantation guidelines for non-electrophysiologists (Curtis et al)

A minority of the Working Group expressed concern with the use of published guidelines that they considered a potential restraint of trade and would lead to reduced access to device implants in some hospitals and communities. Certification of competency remaining at the local hospital level was the preference of these individuals.

Funding the Registry

The Working Group agreed that mechanisms for funding the registry would be part of the business plan put forward by the Centers/Organizations competing to manage the ICD Registry. The Working Group discussed and supported the recent CMS decision to pay providers to complete data for the Oncology Registry described in the November 1, 2004 CMS Press

Releases and Fact Sheets titled *Demonstration of Improved Quality of Care for Cancer Patients Undergoing Chemotherapy*. This is a mechanism for funding the ICD Registry. There was general agreement that CMS or another agency of the Department should have an important role in funding the establishment of the ICD Registry.

Final Comments

The Working Group emphasized that the overall goal of the registry is to improve the care of patients receiving ICDs for primary prevention of sudden cardiac death. Care would be improved through a continuous quality improvement initiative based upon findings of the registry as the data is collected and evaluated. The Working Group wishes to emphasize that this continuous quality improvement initiative should be performed in a non-punitive environment. It is important to recognize that this registry has the potential to be burdensome to hospitals if too many questions are asked and too much data is required to be entered and managed; also, the duration of mandatory data collection by the registry needs to be defined. The Working Group unanimously agreed that CMS should allow ICD implantation and reimbursement to occur following publication of the final coverage decision and that a grace period be present until the registry is operational.

Recommendation

The National ICD Registry Working Group recommends that CMS develop a request for proposal to seek competitive bidding for the National ICD Registry management based upon the recommendations outlined in this document using an open and transparent process. Registry management should involve the appropriate professional organizations and all stakeholders should have access to the data. Centers/Organizations competing to manage the Registry should submit a business plan that outlines the organization's experience, the key lead people and their qualifications, how the registry will operate on a step-by-step basis, the proposed cost of operation, a description of the data elements and planned analysis of the registry data, and a general understanding of the needs of the registry.

The National ICD Registry Working Group appreciated the opportunity to contribute to the development of the ICD Registry. If you have any questions, please contact me at 507-284-4888 or hammill.stephen@mayo.edu.

Sincerely,

Stephen C. Hammill, MD
President, Heart Rhythm Society
Chair, National ICD Registry Working Group

REFERENCES:

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