

**Draft Decision Memo Public Comments for  
Implantable Defibrillators  
CAG-00157R2  
September 28-October 28, 2004**

**Commenter: Abitz, Steven**

Organization: Date: October 25, 2004 Comment:

CMS should be commended for its recent decision to reimburse ICDs for many heart failure patients. ICDs offer the best protection from sudden cardiac arrest. However, there are more Americans who remain without protection. Some heart failure patients that showed benefit from ICDs in recent clinical trials were excluded from the decision. I really question this part of the decision because without an ICD, these people stand very little chance of surviving a sudden cardiac arrest. Please help ALL Americans who could benefit from this amazing device have the protection they need. Your final decision must come before January 2005 to save as many lives as possible.

Thank you for taking the time to hear my concerns.

**Commenter: Ager, Carolyn**

Organization: Date: October 20, 2004 Comment:

Thank you, CMS, for making the decision to reimburse for ICDs for many heart failure patients. ICD's are the best chance these Americans have for preventing sudden cardiac arrest. However, your decision has excluded some Americans who are at the same risk for sudden cardiac arrest. What are those left out of the CMS decision supposed to do for protection from this silent killer?

Please revise your decision to include all patients that need ICDs. And please make that decision now. We need protection from sudden cardiac arrest before it kills thousands more.

**Commenter: Akin, C. David, M.D.**

Organization: Independence Cardiology Associates, PC Date: October 7, 2004 Comment:

I am a cardiologist in private practice. A frequent clinical consideration is the need for an implantable defibrillator in patients with decreased left ventricular function. As you know, this procedure is quite expensive and invasive and leaves the patient with an implanted device for the remainder of their life, subject to all of the complications of such implanted devices. It is much desired by the patient as well as our staff to avoid these devices, unless absolutely necessary; alternatively, we also desire proper placement in patients who truly do need them.

Unfortunately, at this point in time when one relies on "standard" criteria for an implantable defibrillator installation, many patients (about 80%) apparently get the devices unnecessarily as only one out of five devices actually discharges in followup. Microvolt T-wave alternans is an extremely promising tool which promises to "weed out" those patients who do not need defibrillators from the larger group, as it has proven to have an extremely high negative predictive value.

Currently we have difficulty in utilizing this test as broadly as we would like because of the lack of insurance coverage, and some of our patients then have to go on to expensive, invasive

electrophysiological testing and implantable defibrillator implantation simply because we are not able to utilize as fully as we would like this simple microvolt T-wave alternans test.

I understand that CMS is now considering a registry in those patients who receive an implantable defibrillator and I respectfully request the consideration of including MTWA within this registry. I am confident that if MWTA was widely employed, huge savings to the entire health care system would result.

At our own practice, we find that of the patients we screen, only one out of five actually get referred on for implantable defibrillator implantation.

At a cost of \$50,000 per defibrillator and with three or four defibrillators avoided weekly in our small practice, it is easy to see how cost savings quickly accrue.

Of the noninvasive screening modalities, MTWA appears to have the very best potential for properly screening for ICDs and is likely much more accurate than electrophysiological study in that regard.

I appreciate your consideration.

**Commenter: Albright, Clifford**

Organization: Date: October 15, 2004 Comment:

Thank you, CMS, for making the decision to reimburse for ICDs for many heart failure patients. ICD's are the best chance these Americans have for preventing sudden cardiac arrest. However, your decision has excluded some Americans who are at the same risk for sudden cardiac arrest. What are those left out of the CMS decision supposed to do for protection from this silent killer?

Please revise your decision to include all patients that need ICDs. And please make that decision now. We need protection from sudden cardiac arrest before it kills thousands more.

**Commenter: Al-Mudamgha, Ali, MD, FACC**

Organization: St. Joseph's Hospital Date: October 14, 2004 Comment:

I have reviewed the proposal published for expanding ICD coverage. My concern is certification for implanters and hospitals. I would favor adopting the Heart Rhythm Society (NASPE) published requirements for non-electrophysiologists as well as adopting the same guidelines published for EP's competency for ICD's and invasive EP procedures (100 cases). This would ensure that only competent individuals implant these devices and would prevent those physicians who view implanting devices as another procedure to increase practice revenue.

**Commenter: Altschuler, Harold, MD, FACC**

Organization: Date: October 27, 2004 Comment:

I applaud the agency's decision to expand the coverage for ICDs to include MADIT II and most SCD-Heft patients. These two studies clearly identified the life saving value of defibrillator therapy and now more patients being eligible increases our odds for reducing Sudden Cardiac Death.

The purpose of my writing you today is to voice my opinion about the patient registry that the agency has proposed. While at first glance it seems more of a roadblock to ICD use than anything else, with a better understanding of the content of this propose policy, I believe that the registry has value in determining whether ICD therapy is appropriate for all these patients...if Microvolt T-Wave Alternans is a required element.

I believe that by making Microvolt T-wave Alternans a required element of the registry, we will gain valuable and additional information, which should address my concerns about appropriate use of ICD in these new populations. All the potential risk stratifiers mentioned in the policy with the exception of MTWA have been available for some time. MTWA represents a more specialized technology than previously evaluated risk stratifiers because of it's proven very high negative predictive value.

I am concerned that the available data does not allow me to clearly target ICDs to patients that will derive benefit. I believe that using MTWA is critical to ensuring that defibrillator implantation occurs only in those patients most likely to benefit. The use of MTWA in the registry will enable you to evaluate this hypothesis.

It seems to me that with the relatively small absolute decrease in mortality seen in SCD-HeFT and the seemingly low number of appropriate firings, a risk stratifier like Microvolt Twave Alternans should be evaluated more closely and included as a required element of the patient registry.

**Commenter: Anderson, Kate**

Organization: Date: October 26, 2004 Comment:

I am writing to comment on the recent decision of the Centers for Medicare and Medicaid Services to reimburse implantable cardioverter defibrillators.

While it is a first step in the right direction, many people who are at risk have been left out of the preliminary decision, and will not have any other option to prevent a sudden cardiac arrest. For example, many Medicare recipients have that program as their only form of health care and won't be protected under the current decision.

It is crucial that all Americans at high risk get the protection they need from this terrible killer. With up to 450,000 people in this country dying every year from sudden cardiac arrest, the stakes are too high to implement this incomplete approach to reimbursement. Please increase the reimbursement options for ICDs to all at risk. Please don't make additional requests for data too cumbersome. Implementation of this landmark decision shouldn't be delayed past the 1st of the year.

Thank you for the opportunity to present my thoughts on this critical issue.

**Commenter: Andrade, Mary**

Organization: Date: October 12, 2004 Comment:

Thank you for providing coverage for ICDs to many Medicare patients at risk for SCA. But the CMS decision has left out around 100,000 Americans at high-risk for SCA.

I wanted you to know that a large number of Medicare patients have no other healthcare options. If ICDs are not covered for those left out, what will they do if they need this device? How can we deny them access to an ICD?

Please cover all Americans at high risk for SCA. Research has proven who needs an ICD. I'm concerned that waiting to collect more data will result in unnecessary deaths. The fact is that we can't let another day go by without this care.

Thank you for the opportunity to share my opinion on this matter.

**Commenter: Antosz, Daniel**

Organization: Date: October 25, 2004 Comment:

I am very happy to have the chance to provide my comments on ICDs to CMS. Thank you. This is an issue that means so much to me because SCA is a leading killer of Americans. I appreciate CMS's decision to provide critical coverage to so many Americans who depend on Medicare, but CMS must consider those who were left out.

There are approximately 100,000 Americans who are at great risk for SCA and won't have ICD coverage. Please increase coverage to these folks so that they can have access to this amazing technology that makes the difference between life and death sooner rather than later.

**Commenter: Athill, Charles**

Organization: Date: October 2, 2004 Comment:

Your recommendation for coverage of implantable defibrillators for patients with EF < 30% is much applauded. However, the stipulation that patients must be enrolled in a registry is yet another barrier to physicians delivering a proven lifesaving therapy to the patients that need it most. Who will be responsible for setting up this registry? Who will be responsible for the cost of maintaining such a registry? Should it be the device companies, the government? All device are now monitor for quality control both by the company and individual physicians , I see no reason to add another layer of bureacracy to device implantation. The stipulation that patients be enrolled in a registry should be removed.

In addition, excluding class four patients from the benefits of biventricular pacer/defibrillator is also a mistake.

**Commenter: Austin, George**

Organization: Date: October 12, 2004 Comment:

Thank you for the opportunity to submit my comments on this important issue. Sudden cardiac arrest kills more Americans than any other condition. It kills between 340,000 and 450,000 people every year û more than 1,000 people every day. Please, please consider providing ICDs for all at-risk Americans. Your preliminary decision leaves out some Medicare patients who could die without an ICD. People who rely on Medicare have no other options and need to be covered before the end of the year.

Thank you for considering this issue of such significant importance.

**Commenter: Austin, Linda**

Organization: Date: October 25, 2004 Comment:

Thank you for providing coverage for ICDs to many Medicare patients at risk for SCA. But the CMS decision has left out around 100,000 Americans at high-risk for SCA.

I wanted you to know that a large number of Medicare patients have no other healthcare options. If ICDs are not covered for those left out, what will they do if they need this device? How can we deny them access to an ICD?

Please cover all Americans at high risk for SCA. Research has proven who needs an ICD. I'm concerned that waiting to collect more data will result in unnecessary deaths. The fact is that we can't let another day go by without this care.

Thank you for the opportunity to share my opinion on this matter.

**Commenter: Ayanian, Zaven S.**

Organization: Date: October 19, 2004 Comment:

Thank you for the opportunity to submit my comments on this important issue. Sudden cardiac arrest kills more Americans than any other condition. It kills between 340,000 and 450,000 people every year û more than 1,000 people every day. Please, please consider providing ICDs for all at-risk Americans. Your preliminary decision leaves out some Medicare patients who could die without an ICD. People who rely on Medicare have no other options and need to be covered before the end of the year.

Thank you for considering this issue of such significant importance.

**Commenter: Babinski, Tammy**

Organization: Date: October 26, 2004 Comment:

I appreciate the chance to comment on the recent CMS decision regarding coverage and reimbursement of ICDs. Nearly one thousand Americans die every day of SCA, and your decision is an important step in the right direction. However, I urge CMS to expand ICD coverage to every American proven to be at risk for SCA. Some were excluded from the preliminary decision, and that has me worried. Every death from SCA is an unnecessary tragedy, and I respectfully request that you expand coverage. Please don't wait for more data that may cause a delay - many Americans need ICDs to live.

Please work to get this therapy available for Americans this year.

**Commenter: Bailey, William**

Organization: Heart and Vascular Center Lake Charles Date: October 13, 2004 Comment:

I wanted to express my support for including T-wave alternans as a screening tool for ICD pts in the MADIT and SCDHEFT population. I also would be in support of including this as part of a registry. We have been doing T-wave alternans testing in our patients for over two and a half years and find it a very valuable tool to screen for sudden cardiac death. We have tested patients who would not have met EPS indications based on arrhythmia(non-sustained VT by holter), but had positive T- wave, were inducible at EPS ,went on to ICD , and then had events and were saved by their ICD. I would strongly encourage inclusion of T-wave alternans.

**Commenter: Baker, Brett, MD, FACC**

Organization: Date: October 20, 2004 Comment:

As a practicing Cardiac Electrophysiologist, I have used and implanted ICDs for years. I have several comments on the CMS proposal for expanded ICD coverage:

1. The recent data from clinical trials suggests that an ejection fraction of 35% should be used as a basis for ICD coverage (and not 30%) as ICDs have been shown to reduce mortality in these patients.
2. A registry of ICD patients linked to reimbursement is impractical and an unreasonable burden on MDs and providers caring for these patients. Registry data is often unreliable and for that reason is NOT used by the FDA when considering approval of new technology and drugs. Several large, well-structured trials have demonstrated the efficacy of ICDs in the population being considered.
3. Single chamber ICDs have limitations that can lead to a potential increase in the likelihood of inappropriate ICD shocks. These shocks are painful and distressing to patients. These shocks can often be prevented with dual chambers ICDs as they have additional programming options.

Also, the majority of the patients in the group under consideration should be treated with beta-blockers. Beta-blockers produce iatrogenic sinus node dysfunction in many cases, leading to the need for an upgrade of a single chamber ICD to a dual chamber ICD.

The choice of single vs. dual chamber ICD should be left to the discretion of the implanting MD.

3. ICDs should only be implanted by MDs with appropriate training in ICD implantation. Currently,

the most appropriate training for ICD implantation is completion of an approved Cardiac Electrophysiology Fellowship with Board Certification. Limiting implantation of ICDs to appropriately trained MDs will reduce the number of inappropriate ICD implants and the likelihood of procedural complications.

Please consider the above comments and contact me with and questions.

**Commenter: Ballou, Robert**

Organization: Date: October 14, 2004 Comment:

I am writing to comment on the recent decision of the Centers for Medicare and Medicaid Services to reimburse implantable cardioverter defibrillators.

While it is a first step in the right direction, many people who are at risk have been left out of the preliminary decision, and will not have any other option to prevent a sudden cardiac arrest. For example, many Medicare recipients have that program as their only form of health care and won't be protected under the current decision.

It is crucial that all Americans at high risk get the protection they need from this terrible killer. With up to 450,000 people in this country dying every year from sudden cardiac arrest, the stakes are too high to implement this incomplete approach to reimbursement. Please increase the reimbursement options for ICDs to all at risk. Please don't make additional requests for data too cumbersome. Implementation of this landmark decision shouldn't be delayed past the 1st of the year.

Thank you for the opportunity to present my thoughts on this critical issue.

**Commenter: Bane, Lorita**

Organization: Date: October 26, 2004 Comment:

Thank you for the opportunity to submit my comments on this important issue. Sudden cardiac arrest kills more Americans than any other condition. It kills between 340,000 and 450,000 people every year more than 1,000 people every day. Please, please consider providing ICDs for all at-risk Americans. Your preliminary decision leaves out some Medicare patients who could die without an ICD. People who rely on Medicare have no other options and need to be covered before the end of the year.

Thank you for considering this issue of such significant importance.

**Commenter: Barlow, Charles**

Organization: Date: October 26, 2004 Comment:

CMS should be commended for its recent decision to reimburse ICDs for many heart failure patients. ICDs offer the best protection from sudden cardiac arrest. However, there are more Americans who remain without protection. Some heart failure patients that showed benefit from ICDs in recent clinical trials were excluded from the decision. I really question this part of the decision because without an ICD, these people stand very little chance of surviving a sudden cardiac arrest. Please help ALL Americans who could benefit from this amazing device have the protection they need. Your final decision must come before January 2005 to save as many lives as possible.

Thank you for taking the time to hear my concerns.

**Commenter: Barnato, Amber E., MD, MPH, MS**

Organization: University of Pittsburgh Date: October 6, 2004 Comment:

As a physician and health services researcher concerned about the implications for Medicare costs of wider ICD diffusion, I approached the new policy with some trepidation. However, after review, I must applaud CMS for its thoughtful effort to both expand coverage for technologies of proven benefit in RCTs and also to monitor patients as the technology diffuses from patients who meet strict eligibility requirements of an RCT to patients in the "real world."

Although I anticipate that some providers will have resistance to provider certification and registry or trial enrollment requirements of the proposed policy, I would like to record my belief that both stipulations are *very* important. They set a critical precedent for CMS, with FDA, to assure quality and to engage in ongoing surveillance of the safety and efficacy of medical devices that may have untoward consequences.

I encourage CMS to ensure that there is at least one member of any advisory board or group that helps to design the patient registry who is an expert in quality of life assessment. Additionally, CMS might consider including an expert in palliative care on the design team. Although this technology can extend life, most of these patients are nonetheless near the end of their lives so attention must be paid to the interaction between this technology and the quality of life and quality of death.

Congratulations on this excellent effort.

**Commenter: Beck, Tom, CDM**

Organization: Date: October 26, 2004 Comment:

I appreciate the chance to comment on the recent CMS decision regarding coverage and reimbursement of ICDs. Nearly one thousand Americans die every day of SCA, and your decision is an important step in the right direction. However, I urge CMS to expand ICD coverage to every American proven to be at risk for SCA. Some were excluded from the preliminary decision, and that has me worried. Every death from SCA is an unnecessary tragedy, and I respectfully request that you expand coverage. Please don't wait for more data that may cause a delay - many Americans need ICDs to live.

Please work to get this therapy available for Americans this year.

**Commenter: Benn, Bernice**

Organization: Date: October 12, 2004 Comment:

Thank you, CMS, for making the decision to reimburse for ICDs for many heart failure patients. ICDs are the best chance these Americans have for preventing sudden cardiac arrest. However, your decision has excluded some Americans who are at the same risk for sudden cardiac arrest. What are those left out of the CMS decision supposed to do for protection from this silent killer?

Please revise your decision to include all patients that need ICDs. And please make that decision now. We need protection from sudden cardiac arrest before it kills thousands more.

**Commenter: Bennett, Kathy**

Organization: Date: October 12, 2004 Comment:

I am very happy to have the chance to provide my comments on ICDs to CMS. Thank you. This is an issue that means so much to me because SCA is a leading killer of Americans. I appreciate CMS's decision to provide critical coverage to so many Americans who depend on Medicare, but CMS must consider those who were left out.

There are approximately 100,000 Americans who are at great risk for SCA and won't have ICD coverage. Please increase coverage to these folks so that they can have access to this amazing technology that makes the difference between life and death sooner rather than later.

**Commenter: Berns, Ellison**

Organization: Date: October 24, 2004 Comment:

I applaud the expansion of empiric ICD implantation guidelines to patients with non-ischemic dilated cardiomyopathy. However, my understanding is that of the trials reviewed, only DEFINITE enrolled patients who were NYHA functional class

I. Furthermore, it is my understanding that the, albeit small, subset analysis of this group did not show mortality benefit. Thus, if my understanding of the enrolled patients is correct, CMS might wish to consider limiting empiric ICD implant in patients with non-ischemic dilated cardiomyopathy with EF < 30% to those who are NYHA functional class II- III. This is not outlined in the proposed guidelines that were posted.

Also, I would like to take issue with the Cambridge Heart VP of marketing soliciting physicians to submit a comment in support of adding T wave alternans data to the information collected in the registry. Although approved for use, data for its application as a risk stratifier for empiric ICD implant is scant. Requesting that this data be included forces otherwise qualified centers to purchase the Cambridge Heart equipment and perform this test prior to implant, something not done in most of the empiric ICD trials. There is no doubt that this research data would be immensely useful to help determine if this noninvasive test might better determine who is a risk for sudden death. However, if CMS feels that research on this topic is mandatory, and data collected be added to the registry, Cambridge Heart should supply the its device free of charge to those implanting centers until such time enough data is collected to determine if T wave alternans testing be abnormal in order to implant an ICD.

Thank you for the opportunity to comment. I am a member of Heart Rhythm Society, but my comments are submitted representing myself and are not intended to represent Heart Rhythm Society in any way.

**Commenter: Berry, Teresa**

Organization: Date: October 26, 2004 Comment:

Thank you for providing coverage for ICDs to many Medicare patients at risk for SCA. But the CMS decision has left out around 100,000 Americans at high-risk for SCA.

I wanted you to know that a large number of Medicare patients have no other healthcare options. If ICDs are not covered for those left out, what will they do if they need this device? How can we deny them access to an ICD?

Please cover all Americans at high risk for SCA. Research has proven who needs an ICD. I'm concerned that waiting to collect more data will result in unnecessary deaths. The fact is that we can't let another day go by without this care.

Thank you for the opportunity to share my opinion on this matter.

**Commenter: Bigger, J. Thomas, M.D.**

Organization: Columbia University Date: October 23, 2004 Comment:

CMS deserves great credit for its evaluation of new evidence regarding its decision of June 2003 to use an electrocardiographic QRS interval  $>120$  ms to select a subset of MADIT II patients for ICD coverage. Since that time, much new evidence has been presented to support the conclusion that QRS  $>120$  ms has too high a false negative rate to select patients for a critical life-saving technology like ICD. The cardiology community is grateful for this revision in the coverage decision and commends CMS for making it.

The efficacy of ICD prophylaxis has focused our attention on issues related to the selection of patients. The majority of the high risk patients that participated in large trials, e.g., The CABG Patch Trial, MUSTT, MADIT II, and SCD HeFT, has not benefited from ICD therapy, even participants in trials with long follow-up, e.g., SCD HeFT. It remains a goal to improve the selection for ICD prophylaxis a group with high risk of benefiting (high positive predictive accuracy) without excluding patients who would benefit (low false negative rate). Some of our risk predictors fail to meet this test criterion and others have not been fully evaluated. Few tests have been proven to offer both a high positive predictive accuracy and a low false negative rate. Accumulating evidence suggests that microvolt T wave alternans (MTWA) has both characteristics (Bloomfield DM, et al. Microvolt T-Wave Alternans Distinguishes Between Patients Likely and Patients Not Likely to Benefit From Implanted Cardiac Defibrillator Therapy. A Solution to the Multicenter Automatic Defibrillator Implantation Trial (MADIT) II Conundrum. *Circulation* 2004;110:1885-1889.), but most previous studies did not evaluate MTWA in the context of ICD therapy, where the benefit of MTWA for selecting patients for ICD prophylaxis can best be assessed.

SCD HeFT conducted a MTWA substudy to obtain long-term follow-up data on the predictive value of MTWA in patients randomized to ICD prophylaxis or placebo. ICD shocks were carefully evaluated using a standardized protocol and central review of the stored electrograms associated with ICD shocks. When published, these data should add importantly to the knowledge base we need to select patients for ICD prophylaxis with better accuracy by coupling MTWA results with controlled prophylactic ICD experience.

In its current draft coverage decision, CMS proposes that a registry be a condition of extended coverage for ICD prophylaxis. One purpose of the registry would be to prospectively evaluate tests that might improve patient selection for ICD prophylaxis. The registry is an interesting proposal and a worthy concept – initial broad coverage for ICD prophylaxis coupled with ongoing study of risk indicators to refine selection of patients and improve the risk benefit of this therapy. Physicians with an open mind and scientific bent should be attracted to this concept. However, to realize the potential of the registry will require a good planning process, a simple registry, a credible host for the registry, cooperation among the stakeholders, and superb execution.

As it accumulates, the body of evidence for the utility of MTWA for selecting patients for ICD prophylaxis becomes ever more impressive. MTWA is certainly worthy of consideration as one of the risk predictors to track in the new CMS database. If the results of SCD-HeFT are similar to the studies published so far, MTWA will be a convincing predictor with an impressively low false negative rate. A directory could provide the final definitive evidence that MTWA and/or other tests have substantial utility for selection of patients for ICD prophylaxis and should therefore become standards of care.

The faint of heart may shrink at the prospect of the registry and the stakeholders who put self-interest first may reject the notion out of hand. But, advocates for responsible utilization of expensive health-related technology should engage the registry planning with vigor and make an earnest attempt to develop this concept into a viable system. If process and conduct problems can be overcome, the health benefits of a successful registry could be substantial. The opportunities afforded by the registry concept are great for all stakeholders, e.g., the device industry, professional organizations, government agencies (CMS, AHRQ, NIH), physicians, and patients.

I hope that, as a first step, a planning apparatus can be constituted to launch the effort to develop a registry with intelligence and credibility. A success in addressing the ICD prophylaxis issues could promote a new and better process for refining the use of new medical or surgical therapies and thus improving their benefit/risk ratio. The registry concept deserves an earnest try.

**Commenter: Birko, Annette**

Organization: Date: October 12, 2004 Comment:

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**Commenter: Birko, Corrine**

Organization: Date: October 12, 2004 Comment:

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**Commenter: Birko, Matthew**

Organization: Date: October 12, 2004 Comment:

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Thank you for the opportunity to present my thoughts on this critical issue.

**Commenter: Birko, Sue**

Organization: Date: October 26, 2004 Comment:

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Please cover all Americans at high risk for SCA. Research has proven who needs an ICD. I'm concerned that waiting to collect more data will result in unnecessary deaths. The fact is that we can't let another day go by without this care.

Thank you for the opportunity to share my opinion on this matter.

**Commenter: Bocchino, Carmella A., MBA, RN**

Organization: America's Health Insurance Plans Date: October 28, 2004 Comment:

America's Health Insurance Plans (AHIP) is pleased to submit comments, on behalf our member organizations, in response to the Centers for Medicare & Medicaid Services' (CMS) *Draft Decision Memorandum for Implantable Defibrillators*. AHIP is the national trade association representing the private sector in health care. AHIP's member companies provide health benefits to more than 200 million Americans.

The draft decision memorandum outlines the evidence compiled from recent implantable cardioverter defibrillators (ICD) studies and explains CMS' rationale for expanding coverage. As stated in the decision memo, patients with ischemic dilated cardiomyopathy (IDCM), documented prior myocardial infarction (MI) and measured left ventricular ejection fraction (LVEF)  $\leq 30\%$  and, patients with nonischemic dilated cardiomyopathy (NIDCM)  $> 9$  months and measured LVEF  $\leq 30\%$  are now eligible for ICD coverage. While we recognize the detailed review put forth by CMS to establish an evidence base for expanding coverage for implantable defibrillators, until additional research is conducted we recommend that CMS maintain its existing coverage guidelines. We offer the following comments to support this recommendation.

#### **Additional Review of Evidence**

CMS should further evaluate the findings from evidence-based outcome studies to assure that ICDs are provided only to those sub-populations that have been shown by rigorous analysis to have a clear benefit. While CMS relies heavily on two studies (i.e., the MADIT II trial and the recently reported The Sudden Cardiac Death in Heart Failure Trial) for justification of the current coverage decision, several other studies reviewed in the draft decision memo offer conflicting evidence for other sub-group populations, such as patients with NIDCM and reduced Left Ventricular Ejection Fraction.

#### **Ensuring Appropriate Use**

CMS estimates that this new coverage decision will result in the implantation of an additional 500,000 ICDs. We are concerned with the impact of this coverage decision on the private sector and the potential for inappropriate utilization. It is important for CMS to implement a policy that will ensure the safe and appropriate use of ICDs. In order to alleviate these concerns, CMS should fully address the impact of other such technologies that may be equally or more effective. Other medical treatments examined in the draft decision, for example, recounted similar effectiveness as ICDs.<sup>1</sup>

The relatively loose parameters and indications regarding the appropriateness of single versus dual lead devices are of concern to our member health insurance plans. It is important for CMS to clearly define the parameters and indications for the use of the dual lead devices. The potential for inappropriate utilization is great and more explicit clarification about the effectiveness of the two devices would assist providers in selecting the most appropriate device for individual patients.

<sup>1</sup> Strickberger SA, Hummel JD, Bartlett TG, et al. Amiodarone versus implantable cardioverter-defibrillator: randomized trial in patients with nonischemic dilated cardiomyopathy and asymptomatic nonsustained ventricular tachycardia - AMIOVIRT. *J Am Coll Cardiol* 2003;41:1707-1712.

### **Benefit of Single National Registry**

We also encourage CMS to revise its current requirement that patients receiving an ICD are enrolled in either an FDA registered B IDE clinical trial **or** a qualifying national database (emphasis added). Patients instead should be assigned to a **specific, single registry** to facilitate documentation and record auditing related to appropriate ICD use. While we support CMS' requirement for hospitals and providers to participate in one of multiple national registries, a single national registry or database will be the most useful to track the effectiveness and most appropriate use of ICDs, reduce potential inappropriate over-utilization, and document national health outcomes.

In establishing this single national database, CMS should provide clear directions to manufacturers about the data submission process. Such instructions should discuss how compliance with reporting will be monitored and how continued reporting will be maintained.

We also ask that CMS use the information from this national database to conduct formal meta analyses to determine the longitudinal impact of devices such as ICDs. Patient-level data reported by device manufacturers could be pooled together by an independent organization such as the Agency for Healthcare Research and Quality for appropriate analysis.

AHIP appreciates the opportunity to provide comment on the *Draft Decision Memorandum for Implantable Defibrillators*. If you have any questions or wish to discuss our comments, please feel free to contact me at 202.778.3278.

### **Commenter: Bock, William, M.D.**

Organization: Charlotte Cardiology Associates Date: October 17, 2004 Comment:

Regarding the proposed database, I feel that T wave alternans testing would be a very helpful factor to track. I find it to be a very useful test, and possibly the best way to avoid unnecessary ICD implants in lower risk patients. CMS should reexamine the approved indications for this test, and include testing of the post MI population with EF < 45% in my opinion.

### **Commenter: Borgmeyer, Becky**

Organization: Date: October 27, 2004 Comment:

I am very happy to have the chance to provide my comments on ICDs to CMS. Thank you. This is an issue that means so much to me because SCA is a leading killer of Americans. I appreciate CMS's decision to provide critical coverage to so many Americans who depend on Medicare, but CMS must consider those who were left out.

There are approximately 100,000 Americans who are at great risk for SCA and won't have ICD coverage. Please increase coverage to these folks so that they can have access to this amazing technology that makes the difference between life and death sooner rather than later.

**Commenter: Bossart, Barbara**

Organization: Date: October 19, 2004 Comment:

Thank you, CMS, for making the decision to reimburse for ICDs for many heart failure patients. ICD's are the best chance these Americans have for preventing sudden cardiac arrest. However, your decision has excluded some Americans who are at the same risk for sudden cardiac arrest. What are those left out of the CMS decision supposed to do for protection from this silent killer?

Please revise your decision to include all patients that need ICDs. And please make that decision now. We need protection from sudden cardiac arrest before it kills thousands more.

**Commenter: Boston, Dennis**

Organization: Date: October 12, 2004 Comment:

I am writing to comment on the recent decision of the Centers for Medicare and Medicaid Services to reimburse implantable cardioverter defibrillators.

While it is a first step in the right direction, many people who are at risk have been left out of the preliminary decision, and will not have any other option to prevent a sudden cardiac arrest. For example, many Medicare recipients have that program as their only form of health care and won't be protected under the current decision.

It is crucial that all Americans at high risk get the protection they need from this terrible killer. With up to 450,000 people in this country dying every year from sudden cardiac arrest, the stakes are too high to implement this incomplete approach to reimbursement. Please increase the reimbursement options for ICDs to all at risk. Please don't make additional requests for data too cumbersome. Implementation of this landmark decision shouldn't be delayed past the 1st of the year.

Thank you for the opportunity to present my thoughts on this critical issue.

**Commenter: Boulay, Thomas H.**

Organization: Date: October 12, 2004 Comment:

I am writing to comment on the recent decision of the Centers for Medicare and Medicaid Services to reimburse implantable cardioverter defibrillators.

While it is a first step in the right direction, many people who are at risk have been left out of the preliminary decision, and will not have any other option to prevent a sudden cardiac arrest. For example, many Medicare recipients have that program as their only form of health care and won't be protected under the current decision.

It is crucial that all Americans at high risk get the protection they need from this terrible killer. With up to 450,000 people in this country dying every year from sudden cardiac arrest, the stakes are too high to implement this incomplete approach to reimbursement. Please increase the reimbursement options for ICDs to all at risk. Please don't make additional requests for data too cumbersome. Implementation of this landmark decision shouldn't be delayed past the 1st of the year.

Thank you for the opportunity to present my thoughts on this critical issue.

**Commenter: Boutte, Tony**

Organization: Date: October 13, 2004 Comment:

I am very happy to have the chance to provide my comments on ICDs to CMS. Thank you. This is an issue that means so much to me because SCA is a leading killer of Americans. I appreciate CMS's decision to provide critical coverage to so many Americans who depend on Medicare, but CMS must consider those who were left out.

There are approximately 100,000 Americans who are at great risk for SCA and won't have ICD coverage. Please increase coverage to these folks so that they can have access to this amazing technology that makes the difference between life and death sooner rather than later.

**Commenter: Bovarick, Leonard**

Organization: Date: October 12, 2004 Comment:

CMS should be commended for its recent decision to reimburse ICDs for many heart failure patients. ICDs offer the best protection from sudden cardiac arrest. However, there are more Americans who remain without protection. Some heart failure patients that showed benefit from ICDs in recent clinical trials were excluded from the decision. I really question this part of the decision because without an ICD, these people stand very little chance of surviving a sudden cardiac arrest. Please help ALL Americans who could benefit from this amazing device have the protection they need. Your final decision must come before January 2005 to save as many lives as possible.

Thank you for taking the time to hear my concerns.

**Commenter: Boyd, Johnny**

Organization: Date: October 25, 2004 Comment:

I appreciate the chance to comment on the recent CMS decision regarding coverage and reimbursement of ICDs. Nearly one thousand Americans die every day of SCA, and your decision is an important step in the right direction. However, I urge CMS to expand ICD coverage to every American proven to be at risk for SCA. Some were excluded from the preliminary decision, and that has me worried. Every death from SCA is an unnecessary tragedy, and I respectfully request that you expand coverage. Please don't wait for more data that may cause a delay - many Americans need ICDs to live.

Please work to get this therapy available for Americans this year.

**Commenter: Brace, Pam**

Organization: Date: October 26, 2004 Comment:

I am very happy to have the chance to provide my comments on ICDs to CMS. Thank you. This is an issue that means so much to me because SCA is a leading killer of Americans. I appreciate CMS's decision to provide critical coverage to so many Americans who depend on Medicare, but CMS must consider those who were left out.

There are approximately 100,000 Americans who are at great risk for SCA and won't have ICD coverage. Please increase coverage to these folks so that they can have access to this amazing technology that makes the difference between life and death sooner rather than later.

**Commenter: Brooks, Charles**

Organization: Date: October 26, 2004 Comment:

Thank you, CMS, for making the decision to reimburse for ICDs for many heart failure patients. ICD's are the best chance these Americans have for preventing sudden cardiac arrest. However, your decision has excluded some Americans who are at the same risk for sudden cardiac arrest. What are those left out of the CMS decision supposed to do for protection from this silent killer?

Please revise your decision to include all patients that need ICDs. And please make that decision now. We need protection from sudden cardiac arrest before it kills thousands more.

**Commenter: Brown, William**

Organization: Date: October 13, 2004 Comment:

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Please revise your decision to include all patients that need ICDs. And please make that decision now. We need protection from sudden cardiac arrest before it kills thousands more.

**Commenter: Bryce, Miguel, MD, FACC**

Organization: Date: October 21, 2004 Comment:

As a member of The Heart Rhythm Society, I agree with their proposal and consideration for changes. 1] For those patients with Non-Ischemic CMP the period for documentation of severe LV dysfunction on maximal medical therapy should be no longer than 6 months, instead of 9 months. 2] Most of the patients need to be treated with antiarrhythmics as well as with beta blockers so some of them will need atrial pacing for SN dysfunction and should not be limited to a single chamber "shock box" device. 3] My main concern is the "registry", the new expanding indications based on randomized clinical trials need to be in place as soon as possible. The creation of a National Database seems impactful. Maybe against HIPPA regulations, violating patient privacy. The follow up of the patient is not necessary by the Electrophysiologist who does the implant. May not be accurate and will lead to wrong conclusions.

If any registry will be in placed will need to be in placed at later time following the Heart Rhythm Society recommendations. May need to consider only few pilot centers first. The non-Medicare patients will not be part of this registry so no information will be available in this population.

I encouraged the CMS to expand the coverage for ICD implantation for prevention of SCD, as well as create a registry at later time after being tested in few centers at the beginning to see if it is a practical approach.

Thank you.

**Commenter: Buchanan, James**

Organization: Date: October 12, 2004 Comment:

Thank you, CMS, for making the decision to reimburse for ICDs for many heart failure patients. ICDs are the best chance these Americans have for preventing sudden cardiac arrest. However, your decision has excluded some Americans who are at the same risk for sudden cardiac arrest. What are those left out of the CMS decision supposed to do for protection from this silent killer?

Please revise your decision to include all patients that need ICDs. And please make that decision now. We need protection from sudden cardiac arrest before it kills thousands more.

**Commenter: Burkhart, Belinda**

Organization: Date: October 12, 2004 Comment:

CMS should be commended for its recent decision to reimburse ICDs for many heart failure patients. ICDs offer the best protection from sudden cardiac arrest. However, there are more Americans who remain without protection. Some heart failure patients that showed benefit from ICDs in recent clinical trials were excluded from the decision. I really question this part of the decision because without an ICD, these people stand very little chance of surviving a sudden cardiac arrest. Please help ALL Americans who could benefit from this amazing device have the protection they need. Your final decision must come before January 2005 to save as many lives as possible.

Thank you for taking the time to hear my concerns.

**Commenter: Butler, William**

Organization: Date: October 25, 2004 Comment:

CMS should be commended for its recent decision to reimburse ICDs for many heart failure patients. ICDs offer the best protection from sudden cardiac arrest. However, there are more Americans who remain without protection. Some heart failure patients that showed benefit from ICDs in recent clinical trials were excluded from the decision. I really question this part of the decision because without an ICD, these people stand very little chance of surviving a sudden cardiac arrest. Please help ALL Americans who could benefit from this amazing device have the protection they need. Your final decision must come before January 2005 to save as many lives as possible.

Thank you for taking the time to hear my concerns.

**Commenter: Buxton, Alfred**

Organization: Brown Medical School Date: October 24,  
2004 Comment:

1. Not all patients who have coronary artery disease and an LV EF  $\leq 30\%$  are at equal risk for sudden death. Patients who have only low EF but a narrow QRS complex, no symptomatic CHF, no inducible sustained VT by EPS, but spontaneous non-sustained VT have a predicted 2-year total mortality risk of 6.2%, based on modeling of the MUSTT data, presented at the ACC meeting, March, 2004. The predicted 2-year risk of sudden death in such patients was 3.5% (i.e., 1.7% per year). Such patients are unlikely to derive significant benefit from an ICD. Further studies are needed to confirm this. Thus, it is not true that an ICD is "reasonable and necessary" for all pts with CAD and an EF  $\leq 30\%$ . Furthermore, your emphasis on patients whose EF is  $\leq 30\%$  ignores the problem of sudden death in patients whose EF is 30-40% - a far larger group, whose sudden death risk is only slightly less than that of patients whose EF is  $\leq 30\%$ .
2. There would appear to be no basis to require that patients having non-ischemic dilated cardiomyopathy have the diagnosis  $>9$  months in order to allow ICD implantation. Although the trial, included only patients with DCM diagnosed within 9 months, the SCD-HeFT trial required DCM diagnosed  $>3$  months earlier.
3. Nowhere in your Decision Summary do you mention the importance of initiating standard medical therapy for CHF and low EF patients (beta-adrenergic blockade, ACE-I, ARB, etc), and allowing adequate time to observe response (probably  $\geq 3$  months) - many patients' EF will improve to  $>40\%$  with institution of appropriate medical therapy. Even if the EF doesn't improve sufficiently to place the patient in a low risk group, appropriate medical therapy is probably at least as important as ICDs in reducing mortality in such patients!
4. A registry is an excellent idea. However, to do this correctly, and accurately is very expensive. It requires adequate planning. CMS should provide funding for this. Medicare and its recipients benefit directly from the results of clinical research, and should be prepared to fund such research!

Who will certify that hospitals and providers are certified as competent to implant ICDs? Just as important as the ability to implant ICDs is the knowledge and ability to follow-up patients with implanted devices. This is a very time- intensive, expensive practice that requires equal or greater competence as the ability to implant a device. **Commenter: Bynum, Glenda**

Organization: Date: October 16, 2004 Comment:

With up to 1,200 Americans killed daily by sudden cardiac arrest, I'm encouraged by the latest decision to expand Medicare coverage of implantable cardioverter defibrillators for at-risk patients.

But, it is important to note that the new coverage still leaves tens of thousands of people at risk that is preventable if Medicare reimbursement covered everyone at high-risk for sudden cardiac arrest.

Please consider including all Medicare recipients with heart failure who are at high risk for SCA. And please don't delay the decision while waiting for more data/information. We need access to this important medical care by January 1, 2005.

Thank you,

**Commenter: Calvert, Barbara**

Organization: Guidant Corporation Date: October 28, 2004 Comment:

Dr. Steve Phurrough, M.D., M.P.A. Director, Coverage and Analysis Group Centers for Medicare and Medicaid Services Attn: Public Comments, S3-02-01 7500 Security Boulevard; Baltimore, MD 21244-1850

Draft Decision Memo for Implantable Defibrillators (CAG-00157R2)

Dear Dr. Phurrough:

Guidant Corporation welcomes the opportunity to provide comments in response to the Centers for Medicare and Medicaid Services' (CMS) public comment period for the national coverage reconsideration of implantable cardioverter defibrillators (ICDs), posted on the CMS website September 28, 2004.

Headquartered in Indianapolis, Indiana, with manufacturing and/or research and development facilities in the states of Minnesota, California and Washington, as well as in Puerto Rico and Ireland, Guidant Corporation is a leading designer and manufacturer of medical technologies used primarily to treat cardiovascular and vascular illnesses. Guidant's products save and enhance lives.

Guidant commends CMS on its preliminary decision to expand patient access to the life-saving therapy of ICDs based on the positive scientific evidence from multiple, randomized controlled clinical trials. Furthermore we appreciate CMS issuing this draft decision within the legislative timeframes. We also appreciate CMS' efforts to ensure that the national coverage process remains transparent to the public and continuously involves industry stakeholders, including Guidant.

While we strongly support the expansion of ICD coverage, we have several concerns regarding provisions included in the draft decision. Our comments will focus on the following areas:

- (1) Requirement for an ICD patient registry;
- (2) Physician documentation;
- (3) Exclusion of ICD coverage for certain SCD- HeFT patients;

- (4) Coverage for cardiac resynchronization therapy defibrillators (CRT-D) for NYHA Class IV patients; and
- (5) CMS analysis of COMPANION trial results

#### Requirement for an ICD Patient Registry

CMS appears to be moving in the direction of requiring additional post-FDA approval data collection as a condition for national coverage. In addition to the proposed ICD registry, CMS has mandated additional data collection in recent coverage decisions for lung volume reduction surgery, left ventricular assist device implants and PET imaging. CMS has indicated that such data collection is needed to address questions that have not been answered by trials to support FDA approval and to gain knowledge of therapy benefit and related issues in a real world clinical setting. It remains unclear how CMS would use the data generated from such data collection efforts.

As the sponsor of numerous landmark clinical trials, Guidant is a strong supporter of evidence-based medicine. We acknowledge that limited evidence may exist for some technologies at the time of FDA approval and that in some cases additional data collection and research could prove beneficial to patients and providers. However, we are not convinced that national coverage decision mandates are the best way to encourage such research. We do support the Department of Health and Human Services (DHHS) efforts to promote the increased use of healthcare information technology that would greatly facilitate such data collection and research efforts. If CMS continues to pursue data collection requirements as a requirement for national coverage, we recommend that the agency integrate the following principles and considerations into its approach.

- . Evidence collected from a well designed pivotal trial to support FDA approval should be adequate for the purposes of a national coverage decision, without the need for additional data collection.

- . Requirements for additional data collection post-FDA approval pose significant challenges. Post market registries generally are very costly, difficult to design and manage, present potential ethical concerns, could take years to complete and are substantially less scientifically rigorous than randomized controlled trials.

- . Any effort by CMS to collect data subsequent to FDA approval should be limited to situations where that approval is based on limited evidence, and CMS clearly and publicly demonstrates that the collection of additional data will provide significant value for patients and/or providers.

- . In determining the value of additional data collection, CMS should consider and make publicly known the assessment of the potential benefits for patients and providers as well as the cost, burden and ethical concerns associated with the data collection effort.

- . CMS should take into account any post-FDA approval studies and other ongoing or planned clinical research when considering the need for additional data collection.

- . CMS should work closely with manufacturers and other stakeholders to determine whether to initiate additional data collection. Stakeholder consensus on the scientific questions to be addressed, appropriate data collection mechanisms, process management and funding should be obtained.

- . CMS should take at least burdensome approach to data collection and focus research narrowly on the key questions, e.g., relevance to Medicare beneficiaries. All studies should be well designed and appropriately managed in order to ensure scientifically valid results.

- . CMS should provide coverage for all indicated beneficiaries while additional data is collected

and not limit coverage to beneficiaries participating in the data collection effort.

CMS and/or other government agencies should fund all or most of the costs associated with any required data collection, validation, + CMS should require that data collection be structured to promote the development of common clinical data standards to support the increased use of healthcare information technology.

In line with the principles stated above, Guidant is supportive of the establishment of an ICD registry or other data collection mechanism to the extent that it can be clearly demonstrated that the effort will provide significant value for patients and/or providers, taking into account both the potential benefits and the associated costs, burdens and any ethical concerns. We are committed to continuing to work with CMS and other stakeholders to further explore the appropriate questions to address through such data collection, the most appropriate data collection mechanisms, process management, funding and other issues. We understand that CMS plans to implement the coverage policy on the date of publication of the final decision and will not delay coverage pending full implementation of any required data collection mechanisms. We do, however, have a number of concerns about the specific registry proposal included in the draft decision, as detailed below.

**Development of hypotheses.** In the draft decision CMS indicates that a registry should address specific hypotheses. We note that a registry alone, without a control group, is not a rigorous vehicle for assessing the benefit of therapy in patient populations. Rather, the registry, as proposed by CMS, would potentially generate hypotheses that could be tested in a subsequent hypothesis-testing trial, with the most rigorous of these being prospective randomized controlled trials.

CMS cites several examples of the type of questions that the registry could address including ICD benefit in the early post MI period, risk stratification factors, and appropriate ICD functions and settings. In addition, CMS suggests that ICD manufacturers engage an independent research center to pool and analyze clinical trial data to facilitate the identification of questions to be addressed. We acknowledge that the Duke Clinical Research Institute has already performed substantial work in an attempt to develop a broad consensus regarding areas where there is and is not residual controversy regarding ICD benefit, and we encourage that any additional efforts take advantage of the work already accomplished. Additionally, we believe that a promising approach to developing appropriate questions is through the consensus of the many stakeholders in the CMS appointed stakeholder task force. We request that CMS seriously consider the recommendations of that task force in determining which questions might be appropriately addressed by a registry or other data collection mechanism.

**Selection of appropriate data collection mechanism.** In the draft decision CMS calls for the establishment of a national registry as the mechanism for collecting data on ICD therapy. We encourage CMS to consider all possible mechanisms for collecting data and not limit consideration to a national registry approach. The selection of an appropriate data collection mechanism will depend largely on the specific questions to be addressed. In addition, some questions may be the subject of ongoing or planned research and as such will not require additional data collection. We request that CMS consider various data collection mechanisms based on the questions to be addressed, relevant ongoing and planned research and recommendations of the stakeholder task force.

**All-inclusive nature of registry.** In the draft decision CMS states that all Medicare beneficiaries receiving primary prevention ICD therapy must be included in the registry or other data collection mechanism. We believe that it is too early to conclude that an all-inclusive registry is the best approach. Depending on the questions to be addressed and the logistics of data collection, it may be preferable to collect data through sampling techniques. In addition, it is possible that some questions would be best answered through sampling while others would benefit from an all-inclusive approach.

Furthermore, we are concerned that beneficiaries who fail to provide informed consent to participate in a registry would be denied access to therapy under the CMS approach. We request CMS consider the recommendations of the ICD registry task force before deciding on whether to pursue an all-inclusive or sampling approach to data collection. In addition, we urge CMS to clarify that those patients who refuse to provide informed consent will still be covered.

Hospital and provider certification. In the draft decision CMS indicates its desire to ensure that ICD implants are only performed by competent providers in facilities with a history of good outcomes and quality assessment/improvement programs to identify providers with poor outcomes and other areas for improvement. In addition, CMS proposes that the national registry include criteria to assure that hospitals are certified as competent in the implantation of ICDs.

We do not believe it is appropriate or necessary for CMS to require additional hospital or provider certification requirements or performance criteria as part of its coverage decision. While we are aware that in two recent coverage decisions CMS has restricted which hospitals may perform lung volume reduction surgery and left ventricular assist device implantation, such restrictions are not needed in the case of ICD implantation. ICD therapy and procedures are well developed and not a new, relatively untested therapy. Furthermore, hospitals and providers have significant experience in providing safe and effective treatment in both the hospital inpatient and outpatient setting. We believe that existing hospital and physician quality assurance systems, credentialing and risk management programs adequately assure hospital quality of care. We urge CMS not to mandate additional requirements, particularly without clear data on the need for such requirements.

Data collection management. It remains unclear how a patient registry or other data collection mechanism would be managed and how quality would be assured. We believe that quality management is essential in order to assure the generation of valid data. If a patient registry or other data collection mechanism is implemented, we urge CMS to further consult with stakeholders in order to determine the best approach for managing data collection.

Burden on providers. We are concerned that a national registry could result in a considerable burden for hospitals and providers. Data entry, record keeping, patient follow up, additional billing codes and claims submission requirements and other tasks commonly associated with registry participation require considerable time and effort, even in the case of a simple registry. If hospitals and physicians are not adequately compensated for their time, we believe that the quality of registry record-keeping and patient access could suffer. We urge CMS to provide additional compensation for hospitals and providers participating in a registry over and above the existing procedure payment rates.

Funding. It remains unclear how a registry or other data collection mechanism would be funded. As post market data collection can be very expensive, we urge CMS to weigh both the benefits and the costs of data collection in deciding how to proceed. We believe that CMS must prospectively identify the funding sources for the additional costs of this data collection, with possible sources being NIH or AHRQ, and that it would be inappropriate to ask providers, hospitals, or the medical device industry to assume the responsibility for this additional burden.

## Physician Documentation

We understand from conversations with CMS leadership that CMS does not intend to create new, and additional documentation requirements for physicians that prescribe ICD therapy. Rather, CMS will continue its longstanding policy of requiring physicians to document the need for ICD therapy, including the device type most appropriate for patient therapy. Because CMS does not intend to create a new or different policy, we believe that the reference to physician documentation requirements in the coverage policy should reflect that physicians retain the latitude to use patient-specific information, clinical trial results, and their best professional judgment to determine appropriate device selection, and that routine documentation of these determinants is expected. Exclusion of ICD Coverage for Certain SCD- HeFT Patients

As a strong supporter of evidence-based medicine, Guidant believes that coverage decisions based on retrospective post-hoc subset analyses of controlled, randomized trials are inappropriate. Rather, these subset analyses, often based exclusively on small data sets with limited statistical significance and unclear implications are best used to develop hypotheses which then require subsequent and rigorous testing, preferably in prospective randomized controlled trials. The current proposed decision excludes SCD-HeFT patients with ejection fractions greater than 30% and less than or equal to 35%.

We encourage CMS to include these patients in both the coverage decision as well as the proposed data collection mechanism. We also encourage CMS to expand coverage for ICD implantation in the early post-MI period and in other patient populations on the fringe of the proposed coverage pool who are known to be at elevated risk of sudden cardiac death, but for which there remain some questions of the magnitude of ICD benefit. Expanding coverage to such patient groups would provide additional substantial rationale for, and increase the potential utility of, the proposed post-approval data collection mechanism.

## Coverage for CRT-Defibrillators for NYHA Class IV Patients

Guidant continues to believe that CMS should cover cardiac resynchronization therapy defibrillators (CRT-D) for class IV heart failure patients that meet new or existing Medicare coverage indications. It is Guidant's understanding that CMS now covers New York Heart Association (NYHA) class IV patients requiring ICD therapy for the secondary prevention of sudden cardiac death (SCD). We urge CMS to clarify this existing coverage in the final decision in order to avoid confusion on the part of local Medicare contractors and providers. However, CMS's preliminary decision to expand ICD coverage excludes coverage of ICD-based therapy for class IV patients who meet new, proposed covered indications for primary prevention of SCD.

We believe that there is ample, scientific evidence and practical implications that warrant providing coverage for CRT-D for class IV patients. The results of the COMPANION trial demonstrate that the use of CRT-D in patients with class IV results in a 37% relative reduction in mortality compared to patients receiving optimal pharmacologic therapy a similar benefit seen for the entire COMPANION trial cohort. Because the average mortality rates of patients with NYHA class IV are substantially higher than the average mortality rates for patients with NYHA class III, and the relative mortality reduction is similar, the estimate of absolute benefit of therapy is even greater for NYHA class IV patients receiving CRT-D therapy than for NYHA class III patients. CRT-D therapy in class IV patients results in an estimated absolute mortality benefit of 14% after only one year of therapy. Furthermore, class IV patients treated with CRT-D experience sufficient longevity to merit the consideration of therapy. The absolute survival of class IV patients receiving CRT-D within the COMPANION trial was 70% at 1 year (compared to only 56% in the control group). Given the robust scientific evidence supporting the morbidity and mortality benefits of CRT-D, and in light of the FDA- approval for Guidant CRT-D therapy in NYHA class IV patients, the collection of additional data on the value of CRT-D in class IV patients from randomized, controlled clinical trials would involve ethical challenges.

Furthermore, a CMS decision interpreted as not covering CRT-D for class IV may have an unintended and undesirable impact on physician practice patterns, Medicare costs, and patient risk. In the COMPANION trial, the overwhelming majority of class IV patients treated with CRT or CRT-D improved by at least one NYHA class in 6 months. Under the proposed coverage decision, class IV patients who receive CRT-P therapy and experience such an improvement in functional status would then be eligible for reimbursement for upgrade of their device to CRT-D.

As a result, physicians may choose to implant a Medicare covered CRT pacemaker instead of a CRT defibrillator (CRT-D) in order to assure Medicare payment, even if the CRT-D would be most beneficial for the patient. If CRT-P subsequently results in the patient moving from NYHA class IV to class III status, physicians may subsequently decide to remove the CRT-P device and insert a now covered CRT-D device, resulting in added expenditure for the Medicare program and additional surgery and associated risks for the patient.

Based on the positive benefits of CRT-D for class IV and the undesirable impact on practice patterns that could result from non-coverage, we urge CMS to continue to explore possible solutions for providing coverage for this population struggling daily with the burden of severe heart failure.

**CMS Analysis of COMPANION Trial Results** In the draft decision CMS suggests that issues with the design, conduct and analysis of the COMPANION trial hamper its findings and states that additional research is needed to support the findings of the trial. Specifically, CMS suggests that the trial's 1:2:2 randomization ratio is weighted towards device therapy, noting that an equal 1:1:1 randomization format is generally considered more neutral. In addition, CMS notes that the definition of hospitalization was changed during the course of the trial without notifying the FDA and suggests that this potentially has a direct impact on the primary outcome since hospitalization was the dominating factor for the composite endpoint. CMS believes that data should have been collected and reported using both definitions to determine if the change favored one group over another. Lastly, CMS notes that a high number of patients withdrew from the pharmacologic therapy group, many of who obtained device therapy. CMS suggests that patients who were subsequently lost to follow-up were censored in the analyses, which may have led to an inaccurate estimation of the mortality rate.

We believe that the CMS analysis reflects important misconceptions regarding the trial design, management and results as indicated below.

**Randomization ratio.** Prior to any enrollments, the FDA and Guidant reviewed the protocol and statistical plan, and both agreed that it was statistically appropriate to commence the COMPANION trial with a 1:2:2 randomization plan. There is no statistically valid argument that a 1:2:2 randomization plan is less valid or less neutral than a 1:1:1. The benefit of randomization is preserved regardless of the randomization weights.

**Definition of hospitalization.** The definition of hospitalization as determined by the Morbidity and Mortality committee was applied consistently throughout the entire trial. The confusion originated from the fact that the Morbidity and Mortality committee's definition was not shared with the FDA. It is the committee's belief that they had appropriate and necessary latitude to determine hospitalizations. Early in the adjudication process, the definition was clarified after a small percentage of the hospitalizations were adjudicated because it became apparent that discharge times were not uniformly available. Therefore, the committee agreed to adopt the more verifiable and precise approach of a calendar date change. It is Guidant's and the COMPANION Morbidity and Mortality committee's belief that the trial results are in no way compromised.

**Withdrawal from optimal pharmacological therapy (OPT) group.** We note that many patients who crossed over from the OPT group met the indications for CRT and as such, likely chose this approach based on the expected therapy benefits and physician recommendations. Regardless, the COMPANION investigators analyzed the patients as intent to treat, meaning that even if OPT patients ultimately received CRT therapy, they were still analyzed as an OPT patient. It must be noted that this crossover had the effect of making it more difficult to demonstrate the impact of CRT therapy, and that the trial was clearly positive in the face of this bias against a positive outcome speaks to the robust benefit of CRT therapy in the COMPANION patient population. FDA approval and labeling reflect this benefit in this patient population.

COMPANION results are based on knowledge of vital status of 95% of OPT patients, and 99% of the device patients, for an overall vital status rate of 98%, or 1496 patients. Therefore there is a maximum of 2% of patients for whom we do not have vital information. As a result, the number of missing events is small, compares very favorably to trials of similar magnitude and complexity, and does not jeopardize the interpretation of the trial's mortality benefit.

**Need for additional research.** We disagree that additional research is needed to support the findings of the COMPANION trial. The COMPANION trial was a well-designed large randomized controlled trial with clear and compelling positive results that have been peer reviewed and well accepted by the physician and research communities, and have resulted in FDA approval with explicit labeling as to the benefits of this therapy in this population. Additionally, it would be unethical to pursue another randomized controlled trial for this patient population, given the mortality benefit resulting from CRT-D therapy in this population.

## Conclusion

We are committed to continuing to work constructively with CMS to finalize the details of this coverage decision, including any data collection requirements. In addition, we look forward to engaging in further discussions with the agency on broader coverage policy issues that have an impact on technology innovation and patient access. Please let us know if you have any questions about our comments or require additional information.

Sincerely,

**Commenter: Campbell, Dixie**

Organization: Date: October 12, 2004 Comment:

Thank you, CMS, for making the decision to reimburse for ICDs for many heart failure patients. ICDs are the best chance these Americans have for preventing sudden cardiac arrest. However, your decision has excluded some Americans who are at the same risk for sudden cardiac arrest. What are those left out of the CMS decision supposed to do for protection from this silent killer?

Please revise your decision to include all patients that need ICDs. And please make that decision now. We need protection from sudden cardiac arrest before it kills thousands more.

**Commenter: Cannom, David M.D.**

Organization: Good Samaritan Hospital Date: October 25, 2004 Comment:

I would like to respond to the CMS coverage decision that I have read in draft form. I think overall the coverage decisions that CMS makes regarding prophylactic ICDs continues to progress; the current decision is certainly presents significant progress beyond the MADIT II decision in which I was involved.

There are a number of points that I would like to comment upon.

1) Registry requirement. CMS is requiring that all primary prevention patients be placed in a registry as a precursor to coverage. I am not at all sure I understand the rationale for a Registry. As an AVID, MADIT I and MADIT II investigator, I know how difficult it is to get good follow up data in a prospective randomized trial. It is clear that a Registry which would by necessity be of enormous size will give little useful information to either CMS or to the practicing physician. I think this would be a classic example of "garbage in-garbage out." I do not think there is much more to learn about device costs and patient follow up will be extremely difficult to do unless there is a small army of data keepers attempting to track down patient outcomes.

2) There are also questions about which patients should be covered. The requirement that a patient with a nonischemic cardiomyopathy must wait nine months to be implanted is inconsistent with the SCD-HEFT enrollment criteria which required a patient to have NIDC for only three months prior to implant. I also note that patients with an LVF between 31 and 35% are not covered. This is another example of retrospective analysis, including a certain patient category, when the trial was underpowered to analyze this patient group. It is reminiscent of the attention given to QRS duration in the MADIT II Trial.

3) Finally, the idea that the SCD-HEFT patient should receive a "single lead shock only" device seems ill advised. This simply ignores the enormous benefit of antitachycardia pacing. Adding ATP to an ICD has been done for 15 years and does not make the device more expensive.

Overall, one must be pleased with the direction the field is moving regarding ICD therapy. However, I think improvements in the current coverage scheme can be made.

Thank you for your attention.

Sincerely,

**Commenter: Cast, James**

Organization: Date: October 12, 2004 Comment:

I am very happy to have the chance to provide my comments on ICDs to CMS. Thank you. This is an issue that means so much to me because SCA is a leading killer of Americans. I appreciate CMS's decision to provide critical coverage to so many Americans who depend on Medicare, but CMS must consider those who were left out.

There are approximately 100,000 Americans who are at great risk for SCA and won't have ICD coverage. Please increase coverage to these folks so that they can have access to this amazing technology that makes the difference between life and death sooner rather than later.

**Commenter: Cataldo, Renzo**

Organization: Heart Rhythm Society Date: October 28, 2004 Comment:

Thanks for listening to the recommendations from Heart Rhythm Society. Excellent data from clinical trials support your decision.

**Commenter: Chambelrin, Maire**

Organization: Date: October 25, 2004 Comment:

Sudden cardiac arrest is a leading cause of death, of men and women alike, in the United States. It usually shows no signs and symptoms and is responsible for the death of as many as 400,000 Americans each year. Yet there is hope based on the recent ICD study.

ICDs can provide comfort for many people as it acts like a life preserver, preventing sudden glitches in the heart before they can lead to death. While I am appreciative of CMS's recent decision to reimburse ICDs for many heart failure patients, I believe that this measure falls short, as it does not protect all heart failure patients at risk, especially those with no other option for protection from cardiac arrest. I implore you to protect ALL AMERICANS at high risk from this terrible affliction.

Please decide to include all at-risk patients and don't delay implementation of this decision lives are at risk while we wait.

Please step up to the challenge today!

Thank you for your attention to this matter.

**Commenter: Champlin, Anne**

Organization: Date: October 12, 2004 Comment:

Thank you for providing coverage for ICDs to many Medicare patients at risk for SCA. But the CMS decision has left out around 100,000 Americans at high-risk for SCA.

I wanted you to know that a large number of Medicare patients have no other healthcare options. If ICDs are not covered for those left out, what will they do if they need this device? How can we deny them access to an ICD?

Please cover all Americans at high risk for SCA. Research has proven who needs an ICD. I'm concerned that waiting to collect more data will result in unnecessary deaths. The fact is that we can't let another day go by without this care.

Thank you for the opportunity to share my opinion on this matter.

Thank You,

**Commenter: Champlin, Anne**

Organization: Date: October 12, 2004 Comment:

CMS should be commended for its recent decision to reimburse ICDs for many heart failure patients. ICDs offer the best protection from sudden cardiac arrest. However, there are more Americans who remain without protection. Some heart failure patients that showed benefit from ICDs in recent clinical trials were excluded from the decision. I really question this part of the decision because without an ICD, these people stand very little chance of surviving a sudden cardiac arrest. Please help ALL Americans who could benefit from this amazing device have the protection they need. Your final decision must come before January 2005 to save as many lives as possible.

Thank you for taking the time to hear my concerns.

**Commenter: Champlin, Paul**

Organization: Date: October 27, 2004 Comment:

CMS should be commended for its recent decision to reimburse ICDs for many heart failure patients. ICDs offer the best protection from sudden cardiac arrest. However, there are more Americans who remain without protection. Some heart failure patients that showed benefit from ICDs in recent clinical trials were excluded from the decision. I really question this part of the decision because without an ICD, these people stand very little chance of surviving a sudden cardiac arrest. Please help ALL Americans who could benefit from this amazing device have the protection they need. Your final

decision must come before January 2005 to save as many lives as possible.

Thank you for taking the time to hear my concerns.

Sincerely,

**Commenter: Charter, Walter**

Organization: Date: October 13, 2004 Comment:

I appreciate the chance to comment on the recent CMS decision regarding coverage and reimbursement of ICDs. Nearly one thousand Americans die every day of SCA, and your decision is an important step in the right direction. However, I urge CMS to expand ICD coverage to every American proven to be at risk for SCA. Some were excluded from the preliminary decision, and that has me worried. Every death from SCA is an unnecessary tragedy, and I respectfully request that you expand coverage. Please don't wait for more data that may cause a delay - many Americans need ICDs to live.

Please work to get this therapy available for Americans this year.

**Commenter: Christopher, Thomas**

Organization: Heart Group of the Carolinas Date: October 5, 2004 Comment:

I am glad to see this new policy from CMS. I think it reflects the current state of the art and removes a great ethical problem from practicing physicians.

Further risk stratification with T-Wave Alternans should be a consideration, at least for the patients with ischemic cardiomyopathies.

**Commenter: Clarke, Karen**

Organization: Date: October 12, 2004 Comment:

I am writing to comment on the recent decision of the Centers for Medicare and Medicaid Services to reimburse implantable cardioverter defibrillators.

While it is a first step in the right direction, many people who are at risk have been left out of the preliminary decision, and will not have any other option to prevent a sudden cardiac arrest. For example, many Medicare recipients have that program as their only form of health care and won't be protected under the current decision.

It is crucial that all Americans at high risk get the protection they need from this terrible killer. With up to 450,000 people in this country dying every year from sudden cardiac arrest, the stakes are too high to implement this incomplete approach to reimbursement. Please increase the reimbursement options for ICDs to all at risk. Please don't make additional requests for data too cumbersome. Implementation of this landmark decision shouldn't be delayed past the 1st of the year.

Thank you for the opportunity to present my thoughts on this critical issue.

**Commenter: Clark, Kim**

Organization: Date: October 19, 2004 Comment:

Thank you for providing coverage for ICDs to many Medicare patients at risk for SCA. But the CMS decision has left out around 100,000 Americans at high-risk for SCA.

I wanted you to know that a large number of Medicare patients have no other healthcare options. If ICDs are not covered for those left out, what will they do if they need this device? How can we deny them access to an ICD?

Please cover all Americans at high risk for SCA. Research has proven who needs an ICD. I'm concerned that waiting to collect more data will result in unnecessary deaths. The fact is that we can't let another day go by without this care.

Thank you for the opportunity to share my opinion on this matter.

Thank You,

**Commenter: Clemons, Vincient**

Organization: Date: October 26, 2004 Comment:

Sudden cardiac arrest is a leading cause of death, of men and women alike, in the United States. It usually shows no signs and symptoms and is responsible for the death of as many as 400,000 Americans each year. Yet there is hope based on the recent ICD study.

ICDs can provide comfort for many people as it acts like a life preserver, preventing sudden glitches in the heart before they can lead to death. While I am appreciative of CMS's recent decision to reimburse ICDs for many heart failure patients, I believe that this measure falls short, as it does not protect all heart failure patients at risk, especially those with no other option for protection from cardiac arrest. I implore you to protect ALL AMERICANS at high risk from this terrible affliction. Please decide to include all at-risk patients and don't delay implementation of this decision - lives are at risk while we wait.

Please step up to the challenge today!

Thank you for your attention to this matter.

**Commenter: Cohen, Mark**

Organization: The Atlanta Cardiology Group Date: October 21, 2004 Comment:

I am a practicing electrophysiologist. I commend CMS on its decision to expand ICD coverage. I agree with the decision to expand to the population with ejection fraction less than 30%, with no ECG based exclusion criteria. The current disconnection between FDA recommendations and CMS reimbursement guidelines has created considerable anxiety for many patients. The new coverage guidelines will rectify this.

Thank you, and thank you from my patients.

**Commenter: Colavita, Paul**

Organization: Date: October 21, 2004 Comment:

I commend the decision to provide life saving therapy to a larger group of high risk patients. The clinical evidence is well documented and consistent. The requirement for a national registry is problematic on several counts:

1)Reimbursement should not be linked to enrollment in a national registry. Often the implanting physician is not the physician doing the follow-up and data gathering would be haphazard and random.

2)Counting shocks delivered would also not be an effective endpoint as up to 30% of shocks delivered are considered inappropriate. All cause mortality may be a more effective endpoint.

3)The cost of such a registry is enormous not only to the government, but also the physician and his practice who will need to have dedicated staff record, interpret and input data. This is an expense many practices cannot bear. A smaller demonstration project may be more effective with cost defrayed by the government.

Also exclusion of Class IV patients is problematic since these patients have had an accepted indication in secondary prevention trials which should not be eliminated.

Thank you again for the expanded indications, but please allow us the ability to deliver this therapy without additional work, cost and aggravation as proposed.

**Commenter: Coman, James**

Organization: Oklahoma Heart Institute Date: September 29, 2004 Comment:

Congratulations to Drs Tunis and Phurrough on their excellent review of the large data set which impacts this decision. The right decision is often more difficult than others available, but as healthcare providers the mandate must be to provide the best available care to our patients. The decision to

consider coverage of all patients with ischemic heart disease regardless of the width of their QRS is applauded. So often, spurious information clouds judgement. I am pleased to see support within CMS for evidence-based decisions. My patients thank you.

**Commenter: Connors, Jean**

Organization: Date: October 25, 2004 Comment:

With up to 1,200 Americans killed daily by sudden cardiac arrest, I'm encouraged by the latest decision to expand Medicare coverage of implantable cardioverter defibrillators for at-risk patients. But, it is important to note that the new coverage still leaves tens of thousands of people at risk that is preventable if Medicare reimbursement covered everyone at high-risk for sudden cardiac arrest.

Please consider including all Medicare recipients with heart failure who are at high risk for SCA. And please don't delay the decision while waiting for more data/information. We need access to this important medical care by January 1, 2005.

Thank you,

**Commenter: Cooper, Randolph**

Organization: Wake Heart Associates Date: October 18, 2004 Comment:

I do support a registry to follow the primary prevention patients; however by the time a registry would be established, a large group of patients could be missed or delayed from getting a potentially life saving treatment. As a physician, I have trouble telling a patient they must participate in a registry to get the treatment. Our hospital IRB would probably have great concerns about this requirement also. To the people at CMS thank you very much for the very difficult job you do.

**Commenter: Cooper, Robert Jr.**

Organization: Date: October 14, 2004 Comment:

Thank you for providing coverage for ICDs to many Medicare patients at risk for SCA. But the CMS decision has left out around 100,000 Americans at high-risk for SCA.

I wanted you to know that a large number of Medicare patients have no other healthcare options. If ICDs are not covered for those left out, what will they do if they need this device? How can we deny them access to an ICD?

Please cover all Americans at high risk for SCA. Research has proven who needs an ICD. I'm concerned that waiting to collect more data will result in unnecessary deaths. The fact is that we can't let another day go by without this care.

Thank you for the opportunity to share my opinion on this matter.

**Commenter: Copley, Robert**

Organization: Date: October 19, 2004 Comment:

I am writing to comment on the recent decision of the Centers for Medicare and Medicaid Services

to reimburse implantable cardioverter defibrillators.

While it is a first step in the right direction, many people who are at risk have been left out of the preliminary decision, and will not have any other option to prevent a sudden cardiac arrest. For example, many Medicare recipients have that program as their only form of health care and won't be protected under the current decision.

It is crucial that all Americans at high risk get the protection they need from this terrible killer. With up to 450,000 people in this country dying every year from sudden cardiac arrest, the stakes are too high to implement this incomplete approach to reimbursement. Please increase the reimbursement options for ICDs to all at risk. Please don't make additional requests for data too cumbersome. Implementation of this landmark decision shouldn't be delayed past the 1st of the year.

Thank you for the opportunity to present my thoughts on this critical issue.

Regards,

**Commenter: Cosgrove, Kim**

Organization: Date: October 12, 2004 Comment:

Thank you for the opportunity to submit my comments on this important issue. Sudden cardiac arrest kills more Americans than any other condition. It kills between 340,000 and 450,000 people every year - more than 1,000 people every day. Please, please consider providing ICDs for all at-risk Americans. Your preliminary decision leaves out some Medicare patients who could die without an ICD. People who rely on Medicare have no other options and need to be covered before the end of the year.

Thank you for considering this issue of such significant importance.

**Commenter: Coyle, Michael**

Organization: Date: October 28, 2004 Comment:

Steve Phurrough, MD, MPA Director, Coverage and Analysis Group Centers for Medicare & Medicaid Services 7500 Security Boulevard Baltimore, MD 21244

RE: National Coverage Analysis (NCA) of Implantable Cardioverter Defibrillators (ICDs) (# CAG-00157R2)

Dear Dr. Phurrough:

St. Jude Medical, Inc, a developer, manufacturer, and distributor of innovative medical devices including implantable cardioverter defibrillators (ICDs), welcomes the opportunity to comment on the Draft Decision Memo for Implantable Defibrillators (CAG-00157R2). We strongly support the Centers for Medicare and Medicaid Services (CMS) decision to expand coverage of ICDs to a broad segment of heart failure patients at risk of sudden cardiac death (SCD). Further, we appreciate the opportunity to work with CMS, specialty societies like the Heart Rhythm Society (HRS) and other manufacturers to help ensure that Medicare beneficiaries with heart failure receive prompt access to this life-saving therapy.

While we are encouraged that CMS has recognized the life-saving benefits of this technology and the need to ensure more Medicare patients' access to it, we are concerned that the proposed requirement of a practical registry could delay access by beneficiaries to defibrillators. We are also concerned with the following aspects of the proposed decision: the limitation of coverage to patients with an ejection fraction (EF) of less than 30%, excluding a group of patients shown to benefit from ICDs; exclusion of NYHA Class IV patients who require cardiac resynchronization therapy (CRT); the nine-month interval for non-ischemic implant; and the documentation requirement of the use of any device other than a single lead, shock-only device. The following comments on the draft coverage decision will address these concerns.

### Proposed ICD Registry

St. Jude Medical and other industry leaders in the ICD market have shown a sustained commitment to performing large scale, prospective, randomized studies (e.g., MADIT II, SCD-HeFT, DEFINITE, DINAMIT) to provide the clinical data necessary to define patient populations that can benefit from the use of ICDs. Since the initial 1986 decision to provide coverage to treat life-threatening ventricular tachyarrhythmias with defibrillators, ICDs have been studied in numerous prospective, randomized studies. Results from these studies have provided the clinical justification for expanded Medicare coverage for both primary and secondary prevention of ventricular arrhythmias and sudden cardiac death using ICDs, and for such patients who also require treatment for heart failure resulting in ventricular dyssynchrony, using cardiac resynchronization therapy with defibrillation (CRT-D). We remain committed to the development of high-quality clinical trials to identify those patients who will benefit most from ICD therapy.

As part of the recent draft decision to expand ICD coverage for primary prevention of SCD to certain patients who have never had a heart attack, CMS has proposed the development of a practical registry that can help develop additional evidence to better identify who is most likely to benefit from ICD therapy for primary prevention.

While St. Jude Medical believes that an ICD patient registry may provide valuable observational data (quality of life/functionality, device performance trends, device usage patterns, adverse events) on the use of ICDs in community practice, it is unlikely that such a registry will be able to definitively identify subgroups within the primary prevention population that would have the most benefit from ICD therapy. Instead, it is more likely that a registry will provide information on risk stratification, which will be useful in the design of future randomized, prospective studies. Further, the development of a high-quality registry presents a number of challenges, including patient consent; maintaining confidentiality of data; ensuring data consistency, reliability, and accuracy; establishing a means of joint control over the data; ensuring that the cost of data collection is outweighed by the benefits; potential ethical, legal and liability issues; and funding. St. Jude Medical will work with CMS and the Heart Rhythm Society's National ICD Working Group to identify the best approach for data collection on ICD devices to address unanswered questions and overcome obstacles in data collection toward the mutual goal of improved patient outcomes.

St. Jude Medical believes that the requirement for a patient registry should not be coupled to coverage, as the implementation of a practical registry could delay beneficiary access to defibrillators. Uncoupling the registry implementation from coverage of primary prevention patients will ensure that these patients have the opportunity to receive treatment by the scheduled coverage start date of January 1, 2005. It is not possible to research and design, much less implement an ICD registry or an alternative post-SCD-HeFT clinical data collection strategy by that date, based upon experiences of clinicians and industry sponsors who have implemented such registries. We support the HRS request for a grace period while the registry is developed, funding is identified, and the infrastructure

established for a patient registry. During that interval, we request that CMS provide coverage for life-saving primary prevention ICD therapy. Further, we request that CMS clarify its position on this important topic as soon as possible.

### Ejection Fraction

CMS's decision to not cover SCD-HeFT-type patients with LVEF between 31 and 35% is also a serious concern. Patients with an ejection fraction in this range were well represented in the MADIT I and MUSTT trials, as well as the SCD-HeFT trial, and contributed to the overall highly significant results of these trials. The fact that they did not show statistical significance in an unplanned, under-powered, retrospective analysis is not evidence of lack of benefit. There is no scientific justification for this decision. We recommend that the coverage decision be revised to include patients with LVEF of 35% or less.

### Class IV Patients

Under the draft coverage decision, CMS proposes to exclude coverage for primary prevention Class IV patients. The COMPANION trial indicates patients with Class IV heart failure may benefit from biventricular pacing. We support the HRS recommendation that CRT-D should be a covered therapy option for NYHF Class IV primary prevention patients who, in their physician's opinion, are likely to improve to Class III with CRT-D therapy. Further, we recommend that NYHA Class IV patients with an ICD indication and wide QRS continue to be covered for secondary prevention patients. Since none of the trials for secondary prevention CRT-D devices were included in the current analysis, it is inappropriate to remove them from coverage. Additionally, if there is to be a mandatory patients should be included.

### Nine-Month Interval for Non-Ischemic Implant

CMS has proposed that patients must have had non-ischemic dilated cardiomyopathy (NIDCM) for at least nine months prior to being eligible for ICD implant. The source of the CMS nine-month requirement appears to be the CAT trial, which was a pilot study phase of a larger proposed trial, that had a limited sample size and corresponding lack of statistical power, and which was discontinued due to lack of patient enrollment. This minimum of nine months requirement is inconsistent with SCD-HeFT enrollment criteria, which required a patient to have NIDCM for only three months prior to implant. Thus, the CAT trial should not form the basis for a coverage policy limitation. We recommend that the coverage decision be revised to reflect the three-month SCD-HeFT requirement.

### Documenting Device Selection

In the draft decision, CMS requests documentation of the physician's decision to implant all but single-lead, shock only devices. As an indications trial, designed to study patient benefit, SCD-HeFT did not address the question of device type. What it found was that ICD therapy is life-saving compared to placebo in its patient population. Indications trials are addressed through broad labeling by FDA, because they are not device-specific trials. There is no clinical justification for exempting any given device type from a documentation requirement. The requirement should be rewritten to require only that clinical choices be documented as part of the operative notes from the implant procedure. Further, we believe that the clinical justification for device choice should only be consistent with what's currently notated in patients' charts and not misused or enhanced to become a barrier to physician choice of appropriate level of therapy for her/his patient.

In the draft decision, CMS expressed concern about both inappropriate shocks and anti-tachycardia

pacing (ATP). This is inconsistent, as ATP reduces the incidence of shocks painlessly and with negligible battery drain. ATP is standard in current single, dual and biventricular ICDs via the implanted defibrillation lead and does not require the implantation of a separate lead for this purpose. The Pain-Free Rx II trial studied ATP in ICD-indicated patients. The rate cutoff used was the same as the rate cutoff used for detection in SCD-HeFT, so the results are directly applicable. A recently published manuscript (Circulation. 2004;110:2591-2596) showed the study demonstrated a greater than 70% reduction in shocks received and a statistically significant improvement in quality of life with ATP turned on. The study also demonstrates that ATP therapy is equally safe as shock therapy with no differences observed in the incidence of sudden death, syncope or tachyarrhythmia acceleration. In addition, most of ventricular tachyarrhythmia episodes that occur in patients who receive ICDs for primary prevention will be ventricular tachycardia (VT), not ventricular fibrillation (VF), and are therefore amenable to painless ATP therapy.

St. Jude Medical appreciates your consideration of our comments and the opportunity to continue working with CMS and the HRS on developing a plan for establishing a national registry to follow Medicare patients receiving an ICD for primary prevention therapy. If you have any questions, please contact Susan Walker, Director of Reimbursement, at 763-481-7638 or at [swalker@sjm.com](mailto:swalker@sjm.com).

Sincerely,

**Commenter: Crossley, George**

Organization: Date: October 28, 2004 Comment:

Mandate for a single chamber ICD The requirement on single chamber devices is not based on the standard of care. The standard of care is for each physician to carefully evaluate the characteristics of each patient and to prescribe the appropriate therapy for that patient. While many, or possibly most, patients who need a prophylactic ICD can be well taken care of with a single chamber ICD, there are many others where this would not be the best approach. We are concerned that a mandated one-size-fits-all approach may well result in a diminution in the quality of care and a less cost effective approach.

The prescription of the appropriate device is a fairly complicated decision. It is Absolutely acceptable to use a single chamber ICD in a patient who has no other medical issues other than a poor ejection fraction. However, in patients with a prophylactic ICD indication, there is often the coexistence of sinus node dysfunction, paroxysmal atrial fibrillation or high doses of negative chronotropic drugs. In any given patient, one or more of these factors may be reason enough to implant a dual chamber device.

The concept that we should always implant the simplest device and then upgrade it only if the need is unequivocally demonstrated is poorly founded. It is true that upgrading a single chamber ICD to a dual chamber ICD is fairly simple surgery if the veins remain patent. Unfortunately, in many cases, the presence of a lead in the subclavian vein causes occlusion of the vein. In this case the risk of surgery goes up tremendously. Further, it is an expensive process to take out a functional ICD and to replace it. Further, CMS pays exactly the same thing for a dual chamber ICD as they do for a dual chamber ICD.

Banning antitachycardia pacing The ban on antitachycardia pacing (ATP) is most troublesome. Your discussion seems to suggest that inclusion of antitachycardia pacing would (1) increase the cost of the ICD and (2) increase the risk of an ICD system. This is simply not the case. All currently available ICDs in the United States market have the ability perform antitachycardia

pacing. Therefore there is no change in cost.

There are 2 different ways that ATP can be used. First, in patients in whom device testing has revealed monomorphic ventricular tachycardia that is responsive to antitachycardia pacing is present, it would be unethical for us to disable it. To force these patients to endure a shock when we know that ATP would be successful would in fact be malpractice.

In other patients, ATP is used prophylactically. It has long been noted that even in patients in whom the only inducible rhythm in the EP lab is ventricular fibrillation, it is much more common for spontaneously occurring rhythms to be rapid ventricular tachycardia. Based upon this observation, the PAIN FREE I and PAIN FREE II studies were developed. These studies revealed that even generic programming of ATP resulted in a 71% rate of conversion of rapid ventricular rhythms to sinus rhythm. Likewise the rate of acceleration of these rhythm and resultant syncope was very low.

The concept that is expressed in your memorandum that antitachycardia pacing is dangerous and results in excess syncope is therefore not based on science and would only be the case if the ATP feature were to be foolishly programmed. The wise use of antitachycardia pacing is the standard of care.

Conflict of Interest I would strongly consider that you evaluate the advice and data that you have received for the presence of conflict of interest. It appears that you have relied heavily on the SCDHeFT trial for (1) insisting on a single chamber device and (2) banning antitachycardia pacing. It is important to realize that the hypothesis of SCDHeFT was changed during the study. The skeptical evaluator will point out that the principle investigator of this study had a very strong financial interest in concluding that pacing in ICD's is unimportant.

#### Ethics of a Registry

Your memorandum mandates that in order for Medicare patients to have access to this standard of care therapy that they must consent to participate in either an IDE- based clinical trial of an investigational device or to be part of a national registry. The data that is mandated to be included in the registry includes data both from the hospital and from follow-up. It will contain personal health information and will therefore require IRB approval, an informed consent statement and a HIPPA release.

It is clear to me that this falls within the definition of undue coercion as defined by both the Office of Human Research Protections and the Food and Drug Administration. It is inappropriate for CMS to mandate that patients enroll in a study / registry in order for them to receive standard-of-care therapy.

#### **Commenter: Crusse, Sandy**

Organization: Date: November 1, 2004 Comment:

Thank you, CMS, for making the decision to reimburse for ICDs for many heart failure patients. ICD's are the best chance these Americans have for preventing sudden cardiac arrest. However, your decision has excluded some Americans who are at the same risk for sudden cardiac arrest. What are those left out of the CMS decision supposed to do for protection from this silent killer?

Please revise your decision to include all patients that need ICDs. And please make that decision now. We need protection from sudden cardiac arrest before it kills thousands more.

Sincerely,

**Commenter: Daeffler, Roger**

Organization: Date: October 26, 2004 Comment:

Thank you for providing coverage for ICDs to many Medicare patients at risk for SCA. But the CMS decision has left out around 100,000 Americans at high-risk for SCA.

I wanted you to know that a large number of Medicare patients have no other healthcare options. If ICDs are not covered for those left out, what will they do if they need this device? How can we deny them access to an ICD?

Please cover all Americans at high risk for SCA. Research has proven who needs an ICD. I'm concerned that waiting to collect more data will result in unnecessary deaths. The fact is that we can't let another day go by without this care.

Thank you for the opportunity to share my opinion on this matter.

Thank You,

**Commenter: Dahlstrom, Quinn**

Organization: Date: October 20, 2004 Comment:

CMS should be commended for its recent decision to reimburse ICDs for many heart failure patients. ICDs offer the best protection from sudden cardiac arrest. However, there are more Americans who remain without protection. Some heart failure patients that showed benefit from ICDs in recent clinical trials were excluded from the decision. I really question this part of the decision because without an ICD, these people stand very little chance of surviving a sudden cardiac arrest. Please help ALL Americans who could benefit from this amazing device have the protection they need. Your final decision must come before January 2005 to save as many lives as possible.

Thank you for taking the time to hear my concerns.

Sincerely,

**Commenter: Darfus, George**

Organization: Date: October 26, 2004 Comment:

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Please revise your decision to include all patients that need ICDs. And please make that decision now. We need protection from sudden cardiac arrest before it kills thousands more.

Sincerely,

**Commenter: Daoud, Emile**

Organization: Mid-Ohio Cardiology Date: October 13, 2004 Comment:

I agree with and applaud the CMS proposal regarding broadening the use of ICD therapy.

My other comment is that I received an email from Bob LaRoche; VP of Sales and Marketing; Cambridge Heart, which is the company that sells the device and equipment for assessing for microvolt T wave alternans. I do not know Mr. LaRoche and we have never met but I received a standardized email from him asking me to appeal to CMS to ask for T wave alternans testing to be "a required element for the Patient Registry" . This type of solicitation should be restricted and I hope there is some means to penalize Cambridge Heart. I have never received such a solicitation from any ICD company, and I think this type of relationship is exactly what the new ADVIA Med guidelines are designed to prohibit companies from doing....so I am writing to ask that T wave alternans NOT be part of the registry.

**Commenter: DeLozier, Adam**

Organization: Date: October 13, 2004 Comment:

I am very happy to have the chance to provide my comments on ICDs to CMS. Thank you. This is an issue that means so much to me because SCA is a leading killer of Americans. I appreciate CMS's decision to provide critical coverage to so many Americans who depend on Medicare, but CMS must consider those who were left out.

There are approximately 100,000 Americans who are at great risk for SCA and won't have ICD coverage. Please increase coverage to these folks so that they can have access to this amazing technology that makes the difference between life and death sooner rather than later.

**Commenter: DePuew, George**

Organization: Date: October 26, 2004 Comment:

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Thank you for the opportunity to share my opinion on this matter.

**Commenter: Destefano, Roslyn**

Organization: Date: October 27, 2004 Comment:

I am very happy to have the chance to provide my comments on ICDs to CMS. Thank you. This is an issue that means so much to me because SCA is a leading killer of Americans. I appreciate CMS's decision to provide critical coverage to so many Americans who depend on Medicare, but CMS must consider those who were left out.

There are approximately 100,000 Americans who are at great risk for SCA and won't have ICD coverage. Please increase coverage to these folks so that they can have access to this amazing technology that makes the difference between life and death sooner rather than later.

Sincerely,

**Commenter: DeVincentis, Beverly A.**

Organization: Date: October 13, 2004 Comment:

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Thank you for the opportunity to share my opinion on this matter.

**Commenter: Dewers, Alan**

Organization: Date: October 13, 2004 Comment:

Sudden cardiac arrest is a leading cause of death, of men and women alike, in the United States. It usually shows no signs and symptoms and is responsible for the death of as many as 400,000 Americans each year. Yet there is hope based on the recent ICD study.

ICDs can provide comfort for many people as it acts like a life preserver, preventing sudden glitches in the heart before they can lead to death. While I am appreciative of CMS's recent decision to reimburse ICDs for many heart failure patients, I believe that this measure falls short, as it does not protect all heart failure patients at risk, especially those with no other option for protection from cardiac arrest. I

implore you to protect ALL AMERICANS at high risk from this terrible affliction. Please decide to include all at-risk patients and don't delay implementation of this decision û lives are at risk while we wait.

Please step up to the challenge today!

Thank you for your attention to this matter.

**Commenter: DeWitt, Louise**

Organization: Date: October 13, 2004 Comment:

Sudden cardiac arrest is a leading cause of death, of men and women alike, in the United States. It usually shows no signs and symptoms and is responsible for the death of as many as 400,000 Americans each year. Yet there is hope based on the recent ICD study.

ICDs can provide comfort for many people as it acts like a life preserver, preventing sudden glitches in the heart before they can lead to death. While I am appreciative of CMS' recent decision to reimburse ICDs for many heart failure patients, I believe that this measure falls short, as it does not protect all heart failure patients at risk, especially those with no other option for protection from cardiac arrest. I implore you to protect ALL AMERICANS at high risk from this terrible affliction. Please decide to include all at-risk patients and don't delay implementation of this decision û lives are at risk while we wait.

Please step up to the challenge today!

Thank you for your attention to this matter.

**Commenter: Dickler, Robert**

Organization: Association of American Medical Colleges Date: October 26, 2004 Comment:

The Association of American Medical Colleges (AAMC) welcomes the opportunity to comments on the Centers for Medicare and Medicaid draft National Coverage Decision (NCD) for Implantable Cardiac Defibrillators (ICD). The AAMC represents approximately 400 major teaching hospitals and health systems; all 125 accredited U.S. allopathic medical schools; 96 professional and academic societies; and the nation's medical students and residents.

The AAMC's comments will be limited to the proposed establishment of a National ICD Registry. Much can be gained from the establishment of registries. When properly designed and implemented, they may allow for better monitoring of the safety and efficacy of devices or drugs and provide information that targets those patients most likely to benefit from a given intervention. They also have the potential for identifying those providers that are most likely to ensure that their patients have good outcomes. However, establishing a registry is complex, and ensuring that it function properly is challenging. It requires adequate time and discussion of the issues by allaffected parties.

The details about the registry in the draft NCD are vague. The proposal says the registry must be designed to address specific hypotheses, and makes some broad suggestions. The proposed NCD also requires that the registry be established and that the manufacturer define a problem that the data can answer. However, as with all good research the process for formulating hypothesis need to be carefully pursued to assure that the data collection process will answer the relevant questions. More thought should be given to the purpose of the registry and to designing it in a way that will meet the

goals upon which interested parties agree.

There also is no discussion about who will fund the registry, or about access to the information. Since some of the data elements will inevitably be patient-specific important patient privacy concerns will need to be addressed. These are two important issues should be addressed prior to the establishment of the registry.

CMS proposes to tie reimbursement to a beneficiary either being enrolled in an FDA approved clinical trial, or a qualifying national registry. Once a registry has been established and its usefulness demonstrated, it may be reasonable to link payment to inclusion of a patient in the registry. At this point, it seems premature to do so. More discussion is needed, and a thorough consideration of the pros and cons of this requirement should occur. This type of change in payment policy is not within the scope of a national coverage decision. It is more appropriate for CMS to publish a proposed regulation with an adequate comment period before affecting such a major change.

The AAMC would be pleased to work with CMS staff to develop appropriate criteria for establishment of a national registry. You may contact me at 202-8280490.

**Commenter: DiMola, Virginia**

Organization: Date: October 20, 2004 Comment:

Thank you, CMS, for making the decision to reimburse for ICDs for many heart failure patients. ICD's are the best chance these Americans have for preventing sudden cardiac arrest. However, your decision has excluded some Americans who are at the same risk for sudden cardiac arrest. What are those left out of the CMS decision supposed to do for protection from this silent killer?

Please revise your decision to include all patients that need ICDs. And please make that decision now. We need protection from sudden cardiac arrest before it kills thousands more.

Sincerely,

**Commenter: Doherty, Mary** Organization: Date: October 12, 2004 Comment:

I appreciate the chance to comment on the recent CMS decision regarding coverage and reimbursement of ICDs. Nearly one thousand Americans die every day of SCA, and your decision is an important step in the right direction. However, I urge CMS to expand ICD coverage to every American proven to be at risk for SCA. Some were excluded from the preliminary decision, and that has me worried. Every death from SCA is an unnecessary tragedy, and I respectfully request that you expand coverage. Please don't wait for more data that may cause a delay - many Americans need ICDs to live.

Please work to get this therapy available for Americans this year.

**Commenter: Doshi, Rahul**

Organization: Sunrise Hospital and Medical Center Date: October 6, 2004 Comment:

I would congratulate CMS for expanding coverage, however, many of my colleagues and I have some concerns. I would also applaud CMS in requiring that participating hospitals to ensure that implanting physicians are adequately trained and competent, but these criteria need to be established prospectively and strictly reinforced. My concerns address the following issues:

(1) I would question why the decision was made for LVEF of 30% as opposed to 35%, as every study that has been listed except for MADIT II studied patients with LVEF  $\leq$  35%. We have been warned countless times about the difficulty in interpreting subgroup analysis, and we should base our criteria on the science. If we seek to expand coverage because of SCD-HeFT, then shouldn't we adopt the answered question for the primary endpoint?

(2) I am also deeply concerned about the need for justifying a "more advanced ICD"--how will these criteria be established, and who better to determine this than the electrophysiologist who is treating the individual patient? For example, does the high incidence of atrial dysrhythmias for patients largely in sinus rhythm justify placement of an atrial lead? Does the possibility of committing a patient to chronic RV pacing justify an LV lead? These are decisions that should be made on a case-by-case basis, we should be allowed to practice medicine.

(3) In regards to treating Class IV patients--I do not believe that a blanket statement is appropriate. NYHA classification is very subjective. I would think that the best approach is that the treating physician determines on an individual basis whether the overall life expectancy of the patient justifies ICD therapy.

(4) My biggest concern is the prospectively requiring a national registry or database. I would be absolutely thrilled if such a database was created, but the mechanics of this need to be determined first before this is made a requirement for ICD implantation. If this is not done, then only patients participating in an IDE trial would receive therapy, which would blatantly discriminate against universal patient care.

Thank you for your consideration.

**Commenter: Doyle, Timothy**

Organization: Date: October 28, 2004 Comment:

Re: coverage for ICDs for nonischemic cardiomyopathy (SCDHeFT) and MADIT 2 indications

I believe these trials speak for themselves. As the Medicare population grows, the need for these devices will continue to grow with the attendant increase in budget. However, as resuscitation from sudden death episodes increases (due to the availability of AEDs in public places and at home), with average costs per hospitalization exceeding \$100,000 after each event and long-term care costs even higher, a proactive stance to prevent sudden cardiac death appears warranted on economic as well as ethical grounds. ICDs have been well-documented in other groups to prevent sudden cardiac deaths and to lengthen lifespan. Please give consideration to remuneration for these devices.

**Commenter: Dunican, Sandy Organization:**

Date: October 26, 2004 Comment:

I appreciate the chance to comment on the recent CMS decision regarding coverage and reimbursement of ICDs. Nearly one thousand Americans die every day of SCA, and your decision is an important step in the right direction. However, I urge CMS to expand ICD coverage to every American proven to be at risk for SCA. Some were excluded from the preliminary decision, and that has me worried. Every death from SCA is an unnecessary tragedy, and I respectfully request that you expand coverage. Please don't wait for more data that may cause a delay - many Americans need ICDs to live.

Please work to get this therapy available for Americans this year.

Respectfully,

**Commenter: Fanning, Violet**

Organization: Date: October 25, 2004 Comment:

Thank you for providing coverage for ICDs to many Medicare patients at risk for SCA. But the CMS decision has left out around 100,000 Americans at high-risk for SCA.

I wanted you to know that a large number of Medicare patients have no other healthcare options. If ICDs are not covered for those left out, what will they do if they need this device? How can we deny them access to an ICD?

Please cover all Americans at high risk for SCA. Research has proven who needs an ICD. I'm concerned that waiting to collect more data will result in unnecessary deaths. The fact is that we can't let another day go by without this care.

Thank you for the opportunity to share my opinion on this matter.

Thank You,

**Commenter: Fedor, John**

Organization: The Sanger Clinic, PA Date: October 26, 2004 Comment:

CMS

I am writing to comment on proposed changes for reimbursement for patients who need prophylactic automatic implantable cardioverter defibrillators.

1. In view of the results of the Sudden Death Congestive Heart Failure Primary Prevention Trial, I think patients with Class II and III congestive heart failure with ejection fraction less than 35%; even if they have not had a documentation of complex arrhythmias should be eligible for cardiac defibrillators. Certainly patients who have had complex arrhythmias, cardiac arrest, positive electrophysiological studies or meet other established criteria such as MADIT II should be continued eligible for devices unless they have expectancy or compounding other medical issues.
2. I think that a registry of patients undergoing a prophylactic defibrillator because of severe heart disease would potentially provide important observational information as to patient outcome; however, the logistics of implementation and construction of such a registry are far from simple, are very complex and would take time, money as well as a dedicated staff to adequately construct it. I would suggest that an Advisory Board with consultants from academia including clinicians as well as statisticians, clinical practice, and patient advocates to ensure that patients in need of therapy receive such therapy and industry representatives as well as Food and Drug, governmental staff should meet to consider the structure, finances as well as the burden of execution, data collection and other nuts and bolts required for such a registry to be successful. If this is done, I do not think that the decision for implementing expanded coverage should be delayed pending

construction of an adequate registry as people in need of this therapy would be at risk for cardiac sudden death.

3. I think safeguards as to the standards of implementation, physician credentials, hospital center credentials and follow-up staff should remain high to ensure that devices are applied appropriately to the appropriate patients by qualified physicians at qualified electrophysiology centers.

Thank you for your hard work and invitation for comment. I hope these thoughts are of value.

Sincerely,

**Commenter: Feldman, L A. Dr.**

Organization: Date: October 21, 2004 Commenter:

I applaud your preliminary decision to expand coverage for ICDs to the non- ischemic population with significant LV dysfunction! Additionally, the elimination of the QRS width criteria for the ischemic population is wise.

I would like to add the following. SCD-HeFT was careful to include patients with EF of 35% or less and this cutoff should be applied to both the ischemic and non- ischemic cardiomyopathy populations for primary prevention ICD implantation. Furthermore, the proposed registry would be quite burdensome for the majority of qualified clinical electrophysiologists and should be optional (not mandatory). Our cardiomyopathy deserve speedy, facilitated access to this life saving technology. This is the number one epidemic of our time.

The final guidelines might include language to encourage implantation of ICDs by Board certified or eligible EPs only in order to best maintain quality and maximize the benefit of these devices for the long term.

Most sincerely,

**Commenter: Feldman, Leon**

Organization: Eisenhower Medical Center Date: October 21, 2004 Comment:

I applaud your preliminary decision to expand coverage for ICDs to the non- ischemic population with significant LV dysfunction! Additionally, the elimination of the QRS width criteria for the ischemic population is wise.

I would like to add the following. SCD-HeFT was careful to include patients with EF of 35% or less and this cutoff should be applied to both the ischemic and non- ischemic cardiomyopathy populations for primary prevention ICD implantation (not 30% as proposed) Furthermore, a mandated registry would be quite burdensome for the majority of qualified clinical electrophysiologists to fulfill and should be optional (not mandatory). Our cardiomyopathy patients deserve speedy, facilitated access to this life saving technology. This is the number one epidemic of our time.

The final guidelines might include language to certified or eligible EPs only in order to best maintain

quality and maximize the benefit of these devices for the long term.

**Commenter: Feldman, Leon**

Organization: Desert Cardiology Center Date: September 30, 2004 Comment:

I applaud the decision to expand the use of ICDs at populations at risk. I am referring to the inclusion of both the MADIT II patients as well as all those included in SCD-HeFT.

Patients with depressed ejection fractions (35% or less) have been repeatedly shown to be at unacceptably high risk for sudden cardiac death. The expanded use of prophylactic implanted defibrillators should go a long way to improving the outcome of patients with heart disease and lessening the impact of the primary cause of death in this country....cardiac arrest.

CMS should be highly commended for this progressive decision.

**Commenter: Feldman, Nancy**

Organization: Date: October 11, 2004 Comment:

I congratulate CMS on the proposed coverage for the prophylactic use of ICDs in both ischemic and nonischemic patients. The awareness that Sudden Cardiac Death is the leading cause of mortality in this country has been slow in coming.

This will be a significant step to protecting those most vulnerable to cardiac arrest.

These are clearly resources well spent!

**Commenter: Feldman, Nancy**

Organization: Mothers for prevention of Sudden Death Date: October 21, 2004 Comment:

The benefit of primary prevention ICD therapy for patients with Ischemic or Nonischemic cardiomyopathy and left ventricular ejection fraction (LVEF) <30% is supported by the clinical data. I am concerned that the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) showed benefit for patients with LVEF of 35% or less, yet patients with LVEF 30-35% have been excluded from the coverage policy. The decision by CMS to exclude those with LVEF 30-35% is based on a subgroup analysis that the study was not designed to determine.

I recommend that the coverage decision be revised to include patients with LVEF of 35% or less.

SCDHeFT required patients to have stable Class II-III heart failure for 3 months prior to entry into the study. CMS has extended this interval to 9 months without justification. If the intent is to exclude patients with a reversible nonischemic cardiomyopathy, this objective will be met using the 3-month criteria required by

SCDHeFT.

I recommend patients have a diagnosis of nonischemic cardiomyopathy for >3 months on appropriate medical therapy.

The COMPANION trial indicates patients with Class IV heart failure benefit from biventricular pacing. If cardiac resynchronization therapy is employed without an ICD (CRT-D) and the patient improves to NYHA Class III heart failure, then it will be necessary to upgrade the system from CRT to CRT-D. This exposes the patient to two procedures and ultimately increases the cost and risk of therapy.

I recommend that coverage for CRT-D be extended to patients with Class IV heart failure.

The CMS policy excludes patients with acute MI within 1 month or percutaneous transluminal coronary angioplasty within 3 months. I believe that patients with well documented remote MI and longstanding LV dysfunction (LVEF 35% or less), should not be excluded from ICD therapy if they are admitted with another MI or the need for a second PTCA. In such patients the underlying disease is not reversible. They already met criteria for an ICD before their most recent admission.

I recommend that coverage be extended to patients if they already met the criteria for an ICD prior to their most recent MI, CABG, or PTCA.

I concur with CMS that single lead ICDs should be implanted for primary prevention therapy unless there are indications for dual chamber pacing or cardiac resynchronization therapy. We are concerned about the statement that ICDs should be "shock only" devices for primary prevention therapy. Prior clinical studies demonstrated that some patients require pacing after a shock is delivered. Moreover, anti-tachycardia pacing reduces exposure to painful shocks. The inclusion of anti-tachycardia pacing does not have an appreciable impact on the cost of the device. I conclude that this option should be available. The decision to program anti-tachycardia pacing into the arrhythmia termination algorithm should be left to the discretion of the physician. The reality is that all current devices manufactured by Guidant, Medtronic, and St. Jude incorporate anti-tachycardia algorithms. It would be unnecessary and potentially harmful to patients to deactivate this beneficial technology simply to meet the criteria for a "shock only" device.

I recommend that the term shock only be removed from the coverage decision. The remainder of that paragraph regarding physician documentation of device selection is appropriate.

I strongly support the need for Hospitals and providers to be certified as competent in ICD implantation and commends CMS for the inclusion of these criteria in the proposed registry. I urge that the recent guidelines developed by the Heart Rhythm Society and endorsed by the ACC serve as the basis for this certification.

Although I support the principle of requiring an ICD registry, it will clearly take a substantial effort to fully define the registry's mission, objectives, and operational model. It is frankly not possible to finalize a registry's infrastructure and funding by January 1, 2005, therefore it would not be acceptable to withhold primary prevention ICD therapy until it is fully operational.

**Commenter: Fenton, Alexis**

Organization: Date: October 22, 2004 Comment:

I recommend the term "shock only" be removed from the coverage decision. It was shown that antitachycardia pacing (Circulation, Rapid Access Published Ahead of Print, 10-18-04; Wathen et al.) improves quality of life in patients treated w/ antitachycardia pacing for rapid ventricular

tachycardia. As well, antitachycardia pacing was shown to be highly effective and as safe as more painful shocks.

There is also the possibility that the number of costly surgeries to replace the ICD battery will be reduced, if antitachycardia therapy requires less battery energy than shocks.

Respectfully,

**Commenter: Ferguson, T. Bruce**

Organization: LSU Health Sciences Center, New Orleans Date: October 21, 2004 Comment:

It is highly commendable and critically important that CMS implement the Registry requirement for these devices. Also, the requirement for facility and provider qualifications is equally important as well. The only way the (potentially huge) gap between RCT results and everyday clinical practice will be closed is through this post-approval Registry process, and it is absolutely the responsibility of the providers to develop and maintain this type of procedural and follow up information system. The example established in adult cardiac surgery by the Society of Thoracic Surgeons' National Cardiac Database proves that this type of system works and can be of significant benefit for all stakeholders, and that it is directly linked to improvements in care quality and cost effectiveness. This should be the model for other cardiovascular care providers, and implementing this Registry requirement for ICD therapy is a major first step in this process. Given the cost of these devices, CMS cannot afford to have 30%, 20% or even 10% of implanted patients not benefit from the therapy or suffer major complications because the provider community is not keeping track of what they are doing.

**Commenter: Figueroa, Gina**

Organization: Date: October 12, 2004 Comment:

I appreciate the chance to comment on the recent CMS decision regarding coverage and reimbursement of ICDs. Nearly one thousand Americans die every day of SCA, and your decision is an important step in the right direction. However, I urge CMS to expand ICD coverage to every American proven to be at risk for SCA. Some were excluded from the preliminary decision, and that has me worried. Every death from SCA is an unnecessary tragedy, and I respectfully request that you expand coverage. Please don't wait for more data that may cause a delay - many Americans need ICDs to live.

Please work to get this therapy available for Americans this year.

**Commenter: Filipiak, Theodore**

Organization: Date: October 19, 2004 Comment:

Thank you, CMS, for making the decision to reimburse for ICDs for many heart failure patients. ICD's are the best chance these Americans have for preventing sudden cardiac arrest. However, your decision has excluded some Americans who are at the same risk for sudden cardiac arrest. What are those left out of the CMS decision supposed to do for protection from this silent killer?

Please revise your decision to include all patients that need ICDs. And please make that decision now. We need protection from sudden cardiac arrest before it kills thousands more.

Sincerely,

**Commenter: Fineis, Nina**

Organization: Date: October 26, 2004 Comment:

I am very happy to have the chance to provide my comments on ICDs to CMS. Thank you. This is an issue that means so much to me because SCA is a leading killer of Americans. I appreciate CMS's decision to provide critical coverage to so many Americans who depend on Medicare, but CMS must consider those who were left out.

There are approximately 100,000 Americans who are at great risk for SCA and won't have ICD coverage. Please increase coverage to these folks so that they can have access to this amazing technology that makes the difference between life and death sooner rather than later.

Sincerely,

**Commenter: Finta, Bo**

Organization: Date: October 21, 2004 Comment:

I fully support the Heart Rhythm Society's Summary of Comments Submitted to you on Draft ICD Coverage Policy.

1) Ejection Fraction: The benefit of primary prevention ICD therapy for patients with Ischemic or Nonischemic cardiomyopathy and left ventricular ejection fraction (LVEF) <30% is supported by the clinical data. The Heart Rhythm Society is concerned that the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) showed benefit for patients with LVEF of 35% or less, yet patients with LVEF 30-35% have been excluded from the coverage policy. The decision by CMS to exclude those with LVEF 30-35% is based on a subgroup analysis that the study was not designed to determine.

We recommend that the coverage decision be revised to include patients with LVEF of 35% or less.

2) Nine Month Interval for Non-Ischemic Implant SCDHeFT required patients to have stable Class II-III heart failure for 3 months prior to entry into the study. CMS has extended this interval to 9 months without justification. If the intent is to exclude patients with a reversible nonischemic cardiomyopathy, this objective will be met using the 3-month criteria required by SCDHeFT.

We recommend patients have a diagnosis of nonischemic cardiomyopathy for >3 months on appropriate medical therapy.

3) Class IV Patients

The COMPANION trial indicates patients with Class IV heart failure benefit from biventricular pacing. If cardiac resynchronization therapy is employed without an ICD (CRT-D) and the patient improves to NYHA Class III heart failure, then it will be necessary to upgrade the system from CRT to CRT-D.

This exposes the patient to two procedures and ultimately increases the cost and risk of The Heart Rhythm Society recommends that coverage for CRT-D be extended to patients with Class IV heart failure.

#### 4) Documented Myocardial Infarction

The CMS policy excludes patients with acute MI within 1 month or percutaneous transluminal coronary angioplasty within 3 months. The Heart Rhythm Society believes that patients with well documented remote MI and longstanding LV dysfunction (LVEF 35% or less), should not be excluded from ICD therapy if they are admitted with another MI or the need for a second PTCA. In such patients the underlying disease is not reversible. They already met criteria for an ICD before their most recent admission.

The Heart Rhythm Society recommends that coverage be extended to patients if they already met the criteria for an ICD prior to their most recent MI, CABG, or PTCA.

#### 5) Device Selection shock only

The Heart Rhythm Society concurs with CMS that single lead ICDs should be implanted for primary prevention therapy unless there are indications for dual chamber pacing or cardiac resynchronization therapy. We are concerned about the statement that ICDs should be "shock only" devices for primary prevention therapy. Prior clinical studies demonstrated that some patients require pacing after a shock is delivered. Moreover, anti-tachycardia pacing reduces exposure to painful shocks. The inclusion of anti-tachycardia pacing does not have an appreciable impact on the cost of the device. We conclude that this option should be available. The decision to program anti-tachycardia pacing into the arrhythmia termination algorithm should be left to the discretion of the physician. The reality is that all current devices manufactured by Guidant, Medtronic, and St. Jude incorporate anti-tachycardia algorithms. It would be unnecessary and potentially harmful to patients to deactivate this beneficial technology simply to meet the criteria for a "shock only" device.

The Heart Rhythm Society recommends that the term shock only be removed from the coverage decision. The remainder of that paragraph regarding physician documentation of device selection is appropriate.

#### 6) ICD Registry for Primary Prevention ICD Therapy

The Heart Rhythm Society strongly supports the need for Hospitals and providers to be certified as competent in ICD implantation and commends CMS for the inclusion of these criteria in the proposed registry. We urge that the recent guidelines developed by the Heart Rhythm Society and endorsed by the ACC serve as the basis for this certification.

Although the Society supports the principle of requiring an ICD registry, it will clearly take a substantial effort to fully define the registry's mission, objectives, and operational model. It is frankly not possible to finalize a registry's infrastructure and funding by January 1, 2005, therefore it would not be acceptable to withhold primary prevention ICD therapy until it is fully operational. At CMS' request the Heart Rhythm Society has appointed representatives, including the Chair, to the Heart Rhythm Society's National ICD Registry Working Group. Representatives from the ACC, AHA, Heart Failure Society of America, industry, and other groups with experience in national registry management will also be participating. This Working Group will develop the purpose and structure of the registry, as well as, recommend a business model that will improve its sustainability. The Heart Rhythm Society agrees with CMS that reimbursement for primary prevention ICD therapy should be tied to participation in the Registry and that it will be difficult to achieve compliance if the Registry is voluntary.

In addition to establishing an ICD registry, nonelectrocardiologists need time to meet the requirements for certification. Moreover, training programs and comprehensive certification processes can greatly increase compliance with the proposed ICD registry.

The Heart Rhythm Society requests a grace period while the registry is developed, funding is identified, and the infrastructure established for patient data entry. The Heart Rhythm Society National ICD Registry Working Group will advise CMS about a reasonable time frame required to meet this objective. During that interval the Heart Rhythm Society recommends that CMS provide coverage for life-saving primary prevention ICD therapy.

**Commenter: Finta, Bohuslav**

Organization: Date: October 16, 2004 Comments:

ICDs have to be covered immediately for patients fulfilling SCD-HeFT criteria. I know someone who died awaiting CMS decision. Delaying coverage for these patients is unethical.

**Commenter: Fisher, John**

Organization: Montefiore-Einstein Arrhythmia Service Date: October 26, 2004 Comment:

1. For nonischemic DCM (NI-DCM), the 9-month rule is bizarre, and would be appropriate only for those with known or suspected transient problems such as tachycardia-induced cardiomyopathy or myocarditis, all amounting to a small fraction of NI-DCM patients, and discriminating against the majority.
2. NYHA IV. Some candidates are bridge to transplant and + of such patients die suddenly; why exclude? 3. Registry: this is an unfunded mandate, and provides low level of evidence vs. the RCTs. May also discriminate against Medicare patients. Also seems more like a ploy to just make things so hard that implants are discouraged. There should at a minimum be a grandfathering of centers that have been doing ICDs for many years already.
3. More than a single lead. We already have guidelines that we are held to by PROs. Is this different?

**Commenter: Flanagan, Harry**

Organization: Date: November 1, 2004 Comment:

Thank you for the opportunity to submit my comments on this important issue. Sudden cardiac arrest kills more Americans than any other condition. It kills between 340,000 and 450,000 people every year - more than 1,000 people every day. Please, please consider providing ICDs for all at-risk Americans. Your preliminary decision leaves out some Medicare patients who could die without an ICD. People who rely on Medicare have no other options and need to be covered before the end of the year.

Thank you for considering this issue of such significant importance.

Thank you,

**Commenter: Fox, Timothy**

Organization: Date: October 12, 2004 Comments:

Thank you, CMS, for making the decision to reimburse for ICDs for many heart failure patients. ICD's are the best chance these Americans have for preventing sudden cardiac arrest. However, your decision has excluded some Americans who are at the same risk for sudden cardiac arrest. What are those left out of the CMS decision supposed to do for protection from this silent killer?

Please revise your decision to include all patients that need ICDs. And please make that decision now. We need protection from sudden cardiac arrest before it kills thousands more.

**Commenter: Frei, Georgina**

Organization: Date: October 19, 2004 Comment:

I am writing to comment on the recent decision of the Centers for Medicare and Medicaid Services to reimburse implantable cardioverter defibrillators.

While it is a first step in the right direction, many people who are at risk have been left out of the preliminary decision, and will not have any other option to prevent a sudden cardiac arrest. For example, many Medicare recipients have that program as their only form of health care and won't be protected under the current decision.

It is crucial that all Americans at high risk get the protection they need from this terrible killer. With up to 450,000 people in this country dying every year from sudden cardiac arrest, the stakes are too high to implement this incomplete approach to reimbursement. Please increase the reimbursement options for ICDs to all at risk. Please don't make additional requests for data too cumbersome. Implementation of this landmark decision shouldn't be delayed past the 1st of the year.

Thank you for the opportunity to present my thoughts on this critical issue.

Regards,

**Commenter: Friesner, Phyllis**

Organization: Date: October 26, 2004

CMS should be commended for its recent decision to reimburse ICDs for many heart failure patients. ICDs offer the best protection from sudden cardiac arrest. However, there are more Americans who remain without protection. Some heart failure patients that showed benefit from ICDs in recent clinical trials were excluded from the decision. I really question this part of the decision because without an ICD, these people stand very little chance of surviving a sudden cardiac arrest. Please help ALL Americans who could benefit from this amazing device have the protection they need. Your final decision must come before January 2005 to save as many lives as possible.

Thank you for taking the time to hear my concerns.

**Commenter: Furey, Anthony B. DO.O, F.A.C.C.**

Organization: Date: October 19, 2004 Comment:

Draft Decision Memo for Implantable Defibrillators (CAG-00157R2) Dear Ms. Baldwin:

I applaud the agency's decision to expand the coverage for ICDs to include MADIT II and most SCD-Heft patients. These two studies clearly identified the life saving value of defibrillator therapy and now more patients being eligible increases our odds for reducing Sudden Cardiac Death.

The purpose of my writing you today is to voice my opinion about the patient registry that the agency has proposed. While at first blush it seems more a roadblock to ICD use than anything else. With a better understanding of the content of this proposed policy, I realize that the registry will not limit ICD Implants and has value in determining whether ICD therapy is appropriate for all these patients if Microvolt T-Wave Alternans is a required element I believe that by making Microvolt T-Wave Alternans a required element of the registry, we will gain valuable and additional information, which should address my concerns about appropriate use of ICD in these new populations. All the potential risk stratifiers mentioned in the policy with the exception of MIWA have been available for some time. MTVVA represents a more specialized technology than previously evaluated risk stratifiers because of its proven very high negative predictive value.

I am concerned that the available data does not allow me to clearly target ICDs to patients that will derive benefit. I believe that using MTNA is critical to ensuring that defibrillator implantation occurs only in those patients most likely to benefit. The use of MTWA in the registry will enable the agency to evaluate this hypothesis.

It seems to me that with the relatively small absolute decrease in mortality seen in SCD-HeFT and the seemingly low number of appropriate firings, a risk stratifier like Microvolt T-Wave Alternans should be evaluated more closely and Included as a required element of the patient registry.

Sincerely,

**Commenter: Frost, Warren**

Organization: Date: October 12, 2004

Comment:

Thank you for providing me an opportunity to comment on the recent CMS decision on ICD reimbursement.

As you know, sudden cardiac arrest is a leading cause of death in the United States, killing up to 400,000 Americans a year. As a person who has experienced SCA, I know the importance of therapies like ICDs. These devices give people the peace of mind and the opportunity to live long and healthy lives. However, despite your recent decision to reimburse some people for ICDs, you left some people out who are at the same risk. More are at risk, and need the protection that ICDs provide.

Please make the right decision, and help all those who need it to have this life saving technology fully funded and available. You must act immediately and enable at-risk patients to get an ICD as soon as possible. Please give everyone the same opportunity to live.

**Commenter: Fusco, Maria**

Organization: Date: October 17, 2004 Comment:

I am writing to comment on the recent decision of the Centers for Medicare and Medicaid Services to reimburse implantable cardioverter defibrillators.

While it is a first step in the right direction, many people who are at risk have been left out of the preliminary decision, and will not have any other option to prevent a sudden cardiac arrest. For example, many Medicare recipients have that program as their only form of health care and won't be protected under the current decision.

It is crucial that all Americans at high risk get the protection they need from this terrible killer. With up to 450,000 people in this country dying every year from sudden cardiac arrest, the stakes are too high to implement this incomplete approach to reimbursement. Please increase the reimbursement options for ICDs to all at risk. Please don't make additional requests for data too cumbersome. Implementation of this landmark decision shouldn't be delayed past the 1st of the year.

Thank you for the opportunity to present my thoughts on this critical issue.

**Commenter: G, Ravinder**

Organization: Date: October 23, 2004 Comment:

With up to 1,200 Americans killed daily by sudden cardiac arrest, I'm encouraged by the latest decision to expand Medicare coverage of implantable cardioverter defibrillators for at-risk patients.

But, it is important to note that the new coverage still leaves tens of thousands of people at risk that is preventable if Medicare reimbursement covered everyone at high-risk for sudden cardiac arrest.

Please consider including all Medicare recipients with heart failure who are at high risk for SCA. And please don't delay the decision while waiting for more data/information. We need access to this important medical care by January 1, 2005.

Thank you,

**Commenter: Garten, Terry**

Organization: Date: October 26, 2004 Comment:

With up to 1,200 Americans killed daily by sudden cardiac arrest, I'm encouraged by the latest decision to expand Medicare coverage of implantable cardioverter defibrillators for at-risk patients.

But, it is important to note that the new coverage still leaves tens of thousands of people at risk that is preventable if Medicare reimbursement covered everyone at high-risk for sudden cardiac arrest.

Please consider including all Medicare recipients with heart failure who are at high risk for SCA. And please don't delay the decision while waiting for more data/information. We need access to this important medical care by January 1, 2005.

Thank you,

**Commenter: Gellman, Joel MD, FACC**

Organization: Date:

Comment:

I applaud the agency's decision to expand the coverage for ICDs to include MADIT II and most SCD-Heft patients. These two studies clearly identified the life saving value of defibrillator therapy and now more patients being eligible increases our odds for reducing Sudden Cardiac Death.

I believe that the registry has value in determining whether ICD therapy is appropriate for all these patients if Microvolt T wave alternans is a required element. I believe that by making Microvolt Twave Alternans a required element of the registry, we will gain valuable and additional information, which should address my concerns about appropriate use of ICD in these new populations. All the potential risk stratifiers mentioned in the policy with the exception of MTWA have been available for some time. MTWA represents a more specialized technology than previously evaluated risk stratifiers because of its proven very high negative predictive value.

I am concerned that the available data does not allow me to clearly target ICDs to patients that will derive benefit. I believe that using MTWA is critical to ensuring that defibrillator implantation occurs only in those patients most likely to benefit. The use of MTWA in the registry will enable you to evaluate this hypothesis.

It seems to me that with the relatively small absolute decrease in mortality seen in SCD-HeFT and the seemingly low number of appropriate firings, a risk stratifier like Microvolt Twave Alternans should be evaluated more closely and included as a required element of the patient registry.

**Commenter: Gilbert, Myra**

Organization: Date: October 12, 2004 Comment:

I am very happy to have the chance to provide my comments on ICDs to CMS. Thank you. This is an issue that means so much to me because SCA is a leading killer of Americans. I appreciate CMS's decision to provide critical coverage to so many Americans who depend on Medicare, but CMS must consider those who were left out.

There are approximately 100,000 Americans who are at great risk for SCA and won't have ICD coverage. Please increase coverage to these folks so that they can have access to this amazing technology that makes the difference between life and death sooner rather than later.

**Commenter: Goldman, Stephen**

Organization: Date: October 19, 2004 Comment:

With up to 1,200 Americans killed daily by sudden cardiac arrest, I'm encouraged by the latest decision to expand Medicare coverage of implantable cardioverter defibrillators for at-risk patients.

But, it is important to note that the new coverage still leaves tens of thousands of people at risk that is preventable if Medicare reimbursement covered everyone at high-risk for sudden cardiac arrest.

Please consider including all Medicare recipients with heart failure who are at high risk for SCA. And please don't delay the decision while waiting for more data/information. We need access to this important medical care by January 1, 2005.

Thank you,

**Commenter: Goldner, Bruce**

Organization: LIJMC Date: October 24, 2004 Comment:

I commend CMS decision to extend Medicare ICD coverage for patients with coronary artery disease and to include those who have nonischemic cardiomyopathy.

1] However, I am not sure why a registry needs to be set up. This is going to incur more cost to the health care system (personnel need to be paid to set up and manage the registry).

2] Other than for patients with chronic atrial fibrillation, I believe all patients with sinus rhythm (who meet the new criteria) should have a dual chamber ICD to differentiate SVT and VT. Moreover, I have had patients with single chamber ICDs who have subsequently developed pacemaker syndrome -- many of these patients require beta blockers to manage heart failure, and consequently, they become bradycardic. To upgrade from a single to dual chamber ICD is costly.

3] The EF criteria should be changed to 35% Sudden Cardiac Death Heart Failure Trial, upon which these guideline changes rests, uses a cutoff of 35%, not 30%

4] Finally, having shock only devices limits options in the event a patient develops monomorphic ventricular tachycardia. If this happens, the device will need to be changed, incurring more cost.

Again I commend CMS decision to extend Medicare ICD coverage.

**Commenter: Gorman, Jeanne**

Organization: Date: October 25, 2004 Comment:

I am very happy to have the chance to provide my comments on ICDs to CMS. Thank you. This is an issue that means so much to me because SCA is a leading killer of Americans. I appreciate CMS's decision to provide critical coverage to so many Americans who depend on Medicare, but CMS must consider those who were left out.

There are approximately 100,000 Americans who are at great risk for SCA and won't have ICD coverage. Please increase coverage to these folks so that they can have access to this amazing technology that makes the difference between life and death sooner rather than later.

**Commenter: Green, Theresa**

Organization: Date: October 26, 2004 Comment:

I am writing to comment on the recent decision of the Centers for Medicare and Medicaid Services to reimburse implantable cardioverter defibrillators.

While it is a first step in the right direction, many people who are at risk have been left out of the preliminary decision, and will not have any other option to prevent a sudden cardiac arrest. For example, many Medicare recipients have that program as their only form of health care and won't be protected under the current decision.

It is crucial that all Americans at high risk get the protection they need from this terrible killer. With up to 450,000 people in this country dying every year from sudden cardiac arrest, the stakes are too high to implement this incomplete approach to reimbursement. Please increase the reimbursement options for ICDs to all at risk. Please don't make additional requests for data too cumbersome. Implementation of this landmark decision shouldn't be delayed past the 1st of the year.

Thank you for the opportunity to present my thoughts on this critical issue.

Regards,

**Commenter: Gribble, John**

Organization: Date: October 13, 2004 Comment:

With up to 1,200 Americans killed daily by sudden cardiac arrest, I'm encouraged by the latest decision to expand Medicare coverage of implantable cardioverter defibrillators for at-risk patients. But, it is important to note that the new coverage still leaves tens of thousands of people at risk that is preventable if Medicare reimbursement covered everyone at high-risk for sudden cardiac arrest.

Please consider including all Medicare recipients with heart failure who are at high risk for SCA. And please don't delay the decision while waiting for more data/information. We need access to this important medical care by January 1, 2005.

**Commenter: Habeeb, William**

Organization: Date: October 12, 2004 Comment:

I am writing to comment on the recent decision of the Centers for Medicare and Medicaid Services to reimburse implantable cardioverter defibrillators.

While it is a first step in the right direction, many people who are at risk have been left out of the preliminary decision, and will not have any other option to prevent a sudden cardiac arrest. For example, many Medicare recipients have that program as their only form of health care and won't be protected under the current decision.

It is crucial that all Americans at high risk get the protection they need from this terrible killer. With up to 450,000 people in this country dying every year from sudden cardiac arrest, the stakes are too high to implement this incomplete approach to reimbursement. Please increase the reimbursement options for ICDs to all at risk. Please don't make additional requests for data too cumbersome. Implementation of this landmark decision shouldn't be delayed past the 1st of the year.

Thank you for the opportunity to present my thoughts on this critical issue.

**Commenter: Haffner, Randy**

Organization: Florida Hospital Date: October 18, 2004 Comment:

As one of the nations largest cardiac providers, Florida Hospital has monitored with great interest the CMS consideration of the SCD-HeFT study. Although we are supportive of the expanded Medicare coverage of patients in need of these implants, we are concerned with the following provisions under consideration:

- . o Patients should not be forced to participate in a study as a condition of receiving benefits. My IRB is not likely to approve a mandatory, post-market release trial that withholds proven therapies. The requirement also discriminates against Medicare patients since private insurers do not require a registry.
- . o With respect to its size, content and corresponding costs, rather than all patients, an ICD primary prevention patient registry should be limited to a sufficient number of patients and centers to address the questions being posed, possibly in a demonstration project format.
- . o The requirement for a patient registry should be decoupled from coverage. This will ensure that primary prevention patients have the opportunity to receive treatment by the scheduled start date - January 1, 2005. It is not possible to implement a registry in my hospital, within that timeframe.
- . o In addition to registry creation, operation and analysis costs, hospitals and physicians will need to be compensated for their participation. This will require the creation of new Medicare payment codes.

Thank you for your consideration of these items.

**Commenter: Hamilton, Ron**

Organization: Date: October 15, 2004 Comment:

Thank you for providing coverage for ICDs to many Medicare patients at risk for SCA. But the CMS decision has left out around 100,000 Americans at high-risk for SCA. I wanted you to know that a large number of Medicare patients have no other healthcare options. If ICDs are not covered for those left out, what will they do if they need this device? How can we deny them access to an ICD?

Please cover all Americans at high risk for SCA. Research has proven who needs an ICD. I'm concerned that waiting to collect more data will result in unnecessary deaths. The fact is that we can't let another day go by without this care.

Thank you for the opportunity to share my opinion on this matter.

**Commenter: Hammontree, Doris**

Organization: Date: October 26, 2004 Comment:

Sudden cardiac arrest is a leading cause of death, of men and women alike, in the United States. It usually shows no signs and symptoms and is responsible for the death of as many as 400,000 Americans each year. Yet there is hope based on the recent ICD study.

ICDs can provide comfort for many people as it acts like a life preserver, preventing sudden glitches in the heart before they can lead to death. While I am appreciative of CMS's recent decision to reimburse ICDs for many heart failure patients, I believe that this measure falls short, as it does not protect all heart failure patients at risk, especially those with no other option for protection from cardiac arrest. I implore you to protect ALL AMERICANS at high risk from this terrible affliction.

Please decide to include all at-risk patients and don't delay implementation of this decision our lives are at risk while we wait.

Please step up to the challenge today!

Thank you for your attention to this matter.

**Commenter: Harding, Edward**

Organization: Date: October 19, 2004 Comment:

With up to 1,200 Americans killed daily by sudden cardiac arrest, I'm encouraged by the latest decision to expand Medicare coverage of implantable cardioverter defibrillators for at-risk patients.

But, it is important to note that the new coverage still leaves tens of thousands of people at risk that is preventable if Medicare reimbursement covered everyone at high-risk for sudden cardiac arrest.

Please consider including all Medicare recipients with heart failure who are at high risk for SCA. And please don't delay the decision while waiting for more data/information. We need access to this important medical care by January 1, 2005.

Thank you,

**Commenter: Hawkinson, Alex**

Organization: Date: October 28, 2004 Comment:

CMS should be commended for its recent decision to reimburse ICDs for many heart failure patients. ICDs offer the best protection from sudden cardiac arrest. However, there are more Americans who remain without protection. Some heart failure patients that showed benefit from ICDs in recent clinical trials were excluded from the decision. I really question this part of the decision because without an ICD, these people stand very little chance of surviving a sudden cardiac arrest. Please help ALL Americans who could benefit from this amazing device have the protection they need. Your final decision must come before January 2005 to save as many lives as possible.

Thank you for taking the time to hear my concerns.

Sincerely,

**Commenter: Harris, Paulette**

Organization: Date: October 12, 2004 Comment:

With up to 1,200 Americans killed daily by sudden cardiac arrest, I'm encouraged by the latest decision to expand Medicare coverage of implantable cardioverter defibrillators for at-risk patients.

But, it is important to note that the new coverage still leaves tens of thousands of people at risk that is preventable if Medicare reimbursement covered everyone at high-risk for sudden cardiac arrest.

Please consider including all Medicare recipients with heart failure who are at high risk for SCA. And please don't delay the decision while waiting for more data/information. We need access to this important medical care by January 1, 2005.

**Commenter: Hayes, David**

Organization: Mayo clinic, Division of Cardiovascular Diseases Date: October 18, 2004 Comment:

I am writing to comment on the draft coverage decision by the Centers for Medicare and Medicaid Services (CMS) to extend coverage of Implantable Cardioverter Defibrillator (ICD) therapy for primary prevention of sudden cardiac death. Extending the coverage for patients with coronary artery disease and to include those who have nonischemic cardiomyopathy is excellent for quality patient care.

There are several other issues that require comment. The decision by CMS to exclude those with LVEF 30-35% is based on a subgroup analysis that the study was not designed to determine. CMS should not exclude patients who met criteria for entry into the most comprehensive trial conducted to date. Based on the randomized clinical trial data that we have, patients with LVEF of <35% should be included.

SCDHeFT required patients to have stable Class II-III heart failure for 3 months prior to entry into the study. CMS has extended this interval to 9 months without justification. How do you tell a patient that based on the available data that they are at risk for SCD but based on CMS criteria, not determined by

the science that we will have to wait 9 months. It's not good medicine. The diagnosis of nonischemic cardiomyopathy should be required for 3 months with appropriate medical therapy.

Based on COMPANION patients with Class IV heart failure benefit from biventricular pacing. If cardiac resynchronization therapy is employed without an ICD (CRT-D) and the patient improves to NYHA Class III heart failure, then it will be necessary to upgrade the system from CRT to CRT-D. This requires two procedures and increases the total cost. CRT-D should still be available to Class IV patients.

Anti-tachycardia therapy has been shown time and time again to decrease painful and unnecessary shocks. The term Shock only should be removed from the coverage decision!

**Commenter: Higgins, Steven**

Organization: East Tennessee Heart Consultants Date: September 30, 2004 Comment:

First of all, I apologize as I initially could not find this link for comments and sent emails directly to CMS members. I will repeat my comments below for the record:

I applaud CMS for the recent plan to expand the coverage decision regarding ICDs. As an investigator and executive member of the MADIT II study, I appreciate the inclusion of all MADIT II patients now, regardless of QRS width.

Similarly, I support the position to cover patients found to benefit from this therapy in the SCD-HeFT study.

I am puzzled by a few remaining issues. The persistent exclusion of class IV patients is a mystery. These patients have been shown to benefit from ICD therapy and, especially if they are already to undergo surgery for CRT, why was coverage not included for CRT-D therapy? CRT-D therapy frequently dramatically improves the quality of life as well as prolonging life in these patients who suffer most. I can list numerous patients who have improved from Class IV to Class I-II with CRT and have had life-saving anti-tachycardia therapy as well from their devices. These people are alive today because they received CRT-D devices.

The single chamber ICD issue is also puzzling to me. Many patients benefit from dual or triple chamber ICD therapy when they meet single chamber indications and have a need for avoidance of therapy for atrial arrhythmias, AV block, heart failure, etc. When this need is documented in a procedure note, I think coverage should be forthcoming. As physicians, we alone have the clinical skills to determine the number of leads that would best benefit our patient.

Finally, the registry for prophylactic implants seems like a cop-out. Why was this added? Who is to conduct it? What happens if a patient is not enrolled? Who ensures that the data collected is accurate?

In conclusion, I laud CMS for accepting the most recent medical science showing the benefit of ICD therapy for indicated patients. As a physician, one of my primary roles is to be a patient advocate. I truly believe that you have a similar role and have shouldered that responsibility admirably. However, a little fine-tuning is still in order to correct these outstanding issues. Thank you for your consideration.

**Commenter: Herman, Adrienne**

Organization: Date: October 20, 2004 Comment:

With up to 1,200 Americans killed daily by sudden cardiac arrest, I'm encouraged by the latest decision to expand Medicare coverage of implantable cardioverter defibrillators for at-risk patients.

But, it is important to note that the new coverage still leaves tens of thousands of people at risk that is preventable if Medicare reimbursement covered everyone at high-risk for sudden cardiac arrest.

Please consider including all Medicare recipients with heart failure who are at high risk for SCA. And please don't delay the decision while waiting for more data/information. We need access to this important medical care by January 1, 2005.

Thank you,

**Commenter: Hessen, Scott MD**

Organization: Date: October 29, 2004 Comment:

**DRAFT MEDICARE PLAN TO COVER IMPLANTABLE DEFIBRILLATORS  
EXPECTED TO SAVE THOUSANDS OF LIVES; PUBLIC COMMENTS SOUGHT  
(ID=139)**

I tried to submit my comment electronically but unfortunately the link was removed.

Therefore, please allow this to serve as my comments on this issue. This is great news! It is hard to make credible complaints since final decisions have not been made. In general, we praise the expansion of indications for ICDs, but suggest that physician decisions regarding specific devices should stand and that we would like to see creation of a voluntary registry (or none at all).

More specifically, it is interesting to read the actual coverage decision to note the details. First, only single chamber ICDs are indicated for primary prophylaxis. Use of more advanced devices will require supplementary information, the process for submitting this is not yet decided. (Dual Chamber, Bi-V, etc.) In addition, many exclusion timeframes and parameters remain. It is nice that the QRS duration is no longer a disclusionary factor. The biggest problem that I see is the creation of a national registry for ICD implants, including patient follow up and outcomes data. This could create an enormous follow-up documentation problem. I know of many specialty societies that are against the registry aspect of this decision and will work to eliminate it. There has been little information regarding what this will be and how it will affect our paperwork burden. It is hard to make credible complaints since final decisions have not been made. In general, we praise the expansion of indications for ICDs, but suggest that physician decisions regarding specific devices should stand and that we would like to see creation of a voluntary registry (or none at all).

Thank you for the opportunity to respond to this.

**Commenter: Hiers, George**

Organization: Date: October 19, 2004 Comment:

I am writing to comment on the recent decision of the Centers for Medicare and Medicaid Services to reimburse implantable cardioverter defibrillators.

While it is a first step in the right direction, many people who are at risk have been left out of the preliminary decision, and will not have any other option to prevent a sudden cardiac arrest. For example, many Medicare recipients have that program as their only form of health care and won't be protected under the current decision.

It is crucial that all Americans at high risk get the protection they need from this terrible killer. With up to 450,000 people in this country dying every year from sudden cardiac arrest, the stakes are too high to implement this incomplete approach to reimbursement. Please increase the reimbursement options for ICDs to all at risk. Please don't make additional requests for data too cumbersome. Implementation of this landmark decision shouldn't be delayed past the 1st of the year.

Thank you for the opportunity to present my thoughts on this critical issue.

**Commenter: Higgins, Steven**

Organization: Date: October 13, 2004 Comment:

Hello. I have been solicited to comment on adding T wave alternans to the screening process for MADIT II indicated patients. While it does not surprise me that Cambridge Heart is interested in adding this test, I respectfully disagree. MADIT II was an excellent study defining a clear group that benefited from ICD therapy. As a member of the Executive Committee, we consider the Cambridge Heart request to the requirement of the study and excluded it. The test has not undergone rigorous scrutiny. I have used it and found it to not be reliable, reproducible nor easy to apply.

**I STRONGLY ENCOURAGE YOU TO NOT INCLUDE TWA IN YOUR CRITERIA FOR ICD IMPLANTATION.**

**Commenter: Hinterberger, David**

Organization: Date: October 13, 2004 Comment:

Sudden cardiac arrest is a leading cause of death, of men and women alike, in the United States. It usually shows no signs and symptoms and is responsible for the death of as many as 400,000 Americans each year. Yet there is hope based on the recent ICD study.

ICDs can provide comfort for many people as it acts like a life preserver, preventing sudden glitches in the heart before they can lead to death. While I am appreciative of CMS's recent decision to reimburse ICDs for many heart failure patients, I believe that this measure falls short, as it does not protect all heart failure patients at risk, especially those with no other option for protection from cardiac arrest. I implore you to protect ALL AMERICANS at high risk from this terrible affliction. Please decide to include all at-risk patients and don't delay implementation of this decision û lives are at risk while we wait.

Please step up to the challenge today!

Thank you for your attention to this matter.

**Commenter: Ho, Brenda**

Organization: Date: October 12, 2004 Comment:

I appreciate the chance to comment on the recent CMS decision regarding coverage and reimbursement of ICDs. Nearly one thousand Americans die every day of SCA, and your decision is an important step in the right direction. However, I urge CMS to expand ICD coverage to every American proven to be at risk for SCA. Some were excluded from the preliminary decision, and that has me worried. Every death from SCA is an unnecessary tragedy, and I respectfully request that you expand coverage. Please don't wait for more data that may cause a delay - many Americans need ICDs to live.

Please work to get this therapy available for Americans this year.

**Commenter: Holcombe, Sharon**

Organization: Date: October 13, 2004 Comment:

I am very happy to have the chance to provide my comments on ICDs to CMS. Thank you. This is an issue that means so much to me because SCA is a leading killer of Americans. I appreciate CMS's decision to provide critical coverage to so many Americans who depend on Medicare, but CMS must consider those who were left out.

There are approximately 100,000 Americans who are at great risk for SCA and won't have ICD coverage. Please increase coverage to these folks so that they can have access to this amazing technology that makes the difference between life and death sooner rather than later.

**Commenter: Hough, Annette**

Organization: Date: October 12, 2004 Comment:

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There are approximately 100,000 Americans who are at great risk for SCA and won't have ICD coverage. Please increase coverage to these folks so that they can have access to this amazing technology that makes the difference between life and death sooner rather than later.

**Commenter: House, Sue**

Organization: Date: October 12, 2004 Comment:

Thank you, CMS, for making the decision to reimburse for ICDs for many heart failure patients. ICD's are the best chance these Americans have for preventing sudden cardiac arrest. However, your decision has excluded some Americans who are at the same risk for sudden cardiac arrest. What are those left out of the CMS decision supposed to do for protection from this silent killer?

Please revise your decision to include all patients that need ICDs. And please make that decision now. We need protection from sudden cardiac arrest before it kills thousands more.

**Commenter: Huggard, Kelly**

Organization: Date: October 17, 2004 Comment

CMS should be commended for its recent decision to reimburse ICDs for many heart failure patients. ICDs offer the best protection from sudden cardiac arrest. However, there are more Americans who remain without protection. Some heart failure patients that showed benefit from ICDs in recent clinical trials were excluded from the decision. I really question this part of the decision because without an ICD, these people stand very little chance of surviving a sudden cardiac arrest. Please help ALL Americans who could benefit from this amazing device have the protection they need. Your final decision must come before January 2005 to save as many lives as possible.

Thank you for taking the time to hear my concerns.

**Commenter: Hurley, Gail**

Organization: Date: October 13, 2004 Comment:

I appreciate the chance to comment on the recent CMS decision regarding coverage and reimbursement of ICDs. Nearly one thousand Americans die every day of SCA, and your decision is an important step in the right direction. However, I urge CMS to expand ICD coverage to every American proven to be at risk for SCA. Some were excluded from the preliminary decision, and that has me worried. Every death from SCA is an unnecessary tragedy, and I respectfully request that you expand coverage. Please don't wait for more data that may cause a delay - many Americans need ICDs to live.

Please work to get this therapy available for Americans this year.

**Commenter: Jensen, Shirley**

Organization: Date: October 15, 2004 Comment:

Sudden cardiac arrest is a leading cause of death, of men and woman alike, in the United States. It usually shows no signs and symptoms and is responsible for the death of as many as 400,000 Americans each year. Yet there is hope based on the recent ICD study.

ICDs can provide comfort for many people as it acts like a life preserver, preventing sudden glitches in the heart before they can lead to death. While I am appreciative of CMS's recent decision to reimburse ICDs for many heart failure patients, I believe that this measure falls short, as it does not protect all heart failure patients at risk, especially those with no other option for protection from cardiac arrest. I implore you to protect ALL AMERICANS at high risk from this terrible affliction. Please decide to include all at-risk patients and don't delay implementation of this decision lives are at risk while we wait.

Please step up to the challenge today!

Thank you for your attention to this matter.

**Commenter: Janeira, Louis F., MD, FACC**

Organization: Date: October 25, 2004 Comment:

I am writing regarding the coverage for implantable cardioverter-defibrillators (ICDs) by the Centers for Medicare & Medicaid Services (CMS).

I believe non-coverage of these life-prolonging therapies is inappropriate. As you know, certain patient types have been demonstrated to derive this survival benefit. This has been shown in multiple

well-designed scientific clinical trials (MADIT, SCD HeFT and others). To arbitrarily deny some subgroups coverage for this option without data seems unethical and wrong. It also puts the clinician and patient in the middle of a quagmire. It is my duty to prescribe the best available proven therapies for my patients. In essence you prevent me from so doing by regulating non-coverage.

Please reconsider your decisions and allow the scientific data to prevail. Thank you very much.

**Commenter: Jeffries, Edward**

Organization: Date: October 20, 2004 Comment:

I am very happy to have the chance to provide my comments on ICDs to CMS. Thank you. This is an issue that means so much to me because SCA is a leading killer of Americans. I appreciate CMS's decision to provide critical coverage to so many Americans who depend on Medicare, but CMS must consider those who were left out.

There are approximately 100,000 Americans who are at great risk for SCA and won't have ICD coverage. Please increase coverage to these folks so that they can have access to this amazing technology that makes the difference between life and death sooner rather than later.

**Commenter: Johnson, Eric, MD, PC**

Organization: Date: October 22, 2004 Comment:

I applaud the agency's decision to expand the coverage for ICDs to include MADIT II and most SCD-Heft patients. These two studies clearly identified the life saving value of defibrillator therapy and now more patients being eligible increases our odds for reducing Sudden Cardiac Death.

The purpose of my writing you today is to voice my opinion about the patient registry that the agency has proposed. While at first blush it seems more a roadblock to ICD use than anything else. With a better understanding of the content of this propose policy, I believe that the registry has value in determining whether ICD therapy is appropriate for all these patients if Microvolt Twave Alternans is a required element.

I believe that by making Microvolt Twave Alternans a required element of the registry, we will gain valuable and additional information, which should address my concerns about appropriate use of ICD in these new populations. All the potential risk stratifiers mentioned in the policy with the exception of MTWA have been available for some time. MTWA represents a more specialized technology than previously evaluated risk stratifiers because of it's proven very high negative predictive value.

I am concerned that the available data does not allow me to clearly target ICDs to patients that will derive benefit. I believe that using MTWA is critical to ensuring that defibrillator implantation occurs only in those patients most likely to benefit. The use of MTWA in the registry will enable you to evaluate this hypothesis.

It seems to me that with the relatively small absolute decrease in mortality seen in SCD-HeFT and the seemingly low number of appropriate firings, a risk stratifier like Microvolt Twave Alternans should be evaluated more closely and included as a required element of the patient registry.

**Commenter: Johnson, Jackie**

Organization: Date: October 13, 2004 Comment

I am writing to comment on the recent decision of the Centers for Medicare and Medicaid Services to reimburse implantable cardioverter defibrillators.

While it is a first step in the right direction, many people who are at risk have been left out of the preliminary decision, and will not have any other option to prevent a sudden cardiac arrest. For example, many Medicare recipients have that program as their only form of health care and won't be protected under the current decision.

It is crucial that all Americans at high risk get the protection they need from this terrible killer. With up to 450,000 people in this country dying every year from sudden cardiac arrest, the stakes are too high to implement this incomplete approach to reimbursement. Please increase the reimbursement options for ICDs to all at risk. Please don't make additional requests for data too cumbersome. Implementation of this landmark decision shouldn't be delayed past the 1st of the year.

Thank you for the opportunity to present my thoughts on this critical issue.

**Commenter: Jordan, Shirley**

Organization: Date: October 13, 2004 Comment:

Thank you for providing coverage for ICDs to many Medicare patients at risk for SCA. But the CMS decision has left out around 100,000 Americans at high-risk for SCA.

I wanted you to know that a large number of Medicare patients have no other healthcare options. If ICDs are not covered for those left out, what will they do if they need this device? How can we deny them access to an ICD?

Please cover all Americans at high risk for SCA. Research has proven who needs an ICD. I'm concerned that waiting to collect more data will result in unnecessary deaths. The fact is that we can't let another day go by without this care.

Thank you for the opportunity to share my opinion on this matter.

**Commenter: Kay, G. Neal**

Organization: University of Alabama at Birmingham Date: October 15, 2004 Comment:

Comment: I applaud CMS for proposing to reimburse prophylactic ICD implantation for patients at high risk of sudden death. However, it remains true that SCD-HFT demonstrated a survival benefit compared with placebo or amiodarone for patients with CHF of whatever etiology with LVEF <0.35. While there is a clear mandate of our society to deliver cost-effective care, the decision to provide coverage only for patients with LVEF <0.30 runs counter to the scientific evidence that is available. It also continues to place physicians and patients in an intolerable dilemma: either use the available clinical trial data to make clinical decisions (a strategy that we have always emphasized in modern medicine); or risk Medicare fraud for doing so when the coverage decisions run counter to the scientific evidence. It was my sincere hope that we would allow physicians and patients to enjoy the benefits of evidence-based medicine without continuing to place them in an ethical conundrum. So, what does the physician respond to a patient with an LVEF of 0.31 who has read the SCD-HFT data and asks, "shouldn't I have a prophylactic ICD?" If the physician responds, "yes, but your government will not pay for it", there continues to be a heart-wrenching decision for the patient. He must either pay for the device himself or ask his local hospital to pay for it. On the other hand, if the CMS decisions are in line with the best clinical trials, then the physician can answer the patient's question, "yes, and your government will provide you with the necessary coverage". Please understand that this is not an abstract situation but reflects real-life conversations between physicians and their patients that occur every day. Also remember that your coverage decisions have a profound impact on the lives of patients and their doctors. When those decisions are true to scientific evidence everyone in our society is well served. When they are not, ethical chaos results.

**Commenter: Kelly, Annette**

Organization: Date: October 14, 2004 Comment:

I am writing to comment on the recent decision of the Centers for Medicare and Medicaid Services to reimburse implantable cardioverter defibrillators.

While it is a first step in the right direction, many people who are at risk have been left out of the preliminary decision, and will not have any other option to prevent a sudden cardiac arrest. For example, many Medicare recipients have that program as their only form of health care and won't be protected under the current decision.

It is crucial that all Americans at high risk get the protection they need from this terrible killer. With up to 450,000 people in this country dying every year from sudden cardiac arrest, the stakes are too high to implement this incomplete approach to reimbursement. Please increase the reimbursement options for ICDs to all at risk. Please don't make additional requests for data too cumbersome. Implementation of this landmark decision shouldn't be delayed past the 1st of the year.

Thank you for the opportunity to present my thoughts on this critical issue.

**Commenter: Kelly, Carol**

Organization: AdvaMed Date: October 28, 2004 Comment:

AdvaMed appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMSs) draft National Coverage Decision (NCD) to expand coverage for heart failure patients to lifesaving implantable cardioverter defibrillators (ICDs). In light of the precedential nature of this draft NCD, we respectfully submit the following comments.

We commend CMSs draft NCD to expand coverage for heart failure patients to lifesaving ICDs, which have been proven to decrease significantly the risk of sudden cardiac death. This coverage expansion was based primarily on the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT), a landmark trial designed and sponsored by the NIH. The results of the SCD-HeFT trial are clear and indisputable: ICD therapy prolongs the lives of heart failure patients.

While the draft decision appropriately expands coverage to ICD therapy based on the most rigorous of scientific evidence, we have concerns with CMSs approach that merit further consideration in order to ensure patients can appropriately access this therapy.

**Incomplete Coverage:**

We recommend that CMS cover the entire SCD-HeFT population consistent with the results of the trial. Leaving certain sub-populations uncovered on the basis of unplanned, un-powered retrospective analysis is not consistent with evidence-based medicine. We believe that when clinical evidence is generated through the most rigorous of clinical trials, CMS should rely on that evidence and issue a Medicare coverage determination consistent with that evidence in a timely fashion.

**Ongoing Data Collection Requirements:**

CMS is requiring that all primary prevention patients, including those indicated for coverage by the SCD-HeFT trial, be placed in a registry as a precursor to Medicare coverage. While registry requirements may be useful mechanisms for data collection on certain therapies, AdvaMed believes that the requirement for a coverage due to concerns that it may be difficult, if not impossible, to research and design -- much less implement -- a registry or an alternative post-SCD-HeFT clinical strategy within the timeline established by the Medicare Prescription Drug, Improvement, and Modernization Act (MMA). By separating the patient registry implementation from the NCD implementation, CMS will ensure that primary prevention patients have the opportunity to receive treatment by the scheduled start date - January 1, 2005.

The following are some of the significant questions that exist related to the registry: what questions should be studied through the registry, what data should be collected, how should it be collected, and who should compile it, analyze it and have access to it. Where, as here, evidence of the highest caliber is presented to CMS to support a coverage request, any additional data collection requirements imposed by CMS should be scientifically sound, feasible, and provide value to merit the expense of a registry. Thus, while a registry may be appropriate in some circumstances, CMS should ensure that a given registry is a tailored, refined data collection mechanism that is appropriate given the data already in existence on a given technology or procedure.

Moreover, questions exist regarding funding for the registry. In addition to registry creation, operation and analysis costs, which can cost millions of dollars per year, CMS should also consider physician and hospital compensation for participation in the registry. This may necessitate the creation of new provider payment codes that would need to be developed through a consensus based approach. We are concerned that without compensation for the costs of participation, patient access to this important therapy could be jeopardized.

AdvaMed commends CMS on its proposal to expand coverage and looks forward to working with CMS to ensure that this policy, and others that follow, will allow true patient access to these important therapies.

**Commenter: Kelly, William**

Organization: Date: October 12, 2004 Comment:

I appreciate the chance to comment on the recent CMS decision regarding coverage and reimbursement of ICDs. Nearly one thousand Americans die every day of SCA, and your decision is an important step in the right direction. However, I urge CMS to expand ICD coverage to every American proven to be at risk for SCA. Some were excluded from the preliminary decision, and that has me worried. Every death from SCA is an unnecessary tragedy, and I respectfully request that you expand coverage. Please don't wait for more data that may cause a delay - many Americans need ICDs to live.

Please work to get this therapy available for Americans this year.

**Commenter: King, Judy**

Organization: Date: October 12, 2004 Comment:

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Please work to get this therapy available for Americans this year.

**Commenter: Knox, Leonard**

Organization: Date: October 26, 2004 Comment:

I appreciate the chance to comment on the recent CMS decision regarding coverage and reimbursement of ICDs. Nearly one thousand Americans die every day of SCA, and your decision is an important step in the right direction. However, I urge CMS to expand ICD coverage to every American proven to be at risk for SCA. Some were excluded from the preliminary decision, and that has me worried. Every death from SCA is an unnecessary tragedy, and I respectfully request that you expand coverage. Please don't wait for more data that may cause a delay - many Americans need ICDs to live.

Please work to get this therapy available for Americans this year.

**Commenter: Konya, Tess**

Organization: Date: October 25, 2004 Comment:

I am writing to comment on the recent decision of the Centers for Medicare and Medicaid Services to reimburse implantable cardioverter defibrillators.

While it is a first step in the right direction, many people who are at risk have been left out of the preliminary decision, and will not have any other option to prevent a sudden cardiac arrest. For example, many Medicare recipients have that program as their only form of health care and won't be protected under the current decision.

It is crucial that all Americans at high risk get the protection they need from this terrible killer. With up to 450,000 people in this country dying every year from sudden cardiac arrest, the stakes are too high to implement this incomplete approach to reimbursement. Please increase the reimbursement options for ICDs to all at risk. Please don't make additional requests for data too cumbersome. Implementation of this landmark decision shouldn't be delayed past the 1st of the year.

Thank you for the opportunity to present my thoughts on this critical issue.

**Commenter: Kopp, Douglas**

Organization: Date: October 28, 2004 Comment:

As a practicing academic electrophysiologist, I am concerned about the need to broaden the use of this life-saving therapy, but also the rising cost. If anything, this therapy is grossly underutilized, and while we need to further refine selection criteria, I believe we should practice evidence-based medicine and allow the implantation of ICDs in all patients with irreversible LV dysfunction (LVEF < 35%) who are on optimal pharmacologic therapy, regardless of etiology of the LV dysfunction.

In addition, the requirement of a registry will be cumbersome and expensive. Currently, all of my new ICD patients are already being enrolled in research studies (including registries), thereby meeting this requirement. An additional registry will be a burden on already stressed research operations. If CMS wants to pay for it by funding the research nurses and institutional IRBs who are doing the enrolling, then let's proceed. In the interest of keeping ICD costs down, I do not feel that industry should be required to fund the registry, even though they have the most to gain by the ruling.

Lastly, I do not support the practice of general cardiologists or interventional cardiologists placing ICDs without completing an electrophysiology fellowship. This is a safety issue requiring much experience as well as knowledge in the programming and follow-up of these complex devices. Non-electrophysiologists are not able or willing to do the follow-up that these patients require. From a manpower standpoint, we face a difficult situation for the short-term. Long-term, to meet the demand we need to train more electrophysiologists which will require funding from industry as well as Medicare.

**Commenter: Kosmowska, Ewa**

Organization: Date: October 19, 2004 Comment:

Thank you for providing coverage for ICDs to many Medicare patients at risk for SCA. But the CMS decision has left out around 100,000 Americans at high-risk for SCA.

I wanted you to know that a large number of Medicare patients have no other healthcare options. If ICDs are not covered for those left out, what will they do if they need this device? How can we deny them access to an ICD?

Please cover all Americans at high risk for SCA. Research has proven who needs an ICD. I'm concerned that waiting to collect more data will result in unnecessary deaths. The fact is that we can't let another day go by without this care.

Thank you for the opportunity to share my opinion on this matter.

**Commenter: Kremers, Mark**

Organization: Date: October 25, 2004 Comment:

ICD coverage should be based on the science. This means ischemic or non-ischemic cardiomyopathy with EF < 35% (not 30%) of > 3 months duration (not >9 months) in class 3 or 4.

Devices should include ATP and programming be left to the discretion of the MDs caring for the patient. Delay after first MI or intervention is reasonable but not after second if preceding EF criteria were already met. Registry will advance our knowledge and is admirable idea but requires significant preparation to do correctly. Implementation of funding should not be delayed waiting for this.

**Commenter: Kunigonis, Bill**

Organization: Date: October 28, 2004 Comment:

I appreciate the chance to comment on the recent CMS decision regarding coverage and reimbursement of ICDs. Nearly one thousand Americans die every day of SCA, and your decision is an important step in the right direction. However, I urge CMS to expand ICD coverage to every American proven to be at risk for SCA. Some were excluded from the preliminary decision, and that has me worried. Every death from SCA is an unnecessary tragedy, and I respectfully request that you expand coverage. Please don't wait for more data that may cause a delay - many Americans need ICDs to live.

Please work to get this therapy available for Americans this year.

**Commenter: Lamoureux, Steve**

Organization: Date: October 25, 2004 Comment:

Thank you, CMS, for making the decision to reimburse for ICDs for many heart failure patients. ICD's are the best chance these Americans have for preventing sudden cardiac arrest. However, your decision has excluded some Americans who are at the same risk for sudden cardiac arrest. What are those left out of the CMS decision supposed to do for protection from this silent killer?

Please revise your decision to include all patients that need ICDs. And please make that decision now. We need protection from sudden cardiac arrest before it kills thousands more.

Sincerely,

**Commenter: Lampert, Rachel**

Organization: Yale University School of Medicine, Cardiology Date: October 27, 2004 Comment:

Dear Sirs, The decision to cover all patients for ICDs who meet the criteria outlined in the MADIT 2 and SCD-Heft studies is a good one. However, there are several deviations from the studies in the current coverage decision that do not seem supported by the data from the studies. The time-frame for non-ischemic myopathies is not supported by SCD-HEFT, which showed a benefit in pts with CM of at least 3 months duration, there does not seem to be any rationale for the 9 months criteria set out by CMS. Also, the criterion of "no documented MI" does not make sense for pts who have a long history of prior MI and EF <35%. These pts may often come to attention at the time of another MI, and there is no reason to exclude them if their previous history already meets the criteria. Finally, the "shock-only" device does not make sense. ATP already exists in the commonly-used ICDs in this country, and there is no benefit to deactivating these therapies which are painless and have no downside.

**Commenter: Landau, Andre MD, FACC**

Organization: Date: October 15, 2004 Comment:

I applaud the agency's decision to expand the coverage for ICDs to include MADIT II and most SCD-Heft patients. These two studies clearly identified the life saving value of defibrillator therapy and now more patients being eligible increases our odds for reducing Sudden Cardiac Death.

The purpose of my writing you today is to voice my opinion about the patient registry that the agency has proposed. While at first glance it seems more of a roadblock to ICD use than anything else, with a better understanding of the content of this propose policy, I believe that the registry has value in determining whether ICD therapy is appropriate for all these patients.....if Microvolt T-Wave Alternans is a required element.

I believe that by making Microvolt Twave Alternans a required element of the registry, we will gain valuable and additional information, which should address my concerns about appropriate use of ICD in these new populations. All the potential risk stratifiers mentioned in the policy with the exception of MTWA have been available for some time. MTWA represents a more specialized technology than previously evaluated risk stratifiers because of it's proven very high negative predictive value.

I am concerned that the available data does not allow me to clearly target ICDs to patients that will derive benefit. I believe that using MTWA is critical to ensuring that defibrillator implantation occurs only in those patients most likely to benefit. The use of MTWA in the registry will enable you to evaluate this hypothesis.

It seems to me that with the relatively small absolute decrease in mortality seen in SCD-HeFT and the seemingly low number of appropriate firings, a risk stratifier like Microvolt Twave Alternans should be evaluated more closely and included as a required element of the patient

registry.

**Commenter: Langley, Mike**

Organization: Date: October 12, 2004 Comment:

I am very happy to have the chance to provide my comments on ICDs to CMS. Thank you. This is an issue that means so much to me because SCA is a leading killer of Americans. I appreciate CMS's decision to provide critical coverage to so many Americans who depend on Medicare, but CMS must consider those who were left out.

There are approximately 100,000 Americans who are at great risk for SCA and won't have ICD coverage. Please increase coverage to these folks so that they can have access to this amazing technology that makes the difference between life and death sooner rather than later.

**Commenter: Larson, Ed and Arlene**

Organization: Date: October 26, 2004 Comment:

Thank you, CMS, for making the decision to reimburse for ICDs for many heart failure patients. ICD's are the best chance these Americans have for preventing sudden cardiac arrest. However, your decision has excluded some Americans who are at the same risk for sudden cardiac arrest. What are those left out of the CMS decision supposed to do for protection from this silent killer?

Please revise your decision to include all patients that need ICDs. And please make that decision now. We need protection from sudden cardiac arrest before it kills thousands more.

Sincerely,

**Commenter: Lauer, Gerald** Organization: Date: October 12, 2004 Comment:

Thank you for providing coverage for ICDs to many Medicare patients at risk for SCA. But the CMS decision has left out around 100,000 Americans at high-risk for SCA.

I wanted you to know that a large number of Medicare patients have no other healthcare options. If ICDs are not covered for those left out, what will they do if they need this device? How can we deny them access to an ICD?

Please cover all Americans at high risk for SCA. Research has proven who needs an ICD. I'm concerned that waiting to collect more data will result in unnecessary deaths. The fact is that we can't let another day go by without this care.

Thank you for the opportunity to share my opinion on this matter.

**Commenter: Laughter, Connie**

Organization: Date: October 12, 2004 Comment

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Please cover all Americans at high risk for SCA. Research has proven who needs an ICD. I'm concerned that waiting to collect more data will result in unnecessary deaths. The fact is that we can't let another day go by without this care.

Thank you for the opportunity to share my opinion on this matter.

**Commenter: Lee, Ginny**

Organization: Date: October 20, 2004 Comment:

I am very happy to have the chance to provide my comments on ICDs to CMS. Thank you. This is an issue that means so much to me because SCA is a leading killer of Americans. I appreciate CMS's decision to provide critical coverage to so many Americans who depend on Medicare, but CMS must consider those who were left out.

There are approximately 100,000 Americans who are at great risk for SCA and won't have ICD coverage. Please increase coverage to these folks so that they can have access to this amazing technology that makes the difference between life and death sooner rather than later.

**Commenter: Leiserowitz, Amy**

Organization: Iowa Heart Center Date: October 28, 2004 Comment:

On behalf of Iowa Heart Center's 54 physicians, I write to you in support of the proposed changes to extend Medicare Implantable Cardioverter Defibrillator (ICD) coverage for patients with coronary disease and to include those who have nonischemic cardiomyopathy. However, we are in support of the Heart Rhythm Society's (HRS) recommendations for revisions to the proposal. We recommend that the coverage decision be expanded to include those patients with a left ventricular ejection fraction of 35% or less. We recommend that the time interval of 9 months with nonischemic cardiomyopathy prior to ICD implantation be reduced to > 3 months. We recommend the CMS coverage for CRT-D be extended to include those patients with NYHA Class IV heart failure given many patients improve to a Class III with CRT. Iowa Heart Center also supports the HRS recommendation for coverage of ICDs on those patients who have already met the criteria for implantation prior to their most recent MI, CABG, or PCI. We recommend that the term "shock only" be removed from the coverage decision given the usefulness of anti-tachycardia pacing therapy. Finally, we recommend that the implementation of an ICD registry be delayed while the registry is developed, funding is identified and the logistics for patient data entry be established. We support Heart Rhythm Society National ICD Registry Working Group in advising the CMS regarding a reasonable time frame to accomplish this goal.

Respectfully submitted, Amy Leiserowitz R

**Commenter: Levine, Paul**

Organization: Date: October 27, 2004 Comment:

I am a practicing cardiologist with a focused interest in arrhythmia and device therapy. I was notified by the Heart Rhythm Society that CMS was soliciting input and comment on the Draft Decision Memo for Implantable Defibrillators (CAG-00157R2). I strongly support the Centers for Medicare and Medicaid Services (CMS) decision to expand coverage of ICDs to a broad segment of heart failure patients at risk of sudden cardiac death (SCD). It has been very difficult from a clinical perspective being aware of the increasing evidence in favor of device therapy yet not have the reimbursement in place to cover the implant procedure. Many of my patients survive on a fixed income with their medical care covered by Medicare. As much as they might like to avail themselves of the current recommended therapy, they simply cannot afford to do so. They even have trouble affording pharmacologic therapy which, in view of SCD-HeFT, Companion and other trials, is simply not as good as device therapy in preventing sudden cardiac death.

While I am encouraged that CMS has recognized the lifesaving benefits of this technology and the need to ensure more Medicare patients access to it, I am also concerned that the proposed requirement of a practical registry could delay access by beneficiaries to defibrillators. I am also concerned with the following aspects of the proposed decision: the limitation of coverage to patients with an ejection fraction (EF) of less than 30%, excluding a group of patients shown to benefit from ICDs; exclusion of NYHA Class IV patients who require cardiac resynchronization therapy (CRT); the nine month interval for non-ischemic implant; and the documentation requirement of the use of any device other than a single lead, shock-only device. The following comments on the draft coverage decision will address these concerns.

#### Proposed ICD Registry

Industry has already shown a sustained commitment to performing large scale, prospective, randomized studies (e.g., MADIT II, SCD-HeFT, DEFINITE, DINAMIT) to provide the clinical data necessary to define patient populations that can benefit from the use of ICDs. These studies would not have been done without the support and encouragement by industry even though the NIH was an integral partner in the SCD-HeFT trial. Since the initial 1986 decision to provide coverage to treat life-threatening ventricular tachyarrhythmias with defibrillators, ICDs have been studied in numerous prospective, randomized studies, which have provided the clinical justification for expanded Medicare coverage for both primary and secondary prevention of ventricular arrhythmias and sudden cardiac death using ICD therapy and for such patients also requiring treatment for heart failure resulting in ventricular dyssynchrony, using cardiac resynchronization therapy with defibrillation (CRT-D) therapy. Our current understanding of who will benefit most from ICD therapy is a direct result of industries active participation. The general acceptance of these studies by the clinical community also attests to the scientific rigor of the studies. Not all studies are positive such as the DINAMIT study sponsored by St. Jude Medical effectively taught us that we should wait for the initial recovery and remodeling to take place after an acute myocardial infarction, even if the acute EF was very low, before making the decision as to ICD implantation. As part of the recent draft decision to expand coverage for ICDs based on new data, including the results of the SCD-HeFT, DEFINITE and COMPANION trials, to certain patients who have never had a heart attack for primary prevention of SCD, CMS has proposed the development of a practical registry that can help develop additional evidence to better identify who is most likely to benefit from ICD therapy for primary prevention.

While an ICD patient registry may provide valuable observational data (quality of life/functionality, device performance trends, device usage patterns, adverse events) on the use of ICDs in community

practice, it is unlikely that such a registry will be able to definitively identify subgroups within the primary prevention population that would have the most benefit from ICD therapy. A registry is more likely to provide information on risk stratification which will be useful in the design of future randomized, prospective studies. A registry designed to achieve the goals proposed by CMS is very complicated and will involve far more than a simple registration of patients (analogous to the registry for pacemaker implantation required by HCFA in the mid-1980s associated with the introduction of DRGs and this proved impractical). The development of a high-quality registry presents a number of challenges, including patient consent; maintaining confidentiality of data; ensuring data consistency, reliability, and accuracy; establishing a means of ensuring joint control over the data; ensuring that the cost of data collection is outweighed by the benefits; potential ethical, legal and liability issues; and funding. On a personal level, I will actively support CMS and the Heart Rhythm Society's National ICD Working Group to identify the best approach for data collection on ICD devices to address unanswered questions and overcome obstacles in data collection toward the mutual goal of improved patient outcomes. At the same time, I do not have the clinical resources or staff to complete complicated periodic questionnaires or evaluations of my patients for submission to a central registry so that CMS can obtain the information needed to achieve that objectives that are proposed for such a registry.

I do not believe that the requirement for a patient registry should be coupled to coverage as the implementation of a practical registry could delay beneficiary access to defibrillators. As valuable as a properly organized registry might be, the registry will be very complicated to implement. Uncoupling the registry implementation from coverage of primary prevention patients will ensure that these patients have the opportunity to receive treatment by the scheduled coverage start date of January 1, 2005. It is not possible to research and design, much less implement an ICD registry or an alternative post-SCD-HeFT clinical data collection strategy by that date, based upon experiences of clinicians and industry sponsors who have implemented such registries. I support the HRS request for a grace period while the registry is developed, funding is identified, and the infrastructure established for a patient registry. During that interval, I strongly urge that CMS provide coverage for life-saving primary prevention ICD therapy. Further, it is essential that CMS clarify its position on this important topic as soon as practical.

#### Ejection Fraction

CMS's decision to not cover SCD-HeFT-type patients with LVEF between 31 and 35% is also a serious concern. Patients with an ejection fraction in this range were well represented in the MADIT I and MUSTT Trials as well as the SCD-HeFT trial and contributed to the overall highly significant results of these trials. The fact that they did not show statistical significance in an unplanned, under-powered, retrospective analysis is not evidence of lack of benefit. There is no scientific justification for this decision. To base a decision to increase coverage, on the one hand, due to valid rigorously designed scientific studies and then modify that decision base on a statistically invalid retrospective analysis of subselected data from that same scientifically valid study makes no sense. I recommend that the coverage decision be revised to include patients with LVEF of 35% or less.

#### Class IV Patients

Under the draft coverage decision, CMS proposes to exclude coverage for primary prevention Class IV patients. The COMPANION trial indicates patients with Class IV heart failure may benefit from biventricular pacing. We need to examine all of the studies as a whole and not pick and choose from one study for one facet of the decision and another study for a different aspect of the decision. I support the HRS recommendation that CRT-D should be a covered therapy option for NYHF Class IV

primary prevention patients who, in their physician's opinion, are likely to improve to Class III with CRT-D therapy. Further, I recommend that NYHA Class IV patients with an ICD indication and wide QRS continue to be covered for secondary prevention patients. Since none of the trials for secondary prevention CRT-D devices were included in the current analysis, it is inappropriate to remove them from coverage. Additionally, if there is to be a mandatory registry for primary indications, Class IV patients should be included. Nine Month Interval for Non- Ischemic Implant

CMS has proposed that patients must have had non- ischemic dilated cardiomyopathy (NIDCM) for at least nine months prior to being eligible for ICD implant. The source of the CMS nine-month requirement appears to be the CAT trial, which was a pilot study phase of a larger proposed trial, that had a limited sample size and corresponding lack of statistical power, and which was discontinued due to lack of patient enrollment. This minimum of 9 months requirement is inconsistent with SCD-HeFT enrollment criteria, which required a patient to have NIDCM for only 3 months prior to implant. Thus, the CAT trial should not form the basis for a coverage policy limitation. I recommend that the coverage decision be revised to reflect the 3 month SCD-HeFT requirement.

Documenting Device Selection In the draft decision CMS requests documentation of the physician's decision to implant all but single-lead, shock only devices. As an indications trial, designed to study patient benefit, SCD-HeFT did not address the question of device type. What it found was that ICD therapy is lifesaving compared to placebo in its patient population. Indications trials are addressed through broad labeling by FDA, because they are not device-specific trials. There is no clinical justification for exempting any given device type from a documentation requirement. The requirement should be rewritten to require only that clinical choices be documented as part of the operative notes from the implant procedure. Further, we believe that the clinical justification for device choice should only be consistent with what's currently noted in patients' charts and not misused or enhanced to become a barrier to physician choice of appropriate level of therapy for her/his patient. In the draft decision, CMS expressed concern about both inappropriate shocks and anti-tachycardia pacing (ATP). This is inconsistent, as ATP reduces the incidence of shocks painlessly and with negligible battery drain. ATP is standard in current single, dual and biventricular ICDs via the implanted defibrillation lead and does not require the implantation of a separate lead for this purpose. The Pain-Free Rx II trial studied ATP in ICD-indicated patients. The rate cutoff used was the same as the rate cutoff used for detection in SCD-HeFT, so the results are directly applicable. A recently published manuscript (Circulation. 2004;110:2591- 2596) showed the study demonstrated a greater than 70% reduction in shocks received and a statistically significant improvement in quality of life with ATP turned on. The study also demonstrates that ATP therapy is equally safe as shock therapy with no differences observed in the incidence of sudden death, syncope or tachyarrhythmia acceleration. In addition, most of ventricular tachyarrhythmia episodes that occur in patients who receive ICDs for primary prevention will be ventricular tachycardia (VT), not ventricular fibrillation (VF), and are therefore amenable to painless ATP therapy. We have learned that quality of life is seriously compromised by repeated shocks. In addition, it is rare for the primary arrhythmia to be VF. Usually it is VT that degenerates to VF. If we can terminate VT with ATP therapy, this is far better for patients.

I greatly appreciate your consideration of these comments and I will continue to support HRS in working with CMS to establish a national registry to follow Medicare patients receiving an ICD for primary prevention therapy. If you have any questions, please contact me at my home e-mail address of [paul.cele.levine@sbcglobal.net](mailto:paul.cele.levine@sbcglobal.net).

**Commenter: Levinsky, Leon**

Organization: Date: October 25, 2004 Comment:

My comment concerns my eligibility to implant defibrillators in patients meeting requirements under SCD-HeFT. I am a cardiac surgeon who implants over 100 defibrillators and at least 100 cardiac resynchronization devices a year. I usually work in conjunction with an electrophysiologist who determines the defibrillation threshold. Under the proposal for guidelines for eligibility for implanters I would not be eligible. I urge that experienced implanters like myself be grandfathered in. There are no training programs unrelated to industry in existence. I myself have trained an electrophysiologist to become credentialed as an implanter and under these proposed guidelines he would be allowed to implant and I would not be allowed

**Commenter: Lindsay, William**

Organization: East Tennessee Heart Consultants Date: October 3, 2004 Comment:

I think it's a great idea to expand the indications for empiric ICD implant as per the results of SCD-HeFT. The registry may be a bit cumbersome, but will allow for further subset analysis for future tune ups to the indications. When considering "competency" in implanting ICDs, there is one allowance you may wish to consider: As a partially physically disabled physician, I am not able to wear the lead long enough to implant devices anymore. Currently I let either a thoracic surgeon, or one of my partners who has extensive experience with implanting pacemakers, implant the ICD lead and device. I, as a fully trained, boarded, and reboarded, electrophysiologist, then do the lead and device testing. If the results are not acceptable, I make the operating physician either reposition the lead or put in a subcutaneous array. The physicians who put in the leads and devices do not ever test the system by themselves. Please consider this particular arrangement when coming up with the criteria for what defines competency.

Also, to keep length of stay down for inpatients, it would be beneficial to have predefined criteria on when it would be allowable to use a dual chambered device instead of a single chamber, so we don't have to wait as long for a judgment before implantation. I would be happy to assist with coming up with a form that could be faxed, along with whatever other documentation would be required, to make the processing of those requests more efficient, in order to get patients out of the hospitals quicker.

Thank you for your attention to these issues.

**Commenter: Lisenba, Robert**

Organization: Date: October 26, 2004 Comment:

Sudden cardiac arrest is a leading cause of death, of men and women alike, in the United States. It usually shows no signs and symptoms and is responsible for the death of as many as 400,000 Americans each year. Yet there is hope based on the recent ICD study.

ICDs can provide comfort for many people as it acts like a life preserver, preventing sudden glitches in the heart before they can lead to death. While I am appreciative of CMS's recent decision to reimburse ICDs for many heart failure patients, I believe that this measure falls short, as it does not protect all heart failure patients at risk, especially those with no other option for protection from cardiac arrest. I

implore you to protect ALL AMERICANS at high risk from this terrible affliction. Please decide to include all at-risk patients and don't delay implementation of this decision û lives are at risk while we wait.

Please step up to the challenge today!

Thank you for your attention to this matter.

**Commenter: Lisowski, Robert**

Organization: Date: October 20, 2004 Comment:

Thank you, CMS, for making the decision to reimburse for ICDs for many heart failure patients. ICD's are the best chance these Americans have for preventing sudden cardiac arrest. However, your decision has excluded some Americans who are at the same risk for sudden cardiac arrest. What are those left out of the CMS decision supposed to do for protection from this silent killer?

Please revise your decision to include all patients that need ICDs. And please make that decision now. We need protection from sudden cardiac arrest before it kills thousands more.

**Commenter: Luckin, Patricia**

Organization: St. Mary Medical Center, Apple Valley, CA Date: October 11, 2004 Comment:

I would like clarification on the expanded coverage of implantable defibrillators. The document states that a small percentage of patients that are helped have a "narrow QRS." My understanding is that those who benefit have a wide QRS versus narrow. Can you clarify? Thanks

**Commenter: Lustgarten, Daniel L., MD PhD**

Organization: University of Vermont Date: October 6, 2004 Comment:

I am writing to thank CMS for modifying recommendations for ICD implantation coverage to better reflect our current understanding of patient populations known to benefit from ICD therapy. I also agree in spirit with the utility of implementing a national database registry as long as this can be achieved expeditiously. When I last wrote this body I expressed deep concern regarding the use of QRS duration as a means for defining the highest risk patients (as the data did not support this approach) but conceded that better prognosticating methods are badly needed. I referred you to data regarding T wave alternans which is a particularly powerful negative predictor for high risk patients. In the current issue of Circulation (vol.110:1885-1889) Bloomfield and colleagues report the results of a 2 year prospective analysis of 177 MADIT-2-type patients receiving T wave alternans. Patients with a normal T wave alternans test had a mortality rate of 3.8% yielding a false negative rate of 3.5%, contrasting with narrow QRS which had a false negative rate of 10.2%. Moreover, TWA positive patients had a 2-year actuarial mortality rate of 17.8% yielding a statistically significant hazard ratio of 4.8. These findings led the authors to comment that "if TWA testing were used to exclude a low-risk subset of MADIT II pts, about 2/3's of these patients would receive an ICD with the remaining 1/3 having a minimal risk of experiencing ICD-preventable death." I am writing to encourage your body to consider T-wave alternans as a component of the patient registry. This would further our knowledge of

this tool that on the basis of several fairly small trials has shown considerable promise as a prognosticating instrument - with the advantages of it being relatively cheap, noninvasive, and relevant in both ischemic and non-ischemic populations.

**Commenter: Lynch, Marguerite**

Organization: Date: October 13, 2004 Comment:

Thank you, CMS, for making the decision to reimburse for ICDs for many heart failure patients. ICD's are the best chance these Americans have for preventing sudden cardiac arrest. However, your decision has excluded some Americans who are at the same risk for sudden cardiac arrest. What are those left out of the CMS decision supposed to do for protection from this silent killer?

Please revise your decision to include all patients that need ICDs. And please make that decision now. We need protection from sudden cardiac arrest before it kills thousands more.

**Commenter: Machado, Christian, M.D., F.A.C.C.**

Organization: Providence Medical Centers Date: October 21, 2004 Comment:

I am writing to you to give my opinion on this issue I am glad CMS made a favorable decision in regard primary prevention on SCD by expanding ICD indications to poor EF patients

I have concerns with the registry concept unless it does not require extra expenses to our Institutions or yours, It would be very simple if we submit a generic Microsoft excel data base to CMS on a yearly basis and the appropriate tracking of complications etc. be done that way

In my Institution we have such data base , simple inexpensive and allows tracking by Quality assurance and Quality improvement committees

On the issue of who can implant, I strongly believe only trained electrophysiologist could do so, this restriction will keep interpretation of SCDHeaft and MADIT data strictly scientific and less influenced by other factors

There should be a commitment in the medical community that if a decision is made to implant a complicated device with major economical, social, and medical ramification this should only be allowed if the implanting physician is also responsible for follow up . This continuous feed back relationship allows for ICD patients to be properly cared for

**Commenter: Machado, C, M.D.**

Organization: Date: October 25, 2004 Comment:

A few words in to consider utilization of T wave alternans as a reasonable alternative screen tool for patients with EF >30<35 since if your decision of no protection to ScdHeaft like patients goes into effect a registry on these type of patients may help clarify the question what to do with them As you know there are plenty of small trials suggesting TWA may be a useful screening test in this patient population specially if negative

**Commenter: Maquire, John**

Organization: Date: October 21, 2004 Comment:

Thank you, CMS, for making the decision to reimburse for ICDs for many heart failure patients. ICD's are the best chance these Americans have for preventing sudden cardiac arrest. However, your decision has excluded some Americans who are at the same risk for sudden cardiac arrest. What are those left out of the CMS decision supposed to do for protection from this silent killer?

Please revise your decision to include all patients that need ICDs. And please make that decision now. We need protection from sudden cardiac arrest before it kills thousands more.

Sincerely,

**Commenter: Maleki, Kataneh, MD**

Organization: Cardiology Consultants of Philadelphia Date: October 3, 2004 Comment:

The expansion of CMS decision re: ICD implantation in patients with nonischemic CM and ischemic CM without consideration of QRS width is a giant step towards improvement of care for these type of patients. What is concerning now is the EF. As was proved by Companion and SCD-Heft trials patients with  $EF \leq 35\%$  are also at a great risk of sudden cardiac death; these patients should also be included in the CMS coverage. Coverage for these patients as well as resynchronization therapy for class IV patients will prevent multiple hospitalizations, will reduce medication cost which help to reduce the medical expenses significantly. I have multiple examples of class IV heart failure patients on optimal medical treatment and being hospitalized frequently with CHF and being dependent on vasodilators; after resynchronization therapy the number of hospitalizations reduced tremendously, they were controlled on minimum dosage of medications, and they even came off some of them. It is rewarding for me and I think for any conscious mind to hear from a patient that she could shop and cook for the first time after years and not spending days in hospital. I am hopping that CMS would reconsider the coverage and would expand it to patients with  $EF \leq 35\%$  with ischemic and nonischemic CM and resynchronization therapy for patients with CHF class IV.

**Commenter: Maleki, Kataneh, MD**

Organization: Cardiology Consultants of Philadelphia Date: October 3, 2004 Comment:

about single chamber cardioverter defibrillator referred as "shock box". I would like to express my opinion about this. Most of the patients with EF less or equal than 30% have conduction system disease or they suffer from atrial tachyarrhythmias such as atrial fibrillation or atrial tachycardia and so on. In addition, due to severely depressed left ventricular function they are on B blocker therapy such as coreg; therefore most of them have sinus bradycardia and in case of ICD implantation they will require pacing at some point. Recent data and studies have reproducibly demonstrated that right ventricular pacing has deleterious effect on the EF and will reduce it further and the patient will develop refractory CHF and it will require upgrading the system to a biventricular system which will be an additional cost. These patients are also at risk to develop ventricular tachyarrhythmias.

1. Dual chamber ICDs can differentiate between atrial and ventricular tachyarrhythmias and prevent inappropriate shocks and less hospitalizations. There are many examples of hospital admissions with patients with single chamber ICD getting multiple shocks due to atrial fibrillation this could have been

easily prevented by implanting a dual chamber ICD in such patient. Single chamber ICDs are not capable of recognizing atrial Tachyarrhythmias.

1. If patients develop sinus bradycardia secondary to necessary medical treatment; by adjusting the ICD the atrium can be paced only and not the ventricle. This can prevent atrial fibrillation and prevent RV pacing with subsequent CHF and its consequences hence less hospitalization.
2. Dual chamber ICDs can also treat atrial tachyarrhythmias by shocking the atrium in atrial fibrillation or by burst pacing the atrium terminating the atrial tachycardia. There are many data supporting the early treatment of atrial fibrillation will prevent remodeling of the atrium and will reduce the atrial fibrillation burden. This again will make treatment of atrial fibrillation much easier for the physician and will prevent frequent hospitalizations.
3. Since the EF is very poor in this type of patient population they are also at high risk of developing ventricular tachycardia that can be treated easily by ventricular burst pacing which is referred to painless therapy and most of these therapies are successful. The patient wont be aware of them and prevent shocking when successful.

In summary, patients with low EF are at high risk of developing conduction system disease, sick sinus syndrome and atrial as well as ventricular tachyarrhythmias. Implantation of a dual chamber ICD is more beneficial in these patients and would prevent unnecessary medical expenses. I have been always proud to live in an country that provides an excellent care for its citizens, value them, and do not discriminate them based on age, or income like some European countries.

With the help of Medicare and Medicaid this would have not been impossible, I hope that this will continue in the future.

Thank you for your time

**Commenter: Mallon, Ronald**

Organization: Data: October 20, 2004 Comment:

Thank you, CMS, for making the decision to reimburse for ICDs for many heart failure patients. ICD's are the best chance these Americans have for preventing sudden cardiac arrest. However, your decision has excluded some Americans who are at the same risk for sudden cardiac arrest. What are those left out of the CMS decision supposed to do for protection from this silent killer?

Please revise your decision to include all patients that need ICDs. And please make that decision now. We need protection from sudden cardiac arrest before it kills thousands more.

Sincerely,

**Commenter: Marshall, Patrick**

Organization: Date: October 25, 2004 Comment:

Thank you for providing coverage for ICDs to many Medicare patients at risk for SCA. But the CMS decision has left out around 100,000 Americans at high-risk for SCA.

I wanted you to know that a large number of Medicare patients have no other healthcare options. If ICDs are not covered for those left out, what will they do if they need this device? How can we deny

them access to an ICD?

Please cover all Americans at high risk for SCA. Research has proven who needs an ICD. I'm concerned that waiting to collect more data will result in unnecessary deaths. The fact is that we can't let another day go by without this care.

Thank you for the opportunity to share my opinion on this matter.

Thank You,

**Commenter: Martinez, T.**

Organization: Date: October 14, 2004 Comment:

Thank you, CMS, for making the decision to reimburse for ICDs for many heart failure patients. ICD's are the best chance these Americans have for preventing sudden cardiac arrest. However, your decision has excluded some Americans who are at the same risk for sudden cardiac arrest. What are those left out of the CMS decision supposed to do for protection from this silent killer?

Please revise your decision to include all patients that need ICDs. And please make that decision now. We need protection from sudden cardiac arrest before it kills thousands more.

**Commenter: Mastin, Carrol**

Organization: Date: October 12, 2004 Comment:

I am very happy to have the chance to provide my comments on ICDs to CMS. Thank you. This is an issue that means so much to me because SCA is a leading killer of Americans. I appreciate CMS's decision to provide critical coverage to so many Americans who depend on Medicare, but CMS must consider those who were left out.

There are approximately 100,000 Americans who are at great risk for SCA and won't have ICD coverage. Please increase coverage to these folks so that they can have access to this amazing technology that makes the difference between life and death sooner rather than later.

Sincerely,

**Commenter: Mattioni, Thomas**

Organization: Date: October 14, 2004 Comment:

If the purpose of the registry of patients receiving ICD therapy under this indication is to better determine who would benefit, I would propose that an additional risk stratifier such as T Wave Alternans be incorporated.

**Commenter: McCann, Kevin**

Organization: Date: October 26, 2004 Comment:

Thank you for providing coverage for ICDs to many Medicare patients at risk for SCA. But the CMS decision has left out around 100,000 Americans at high-risk for SCA.

I wanted you to know that a large number of Medicare patients have no other healthcare options. If ICDs are not covered for those left out, what will they do if they need this device? How can we deny them access to an ICD?

Please cover all Americans at high risk for SCA. Research has proven who needs an ICD. I'm concerned that waiting to collect more data will result in unnecessary deaths. The fact is that we can't let another day go by without this care.

Thank you for the opportunity to share my opinion on this matter.

Thank You,

**Commenter: McClanahan, Shirley**

Organization: Date: October 27, 2004 Comment:

Sudden cardiac arrest is a leading cause of death, of men and women alike, in the United States. It usually shows no signs and symptoms and is responsible for the death of as many as 400,000 Americans each year. Yet there is hope based on the recent ICD study.

ICDs can provide comfort for many people as it acts like a life preserver, preventing sudden glitches in the heart before they can lead to death. While I am appreciative of CMS's recent decision to reimburse ICDs for many heart failure patients, I believe that this measure falls short, as it does not protect all heart failure patients at risk, especially those with no other option for protection from cardiac arrest. I implore you to protect ALL AMERICANS at high risk from this terrible affliction. Please decide to include all at-risk patients and don't delay implementation of this decision - lives are at risk while we wait.

Please step up to the challenge today!

Thank you for your attention to this matter.

**Commenter: McClure, Donna**

Organization: Date: October 27, 2004 Comment:

Thank you for the opportunity to submit my comments on this important issue. Sudden cardiac arrest kills more Americans than any other condition. It kills between 340,000 and 450,000 people every year - more than 1,000 people every day. Please, please consider providing ICDs for all at-risk Americans. Your preliminary decision leaves out some Medicare patients who could die without an ICD. People who rely on Medicare have no other options and need to be covered before the end of the year.

Thank you for considering this issue of such significant importance.

Thank you,

**Commenter: McConnell, Mitch, MD, FACC**

Organization: Stanford University School of Medicine Date: October 26, 2004 Comment:

I would like to provide public comment regarding the draft decision memo for implantation of Implantable Defibrillators (CAG-00157R2).

The proposed document indicates that ejection fraction “*must be measured by angiography, radionuclide scanning or echocardiography.*”

I am a specialist in cardiovascular imaging and an attending cardiologist in the echocardiography laboratory here at Stanford. I also direct our cardiovascular MRI program. Both from my personal experience and from the medical literature, it is clear that cardiac MRI is a more accurate and reproducible method for measuring left ventricular ejection fraction than any other imaging modality. Thus, both scientifically and clinically, it would be *prudent to add cardiac MRI to the list of methods that may be used to determine ejection fraction.*

My colleagues who specialize in cardiomyopathy and electrophysiology regularly rely on cardiac MRI to provide a detailed and comprehensive evaluation of cardiac structure and function. It would seem counterproductive to then require an additional imaging test, which may be less accurate, in order to qualify for an ICD. The more accurate the assessment of ejection fraction, the more appropriate the use of ICDs in this population will be, to the benefit of patients and CMS.

Thank you and please do not hesitate to contact me if I can provide further information.

**Commenter: McGlone, Carrie**

Organization: Date: October 12, 2004 Comment:

Thank you for the opportunity to submit my comments on this important issue. Sudden cardiac arrest kills more Americans than any other condition. It kills between 340,000 and 450,000 people every year ù more than 1,000 people every day. Please, please consider providing ICDs for all at-risk Americans. Your preliminary decision leaves out some Medicare patients who could die without an ICD. People who rely on Medicare have no other options and need to be covered before the end of the year.

Thank you for considering this issue of such significant importance.

**Commenter: McIntyre, Bill**

Organization: Date: October 12, 2004 Comment

I am very happy to have the chance to provide my comments on ICDs to CMS Thank you. This is an issue that means so much to me because SCA is a leading killer of Americans. I appreciate CMS’s decision to provide critical coverage to so many Americans who depend on Medicare, but CMS must consider those who were left out.

There are approximately 100,000 Americans who are at great risk for SCA and won't have ICD coverage. Please increase coverage to these folks so that they can have access to this amazing technology that makes the difference between life and death sooner rather than later.

**Commenter: McKee, Josephine**

Organization: Date: October 19, 2004 Comment:

CMS should be commended for its recent decision to reimburse ICDs for many heart failure patients. ICDs offer the best protection from sudden cardiac arrest. However, there are more Americans who remain without protection. Some heart failure patients that showed benefit from ICDs in recent clinical trials were excluded from the decision. I really question this part of the decision because without an ICD, these people stand very little chance of surviving a sudden cardiac arrest. Please help ALL Americans who could benefit from this amazing device have the protection they need. Your final decision must come before January 2005 to save as many lives as possible.

Thank you for taking the time to hear my concerns.

Sincerely,

**Commenter: McQuillen, John**

Organization: Date: October 21, 2004 Comment:

With up to 1,200 Americans killed daily by sudden cardiac arrest, I'm encouraged by the latest decision to expand Medicare coverage of implantable cardioverter defibrillators for at-risk patients.

But, it is important to note that the new coverage still leaves tens of thousands of people at risk that is preventable if Medicare reimbursement covered everyone at high-risk for sudden cardiac arrest.

Please consider including all Medicare recipients with heart failure who are at high risk for SCA. And please don't delay the decision while waiting for more data/information. We need access to this important medical care by January 1, 2005.

**Commenter: Mela, Theofanie, M.D.,**

Organization: Massachusetts General Hospital Date: October 18, 2004 Comment:

I applaud the agency's decision to expand the coverage for ICDs to include MADIT II and most SCD-Heft patients. These two studies clearly identified the life saving value of defibrillator therapy and now more patients being eligible increases our odds for reducing Sudden Cardiac Death.

The purpose of my writing you today is to voice my opinion about the patient registry that the agency has proposed. While at first blush it seems more a roadblock to ICD use than anything else. With a better understanding of the content of this proposed policy, I believe that the registry has value in determining whether ICD therapy is appropriate for all these patients if Microvolt

Twave Alternans is a required element.

I believe that by making Microvolt Twave Alternans a required element of the registry, we will gain valuable and additional information, which should address my concerns about appropriate use of ICD in these new populations. All of the potential risk stratifiers mentioned in the policy with the exception of MTWA have been available for some time. MTWA represents a more specialized technology than previously evaluated risk stratifiers because of its proven very high negative predictive value.

I am concerned that the available data does not allow me to clearly target ICDs to patients that will derive benefit. I believe that using MTWA is critical to ensuring that defibrillator implantation occurs only in those patients most likely to benefit. The use of MTWA in the registry will enable you to evaluate this hypothesis.

It seems to me that with the relatively small absolute decrease in mortality seen in SCD-HeFT and the seemingly low number of appropriate firings, a risk stratifier like Microvolt Twave Alternans should be evaluated more closely and included as a required element of the patient registry.

**Commenter: Melnick, Amy**

**Hammill, Stephen MD**

**Wolk, Michael J. MD, FACC** Organization: Heart Rhythm Society Date: October 28,

2004 Comment:

Attached is the joint response from the Heart Rhythm Society and the American College of Cardiology on the draft National Coverage Decision on Implantable Cardioverter Defibrillators. As requested by your staff, it is attached as a PDF. This submission is in lieu of using the public comment feature on the CMS website.

Please do not hesitate to contact me, Barbara Greenan at the ACC, [greenan@acc.org](mailto:greenan@acc.org) or our leadership directly if you have any questions. Thanks very much for your consideration.

The Heart Rhythm Society (HRS) is the international leader in science, education, and advocacy for cardiac arrhythmia professionals and patients, and the primary information resource on heart rhythm disorders. The Heart Rhythm Society mission is to improve the care of patients by promoting research, education, and optimal health care policies and standards. The Heart Rhythm Society's 3,800 members are physicians, scientists and their support personnel who implant pacemakers and implantable cardioverter defibrillators (ICDs) in patients who require these lifesaving devices.

The American College of Cardiology (ACC) is a 31,000 member non-profit professional medical society and teaching institution whose purpose is to advocate for quality cardiovascular care-through education, research promotion, development and application of standards and guidelines-and to influence health care policy. The College represents more than 90 percent of the cardiologists practicing in the United States.

The Heart Rhythm Society and the ACC welcome this opportunity to comment on the draft coverage decision by the Centers for Medicare and Medicaid Services (CMS) to extend coverage of Implantable Cardioverter Defibrillator (ICD) therapy for primary prevention of sudden cardiac death. Our response is based on the comprehensive and thoughtful analysis by CMS of the primary prevention trials and the conclusions drawn from this analysis. We commend CMS on the high quality of their careful review and the criticisms they raised. We applaud the decision to extend coverage for patients with coronary artery disease and to include those who have nonischemic cardiomyopathy.

The concerns raised by our societies focus on specific clinical criteria for coverage and the practical logistics of developing and maintaining a Registry. Our comments are summarized below: 1) **Ejection**

**Fraction:** The benefit of primary prevention ICD therapy for

patients with ischemic or nonischemic cardiomyopathy and left ventricular ejection fraction (LVEF)  $\leq 30\%$  is supported by the clinical data. Our members have expressed concern that the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) showed benefit for patients with LVEF of 35% or less, yet patients with LVEF 30-35% have been excluded from the coverage policy.

The decision by CMS to exclude those with LVEF 30-35% is based on a subgroup analysis that the study was not designed to determine. HRS and ACC believe the Registry can be used to resolve this question. In the mean time, CMS should not exclude patients who met criteria for entry into the most comprehensive trial conducted to date.

**HRS and ACC recommend that the coverage decision be revised to include patients with LVEF of 35% or less.**

## 2) **Nine Month Interval for Non-Ischemic Cardiomyopathy**

SCD HeFT required patients to have stable Class II-III heart failure for 3 months prior to entry into the study. CMS has extended this interval to 9 months, ostensibly to exclude patients with a reversible nonischemic cardiomyopathy. This interval also allows time for patients to be treated with optimal medical therapy before considering implantable device therapy.

**HRS and ACC accept CMS' recommendation that patients have a diagnosis of nonischemic cardiomyopathy for >9 months prior to consideration of prophylactic ICD therapy.**

## 3) **Class IV Patients**

The COMPANION trial indicates that patients with Class IV heart failure who have received optimal medical therapy benefit from biventricular pacing. If cardiac resynchronization therapy is employed without an ICD (CRT-D) and the patient improves to NYHA Class III heart failure, then it will be necessary to upgrade the system from CRT to CRT-D. This exposes the patient to two procedures and ultimately increases the cost and risk of therapy. Therefore, patients with early Class IV heart failure who are receiving CRT therapy to improve them to Class III should receive a CRT-D device. HRS and ACC emphasize that CRT-D should be reserved for patients who do not respond to optimal medical therapy.

**HRS and ACC recommend that CMS consider extending coverage of CRT-D therapy to patients with early Class IV heart failure (not dependent on inotropic therapy) who have a reasonable expectation of improving to Class**

**III. The proposed Registry could be used to assess the benefit of ICD therapy in patients with NYHA Class IV symptoms of heart failure.**

## 4) **Documented MI**

The CMS policy excludes patients with acute MI within 1 month or percutaneous transluminal coronary angioplasty within 3 months. We believe that patients with well documented remote MI and longstanding LV dysfunction (LVEF 35% or less), should not be excluded from ICD therapy if they are

admitted with another MI or the need for a second PTCA. In such patients the underlying disease is not reversible. They already met criteria for an ICD before their most recent admission.

**HRS and ACC recommend that coverage be extended to patients if they already met the criteria for an ICD prior to their most recent MI, CABG, or PTCA. We agree that patients who present with a new acute MI as the cause of left ventricular dysfunction should wait at least one month prior to ICD implantation.**

#### **5) Device Selection “shock only”**

HRS and ACC concur with CMS that single lead ICDs should be implanted for primary prevention therapy unless there are indications for dual chamber pacing or cardiac resynchronization therapy. We are concerned about the statement that ICDs should be "shock only" devices for primary prevention therapy. Prior clinical studies demonstrated that some patients require pacing after a shock is delivered. Moreover, anti-tachycardia pacing reduces exposure to painful shocks. The inclusion of anti-tachycardia pacing does not have an appreciable impact on the cost of the device. We conclude that this option should be available. The decision to program anti-tachycardia pacing into the arrhythmia termination algorithm should be left to the discretion of the physician. The reality is that all current devices manufactured by Guidant, Medtronic, and St. Jude incorporate anti-tachycardia algorithms. It would be unnecessary and potentially harmful to patients to deactivate this beneficial technology simply to meet the criteria for a "shock only" device.

HRS and ACC recommend that the term “shock only” be removed from the coverage decision. The remainder of that paragraph regarding physician documentation of device selection is appropriate.

#### **Additional Points of Agreement**

HRS and ACC concur that cardiogenic shock, irreversible brain damage, or other diseases that portend a poor prognosis (survival < 1 year) are contraindications to ICD therapy. We agree that LVEF must be documented by ventriculography, radionuclide scanning, echocardiography, magnetic resonance imaging or other cardiovascular imaging as appropriate. We also concur that defibrillation threshold testing is indicated at the time of ICD implantation.

#### **6) ICD Registry for Primary Prevention ICD Therapy**

HRS and ACC strongly support the need for Hospitals and providers to be certified as competent in ICD implantation and commends CMS for the inclusion of this criterion in the proposed registry. We urge that the recent guidelines developed by Heart Rhythm Society and endorsed by the ACC serve as the basis for this certification. Although we both support the principle of requiring some type of registry, it will take a substantial effort to develop a database that will meet the objectives outlined by CMS. It is frankly not possible to finalize the infrastructure and funding for the database by January 1, 2005. In addition to establishing a database, nonelectrophysiologists need time to meet the requirements for certification. Moreover, training programs and a certification process must be established to facilitate their compliance with the proposed Registry. It would not be acceptable to withhold primary prevention ICD therapy until the database is fully operational. At CMS' request, the Heart Rhythm Society has appointed representatives, including the Chair, to the National ICD Registry

Working Group. Representatives from the ACC, AHA, Heart Failure Society of America, industry, and other groups with experience in data base management will also be participating. This Working Group will be asked to develop the database and a business model to sustain it as soon as feasible. We agree with CMS that reimbursement for primary prevention ICD therapy should be tied to participation in the Registry. It will be difficult to achieve compliance if the Registry is voluntary.

**HRS and ACC request a grace period while the registry is developed, funding is identified, and the infrastructure established for patient entry. The National ICD Registry Working Group will advise CMS about a reasonable time frame required to meet this objective. During that interval we recommend that CMS provide coverage for life-saving primary prevention ICD therapy.**

In summary, we appreciate the opportunity to work with CMS in refining the coverage decision and developing an ICD Registry that will meet the objectives outlined by CMS. We encourage CMS to stand by its requirement that ICDs should only be implanted by physicians with appropriate training for patient selection and implantation of these devices as outlined by the Heart Rhythm Society Clinical Competency Statement: Training Pathways for Implantation of Cardioverter Defibrillators and Cardiac Resynchronization Devices.

HRS and ACC look forward to working with you towards implementation of this critical coverage decision that will ultimately save many lives. If you have any questions, please contact Amy Melnick, Vice President, Health Policy, HRS, at [amelnick@HRSonline.org](mailto:amelnick@HRSonline.org) , 202-327-5430 or Barbara Greenan, Senior Director, Advocacy, ACC, [bgreenan@acc.org](mailto:bgreenan@acc.org) or 301-897-2687. Thank you very much for your consideration of our comments.

**Commenter: Mercury, Rhyann**

Organization: Date: October 14, 2004 Comment:

Sudden cardiac arrest is a leading cause of death, of men and women alike, in the United States. It usually shows no signs and symptoms and is responsible for the death of as many as 400,000 Americans each year. Yet there is hope based on the recent ICD study.

ICDs can provide comfort for many people as it acts like a life preserver, preventing sudden glitches in the heart before they can lead to death. While I am appreciative of CMS's recent decision to reimburse ICDs for many heart failure patients, I believe that this measure falls short, as it does not protect all heart failure patients at risk, especially those with no other option for protection from cardiac arrest. I implore you to protect ALL AMERICANS at high risk from this terrible affliction. Please decide to include all at-risk patients and don't delay implementation of this decision û lives are at risk while we wait.

Please step up to the challenge today!

Thank you for your attention to this matter.

**Commenter: Michaud, Gregory**

Organization: Date: October 27, 2004 Comment:

I would like to commend the CMS for its decision to extend Medicare ICD coverage for patients with coronary artery disease and to include those who have nonischemic cardiomyopathy. Every day I must face the decision whether or not to implant a potentially life-saving device. Clinical data clearly supports ICD implant in many of my patients, but issues of coverage make the decision uselessly confusing in many cases. Can you imagine explaining to a patient that there are good data to support implanting a defibrillator to potentially save his life, but that he may be taking a chance that it will not be reimbursed? Along with the Heart Rhythm Society, of which I am a member, I have several concerns I would like to share with CMS, including recommending specific clinical criteria for coverage be revised.

1) Ejection Fraction: The benefit of primary prevention ICD therapy for patients with Ischemic or Nonischemic cardiomyopathy and left ventricular ejection fraction (LVEF) <30% is supported by the clinical data. The Heart Rhythm Society is concerned that the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) showed benefit for patients with LVEF of 35% or less, yet patients with LVEF 30-35% have been excluded from the coverage policy. The decision by CMS to exclude those with LVEF 30-35% is based on a subgroup analysis that the study was not designed to determine.

We recommend that the coverage decision be revised to include patients with LVEF of 35% or less.

2) Nine Month Interval for Non-Ischemic Implant SCDHeFT required patients to have stable Class II-III heart failure for 3 months prior to entry into the study. CMS has extended this interval to 9 months without justification. If the intent is to exclude patients with a reversible nonischemic cardiomyopathy, this objective will be met using the 3-month criteria required by SCDHeFT. We recommend patients have a diagnosis of nonischemic cardiomyopathy for >3 months on appropriate medical therapy.

### 3) Class IV Patients

The COMPANION trial indicates patients with Class IV heart failure benefit from Biventricular pacing. If cardiac resynchronization therapy is employed without an ICD (CRT-D) and the patient improves to NYHA Class III heart failure, then it will be necessary to upgrade the system from CRT to CRT-D. This exposes the patient to two procedures and ultimately increases the cost and risk of therapy. The Heart Rhythm Society recommends that coverage for CRT-D be extended to patients with Class IV heart failure.

4) Documented Myocardial Infarction The CMS policy excludes patients with acute MI within 1 month or percutaneous transluminal coronary angioplasty within 3 months. The Heart Rhythm Society believes that patients with well documented remote MI and longstanding LV dysfunction (LVEF 35% or less), should not be excluded from ICD therapy if they are admitted with another MI or the need for a second PTCA. In such patients the underlying disease is not reversible. They already met criteria for an ICD before their most recent admission. The Heart Rhythm Society recommends that coverage be extended to patients if they already met the criteria for an ICD prior to their most recent MI, CABG, or PTCA.

5) Device Selection shock only The Heart Rhythm Society concurs with CMS that single lead ICDs should be implanted for primary prevention therapy unless there are indications for dual chamber pacing or cardiac resynchronization therapy. We are concerned about the statement that ICDs should be "shock only" devices for primary prevention therapy. Prior clinical studies (Circ 2004;110:2591-2596) demonstrated that some patients require pacing after a shock is delivered. Moreover, anti-tachycardia pacing reduces exposure to painful shocks. The inclusion of anti-tachycardia pacing does not have an appreciable impact on the cost of the device. We conclude that this option should be available. The decision to program anti-tachycardia pacing into the arrhythmia

termination algorithm should be left to the discretion of the physician. The reality is that all current devices manufactured by Guidant, Medtronic, and St. Jude incorporate anti-tachycardia algorithms. It would be unnecessary and potentially harmful to patients to deactivate this beneficial technology simply to meet the criteria for a "shock only" device. The Heart Rhythm Society recommends that the term shock only be removed from the coverage decision. The remainder of that paragraph regarding physician documentation of device selection is appropriate.

6) ICD Registry for Primary Prevention ICD Therapy The Heart Rhythm Society strongly supports the need for Hospitals and providers to be certified as competent in ICD implantation and commends CMS for the inclusion of these criteria in the proposed registry. We urge that the recent guidelines developed by the Heart Rhythm Society and endorsed by the ACC serve as the basis for this certification. Although the Society supports the principle of requiring an ICD registry, it will clearly take a substantial effort to fully define the registry's mission, objectives, and operational model. It is frankly not possible to finalize a registry's infrastructure and funding by January 1, 2005, therefore it would not be acceptable to withhold primary prevention ICD therapy until it is fully operational. At CMS' request the Heart Rhythm Society has appointed representatives, including the Chair, to the Heart Rhythm Society's National ICD Registry Working Group. Representatives from the ACC, AHA, Heart Failure Society of America, industry, and other groups with experience in national registry management will also be participating. This Working Group will develop the purpose and structure of the registry, as well as, recommend a business model that will improve its sustainability. The Heart Rhythm Society agrees with CMS that reimbursement for primary prevention ICD therapy should be tied to participation in the Registry and that it will be difficult to achieve compliance if the Registry is voluntary. In addition to establishing an ICD registry, nonelectrophysiologists need time to meet the requirements for certification. Moreover, training programs and comprehensive certification processes can greatly increase compliance with the proposed ICD registry.

The Heart Rhythm Society requests a grace period while the registry is developed, funding is identified, and the infrastructure established for patient data entry. The Heart Rhythm Society National ICD Registry Working Group will advise CMS about a reasonable time frame required to meet this objective. During that interval the Heart Rhythm Society recommends that CMS provide coverage for life-saving primary prevention ICD therapy.

Thank you for your consideration. My patients who will be saved by ICD implants thank you.

**Commenter: Miller, Maurice**

Organization: Date: October 26, 2004 Comment:

With up to 1,200 Americans killed daily by sudden cardiac arrest, I'm encouraged by the latest decision to expand Medicare coverage of implantable cardioverter defibrillators for at-risk patients.

But, it is important to note that the new coverage still leaves tens of thousands of people at risk that is preventable if Medicare reimbursement covered everyone at high-risk for sudden cardiac arrest.

Please consider including all Medicare recipients with heart failure who are at high risk for SCA. And please don't delay the decision while waiting for more data/information. We need access to this important medical care by January 1, 2005.

**Commenter: Morrison, Laura**

Organization: Baylor College of Medicine Date: October 6, 2004 Comment:

As a physician who is pursuing research into the appropriate management of Implantable Defibrillators and pacemakers in patients approaching the end of life, I urge CMS to consider the implications for end of life care of the already increasing implantable cardiac device numbers. This specific realm within end of life care is poorly defined at present largely because those involved in implanting such devices do not currently address the potential management issues that might arise for the patient when the patient someday approaches the end of his/her life (perhaps the need or desire to "turn off" the device or to address future battery replacement). For this reason, I am very interested in how you might use your potential data base/device registry to measure such outcomes. I would definitely be interested in accessing this data base at some point.

Additionally and More Importantly, I wonder if you might build in incentives or requirements for completion of advance directives, advance care planning, and/or an educational pathway (including addressing potential device issues around the end of life) to be completed by the health care provider with the patient, at the time of device implantation. We've begun to define this implantation time as a potential intervention point for addressing these issues. This subarea of end of life care deserves and should be receiving an increased level of attention in the near future. The ethical and practical aspects of end of life device management need to be addressed to give patients quality end of life care.

I welcome any contact.

**Commenter: Mossler, Jeffrey**

Organization: Date: October 21, 2004 Comment:

The language about expecting the majority of ICD's to be single chamber devices ignores some of the advantages of dual chamber devices. Although an atrial lead may not affect mortality, it can contribute to quality of life, both by allowing atrial paced pacing and chronotropic support, and by avoiding inappropriate shocks by differentiating between supraventricular and ventricular arrhythmias using information from the atrial lead. Just because the single chamber device was shown to save lives doesn't mean that a dual chamber device is "unproven." I am concerned that patients will get single chamber devices and subsequently require upgrades when a brady indication arises. This subjects patients to a 2nd procedure and excess cost. Implanting the best device for a patient the first time seems most prudent

**Commenter: Mulder, Barbara**

Organization: Date: October 25, 2004 Comment:

Thank you for providing coverage for ICDs to many Medicare patients at risk for SCA. But the CMS decision has left out around 100,000 Americans at high-risk for SCA.

I wanted you to know that a large number of Medicare patients have no other healthcare options. If ICDs are not covered for those left out, what will they do if they need this device? How can we deny them access to an ICD?

Please cover all Americans at high risk for SCA. Research has proven who needs an ICD. I'm concerned that waiting to collect more data will result in unnecessary deaths. The fact is that we can't let another day go by without this care.

Thank you for the opportunity to share my opinion on this matter.

Thank You,

**Commenter: Murphy, Barbara**

Organization: Date: October 12, 2004 Comment:

Thank you for providing coverage for ICDs to many Medicare patients at risk for SCA. But the CMS decision has left out around 100,000 Americans at high-risk for SCA.

I wanted you to know that a large number of Medicare patients have no other healthcare options. If ICDs are not covered for those left out, what will they do if they need this device? How can we deny them access to an ICD?

Please cover all Americans at high risk for SCA. Research has proven who needs an ICD. I'm concerned that waiting to collect more data will result in unnecessary deaths. The fact is that we can't let another day go by without this care.

Thank you for the opportunity to share my opinion on this matter.

Thank You,

**Commenter: Murphy, Joseph**

Organization: Date: October 20, 2004 Comment:

I am very happy to have the chance to provide my comments on ICDs to CMS. Thank you. This is an issue that means so much to me because SCA is a leading killer of Americans. I appreciate CMS's decision to provide critical coverage to so many Americans who depend on Medicare, but CMS must consider those who were left out.

There are approximately 100,000 Americans who are at great risk for SCA and won't have ICD coverage. Please increase coverage to these folks so that they can have access to this amazing technology that makes the difference between life and death sooner rather than later.

Sincerely,

**Commenter: Negri, Patricia**

Organization: Date: October 12, 2004 Comment:

With up to 1,200 Americans killed daily by sudden cardiac arrest, I'm encouraged by the latest decision to expand Medicare coverage of implantable cardioverter defibrillators for at-risk patients.

But, it is important to note that the new coverage still leaves tens of thousands of people at risk that is preventable if Medicare reimbursement covered everyone at high-risk for sudden cardiac arrest.

Please consider including all Medicare recipients with heart failure who are at high risk for SCA. And

please don't delay the decision while waiting for more data/information. We need access to this important medical care by January 1, 2005.

Thank you,

**Commenter: Nelson, Roy**

Organization: Date: October 19, 2004 Comment:

Thank you, CMS, for making the decision to reimburse for ICDs for many heart failure patients. ICD's are the best chance these Americans have for preventing sudden cardiac arrest. However, your decision has excluded some Americans who are at the same risk for sudden cardiac arrest. What are those left out of the CMS decision supposed to do for protection from this silent killer?

Please revise your decision to include all patients that need ICDs. And please make that decision now. We need protection from sudden cardiac arrest before it kills thousands more.

Sincerely,

**Commenter: Newman, Mary**

Organization: Date: October 28, 2004 Comment:

Members of the Sudden Cardiac Arrest Alliance, comprised of the healthcare and public safety organizations and patient associations that are signatories to this letter, would like to commend the Centers for Medicare & Medicaid Services (CMS) for broadening its coverage of implantable cardioverter-defibrillators (ICDs) to the thousands of Americans at risk for sudden cardiac arrest (SCA). As ardent supporters for increased access to early defibrillation, we believe that this decision will help save thousands of lives each year from the nation's #1 killer.

We are, however, concerned that the preliminary decision limited coverage to those patients with an ejection fraction of 30 percent or less, leaving nearly 100,000 high-risk Americans without adequate protection from SCA. Clinical trial data demonstrate that patients with an ejection fraction of 35 percent also would benefit from ICD therapy. We support this clinical evidence and encourage you to reconsider.

The Alliance also is concerned that an additional condition in the preliminary Decision could further delay coverage. Specifically, postponing reimbursement to implement a registry or other bureaucratic process would result in many unnecessary deaths.

As advocates for the thousands of individuals who are at high risk for SCA and in honor of those who die tragically and needlessly every day, the Sudden Cardiac Arrest Alliance respectfully requests CMS to consider our concerns and act with firm resolve to prevent further fatalities from SCA.

Thank you in advance for your consideration.

Sincerely,

**Commenter: Olive, Tasha**

Organization: Date: October 12, 2004 Comment:

With up to 1,200 Americans killed daily by sudden cardiac arrest, I'm encouraged by the latest decision to expand Medicare coverage of implantable cardioverter defibrillators for at-risk patients.

But, it is important to note that the new coverage still leaves tens of thousands of people at risk that is preventable if Medicare reimbursement covered everyone at high-risk for sudden cardiac arrest.

Please consider including all Medicare recipients with heart failure who are at high risk for SCA. And please don't delay the decision while waiting for more data/information. We need access to this important medical care by January 1, 2005.

Thank you,

**Commenter: Pace, James**

Organization: Date: October 19, 2004 Comment:

With up to 1,200 Americans killed daily by sudden cardiac arrest, I'm encouraged by the latest decision to expand Medicare coverage of implantable cardioverter defibrillators for at-risk patients.

But, it is important to note that the new coverage still leaves tens of thousands of people at risk that is preventable if Medicare reimbursement covered everyone at high-risk for sudden cardiac arrest.

Please consider including all Medicare recipients with heart failure who are at high risk for SCA. And please don't delay the decision while waiting for more data/information. We need access to this important medical care by January 1, 2005.

Thank you,

**Commenter: Palmer, James**

Organization: Date: October 25, 2004 Comment:

I am very happy to have the chance to provide my comments on ICDs to CMS. Thank you. This is an issue that means so much to me because SCA is a leading killer of Americans. I appreciate CMS's decision to provide critical coverage to so many Americans who depend on Medicare, but CMS must consider those who were left out.

There are approximately 100,000 Americans who are at great risk for SCA and won't have ICD coverage. Please increase coverage to these folks so that they can have access to this amazing technology that makes the difference between life and death sooner rather than later.

Sincerely,

**Commenter: Parnell, Herb**

Organization: Date: October 27, 2004 Comment:

Thank you for providing coverage for ICDs to many Medicare patients at risk for SCA. But the CMS decision has left out around 100,000 Americans at high-risk for SCA.

I wanted you to know that a large number of Medicare patients have no other healthcare options. If ICDs are not covered for those left out, what will they do if they need this device? How can we deny them access to an ICD?

Please cover all Americans at high risk for SCA. Research has proven who needs an ICD. I'm concerned that waiting to collect more data will result in unnecessary deaths. The fact is that we can't let another day go by without this care.

Thank you for the opportunity to share my opinion on this matter.

Thank You,

**Commenter: Perry, Dorothy**

Organization: Date: October 22, 2004 Comment:

Sudden cardiac arrest is a leading cause of death, of men and women alike, in the United States. It usually shows no signs and symptoms and is responsible for the death of as many as 400,000 Americans each year. Yet there is hope based on the recent ICD study.

ICDs can provide comfort for many people as it acts like a life preserver, preventing sudden glitches in the heart before they can lead to death. While I am appreciative of CMS's recent decision to reimburse ICDs for many heart failure patients, I believe that this measure falls short, as it does not protect all heart failure patients at risk, especially those with no other option for protection from cardiac arrest. I implore you to protect ALL AMERICANS at high risk from this terrible affliction. Please decide to include all at-risk patients and don't delay implementation of this decision - lives are at risk while we wait.

Please step up to the challenge today!

Thank you for your attention to this matter.

**Commenter: Peters, Glenn**

Organization: Date: October 12, 2004 Comment:

CMS should be commended for its recent decision to reimburse ICDs for many heart failure patients. ICDs offer the best protection from sudden cardiac arrest. However, there are more Americans who remain without protection. Some heart failure patients that showed benefit from ICDs in recent clinical trials were excluded from the decision. I really question this part of the decision because without an ICD, these people stand very little chance of surviving a sudden cardiac arrest. Please help ALL Americans who could benefit from this amazing device have the protection they need. Your final decision must come before January 2005 to save as many lives as possible.

Thank you for taking the time to hear my concerns.

Sincerely,

**Commenter: Pinski, Sergio L. MD**

Organization: Date: October 28, 2004 Comment:

My name is Sergio L. Pinski, MD. I am a practicing electrophysiologist. I am the Head, Section of Cardiac Pacing and Electrophysiology at Cleveland Clinic Florida. I have a few comments regarding your recent draft decision memo regarding defibrillator coverage.

I strongly oppose your proposal to create a mandatory National Registry for prophylactic defibrillator implants. It is indeed possible to enter implant information into such a registry, as the vast majority of implants are performed in relatively large hospitals and by a small number of electrophysiologists. However, it will be almost impossible to obtain reliable follow-up information. You are interested in collecting data regarding "appropriate" and spurious ICD shocks. Do you know that these patients and devices are followed-up in thousands of private offices, often times hundreds of miles away from the implanting center? Many of these follow-up doctors are general cardiologists, not electrophysiologists. How could you enforce data submission? As a doctor practicing in South Florida, I can tell you that most Medicare beneficiaries in whom I implant defibrillators are "snowbirds". They return to their East coast and Midwest hometowns, which are often small and without electrophysiologists. How could I be responsible for their follow-up data? Some patients never return to me. If you only consider the ones who do, you'll end up with a biased sample. Your idea of a follow-up registry reflects profound lack of knowledge regarding how health care is delivered in this country and the geographical mobility of the Medicare population.

My second concern regarding the Registry is the need for local Institutional Review Board approval. Most IRBs would require written informed consent to allow data to be submitted outside the institution for research and publication purposes. The need for such an informed consent would be very detrimental. Many patients will believe that the proposed therapy with an implantable defibrillator is investigational or experimental and will turn it down. Long, otherwise unnecessary discussions will be needed. This is a big disservice to the patients. As a matter of fact, this therapy is supported by more data than most others.

I also urge you to drop your requirement of a "shock-only" device for prophylactic insertion. The previous round of comments showed a consensus regarding the value of antitachycardia pacing. This was further supported by the recently published PainFreeII trial (Circulation 2004;110:2591-2596). Insistence on such a requirement will have an undesirable consequence. Many electrophysiologists will perform an otherwise unnecessary electrophysiological study before ICD implant in order to justify the type of device that they feel the patient needs based on clinical grounds. Thus, costs will paradoxically increase. Your tactic aimed at reducing costs could backfire!

Thank you for your consideration. Please do not hesitate to call me if I can be of any assistance.

**Commenter: Powell, Patricia**

Organization: Date: October 25, 2004 Comment:

I am writing to comment on the recent decision of the Centers for Medicare and Medicaid Services to reimburse implantable cardioverter defibrillators.

While it is a first step in the right direction, many people who are at risk have been left out of the

preliminary decision, and will not have any other option to prevent a sudden cardiac arrest. For example, many Medicare recipients have that program as their only form of health care and won't be protected under the current decision.

It is crucial that all Americans at high risk get the protection they need from this terrible killer. With up to 450,000 people in this country dying every year from sudden cardiac arrest, the stakes are too high to implement this incomplete approach to reimbursement. Please increase the reimbursement options for ICDs to all at risk. Please don't make additional requests for data too cumbersome. Implementation of this landmark decision shouldn't be delayed past the 1st of the year.

Thank you for the opportunity to present my thoughts on this critical issue.

Regards,

**Commenter: Preuss, G**

Organization: Date: October 12, 2004 Comment:

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While it is a first step in the right direction, many people who are at risk have been left out of the preliminary decision, and will not have any other option to prevent a sudden cardiac arrest. For example, many Medicare recipients have that program as their only form of health care and won't be protected under the current decision.

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Thank you for the opportunity to present my thoughts on this critical issue.

Regards,

**Commenter: Pushee, Gordon**

Organization: Date: October 19, 2004 Comment:

Thank you for providing coverage for ICDs to many Medicare patients at risk for SCA. But the CMS decision has left out around 100,000 Americans at high-risk for SCA.

I wanted you to know that a large number of Medicare patients have no other healthcare options. If ICDs are not covered for those left out, what will they do if they need this device? How can we deny them access to an ICD?

Please cover all Americans at high risk for SCA. Research has proven who needs an ICD. I'm concerned that waiting to collect more data will result in unnecessary deaths. The fact is that we can't let another day go by without this care.

Thank you for the opportunity to share my opinion on this matter.

Thank You,

**Commenter: Pyne, Vicki**

Organization: Date: October 26, 2004 Comment:

I am very happy to have the chance to provide my comments on ICDs to CMS. Thank you. This is an issue that means so much to me because SCA is a leading killer of Americans. I appreciate CMS's decision to provide critical coverage to so many Americans who depend on Medicare, but CMS must consider those who were left out.

There are approximately 100,000 Americans who are at great risk for SCA and won't have ICD coverage. Please increase coverage to these folks so that they can have access to this amazing technology that makes the difference between life and death sooner rather than later.

Sincerely,

**Commenter: Rankin, James**

Organization: Date: October 26, 2004 Comment:

Sudden cardiac arrest is a leading cause of death, of men and women alike, in the United States. It usually shows no signs and symptoms and is responsible for the death of as many as 400,000 Americans each year. Yet there is hope based on the recent ICD study.

ICDs can provide comfort for many people as it acts like a life preserver, preventing sudden glitches in the heart before they can lead to death. While I am appreciative of CMS's recent decision to reimburse ICDs for many heart failure patients, I believe that this measure falls short, as it does not protect all heart failure patients at risk, especially those with no other option for protection from cardiac arrest. I implore you to protect ALL AMERICANS at high risk from this terrible affliction.

Please decide to include all at-risk patients and don't delay implementation of this decision - lives are at risk while we wait.

Please step up to the challenge today!

Thank you for your attention to this matter.

**Commenter: Renke, Rosemary**

Organization: Date: October 12, 2004 Comment:

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There are approximately 100,000 Americans who are at great risk for SCA and won't have ICD coverage. Please increase coverage to these folks so that they can have access to this amazing technology that makes the difference between life and death sooner rather than later.

Sincerely,

**Commenter: Reynolds, Matthew**

Organization: Date: October 27, 2004 Comment:

We appreciate the effort CMS has put into this coverage decision, and the opportunity provided for public commentary. We will restrict our comments to the idea of creating a national ICD registry, as suggested in your draft decision memorandum. This is potentially a very ambitious undertaking, with significant scientific, organizational, and technologic challenges to be considered.

It may be worthwhile to assess first the type of data that already gets collected on patients having ICDs implanted, and then thinking about what type of additional data might be desired, and for what purposes. Once those issues are defined, thought must be given to how additional data could be collected, centralized, and analyzed.

Current data collection

Medicare patients currently undergoing ICD implantation have data collected in at least two places: first Medicare's own billing files (e.g. the Standard Analytical Files and Medical Provider Analysis and Review Files), and second, in industry databases. The CMS files contain limited demographic data, diagnosis and procedure codes, and charge/cost data, as well as data on the billing institutions and physicians.

ICD manufacturers collect a limited set of data on all patients currently undergoing ICD implantation. Data includes limited demographics, limited cardiac history (e.g. diagnosis, ejection fraction, indication for procedure) and more detailed information about the pulse generators and leads (model and serial numbers, implant measurements, etc.). Manufacturers have good information systems for tracking device recipients, technical performance of devices over time, and timing of device replacement. To the best of our knowledge, this data is managed in-house at the device companies.

At present, the combined data collected by CMS and the device companies lack the richness in clinical detail that a more ambitious registry would aim to capture. What additional data should be collected will depend on the specific aims of the registry.

The data that is collected at the local practitioner/hospital level is likely highly variable. Electronic medical record systems are rapidly growing in use around the country, but at present, there are many different systems in use, many hospitals have not yet adopted them, and we would expect great variability both in the nature of the data contained in such systems and in the ability of the systems to transfer data to external sites.

Possible aims of an ICD registry

One possible aim of an ICD registry would be to assist in regulatory oversight. Collecting slightly more detailed information regarding patient characteristics, types of devices implanted, and practice settings and qualifications of implanting physicians will allow CMS and other parties to monitor compliance with reimbursement and other policy. This will help insure that devices are implanted by qualified physicians for appropriate indications, and that off-label use of the devices is minimized. However, other mechanisms (e.g. institutional audits) are probably equally or more effective at promoting compliance, and some of the issues for which guidelines have been published (e.g. recommended qualifications of implanting physicians) are not currently associated with any enforcement mechanisms.

Another possible aim of a registry would be quality improvement. A number of regional and now national registries have been developed for tracking the outcomes of patients undergoing cardiac catheterization, percutaneous coronary interventions, and bypass surgery. These databases have been used to generate risk-adjusted outcome measures against which individual institutions can benchmark their performance. Researchers have also been able to use this data to scientifically explore various quality indicators (e.g. by exploring the relationship between surgical volume and outcomes). Making quality improvement a focused part of the registry activities has improved buy-in from the clinical community, and empirical evidence suggests that collecting and publicly reporting outcomes data helps identify and promote the adoption of best practices nationwide.

Unfortunately, we do not see as compelling a role for quality improvement with an ICD registry as with other registries, although this possibility should not be ignored. This is mainly because current outcomes with ICD implantation appear to be generally excellent. Mortality and significant morbidity with ICD implants are quite low, and the overall impact of minor complications (lead dislodgements, pocket hematomas, etc.) is small. While much could be learned regarding the optimal programming of devices for different patient groups (e.g. avoidance of RV pacing and its relationship with heart failure decompensation; efficacy of anti-tachycardia pacing; incidence and avoidance of inappropriate shocks, etc.) some of these questions will be better addressed by more focused study designs. Nonetheless, the large scale outcomes data generated by a national registry should be used for an analysis of uncommon but important device related complications.

We feel the most important aims for an ICD registry are the analysis of patient Outcomes in real-world practice, and the exploration of scientific questions that require very large sample sizes, including the issue of risk stratification. A number of authorities have expressed concerns about the generalizability of ICD trials. For example, trials have enrolled very small numbers of subjects >80 years in age. It stands to reason that elderly patients with multiple comorbid illnesses may not enjoy the same benefits from ICD implantation as subjects in published clinical trials. Under-powered sub-group analyses have also raised questions about the efficacy of ICDs in women as compared with men. The enhanced statistical power of registry data will allow for assessment of these and other questions.

We have stated previously that the issue of risk stratification for potential ICD recipients merits further study. Although ICDs were associated with statistically significant survival benefits in both MADIT 2 and SCD-HeFT, the magnitude of benefit was smaller than in earlier studies like MADIT and MUSTT that employed additional risk stratifiers beyond ejection fraction alone, such as non-sustained VT and programmed ventricular stimulation. More recently, microvolt t-wave alternans has shown potential value for stratifying risk in both coronary and non-coronary myopathy patients. However, the clinical community has been unable to reach any consensus on how to risk-stratify patients. If properly designed, an ICD registry might help in the search for ways to optimally target ICDs through risk-stratification.

The major limitation for outcomes research with an ICD registry will be the fact that, presumably, only patients actually receiving ICDs will get enrolled. This will confound many possible analyses, since patient outcomes in the absence of intervention will not be available for comparison. An additional challenge, as well, is that sophisticated outcomes research will require follow-up data on these patients, which will be much more complicated to collect and analyze than data regarding patient and procedural characteristics and outcomes at a single point in time. Certain surrogate end point data such as ICD shocks may be obtainable, but we would stress that ICD shocks are not equivalent to death, as empirical evidence shows that ICD shocks are 2-3 times more prevalent in trial populations than all-cause mortality in control groups.

It seems likely, therefore, that risk stratification data from an ICD registry will at best be hypothesis generating. Nonetheless, the possibility of creating rich data sets for exploration of these scientific questions remains valuable.

#### Data Elements

It will not be possible to generate a full list of data fields until consensus is reached on the aims, funding, and organization of a registry. We are aware of the formulation of a working group, including the American College of Cardiology (ACC), the Heart Rhythm Society (HRS), device companies, and others to address these questions.

Rather than attempt to duplicate the activity of that working group, for now, we would simply state that the choice of data fields will be driven by (1) the chosen aims of the registry, (2) the willingness of parties involved to share data already being collected, (3) the feasibility of extracting data from the local practitioner level, including follow-up data, and (4) the amount of funding available to implement data collection and analysis. Obviously, the more ambitious the registry's aims, the more it will require collecting detailed clinical information from individual practice sites including follow-up data at greater cost.

We would add that, based on the different possible registry aims discussed above, it may make sense to construct two registries, or a comprehensive registry with a small sub-registry. For example, administrative, demographic, and basic device data would be fairly straightforward to combine using existing data collection methods. With little to no additional input from local practitioners, a full registry of all ICD recipients could be constructed to address the aims of regulatory oversight and perhaps limited aspects of outcomes assessment and quality improvement in the acute setting. It would appear possible to make the data collection for this type of registry mandatory for payment from CMS. The collection of more detailed clinical and follow-up information could be reserved for a smaller number of centers on a voluntary basis that have higher volumes, better medical information systems, and more interest in the scientific questions under investigation.

## Data Collection Issues

As alluded to above, practitioners and the institutions at which they work currently possess medical information with everything from paper charts to sophisticated electronic systems. While most hospitals have relatively mature systems for the handling of billing data, billing systems typically have little integration with the collection and storage of clinical data. While a number of software vendors have developed medical information systems for other registry efforts (e.g. the ACC's National Cardiovascular Data Registry), existing software is relatively primitive for electrophysiology applications, and not widely used at present.

Successful data collection for an ICD registry will therefore require significant effort both at local and central levels. This may create resistance at local levels particularly if the registry is mandatory due to the need for data entry that is either additive or duplicative to current practice. Efforts to simplify and facilitate local data collection, such as with electronic data capturing systems, will be needed.

A centralized clearinghouse for data collection and management will have to be selected or created. Optimally, this task should be performed by an independent or academically affiliated data coordinating center, and not the government or the device industry. The data coordinating center will need to have the capacity to perform electronic data capture. This will allow data entry and cleaning to be done at the local level, which will substantially lower the costs of data management centrally. The data coordinating center will need to work closely with the bodies that oversee the registry.

## Sponsorship

The cost of an ICD registry should be shared primarily between industry and government. With the currently favorable coverage decision on SCD-HeFT, the device industry stands to enjoy continued rapid growth in device implantation rates. Device companies will not have a strong 'business case' for sponsoring additional risk stratification studies or conducting cost-effectiveness analyses. The existing data collection methods in use by device manufacturers today should be leveraged.

The federal government has a major stake in an ICD registry and will have to support it financially, particularly if the aims include regulatory oversight and improvement of patient selection, the latter of which might eventually reduce medical expenditures. Several sources of funding could be pursued, including grants from CMS itself, from the Agency for Healthcare Research and Quality, and from the National Institutes of Health. Each, of course, has its own competitive processes for selecting investigators.

Finally, national cardiology organizations including the ACC and HRS may be able to provide limited financial support to the registry, although we expect advice, organizational support, and leadership to be more important.

## Planning/oversight/participation

The organization of a multi-disciplinary group to spearhead the registry has already been announced, with stated involvement from academia, industry, government, and national cardiology organizations. At this point, we would only stress the vital importance of keeping the process open, transparent, and balanced. Both the device industry and implanting electrophysiologists stand to benefit from an expansion in ICD implantation around the country. A high degree of intellectual honesty will be needed to maximize the yield of a registry effort. A broadly representative steering committee with

diverse and global perspectives should be involved at every step.

#### Meta-analysis of existing data

Finally, we strongly agree with comments made by CMS and others that pooling of data from already completed clinical trials would be a good way to begin addressing some of the scientific questions that have arisen regarding risk stratification and other topics. For example, under the supervision of Dr. Al Buxton, the MUSTT data has been retrospectively reviewed in order to identify markers of risk (data on the prognostic significance of signal-averaged ECG, standard baseline ECGs, and programmed stimulation have been published; additional data evaluating a composite risk score has been presented at meetings and is pending publication). The MADIT investigators have also retrospectively evaluated different risk markers in their data sets.

Pooling data from completed ICD trials would have one major advantage over analysis of registry data, particularly on the topic of risk stratification, and that is the careful evaluation and follow-up of control group patients who did not have ICDs implanted. Information regarding outcomes in such patients is necessary in order to compare risk stratification schemes, since ICD implantation will reduce the overall mortality of a registry population, and ICD shocks cannot be used as an accurate proxy for death.

We strongly urge the principal investigators of the comparable major primary prevention ICD trials (MUSTT, MADIT, MADIT 2, DEFINITE, and SCD- HeFT) to pool their data in order for such analysis to be performed. Again, optimally, such analysis could be directed through an independent data coordinating center with oversight from a steering committee similar to the one directing the registry effort.

Sincerely,

**Commenter: Richardson, June**

Organization: Date: October 12, 2004 Comment:

I appreciate the chance to comment on the recent CMS decision regarding coverage and reimbursement of ICDs. Nearly one thousand Americans die every day of SCA, and your decision is an important step in the right direction. However, I urge CMS to expand ICD coverage to every American proven to be at risk for SCA. Some were excluded from the preliminary decision, and that has me worried. Every death from SCA is an unnecessary tragedy, and I respectfully request that you expand coverage. Please don't wait for more data that may cause a delay - many Americans need ICDs to live.

Please work to get this therapy available for Americans this year.

Respectfully,

**Commenter: Riley, Joan**

Organization: Date: October 12, 2004 Comment:

Thank you, CMS, for making the decision to reimburse for ICDs for many heart failure patients. ICD's are the best chance these Americans have for preventing sudden cardiac arrest. However, your decision has excluded some Americans who are at the same risk for sudden cardiac arrest. What are those left out of the CMS decision supposed to do for protection from this silent killer?

Please revise your decision to include all patients that need ICDs. And please make that decision now. We need protection from sudden cardiac arrest before it kills thousands more.

Sincerely,

**Commenter: Risk, Alicia**

Organization: Date: October 12, 2004 Comment:

Thank you, CMS, for making the decision to reimburse for ICDs for many heart failure patients. ICD's are the best chance these Americans have for preventing sudden cardiac arrest. However, your decision has excluded some Americans who are at the same risk for sudden cardiac arrest. What are those left out of the CMS decision supposed to do for protection from this silent killer?

Please revise your decision to include all patients that need ICDs. And please make that decision now. We need protection from sudden cardiac arrest before it kills thousands more.

Sincerely,

**Commenter: Rittelmeyer, James T., MD**

Organization: Date: August 11, 2004 Comment:

This letter is being sent in support of Microvolt T-wave alternans as being useful in the decision making regarding implantation of implantable defibrillators.

I am a board certified cardiologist who has been interested in electrophysiology and pacing for over 20 years. I am a member of a 9 person cardiology group with a very busy practice. I am involved in the decision making regarding implantation of pacemakers and defibrillators for a very large group of internists and cardiologists in our referral area. I am also quite cost conscious when it comes to deciding who should get a defibrillator. As you can imagine, deciding who gets a defibrillator and who does not, in some people's eyes, takes on some unintended implications. For instance, some people believe you are condemning them to death if you decide not to put in a defibrillator. Other people think that the physicians deem the patient's life to be unimportant when they decide not to go forward with the defibrillator. Although this is no one's fault, patients are quite informed and when a negative decision for implantation is reached certain feelings are unavoidable.

The Microvolt T-wave alternans test has been incredibly useful in my practice. If I can demonstrate to the patient or referring physician that they are at low risk for lethal ventricular arrhythmias the decision to not implant a defibrillator can be made much more easily. I believe that we should not implant defibrillators in every person that meets MADIT II criteria but should try and be more selective for those that are high risk. The T-wave alternans test is very important in my practice in risk stratifying

patients.

The treatment of sudden cardiac death has a very interesting twist from my point of view. It is a disease (sudden cardiac death) where we have a treatment (implantable defibrillator) but we do not have a very accurate way to diagnose the disease. Normally we find the disease and then develop a treatment in a logical fashion. With sudden cardiac death, we have the treatment before we have a way to diagnose who is at high risk for sudden death. The T-wave alternans test can help bridge that gap by identifying high and low risk patients.

In summary I would say the T-wave alternans test is noninvasive, relatively inexpensive and as reliable as any other test we have out there to predict patients at high risk for sudden cardiac death. I would strongly encourage you to recommend that T-wave alternans testing be incorporated into the decision tree regarding implantation of defibrillators.

**Commenter: Rittelmeyer, James T., MD**

Organization: Date: October 5, 2004 Comment:

I would like to thank CMS for broadening the indications for ICD therapy in appropriate patients. It also gives me the feeling that someone is listening to what the physicians have to say.

I would also like to reaffirm my opinion that Microvolt T-WAVE alternans is an important discriminator in high risk patients that may need an expensive implantable defibrillator. I know that CMS wants a registry to enroll patients who have received ICDs. I have found the T-WAVE alternans test to be extremely valuable in evaluating my patients. I think it would be terrific if the registry would include T-WAVE alternans as one of the tests allowed or required in the registry.

I have attached my previous E-mail to you dated 08/11/04 to simply restate my feelings about the treatment of patients who are at risk for sudden cardiac death.

Thank you for listening.

**Commenter: Rock, Michele**

Organization: Date: October 25, 2004 Comment:

I am very happy to have the chance to provide my comments on ICDs to CMS. Thank you. This is an issue that means so much to me because SCA is a leading killer of Americans. I appreciate CMS's decision to provide critical coverage to so many Americans who depend on Medicare, but CMS must consider those who were left out.

There are approximately 100,000 Americans who are at great risk for SCA and won't have ICD coverage. Please increase coverage to these folks so that they can have access to this amazing technology that makes the difference between life and death sooner rather than later.

Sincerely,

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**Commenter: Rodriguez, Michelle**

Organization: Date: October 19, 2004 Comment:

I am very happy to have the chance to provide my comments on ICDs to CMS. Thank you. This is an issue that means so much to me because SCA is a leading killer of Americans. I appreciate CMS's decision to provide critical coverage to so many Americans who depend on Medicare, but CMS must consider those who were left out.

There are approximately 100,000 Americans who are at great risk for SCA and won't have ICD coverage. Please increase coverage to these folks so that they can have access to this amazing technology that makes the difference between life and death sooner rather than later.

Sincerely,

**Commenter: Rosenberg, Cora**

Organization: Date: October 26, 2004 Comment:

I am very happy to have the chance to provide my comments on ICDs to CMS. Thank you. This is an issue that means so much to me because SCA is a leading killer of Americans. I appreciate CMS's decision to provide critical coverage to so many Americans who depend on Medicare, but CMS must consider those who were left out.

There are approximately 100,000 Americans who are at great risk for SCA and Won't have ICD coverage. Please increase coverage to these folks so that they can have access to this amazing technology that makes the difference between life and death sooner rather than later.

Sincerely,

**Commenter: Ross, Thomas**

Organization: Date: October 4, 2004 Comment:

As a practicing electrophysiologist, I support your recommendation to extend prophylactic defibrillators to those patients with dilated cardiomyopathies, not due to coronary disease.

I feel, however, that Class IV patients should not be excluded arbitrarily. If a Class IV patient met the criteria for a CRT device, they may not be entitled to receive a combination CRT-defibrillator, despite their increased risk for sudden death. 33% of Class IV patients die from Ventricular Tachycardia or Fibrillation and it is inappropriate to exclude the implant of a combination CRT-defibrillator device (where the risk to the patient is minimal for the combination device).

I also am concerned about the true role and function of the proposed defibrillator registry. The recommendations indicate that devices can only be implanted by certified physicians at certified institutions. What are the qualifications for certification and who will supervise this? Will the creation of this registry delay the availability of devices to patients and who will be responsible for

following the patients in the registry?

In summary, I support the broader recommendation for expanding the indications for a defibrillator, but feel the restrictions of Class IV patients and the registry should be eliminated.

**Commenter: Rugh, Douglas**

Organization: Date: October 12, 1004 Comment:

I appreciate the chance to comment on the recent CMS decision regarding coverage and reimbursement of ICDs. Nearly one thousand Americans die every day of SCA, and your decision is an important step in the right direction. However, I urge CMS to expand ICD coverage to every American proven to be at risk for SCA. Some were excluded from the preliminary decision, and that has me worried. Every death from SCA is an unnecessary tragedy, and I respectfully request that you expand coverage. Please don't wait for more data that may cause a delay - many Americans need ICDs to live.

Please work to get this therapy available for Americans this year.

Respectfully,

**Commenter: Sabicer, Steve**

Organization: Date: October 12, 2004 Comment:

With up to 1,200 Americans killed daily by sudden cardiac arrest, I'm encouraged by the latest decision to expand Medicare coverage of implantable cardioverter defibrillators for at-risk patients.

But, it is important to note that the new coverage still leaves tens of thousands of people at risk that is preventable if Medicare reimbursement covered everyone at high-risk for sudden cardiac arrest.

Please consider including all Medicare recipients with heart failure who are at high risk for SCA. And please don't delay the decision while waiting for more data/information. We need access to this important medical care by January 1, 2005.

Thank you,

**Commenter: Salvia, Leonard**

Organization: Date: October 25, 2004 Comment:

I believe T Wave alternans testing should be

**Commenter: Sanders, Alice**

Organization: Date: October 14, 2004 Comment:

Thank you, CMS, for making the decision to reimburse for ICDs for many heart failure patients. ICDÆs are the best chance these Americans have for preventing sudden cardiac arrest. However, your decision has excluded some Americans who are at the same risk for sudden cardiac arrest. What are those left out of the CMS decision supposed to do for protection from this silent killer?

Please revise your decision to include all patients that need ICDs. And please make that decision now. We need protection from sudden cardiac arrest before it kills thousands more.

Sincerely,

**Commenter: Sanders, Karen**

Organization: Date: October 12, 2004 Comment:

Thank you for providing coverage for ICDs to many Medicare patients at risk for SCA. But the CMS decision has left out around 100,000 Americans at high-risk for SCA.

I wanted you to know that a large number of Medicare patients have no other healthcare options. If ICDs are not covered for those left out, what will they do if they need this device? How can we deny them access to an ICD?

Please cover all Americans at high risk for SCA. Research has proven who needs an ICD. I'm concerned that waiting to collect more data will result in unnecessary deaths. The fact is that we can't let another day go by without this care.

Thank you for the opportunity to share my opinion on this matter.

Thank You,

**Commenter: Sarter, Brian**

Organization: Date: September 30, 2004 Comment:

I am a practicing electrophysiologist and have implanted ICDs over the past ten years. I am very concerned with CMS decision to require participation in a national registry in order to use ICD implantation for primary prevention of SCD. This requirement will undoubtedly delay or deny the use of these life saving devices in appropriate patients. Careful review of the data suggests that the scientific basis for primary prevention is stronger than previous studies evaluating secondary prevention. Therefore this requirement appears to be arbitrary and overly restrictive. I urge you to remove this requirement and allow us to provide this crucial life saving therapy for our patients.

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**Commenter: Scarborough, Rebecca**

Organization: Date: October 19, 2004 Comment:

CMS should be commended for its recent decision to reimburse ICDs for many heart failure patients. ICDs offer the best protection from sudden cardiac arrest. However, there are more Americans who remain without protection. Some heart failure patients that showed benefit from ICDs in recent clinical trials were excluded from the decision. I really question this part of the decision because without an ICD, these people stand very little chance of surviving a sudden cardiac arrest. Please help ALL Americans who could benefit from this amazing device have the protection they need. Your final decision must come before January 2005 to save as many lives as possible.

Thank you for taking the time to hear my concerns.

**Commenter: Schatz, Bernie**

Organization: Date: October 19, 2004 Comment:

With up to 1,200 Americans killed daily by sudden cardiac arrest, I'm encouraged by the latest decision to expand Medicare coverage of implantable cardioverter defibrillators for at-risk patients.

But, it is important to note that the new coverage still leaves tens of thousands of people at risk that is preventable if Medicare reimbursement covered everyone at high-risk for sudden cardiac arrest.

Please consider including all Medicare recipients with heart failure who are at high risk for SCA. And please don't delay the decision while waiting for more data/information. We need access to this important medical care by January 1, 2005.

Thank you,

**Commenter: Schnellbaecher, Matthew**

Organization: Date: October 28, 2004 Comment:

I applaud the agency's decision to expand the coverage for ICDs to include MADIT II and most SCD-Heft patients. These two studies clearly identified the life saving value of defibrillator therapy and now more patients being eligible increases our odds for reducing Sudden Cardiac Death.

I care for Alaska Native patients here at the Alaska Native Medical Center in Alaska. Many of my patients live in rural villages and many are very reluctant to have a defibrillator implanted when they feel well, in spite of the risk reduction demonstrated in MADIT II and SCUD-HEFT. I believe that the proposed registry has value in determining whether ICD therapy is appropriate for all these patients if Microvolt Twave Alternans is a required element.

I believe that by making Microvolt Twave Alternans a required element of the registry, we will gain valuable and additional information, which should address my concerns about appropriate use of ICD in these new populations. All the potential risk stratifiers mentioned in the policy with the exception of MTWA have been available for some time. MTWA represents a more specialized technology than previously evaluated risk stratifiers because of its proven very high negative predictive value.

Using T wave alternans to further risk stratify patients will assist me greatly in knowing which patients need to be convinced more firmly that an AICD is a reasonable option.

It seems to me that with the relatively small absolute decrease in mortality seen in SCD-HeFT and the seemingly low number of appropriate firings, a risk stratifier like Microvolt Twave Alternans should be evaluated more closely and included as a required element of the patient registry.

**Commenter: Seifert, Mark**

Organization: Date: October 15, 2004 Comment:

I have serious reservations regarding the requirement that patients receiving ICDs for indications derived from the recently published SCD-HeFT study be enrolled in a registry. I am aware of no other proven therapy with such a requirement for Medicare reimbursement. The registry will require disclosure of information that, if disclosed without patient authorization, would clearly violate HIPPA requirements. The requirement that patients trade their privacy for appropriate care and agree to enroll in a registry or be denied a life saving therapy raises serious ethical concerns.

**Commenter: Seumalo, Tulele**

Organization: Date: October 12, 2004 Comment:

Thank you for the opportunity to submit my comments on this important issue. Sudden cardiac arrest kills more Americans than any other condition. It kills between 340,000 and 450,000 people every year - more than 1,000 people every day. Please, please consider providing ICDs for all at-risk Americans. Your preliminary decision leaves out some Medicare patients who could die without an ICD. People who rely on Medicare have no other options and need to be covered before the end of the year.

Thank you for considering this issue of such significant importance.

Thank you,

**Commenter: Sexson, Richard**

Organization: Date: October 25, 2004 Comment:

Thank you for providing coverage for ICDs to many Medicare patients at risk for SCA. But the CMS decision has left out around 100,000 Americans at high-risk for SCA.

I wanted you to know that a large number of Medicare patients have no other healthcare options. If ICDs are not covered for those left out, what will they do if they need this device? How can we deny them access to an ICD?

Please cover all Americans at high risk for SCA. Research has proven who needs an ICD. I'm concerned that waiting to collect more data will result in unnecessary deaths. The fact is that we can't let another day go by without this care.

Thank you for the opportunity to share my opinion on this matter.

Thank You,

**Commenter: Shorofsky, Stephen**

Organization: Date: October 18, 2004 Comment:

I strongly agree with the proposed changes. The data is clear that patients with cardiomyopathies (no matter the cause) and low ejection fractions benefit from ICDs. The idea of the registry is also good. My concerns are about its

implementation and financing. Who is going to run it and who is going to pay for it? A registry similar to the cardiac surgery registry would be useful for both research and quality improvements.

**Commenter: Silver, Murray**

Organization: Date: October 13, 2004 Comment:

I am very happy to have the chance to provide my comments on ICDs to CMS. Thank you. This is an issue that means so much to me because SCA is a leading killer of Americans. I appreciate CMS's decision to provide critical coverage to so many Americans who depend on Medicare, but CMS must consider those who were left out.

There are approximately 100,000 Americans who are at great risk for SCA and won't have ICD coverage. Please increase coverage to these folks so that they can have access to this amazing technology that makes the difference between life and death sooner rather than later.

Sincerely,

**Commenter: Simons, Grant R., M.D.**

Organization: Englewood Hospital and Medical Center Date: October 7, 2004 Comment:

I am a practicing electrophysiologist, and I implant prophylactic ICD's per the existing indications and CMS reimbursement policies. It is important that we permit appropriate access without bankrupting CMS. In my opinion, the SCD-Heft trial results should not change anything we do for patients with ischemic cardiomyopathy, since the absolute mortality benefit was even smaller than that seen in MADIT-II, and the data have not even been published. Furthermore, the absolute mortality benefit was hidden in the presentation, and you have to deduce it yourself. The relative mortality benefit was given, but this is of course irrelevant to cost effectiveness considerations. Thus, I suggest that we keep the 30% cut-off for ischemic cardiomyopathy.

The wide QRS requirement is generally accepted to be without scientific merit, and the CMS allowance for inducible VF has served as a loophole. If CMS wishes for risk stratification, a more rigorous definition of a positive EP study will be required, including the stimulation protocol. Personally, I think that we should dump the wide QRS requirement and withhold ICD's only from patients with both negative T-wave alternans and EP studies. This is supported in the literature. Thus, we could start with a T-wave alternans. If it is positive or indeterminate, an ICD would be placed. If it is negative, an EP study would be performed, with an ICD for those with positive EP studies. This would reduce the number of EP studies and also provide the possibility of withholding ICD's from truly low-risk patients.

With regards to non-ischemic cardiomyopathy, it is unlikely that another trial will be performed, and the SCD-Heft results, coupled with the DEFINITE trial, (which I think had a type II error), persuade me that we should be putting in ICD's for nonischemics with low EF's perhaps below 30% as well. I hope that CMS will change its policy in this regard.

Finally, I think that CMS should make a stand regarding who puts these devices in, to prevent what has happened in the area of pacemaker insertion, where poorly qualified, mercenary physicians have over-prescribed pacemakers for over a decade, often with the help of device companies. There are too many pacemakers being put in, and many of them don't work properly. In the case of ICD's, there is more cost and more danger.

I hope that CMS will do what NASPE was afraid to do-require insertions and follow-ups by physicians who have completed an electrophysiology fellowship. This will help to insure that our limited resources are conserved and our patients are cared for by qualified practitioners. Furthermore, the small mortality benefit seen in these trials can be wiped out by poor technique. Of course, exemptions should be granted for rural areas where access is a problem. Despite what the device companies say, however, there are few places in the United States where this is actually the case. There is nothing wrong with CMS stating that fellowship-trained physicians are more qualified, since CMS is paying the bills.

**Commenter: Singer, Sid**

Organization: Date: October 25, 2004 Comment:

Sudden cardiac arrest is a leading cause of death, of men and women alike, in the United States. It usually shows no signs and symptoms and is responsible for the death of as many as 400,000 Americans each year. Yet there is hope based on the recent ICD study.

ICDs can provide comfort for many people as it acts like a life preserver, preventing sudden glitches in the heart before they can lead to death. While I am appreciative of CMS's recent decision to reimburse ICDs for many heart failure patients, I believe that this measure falls short, as it does not protect all heart failure patients at risk, especially those with no other option for protection from cardiac arrest. I implore you to protect ALL AMERICANS at high risk from this terrible affliction.

Please decide to include all at-risk patients and don't delay implementation of this decision û lives are at risk while we wait.

Please step up to the challenge today!

Thank you for your attention to this matter.

**Commenter: Sloan, Stephen**

Organization: Date: October 8, 2004 Comment:

I recently reviewed your position on expanded indications for the ICD. I am happy to see that the entire MADIT II patient population will now be covered. I really wonder how many more patients will die while we await the formulation of a registry? As a practicing EP it will really be virtually impossible to continue to withhold the ICD from patients who meet MADIT II criteria. If a nonischemic class III chf patient who is 65 yr and whose measured EF is 32 % dies suddenly should I really feel that

I did the right thing for the patient by withholding the ICD. I really do not think so.

I think that we do need some caution in implanting ICDs in elderly patients with serious comorbidities. And I really do not believe that ICD's should be placed in Nursing Home patients or patients close to being placed in a nursing home. But I cannot endorse my values on my patients, although I do have frank discussions with the patients and family.

**Commenter: Sogade, Felix MD**

Organization: Date: October 26, 2004 Comment:

I believe the use of defibrillators in general will help the risk of sudden death. However, indiscriminate prescription of this therapy by inadequately trained practitioners can negate the benefits. The registry should report outcomes based on the background training and experience of the practitioners. It should track every attempted but failed implant and implant related adverse events

**Commenter: Sorrentino, Robert MD**

Organization: Duke University Medical Center-Cardiac EP Date: October 21, 2004 Comment:

Having personally reviewed the CMS recommendation for the expanded indication for ICD I have to agree with the suggestions as laid out by the Heart Rhythm Society. I think that all of their points are valid, practical and supported by the data in the medical literature. I too have concerns about creating, funding and implementing an ICD registry. One of my concerns is also that of patient confidentiality and HIPPA. Not only would a patient need to meet indications for implantation but the patient would be forced to participate in the registry which is likely to be illegal or unconstitutional and may even be unethical. Otherwise I agree with the Heart Rhythm Society's comments as written below.

Otherwise I agree with the Heart Rhythm Society's comments as written below.

Robert A. Sorrentino, MD FACC Clinical Director, Cardiac Electrophysiology Duke University Medical Center Durham, NC

Heart Rhythm Society û Summary of Comments Submitted to CMS on Draft ICD Coverage Policy

1) Ejection Fraction: The benefit of primary prevention ICD therapy for patients with Ischemic or Nonischemic cardiomyopathy and left ventricular ejection fraction (LVEF) We recommend that the coverage decision be revised to include patients with LVEF of 35% or less.

2) Nine Month Interval for Non-Ischemic Implant SCDHeFT required patients to have stable Class II-III heart failure for 3 months prior to entry into the study. CMS has extended this interval to 9 months without justification. If the intent is to exclude patients with a reversible nonischemic cardiomyopathy, this objective will be met using the 3-month criteria required by SCDHeFT. We recommend patients have a diagnosis of nonischemic cardiomyopathy for >3 months on appropriate medical therapy.

3) Class IV Patients

The COMPANION trial indicates patients with Class IV heart failure benefit from biventricular pacing. If cardiac resynchronization therapy is employed without an ICD (CRT-D) and the patient improves to NYHA Class III heart failure, then it will be necessary to upgrade the system from CRT to CRT-D. This exposes the patient to two procedures and ultimately increases the cost and risk of therapy. The Heart Rhythm Society recommends that coverage for CRT-D be extended to patients with Class IV heart failure.

#### 4) Documented Myocardial Infarction

The CMS policy excludes patients with acute MI within 1 month or percutaneous transluminal coronary angioplasty within 3 months. The Heart Rhythm Society believes that patients with well documented remote MI and longstanding LV dysfunction (LVEF 35% or less), should not be excluded from ICD therapy if they are admitted with another MI or the need for a second PTCA. In such patients the underlying disease is not reversible. They already met criteria for an ICD before their most recent admission. The Heart Rhythm Society recommends that coverage be extended to patients if they already met the criteria for an ICD prior to their most recent MI, CABG, or PTCA.

5) Device Selection shock only The Heart Rhythm Society concurs with CMS that single lead ICDs should be implanted for primary prevention therapy unless there are indications for dual chamber pacing or cardiac resynchronization therapy. We are concerned about the statement that ICDs should be "shock only" devices for primary prevention therapy. Prior clinical studies demonstrated that some patients require pacing after a shock is delivered. Moreover, anti-tachycardia pacing reduces exposure to painful shocks. The inclusion of anti-tachycardia pacing does not have an appreciable impact on the cost of the device. We conclude that this option should be available. The decision to program anti-tachycardia pacing into the arrhythmia termination algorithm should be left to the discretion of the physician. The reality is that all current devices manufactured by Guidant, Medtronic, and St. Jude incorporate anti-tachycardia algorithms. It would be unnecessary and potentially harmful to patients to deactivate this beneficial technology simply to meet the criteria for a "shock only" device. The Heart Rhythm Society recommends that the term shock only be removed from the coverage decision. The remainder of that paragraph regarding physician documentation of device selection is appropriate.

6) ICD Registry for Primary Prevention ICD Therapy The Heart Rhythm Society strongly supports the need for Hospitals and providers to be certified as competent in ICD implantation and commends CMS for the inclusion of these criteria in the proposed registry. We urge that the recent guidelines developed by the Heart Rhythm Society and endorsed by the ACC serve as the basis for this certification. Although the Society supports the principle of requiring an ICD registry, it will clearly take a substantial effort to fully define the registry's mission, objectives, and operational model. It is frankly not possible to finalize a registry's infrastructure and funding by January 1, 2005, therefore it would not be acceptable to withhold primary prevention ICD therapy until it is fully operational. At CMS' request the Heart Rhythm Society has appointed representatives, including the Chair, to the Heart Rhythm Society's National ICD Registry Working Group. Representatives from the ACC, AHA, Heart Failure Society of America, industry, and other groups with experience in national registry management will also be participating. This Working Group will develop the purpose and structure of the registry, as well as, recommend a business model that will improve its sustainability. The Heart Rhythm Society agrees with CMS that reimbursement for primary prevention ICD therapy should be tied to participation in the Registry and that it will be difficult to achieve compliance if the Registry is voluntary. In addition to establishing an ICD registry, nonelectrophysiologists need time to meet the requirements for certification. Moreover, training programs and comprehensive certification processes can greatly increase compliance with the proposed ICD registry. The Heart Rhythm Society requests a grace period while the registry is developed, funding is identified, and the infrastructure established for patient data entry. The Heart Rhythm Society National ICD Registry Working Group will advise

CMS about a reasonable time frame required to meet this objective. During that interval the Heart Rhythm Society recommends that CMS provide coverage for life-saving primary prevention ICD therapy.

**Commenter: Souresrafil, Omid, MBBS**

Organization: Date: October 26, 2004 Comment:

The decision for the expansion of coverage for ICDS is no doubt welcomed by all colleagues in the field. However there is quite a few issues with the conditions attached. Lets examine the taking part of the patients in a registry type study. The process of consenting patients and making sure the patients finish the study without missing follow-up visits is a serious issue.

In the process of consenting patients, they are given a choice, and are told about alternative therapies. I seriously doubt any patient would take part in a clinical study where the alternative is the therapy itself. There are serious ethical issues in withholding ICD therapy for patients who due to various reasons cannot take part in a study. And there are hundreds of legitimate reasons. I absolutely cannot a proven therapy to patients who are indicated for it. Lets have a look at the registry issue. Having taken parts in clinical trials, and conducted IDE and post market registry type of studies, I am certain that designing such a trial of massive proportions in beyond the capability of a single entity be it device companies or national government bodies.

And I fail to imagine what the primary endpoint of this registry would be. SCDHeft did a good job of answering the key question of whether ICDs save lives. And they do.

**Commenter: Spinoso, Robert**

Organization: Date: October 27, 2004 Comment:

CMS should be commended for its recent decision to reimburse ICDs for many heart failure patients. ICDs offer the best protection from sudden cardiac arrest. However, there are more Americans who remain without protection. Some heart failure patients that showed benefit from ICDs in recent clinical trials were excluded from the decision. I really question this part of the decision because without an ICD, these people stand very little chance of surviving a sudden cardiac arrest. Please help ALL Americans who could benefit from this amazing device have the protection they need. Your final decision must come before January 2005 to save as many lives as possible.

Thank you for taking the time to hear my concerns.

Sincerely,

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**Commenter: Springer, Michael**

Organization: Medical Center Cardiologists PSC Date: October 17, 2004 Comment:

Please do not use a registry as an excuse to deny coverage. Why do we need a registry when well controlled studies have proven the benefits of ICD's and BiV ICD's?

I would like to suggest that CMS formulate a rule that implanting physicians for ICD's must be Board Eligible in Electrophysiology or pass an exam to be created by the Heart Rhythm Society. The HRS recently made recommendations for cardiologists who are not electrophysiologists to be able to implant ICD's. One of the criteria is that the physician take a didactic course not sponsored by industry. I think this is way too vague and no one is going to police this.

**Commenter: Stauffer, Charles**

Organization: Date: October 25, 2004 Comment:

Thank you for the opportunity to submit my comments on this important issue. Sudden cardiac arrest kills more Americans than any other condition. It kills between 340,000 and 450,000 people every year - more than 1,000 people every day. Please, please consider providing ICDs for all at-risk Americans. Your preliminary decision leaves out some Medicare patients who could die without an ICD. People who rely on Medicare have no other options and need to be covered before the end of the year.

Thank you for considering this issue of such significant importance.

Thank you,

**Commenter: Stiefel, Raymond**

Organization: Date: October 27, 2004 Comment:

Thank you for providing coverage for ICDs to many Medicare patients at risk for SCA. But the CMS decision has left out around 100,000 Americans at high-risk for SCA.

I wanted you to know that a large number of Medicare patients have no other healthcare options. If ICDs are not covered for those left out, what will they do if they need this device? How can we deny them access to an ICD?

Please cover all Americans at high risk for SCA. Research has proven who needs an ICD. I'm concerned that waiting to collect more data will result in unnecessary deaths. The fact is that we can't let another day go by without this care.

Thank you for the opportunity to share my opinion on this matter.

Thank You,

**Commenter: Stieger, Mike**

Organization: Date: October 19, 2004 Comment:

Thank you for providing coverage for ICDs to many Medicare patients at risk for SCA. But the CMS decision has left out around 100,000 Americans at high-risk for SCA.

I wanted you to know that a large number of Medicare patients have no other healthcare options. If ICDs are not covered for those left out, what will they do if they need this device? How can we deny them access to an ICD?

Please cover all Americans at high risk for SCA. Research has proven who needs an ICD. I'm concerned that waiting to collect more data will result in unnecessary deaths. The fact is that we can't let another day go by without this care.

Thank you for the opportunity to share my opinion on this matter.

Thank You,

**Commenter: Stillwell, Teresa**

Organization: Date: October 12, 2004 Comment:

I am writing to comment on the recent decision of the Centers for Medicare and Medicaid Services to reimburse implantable cardioverter defibrillators.

While it is a first step in the right direction, many people who are at risk have been left out of the preliminary decision, and will not have any other option to prevent a sudden cardiac arrest. For example, many Medicare recipients have that program as their only form of health care and won't be protected under the current decision.

It is crucial that all Americans at high risk get the protection they need from this terrible killer. With up to 450,000 people in this country dying every year from sudden cardiac arrest, the stakes are too high to implement this incomplete approach to reimbursement. Please increase the reimbursement options for ICDs to all at risk. Please don't make additional requests for data too cumbersome. Implementation of this landmark decision shouldn't be delayed past the 1st of the year.

Thank you for the opportunity to present my thoughts on this critical issue.

Regards,

**Commenter: Stinnett, Paul**

Organization: Date: October 26, 2004 Comment:

CMS should be commended for its recent decision to reimburse ICDs for many heart failure patients. ICDs offer the best protection from sudden cardiac arrest. However, there are more Americans who remain without protection. Some heart failure patients that showed benefit from ICDs in recent clinical trials were excluded from the decision. I really question this part of the decision because without an ICD, these people stand very little chance of surviving a sudden cardiac arrest. Please help ALL Americans who could benefit from this amazing device have the protection they need. Your final decision must come before January 2005 to save as many lives as possible.

Thank you for taking the time to hear my concerns.

Sincerely,

**Commenter: Strine, Charles**

Organization: Date: October 25, 2004 Comment:

Thank you for providing coverage for ICDs to many Medicare patients at risk for SCA. But the CMS decision has left out around 100,000 Americans at high-risk for SCA.

I wanted you to know that a large number of Medicare patients have no other healthcare options. If ICDs are not covered for those left out, what will they do if they need this device? How can we deny them access to an ICD?

Please cover all Americans at high risk for SCA. Research has proven who needs an ICD. I'm concerned that waiting to collect more data will result in unnecessary deaths. The fact is that we can't let another day go by without this care.

Thank you for the opportunity to share my opinion on this matter.

Thank You,

**Commenter: Sweeney, Michael Owen, M.D.**

Organization Date: October 25, 2004 Comment:

I have read the recent CMS Decision Summary regarding expanded coverage for ICD therapy. I appreciate the care and thought that went into the construction of this document. The reference list is complete and up to date. While I do not agree entirely with some proposed implementations I applaud the decision to advance the cause of primary prevention of sudden cardiac death, which as you know, kills more Americans each year than breast cancer, lung cancer, HIV and stroke combined.

However, I would like to refocus your attention on a difficult and unresolved clinical problem accompanying ICD therapy that has significant implications for optimal patient care and healthcare costs. Though conventional ICD therapy has been consistently shown to reduce mortality in appropriately selected patient populations, this has come at the cost of increased risk of heart failure hospitalization. This observation is consistent across 4 trials of primary prevention (CABG-PATCH,

MADIT, MADIT II and SCD-HeFT) even when a mortality benefit is not conferred by ICD therapy (CABG-PATCH). In fact, the increased risk of heart failure hospitalization in MADIT II was nearly equivalent in magnitude to the risk reduction of mortality attributed to ICD therapy (1). This is very concerning, since heart failure is a major and growing health problem with nearly five million Americans currently diagnosed and up to 550,000 new cases diagnosed annually. The cost of managing heart failure is estimated to be as high as \$56.6 billion annually with heart failure contributing 5-10% of all hospital admissions and 12-15 million office visits each year (2).

The CMS document correctly notes that this increased risk of heart failure associated with ICD therapy appears to be caused by unnecessary and potentially deleterious right ventricular pacing. This problem has been the focus of intense clinical research. Right ventricular apical pacing produces a left ventricular electrical activation sequence resembling left bundle branch block. This may result in prolonged QRSd and ventricular desynchronization. The resulting alteration in mechanical activation may result in impaired hemodynamic performance and mitral regurgitation (3). Right ventricular apical pacing also causes chronic changes in regional myocardial perfusion (4), cellular structure (5), and ventricular geometry (6) that may impair ventricular performance (7, 8). These experimental observations are validated by the clinical observation that chronic ventricular pacing causes increased left atrial diameters and reduced left ventricular fractional shortening compared to atrial pacing (8).

The DAVID Trial was conducted to test whether dual-chamber (DDDR) pacing would enable optimal heart failure management and reduce heart failure hospitalization and death in ICD patients compared to ICD patients programmed to ventricular only backup pacing (VVI 40) (9). In fact, the opposite outcome occurred with increased heart failure hospitalization and death in the DDDR pacing mode. The increased heart failure hospitalization and death in the DDDR mode was presumably due to the high percentage of ventricular pacing in the DDDR arm. The common misinterpretation of the DAVID Trial is that "complex" ICDs worsen systolic heart failure. However, note that vast majority of patients who experience worsening heart failure in the primary prevention studies cited above had "simple" single chamber ICD systems. Specifically, 100% of patients had "simple" single chamber ICD systems in CABG-PATCH, DINAMIT and SCD-HeFT, whereas 54% of patients in MADIT II had single chamber ICDs. Furthermore, a recent analysis of MADIT II demonstrated that the adverse effects of ventricular pacing on heart failure, ventricular arrhythmias and death were insensitive to ICD system and pacing mode (single or dual)(10), consistent with data from the Mode Selection Trial (MOST)(11). The accurate interpretation of this evidence base is that any unnecessary right ventricular pacing, even small amounts from "simple" single chamber ICD systems can worsen heart failure in susceptible individuals. The magnitude of the effect relates to the frequency of ventricular pacing, not the ICD system specifically. Interestingly, a subsequent analysis of the DAVID population revealed that the heart failure hospitalization event-free rate was lowest in the DDDR arm where cumulative percent VP < 40% even compared to ventricular only backup pacing (VVI 40) (12). The correct conclusion is that DAVID is a study in the mismanagement of ventricular pacing in failing ventricles.

Misinterpretation of the DAVID results, economic considerations, and paranoia about coverage and reimbursement have resulted in a scientifically unsound posture regarding device selection, particularly in primary prevention patients. Many electrophysiologists now believe that all ICD patients who require, or "might" require cardiac pacing should be treated with resynchronization therapy (CRTD). The misguided corollary is that all remaining patients are well served by "simple" single chamber ICD systems. Though means of identifying appropriate patients for CRT are evolving, it is probably true that <40% of primary prevention ICD candidates meet qualifying criteria for CRT. Thus, there is a real concern about overuse of CRTD among ICD patients who require or "might" require physiologic pacing support, which will increase costs and place patients at risk for potentially serious and expensive

complications. Similarly, the use of "simple" single chamber ICD systems among all other patients will be accompanied by increased healthcare costs due to the increased incidence of heart failure hospitalization. The penalty of living longer with conventional ICD therapy is an increased risk of heart failure due to sub-optimal management of ventricular pacing.

All available clinical trial data suggests that a pacing mode capable of maintaining atrial rate support (atrioventricular synchrony) while preserving normal ventricular activation (ventricular synchrony) by minimizing ventricular pacing would achieve equivalent or lower heart failure hospitalization rates compared to ventricular only backup pacing (VVI 40) (11-13). Two conventional solutions have been proposed in ICD and pacemaker systems for providing atrial support while reducing ventricular pacing: dual chamber modes (DDD/R or DDI/R) with fixed long atrioventricular (AV) intervals and single chamber atrial pacing (AAI/R). Dual chamber modes with long AV intervals can reduce ventricular pacing. However, nearly a third of the patients still have >30% ventricular pacing with potentially deleterious effects on ventricular pumping function and a high susceptibility to pacemaker-mediated arrhythmias (8, 14, 15). By definition, AAI/R pacing eliminates the possibility of ventricular pacing and may provide effective pacing support for patients with intact AV conduction. Though the annualized risk of AV block is low during AAI/R pacing in carefully selected patients, the first manifestation is syncope in more than 50% of cases (8, 16, 17). Since the fundamental purpose of cardiac pacing is to prevent symptomatic bradycardia, syncope due to the lack of a ventricular pacing lead is unacceptable. Furthermore standard AAI/R pacing does not consider ventricular activity; therefore during a ventricular arrhythmia asynchronous atrial paces in AAI/R mode can blank (conceal) ventricular events potentially resulting in a delay in arrhythmia detection with potentially lethal consequences (18). Since the inclusion of a ventricular pacing lead in ICDs is mandatory for the detection of ventricular arrhythmias, delivery of antitachycardia pacing, delivery of ventricular defibrillation therapy and to prevent potentially lethal post-defibrillation bradycardia, an algorithm to effectively utilize the information from the ventricular lead within the context of an AAI mode is warranted. Therefore, single chamber AAI/R pacing does not infer a reduction in system cost and complexity in ICDs. To put it simply, a ventricular lead is needed to prevent death and there is growing evidence that an atrial lead is needed to provide physiologic pacing support and prevent unnecessary heart failure due to incidental ventricular pacing. A novel solution to this problem is Managed Ventricular Pacing (MVP). MVP was developed to address the inherent limitations of AAI/R pacing and dual chamber modes that incorporate a fixed or dynamic atrioventricular interval. The MVP modes promote intrinsic conduction by reducing unnecessary right ventricular pacing. MVP provides atrial-based pacing with ventricular backup. For loss of atrioventricular conduction the device switches to DDD/R mode. Periodic checks are performed, and if atrioventricular conduction resumes, the device switches back to AAI/R mode.

The MVP mode has been demonstrated to be feasible, safe and effective on the basis of 2 FDA IDE studies (19, 20). Ventricular pacing was reduced from a mean value of 73.8% (median value 87.9%) to a mean value of 4.1% (median value of 0.06%) compared to conventional DDD/R pacing. Furthermore, cumulative ventricular pacing was less than 1% occurred in 75% of patients. This reduction in ventricular pacing was achieved without sacrificing atrial pacing support, atrioventricular synchrony and ventricular synchrony (unlike the VVI/R mode), and without forced ventricular desynchronization due to right ventricular apical pacing (unlike the DDD/R mode).

MVP provides atrial rate support while preserving normal ventricular activation. MVP's capabilities may enable a more optimal heart failure therapy regimen in ICD patients compared to VVI 40 pacing mode. This hypothesis is being tested in the MVP Trial, which is being carried out at 80 sites in the United States, Canada and Europe with an enrollment target of 1000 patients. This study is designed to determine if minimization of ventricular pacing with MVP is equivalent to or superior to VVI 40 pacing

with regard to freedom from all cause mortality and heart failure-related urgent care and heart failure hospitalization.

I have included some selected slides to highlight important points in this letter. I would be happy to come to Baltimore and discuss these issues with you and your colleagues in whatever format was deemed most suitable. If you have other suggestions for communication regarding these complex and important considerations, please advise. Thank you for consideration.

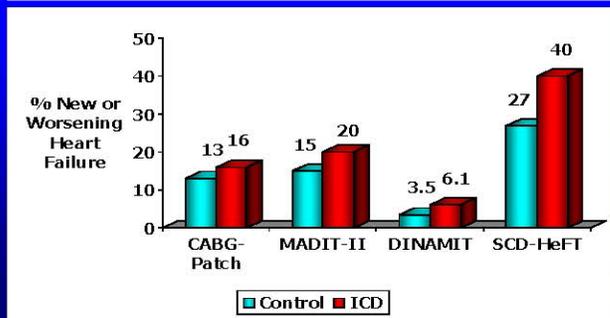
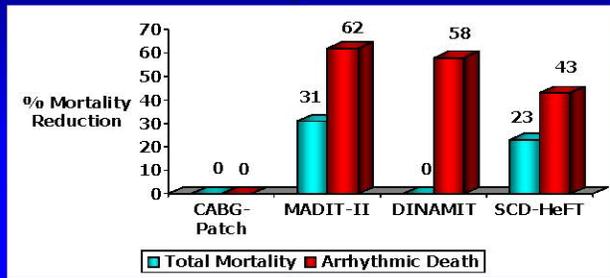
Sincerely,

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# Primary Prevention ICDs: New or Worsening Heart Failure



**Commenter: Swinnie, Jackie**

Organization: Date: October 26, 2004 Comment:

Sudden cardiac arrest is a leading cause of death, of men and women alike, in the United States. It usually shows no signs and symptoms and is responsible for the death of as many as 400,000 Americans each year. Yet there is hope based on the recent ICD study.

ICDs can provide comfort for many people as it acts like a life preserver, preventing sudden glitches in the heart before they can lead to death. While I am appreciative of CMS's recent decision to reimburse ICDs for many heart failure patients, I believe that this measure falls short, as it does not protect all heart failure patients at risk, especially those with no other option for protection from cardiac arrest. I implore you to protect ALL AMERICANS at high risk from this terrible affliction. Please decide to include all at-risk patients and don't delay implementation of this decision - lives are at risk while we wait.

Please step up to the challenge today!

**Commenter: Takata, Theodore**

Organization: Consultants in Cardiology Date: October 21, 2004 Comment:

Recommend decreasing from nine month to three month the wait for nonischemic dilated cardiomyopathy.

Reversibility of transient dilated cardiomyopathy will be captured after a three month period; A recent myocardial infarction or revascularization procedure should not exclude an individual for ICD consideration if there is a remote history of a myocardial infarction and previously documented EF < 35% (i.e., their clinical status prior warranted ICD consideration); 3. The term "shock only" devices should be removed. Antitachycardia pacing is an important component of modern ICD therapy;

The term "shock only" devices should be removed. Antitachycardia pacing is an important component of modern ICD therapy;

**Commenter: Techtman, Rita**

Organization: Date: October 26, 2004 Comment:

Thank you for providing coverage for ICDs to many Medicare patients at risk for SCA. But the CMS decision has left out around 100,000 Americans at high-risk for SCA.

I wanted you to know that a large number of Medicare patients have no other healthcare options. If ICDs are not covered for those left out, what will they do if they need this device? How can we deny them access to an ICD?

Please cover all Americans at high risk for SCA. Research has proven who needs an ICD. I'm concerned that waiting to collect more data will result in unnecessary deaths. The fact

is that we can't let another day go by without this care.

Thank you for the opportunity to share my opinion on this matter.

Thank You,

**Commenter: Thompson, Bob**

Organization: Date: October 28, 2004 Comment

Medtronic, Inc. is one of the world's leading medical technology companies specializing in implantable and interventional therapies that alleviate pain, restore health, and extend life. We are committed to the continual research and development necessary to produce high quality products and to support innovative therapies that improve patients' health outcomes. We appreciate the opportunity to comment on the SCD-HeFT draft national coverage decision (NCD) for implantable cardioverter defibrillators (ICDs) that expands coverage to thousands of heart failure patients at risk of sudden cardiac death. While the draft NCD increases coverage of ICD therapy based on the most rigorous of scientific evidence, we are concerned that the draft decision imposes unnecessary obstacles to our mutual objective that patients at risk for sudden cardiac death can appropriately access this important therapy.

### **Registry requirement**

#### Feasibility

Medtronic is an active participant in the Heart Rhythm Society (HRS) led "working group" which has been charged with exploring the best scientific approach, including the merit and feasibility of a broad registry approach, to address any outstanding CMS questions regarding ICD therapy for primary prevention patients. Some of the issues this group will address include: what questions should be studied through a registry, what data should be collected, how should it be collected, who should compile it, analyze it and have access to it, and finally, who should pay for it and how will physicians and hospitals be reimbursed for the additional burden. Since this group will not complete its work before the end of the comment period, we will respond to the registry requirement as proposed by CMS.

While we have serious concerns with a broad registry linked to Medicare coverage for the reasons cited below, Medtronic is absolutely committed to continued research on the primary prevention population. We have numerous significant studies underway (see Appendix A for partial list) and others planned to continue to understand the characteristics of patients who benefit from ICD therapy. We are also supportive of any collective research effort that emerges from the HRS led working group as long as its scientifically sound, feasible, provides value in proportion to expense, and ensures patient access to this therapy.

Decoupling As proposed in the draft policy, CMS requires that all primary prevention patients agree to participate in a registry as a requirement for receiving coverage. However, since the scientific question to be addressed has not yet been determined and it is not possible to create the infrastructure necessary for such an undertaking in the time remaining before coverage goes into effect, it is imperative that the registry requirement be decoupled from the coverage decision. This will ensure that primary prevention patients have the opportunity to receive treatment by CMS's scheduled start date - January 1, 2005 – the timeframe established by the Medicare Modernization Act (MMA).

Scientific question

The evidentiary need for the registry requirement is lacking. CMS has proposed no specific question to be addressed by the registry in the preliminary coverage proposal, just that participation in a registry be a requirement for coverage. ICD therapy has been FDA approved for nearly 20 years and Medicare coverage has been in place since 1986. ICD therapy research is the best research in the device industry, with numerous large randomized controlled trials, including SCD-HeFT, which is the largest and longest follow up ICD trial ever performed.

The SCD-HeFT draft policy CMS lists registries as sixth in the hierarchy of evidence, much lower than the quality of evidence from a randomized trial. This places the proposed registry behind a number of higher caliber research efforts currently underway or being planned. For example, Medtronic is already conducting more than 15 prospective ICD studies including studies directed toward risk stratification for implant, e.g. T-wave alternans (Medtronic's MASTER study), genetics, and biomarkers (Appendix A). Given the history of rigorous research of ICD therapy, it is not clear what questions remain to be answered as a prerequisite to coverage for this population that has proven to be at risk of sudden cardiac death. For areas with lesser quantity or quality of data, a post coverage registry requirement may make sense.

### Scope

With respect to its size, content and corresponding costs, any ICD primary prevention patient registry, or other data collection mechanism, should be scoped to a sufficient number of patients and centers to address the question being posed, possibly in a demonstration project format. Gathering more complete data on a sample of patients, rather than very limited data on a census, expands the number of questions that can be answered scientifically and the value of the data collection. The sample of patients could be as large as necessary to answer the question, but it is difficult to envision an outstanding question about ICD therapy that would require enrollment of every Medicare beneficiary implanted with a device for a primary prevention indication, particularly when ICD mortality reduction in primary prevention trials has been shown to equal or exceed those in secondary prevention trials.

### Ethical concerns

There are serious ethical questions regarding the proposed registry requirement. For a well-established therapy such as ICDs, patients should not be forced to participate in a study as a condition of receiving benefits. IRBs will be reluctant to approve a mandatory post-market release trial that withholds proven therapies. The requirement discriminates against Medicare patients (since private insurers do not require a registry) and places primary prevention patients at an unjustifiable disadvantage compared to secondary prevention. A number of IRBs have already stated that the FDA Human Subject Protection regulations prevent linking study participation to receiving care. A voluntary, sample based, registry rather than a required, census based approach would mitigate these ethical concerns.

### Funding

CMS has made no provision for funding the registry. The cost of registry creation, operation and analysis, of millions of dollars per year, should be compared to other nationally funded research priorities. Providers will also need to be compensated for their participation in a registry. The registry proposal is currently an unfunded mandate which would necessitate the creation of new provider payment codes to enable the participation of hospitals and physicians. Without additional funding, patient access to this important therapy will be jeopardized.

### Coverage concerns

## Nine month requirement

In the draft policy language, CMS proposes that patients have had non-ischemic dilated cardiomyopathy (NIDCM) for at least nine months to be eligible for ICD implant coverage. This is inconsistent with SCD-HeFT enrollment criteria, which required 1,211 patients to have NIDCM for only 3 months prior to implant. According to CMS, the source of the nine-month requirement is the CAT trial, which was discontinued having achieved 10% (104) of its planned enrollment of a 1,000 patients. Given the resulting lack of statistical power, the fact that the CAT trial found no difference between treatment groups is to be expected and can not form the basis for a coverage policy limitation as it does not meet the test of evidence-based medicine.

## Ejection fraction

The proposal to exclude SCD-HeFT patients with LVEF between 30% and 35% raises significant clinical issues. Patients with an ejection fraction in this range contributed to the overall highly significant result. The study did not stratify patients by LVEF, and the fact that this sub group did not show statistical significance in an unplanned, unpowered, retrospective analysis is not evidence of lack of benefit. Many experts, including those from the NIH, have cautioned against using unplanned, post-hoc analysis for anything other than hypothesis generation.

Given the existence of appreciable risk, physicians should be allowed to consider these patients for implant. Coverage allows, but does not require that a patient receive a device. Because patient lives are at stake, denying coverage to this subgroup of the SCD-HeFT population will place clinicians in the same ethical dilemma as the QRS width limitations in the MADIT II coverage decision. We recommend reducing the duration of time that patients must have had non-ischemic dilated cardiomyopathy (NIDCM) prior to being eligible for ICD implant coverage from nine months to three.

## Class IV coverage

ICD based cardiac resynchronization therapy (CRT-D) is approved by FDA and currently covered for secondary prevention Class IV patients with both an ICD indication and wide QRS. COMPANION trial patients, the only Class IV patients CMS studied in its analysis, have wide QRS, alone. Since none of the trials for secondary prevention CRT-D devices were included in CMS' analysis, we assume these secondary prevention Class IV patients will continue to receive coverage. A consideration to expand Medicare coverage for primary prevention patients should not result in any elimination of existing coverage for secondary prevention patients without examining the clinical evidence. (See Appendix B for a complete bibliography and selected articles.) Contrary to the recommendation of HRS to its members, CMS proposes to exclude coverage for primary prevention Class IV COMPANION patients. We support coverage for primary prevention Class IV's.

## **Device concerns**

### Shock only

In the draft policy CMS requests documentation of the physician's decision to implant all but

“single-lead, shock only” devices. As an “indications” trial, designed to study patient benefit, SCD-HeFT did not address the question of device type. It demonstrated that ICD therapy is lifesaving compared to placebo in its patient population. FDA recognizes the distinction between indications and device-specific trials. Indications trials are addressed by FDA through broad functional labeling, because they are not device-specific and their results are generalizable across devices. More specifically to SCD-HeFT, the ICD used in the trial was not a shock-only device. It had back-up bradycardia pacing which was left on during the trial and had antitachycardia pacing capability, which was programmed on in some patients. There is no clinical justification for exempting any given device type from a documentation requirement. The requirement should be rewritten to simply require that choice of device be documented as part of the operative notes from the implant procedure. Reference to a “shock only” device is not supported by SCD-HeFT and should be removed from the NCD.

ATP In the draft policy CMS expressed concern about both inappropriate shocks and anti-tachycardia pacing (ATP). ATP reduces shocks including those thought to be inappropriate. The idea of adding ATP to an ICD is not new and does not lead to a more expensive device. As an alternative to high-energy defibrillation, ATP is available on single, dual and biventricular ICDs. The recently published “PainFREE Rx II” randomized, controlled trial of 634 patients showed that 81% of fast heart rhythms were terminated without shocks, and that ATP did so without any increase in adverse events such as syncope (fainting), acceleration to other potentially harmful heart rhythms or sudden death. CMS’ discussion of ATP is not germane to the question of SCD-HeFT coverage and should be dropped from the final decision or, at the very least, updated to reflect this latest research. (See Appendix C for the publication.)

## Appendix A

### **Current Medtronic ICD clinical research initiatives that address CMS’s draft decision**

\* ATP reduces shocks 81% and

Study	Study Design	Primary Objective	Inclusion Criteria	Health Care Util. Data	Quality of Life Data	Phys Pr a Ref D
PainFREE RxII*	Randomized to FVT ATP On vs. Off	Episode duration/ATP efficacy	All ICD patients		☐	
EMPIRIC	Randomized to standardized vs. tailored programming	Prop. of episodes shocked	All ICD patients	☐		
WAVE	Program Wavelet On in single chamber	PPV, Sensitivity, specificity	All single chamber ICD patients			
IDEA-VF	Blood draw of patients with and w/o history of VT/VF	Identify potential biomarkers assoc. with VT/VF (SCD)	Patients with and w/o history of VT/VF			
MASTER Main	Pts tested for TWA	Compare time to first life-threatening event in TWA+ vs. TWA- patients	EF<30, no history of VT/VF			
MASTER BioMarkers	Blood draw of all patients	Identify/validate potential biomarkers assoc. with VT/VF (SCD)	EF<30, no history of VT/VF	Health Care Util. Data	Quality of Life Data	Phys Pr a Ref D
MVP Post-Market Study	Randomized to MVP vs. VVI	All cause death and HF hospitalizations	All dual chamber ICD pts w/o pacing indication	☐	☐	
PREPARE	Non-randomized prescribed programming	Rate of syncope, VT/VF and shocks vs. physician	ICD/CRT-D pts without history of spontaneous			
PainFREE RxII*	Randomized to FVT ATP On vs. Off	Episode duration/ATP efficacy	All ICD patients		☐	
EMPIRIC	Randomized to standardized vs. tailored programming	Prop. of episodes shocked	All ICD patients	☐		
WAVE	Program Wavelet On in single chamber	PPV, Sensitivity, specificity	All single chamber ICD patients			
IDEA-VF	Blood draw of patients with and w/o history of VT/VF	Identify potential biomarkers assoc. with VT/VF (SCD)	Patients with and w/o history of VT/VF			
MASTER Main	Pts tested for TWA	Compare time to first life-threatening event in TWA+ vs. TWA- patients	EF<30, no history of VT/VF			
MASTER BioMarkers	Blood draw of all patients	Identify/validate potential biomarkers assoc. with VT/VF (SCD)	EF<30, no history of VT/VF			
MVP Post-Market Study	Randomized to MVP vs. VVI	All cause death and HF hospitalizations	All dual chamber ICD pts w/o pacing indication	☐	☐	
PREPARE	Non-randomized prescribed programming for primary prevention patients	Rate of syncope, VT/VF and shocks vs. physician discretion (historical control)	ICD/CRT-D pts without history of spontaneous VT/VF			
InSights	Registry	Describe practice patterns including patient profiles, ICD therapies usage and outcomes	All ICD patients			☐
MAVRIC	Registry	Describe practice patterns including patient profiles, ICD therapies usage and outcomes, as well as	All single chamber ICD patients			☐

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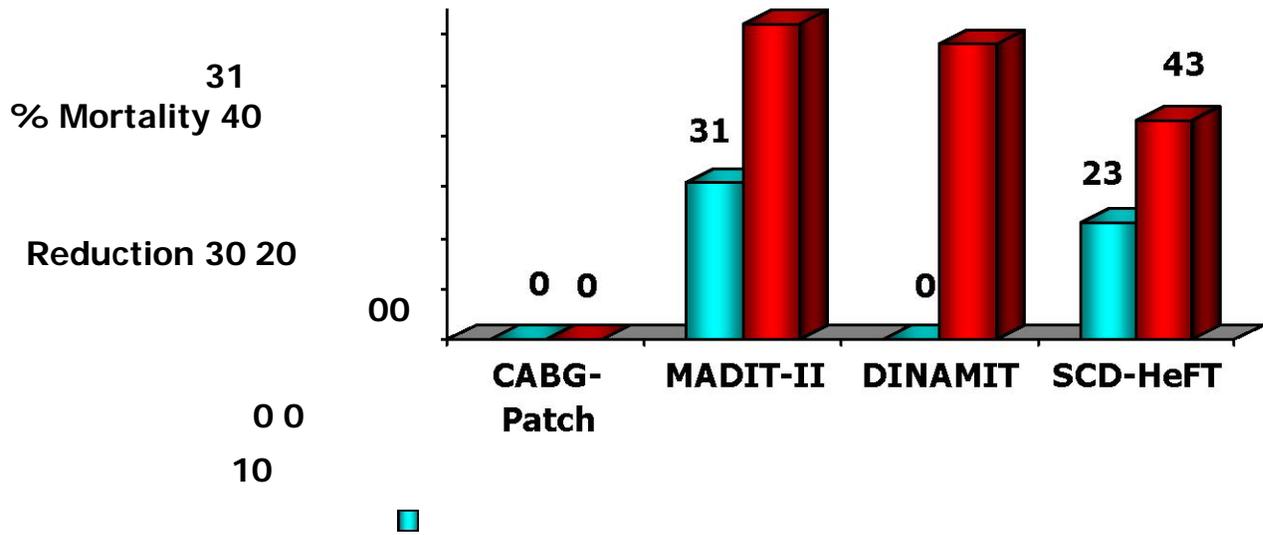
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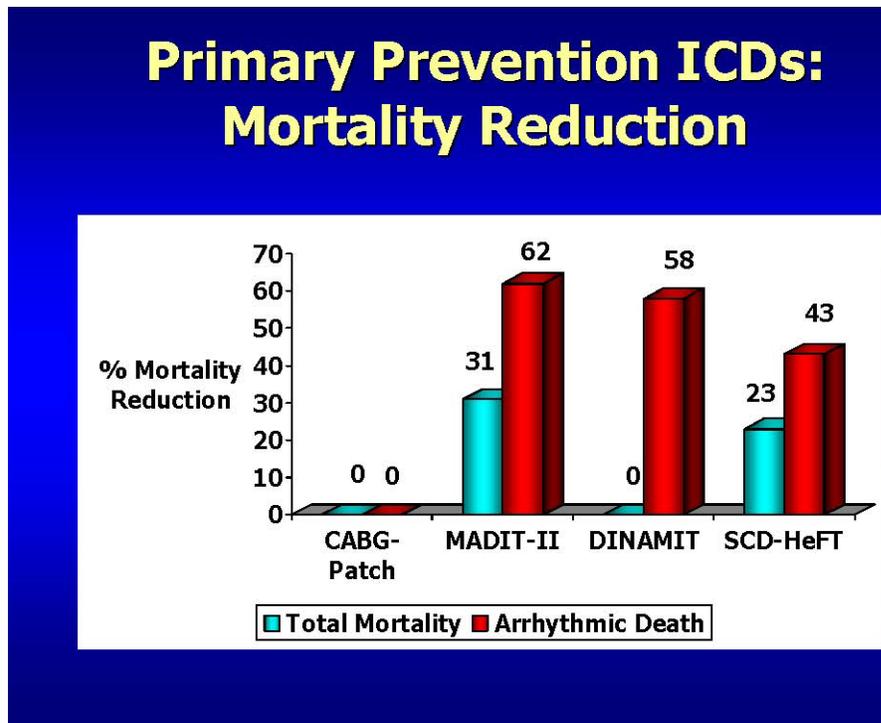
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## APPENDIX B

### CRT and Defibrillation Bibliography

Based on selections<sup>1</sup> from

Medtronic's Cardiac Resynchronization for Heart Failure Biblio

Garrigue S, Barold SS, Clementy J. Double jeopardy in an implantable cardioverter defibrillator patient.

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<sup>1</sup> Key word / term search using “defibrillat”, “ventricular tachy”, and ICD.

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I am a non-EP physician who has been implanting ICD's for 2 years with over 50 devices implanted. I have passed the NASPE exam but had fewer than the 10 proctored implants currently recommended by the HRS guidelines for non-EP implanters. If CMS plans to incorporate the HRS guidelines, a comment should be made for a possible "grandfather clause" directed at non-EP physicians who already implant ICD's. You should strongly consider including MTWA testing results in the proposed of CD registry. We have extensive experience with MTWA and are part of a national study with Medtronic (MASTER study) looking at the prospective value of MTWA testing and ventricular arrhythmias. We are very comfortable NOT recommending prophylactic ICD implantation in patients with a negative MTWA. I would favor coverage for ICD implantation on all patients with LVEF  $\leq 35\%$  (SCD-HeFT criteria) AND a non-negative MTWA. This would be a very cost-effective and clinically acceptable option, in my opinion. **Commenter: Thompson, Marvin**

Organization: Date: October 25, 2004 Comment:

Thank you, CMS, for making the decision to reimburse for ICDs for many heart failure patients. ICD's are the best chance these Americans have for preventing sudden cardiac arrest. However, your decision has excluded some Americans who are at the same risk for sudden cardiac arrest. What are those left out of the CMS decision supposed to do for protection from this silent killer?

Please revise your decision to include all patients that need ICDs. And please make that decision now. We need protection from sudden cardiac arrest before it kills thousands more.

Sincerely,

**Commenter: Timm, Scott**

Organization: Date: October 26, 2004 Comment:

With up to 1,200 Americans killed daily by sudden cardiac arrest, I'm encouraged by the latest decision to expand Medicare coverage of implantable cardioverter defibrillators for at-risk patients.

But, it is important to note that the new coverage still leaves tens of thousands of people at risk that is preventable if Medicare reimbursement covered everyone at high-risk for sudden cardiac arrest.

Please consider including all Medicare recipients with heart failure who are at high risk for SCA. And please don't delay the decision while waiting for more data/information. We need access to this important medical care by January 1, 2005.

Thank you,

**Commenter: Tomlinson, Alexander**

Organization: Date: October 28, 2004 Comment:

With up to 1,200 Americans killed daily by sudden cardiac arrest, I'm encouraged by the latest decision to expand Medicare coverage of implantable cardioverter defibrillators for at-risk patients.

But, it is important to note that the new coverage still leaves tens of thousands of people at risk that

is preventable if Medicare reimbursement covered everyone at high-risk for sudden cardiac arrest.

Please consider including all Medicare recipients with heart failure who are at high risk for SCA. And please don't delay the decision while waiting for more data/information. We need access to this important medical care by January 1, 2005.

Thank you,

**Commenter: Travnikar, Bernie**

Organization: Date: October 16, 2004 Comment:

Thank you for the opportunity to submit my comments on this important issue. Sudden cardiac arrest kills more Americans than any other condition. It kills between 340,000 and 450,000 people every year - more than 1,000 people every day. Please, please consider providing ICDs for all at-risk Americans. Your preliminary decision leaves out some Medicare patients who could die without an ICD. People who rely on Medicare have no other options and need to be covered before the end of the year.

Thank you for considering this issue of such significant importance.

Thank you,

**Commenter: Tubbs, Kelly**

Organization: Date: October 12, 2004 Comment:

With up to 1,200 Americans killed daily by sudden cardiac arrest, I'm encouraged by the latest decision to expand Medicare coverage of implantable cardioverter defibrillators for at-risk patients.

But, it is important to note that the new coverage still leaves tens of thousands of people at risk that is preventable if Medicare reimbursement covered everyone at high-risk for sudden cardiac arrest.

Please consider including all Medicare recipients with heart failure who are at high risk for SCA. And please don't delay the decision while waiting for more data/information. We need access to this important medical care by January 1, 2005.

Thank you,

**Commenter: Tupler, Marjorie**

Organization: Date: October 27, 2004 Comment:

I am writing to comment on the recent decision of the Centers for Medicare and Medicaid Services to reimburse implantable cardioverter defibrillators.

While it is a first step in the right direction, many people who are at risk have been left out of the preliminary decision, and will not have any other option to prevent a sudden cardiac arrest. For example, many Medicare recipients have that program as their only form of health care and won't be protected under the current decision.

It is crucial that all Americans at high risk get the protection they need from this terrible killer. With up to 450,000 people in this country dying every year from sudden cardiac arrest, the stakes are too high to implement this incomplete approach to reimbursement. Please increase the reimbursement options for ICDs to all at risk. Please don't make additional requests for data too cumbersome. Implementation of this landmark decision shouldn't be delayed past the 1st of the year.

Thank you for the opportunity to present my thoughts on this critical issue.

Regards,

**Commenter: Twardowski, Radomysl**

Organization: R.Twardowski MD Cardiology Date: October 13, 2004 Comment:

I have had contact with Cambridge Heart Company and used their equipment for over 2 years in practice. I believe MTWA is going to be an excellent noninvasive tool to risk-stratify patients before possible ICD implantation. This being in addition to careful clinical assessment and Echocardiography. One could see cost savings if some EP studies and some ICD implants were postponed. It would enhance our clinical assessment. I believe patients in North Dakota would benefit from this service.

**Commenter: Valencia, Rosia**

Organization: Date: October 25, 2004 Comment:

I am writing to comment on the recent decision of the Centers for Medicare and Medicaid Services to reimburse implantable cardioverter defibrillators.

While it is a first step in the right direction, many people who are at risk have been left out of the preliminary decision, and will not have any other option to prevent a sudden cardiac arrest. For example, many Medicare recipients have that program as their only form of health care and won't be protected under the current decision.

It is crucial that all Americans at high risk get the protection they need from this terrible killer. With up to 450,000 people in this country dying every year from sudden cardiac arrest, the stakes are too high to implement this incomplete approach to reimbursement. Please increase the reimbursement options for ICDs to all at risk. Please don't make additional requests for data too cumbersome. Implementation of this landmark decision shouldn't be delayed past the 1st of the year.

Thank you for the opportunity to present my thoughts on this critical issue.

Regards,

**Commenter: Vang, Patricia**

Organization: Date: October 18, 2004 Comment:

I appreciate the chance to comment on the recent CMS decision regarding coverage and reimbursement of ICDs. Nearly one thousand Americans die every day of SCA, and your decision is an important step in the right direction. However, I urge CMS to expand ICD coverage to every American proven to be at risk for SCA. Some were excluded from the preliminary decision, and that has me worried. Every death from SCA is an unnecessary tragedy, and I respectfully request that you expand coverage. Please don't wait for more data that may cause a delay - many Americans need ICDs to live.

Please work to get this therapy available for Americans this year.

Respectfully,

**Commenter: Van Noy, Glenn**

Organization: Date: October 25, 2004 Comment:

Thank you for providing coverage for ICDs to many Medicare patients at risk for SCA. But the CMS decision has left out around 100,000 Americans at high-risk for SCA.

I wanted you to know that a large number of Medicare patients have no other healthcare options. If ICDs are not covered for those left out, what will they do if they need this device? How can we deny them access to an ICD?

Please cover all Americans at high risk for SCA. Research has proven who needs an ICD. I'm concerned that waiting to collect more data will result in unnecessary deaths. The fact is that we can't let another day go by without this care.

Thank you for the opportunity to share my opinion on this matter.

Thank You,

**Commenter: Wallace Mike Jr.**

Organization: Date: October 13, 2004 Comment:

I appreciate the chance to comment on the recent CMS decision regarding coverage and reimbursement of ICDs. Nearly one thousand Americans die every day of SCA, and your decision is an important step in the right direction. However, I urge CMS to expand ICD coverage to every American proven to be at risk for SCA. Some were excluded from the preliminary decision, and that has me worried. Every death from SCA is an unnecessary tragedy, and I respectfully request that you expand coverage. Please don't wait for more data that may cause a delay - many Americans need ICDs to live.

Please work to get this therapy available for Americans this year.

**Commenter: Washington, Barbara**

Organization: Date: October 26, 2004 Comment:

Thank you for providing coverage for ICDs to many Medicare patients at risk for SCA. But the CMS decision has left out around 100,000 Americans at high-risk for SCA.

I wanted you to know that a large number of Medicare patients have no other healthcare options. If ICDs are not covered for those left out, what will they do if they need this device? How can we deny them access to an ICD?

Please cover all Americans at high risk for SCA. Research has proven who needs an ICD. I'm concerned that waiting to collect more data will result in unnecessary deaths. The fact is that we can't let another day go by without this care.

Thank you for the opportunity to share my opinion on this matter.

Thank You,

**Commenter: Washington, Carla**

Organization: Date: October 15, 2004 Comment:

Thank you for the opportunity to submit my comments on this important issue. Sudden cardiac arrest kills more Americans than any other condition. It kills between 340,000 and 450,000 people every year more than 1,000 people every day. Please, please consider providing ICDs for all at-risk Americans. Your preliminary decision leaves out some Medicare patients who could die without an ICD. People who rely on Medicare have no other options and need to be covered before the end of the year.

Thank you for considering this issue of such significant importance.

**Commenter: Waterman, Kenneth**

Organization: Date: October 25, 2004 Comment:

Thank you, CMS, for making the decision to reimburse for ICDs for many heart failure patients. ICDÆs are the best chance these Americans have for preventing sudden cardiac arrest. However, your decision has excluded some Americans who are at the same risk for sudden cardiac arrest. What are those left out of the CMS decision supposed to do for protection from this silent killer?

Please revise your decision to include all patients that need ICDs. And please make that decision now. We need protection from sudden cardiac arrest before it kills thousands more.

**Commenter: Wathen, Mark**

Organization: Date: October 28, 2004 Comment:

Response to CMS 9/28 ruling on expanded ICD coverage for congestive heart failure I appreciate your efforts to read comments from the clinical field regarding heart failure mortality risk reduction. I am an Electrophysiologist, SCDHeFT investigator, and ICD researcher. I would like to add supportive data that will be helpful in selecting an appropriate response to the SCDHeFT, DEFINITE and other recent trials. I must disclose to you that I am an investigator of clinical trials sponsored by St Jude, Medtronic and Guidant. I have also consultant relationships with Guidant and Medtronic. I do not have any personal financial relationships with these or any other company that may benefit/harm by the ruling by CMS on expanded coverage of ICDs. I only invest in large mutual funds to avoid any conflict of interest. My potential conflict of interests lies in the fact that I am an Electrophysiologist who derives personal income from Cardiac arrhythmia care including ICD patient care. However, I am a physician/scientist at Vanderbilt with salary based income because my career interests are something other than financial income. My true passion is to see appropriate and compassionate care delivered to patients, thus my motive for writing.

I) ICD therapy improves Medicare's efficiency of dollars spent on healthcare. Statistics show that more healthcare dollars are spent in the US per person than Canada, Japan or Western European countries however longevity is not higher. In fact, longevity is falling farther behind. The CMS is not responsible for this by itself; however Medicare is saddled with the single largest portion of health care costs and is looked to as the leader in value of healthcare dollars spent. The appropriateness of these dollars is being measured in terms of survival. If the CMS wants to improve the overall efficiency of its own dollars in terms of survival benefit then it needs to produce cost savings in areas other than life saving therapies like the ICD for congestive heart failure. Restricting ICD therapy for CHF class II and III patients to those with EF <30% seems to restrict the mortality benefit. ICD therapy may be an area of great yield in survival benefit for the dollar. Disproportionately few dollars are spent on ICD therapy considering its survival benefit compared to dollars spent on non-Cardiology as well as other Cardiology therapies. Because sudden death represents the lions share (60%) of all mortality from Cardiac disease, nearly every single therapy known to improve cardiac survival has done so principally if not entirely through sudden death reduction. If a therapy fails to reduce sudden death then it has little chance of reducing cardiac mortality. The list of successful therapies includes beta blockers, spironolactone, ACE inhibitors, and coronary bypass surgery. Despite these therapeutic advancements, sudden death represented 19.1% of all US adult deaths in 1999. There is no single, larger cause of death in adults. The reason for continued death despite advanced therapies is that all the above are preventative (prophylactic) therapies. They do not treat the arrhythmia once it starts. Only the ICD can do so. Thus, the ICD is not prophylactic it is therapeutic. The concept that the device is prophylactic in some and not others is false. Since survival of a sudden death event is only 5% our duty is to identify those at risk before it occurs. It is the at risk group that must be treated. We do not yet understand exactly who is at risk. SCDHeFT and other future trials will probe who is at risk.

II) LVEF is not the issue. Substrate for arrhythmia is the issue. This author agrees with the spirit of the ruling. The purpose of the ICD is to prevent sudden arrhythmic death in persons at risk. There may be many clinical predictors of sudden death. A history of sudden death or sustained ventricular tachycardia is only a single predictor. The CMS ruling recognizes that reduced LVEF also impacts sudden death risk. However, CMS is developing inconsistent rulings when it fails to concede that the presence of CHF symptoms is an independent predictor. It would appear that underlying the CMS ruling is the concept that systolic dysfunction is the central issue for sudden death. This author would suggest that substrate for arrhythmia is the key element not LVEF. Many patients have high risk of sudden death without any systolic dysfunction. In fact, hypertrophic cardiomyopathy patients have exuberant systolic function and LVEF yet die principally by sudden death. Other conditions include Congenital Long QT syndrome, cardiac sarcoidosis, other infiltrative cardiomyopathies, familial forms of cardiomyopathies, arrhythmogenic RV dysplasia and others. Perhaps the most pertinent fact is that the greatest number of sudden deaths in the US occur in normal LVEF hearts yet with cardiac hypertrophy simply from systemic arterial hypertension. Sudden death occurs in the normal LVEF population with only cardiac hypertrophy from hypertension 15:1 over the low EF CHF patients in this trial. Cardiac hypertrophy and associated structural changes are the source of the electrical uncoupling that leads to arrhythmic death. It is not the low LVEF itself. These statements do not serve to render policy but serve as critical framework from which the CMS may proceed as this and future expanded ICD indications arise.

### III) Beware of unscientifically dissecting scientific data

Every patient in the SCDHeFT trial had symptomatic CHF principally due to systolic dysfunction. It was a CHF trial. It was not a low EF trial. Patients with low EF <35% and CHF pts class II and III with LVEF <35% are two different groups of patients. There are some patients that overlap between groups but it is only partial overlap. Yet the CMS ruling fails to include CHF as a requirement for coverage and fails to recognize the importance of CHF symptoms to mortality risk. Selecting simply low EF is once again (similar to the QRS <120ms issue) micro-manipulating the known data so that the final rendering is left without scientific basis. It is well established that the presence of CHF symptoms is a potent marker of death. In fact, the degree of symptoms is the most important predictor in patients with LV systolic dysfunction. A patient with LVEF 35% and no CHF has very different mortality rate as one with LVEF 35% and CHF class III. How can CMS be expected to subselect effectively such sub-factors to affect positively the # of lives saved per dollars spent? This author disagrees with the whole approach. It would seem a risky strategy for the CMS to rule on expanded ICD coverage by accepting data from new clinical trials and agreeing to new coverage yet to do so for only subpopulations within that trial which have not been studied. The prior CMS ruling regarding QRS width > 120ms for ischemic cardiomyopathy with LVEF <30% was delivered after the results of the MADIT II trial were known. That trial tested the value of using QRS 120ms width as a cut off to predict ICD mortality benefit and found it was not useful. Multiple subsequent data have consistently supported the MADIT II trial's findings and discredit the prior CMS ruling. The CMS' credibility is at risk should it repeat.

III) When CMS expands coverage only partially based upon the recognized data, it should acknowledge the fiscal basis for its decision and concede that the data show other coverage may be warranted. The ruling to incompletely expand coverage seemed purely a dollars saving rationing attempt however it seemed disguised as scientifically based. On the one hand CMS demands specific data for specific populations (as it should) but on the other hand it contrives the data into scientifically nonsensical policy. If CMS rules purely to save dollars the ruling needs to state exactly that and at the same time acknowledge benefit to uncovered patients. When the guidelines for ICD implantation are developed by the recognized experts in Cardiology differ from CMS coverage what should physicians do? This is understandable for elective therapies, those without lifesaving benefit but it becomes very difficult for mortality benefit therapies. What do I do with Mr. Johnson who is sitting in front of me and I must inform him: that his greatest risk of death is sudden death, that therapies with 98% efficacy are available, that one therapy has been proven in the largest blinded placebo controlled randomized ICD trial to date, yet that Medicare will not pay? This puts Medicare in the hot seat.

IV) When CMS expands coverage only partially based upon the recognized data, it should acknowledge the fiscal basis for its decision and concede that the data show other coverage may be warranted. The ruling to incompletely expand coverage seemed purely a dollars saving rationing attempt however it seemed disguised as scientifically based. On the one hand CMS demands specific data for specific populations (as it should) but on the other hand it contrives the data into scientifically nonsensical policy. If CMS rules purely to save dollars the ruling needs to state exactly that and at the same time acknowledge benefit to uncovered patients. When the guidelines for ICD implantation are developed by the recognized experts in Cardiology differ from CMS coverage what should physicians do? This is understandable for elective therapies, those without lifesaving benefit but it becomes very difficult for mortality benefit therapies. What do I do with Mr. Johnson who is sitting in front of me and I must inform him: that his greatest risk of death is sudden death, that therapies with 98% efficacy are available, that one therapy has been proven in the largest blinded placebo controlled randomized ICD trial to date, yet that Medicare will not pay? This puts Medicare in the hot seat.

#### V) Shock only ICDs

Shock only devices are a thing of the ugly and painful past. At this time there is not a single implanted defibrillator with shock only capability available on the market in the US. The ruling by CMS states: A provider implanting any ICD other than a single lead, shock only device for primary prevention must maintain and furnish upon request to CMS, its agents or other authorized personnel the documentation to verify the medical necessity for a more advanced ICD. Does CMS expect a response from EVERY provider for EVERY ICD implanted for primary prevention? What is the purpose of dictating shock only devices? Since no device is shock-only, it would cost a great deal of money to develop and get approval by the FDA. If such a device was made, the cost savings of producing it may be negligible. Specifically, the issue is that there are two therapies delivered by ICDs for ventricular tachycardia, painful shock or painless anti-tachycardia pacing (ATP). The only difference would be the inclusion of the algorithms for antitachycardia pacing. Inclusion of a previously developed and approved algorithm costs nothing. Early experience with the ICD showed that shock termination of VT and VF led to asystolic death. Subsequently, all ICDs have pacing capabilities in the bradycardia zone. Once bradycardia pacing capabilities are instilled, the addition of tachycardia pacing is only an algorithm issue. One potential benefit is that by dictating utilization of simpler shock only devices could potentially lower the threshold so that a new competitor could potentially come into the market, gain market share enough to compete

against the few manufacturers that exist and to drive down overall market prices. Of course, this scenario presumes the new manufacturer is somehow motivated to significantly change market price. More likely, a new competitor would shave downward the price by competing rather than erode the price significantly.

#### VI) Antitachycardia Pacing: A defibrillator no longer defibrillates.

An ICD is a medical device that similar to chemotherapeutic agents treats a life threatening problem yet with great side effects. The process of delivering therapy by the ICD creates side effect of the ICD because it is painful. Not only is it painful at that moment, but ICD patients who have been shocked state that fear of the next shock has become a worse quality of life factor than their underlying cardiac disease. Anxiety syndromes

Such antitachycardia pacing is not painful; rather it usually cannot be detected by the patient at all. Furthermore, a recently completed trial extended the benefit of ATP to VT all the way up to 250 bpm. The PainFREE Rx II trial was a 634 patient multicenter and single-blinded ICD trial that randomized patients to shock vs. ATP for even faster VTs 188- 250bpm. The investigators considered randomizing slower VTs < 188 bpm to shock vs ATP but believed it unethical to withhold ATP therapy due to the overwhelming data documenting its success for VT < 190 bpm. However, in an attempt to complete the picture and to understand the role of ATP for the entirety of VT from the slowest (100bpm) to the fastest 250bpm the investigators studied ATP in the faster VTs. The main result of the trial was that ATP had 81% success in terminating event these extremely fast arrhythmias. Importantly, it documented the safety of such therapy as well. ATP does not drain ICD battery like shocks and has been shown to significantly prolong ICD longevity when calculated over the lifetime of the ICD 2. There have been various arguments against ATP all of which center around safety. Safety of ATP can be determined by measuring the risk of increased syncope, sudden death, acceleration of arrhythmia, and duration of arrhythmias. A registry trial reviewed the safety of shock-only ICDs vs ATP capable ICDs and demonstrated a statistical improvement in mortality, figure 2.

Note: Std = 1553 pts with shock only ICDs, ATP = 242 pts with ATP capable ICDs. 24 month survival was superior for ATP devices, 89 vs 94%.

However, no randomized trial existed proving the safety of ATP over shock until the recent publication of the PainFREE Rx II trial 1. The PainFREE Rx II trial prospectively defined all the above safety markers as endpoints of the trial. The results showed that not a single one of them were increased. There was no increase in syncope, sudden death, duration of arrhythmias, acceleration of arrhythmia or symptoms. In fact, the contrary was true there were fewer symptoms in the ATP arm of the trial. The authors point out that since 90% of all arrhythmias are effectively treated by ATP that the whole functional concept of the ICD has now changed to be an anti-tachycardia pacing therapy with shock being relegated only to a secondary therapy when ATP fails. Furthermore, ATP was effective in all populations of patients, young or old, coronary artery disease or non-, LVEF, CHF class, gender, etc. No clinical factor was found that demonstrated ATP's inefficacy. Those thought least likely, non-Coronary artery disease patients had very high ATP success that was nearly statistically superior to coronary artery disease patients. The lower the LVEF, the less ATP success but even in the lowest quartile there was over 50% success without any measurable risk, (unpublished). It is important to point out that all ICDs on the market today are capable of performing this simple ATP therapy. The PainFREE Rx II trial also demonstrated quality of life benefit by the ATP as reported by the patients. The trial included both primary and secondary prevention patients, (45% primary) and CHF (53% of patients). Neither primary indication for ICD nor CHF predicted ATP

failure, thus the ATP can be applied to the SCDHeFT population. Reversing this important advancement in therapy would be viewed as a great mistake in the medical community. This data was known by the single expert with whom CMS consulted. One questions why there was no reference to the broad and deep ATP data published over the past decade. In fact, the investigators In SCDHeFT tried to include ATP in the protocol yet the principal investigator refused to permit it for unclear reasons. This was believed to have been an important addition to the protocol because one of the SCDHeFT trial's secondary endpoint was: To compare health-related quality of life (QOL) for the arms. Also, the original hypothesis of the trial said nothing of shock box only. It was: Amiodarone or ICD will improve survival compared to placebo in patients with Class II and III CHF and EF < 35% without a history of sustained VT. Yet, the principal author changed the final version to include a shock box concept of the ICD which is not shared by the investigators of the trial.

In summary, ATP has become standard therapy, is safe and improves quality of life in ICD patients. My recommendation is to expand coverage to CHF patients Class II and III, with and without coronary artery disease as per SCDHeFT trial; also, to expand coverage to coronary artery disease patients with QRS < 120ms and low EF <30% as per MADIT II.

1. Heller SS, Ormont MA, Lidagoster L, et al. Psychosocial outcome after ICD implantation: a current perspective. *Pacing Clin Electrophysiol.* 1998;21:1207-15.
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**Commenter: Webster, Jennifer, RN**

Organization: Date: October 12, 2004 Comment:

I appreciate the chance to comment on the recent CMS decision regarding coverage and reimbursement of ICDs. Nearly one thousand Americans die every day of SCA, and your decision is an important step in the right direction. However, I urge CMS to expand ICD coverage to every American proven to be at risk for SCA. Some were excluded from the preliminary decision, and that has me worried. Every death from SCA is an unnecessary tragedy, and I respectfully request that you expand coverage. Please don't wait for more data that may cause a delay - many Americans need ICDs to live.

Please work to get this therapy available for Americans this year.

**Commenter: Weiner Stanislav**

Organization: Date: October 28, 2004 Comment:

I applaud the recent CMS decision to expand coverage for prophylactic ICDs in patients with heart failure. Furthermore, I strongly agree with notion that the use of ICDs should be restricted to physicians and hospitals with appropriate experience. In 2004 ICDs are proven beyond reasonable doubt to be an effective lifesaving technology. However, there are several concerns about indiscriminate application of this technology. There are both theoretical and practical reasons to believe that wide use of ICDs by physicians with limited background and experience in the field is not going to provide the same benefit as demonstrated in the clinical trials. Clinical trials that provide a solid scientific basis for the use of ICDs in patients with heart failure (as outlined in the CMS memorandum) were performed by a select group of centers and physicians with extraordinary extensive experience in managing patients with malignant arrhythmias and implanted devices. These physicians represent a small subset of the electrophysiology community. Extrapolation of the findings of MADIT, COMPANION, SCD-HeFT etc may be reasonable to other centers with similar procedure volume, background and experience. However, I think it is absurd to expect a comparable degree of benefit from physicians who have limited insight into the issues of chronic follow-up of these patients by virtue of inadequate training or experience. This theoretical concern stands in sharp contrast with the current practice (at least in my geographical area) of aggressive recruitment of physicians with marginal or no experience in this area by the ICD salesmen. From the practical standpoint, one should consider the difference between ICDs and other types of procedures provided to the Medicare beneficiaries. ICD implantation carries a small risk of periprocedural complications (just like any other procedure). While there will always be differences in the complication rates between the high and low volume centers it is unlikely that this difference will be significant in the long term. A much more disturbing issue is that one of late complications of ICDs (e.g. inappropriate shocks, lead failures, infections requiring lead extractions etc). This is a unique set of complications not frequently encountered in other procedures. The problem is further exacerbated by the fact that ICDs are extremely effective at keeping patients alive and therefore will by definition extend the "at risk" period for these late complications. The frequency of late complications in the setting of less experienced operators has not been studied. I think that the complication rate will be substantial. This has three untoward effects: (1) Increased morbidity to the Medicare beneficiaries; (2) Increased burden of troubleshooting of problematic ICDs on the more experienced physicians which will shift resources away from more productive activities (i.e. it is more efficient to do things right the

first time);

(2) Increased resource utilization with reevaluation of problematic ICDs in the

(3) office and the hospital, revisions, extractions, and upgrades. In summary, I think

(4) that late complications (that have not been studied to date) will become the AchillesGÇÖ heal of the widespread ICD use by inexperienced and low-volume operators.

In light of the above I recommend that CMS restrict coverage of ICD implantation to hospitals and physicians with appropriate training, experience and certification regardless of indications for the procedure.

Respectfully,

**Commenter: Whelan, Paulette**

Organization: Date: October 13, 2004 Comment:

Thank you for providing coverage for ICDs to many Medicare patients at risk for SCA. But the CMS decision has left out around 100,000 Americans at high-risk for SCA.

I wanted you to know that a large number of Medicare patients have no other healthcare options. If ICDs are not covered for those left out, what will they do if they need this device? How can we deny them access to ICD?

Please cover all Americans at high risk for SCA. Research has proven who needs an ICD. I'm concerned that waiting to collect more data will result in unnecessary deaths. The fact is that we can't let another day go by without this care.

Thank you for the opportunity to share my opinion on this matter.

**Commenter: Whitehead, Carolyn**

Organization: Date: October 12, 2004 Comment:

Thank you for providing coverage for ICDs to many Medicare patients at risk for SCA. But the CMS decision has left out around 100,000 Americans at high-risk for SCA.

I wanted you to know that a large number of Medicare patients have no other healthcare options. If ICDs are not covered for those left out, what will they do if they need this device? How can we deny them access to an ICD?

Please cover all Americans at high risk for SCA. Research has proven who needs an ICD. I'm concerned that waiting to collect more data will result in unnecessary deaths. The fact is that we can't let another day go by without this care.

Thank you for the opportunity to share my opinion on this matter.

**Commenter: Widrig, Wayne**

Organization: Date: Comment:

With up to 1,200 Americans killed daily by sudden cardiac arrest, I'm encouraged by the latest decision to expand Medicare coverage of implantable cardioverter defibrillators for at-risk patients.

But, it is important to note that the new coverage still leaves tens of thousands of people at risk that is preventable if Medicare reimbursement covered everyone at high-risk for sudden cardiac arrest.

Please consider including all Medicare recipients with heart failure who are at high risk for SCA. And please don't delay the decision while waiting for more data/information. We need access to this important medical care by January 1, 2005.

**Commenter: Wilde, Debbie**

Organization: Date: October 13, 2004 Comment:

Thank you, CMS, for making the decision to reimburse for ICDs for many heart failure patients. ICD's are the best chance these Americans have for preventing sudden cardiac arrest. However, your decision has excluded some Americans who are at the same risk for sudden cardiac arrest. What are those left out of the CMS decision supposed to do for protection from this silent killer?

Please revise your decision to include all patients that need ICDs. And please make that decision now. We need protection from sudden cardiac arrest before it kills thousands more.

**Commenter: Wilkins, Barbara**

Organization: Date: October 20, 2004 Comment:

Thank you for providing coverage for ICDs to many Medicare patients at risk for SCA. But the CMS decision has left out around 100,000 Americans at high-risk for SCA.

I wanted you to know that a large number of Medicare patients have no other healthcare options. If ICDs are not covered for those left out, what will they do if they need this device? How can we deny them access to an ICD?

Please cover all Americans at high risk for SCA. Research has proven who needs an ICD. I'm concerned that waiting to collect more data will result in unnecessary deaths. The fact is that we can't let another day go by without this care.

Thank you for the opportunity to share my opinion on this matter.

Thank You,

**Commenter: Williamson, Brian, MD**

Organization: Date: October 15, 2004 Comment:

I am a board certified cardiac electrophysiologist in private practice at a large teaching hospital (William Beaumont, MI). I have been closely following CMS decisions over the years, and have not submitted comments in the past. I would like to applaud the CMS and the staff of the CMS for the thoughtful deliberation that it has exhibited over the years in response to new studies. I wish all 3rd party payors had such a reasoned, transparent approach.

I have several comments, many of which I'm sure echo others. I agree with expansion of ICD indications to cover MADIT II and SCD-HFT patients.

I believe DFT testing should continue, to insure that all patients receive the optimally effective therapy. It is not unusual to identify, from DFT testing, circumstances requiring lead repositioning, or a different system or programming. This can be safely done by experienced electrophysiologists at properly equipped and experienced hospitals. The only way we can replicate the benefit shown in the clinical trials is to follow the same implant approach, with properly trained implanters. I personally believe the NASPE training guidelines for non-ep implanters was a "cop-out" to the device industry, and if you are to enforce a registry, that the training necessary be limited to board eligible or certified electrophysiologists (unless a large trial shows non-ep trained implanters can do as good of a job).

It has been shown that ATP can safely be used to reduce the need for ICD shocks without sacrificing patient safety (ie the Pain-Free Trial). Additional trials, such as the Prepare Trial, continue to evaluate the most appropriate programming in prophylactic indications. In the meantime, electrophysiologists are most qualified to implant and follow these patients.

Microvolt T-wave alternans has been proposed as an additional stratifier. I have access to T-wave alternans testing, and use it at times as a risk factor. I am concerned however, that Cambridge Heart, the sole commercial provider of the testing equipment, is the real force behind this movement to include this in the registry (in fact my comments are prompted by an e-mail from Cambridge Heart asking me to support T-wave alternans testing).

I am willing to participate in a registry for these patients, but I am concerned about its design. I have participated in many clinical trials, and understand that good data requires research staff for its collection. Who will provide the research staff, and who will pay the costs. Unless good data is collected, the registry will be a colossal waste of time. I will look forward the next CMS posting.

**Commenter: Winter, J.**

Organization: Date: October 26, 2004 Comment:

I am writing to comment on the recent decision of the Centers for Medicare and Medicaid Services to reimburse implantable cardioverter defibrillators.

While it is a first step in the right direction, many people who are at risk have been left out of the preliminary decision, and will not have any other option to prevent a sudden cardiac arrest. For example, many Medicare recipients have that program as their only form of health care and won't be protected under the current decision.

It is crucial that all Americans at high risk get the protection they need from this terrible killer. With up to 450,000 people in this country dying every year from sudden cardiac arrest, the stakes are too

high to implement this incomplete approach to reimbursement. Please increase the reimbursement options for ICDs to all at risk. Please don't make additional requests for data too cumbersome. Implementation of this landmark decision shouldn't be delayed past the 1st of the year.

Thank you for the opportunity to present my thoughts on this critical issue.

Regards,

**Commenter: Witt, Tom**

Organization: Date: October 19, 2004 Comment:

With up to 1,200 Americans killed daily by sudden cardiac arrest, I'm encouraged by the latest decision to expand Medicare coverage of implantable cardioverter defibrillators for at-risk patients.

But, it is important to note that the new coverage still leaves tens of thousands of people at risk that is preventable if Medicare reimbursement covered everyone at high-risk for sudden cardiac arrest.

Please consider including all Medicare recipients with heart failure who are at high risk for SCA. And please don't delay the decision while waiting for more data/information. We need access to this important medical care by January 1, 2005.

Thank you,

**Commenter: Wohlers, Fred**

Organization: Date: October 12, 2004 Comment:

Thank you for the opportunity to submit my comments on this important issue. Sudden cardiac arrest kills more Americans than any other condition. It kills between 340,000 and 450,000 people every year more than 1,000 people every day. Please, please consider providing ICDs for all at-risk Americans. Your preliminary decision leaves out some Medicare patients who could die without an ICD. People who rely on Medicare have no other options and need to be covered before the end of the year.

Thank you for considering this issue of such significant importance.

**Commenter: Wood, Cherry**

Organization: Date: October 19, 2004 Comment:

I am very happy to have the chance to provide my comments on ICDs to CMS. Thank you. This is an issue that means so much to me because SCA is a leading killer of Americans. I appreciate CMS's decision to provide critical coverage to so many Americans who depend on Medicare, but CMS must consider those who were left out.

There are approximately 100,000 Americans who are at great risk for SCA and won't have ICD coverage. Please increase coverage to these folks so that they can have access to this amazing technology that makes the difference between life and death sooner rather than later.

**Commenter: Wooten, Gladys**

Organization: Date: October 20, 2004 Comment:

Thank you for the opportunity to submit my comments on this important issue. Sudden cardiac arrest kills more Americans than any other condition. It kills between 340,000 and 450,000 people every year û more than 1,000 people every day. Please, please consider providing ICDs for all at-risk Americans. Your preliminary decision leaves out some Medicare patients who could die without an ICD. People who rely on Medicare have no other options and need to be covered before the end of the year.

Thank you for considering this issue of such significant importance.

**Commenter: Wright, Winnie**

Organization: Date: October 27, 2004 Comment:

CMS should be commended for its recent decision to reimburse ICDs for many heart failure patients. ICDs offer the best protection from sudden cardiac arrest. However, there are more Americans who remain without protection. Some heart failure patients that showed benefit from ICDs in recent clinical trials were excluded from the decision. I really question this part of the decision because without an ICD, these people stand very little chance of surviving a sudden cardiac arrest. Please help ALL Americans who could benefit from this amazing device have the protection they need. Your final decision must come before January 2005 to save as many lives as possible.

Thank you for taking the time to hear my concerns.

**Commenter: Wuerch, Cathy**

Organization: Date: October 26, 2004 Comment:

Thank you for the opportunity to submit my comments on this important issue. Sudden cardiac arrest kills more Americans than any other condition. It kills between 340,000 and 450,000 people every year û more than 1,000 people every day. Please, please consider providing ICDs for all at-risk Americans. Your preliminary decision leaves out some Medicare patients who could die without an ICD. People who rely on Medicare have no other options and need to be covered before the end of the year.

Thank you for considering this issue of such significant importance.

**Commenter: Young, Charlie**

Organization: Date: October 11, 2004 Comment: TPMG, Inc.

Before this decision is finalized, I will like to offer what I think about the data being put forth to justify this cost-ineffective management of sudden death. In brief, we have agreed to treat sudden death as public health issue by "vaccinating" the at risk group with implantable defibrillators. I propose that for the most part, MADIT II is simply a dilution of the benefits in MADIT I with a much larger group of patients who would not benefit from an ICD. Consider the "fuzzy math" that has lead to this. 1,000 patients with EF <30% will probably be inducible to VT 1/4 of the time based on clinical practice and informal registry data from MADIT I. This means in this group, 250 patients will receive an ICD and using MADIT I numbers (39% 16% =23% absolute mortality difference) about 1/4 of the patients will benefit. For those implanted this way 23% mortality difference is a very significant benefit. However, looking at the original 1000 patients (EF <30%) who are in essence like MADIT II patients, then approximately 1/16th or 62 patients will have an actual mortality benefit if you simply apply only the

benefits derived from MADIT I implant criteria. Why then is the absolute benefit from MADIT II essentially the same at 5.8% or 58/1000 patients in a similar group of patients with EF<30%. Is MADIT II therefore simply a dilution of MADIT I with implantation of 750 unnecessary ICD's in a group of non-inducible patients. It becomes very deceptive when you look at benefit across the board without teasing out where this benefit is coming from. We have already settled the question of implantation in the inducible group where the benefit is large. If there is such a concern for the remainder of the group made up of non-inducible patients, why is there no study to assess the additional benefit derived by specifically treating this group with an ICD. The math supports, the notion that in our rush to protect everyone from sudden death with an ICD, we are increasing the implant rate 300% (250 to 750 patients) and in patients who are not shown to directly benefit.

**Commenter: Zimmern, Samuel**

Organization: Date: October 24, 2004 Comment:

I am a cardiac electrophysiologist in clinical practice in Charlotte, NC. CMS made an excellent decision to extend coverage for ICD insertion into the large group of patients with poor LV function. I appreciate the agency's continued analysis of the expanding data base in this area. I disagree with the proposal to insist that patients receiving ICDs should be entered into a registry. Such a registry will be time consuming and costly. I agree that there are many important questions to answer regarding ICD use in patients. However these issues can be addressed in more efficient and scientifically sound ways by well executed clinical trials. The effects of running a national registry for ICDs will likely include preventing use of this therapy in people who would benefit from it as well as higher costs.

**Commenter: Zipes, Douglas**

Organization: Date: October 16, 2004 Comment:

I am co-chair of the Ventricular Arrhythmia Guidelines for the ACC/AHA/ESC. We are going to indicate (not published nor officially approved as yet) that an EF of 35% post MI will be a 2a indication, and thus, from your decision, will not be reimbursable. That will become a problem.



David A. Chazanovitz  
President and CEO

October 18, 2004

Steve Phurrough, MD, MPA  
Director, Coverage and Analysis Group  
Centers for Medicare and Medicaid Services  
7500 Security Blvd.  
Baltimore, MD 21244

**Re: Implantable Defibrillators (CAG - 00157R2)**

Dear Dr. Phurrough:

I am writing to comment on the draft National Coverage Decision on Implantable Defibrillators posted by the Centers for Medicare and Medicaid Services (CMS) on September 28, 2004. Cambridge Heart strongly supports the draft decision and the evidence-based medicine framework proposed in the decision. The draft NCD allows for coverage of implantable cardioverter-defibrillator (ICD) devices in significantly broader populations while seeking further information to help advise the medical community as to which of those patients have a high likelihood to benefit from the ICD versus those which are unlikely to benefit from this therapy. We also appreciate you and your staff taking the time to meet with me and members of the medical community to discuss the merits of utilizing Microvolt T-Wave Alternans (MTWA) as a risk stratifier in the MADIT II and SCD-HeFT populations.

These written comments are directed at the specific issue of the implementation of a National ICD Data Registry as discussed in the draft NCD. Cambridge Heart strongly supports the concept of a data registry and would like to work with CMS during the comment period to help structure this registry. We believe that a well structured registry will build upon the evidence coming from the MADIT II and SCD-HeFT studies to provide the data that will enable more effective identification of at-risk patients who would benefit from ICD therapy. Cambridge Heart believes that the incorporation of Microvolt T-Wave Alternans in the National Data Registry would help improve the quality of care for Medicare beneficiaries and mitigate any budgetary concerns for the Medicare program stemming from potential over-utilization of ICDs.

#### **Summary of Key Points**

- Cambridge Heart strongly supports the proposed NCD to greatly expand Medicare beneficiary access to ICDs. In the draft NCD, CMS correctly proposed the implementation of a National Data Registry to better ensure that ICD implantation only occurs in those patients who are most likely to benefit.

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- Microvolt T-Wave Alternans (MTWA) is an accurate risk stratifier that could be easily incorporated into the national registry. MTWA would help accurately predict which Medicare beneficiaries need an ICD and would save CMS significant funds.
- In our meetings with CMS, we demonstrated that approximately one-third of patients tested in the MADIT II and SCD-HeFT type group test negative with MTWA and that this group consistently has less events than similar patients treated with ICDs. MTWA is a rapid and easy-to-perform test that could save the Medicare system significant resources not currently budgeted for ICD placements.
- Cambridge Heart would like to work closely with the CMS Coverage and Analysis Group during the public comment period on the design and implementation of the National Data Registry. We believe that this Data Registry can be implemented with little burden to clinicians and without any impediment to beneficiary access, while building on current best clinical and industry practices.

### **I. Background on Microvolt T-Wave Alternans**

As you know, MTWA is a non-invasive diagnostic test which was cleared by the Food and Drug Administration (FDA) for its ability to predict ventricular tachyarrhythmias and sudden cardiac death. Cambridge Heart has been actively marketing Microvolt T-Wave Alternans and has a fielded base of units which can easily accommodate the 25,000 additional ICD placements for Medicare beneficiaries anticipated in the first year of coverage under the draft NCD. There are presently 500 to 700 MTWA units at hospitals and providers around the country. Clearly, additional sites would be necessary from a geographical basis and or convenience factor. In addition to Cambridge Heart, Burdick Inc. (a subsidiary of Quinton Cardiology), a highly respected cardiology diagnostic company, sells and distributes Microvolt T-Wave Alternans incorporated into their Quest Stress System. This partnership adds considerable MTWA procedural capacity.

MTWA has been assigned a unique CPT Code (93025) and is covered throughout the United States by local Medicare carriers under LCDs and LMRPs. Private insurance coverage of MTWA has been slowly following Medicare policy. In the past year, the Blue Cross/Blue Shield Plans in Michigan, Iowa, South Dakota, Virginia, Washington DC, Delaware and Maryland have revised their policies to cover and pay for MTWA testing. We believe that both the clinical data demonstrating the high negative predictive value of MTWA and the savings associated with identifying those not likely to benefit from ICD therapy are the compelling reasons for new payment policies on MTWA. While these private payers have no direct impact on Medicare patients, their policies reflect the multifaceted benefits of incorporating MTWA into their diagnosis algorithms.

### **II. MTWA is Established as an Accurate Risk Stratifier**

In our meetings with CMS, Cambridge Heart demonstrated that approximately one-third of patients tested in the MADIT II and SCD-HeFT type group test negative with MTWA and that this group consistently has fewer events than those similar patients treated with ICDs. We demonstrated that, as a

rapid, easy-to-perform and clinically validated test, MTWA could save the Medicare system significant resources not currently budgeted for ICD placements. During the February 2003 Medicare Coverage Advisory Committee (MCAC) meeting, three physician experts presented information supporting the use of Microvolt T-Wave Alternans as a risk stratifier in the MADIT II population. In June 2004 and July 2004, Cambridge Heart representatives met with you and the CMS Coverage and Analysis Group to discuss MTWA and its demonstrated benefits as a risk stratifier within MADIT II and SCD-HeFT type populations. The physicians presented information detailing the efficacy of MTWA on the basis of numerous prospectively conducted studies, some single center, some multi-center, and one study supported by the National Heart, Lung and Blood Institute at NIH.

In addition to the numerous published studies already submitted to CMS, one additional significant research work has just been published in the journal *Circulation* by Dr. Daniel Bloomfield as the lead author. The article, "*Microvolt T-Wave Alternans Distinguished Between Patients Likely and Patients Not Likely to Benefit from Implanted Cardiac Defibrillator Therapy – A Solution to the Multicenter Automatic Defibrillator Trial (MADIT II) Conundrum*" is attached. The article substantiates the remarkably high negative predictive value of Microvolt T-Wave Alternans and also calls into question the validity of QRS duration in eliminating two thirds of the MADIT II population from being considered for defibrillator therapy.

We are aware that numerous physicians contacted CMS to voice their opinion that MTWA should be used in determining which patients qualify for an ICD. MTWA has been proven both in the clinical literature and in clinical practices to have a very high negative predictive value. This technology has consequently saved many patients the needless risk and discomfort of having a defibrillator implanted when it is very unlikely they will benefit from the device. Other commenters pointed out that the use of MTWA can save the Medicare system substantial resources by helping to place ICDs only in those patients who truly have need for the device, rather than in a broad-based population who have shown a modest statistical advantage.

In previous comment letters, Cambridge Heart has supplied analyses to demonstrate potential savings associated with MTWA testing. The savings has been based on the current statistics that show approximately 1/3 of the discussed populations test negative for MTWA. The potential savings exceeds \$1 billion. However, as a result of CMS' draft decision to pay for ICDs in this entire patient population, the potential savings from not putting ICDs in low risk of SCD/MTWA identified patients can be best estimated pending future analysis of the patient registry data.

### **III. Comments On Draft NCD**

The approval of SCD-HeFT type patients with an Ejection Fraction  $\leq 30\%$  and the elimination of the QRS requirement of  $> 120$  milliseconds substantially expands the population of patients eligible for implantable defibrillator therapy. As noted, we strongly support the CMS evidence-based Medicare review and draft NCD policy.

In the body of the decision, CMS has concluded that the use of ICDs for primary prevention of 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). CMS states as follows:

*Finally, we desire to ensure that defibrillator implantation only occurs in those patients who are most likely to benefit and that the procedures are done only by competent providers in facilities with a history of good outcomes and a quality assessment/improvement program to identify providers with poor outcomes and other areas for improvement. As mentioned above, we are concerned that the available evidence does not allow providers to target these devices to patients who will clearly derive benefit.*

The decision further states that the data set from the registry must collect characteristics including baseline patient characteristics, device type and characteristics, facility and provider characteristics, extent of disease progression, periodic device interrogation for firing data and long term patient outcomes. Additionally CMS has asked that specific hypotheses be addressed including “screening tests, such as T-Wave Alternans, that predict which patients receive defibrillator therapy”.

The collection of data as discussed by CMS will enable CMS to refine the population who benefits from ICD implantation and that tests such as T-Wave Alternans could determine which patients are at very low risk and therefore do not require defibrillator therapy. The data registry / data collection activity may present the best possible alternative to assist the medical community in refining the guidelines, as undertaking a classic randomized study in this population may no longer be practical or ethical.

Throughout the discussions of the proposed ICD coverage revisions, it has been well publicized that thousands of patients who are generally acknowledged as excellent candidates for ICD implantation are not receiving therapy due to a dysfunctional referral network. Most patients are never referred to an electrophysiologist for reasons that include negative attitudes regarding the therapy, patient concerns, as well as economic considerations. It is widely acknowledged that the market penetration of ICDs is approximately 20% for clearly defined patient populations. Utilization of MTWA, as a result of the registry, will enable clinical cardiologists who may be reluctant to refer their patients for ICD therapy to make improved decisions on patient care. As a result, the clinically proven, very high negative predictive value of MTWA testing can serve to encourage smoother referral patterns and improve patient access to ICD therapy.

#### **IV. Proposed Framework for National ICD Registry**

Cambridge Heart is pleased to present some initial ideas regarding the data registry, and believes that the registry can be conducted in a manner which does not place significant burdens on the health care professional while collecting useful and necessary information previously discussed. Much of the information requested is already available and easily being captured by both the care giver (physician / hospital) and the ICD companies. The challenge is to coordinate a standardized approach that can then be combined and analyzed with minimal burden to the care givers.

MTWA is a non invasive test which averages 30-35 minutes to conduct. It is a heart rate dependent test (target 110-120 BPM) which can be performed as an exercise stress test, a pharmacological stress test or a paced study. Following the data collection activity there is a computer generated result of the test which can be positive, negative or indeterminate. Patients with ongoing Atrial Fibrillation and/or Flutter (AF) will typically yield an indeterminate result and should therefore be excluded from the MTWA registry requirement. We suggest that one set of fields be added to the data registry form as such:

<b><u>Microvolt T-Wave Alternans Test</u></b>	Date of Test _____
Type of Test: Exercise <input type="checkbox"/> Pharmacologic <input type="checkbox"/> Paced <input type="checkbox"/>	
Result: Positive <input type="checkbox"/> Negative <input type="checkbox"/> Indeterminate <input type="checkbox"/> <u>OR</u> Excluded due to AF <input type="checkbox"/>	
Type of Equipment: Heartwave <input type="checkbox"/> CH2000 <input type="checkbox"/> Quest <input type="checkbox"/> Other <input type="checkbox"/>	

Adding this simple verbiage above to the data collection document will provide CMS with more science with which to further refine the target population or to develop further hypotheses to test.

**Conclusion**

The draft NCD recognizes that, as good as current studies may be, only a small percentage of the implanted patients will actually receive therapeutic benefit from these life-saving but invasive and expensive devices. Microvolt T-Wave Alternans Testing is increasingly recognized by the medical community as a valid risk-stratifier which can serve to help better define the population likely to benefit from an ICD due to its very high negative predictive value. Cambridge Heart is very supportive of CMS' approach and welcomes the opportunity to work with the agency and other stakeholders during the comment period on the development on the National ICD Registry and the completion of the ICD National Coverage Decision.

Sincerely,



David A. Chazanovitz



10/21/04

Steve E. Phurrough, MD, MPA  
Director, Coverage and Analysis Group  
CAG-00157R2  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850

RE: CAG-00157R2

Dear Dr. Phurrough,

I am sending this letter as part of the public commentary regarding the draft memo for implantation of Implantable Defibrillators (CAG-00157R2) and posted on the web at [<http://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=139>].

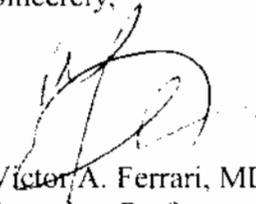
CMS has announced that it deems that an implantable cardioverter-defibrillator (ICD) may be used for patients with certain cardiomyopathies, and a measured left ventricular ejection fraction (LVEF) < 30%. In the criteria section, the determination of ejection fraction states that LVEF "must be measured by angiography, radionuclide scanning or echocardiography." I believe this latter phrase should include another imaging modality - cardiac magnetic resonance (CMR).

While the listed modalities have routinely been used to assess LVEF, CMR is now widely utilized and is regarded as the most accurate, reproducible, and reliable method for determination of chamber volumes and LVEF. CMR is the current reference standard by which methods such as 3-dimensional echo are currently validated. Furthermore, CMR is competitive with other imaging modalities, is noninvasive, and exposes the patient to no radiation or contrast dye.<sup>1</sup>

We have used the CPT codes for CMR assessment of left ventricular function [#75554, #75555] for over 10 years, and there has been a remarkable level of interest in learning and using CMR over the past 5 years. CMR is also being utilized in an increasing number of large clinical trials where accurate assessment of LVEF, mass, and chamber volumes are required.<sup>2</sup> Given these facts, I believe it is extremely important that CMR be added to the list of imaging modalities for assessment of LVEF, for the benefit of patients and their physicians alike.

Thank you for your full review of this important matter.

Sincerely,



Victor A. Ferrari, MD  
Associate Professor of Medicine and Radiology  
University of Pennsylvania School of Medicine

Associate Director  
Cardiac Noninvasive Imaging Laboratory  
Hospital of the University of Pennsylvania

1. Rajappan K, Bellenger NG, Anderson L, Pennell DJ. The role of cardiovascular magnetic resonance in heart failure. *Eur J Heart Fail.* 2000 Sep;2(3):241-52.
2. Bellenger NG, Rajappan K, Rahman SL, Lahiri A, Raval U, Webster J, Murray GD, Coats AJ, Cleland JG, Pennell DJ; CHRISTMAS Study Steering Committee and Investigators. Effects of carvedilol on left ventricular remodelling in chronic stable heart failure: a cardiovascular magnetic resonance study. *Heart.* 2004;90(7):760-4.

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October 28, 2004

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www.hfsa.org

Centers for Medicare and Medicaid Services  
Office of Clinical Standards and Quality  
Coverage and Analysis Group  
Attention: Public Comments, S3-02-01  
7500 Security Blvd  
Baltimore, MD 21244-1850

**To Whom It May Concern:**

The Heart Failure Society of America (HFSA) greatly appreciates the opportunity to provide comment on CMS' draft coverage decision regarding implantable cardioverter defibrillators (ICDs), stemming from the results of recently completed randomized controlled trials. HFSA is an organization of health care providers and scientists with an interest and expertise in heart failure. The organization's mission is improvement of clinical outcomes for patients with this condition.

Along with CMS, we believe that recent evidence clearly expands the population for which ICD therapy is known to improve survival likelihood. We will direct our comments toward 1) specific characteristics of the population to be covered and 2) the proposal for requiring registry participation as a requirement for coverage.

**Comments regarding population characteristics**

First, we are concerned about the requirement that patients with non-ischemic dilated cardiomyopathy (NIDCM) carry this diagnosis for a minimum of 9 months prior to availability of ICD coverage. We recognize the rationale for delaying implant for a period of time following initial diagnosis. Patients enrolled in SCD-HeFT were well-managed, medically, and were stable for a period of 3 months. Furthermore, there is evidence that patients treated medically manifest improved ejection fraction over 3 months. However, we know of no rationale for withholding ICD implant for longer than 3 months. We therefore recommend that coverage be offered to patients who have been under medical treatment for NIDCM for at least 3 months.

Second, we are concerned about the routine exclusion of patients with ischemic dilated cardiomyopathy (IDCM) with either MI within the prior month or revascularization procedure within the prior 3 months. We believe that for patients who have suffered a prior MI (earlier than 1 month previously) and have previously manifested reduced ejection fraction, the rationale for benefit from ICD placement is not diminished by their suffering an additional MI. Likewise, although a brief period (e.g., several weeks) following revascularization may be warranted to determine whether ejection fraction improves, we do not believe that delaying for 3 months is justified.

Third, we believe that coverage should be extended to select patients with class IV heart failure. Cardiac resynchronization therapy (CRT) has been shown to improve NYHA class. Without providing coverage for a combined device for class IV patients, a repeat procedure with exchange of the device would be needed for patients whose clinical status improves. Such a repeat procedure does not appear rational or cost-effective. Therefore, for patients who meet criteria for CRT, based on results of COMPANION, we believe that the physician should be offered some discretion regarding implant of a combined CRT-ICD device. Additionally, ICD implant is justifiable in patients awaiting cardiac transplant out of the hospital.

### **Comments regarding the proposed registry**

We acknowledge the desirability of systematically acquiring additional information regarding patients receiving ICDs. However, we have a number of concerns regarding the concept of a registry and its implication for ICD coverage.

First, we are uncertain that a registry can achieve the stated goal of clarifying characteristics of patients who do and do not benefit from ICD implant. Generally speaking, incremental knowledge regarding therapeutic benefit has derived from prospective, randomized, controlled trials. There are significant methodologic challenges to drawing conclusions regarding treatment benefit from a registry of ICD recipients. We recommend that the specific hypotheses and analytic plan should be clarified prior to declaring that a registry is required for coverage.

Second, we are concerned about withholding ICDs from patients who stand to benefit between now and the time that a registry might be implemented. We urge strong consideration of initiating coverage immediately, while discussions and efforts are carried out toward implementing a registry.

Third, we would ask for clarification regarding the informed consent implication for individual participation in a registry. We would hope that individual patients for whom ICD implant is indicated, but who decline registry participation, would not be denied coverage.

Again, the HFSA appreciates the opportunity to comment regarding ICD coverage. We stand willing and able to provide advice and other forms of assistance in all matters that impact on clinical outcomes in patients with heart failure.

Sincerely,



Gary Francis, M.D.  
President



Marvin A. Konstam, M.D.  
Chair, Advocacy Committee

cc: Sean Tunis, MD, MSc

CMS comment ICD coverage

SECTION ON CARDIOLOGY

Department of Internal Medicine

October 25, 2004

APPOINTMENTS  
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*Professors Emeriti*  
Henry S. Miller, M.D.  
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L. Earl Watts, M.D.

Steve E. Phurrough, MD, MPA  
Director, Coverage and Analysis Group  
CAG-00157R2  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850

RE: CAG-00157R2

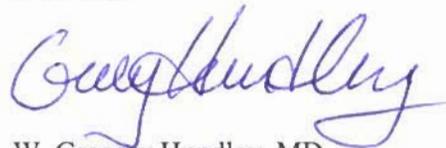
Dear Dr. Phurrough,

I am responding as part of the public comment regarding the draft decision memo for implantation of Implantable Defibrillators (CAG-00157R2). In this document, CMS proposes to conclude that an "implantable cardioverter-defibrillator (ICD) is reasonable and necessary for patients with ischemic dilated cardiomyopathy (IDCM), documented prior myocardial infarction (MI) and **measured left ventricular ejection fraction (LVEF)  $\leq$  30%.**" Under the criteria section, the determination of ejection fraction "**must be measured by angiography, radionuclide scanning or echocardiography.**"

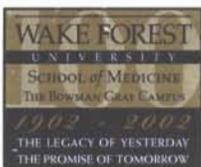
**Cardiovascular magnetic resonance (CMR)** is the current "gold standard" by which other methods (e.g., 3D echo) are being validated. In addition, CMR assessment of left ventricular volumes/ejection fraction is cost effective compared with other imaging modalities and CPT codes for CMR determination of left ventricular function [#75554, #75555] have been in use for over a decade. As the most accurate and reproducible mechanism for determination of left ventricular ejection fraction, I believe that it is imperative that the **inclusion of magnetic resonance imaging as an acceptable imaging modality option for determination of left ventricular ejection fraction** is in the best interest of serving the needs of both the patient and CMS.

Thank you for your attention to this important matter.

Sincerely,



W. Gregory Hundley, MD  
Associate Professor Internal  
Medicine (Cardiology) and  
Radiology  
Wake Forest University Health Sciences



Wake Forest University Health Sciences

Medical Center Boulevard • Winston-Salem, North Carolina 27157



Christopher M. Kramer MD  
Departments of Radiology  
and Internal Medicine (Cardiology)  
Box 800170  
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ckramer@virginia.edu Email

October 22, 2004

Steve E. Phurrough, MD, MPA  
Director, Coverage and Analysis Group  
CAG-00157R2  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850

RE: CAG-00157R2

Dear Dr. Phurrough,

I am responding as part of the public comment regarding the draft decision memo for implantation of Implantable Defibrillators (CAG-00157R2) and posted on the web at [<http://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=139>]. CMS proposes to conclude that an "implantable cardioverter-defibrillator (ICD) is reasonable and necessary for patients with ischemic dilated cardiomyopathy (IDCM), documented prior myocardial infarction (MI) and measured left ventricular ejection fraction (LVEF)  $\leq$  30%." Under the criteria section, the determination of ejection fraction "must be measured by angiography, radionuclide scanning or echocardiography."

I would like to suggest that you include cardiac magnetic resonance imaging (CMR) as another acceptable method for measuring LV ejection fraction. It is currently considered the gold standard method for making these measurements in patients with left ventricles deformed by prior myocardial infarction. Other imaging modalities including the above named modalities as well as 3D echo are compared against CMR in these measures. (See Buck et al *Circulation* 1997;96:4286 and Mor-Avi et al *Circulation* 2004;110:1814). Previous studies have also documented the reduction in potential sample sizes in clinical studies of ejection fraction measurements when comparing CMR to echocardiography (Bellenger et al, *J Cardiovasc Magn Reson* 2000;2:271) due to its reproducibility and accuracy. I believe that it is quite important that the CMR be included as an acceptable imaging modality option for determination of left ventricular ejection fraction to best serve the interests of the patient and CMS.

Thank you for your attention to this matter.

Sincerely,

A handwritten signature in black ink that reads "Chris M. Kramer".

Christopher M. Kramer MD



BRIGHAM  
AND  
WOMEN'S  
HOSPITAL



Harvard Medical School

Raymond Kwong, M.D.  
Co-Director, Cardiac Magnetic Resonance Imaging  
Cardiovascular Division  
Department of Medicine

75 Francis Street  
Boston, Massachusetts 02115  
(617) 732-6376  
(617) 277-4981 (fax)  
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Steve E. Phurrough, MD, MPA  
Director, Coverage and Analysis Group  
CAG-00157R2  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850

October 21, 2004

Dear Dr. Phurrough,

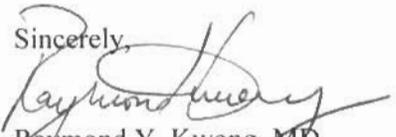
A recent draft decision memo for implantation of Implantable Defibrillators (CAG-00157R2) as posted on the website of the Centers for Medicare and Medicaid Services proposes that an implantable cardioverter-defibrillator (ICD) is necessary for patients with cardiomyopathy and measured left ventricular ejection fraction (LVEF)  $\leq 30\%$ . Under the criteria section, the determination of ejection fraction "must be measured by angiography, radionuclide scanning or echocardiography".

There is no controversy in medical literature or within the cardiac imaging community that cardiovascular magnetic resonance imaging (CMR) is the most accurate and precise technique in assessing ventricular sizes and ejection fraction. Cine CMR offers 3-D volumetric quantitation of left ventricular function and size without the use of contrast agent or radiation in less than 10 minutes. In patients suitable for CMR imaging, the best diagnostic information is acquired in essentially all patients and this "gold standard" technique is in common clinical use in many academic or private practice healthcare institution. Therefore, amongst all other existing imaging techniques, CMR is convenient, safe, and most important of all, the most accurate and reproducible in the quantitation of ventricular sizes and functions.

Omitting CMR in the list of imaging technology for assessment of left ventricular function will prevent the majority of heart failure patients from the benefits of the diagnostic information of CMR. CMR assessment of left ventricular volumes/ejection fraction is **cost effective** compared with other imaging modalities and CPT codes for CMR determination of left ventricular function [#75554, #75555] have been in use for over a decade. I firmly believe that CMR must be included as an acceptable imaging modality for determination of left ventricular ejection fraction in cardiomyopathy patients in this draft decision.

Thank you for your kind attention.

Sincerely,



Raymond Y. Kwong, MD  
Brigham and Women's Hospital  
Harvard Medical School

Cardiology Specialists of Casa Grande, PC  
1780 E. Florence Blvd., Ste. 108  
Casa Grande, AZ 85222

October 26, 2004

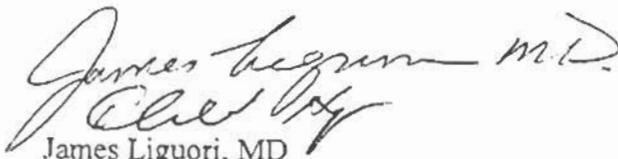
Re: Micro T-wave Alternans (MTWA)

We are writing to express support for MTWA Testing inclusion in the CMS proposed Registry for ICD implantation. With the CMS draft policy for ICD implantation in 2005; the potential patient population that would qualify for treatment of SCD has greatly expanded.

The potential degree of risk/benefit to patients, in addition to the potential burden to the health care system could be clarified by inclusion of MTWA testing in a patient registry. MTWA testing as a means of identifying patients who will not benefit from AICD placement could reduce patient risk, in addition to providing appropriate use of health care dollars.

Please consider MTWA Test inclusion in the proposed CMS Registry for ICD implantation.

Sincerely,

  
James Liguori, MD  
Khalid Naqi, MD  
Camille Woods, NP  




## SOCIETY FOR CARDIOVASCULAR MAGNETIC RESONANCE

WARREN J. MANNING, MD, FACP, FACC, FAHA

*President, SCMR*

*Professor of Medicine and Radiology*

*Harvard Medical School*

**Beth Israel Deaconess Medical Center**

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[wmanning@bidmc.harvard.edu](mailto:wmanning@bidmc.harvard.edu)

19 October, 2004

Steve E. Phurrough, MD, MPA  
Director, Coverage and Analysis Group  
CAG-00157R2  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850

RE: CAG-00157R2

Dear Dr. Phurrough,

I am responding as part of the public comment regarding the draft decision memo for implantation of Implantable Defibrillators (CAG-00157R2) and posted on the web at [<http://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=139>].

In this document, CMS proposes to conclude that an “implantable cardioverter-defibrillator (ICD) is reasonable and necessary for patients with ischemic dilated cardiomyopathy (IDCM), documented prior myocardial infarction (MI) and **measured left ventricular ejection fraction (LVEF)  $\leq$  30%.**” Under the criteria section, the determination of ejection fraction “**must be measured by angiography, radionuclide scanning or echocardiography.**”

While left ventricular angiography, radionuclide scanning and echocardiography are commonly used imaging modalities to determine left ventricular ejection fraction, **cardiovascular magnetic resonance (CMR)** is also both widely utilized and generally regarded as *the most accurate and reproducible method* for determination of left ventricular chamber volumes and ejection fraction having been validated against numerous standards. CMR is the current “gold standard” by which other methods (e.g., 3D echo) are being validated. In addition, CMR assessment of left ventricular volumes/ejection fraction is cost effective compared with other imaging modalities and CPT codes for CMR determination of left ventricular function [#75554, #75555] have been in use for over a decade. As the most accurate and reproducible mechanism for determination of left ventricular ejection fraction, I

believe that it is imperative that the **inclusion of magnetic resonance imaging as an acceptable imaging modality option for determination of left ventricular ejection fraction** is in the best interest of serving the needs of both the patient and CMS.

Thank you for your attention to this important matter.

Sincerely,

A handwritten signature in blue ink, appearing to read "Warren J. Manning", is written over the printed name.

Warren J. Manning, MD  
President

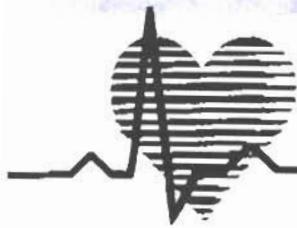
Society for Cardiovascular Magnetic Resonance

# San Joaquin Cardiology Medical Group, Inc.

Ramin Manshadi, M.D.

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Associates:

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Alvin C. Cacho, M.D.  
Gurinder S. Grewal, M.D.

Hooman Madyoon, M.D.  
Ramin Manshadi, M.D.  
Stephen Stark, M.D.

October 18, 2004

TO: WHOM IT MAY CONCERN

I AM A CARDIOLOGIST IN PRIVATE PRACTICE. A FREQUENT CLINICAL CONSIDERATION IS THE NEED FOR AN IMPLANTABLE DEFIBRILLATOR IN PATIENTS WITH DECREASED LEFT VENTRICULAR FUNCTION. AS YOU KNOW, THIS PROCEDURE IS QUITE EXPENSIVE AND INVASIVE AND LEAVES THE PATIENT WITH AN IMPLANTED DEVICE FOR THE REMAINDER OF THEIR LIFE, SUBJECT TO ALL OF THE COMPLICATIONS OF SUCH IMPLANTED DEVICES. IT IS MUCH DESIRED BY THE PATIENT AS WELL AS OUR STAFF TO AVOID THESE DEVICES, UNLESS ABSOLUTELY NECESSARY; ALTERNATIVELY, WE ALSO DESIRE PROPER PLACEMENT IN PATIENTS WHO TRULY DO NEED THEM.

UNFORTUNATELY, AT THIS POINT IN TIME WHEN ONE RELIES ON "STANDARD" CRITERIA FOR AN IMPLANTABLE DEFIBRILLATOR INSTALLATION, MANY PATIENTS (ABOUT 80%) APPARENTLY GET THE DEVICES UNNECESSARILY AS ONLY ONE OUT OF FIVE DEVICES ACTUALLY DISCHARGES IN FOLLOW-UP. MICROVOLT T-WAVE ALTERNANS IS AN EXTREMELY PROMISING TOOL WHICH PROMISES TO "WEED OUT" THOSE PATIENTS WHO DO NOT NEED DEFIBRILLATORS FROM THE LARGER GROUP, AS IT HAS PROVEN TO HAVE AN EXTREMELY HIGH NEGATIVE PREDICTIVE VALUE.

CURRENTLY WE HAVE DIFFICULTY IN UTILIZING THIS TEST AS BROADLY AS WE WOULD LIKE BECAUSE OF THE LACK OF INSURANCE COVERAGE, AND SOME OF OUR PATIENTS THEN HAVE TO GO ON TO EXPENSIVE, INVASIVE ELECTROPHYSIOLOGICAL TESTING AND IMPLANTABLE DEFIBRILLATOR IMPLANTATION SIMPLY BECAUSE WE ARE NOT ABLE TO UTILIZE AS FULLY AS WE WOULD LIKE THIS SIMPLE MICROVOLT T-WAVE ALTERNANS TEST.

I UNDERSTAND THAT CMS IS NOW CONSIDERING A REGISTRY IN THOSE PATIENTS WHO RECEIVE AN IMPLANTABLE DEFIBRILLATOR AND I RESPECTFULLY REQUEST THE CONSIDERATION OF INCLUDING MTWA WITHIN THIS REGISTRY. I AM CONFIDENT THAT IF MTWA WAS WIDELY EMPLOYED, HUGE SAVINGS TO THE ENTIRE HEALTH CARE SYSTEM WOULD RESULT.

AT OUR OWN PRACTICE, WE FIND THAT OF THE PATIENTS WE SCREEN, ONLY ONE OUT OF FIVE ACTUALLY GET REFERRED ON FOR IMPLANTABLE DEFIBRILLATOR IMPLANTATION.

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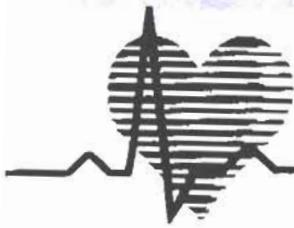
**Business Office:** 2800 N. California Street, Suite 14-A, Stockton, CA 95204. (209) 942-1005, FAX (209) 942-0455

# San Joaquin Cardiology Medical Group, Inc.

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Alvin C. Cacho, M.D.  
Gurinder S. Grewal, M.D.

Hooman Madyoon, M.D.  
Ramin Manshadi, M.D.  
Stephen Stark, M.D.

AT A COST OF \$50,000 PER DEFIBRILLATOR AND WITH THREE OR FOUR DEFIBRILLATORS AVOIDED WEEKLY IN OUR SMALL PRACTICE, IT IS EASY TO SEE HOW COST SAVINGS QUICKLY ACCRUE.

OF THE NONINVASIVE SCREENING MODALITIES, MTWA APPEARS TO HAVE THE VERY BEST POTENTIAL FOR PROPERLY SCREENING FOR ICDS AND IS LIKELY MUCH MORE ACCURATE THAN ELECTROPHYSIOLOGICAL STUDY IN THAT REGARD.

I APPRECIATE YOUR CONSIDERATION.

SINCERELY,

RAMIN-MANSHADI, MD, FACC

October 27, 2004

Steve Phurrough, M.D., Director of Coverage and Analysis Group  
Office of Clinical Standards and Quality  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
7500 Security Blvd.: C1-11-08  
Baltimore, MD 21244

RE: **ICD Coverage : Registry**

Dear Dr. Phurrough,

I wanted to applaud you and the CMS leadership on providing revised coverage for ICD therapy in patients at high risk for sudden cardiac death.

I believe in order to properly understand the impact of this new technology on this high risk population it is important that a data registry be established and that ongoing data collection efforts continue in order to seek to identify and define patient benefit.

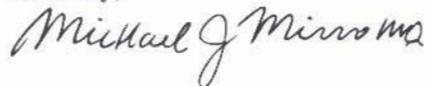
I would wish that you consider the following items:

- 1) The ACC as an organization could facilitate the data collection (ACC NCDR)
- 2) The registry not restrict ICD implant based on your coverage determination (EF less than or equal to 30% in patients with and without ischemic cardiomyopathy).
- 3) Microvolt T-wave alternans be a required element of the patient registry in order to attempt to identify low risk patients within this population.

The continued efforts of specialty societies including the ACC and the Heart Rhythm Society have been laudable in an attempt to scientifically define the appropriate patient population that would benefit the greatest from ICD implant. I do believe the elimination of QRS duration was an important step forward based on the lack of science supporting its use. However, I do believe that the use of microvolt T-wave alternans which has demonstrated a high negative predictive value, would be of benefit in identifying patients that would receive the greatest benefit.

Thank you for considering these comments.

Sincerely,



Michael J. Mirro, M.D., F.A.C.C.

MJM:mah  
mjm1509 04.doc  
cc: Kathy Flood

CARDIOLOGISTS

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M. Todd Alderson, M.D.

Linda Landin, M.D.

Elsa D. Pascual, M.D.

**Elsa D. Pascual, M.D., P.C.**

3302 Route 207  
Goshen, New York 10924  
Tel. 845-294-8817 Fax. 845-294-3612

Christine M. Cesarz, M.S., A.N.P.

October 19, 2004

JoAnna F Baldwin  
Lead Analyst  
Division of Medical & Surgical Services  
Centers for Medicare and Medicaid Service  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Draft Decision Memo for Implantable Defibrillators (CAG-00157R2)

Dear Ms. Baldwin:

I applaud the agency's decision to expand the coverage for ICDs to include MADIT II and most SCD-Heft patients. These two studies clearly identified the life saving value of defibrillator therapy and now more patients being eligible increases our odds for reducing Sudden Cardiac Death.

The purpose of my writing you today is to voice my opinion about the patient registry that the agency has proposed. While at first blush it seems more a roadblock to ICD use than anything else. With a better understanding of the content of this proposed policy, I realize that the registry will not limit ICD implants and has value in determining whether ICD therapy is appropriate for all these patients **if Microvolt T-Wave Alternans is a required element.**

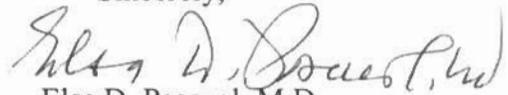
I believe that by making Microvolt T-Wave Alternans a required element of the registry, we will gain valuable and addition information, which should address my concerns about appropriate use of ICD in these new populations. All the potential risk stratifiers mentioned in the policy with the exception of MTWA have been available for some time. MTWA represents a more specialized technology than previously evaluated risk stratifiers because of its proven very high negative predicted value.

I am concerned that the available data does not allow me to clearly target ICDs to patients that will derive benefit. I believe that using MTWA is critical to ensuring that defibrillator implantation occurs only in those patients most likely to benefit. The use of MTWA in the registry will enable the agency to evaluate this hypothesis.

It seems to me that the relatively small absolute decrease in mortality seen in SCD-HeFT and the seemingly low number of appropriate firings, a risk stratifier like Microvolt T-Wave Alternans should be evaluated more closely and included as a required element of the patient registry.

At the present time, I have been utilizing MTWA within the recommended, justifiable indications within my patient population, and I have already seen its tremendous value in choosing appropriate candidates for further studies, such as EP studies, and eventual device therapy.

Sincerely,

  
Elsa D. Pascual, M.D.

# St. Francis Hospital



THE HEART CENTER®

Nathaniel Reichek, M.D., F.A.C.C.

Director

Research and Education

October 22, 2004

Steve E. Phurrough, MD, MPA  
Director, Coverage and Analysis Group  
CAG-00157R2  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850

RE: CAG-00157R2

Dear Dr. Phurrough,

I am writing to offer public comment regarding the draft decision memo on Implantable Defibrillators [<http://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=139>] (CAG-00157R2). CM proposes that an “implantable cardioverter-defibrillator (ICD) is reasonable and necessary for patients with ischemic dilated cardiomyopathy (IDCM), documented prior myocardial infarction (MI) and **measured left ventricular ejection fraction (LVEF)  $\leq$  30%.**” Under the criteria section, the determination of ejection fraction “**must be measured by angiography, radionuclide scanning or echocardiography.**” A similar recommendation is made for idiopathic dilated cardiomyopathy.

While left ventricular angiography, radionuclide scanning and echocardiography are commonly used imaging modalities to determine left ventricular ejection fraction, **cardiovascular magnetic resonance (CMR)** is also both widely utilized and generally regarded as a gold standard three dimensional method for LVEF. It is the most accurate and reproducible method for determination of left ventricular chamber volumes and ejection fraction and has been extensively validated against various invasive and anatomic reference techniques. Indeed, CMR is currently used to validate other candidate methods such as 3D echo and SPECT MUGA. Further, emerging evidence indicates that CMR is more reliable than 2D echo for LVEF in the "MADIT II" population. CMR assessment of left ventricular volumes/ejection fraction is cost effective compared with other imaging modalities and CPT codes for CMR determination of left ventricular function [#75554, #75555] have been in use for over a decade. In my own program, which provides echo, nuclear, CT and CMR imaging for patients referred to us by practitioners at a very busy, high volume Heart Center, we have encouraged use of CMR LVEF to improve patient selection for ICD implantation even though it is economically disadvantageous to us to do so because of low reimbursement. I believe that it is essential that **cardiac magnetic resonance imaging be included as an acceptable imaging modality option for determination**

A Member of Catholic Health Services of Long Island  
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**of left ventricular ejection fraction in the evaluation of patients for ICD implantation.** This is certainly in the best interests of both patients and CMS. I would be happy to provide additional information in support of this letter if you thought it would be helpful. You may also find it useful to obtain input in regard to this matter from Rod Pettigrew, MD PhD, Director, National Institute of Imaging and Biomedical Engineering, NIH.

Thank you very much for your attention to this matter.

Sincerely,



Nathaniel Reichel MD FACC FAHA  
Director, Research and Education  
St. Francis Hospital-The Heart Center  
100 Port Washington Blvd  
Roslyn, NY 11576, USA  
Professor of Medicine and Biomedical Engineering  
Stony Brook University, SUNY

October 15, 2004

JoAnna F. Baldwin  
Lead Analyst  
Division of Medical & Surgical Services  
Centers for Medicare and Medicaid Services\  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Draft Decision Memo for Implantable Defibrillators (CAG-00157R2)

Dear Ms. Baldwin:

I applaud the agency's decision to expand the coverage for ICDs to include MADIT II and most SCD-Heft patients. These two studies clearly identified the life saving value of defibrillator therapy and now more patients being eligible increases our odds for reducing Sudden Cardiac Death.

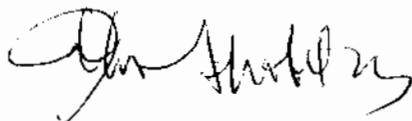
The purpose of my writing you today is to voice my opinion about the patient registry that the agency has proposed. While at first blush it seems more a roadblock to ICD use than anything else. With a better understanding of the content of this proposed policy, I realize that the registry will not limit ICD implants and has value in determining whether ICD therapy is appropriate for all these patients **if Microvolt T-Wave Alternans is a required element.**

I believe that by making Microvolt T-Wave Alternans a required element of the registry, we will gain valuable and additional information, which should address my concerns about appropriate use of ICD in these new populations. All the potential risk stratifiers mentioned in the policy with the exception of MTWA have been available for some time. MTWA represents a more specialized technology than previously evaluated risk stratifiers because of its proven very high negative predictive value.

I am concerned that the available data does not allow me to clearly target ICDs to patients that will derive benefit. I believe that using MTWA is critical to ensuring that defibrillator implantation occurs only in those patients most likely to benefit. The use of MTWA in the registry will enable the agency to evaluate this hypothesis.

It seems to me that with the relatively small absolute decrease in mortality seen in SCD-HeFT and the seemingly low number of appropriate firings, a risk stratifier like Microvolt T-Wave Alternans should be evaluated more closely and included as a required element of the patient registry.

Sincerely,



**John K. Terzian, MD, FACC**

**Internal Medicine/Cardiology**

**Caritas Good Samaritan  
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October 20, 2004

JoAnna F. Baldwin  
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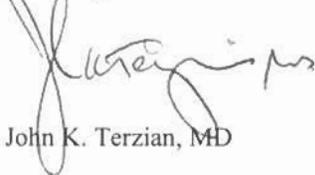
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Sincerely,



John K. Terzian, MD

Commenter: Cohen, Richard M.D., Ph. D.

Organization: Date: October 21, 2004 Comment:

I am writing to comment on the Draft Decision Memo for Implantable Defibrillators which you issued on September 28, 2004. I very much appreciate the opportunity that you provided me to express my views on this issue prior to your issuing the draft decision

As you know I felt that it would have been appropriate based on the published clinical data to require a non-negative Microvolt T-Wave Alternans (MTWA) test as a requirement for reimbursement of an implantable cardioverter/defibrillator (ICD) as primary prevention therapy in patients with LVEF  $\leq$  .30 approve reimbursement for ICDs in all such patients provided that they are entered into a national registry.

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\* By way of disclosure, I am a member of the board of directors, consultant, and have a financial interest in Cambridge Heart, Inc. a manufacturer of equipment for the measurement of Microvolt T-Wave Alternans.

A required national registry can provide a comprehensive database for identifying which patients are most likely to actually receive therapy from the implanted ICDs. The data from this registry can be used to inform clinical practice and to form hypotheses to be tested in future clinical trials.

The clinical data I have already shared with you indicate that the risk of sudden death and cardiac arrest in patients who test negative for MTWA is extraordinarily

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low. Thus MTWA is the most attractive risk stratifier for the LVEF  $\leq$  .30 Accordingly, MTWA testing should be a required element for all patients in the national registry. Only by making MTWA a required element of the registry will patient selection bias within the registry be eliminated so that the data may be meaningfully interpreted. MTWA is an easily performed non-invasive test available on a number of equipment platforms that can be seamlessly incorporated into the workup of patients prior to ICD implantation. It could even be performed in the electrophysiology laboratory at the time of ICD implantation.

In addition, as referring physicians begin to incorporate MTWA testing into their practice, given the published studies as well as the data that will come from the registry, I believe physicians will increasingly use MTWA to risk stratify their LVEF  $\leq$  .30 CD only in those patients who do not test MTWA negative. This will lead physicians to place ICDs only in patients who are likely to benefit from the therapy.

The registry should be constructed so that one may examine the relationship between patient characteristics prior to ICD implant and end-point events. I would suggest that required patient characteristics include: age, gender, left ventricular ejection fraction, type of heart disease, history of myocardial infarction (including date of most recent myocardial infarction if known), NYHA class, QRS width, and MTWA. All test data should be obtained within six months prior to implant.

Microvolt T-Wave Alternans Testing

As I discussed above MTWA should be required element of the registry for all patients. MTWA has been demonstrated to be predictive of ventricular tachyarrhythmias when measured during exercise or pharmacologic stress or during cardiac pacing. The MTWA measurement obtained is dependent on the equipment used to collect the data and the specific processing algorithms it utilizes. Thus it is important to document the type of equipment used to perform the measurement. Furthermore, the equipment provides an automated computer interpretation of the MTWA test. In order to eliminate variability of individual physician interpretation of the test, I strongly suggest that the registry should record the result of the automated computer interpretation of the MTWA test.

Thus the data elements for the MTWA test should include:

- Date of MTWA test

TM TMTM

- Equipment used: Heartwave , CH2000 , Quest , Other
- Type of Stress: exercise, stress, or cardiac pacing
- Automated Computer Interpretation of Test: Positive, Negative, Indeterminate (or Excluded due to continuous atrial fibrillation or flutter)

End-Point Data

The most important end-point data will be ICD firing data and death.

The types of hypotheses to be tested will be, for example, the relationship between the patient characteristics and the ICD firing data. One problem with using ICD firing (delivery of rapid pacing stimuli or defibrillation shock) is that ICDs may terminate non-sustained episodes of ventricular tachycardia (VT) that if untreated may have self-terminated and not resulted in either cardiac arrest or sudden cardiac death. This problem may be mitigated to some extent by using heart rate criteria to define a life threatening ventricular tachyarrhythmic event. For example one may define a life threatening ventricular tachyarrhythmic event as ventricular tachyarrhythmia with an intrinsic rate above some critical value, say 185 beats per minute, which persisted long enough to trigger delivery of electrical therapy from the ICD.

In a clinical study it would be desirable to have the stored electrograms for each event reviewed by an expert to see if the ICD firing was “appropriate”. This may not be feasible in a registry. It may be desirable to have only “appropriate” ICD discharges entered into the registry as determined by the local physician.

Optimally ICD firing data for all events would be obtained (including stored electrograms). However, Kaplan Meier analysis and multivariate Cox regression analysis usually just analyze the time to the first event. If all firing data for all events are available, additional analyses related to firing frequencies would be possible.

In summary, for each ICD discharge entered into the registry it is important to record the date of the event and the rate of the preceding ventricular tachyarrhythmia. If not all ICD discharge data are to be stored then at the very least the date of the first life threatening ventricular tachyarrhythmic event should be recorded (excluding the first 24 hours after implant).

Date of death should also be recorded.

Summary

I support the draft decision including the requirement for a registry for patients receiving ICDs for purposes of primary prevention. A required element for all patients in the registry should be microvolt T-wave alternans testing as the preeminent risk stratifier for the population in question. In order to avoid bias in patient selection, all data elements should be required for all patients in the registry. The views expressed in this letter are exclusively my own and do not represent the views of Harvard or MIT.

Please feel free to contact me if I can be of further assistance.