

**MEETING MINUTES
OF THE
CENTERS FOR MEDICARE AND MEDICAID SERVICES
MEETING OF THE
MEDICARE COVERAGE ADVISORY COMMITTEE**

February 12, 2003

**Baltimore Convention Center
One West Pratt Street
Baltimore, Maryland**

Medicare Coverage Advisory Committee Meeting

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Attendees

Harold C. Sox, M.D.
Chairperson

Janet Anderson
Executive Secretary

Voting Members

Colleen Conway-Welch, Ph.D.
Anne Curtis, M.D., FACC
Carole Flamm, M.D., M.P.H.
Thomas V. Holohan, M.A., M.D., F.A.C.P.
Alexander Krist, M.D.
Karl Matuszewski, PharmD, M.S.
Rita F. Redberg, M.D., M.Sc., FACC

CMS Liaison

Sean R. Tunis, M.D., M.Sc.

Consumer Representative

Phyllis E. Greenberger, M.S.W.

Industry Representative

Jonathan Weil, Ph.D., J.D.

Invited Guests

Thomas Bigger, M.D.
Alfred Buxton, M.D.
Mark D. Carlson, M.D., M.A., FACC
Kerry Lee, Ph.D.
Bruce Wilkoff, M.D.

Wednesday, February 12, 2003, 8:07 a.m.

The Medicare Coverage Advisory Committee (MCAC) met on February 12, 2003, to hear and discuss evidence and testimony regarding the expansion of indications for implantable cardioverter defibrillators (ICD).

The meeting began with the introduction of the Committee, a reading of the conflict of interest statement, opening remarks by the Centers for Medicare & Medicaid Services (CMS) Liaison, and a charge to the committee by the Chair.

CMS Presentation of Implantable Defibrillators Request and Voting/Discussion

Questions. Joseph Chin, MD presented the panel with background about current coverage, the coverage request received and being discussed before this panel, and a summary of articles about implantable defibrillators. CMS' major concern was that the MADIT II trial enrolled a large number of patients that already had a known ICD indication with a large mortality benefit, and that this group of patients might be responsible for most of the mortality benefit in the treatment group. In addition, CMS was also interested in identifying a patient sub-population within the MADIT II trial that received most of the benefit from ICD therapy. Steven Goodman, MD then presented the panel with his analysis of the MADIT II trial data. Dr. Chin concluded the presentation by introducing the following voting questions:

- (1) a. Is the evidence adequate to draw conclusions about the net health outcomes in Medicare patients with evidence of a ventricular tachyarrhythmia either induced or spontaneous, with or without documented coronary artery disease and reduced left ventricular ejection fraction undergoing implantable defibrillator therapy as primary prevention of sudden cardiac death?
- b. If yes, what is the size of the net health outcomes in this Medicare population as compared to established therapies?

- (2) a. Is the evidence adequate to draw conclusions about the net health outcomes in Medicare patients with a prior myocardial infarction, ejection fraction less than or equal to 30 percent, and without evidence of an induced or spontaneous ventricular tachyarrhythmia undergoing implantable defibrillator therapy as primary prevention of sudden cardiac death?
- b. If yes, what is the size of the net health outcomes in this Medicare population as compared to established therapies?

In addition, Dr. Chin also introduced a discussion question:

- (1) Two of the summarized trials used electrophysiologic testing to identify high risk patients. Two did not. What is the utility of electrophysiologic testing?

Following these presentations, the Chair offered panelists the opportunity to ask clarifying questions of Dr. Chin and Dr. Goodman.

Requestor's Presentation: Guidant Corporation. Joseph Smith, MD, senior vice president and chief medical officer of Guidant Corporation, addressed the panel on behalf of Guidant. Dr. Smith urged the MCAC to recommend CMS cover ICDs for patients who meet the MADIT II inclusion and exclusion criteria. Dr. Smith introduced Arthur Moss, MD, who was the principal investigator of the MADIT II trial. Dr. Moss made a detailed presentation of the MADIT II trial data, including analyses conducted in response to the evidence summary developed by CMS staff. Both presented MADIT II study data that had not previously been made public or provided to CMS or MCAC panelists.

Medtronic, Inc. Marshall Stanton, MD, vice president and medical director of the Cardiac Rhythm Management Division of Medtronic, urged the panel and CMS to take rapid action to institute coverage for ICDs.

Committee Discussion – Questions to Presenters. Panelists were given the opportunity to question CMS presenters, the requestors and their representatives.

Scheduled Public Comments. The panel heard from eight speakers who had applied for the opportunity to address the panel. These speakers included representatives of the American College of Cardiology (Gabriel Gregoratos, MD), the North American Society of Pacing and Electrophysiology (Bruce Lindsay, MD), two researchers in T-wave Alternans (Theodore Chow, MD and Richard Cohen, MD), and four clinicians (Mark Hlatky, MD; David Cannom, MD; John Boehmer, MD and Joanne Lynn, MD).

Open Public Comments. Following lunch, the panel heard from 11 members of the public, nine electrophysiologists, one cardiologist and one electrophysiologist/cardiologist, all speaking in support of coverage for ICDs.

Committee Deliberations and Voting. The panel conducted extensive discussions, and asked many questions of the requestors and the guest panelists. Following these discussions, it was the consensus of the voting members of the panel that they should principally address voting question 2. It was further agreed to amend the question from what was originally submitted, and a motion was made to vote on the following question:

Is the evidence adequate to draw conclusions about the net health outcomes in Medicare aged patients who meet the inclusion and exclusion criteria in the MADIT II trial and who receive an ICD as primary prevention for Sudden Cardiac Death (SCD)?

The panel voted 'YES' unanimously to this question.

Following further discussion, a motion was made to vote on the following question:

Is the evidence adequate to apply the findings of MADIT II to all Medicare patients with a prior MI and an EF less than or equal to 30 percent without requiring evidence of an arrhythmia?

The panel voted 'NO' unanimously to this question.

Following additional discussion, a motion was made to vote a third question:

Is the evidence adequate to apply the findings of the MADIT II trial to all Medicare patients who meet the inclusion and exclusion criteria for the MADIT II trial?

The panel voted 'YES' unanimously to this question.

With the approval of the CMS liaison, the panel did not discuss the original first voting question or the discussion question.

Adjournment. The meeting adjourned at 3:40 p.m.

I certify that I attended the meeting of the Medicare Coverage Advisory Committee on February 12, 2003, and that these minutes accurately reflect what transpired.

Janet Anderson
Executive Secretary, MCAC, CMS

I approve the minutes of this meeting as recorded in this summary.

Harold C. Sox, M.D.
Chairperson