MEETING MINUTES
OF THE
CENTERS FOR MEDICARE AND MEDICAID SERVICES
MEDICARE EVIDENCE DEVELOPMENT & COVERAGE ADVISORY COMMITTEE

November 9, 2011

Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD

Medicare Evidence Development & Coverage Advisory Committee
November 9, 2011

Attendees

Clifford Goodman, PhD
Chairperson

Steve E. Phurrough, MD, MPA
Vice Chairperson

Maria A. Ellis
Executive Secretary

Voting Members
Renè Cabral-Daniels, JD, MPH
Peter Heseltine, MD
Warren Janowitz, MD, JD, FACC, FAHA
Robert McDonough, MD, JD
Ryan H. Saadi, MD, MPH
David J. Samson, MS
Robert L. Steinbrook, MD

Industry Representative
Brian Seal, RPH, MBA, PhD

Guest Panel Member
Yoram Rudy, PhD

CMS Liaison
James Rollins, MD

Invited Guest Speakers
Jerome L. Fleg, MD
Rob MacLeod, PhD

TA Presenters
Remy R. Coeytaux, MD, PhD
Philip Leisy, BS, MD Candidate

Scheduled Public Speakers
Amir Beker, PhD
Michael Imhoff, MD, PhD
Joseph T. Shen, MD
John E. Strobeck, MD, PhD

Wednesday, November 9, 2011, 8:03 a.m.

The Medicare Evidence Development & Coverage Advisory Committee met to discuss the evidence, hear presentations and public comment, and make recommendations concerning the use of electrocardiogram (ECG) based signal analysis (SAECG) technologies used for the purpose of detecting coronary artery disease (CAD) in patients who are asymptomatic but have increased risk factors for CAD or in patients who present with signs or symptoms suggestive of acute coronary artery syndrome (ACS) with or without chest pain and who are not triaged for emergency reperfusion therapy.

The meeting began with a conflict of interest statement, welcoming remarks, and an introduction of the panel, together with disclosure of any conflicts of interest.

CMS Presentation of Voting Questions. Lisa Eggleston, RN, MS, a CMS representative, presented the panel and audience with a background of the MEDCAC, an explanation of the voting scale to be used, and a presentation of the voting and discussion questions to be considered by the panel.

Presentation by Invited Guest Speakers. The panel heard presentations from two invited guest speakers. Rob McLeod, PhD of the Utah Scientific Computing and Imaging Institute presented the panel with background on electrocardiographic imaging (ECGI), how it works, questions on whether or not it provides additional information that improves diagnostic capabilities, what additional methods and approaches can be used to exploit that information, and signal analysis. Jerome I. Fleg, MD, of the National Heart, Lung, and Blood Institute of the National Institutes of Health spoke on the diagnostic evaluation for suspected CAD. The presentation touched on the different tests used. Following each presentation, there was an opportunity for the panelists to pose questions.

Presentation of the Technology Assessment. The panel heard a presentation from Remy R. Coeytaux, MD, PhD, of the Duke Clinical Research Institute and Philip Leisy, an MD candidate at the ECU Brody School of Medicine on the technology assessment performed under contract to AHRQ. They examined limitations of standard ECG and at ECG-based signal analysis devices. The presentation listed future research needs. Following the presentation, there was a period of questions from the panel.

Scheduled Public Comments. The panel heard from four schedules speakers: Dr. Joseph Shen, an MCG technology developer and founder of Premier Heart, LLC; Dr. Michael Imhoff of the Ruhr-University, who spoke on validation studies on coronary angiography done with MCG; Dr. John E. Strobeck, a practicing cardiologist with Heart-Lung Associates, PC; and Dr. Amir Beker, Chairman of Biological Signal Processing, Inc., a developer of computerized systems for the diagnosis and monitoring of ischemic heart disease. There were opportunities for the panel to address questions to the speakers after each presentation.

Open Public Comments. No member of the public signed up to address the panel.

Questions to Presenters, Open Panel Discussion, and Voting Questions. There was a question and answer session with the invited guest speakers, scheduled public speakers, and presenters of the technology assessment, focusing on questions that would aid the panel in answering the voting questions. The presenters remained available and continued to answer questions during the discussion and voting. For each question, the panelists voted electronically and announced their votes individually. The non-voting members also announced how they would have voted. The votes were collected on a Likert scale of one (low confidence) to five (high confidence), and there was an opportunity for brief discussion before and after each vote. The votes are recorded in the transcript.

Final Open Panel Discussion. Following the voting questions, the panel addressed questions 9 and 10, which asked about evidence gaps in the field of signal analysis ECG devices and the panel's confidence in the panel's conclusions being generalizable to the Medicare patient population and in community-based settings. After discussing the evidence gaps, the panel voted on question 10. The presenters were offered an opportunity to comment after the votes, and each panel member was asked to give a closing comment.

Adjournment. In closing, Dr. Goodman made summary remarks about the overall quality of the available body of relevant evidence and the need to link the performance of tests to health outcomes, and emphasized that the MEDCAC can only appraise the evidence brought before it. He thanked the panelists, the presenters, and the Executive Secretary for their work. Dr. Rollins thanked the panel, speakers, and audience and adjourned the meeting at 3:10 p.m.

I certify that I attended the meeting of the Medicare Evidence Development & Coverage Advisory Committee on November 9, 2011 and that these minutes accurately reflect what transpired.

Maria A. Ellis

Maria A. Ellis
Executive Secretary, MEDCAC, CMS

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

Clifford Goodman

Clifford Goodman, PhD
Chairperson