

MEDCAC Goals and Proceedings

Michael R. Jaff, DO, interviews Louis Jacques, MD, Director of the Coverage and Analysis Group in the Centers for Clinical Standards and Quality at the Centers for Medicare & Medicaid Services.

Dr. Jaff: What was your background prior to joining the Centers for Medicare & Medicaid Services (CMS)?

Dr. Jacques: I'm originally from the Washington, DC, area, and was a National Health Service Corps Scholar during medical school. With that in mind, I completed a primary care residency and was then assigned to a community health center in Waterloo, Iowa, for 4 years.

Subsequently, I was recruited by the Henry Ford Medical Group in Detroit, where I combined day-to-day patient care with practice administration. I got into academics and academic administration at Wayne State University. I eventually returned to the Washington, DC area as faculty at Georgetown and, after a few years, became one of the curriculum deans in the school of medicine.

Dr. Jaff: When did you first come to CMS?

Dr. Jacques: I first came to CMS in 2003 as a medical officer in the Program Integrity Group. After a year, I was recruited to be one of the division directors in the Coverage and Analysis Group. I saw that as a return to my academic roots. I became the coverage group director three and a half years ago.

It's a group of about 40 people—a good mix of physicians and nonphysicians. It replicates as closely as I think is possible in our particular agency what an academic department would be doing in terms of having not only the mix of staff, but an emphasis on critical assessment and things like that. I really enjoy it, and the best part is the people I work with both internally and externally.

Dr. Jaff: What is a MEDCAC's primary responsibility?

Dr. Jacques: MEDCAC is the Medicare Evidence Development & Coverage Advisory Committee. It was initially called the Medicare Coverage Advisory Committee. In 2007, the name was expanded to give a better sense of its remit or its purview.¹

The major thing a MEDCAC helps us to do is, in a public format, generate discussion and get recommendations about the evidence. A MEDCAC does not actually make a coverage recommendation to CMS; the coverage decision is something that we essentially have to do ourselves. But there are topics that benefit from a broad public discussion because they're contentious, and the medical community doesn't appear to agree on the best option for patients. The January 2012 MEDCAC on carotid atherosclerosis was a good example of that. A MEDCAC may also be useful in a situation where there is not necessarily disagreement among physician stakeholders or other scientists, but rather a sense that there is so much information that it would be beneficial to have the committee provide an overall sense of a large body of evidence.

Dr. Jaff: Does your office alone determine if a MEDCAC event would be helpful, or could this be requested from outside your office?

Dr. Jacques: A MEDCAC is always generated internally. There is no formal way for an outsider to request a MEDCAC. However, part of our decision about whether a MEDCAC is appropriate might be informed by what we hear from the public around a particular issue.

Dr. Jaff: Is it onerous to launch a MEDCAC?

Dr. Jacques: It takes a lot of people power to actually convene a MEDCAC. A lot of work goes on behind the scenes, largely unsung. We recognize this work internally, but there isn't that much public recognition for the amount of work that goes into preparing documents, preparing travel, scheduling, building an infrastructure, and all the other things we undertake as the sponsor of a meeting.

Dr. Jaff: Once you decide that you're going to do a MEDCAC, how does the panel get formed?

Dr. Jacques: MEDCAC has a charter that describes the way a MEDCAC works, and all this information is available

on our coverage website (See *MEDCAC at a Glance*). The MEDCAC has solicitations that occur once or more during a given calendar year for the underlying roster for the panel. Members serve for a term, and their membership can be renewed for an additional term. It is Federal Advisory Committee Act (FACA) compliant, so we attend to all the FACA rules as well, including vetting for conflicts of interest.

We select individual voting panelists for any given meeting from the roster, based on expertise relevant to the topic. We also invite an industry representative from the roster, and outside guest panelists. All votes are announced publicly and recorded in the transcript, but the votes of the industry representative and the guest panelists do not contribute to the final mean score. The MEDCAC chair is selected from the roster of voting members but does not have a vote except to break a tie. I don't recall any instance where the chair has actually voted. If there's a particular issue for which we believe the committee could use some additional outside expertise or there are others who have a track record of expertise on a topic, and we think the meeting would benefit from having them there as guest panelists or potentially as invited speakers, we invite them. These people can be either from the United States or outside the country. There are a number of topics for which there are some very good thought leaders in various parts of the world.

Dr. Jaff: Once the MEDCAC has been formed and is publicly announced, there is an opportunity for anyone to sign up to attend or speak. There are also specific people who you ask to speak for longer time periods. The voting happens on each of the issues raised by the MEDCAC in front of the audience. How does the voting work?

Dr. Jacques: There are two types of questions in the MEDCAC. There are voting questions, and there are discussion questions. There are some types of questions that just do not lend themselves to a numeric score, so we try not to force that sort of paradigm when it wouldn't be appropriate. The questions generally follow a pattern. The initial question will ask the panelists if they believe there is enough evidence to definitively consider the question. If the panelists essentially say in aggregate that there isn't enough evidence to meaningfully tackle this question yet, then we would move to a discussion on what those gaps are and what evidence you would need to more definitively consider the question.

If there is at least an intermediate level of confidence that there is enough evidence to move on to more definitive questions, the panel would tackle those next. After the meeting, minutes and a verbatim transcript are generated from a court reporter and published, along with an archived video feed. The actual score report, which has the individual

MEDCAC AT A GLANCE

- A MEDCAC is established to provide guidance and advice to CMS on specific evidentiary topics.
- A MEDCAC meeting is generated internally by CMS.
- A MEDCAC reviews and evaluates medical literature, technology assessments, and examines data.
- Panelists are selected from a roster of experts on a particular topic.
- Anyone may attend a MEDCAC, and the information is made available publicly after the meeting.
- A MEDCAC does not make a coverage decision, but the information generated is used to supplement CMS's internal expertise.
- To download a pdf of the MEDCAC charter describing how the system works, visit: <http://bit.ly/EVTodayMEDCAC>.

scores as well as the mean of the voting members, is also published.

Dr. Jaff: Do these ever get published in scientific journals, or are they always on your website? Some of the information that came out of the carotid MEDCAC was phenomenal, for example.

Dr. Jacques: It depends. There have been times in the past when we might publish a commentary about a MEDCAC—what are the evidentiary lessons learned going forward on a particular topic? The guts of the MEDCAC—the salient points of the MEDCAC—are quite public. We don't discourage the MEDCAC panelists or anyone in the room from writing about the MEDCAC and publishing it in a peer-reviewed journal or somewhere else. There are often press reporters in the room, and the MEDCAC even used to be telecast on the Bloomberg network. Whether it's more of a "Wall Street" look at it, or whether it's a scientific look at it, there's probably a lot more published on the MEDCAC than I would ever see personally.

Dr. Jaff: You speak to experts all over the world and know where the field stands now. Do you think that there is an opportunity for scientific evidence to advance coverage of carotid stenting in the United States?

Dr. Jacques: Yes.

Dr. Jaff: What could physicians do as a cohesive group to make this happen?

Dr. Jacques: I think there are lessons to be learned from

PERSPECTIVE:

CMS Coverage and Analysis

VOTING QUESTIONS FROM THE MANAGEMENT OF CAROTID ATHEROSCLEROSIS MEDCAC	
<i>For the voting questions, use the following scale identifying level of confidence, with 1 being the lowest or no confidence and 5 representing a high level of confidence.</i>	
Question	Voting Member Average
1. How confident are you that there is adequate evidence to determine if persons in the Medicare population who are asymptomatic for carotid atherosclerosis can be identified as being at high risk for stroke in either cerebral hemisphere?	3.00
2. How confident are you that there is adequate evidence to determine if persons in the Medicare population, who are considering carotid revascularization, can be identified as being at high risk for adverse events from CEA?	3.56
3. For persons with symptomatic carotid atherosclerosis and carotid narrowing ($\geq 50\%$ by angiography or $\geq 70\%$ by ultrasound) who are not generally considered at high risk for adverse events from CEA:	
a. How confident are you that there is adequate evidence to determine whether or not either CAS or CEA is the favored treatment strategy, as compared to BMT alone, to decrease stroke or death in the Medicare population?	3.33
b. If there is at least intermediate confidence (score ≥ 2.5 above), how confident are you that:	
i. CAS is the favored treatment strategy in this population?	2.00
ii. CEA is the favored treatment strategy in this population?	3.44
iii. BMT alone is the favored treatment strategy in this population?	1.56
4. For persons with asymptomatic carotid atherosclerosis and carotid narrowing ($\geq 60\%$ by angiography or $\geq 70\%$ by ultrasound) who are not generally considered at high risk for adverse events from CEA, how confident are you that there is adequate evidence to determine whether or not either CAS or CEA is the favored treatment strategy, as compared to BMT alone, to decrease stroke or death in the Medicare population?	2.00
5. For persons with asymptomatic carotid atherosclerosis who are not generally considered at high risk for stroke in either cerebral hemisphere:	
a. How confident are you that there is adequate evidence to determine whether or not CAS or CEA or BMT alone is the favored treatment strategy to decrease stroke or death in the Medicare population?	2.89
b. If there is at least intermediate confidence (score ≥ 2.5 above), how confident are you that:	
i. CAS is the favored treatment strategy in this population?	1.00
ii. CEA is the favored treatment strategy in this population?	1.00
iii. BMT alone is the favored treatment strategy in this population?	4.22
6. In the general Medicare population:	
a. How confident are you that there is adequate evidence to determine whether or not carotid artery screening of asymptomatic persons decreases stroke or death?	3.33
b. If there is at least intermediate confidence (score ≥ 2.5 above), how confident are you that carotid artery screening of asymptomatic persons decreases stroke or death?	1.33

our experience with transcatheter aortic valve replacement, when the surgeons and the interventional cardiologists were able to collaborate on a combined request for a National Coverage Determination (NCD) and continue, within their specialties, to exercise some stewardship over the topic even now, when the NCD is completed.

I think one of the clear lessons from the carotid atherosclerosis MEDCAC was that there are three distinct schools

of physician thought on this. There are physician groups who favor carotid endarterectomy, carotid artery stenting, or best medical therapy. In our planning of that meeting, we wanted to make sure that each of those three groups had an opportunity to have someone well versed in that field present the perspective of that physician group. It worked well in the MEDCAC with the three invited speakers (see *January 2012 MEDCAC Voting Questions and Roster*).

I believe it would be unfortunate that if what happens to a patient is idiosyncratically dependent on what door he or she happens to walk into in a physician office building, or which clinic happens to have the most convenient appointment. If what that patient is told is significantly different in each instance, I think it speaks ill of the way we do health care in this country.

I would like to see physicians acknowledge that, at the end of the day, it's about finding out what is the best thing for each patient and not just patients in general. If there is a reason to treat this patient differently from those patients, what is the scientific basis? In an ideal setting, the three

major lines of physician thought would come to CMS with a unified strategy to address the significant questions that the MEDCAC raised. When people ask me what happens after the MEDCAC, I tell them to read the transcript, look at the webcast footage, and talk to friends or colleagues who were there. I would ask physicians, what is your strategy to address—robustly and in an unbiased way—the questions raised by the MEDCAC. I always bring everybody back to the MEDCAC. ■

1. CMS: Medicare Program; Renewal and Renaming of the Medicare Coverage Advisory Committee (MCAC) to Medicare Evidence Development Coverage Advisory Committee (MEDCAC) and a Request for Nominations for Members for the Medicare Evidence Development & Coverage Advisory Committee. Federal Register. 2007;72:3853.

MEDCAC ROSTER: JANUARY 25, 2012

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