BACKGROUNDER:
NIH Consensus Development and State-of-the-Science Conferences

Q: What are Consensus Development and State-of-the-Science Conferences? How do they differ? Why are they important?

A: A National Institutes of Health (NIH) State-of-the-Science or Consensus Development Conference is a conference coordinated by the NIH that has the goal of producing statements on important and controversial topics in health and medicine. As the agency responsible for the Consensus Development Program, the NIH Office of Medical Applications of Research (OMAR) organizes both types of conferences.

A conference is titled a **State-of-the-Science Conference** when planners determine that the topic under review does not have an adequately defined and available base of scientific evidence and information for a meaningful consensus to be established. This type of conference has as its primary goal summarizing all of the available evidence on a given topic and recommending appropriate directions for future research, based on the evidence gaps and questions identified during conference discussions. It is a means of examining a controversial health topic in order to draw out all of the difficult issues feeding the debate on the subject, and a means to make the public and health professionals aware of these factors, in order to promote informed decisionmaking in clinical practice. In short, State-of-the-Science Conferences are used in cases where the evidence base is weaker, and their emphasis is on shaping future research and priority-setting.

Consensus Development Conferences are undertaken where there is a strong body of higher quality evidence (randomized trials, well-designed observational studies), and it is reasonable to expect that the panel will be able to give clinical direction.

It should be emphasized that the development and execution process for both conference types is completely identical; it is only the level of available evidence that differs.

The NIH Consensus Development Program, unlike many other conference processes, is built around an independent panel and a body of rigorously reviewed evidence, somewhat akin to a scientific court or jury. Panelists are carefully reviewed to ensure that they have no financial or other conflicts of interest. The panel members are shielded from outside influences before and during the conference, and even the sponsoring NIH Institute or Center is barred from contact with the panel.

The statements emanating from NIH Consensus Development and State-of-the-Science Conferences are not intended to represent policy statements of NIH or the Federal Government, nor are they meant to serve as practice guidelines for physicians. Rather, they are an attempt to provide informed, balanced, objective, and knowledgeable attention to difficult topics so that health professionals and the public may consider the topic in a thoughtful and enlightened manner.

Q: How are State-of-the-Science or Consensus Development Conference topics chosen?

A: Topics for State-of-the-Science or Consensus Development Conferences can be suggested by NIH Institutes or Centers, other Government health agencies, Congress, or the public. Topic proposals from non-NIH individuals or organizations are referred to an appropriate NIH Institute or Center for consideration. Once a topic is formally proposed by an NIH Institute or Center, it is reviewed by OMAR to determine whether it meets essential criteria for acceptance:

- The topic has public health significance and applies to and has an impact on a large number of people.
- The controversies surrounding the topic can be clarified, and a gap between current knowledge and practice can be identified and narrowed.
- There is adequate scientific evidence to assure that the outcome of the conference will be an objective evaluation by an informed, impartial panel.

An agreement is then reached between OMAR and the Institute or Center that has proposed the topic to develop a Consensus or State-of-the-Science Conference addressing this topic. OMAR will not proceed with a conference without the endorsement of an NIH Institute or Center.

Q: How is a conference panel chair chosen?

A: Panel chair nominations are made by an organizational committee, which is made up of OMAR staff, representatives of the NIH Institute or Center proposing the topic, and other interested government agencies (U.S. Food and Drug Administration [FDA], Centers for Disease Control and Prevention [CDC], etc.). OMAR staff then review the nominees to determine whether they meet the following criteria:

- Knowledgeable and prestigious figure in the field under consideration
- Not identified with an advocacy opinion on the topic in question
- Has not performed research that may be utilized in the discussion of the topic
- Does not have a financial interest in the topic under discussion
- Is a U.S. citizen but is not an employee of the U.S. Department of Health and Human Services

After careful review of the candidates, final selection is made by OMAR and the proposing NIH Institute or Center.

Q: Who plans NIH State-of-the-Science and Consensus Development Conferences?

A: A planning committee made up of representatives from OMAR, the sponsoring NIH Institute or Center, non-Government-employed recognized experts from the research community on the topic, other NIH Institutes or Centers, the Agency for Healthcare Research and Quality (AHRQ), other Federal agencies with an interest in the topic, and the panel chair gather for a 2-day meeting to determine the conference's scope, develop four to six key questions to be addressed at the conference, draft a rough conference agenda, and nominate speakers and panel members.

The conference questions developed by the Planning Committee typically involve issues such as incidence and prevalence, efficacy, risks and benefits of interventions, and directions for future research.

The Planning Committee's decisions are carried out by OMAR staff in consultation with a primary representative from the sponsoring NIH Institute or Center and occasional additional input from other members of the planning committee.

Q: How are the remaining panel members and conference speakers chosen?

A: The Planning Committee recommends individuals to serve on the panel based upon the goal of representing a diversity of expertise and experience relating to the topic. The panel is intended to represent various sectors of professional and community life that are impacted by the chosen topic, including:

- Research investigators in the field
- Health professionals (doctors, dentists, nurses, and so forth)
- Methodologists (epidemiologists, biostatisticians, and clinical trialists)
- Public representatives (patients, ethicists, public interest groups, and so forth)

All panel members must meet the following criteria to be chosen:

- Is a U.S. citizen, but not a Federal employee
- Is not identified with an advocacy position on the topic in question
- Is not associated with research that may be used during discussions of the topic
- Does not have a vested financial interest in the topic
- Cannot also be a speaker at the conference

Panels are typically composed of 9 to 16 members.

The Planning Committee also recommends speakers appropriate to each session in the draft conference agenda. In considering possible speakers, planners look for individuals with well-known expertise in the area under consideration, including clinical investigators, basic scientists, or other authorities in the field.

Q: What happens at the conference?

A: The conference lasts 3 days, and is always free and open to the public. On the night before the conference begins, the panel meets in executive session to broadly review the topic and discuss the areas that are likely to present controversy and debate.

On the first day of the conference, the panel listens to presentations by the selected speakers addressing each of the key questions chosen as critical for the topic. An open public discussion period follows each set of three to four speaker presentations. During lunch and dinner, the panel meets again in executive session to begin preliminary work on a draft statement of conclusions reached.

On the morning of the second day, speaker presentations and discussions continue. The afternoon and evening of this day are spent in an executive session; the panel continues work on the draft statement and finishes the first version. This work often continues late into the night.

On the morning of the third conference day, the panel publicly presents its draft statement to the conference attendees, and then takes questions and comments from those present. The panel then meets in a closed executive session to consider the comments received on the statement and proposes revisions as needed. The panel also holds a press conference that afternoon to address questions from the media. The revised draft statement is posted on the Web later that day.

Following the conference, the panel will collaborate on any further edits to the statement that they deem necessary, but generally these are minimal. The draft is revised accordingly and the final version is posted to the Web 3 to 4 weeks after the end of the conference.

Q: What evidence does the Panel consider in preparing its statement?

A: In addition to the material presented at the conference by speakers, the Panel may consider any pertinent research from the published literature. They will also consider the results of a systematic review of the literature commissioned for each conference topic by OMAR. The review is prepared through the AHRQ Evidence-based Practice Center (EPC) program.

The EPCs develop evidence reports and technology assessments based on rigorous, comprehensive syntheses and analyses of the scientific literature on topics relevant to clinical, social science/behavioral, economic, and other healthcare organization and delivery issues. EPC reports and assessments emphasize explicit and detailed documentation of methods, rationale, and

assumptions. All EPCs collaborate with other medical and research organizations so that a broad range of experts is included in the development process.

More information about the EPC program and resulting reports is available at http://www.ahrq.gov/clinic/epcix.htm.

The evidence reports prepared by the EPCs for NIH State-of-the-Science and Consensus Development Conferences are centered on the key conference questions developed by each conference's planning committee. The authors of the evidence reports also present portions of their reports during the conference.

In developing its State-of-the-Science or Consensus Statement, the Panel also considers the comments and concerns of conference participants presented during discussion periods. In cases where time runs out, and some comments can not be heard in open session, facilities are available for participants to provide written comments for the panel to review.

Q: How can I access conference materials?

A: The Panel's draft statement will be available in hard copy at the press conference on the third day of the conference. This will be the same version presented at the 9:00 a.m. session that morning. Between 11:00 a.m. and 2:00 p.m., the Panel may revise its draft, and it is that revised draft that will be posted late that day at http://consensus.nih.gov/. The Panel will finalize its statement over the 3–4 weeks following the conference, and the final version will be posted to the same location.

The evidence report prepared for the conference under contract with AHRQ will be available online the third day of the conference, at http://www.ahrq.gov/clinic/epcix.htm.

Abstracts of the speakers' presentations are made available online at http://consensus.nih.gov/ the day the conference begins. They are also available to reporters in advance, upon request.

Speakers' slides may be available as well; requests are handled on an individual basis. Please contact the OMAR Communications Director for details, or you may contact speakers directly.

Q: Are conference speakers and panel members available for interviews?

A: We request that you not approach the Panel members for interviews until after the press conference on the third day. The majority of them will be available to you after that time, on-site, as well as by phone in the days following. The Communications Director for OMAR will be happy to coordinate interviews with Panel members for you.

Conference speakers are free to speak with you at any point before or after their presentations. You are welcome to approach them directly, or seek assistance from the OMAR conference staff in arranging interviews. For assistance, please contact Kelli Marciel via e-mail at marcielk@od.nih.gov, or phone 301–496–4819.

Q: If I am unable to attend the conference in person, can I still participate?

A: A live Webcast of the conference will be available at http://videocast.nih.gov/. If additional services would be helpful to you in covering the conference, please contact the OMAR Communications Director for assistance.