

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION**

Coordinating Office for Terrorism

Preparedness and Emergency Response (COTPER)

Board of Scientific Counselors (BSC)

Summary Report

Fiscal Allocation Process Peer Review

Ad Hoc Expert Panel Report

April 27, 2009

2:00 – 4:30 pm

via Web Conference

Fiscal Allocation Process Peer Review

Coordinating Office for Terrorism Preparedness and Emergency Response

April 27, 2009

Meeting Agenda

2:00 – 2:10 p.m.

Welcome and Introductions

Sharona Hoffman, J.D., L.L.M., COTPER BSC

Barbara Ellis, Ph.D., Deputy Associate Director for Science, COTPER Designated Federal Official (DFO), COTPER BSC

2:10 – 2:15 p.m.

Welcome

Dr. Dan Sosin, MD, MPH, FACP, Acting Director, COTPER

2:15 – 2:20 p.m.

Review of FACA Conflict of Interest Issues

Barbara Ellis, Ph.D., Deputy Associate Director for Science, COTPER Designated Federal Official (DFO), COTPER BSC

2:20 – 2:40 p.m.

Fiscal Allocation Process (FAP) External Peer Review Ad Hoc Expert Panel Report

Sharona Hoffman, J.D., L.L.M., COTPER BSC

Chair, FAP Peer Review Ad Hoc Expert Panel

Cindy Williams, Ph.D., FAP Peer Review Ad Hoc Expert Panel Member

2:40 – 3:15 p.m.

Discussion and Recommendations

Sharona Hoffman, J.D., L.L.M., COTPER BSC

3:15 – 3:20 p.m.

Break

3:20 – 3:40 p.m.

Discussion and Recommendations (*Continued*)

Sharona Hoffman, J.D., L.L.M., COTPER BSC

3:40 – 3:55 p.m.

Public Comment Period

3:55 – 4:30 p.m.

Vote on Recommendations

Sharona Hoffman, J.D., L.L.M., COTPER BSC

4:30 p.m.

Adjourn

Barbara Ellis, Ph.D., Deputy Associate Director for Science, COTPER Designated Federal Official (DFO), COTPER BSC

Welcome and Review of FACA Conflict of Interest Issues

Purpose

Deliberate and vote on recommendations from the external peer review of COTPER's internal fiscal allocation process.

Goals

Help create and support a transparent, multi-disciplinary process for external expert review and improve COTPER's capacity to continuously improve processes, programs and vision through the input of the board. The recommendations made will ensure that COTPER programs are well-grounded in science and are evaluated and put into evidence-based practices, protocols, and policies to improve COTPER's national and international role in emergency preparedness and response.

Charter

The Board of Scientific Counselors, Coordinating Office for Terrorism and Emergency Response, shall advise the Secretary, HHS, and the Director, CDC, concerning strategies and goals for the programs and research within the divisions; shall conduct peer-review of scientific programs; and monitor the overall strategic direction and focus of the divisions. The board, after conducting its periodic reviews, shall submit a written description of the results of the review and its recommendations to the Director, CDC. The board shall perform second-level peer review of applications for grants-in-aid for research and research training activities, cooperative agreements, and research contract proposals relating to the broad areas within the coordinating office.

No conflicts of interest were presented.

Discussion: Fiscal Allocation Process (FAP) External Peer Review

Ad Hoc Expert Panel Report

FAP Background

The fiscal allocation process allocates \$1.5 billion in Terrorism Preparedness and Emergency Response funds. These funds are allocated across CDC, not only to COTPER. Of the allocation, 91% is defined by Congressional language (e.g., Strategic National Stockpile); 4% is allocated to COTPER operations; 5% is allocated to CDC operations other than COTPER operations (e.g., laboratories, surveillance systems); and <0.1% is reserved for new projects.

FAP FY 2009 Stages 1-6

The fiscal allocation process is a six-stage process. Stage 1 is Pre-planning and Priority Setting; Stage 2 is a Call for Proposals and Provision of Guidance to those submitting proposals; Stage 3 is a Primary Review Process; Stage 4 is a Secondary Review and Selection Process; Stage 5 is Communication of Results; and Stage 6 is Performance Measurement and Evaluation. Stage 6 was technically outside the scope of the review, but so much of the material presented raised performance measurement issues, that the panel offered general findings and recommendations about this area as well.

Primary Review Process

There are different levels of review in the Primary Review Process, some of which are streamlined. Management Review Level 1 provides an accountability review by two COTPER senior staff. Somewhat greater scrutiny is provided by Management Review Level 2, which is a more comprehensive accountability review. The greatest scrutiny is provided by Competitive Review, which is an analysis by subject matter experts. This is given to some CDC operations, some CDC projects with performance issues and all new projects. Streamlining promotes efficiency, which can be valuable, but it raises some concerns as well.

FY 2009 Project Categorization and Funding

There were 18 proposals for Congressional or agency required activities, all 18 of which were funded. There were 74 requests for on-going operations, all 74 of which were funded. There were 21 requests for on-going projects, 21 of which were funded. There were 64 new proposals, six of which had been funded by the end of February 2009, which is a 9% funding rate. The panel was told that 5 of the 6 new proposals that had been funded pertained to quarantine, and thus, there was a lack of diversity in the subject matter of the funded projects.

Panel Findings and Recommendations: Key Areas

From the background information that the panel read and the presentations it heard, four areas of concern emerged. Therefore, the report is organized around the 4 areas which include 2 findings and recommendations about Strategic Planning; 4 findings and

recommendations about Management; 5 findings and recommendations about Submission and Review of Proposals; and 3 findings and recommendations about Evaluation, Lessons Learned, and Feedback.

Strategic Planning

Issue #1

Finding: Information from the federal government's threat assessment is not transparently incorporated into the FAP.

Recommendation: Use input from leaders or managers who have access to and knowledge of threat assessment to inform the FAP.

Issue #2

Finding: The FAP is not well-suited to elements of uncertainty and surprise (e.g., 9/11).

Recommendation: Use foresight techniques to inform the FAP, which can be done through broad environmental scans of social, economic, and technological factors that could impact threats. Urge that new scenarios be envisioned because there seems to be too much reliance on history, experience, and traditional emergency preparedness concerns and not enough openness to creativity and innovation.

Management

Issue #1

Finding: The consensus-based mechanism for identifying priorities may run counter to the need for innovation. Consensus can be politically valuable, but insistence on consensus may hinder achievement of optimal results.

Recommendation: Seek more input and collaboration with outsiders, including more direct involvement of federal partners in order to generate more original ideas.

Issue #2

Finding: The FAP does not appear to link costs, budget, and performance. Therefore, managers are not requiring enough accountability or engaging in enough fiduciary oversight.

Recommendation: Managers should link costs, budgets, and performance data so that leadership has information about the costs, benefits, risks and redundancies of investment choices.

Issue #3

Finding: The FAP does not meaningfully address a significant portion of COTPER funds that are Congressionally directed.

Recommendation: To the extent there is flexibility, take advantage of it. Encourage partnerships with other parts of CDC to support innovative projects. There are other parts of CDC that engage in emergency preparedness work, but there seems to be very limited communication with them.

Issue #4

Finding: It is unclear whether the FAP is supported by resources or organizational capacity comparable to those available in other federal agencies that manage planning, programming and budget functions.

Recommendation: COTPER should strengthen its capacity to measure operations and projects with the greatest public health impact using internal and external experts.

Submission and Review of Proposals

Issue #1

Finding: The streamlined review process for most on-going activities and the intense review process for new projects make it difficult for new activities to compete for funds.

Recommendation: While some ongoing activities must be funded, review all others more critically with a high degree of scrutiny.

Issue #2

Finding: There are ways to simplify and significantly improve the proposal and review process for new projects. The process for submitting new proposals is time-consuming and burdensome, and very limited funds are available. These circumstances discourage some from submitting proposals for new projects.

Recommendation: Initially, call for three-page concept papers. Those would be far less burdensome to submit than a fully detailed proposal. COTPER could then select 10 finalists and require only those to submit full proposals. Only those 10 would be assessed through peer review with external experts.

Issue #3

Finding: HI.net, the web-based tool that is used to submit proposals, can be difficult to use and is not well-suited to some of COTPER's purposes.

Recommendation: Continue to improve HI.net so that it better suits all of COTPER's needs.

Issue #4

Finding: There is a lack of non-conflicted internal subject matter experts to serve as peer reviewers.

Recommendation: Find ways to engage external subject matter experts when appropriate.

Issue #5

Finding: There appears to be no institutionalized process for linking information gathered during the current FAP into the next year's planning and budget formulation process.

Recommendation: Institutionalize the link between one year's FAP and the next year's planning and budget formulation process.

Evaluations, Lessons Learned, and Feedback

Issue #1

Finding: Self-evaluation of the performance of on-going programs may fail to reveal some performance problems.

Recommendation: Create mechanisms for an independent peer review process for on-going programs.

Issue #2

Finding: Under-performing on-going projects drain resources that could be invested in new activities.

Recommendation: Discontinue funding for under-performing projects and be more willing to shift funding to priority projects that are meeting accepted agency-wide standards.

Issue #3

Finding: The annual feedback mechanism developed for the FAP leads to excessive complexity, confusion and lack of continuity because changes are made too frequently.

Recommendation: Shift to a 2-year FAP and adjust the process every 2 years or keep annual FAP and adjust guidelines and processes for proposal submission and review only once every 2 years.

Discussion and Recommendations

- When CDC and COTPER assess a project that they wish to fund, do they look across departments to ensure the funds are not being duplicated?
 - COTPER response: There really is not a mechanism in place other than the Principal Investigators (PIs) cross-referencing their departmental and federal agency contacts.

- It seems that part of the difficulty with multi-year grants is that progress is reviewed each year when a project takes several years for the data to be collected.
 - COTPER response: COTPER and the individuals agree on milestones. There are a variety of ways to assess progress minus the outcomes and data. A peer review of progress can be requested in order to make sure the work is actually on track.
- It is acceptable to have external review, but some attempt should be made to make those reviews objective, and perhaps have a protocol developed for the peer reviewers to use in the evaluation of funded projects. Both internal and external expert reviewers can have biases, so steps must be taken to ensure the reviews' fairness and objectivity.
- There is room for improvement in the areas of innovation and novel thinking with respect to threat assessment. NIH has extensive exchange with review committees.
- Are there criteria and protocols in place for review of the projects?
 - COTPER response: FY 09 instituted the use of the NIH standard process and criteria as a standard for all of the reviewers to use across all of the objective areas for all projects.
- Fund certain grants if there are objective criteria by which they will be reviewed.
 - COTPER: To clarify one term, these are not grants; they are intra-agency funds. Part of the fiscal allocation process, Stage 6, is the Performance Measurement and Evaluation piece that is built into the fiscal award such that each Coordinating Center Director, along with the COTPER Director, signs a Memorandum of Agreement (MOA). The reporting period occurs twice per year when performance data are collected on the projects.
 - COTPER: The performance data that are collected subsequently inform the decision-making process of the next year's cycle of funding decisions. There are criteria and standards that are used during the selection process for projects and then the performance data that have been collected over the previous year are also incorporated for those activities that are continuing. Both of those are used in the decision-making process in the selection and funding for the next cycle.
- If more new projects are funded, where would that money come from?
 - COTPER response: It would come from the discretionary money that COTPER has for CDC infrastructure including ongoing projects and operations (internal and external to COTPER).

- COTPER response: Even though COTPER’s total budget seems large on the surface, the discretionary amounts have been reduced over time. There is very little to sustain some major activities within COTPER’s own infrastructure, much less new projects. The activities that were attached to specific funding lines were funded. However, funding for ongoing projects and operations (internal and external to COTPER) to upgrade CDC capacity was decreased.
- Encourage COTPER’s partners who receive COTPER funds to do a better job explaining their projects (during the proposal submission process) including explaining them in simpler terms.
- COTPER clarified the statement, “100% of ongoing projects funded.” Before the FAP started, a fair number of projects were told that their funding would not continue. The “100% funded” refers to the remaining projects that COTPER did not eliminate before the FAP started.
- COTPER indicated that they had found some savings in the projects that they ended, but because our total budget decreased, those funds went toward maintaining current projects. COTPER is functioning in a resource declining environment.
- COTPER indicated that there were high profile projects that they have been funding and were unable to stop funding for political reasons. COTPER vastly limited their funding for one year and asked them to perform a thorough evaluation and needs assessment for their programs with the stipulation that if they did not provide evidence that their program should continue, they would not receive funding that following year. These high-profile projects successfully showed that they should be funded the following year.

The following revisions and additions to the recommendations were proposed:

- A revision and addition to the first recommendation under Evaluation, Lessons Learned and Feedback,
- An addition to the fourth recommendation under Management, and
- An addition to the second recommendation under Evaluation, Lessons Learned and Feedback.

Recommendation

Change Issue #1: Recommendation under Evaluation, Lessons Learned and Feedback to:

“Create a mechanism for an independent yearly review process for ongoing programs connected to the external review protocol in the initial project review.”

Also add sub-bullet:

“Include appropriate external reviewers within the primary review process.”

Recommendation

Add the following statement to Issue #4: Recommendation under Management to be more specific:

“Provide peacetime bonus to other non-preparedness public health issues; provide accelerated positive outcomes through translational research from other CDC programs.”

Recommendation

Add sub-bullet to Issue #2: Recommendation under Evaluation, Lessons Learned and Feedback which states:

“Shift funding by shifting objectives for existing programs to preserve their relevant components.”

Public Comment Period

All lines were opened at 3:37 p.m. At this time, no public comments were offered.

Voting Session

Motion

Jack Muckstadt motioned to vote on all 14 Recommendations simultaneously. The motion was seconded by Lou Rowitz. With no objections raised, the motion passed unanimously. Sharona Hoffman, Jack Muckstadt, Robert Ursano, Jack Harrald, Bill Stephens, Lou Rowitz, Mary Mazanec, Diane Berry voted to approve all 14 Recommendations as they stand (with the revisions and additions noted above). Recommendations passed as official BSC Recommendations.

The program will respond to these approved recommendations and will provide an update of progress on August 14, 2009.

The web conference ended and the meeting was officially adjourned by the Designated Federal Official at 3:44 p.m.

Adjourn / Certification

With no further business raised or discussion posed, Dr. Ellis officially adjourned the COTPER BSC meeting.

I hereby certify that to the best of my knowledge, the foregoing minutes of the April 27, 2009 COTPER BSC meeting are accurate and complete:

Date: 07/27/2009

_____/S/_____

Barbara A. Ellis, Ph.D.

COTPER BSC Designated Federal Official

ATTACHMENT 1

List of Participants

COTPER BSC Members, Ex Officios, and Liaisons:

Barbara Ellis, Designated Federal Official, COTPER BSC
Sharona Hoffman, Chair, FAP Peer Review Ad Hoc Expert Panel
Jack Harrald (by phone)
Jack Muckstadt (by phone)
Louis Rowitz (by phone)
Williams Stephens (by phone)
Robert Ursano (by phone)
Mary Mazanec, DHHS (by phone)
Diane Berry, DHS, alternate Ex Officio for Terry Adirim (by phone)
Amy Kircher, DOD, alternate Ex Officio for James Terbush (by phone)
Mary Gilchrist, Liaison for APHL (by phone)
James Curran, Liaison for ASPH (by phone)

Invited Speakers:

Cindy Williams, FAP Peer Review Ad Hoc Expert Panel Member (by phone)

CDC Participants:

Dan Sosin, COTPER
Marinda Logan, COTPER
Kim Gadsden-Knowles, COTPER
Mark Wooster, COTPER
Andrea Young, COTPER
Georgia Moore, CCHIS/OD/CDC
Kim Lindsey, COTPER
Craig Thomas, COTPER
Lynn Austin, COTPER
Julie Madden, CCEHIP
Leanna Fox, COTPER
Christa Singleton, COTPER

Colleen DiLiddo, COTPER
Lisa M. Lee, OCSO/OD/CDC
Peter Rzeszotarski, COTPER
Diane Manheim, COTPER
Theresa Kanter, COTPER
Christine, Kosmos, COTPER
Ann O'Connor, COTPER
Mildred Williams-Johnson, COTPER
Matthew Jennings, COTPER
Stephanie Zaza, COTPER (by phone)
Diane Caves, COTPER (by phone)
Cecilia Meijer, COTPER (by phone)
Dia Taylor, COTPER (by phone)
David Withum, CCID/OD/CDC (by phone)

Public Participants:

Mark E. Cooke, Senior Director, Government Affairs, PharmAthene Inc. (by phone)