NATIONAL INSTITUTES OF HEALTH

+ + + + +

ADVISORY COMMITTEE TO THE DIRECTOR (ACD)

MEETING ON PEER REVIEW BY TELECONFERENCE

+ + + + +

THURSDAY
FEBRUARY 21, 2008

+ + + + +

The meeting convened at the NIH via teleconference at 2:00 p.m. This transcript begins with Dr. Keith R. Yamamoto's comments that commenced at approximately 2:40 p.m.

PARTICIPANTS:

ELIAS ZERHOUNI, M.D.
RAYNARD KINGTON, M.D., Ph.D.
LAWRENCE TABAK, D.D.S., Ph.D.
KEITH R. YAMAMOTO, Ph.D.
JEREMY BERG, Ph.D.
JOHN BURKLOW
NANCY E. ADLER, Ph.D.
CHRISTINE E. SEIDMAN, M.D.
CATHERINE D. DE ANGELIS, M.D., MPH
KAREN A. HOLBROOK, Ph.D.
RALPH I. HORWITZ, M.D.

PARTICIPANTS (continued):

MARY-CLAIRE KING, Ph.D.
ALAN I. LESHNER, Ph.D.
BARBARA L. WOLFE, Ph.D.
MARY BECKERLE, Ph.D.
COLLEEN CONWAY-WELCH, Ph.D., CNM, FAAN, FACNM
THOMAS J. KELLY, M.D.
JAMES WENDORF
BRUCE ALBERTS, Ph.D.
HELEN HOBBS, M.D.
PHILIPPA MARRACK, Ph.D.
EDWARD PUGH, Ph.D.
ANTONIO SCARPA, M.D., Ph.D.
NORKA RUIZ BRAVO, Ph.D.
JOHN SCHREIBER, M.D.

C-O-N-T-E-N-T-S

P R O C E E D I N G S

(2:40 p.m.)

DR. TABAK: I would like to now turn this over to Dr. Yamamoto for his comments.

COMMENTS

DR. YAMAMOTO: My comments will be very brief. I'm not going to add more to the list that Larry has given, nor add any detail to what he has said but instead to do quite the opposite before opening this up for general discussion, your comments and questions.

And pull back a ways, and look at this whole issue from maybe 10,000 feet off the ground rather than on the ground that you have just heard from Larry, and to remind us all of what the overall goals of these recommendations are, the overall significance of them.

We have a major challenge in front of us in looking at the practice and procedures for review and funding of research, in that there are essentially three moving targets that we are trying to align.

Biomedical research of course itself is moving in all directions at the same time in a very dynamic and exciting way.

The behavior of scientists as they approach both their research and as they interface with the review process has changed dramatically over the recent years going from an isolated investigator culture to one where there is lots of collaborative science; going from situations where a scientist may work on a single experimental organism, or a single technique, all of his or her career, to one where there is a much more global reach to every research program, every research grant that comes in. And of course also looking at a system in our current era where the interaction of investigators with the review process has changed rather dramatically. So a second moving target.

And the third of course is the review and funding process itself. And our goal is nothing less than to try to align those in a way that the bureaucratic aspects of the way that we operate this endeavor do

not actually serve as impediments to the progress of science.

If you look at - if you consider what this might comprise, we can think about what the properties of the best system for review and funding of endeavor might look like, and let me just point out three that come to my mind that if all could be accomplished would I think move us in the right direction. Whether it does everything or not is not clear.

But certainly if we would have a rating scheme for grant applications that accurately reflects excellence and impact, in which the community of investigators agrees that that is a scheme that accurately reflects these characteristics, and of course those who are involved in the review process itself. But certainly that would be a great characteristic of a best system for review and funding of research.

A second would be a review process that motivates top scientists to participate, to serve in the review system, so they see it

as something that is a real service that they feel has impact when they participate in it; that they feel their time is not being wasted, and that their advice actually can turn into results.

And then thirdly, a third characteristic, would be an evaluation, funding policy and mechanism that recognizes that this serves multiple types of science and scientists; the recognition that this is a dynamic process, that writing down anything in a bureaucratic sense has to incorporate the knowledge that things are changing even as the writing is being done, and is able to accommodate these things in particular if not to anticipate, at least accommodate, emerging opportunities as they come up.

So there's three best properties. And what I would say as you think about the list of recommendations that Larry made, is that many of the recommendations bear on at least one of these three.

Let me just mention a couple under each of them without trying to be exhaustive

in anyway.

For the rating scheme that accurately reflects excellence and impact, a shorter reconfigured application that now focuses on idea and impact over preliminary data, methodological detail, would in our view move things in the correct direction of reflecting accurately excellence and impact.

More eyes on each application; more reviewers per application, presumably would lead to better judgments on the quality of an investigation.

We talked about ranking or scoring schemes that were coupled with explicit assessments of the individual rating criteria, something that we think would both provide more information, exclusive information to the investigator, and to programs that have to make decisions about funding.

The not-recommended-for-resubmission category of assessment would provide a clear message to investigators that it's really time to go back and rethink the project rather than reflexively resubmit.

In the second category of the review process that motivates the top scientists to serve, certainly a shorter application, and a shorter review might motivate people to be able to participate in the process, people who are very time-constrained already, whether it's running their research programs or writing their own grants.

Focusing on idea and impact over preliminary data, methodological details, things that you have already heard me and Larry mention in previous criteria fits this one as well.

The editorial board model allows the study section to focus on the big ideas rather than the methodological details.

Things of this sort would move certainly in this direction.

In the third category of looking for evaluation policies and mechanisms that recognize and serve multiple types of science and scientists, certainly an increased consideration of the investigator in the

review process, proposed in several different recommendations; increased funding rates for new investigators in various programs, to help support new investigators.

An elite program to serve - recognize and support transformational research, that's 1 percent of RO1 program that Larry mentioned; and longer term accomplishment-based mechanisms to support outstanding investigators, and then support interdisciplinary research that again Larry mentioned.

So this is a few of these notions, parts of recommendations, that we think would serve well this set of ideas that would move us toward this best system ideal.

And I think that an important part in thinking about all of this is the fact that if it's to have real maximum impact, it will be important not to adopt these things piecemeal or one at a time, but to think about being able to adopt them in combinations, that it's a combination of multiple recommendations of these sorts that will really be able to

work together, some of them in an obligate way toward having a genuine impact.

So with that, again, rapid fire summary, let me stop, and let us open up the floor, the phone lines, for any discussion points or questions that anyone on the phones might have.

ACD DISCUSSION OF RECOMMENDED ACTIONS

MR. BURKLOW: Thank you, Dr. Yamamoto.

This is John Burklow again. I just want to remind ACD and ACD working group members, if you would like to get in the queue to comment or ask questions, please press star one on your telephone to enter the queue.

ANNOUNCER: John Schreiber, the line is open.

DR. SCHREIBER: Yes, hi, John Schreiber, chairman of pediatrics at Tufts University.

First off, I wanted to congratulate you on what's obviously been a huge amount of work, and a very detailed and I think exciting analysis in many ways.

I do have one concern, only really on one area that you examined, and that concerns slide eight, looking at every application as a new application.

I was funded for 18 years, and was on study section for six, and the biggest impact I had as a young investigator was an

outstanding review that I responded to, and I think - and got funded.

And I wondered whether we wouldn't seriously impact young investigators with having every application as a new one. And this would be the person just putting in their second R01, or maybe in a new area putting in an R01, and I wonder if you couldn't modify this, and have really a two strike kind of thing, where you are allowed to do one review that would be considered, and then the reviewers would look at the previous review once, and then if you don't make it, any new application would be a new application, and I wondered on your thoughts on that.

DR. YAMAMOTO: We may not have been clear, so thanks for asking that question.

The - considering every application as a new application does not preclude resubmitting the application at all. It simply means that you would not be responding to the previous review in an explicit way as is done now. There is actually a page or two or three pages that is set aside for that, but

instead, would take the advice or not of the review that you got; prepare a new application; it would be assigned a new number.

DR. SCHREIBER: So to reiterate my comment, I understood - as a young investigator when I responded to the review, in my three-page response, that modified the direction of my science quite elegantly, and I think resulted quite honestly in much better work; that was a valuable process for a young investigator.

And again I worry - and the review, yes, it's a pain as a reviewer on study section to have to go back and see what the comments were. But sometimes there is an ah-ha when you do that. And again I worry about abandoning it completely.

DR. TABAK: So thank you for raising those points, and obviously these are being considered as options.

Unfortunately, the good experience that you had is not uniform, and in many instances what was reported to us through the

request for information was a not-so-optimal result; namely, that advice was provided, followed, and then led to not a happy ending as the one that you report.

But certainly the option as you describe it was considered, and we do thank you for bringing that to our attention again.

DR. SCHREIBER: Thanks much.

MR. BURKLOW: This is John Burklow again. The members of the ACD and the ACD working group can access the only - the star one, and the others are listen only.

Thank you very much.

ANNOUNCER: Alan Leshner, you may ask a question.

DR. LESHNER: Hi. So this - the final product of this - looks wonderful. I just have three things that I couldn't tell whether we had lost them in the process.

One was the issue of explicitly to what degree would we shorten the size of a proposal; that is, to how few pages?

Why don't I do all three of them, and then you can answer?

And then secondly, I think I understand that increasing the Pioneer, new Innovator and whatever awards, that would be seen potentially as the separate category for transformative research, but it might not, and it might be worth considering having that transformative thing explicitly.

The third was the question of whether to review clinical studies separately from basic study, basic science proposals in review sections? Personally I favor it.

DR. ZERHOUNI: You favor separate, Alan?

DR. LESHNER: I do. I think it is confusing when - because of the definition of clinical, right? If it's really clinical as opposed to just doing in a human what you might have done in a rat. But if it's clinical in the common English language use of the term clinical, then I think that it would be very difficult to compare the two categories of proposals.

DR. TABAK: Okay. So Alan, addressing the three questions in order, as

you know, the length of the application has been hotly discussed and debated. But we all agreed that we were going to delay the specifics of implementation to a later time.

And surely the specific length of the application falls in that category. But we have heard loud and clear that there is a need to shorten the length. And that is yet to be decided if that is one of the recommendations that is ultimately accepted, yet to be decided is the specific length.

With regard to the innovative - or excuse me, transformative research, let me turn to Jeremy for comment.

DR. BERG: So I think in addition to the Pioneer and new Innovator award, the NIGMS and a few other institutes have started a new impact-based mechanism, an R01 mechanism, but a new review process, the Eureka award, and we've just gotten the applications in. So that is another pilot that's going forward. And once we have data from all the mechanisms, we will take a look and see where we are in terms of the need to expand these programs,

and if there are gaps we can always add additional mechanisms. But I think our first task is to avoid confusing ourselves and everybody else by adding yet another new transformative sort of mechanism.

DR. LESHNER: Okay.

DR. TABAK: And then with regard to your third point, Alan, whether one should review clinical research together or separate from basic science, the report is silent on this issue, because frankly there was no clear recommendation that emerged.

As many people as yourself who were ardent in their support of having a separate review, there were an equal number who were equally forceful in their notion that to do that would diminish the rigor of the review.

And so as part of the analysis that is being recommended to understand why there are differences in the outcomes as observed in the Center for Scientific Review, versus the institutes and centers. That very point can be subject to study because in the institutes and centers, as you well know, the tendency is

to be more clinical only in terms of the review, versus the more hybrid approach that is usually taken on by the center for scientific review.

ANNOUNCER: Question from Nancy Adler.

DR. ADLER: I have a question on the rating system, and this may be too detailed for where the report is. But the five indicators, impact, investigators, innovation, climate and environment, I wasn't clear whether those would be given equal weighting.

And I am particularly concerned that you have both the investigator and within the environment, the institutional support; and this may penalize particularly young investigators in emerging areas where their institutions may not be particularly supportive, but their research is really important.

DR. BERG: Hi, this is Jeremy again. I think the intent was to have separate scores in these areas, and then to have an

overall gestalt score that allows the reviewers to weight the different criteria as they see fit, because the criteria are not really independent of one another.

So there wouldn't be any explicit weighting. The decision to separate investigator and environment was the topic of a lot of discussion, and the conclusion was that they were really separate things; that there are spectacular investigators at less well known institutions; and there are some less spectacular investigators at really well known institutions; and that getting comments from the reviewers about the two things separately could provide useful information to program staff in trying to make eventual funding decisions.

MR. BURKLOW: Okay, and we'll hear from Dr. Seidman.

DR. SEIDMAN: Yes, I also had a question about the ranking that again may be too granular at this time. The slide 11 indicated that at the conclusion of the meeting you are expecting charter members to

rank all the applications.

I think the average number of applications reviewed in one study section is considerable, and I hope that you are not going to rank the ones that were - what did you call it? - NRR, don't recommend for resubmission?

I mean are you only ranking those that are above a certain level? And is this truly a rank order, or is a ballpark rank?

DR. TABAK: So again we have not gotten into those fine details yet. But I would imagine that you would not - you would only rank the subset of applications that were judged to be the most meritorious, but again, the specific details have not been discussed as yet.

DR. SEIDMAN: And with regard to that, as we've all recognized, there tends to be drift of participation towards the exit door towards the end of some study sections.

And my concern is whether that will actually potentially change ranking, and I think that is going to need some attention,

obviously.

My other question had to do with the idea of piloting prebuttals, and given the electronic submission of scores prior to attending study section, I wonder if you have some sense with regard to how soon individuals are actually reviewing applications once they have received them.

Again, my perhaps jaded view is that it's pretty darn close to when study section meets.

DR. TABAK: So you have brought up two very important issues, both of which fall under the general heading of culture of study sessions. And there is no question that for these recommendations to be successful, if they are accepted, there will need to be a change in culture.

We in considering these recommendations found evidence from other agencies, and foundations in particular, that make use of the ranking at the end of the meeting strategy; and what has evolved in these places is a culture where all members of

the study section equivalent know that for their vote to count, they need to plan to be at the entire meeting.

It keeps people more engaged. It creates an esprit de corps that frankly many feel is currently lacking from a number of our current study sessions.

DR. SEIDMAN: If I may just jump in, I don't disagree with that at all, and as all of us who participated in those other funds recognize, that's sort of the pleasurable part.

But I would suggest that two elements make that more pleasurable. One, there are a lot fewer applications; and two, there is if you will rediscussion at that point.

My concern, as you might have anticipated, would be, if after discussion one rediscusses, for ranking, the duration of study section could actually become longer, considerably longer.

DR. TABAK: And again, hence the need for piloting; hence the need for

decreasing both the length of the application and the length of the review that will be required in terms of a summary statement that is prepared.

But again that is not to minimize the issues you are raising. These are real and will have to be dealt with.

With regard to the point that you raised about prebuttal, again, making use of electronic modalities without the specifics of a potential implementation, because we really haven't thought them through yet, but one would envision the posting of the review. We would have to change the culture so that this occurred a little bit earlier than perhaps is currently practiced.

There would be a very short window of opportunity for the applicant to correct factual errors; again, we appreciate that one person's fact is another person's interpretation, but we'll need to work through that.

But again, the idea here would be to prevent a circumstance where genuine

factual error has crept into a review, basically leading to a very poor score, necessitating that applicant to come back again where if the error could have just been corrected up front the whole thing could have been avoided.

Again, not trivializing or minimizing the issues that you raise - they are real - but through piloting and some additional work we think we can come up with an approach that will be satisfactory to do this.

MR. BURKLOW: Okay, thank you, Dr. Seidman.

We will hear from Dr. Conway-Welch.

DR. CONWAY-WELCH: Yes, thank you.

Again, congratulations on a lot of hard work.

I had a question on page 13 about the electronic-assisted reviews. I wondered if you could speak a little bit about that.

The reason I'm asking is, when I was reading that, some ideas came to mind, such as that the material could go out to the

two or three primary reviewers who, prior to getting together, and then the three could have a conference call with the applicant on standby, so that if they had any questions, that were appropriate, that they could get the answers right at that moment, and then confer together.

What I'm trying to figure out is if there is more efficient ways than gathering X number of people in a room for two or three days; again, having experienced the folks leaving to catch planes early on, I was just wondering how you were thinking about the electronic-assisted reviews.

DR. TABAK: Well, so you have certainly provided one example where the use of electronic review could be employed in a novel and very useful manner.

Electronic review has been interesting: people either love it or they despise it. And I don't know if it's generational, or if it relates to the specific area of science that one is in. But there are many, as you have just articulated, feel that

it would allow for review to be conducted in a much more efficient manner.

The flip side of this, which we also heard very clearly from some, is that the face-to-face meeting which allows for the creation of a certain personalized dynamic can be very, very useful.

And so one could envision in a two-step review process where you could potentially have the best of both worlds, and this is one thing that we certainly hope to be given the green light to pilot in the future.

DR. CONWAY-WELCH: I think that would be very helpful.

MR. BURKLOW: Thank you. Now we'll hear from Dr. King.

DR. KING: Thank you. This is Mary-Claire. I apologize for my laryngitis.

This is a higher level comment. As I was listening to this, it's elegant, it's absolutely lovely. I think the suggestions are very well put.

But it is in many ways working out with such a very small pie, and as we've

discussed it at every committee meeting, the problem is the amount of funds we currently have to distribute to investigator-initiated research, and the fact that we are still stuck in a time warp in terms of distribution of funds.

So I would like to ask the committee if they thought about the way in which the timing of this new model is best made with respect to what we anticipate will be a loosening of funds as the obligations that NIH accrued years ago are resolved and new funds are opened up.

DR. ZERHOUNI: Mary-Claire, are you referring to the recycling of dollars?

DR. KING: Yes.

DR. ZERHOUNI: Okay, so basically the phenomenon is that, okay, we have the 2005 dollars that are going to recycle.

DR. KING: Yes, more than one year, of course, but that phenomenon, yes.

DR. ZERHOUNI: So when you look at that you have to look at the peak year which is 2005, and 2005 was the year when we had

more funding actually than `04 and `03.

DR. KING: Indeed.

DR. ZERHOUNI: So the recycling starts in `09.

DR. KING: Right.

DR. ZERHOUNI: But after that it flattens out.

So I think you are right. The other is, do we have a forecast of what would be available, and obviously you have a relationship. Peer review doesn't need to be as stringently quality focused when there is a lot of money, reviewers and review panels do find it easier, and they've reported that to us.

DR. KING: And it's more fun.

DR. ZERHOUNI: It's more fun, easier. There is positive reinforcement.

So yes, I think we will adapt to those. However, nobody has a crystal ball in terms of how it's going to evolve in terms of resources available to us.

So I think we have to really, from my standpoint, work with a scenario that is

realistic, optimistic, and pessimistic, and really design a system that adopts to all of those.

DR. KING: I guess my thinking is that if a study section can fund only a very small fraction of grants, that no matter how elegant the process it's going to be disappointing for everyone involved in it.

DR. ZERHOUNI: That's right, and if you really look at the average numbers, it's about 20 percent, the issue that we find really is that it's very unequal across first submission, second submission, and third submission.

First submission, people have really punished almost the first submitters by going to 7 percent, 8 percent success rate, which is what people quote.

But in the A1 it's more like 20 percent, and in the A2 it's more like 40 percent success rate. So it's a system that rewards persistence over brilliance sometimes. And we want to really change that, because ideally we would want to have a success rate

or 25 plus, because the average length of grant is four years, and steady state is 25 percent; makes sense.

DR. KING: But a change in process cannot buy you a greater success rate. Only more money can buy us a greater success rate.

DR. ZERHOUNI: Are you suggesting we print money or something?

DR. KING: Yes.

(Laughter)

DR. ZERHOUNI: Mary-Claire, we appreciate that.

Yes, Jeremy.

DR. BERG: Mary-Claire, this is Jeremy Berg. One other thing is, the success rate is the ratio of the number of awards to the number of applications.

DR. KING: Good point, so it will go up.

DR. BERG: We can find ways to decrease the number of applications.

DR. KING: That's a very good point. So it will be less frustrating for the individual person.

DR. BERG: And for the applicant.

DR. ZERHOUNI: That's the idea, instead of delaying the decision to the A2 stage, and making it earlier, you will immediately run up the success rate, if we can reduce the number of applications.

Remember the applicants' success rate is always 5 percent above the -

DR. KING: Of course.

DR. ZERHOUNI: Generally 5 percent above. So that is what we are trying to accomplish by improving the experience.

DR. KING: You are trying to reduce the frustration for people who write very good first applications.

DR. ZERHOUNI: That is exactly it.

DR. KING: Got it.

DR. YAMAMOTO: And the goal of course - this is Keith - the goal of all of these, Mary-Claire, as you well understand, is that we are hoping that in aggregate all of these will lead to an improved process that people will appreciate, and will gain from.

For the individual who is faced

with not enough money in the budget problems, that may not - that's sort of a small salve. And you are also correct of course that change is always difficult for people, so change in the middle of other stresses is going to be hard.

But we are hoping that some of these will be recognized pretty quickly as improvements in the system, and that - and appreciated as such, and when the money does come there will be a real impact.

DR. KING: I think that’s likely.

MR. BURKLOW: Thank you, Dr. King.

DR. KING: Thank you.

MR. BURKLOW: Next we'll hear from Dr. Barbara Wolfe.

DR. WOLFE: First of all I wanted to commend you on this wonderful job. I think it's very creative. It's just far beyond my expectations when this process began. So congratulations.

The questions I wanted to ask was, the first was that on slide 10 you talk about that there will be - the length of a

discussion in terms of methodology and on prior research will be shorter.

So I wondered if you could give some greater sense to that, because it always strikes me that the big work that takes place and involves a lot of time is putting together the data that justify the continuation of what could be a new research project.

DR. TABAK: So again we are not at this point certainly being prescriptive. But there was a sense that we gained from the input that we received that many feel that they have to do the research before applying for the reward.

DR. WOLFE: Exactly.

DR. TABAK: And so the idea would be to reverse that, and to have only the preliminary data that is absolutely essential to make the case. And certainly with regard to methodology to really just eliminate all of the standard methodological approaches.

So for example if one is as part of the research describing a new method or approach to solving some problem, then of

course that would form the basis of what the application would look like.

But if someone is measuring protein levels or sequencing DNA, you just concede the point that one can accomplish that, and not worry too much about which primers and so forth.

So that's really the intention here, is to distill the essence that is required, taking out frankly what everybody looks at as being somewhat superfluous.

DR. WOLFE: Well, tied to that, in the idea of a prebuttal, the way it's described is to answer factual errors of the reviewer, but is there also an opportunity here for a reviewer to raise a question so that if something about the methods was not provided it's an opportunity to fill that in as well?

DR. TABAK: So that's an interesting extension of what the prebuttal would be about. And in fact some of the more creative suggestions that we received from the community suggested an almost blog-like

experience, where a reviewer and applicant would interact with each other.

Now in the interests of getting things done in a timely manner I'm not sure that we could go to that extreme, but yes, an extension of the prebuttal could be what you have just suggested, and it's something that people would have to be willing to pilot to see whether the value gained is worth the potential diminishment in efficiency that might occur as a result of doing it that way.

DR. WOLFE: But you might really get exactly what you want, because people, the applicants, might be more willing to not provide some of that information, if they think they can provide it in a prebuttal.

DR. ZERHOUNI: I think this is a very good point. This is the kind of enhancement of the report that we would welcome from members of the ACD. Because indeed if the mechanism is there, you can see that it's a bidirectional mechanism where the reviewer could ask a prospective question, to be prebutted or answered. That is a terrific

suggestion.

DR. WOLFE: Thank you.

MR. BURKLOW: Thank you, Dr. Wolfe.

Now we will hear from Dr. Bruce Alberts.

DR. ALBERTS: Can you hear me?

MR. BURKLOW: Yes.

DR. ALBERTS: I just wanted to go to an even higher level. Our working group had a concern that the kind of expansion that we are seeing in the system, being driven by the opportunity for soft money positions and cost recovery, at least at many institutions it causes them to advertise when they try to get to building a building, it's not going to cost us anything in the long run; in fact we might make money on this.

That incentive system needs to be analyzed, and we need to do something about it, because otherwise the system is not sustainable.

That was a major point of discussion at our last meeting. I don't think it's quite reflected enough in the final

report me. But I think it's a very serious issue.

I mean what you do about it is another question. If institutions even knew we were - the NIH was especially looking at that question, maybe it would restrain some of their over-optimistic building programs.

So I would personally urge that that situation be looked into.

DR. TABAK: So Bruce, on slide 23, and I appreciate, I went through things very, very rapidly; I apologize.

But among the recommended actions in slide 23 is to investigate the issue of salary and support for principal investigators, recognizing that there are this diversity of business models that applicant organizations use.

So the notion that institutions will understand that NIH needs to begin to look at this is in fact one of the recommendations.

And you might remember from the very complete discussions that we had during

the working group sessions that the subset of the committee who represent organizations that are really soft money organizations were quite strong in their defense of the need to have these diverse business models out there.

That said, I think your main point is a very important one, and it is our hope that this recommendation is accepted so that we do begin an analysis of how this is being used across institutions, applicant organizations, around the country.

DR. ZERHOUNI: This is Elias.

Bruce, are you suggesting that NIH be more proactive or formalize the supply-demand model in terms of what it is we can support in terms of good science and well supported science as opposed to many, many, many grants that may not - may be suboptimal on soft money?

DR. ALBERTS: I wasn't getting on that level of detail. It was just basically the fact that - I see it at every institution that I know about, the idea that build a building, and populate it with people who get

research grants from NIH, whose salaries can be paid entirely from the NIH, and we'll get direct costs on those salaries; basically a business model that is encouraging the (inaudible)

DR. ZERHOUNI: Excess demand is what it is.

DR. ALBERTS: Excess expansion, and it could be almost some kind of game. You hire people, and it's exploiting people in a sense. And then if they can't get their money, they don't have a job.

I mean it's without any commitment of institutions to the person; I worry about some of the selections that are going on (inaudible)

So I just think the whole model, which is very encouraging, the NIH needs to think about perhaps adjusting indirect cost recovery rules so that if you are not paying the salary of your investigator, you don't - get some kind of bonus for not paying that salary; direct costs for example.

But we should look carefully - I

think the NIH should look carefully - at how it looks from the university level, make it clear that we have tried to get a system that won't encourage sort of speculative overbuilding.

DR. YAMAMOTO: Versus the wording that is in this recommendation now you think is suitable? Or is it something that we need to be more -

DR. ALBERTS: I think it's so vague that it's not clear. And I don't think universities are going to get any kind of message from that. I mean people who are responsible for building.

DR. YAMAMOTO: So could you maybe try to put down something you think is appropriately explicit, and then we can work with it?

DR. ALBERTS: Yes, actually I made some comments.

DR. YAMAMOTO: Right, in your letter.

DR. ALBERTS: Well, in my comments on the draft. But I can send it back .

DR. ZERHOUNI: Okay, that'd be great. Okay, and I guess what you are saying in the final report, you'd like that to be highlighted more specifically.

DR. ALBERTS: Well, to be more explicit about it. It's sort of unclear what actually is meant by it.

DR. YAMAMOTO: Good.

MR. BURKLOW: Thanks, Dr. Alberts.

Now we will hear from Dr. Helen Hobbs.

DR. HOBBS: Hi. Just to be a little bit more explicit about that last point, and that was, we discussed the possibility of mandating that a certain portion of the salary of investigators be supported by the institution, not - maybe it wouldn't be the same for all types of institutions, but something to that effect, that institutions, had to provide some level of support for those faculty members, salary support.

And again I think that that point kind of got lost in the report.

I just want to make two other

points. One is, I think that one idea that we discussed was to address this problem of who is actually sitting on study sections, or really are the best people sitting on study sections? Do we really have the best, most respected scientists chairing the study sections?

I think these are really substantial problems that are not going to go away without some changes. And there definitely were differences of opinion in the working group. But my feeling is that everyone who gets a grant should be expected to serve.

It doesn't mean everybody would be a good reviewer, but at least there should be the expectation that they should serve. And exactly again the details, how many years of support versus how much service, not really clear.

But I think that that is really important. Because there are many people that are not serving on study sections that really need to, and we need them because we need

better qualified reviewers to serve on study section.

And I just want to make one other comment. And the way it's worded, I think there is a deemphasis on preliminary data. I am also for deemphasizing methodological details. But one of the things that we discussed at great length was the fact that many times a person's past performance is not adequate - is not adequately reflected in the score for the current grant.

So past performance can be used very effectively for people who have past performance. But for the younger investigators, preliminary data is important, but hopefully not deemphasizing methodological details.

And one final point, and that is, we discussed at great length this word, innovation. And innovation means a lot of different things to different people. And I think that it can be a little problematic to reviewers, because they think about it in very different ways.

And of course much of science uses established techniques, methods and approaches. And sometimes these are actually what lead to major advances in breaking down paradigms, et cetera.

So I think we just have to be careful of this word. We've thought of other words. Bruce Alberts used originality; uniqueness. I just think this is something that has to be sorted out before it becomes the word that is used in the new system as detailed rating.

Anyway, those are just a few comments.

DR. TABAK: So Helen, thank you for each of those comments.

If I may just offer a brief commentary back.

With the issue related to requiring or suggesting a specific salary support from institutions, you are right, that has been deemphasized. And the reason it was deemphasized is because we really didn't reach a true consensus. Given the spectrum of

business models out there, and in particular, there were members of the ACD working group as well as people in a steering committee working group that felt that our additional data, where we really could understand the support patterns more thoroughly, that it would be premature to go forward with that type of explicit recommendation.

On the issue of making service mandatory for all, if asked, again was something that was discussed very, very thoroughly, both within the steering committee working group as well as the ACD working group.

And the consensus was that there were just so many folks out there that if they felt they were being conscripted would perhaps do a suboptimal job.

But again thank you for re-raising that point. Because what we did was sort of an intermediate measure where we link it to our most prestigious awards but not all awards.

But thank you for re-raising it,

and we should take another look at that perhaps.

And then finally, your comment related to preliminary data perhaps being even more important for early career folks relative to those more established, I think as Keith has pointed out a number of times, even an early career investigator has a track record, and certainly all of us in academia hire people on the basis of how their performance was as fellows and so forth.

But your point is well taken, and I think all agree that the first thing that needs to be truncated if you will are the sort of standard methodologic issues, and we need to make sure that we don't disincent people, particularly the early career folks, from putting their best foot forward in terms of preliminary data.

So thank you for all of those points.

MR. BURKLOW: Thank you, Dr. Hobbs.

Now we will hear from Dr. Mary Beckerle.

DR. BECKERLE: Hi. Thank you very much.

I just want to make two brief comments on process, and then two general comments about the implementation phase.

I think everybody who was involved in the working group as I was appreciates these things that I am about to say in terms of process. But for Dr. Zerhouni and for other members of the ACD, I wanted to make sure they were articulated for the record.

First of all I think we were all really impressed with the incredible interest in the community and the broad input that we received from individual scientists, from institutions, from scientific societies, and from our community forums that were held around the country.

I think the level of engagement in the community speaks to the importance of the NIH system and the peer review process to a very, very broad group of people across our country.

So that was very gratifying, and

incredibly helpful I think as we went forward to develop our assessment and recommendations.

I also, as was acknowledged I think by several of the other speakers who were on the ACD working group, appreciated as a member of that group that these are tough issues, and for every challenge that we identified there were many, many possible solutions, and sometimes conflicting solutions.

And I really want to just commend Larry Tabak, Keith Yamamoto and Jeremy Berg for what I thought was really exceptional leadership of this group.

They were remarkably open-minded throughout the entire process, really good listeners. And I think they were able, because of their skill and their genuine passion for the mission here to really build consensus.

Obviously we didn't reach consensus on every detail point, but I think that the report you see really broadly reflects a consensus opinion of the group.

And two points related to

implementation that I'd just like to emphasize at the time. Again, taking off on something that Keith said, I think that the diagram on page 76 of the report that shows all of those interactions and that combinatorial network really illustrates that there is not a single action that is going to have a complete desired effect; that it is really going to be through looking at a network of actions to address each of the challenges that have been identified that we are really going to get some traction here.

And I think it's very helpful to look at it graphically to see you know for example just in terms of funding the best clients, what can we do in terms of reviewers? What can we do in terms of restructuring the application? And the many other different mechanisms that have been proposed, et cetera, and really try and tackle each of these challenges from a multifaceted perspective.

And finally I think we are all scientists, and I think it was extremely important during the process to really rely on

data rather than just suspicion as we analyze the challenges that we are facing and try to think about how we could maximize the peer review process.

And from that perspective I think the report suggests many pilots. And I would just put in a plug that whenever we are making a proposed change that we really look carefully at how we can implement that change initially as a sort of experiment that is controlled; and that we really put the time and energy into designing the experiment carefully, and having a really clear mechanism for assessment of the outcomes at the end.

And just one example would be in terms of the recommendation around nurturing young investigators, and ensuring that we support the most talented young investigators.

One proposal was to consider perhaps reviewing some of those applications in a group or a separate review section. And I think a really interesting pilot would be to take 40 of those applications and review them as a group, and then scatter them to where

they would have gone naturally out to the other review sections, and look at whether there is a substantial difference in the outcome in terms of what awards get funded.

That would be just one example, but I guess my general point is, let's do some experiments and get some data, and make final decisions based on data.

MR. BURKLOW: Okay, thank you very much, Dr. Beckerle.

DR. TABAK: Just to thank Mary for her very helpful comments, and for all her of her efforts throughout the process.

MR. BURKLOW: We will hear from Dr. Seidman.

DR. SEIDMAN: Just a brief comment with regard to supporting of young investigators. While I would sanction Helen's and several other people's comments about inclusiveness in reviewers, I think that one group of individuals who should not be participating are those brand new R01 investigators who we've finally gotten the money to get them to launch their scientific

careers. And I think these individuals are not the ones who should be serving on study section.

Another way to - it reduces your quota, but to put some academic rank so that we know that they have some seniority at least in terms of writing applications, getting applications, but also being protected from what is, for all intents and purposes, hard work and good service on being on an NIH study section.

DR. TABAK: Thank you, and that point is well taken.

If I may, I would just like to ask all members of the ACD working group and members of the ACD, to provide us any written comments that they may have, if possible by the end of the weekend.

I apologize for that short timeframe, but now that you've had the document for about a week or so, we hope that you are in a good position to respond back to us with any specific comments that you may have.

Again the timeframe is that we would like to present to the NIH director the draft recommendations, the draft report, by the end of February.

And Dr. Zerhouni has reminded us that this is a leap year, and we should stop complaining about how quickly we want to do everything, because we have an extra day. And we are going to use that extra day.

And so if you could, we would appreciate it if you could send those comments directly to me and then I will make sure they are sent around to the various members of the team, all of whom you have had an opportunity to meet.

So with that I want to thank you, and I will turn it back to John.

MR. BURKLOW: This brings us to the end of the telebriefing. And so Dr. Zerhouni, if you'd like to -

CLOSING COMMENTS

DR. ZERHOUNI: Well, first of all, let me thank all of you for reading the report

and listening to the presentation.

And what I'd like to also say is that in addition to your recommendations for editing of the draft report, we will also be well-served by making your comments on the record, and all of the suggestions that were made through the open discussion, attached as an appendix to the report, so that we will accurately reflect your input.

At this point I think by procedure the one action that the ACD members have to undertake is whether or not to accept Dr. Yamamoto's proposal that this be considered a draft report to the ACD, with the proviso that your comments will be attached as an appendix, and that the edits will be included in the reports as sent to Larry Tabak.

So I guess what I am asking, because of procedures, I'm asking for a motion here.

You can press star 1 and make your motion.

If you're still on line.

DR. ZERHOUNI: Dr. Adler?

DR. ADLER: I move that we accept it.

DR. ZERHOUNI: Dr. King?

DR. KING: Second.

DR. ZERHOUNI: And any objection? Dr. Leshner?

DR. LESHNER: Fine.

DR. ZERHOUNI: Dr. Wolfe?

DR. WOLFE: Fine

DR. ZERHOUNI: Dr. Conway-Welch?

DR. CONWAY-WELCH: Fine.

DR. ZERHOUNI: And if there is any objection please forward it to us.

At this point I'd like to basically thank you, and stay tuned. The plan, just so you know, is that at the issuance of the final edited report - we will run the report by you one more time just to make sure there is nothing there that is a showstopper.

In four to six weeks after that, I'm assembling an implementation team that will take the recommendations and develop essentially an implementation plan.

As you recall, when we entered this

adventure we decided to have a diagnostic phase, the end of which is essentially what we are witnessing today. And we are entering a therapeutic phase or implementation phase. (Laughter) And so report back to you in about six weeks after the – four to six weeks - after that to be more explicit, and particularly about the point that Mary Beckerle made, and that is that it would be unwise for us to be going into these changes without some experimental data ahead of the full implementation of the change.

So that is clearly good advice, and we will certainly try to design the implementation so that you will have the opportunity to in fact assess many of these recommendations in the dry-run basis, for most of them anyway.

So with that I'd like to close the meeting at this point, and thank you, and stay tuned for the implementation.

Thank you all.

(Whereupon at 3:19 p.m. the proceedings were adjourned.)

This transcript produced from audio CDs by Neal R. Gross Court Reporters and Transcribers.