

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTERAGENCY AUTISM COORDINATING COMMITTEE

SUBCOMMITTEE FOR
BASIC AND TRANSATIONAL RESEARCH

STRATEGIC PLAN QUESTION 3 PLANNING GROUP

CONFERENCE CALL

OCTOBER 30, 2013

The Strategic Plan Question 3 Planning Group convened via conference call at 2:00 p.m., Susan Daniels, Ph.D., *Executive Secretary*, IACC, presiding.

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PROCEEDINGS:

Dr. Susan Daniels: Thank you. Welcome to our listening audience and to members of the IACC who are joining us for this call of the IACC Strategic Plan Update Question 3 Planning Group.

We're going to be talking today about Question 3, which pertains to environmental and genetic risk factors for autism spectrum disorders. And we are going to be going through a list of materials that our Office has prepared and talking about progress in terms of funding for the Strategic -- for projects related to the Strategic Plan. First, I'd like to start with a roll call so that we know who's here.

Matt Carey, are you here?

Matt is supposed to be joining us, so I assume he'll be joining us later. And hopefully, if he's on mute right now, Matt, please let us know when you've joined the call.

Cindy Lawler?

Dr. Cindy Lawler: I'm here.

Dr. Daniels: For Linda Birnbaum, thanks.

And Lyn Redwood?

Ms. Lyn Redwood: Here.

Dr. Daniels: Thank you. So, today, I'm going

to lead you through some documents that I shared. For people who are listening on the phone, please go to our Web site to access the materials. Just look for the time of this call. It's October 30th, 2:00 to 4:00 p.m. on our Meetings and Events page, and you'll see a link for all the materials, and you can access them there.

Today, we're going to be talking about progress on the Strategic Plan in terms of implementation, in terms of the projects that have been funded by various Federal agencies and outside organizations that are involved in autism activities. I provided some information that is taken from the IACC Portfolio Analysis documents that have been compiled over the past 5 years.

There is some new information that is from the 2011 and 2012 Portfolio Analyses that that document has not been released yet. But we provided the information for you. It's still in draft, but it's, for the most part, complete at this point and should be a pretty good indicator of what's in the portfolio.

So, I'd like to briefly tell you what's in the packet that you all received. You have a 5-year Strategic Plan Status Chart for Question 3, and

this is also referred to as the "cumulative funding table" in the subject, or the file name, that you received on email. And this chart shows 5 years, worth of funding for Question 3-related projects.

There is a set of pie charts that show the distribution of funding across the entire Strategic Plan for the year 2008 through 2012, by question, just to give you an idea of how funding, what the relative amount of funding is for Question 3 versus the other six questions.

We also provided subcategory pie charts for Question 3. And this document shows a breakdown of the projects that are in Question 3 into some subcategories that OARC developed, actually in response, I believe, to a comment that you had, Lyn, back a few years ago when we were looking at the Portfolio Analysis and looking at, especially, the "Other" category, and you had questions about what might be in that category because "Other" is not a very descriptive term.

And so, to try to address that, OARC the following year developed a list of subcategories within each question area that are very simple and straightforward categories to try to break down

the projects a little bit more to give you an idea of what's in there. And so, from 2010 through 2012, we've provided the subcategory proportions for you in pie charts.

So the four subcategories that we have for Question 3 are environment, epigenetics, gene-environment, and genetic risk factors.

The next document we have, we have two documents, the full project listings for Question 3 for 2011 and 2012. We've provided these in attachments. For those earlier years, we provided a link to the Web tool for 2008 through 2010, because all the data is already live in the Web tool, and it can be accessed there. But for 2011 and 2012, the data aren't yet live in the Web tool, so we've provided it in these tables.

And if you click on the links for the projects, there may be some links that aren't active yet because if it's a new project, those project pages haven't been made active in the Web tool yet. But if you click on older projects that are continuations, you will be able to pull up abstracts for those.

So that was provided to you, but you have a listing of all the project titles, principal

investigators, institutions, funding amounts, and funders. And then we have a summary sheet at the end that provides some information, including the projects that are categorized as "Other."

So what I'm going to do today is walk us through the cumulative funding table. And we're going to discuss each of the objectives for Question 3. There are 15 objectives, I believe.

So let me give you a little bit of background before we start on our task. As you look at the table, the first column provides you with 2008 funding amounts and projects. This is a baseline because the first analysis was looking back at 2008 autism funding, looking at the projects that were funded in 2008, which was prior to the launch of the Strategic Plan. And so it really serves as a baseline as to what was happening before the Strategic Plan came into being and was starting to be used.

And then following that, you have 2009 through 2012, which show how the distribution of research was after the start of the Strategic Plan. In the last column, you have a total amount of funding for each of the objectives. And if you look across the rows, you'll see amounts for each

of the years, each of the objectives. And you have both the number of projects, and as I mentioned, the links in this table are active for 2008 through 2010. So you can actually go to those projects and get more information about the projects.

There is red, yellow, and green highlighting on each of these areas, trying to indicate the level of completion of each of these objectives. So the green indicates across the rows annualized funding. So, if you take the IACC-recommended budget and annualize it, if you see green indicated as a highlight that indicates that the annualized IACC-recommended budget was met.

And we realize that the annualized budget might not be completely meaningful, because sometimes some of these objectives are recommended to be completed over a shorter number of years than what's measured here. But it gives you an indication of whether you are moving toward the full meeting of these recommendations in terms of the budget.

And for background about the recommended budgets, these recommended budgets are required in the Combating Autism Act to go along with each of

the objectives to provide guidance to the agencies as to what it might cost to implement the objectives as written.

They're not directives to the agencies that they must spend that amount. And in fact, sometimes it can be a good thing if you can achieve the objective without spending the maximum amount. But this was recommended as a potential realistic budget for achieving some of these objectives and that the objectives were deemed by the Committee to be the minimal amount of work that would be required to get work started in each of these key areas.

The objectives represent gap areas that were identified by the Committee. There also was base, core funding associated with each of these question areas prior to the existence of the Strategic Plan. So each of the agencies and organizations involved in autism activities was already funding a body of work, and that body of work is represented in the category called "Other," which is toward the bottom of the second page of the table.

In previous calls, we've talked about this "Other" designation, and I think most of the

Committee agreed that "Other" isn't a very descriptive term and might lead one to think that the funding or these projects aren't important. And really, in reality, they're the foundational, or core, funding or core activities that were already ongoing prior to the Committee's work to identify specific objectives to address important gap areas.

When you're looking at the left-hand side at the text of the objectives, the red and blue texts just indicate where these objectives changed over the years. And one of the other points is that each year, in many of the years, the number of objectives expanded. And so there might be cases where there's more funding in one year for a particular objective, and the following year it might look like a reduction, but it might be the case that some of those projects were moved into a different category because a new objective was created that was more appropriate for those projects. So just keep that in mind.

And I believe I've covered most of the background. Do any of you have questions about the table before we start going through it?

Ms. Redwood: Susan, I have a quick question

just for clarification.

Dr. Daniels: Sure.

Ms. Redwood: With regard to the budget, for example, on Question 2, the budget was over 3 years, but we've got 5 years of funding.

Dr. Daniels: Um-hmm.

Ms. Redwood: So did you average the 3-year budget over the 5 years? Did I understand that correctly?

Dr. Daniels: Well, what we did was we just -- yes, we did. We took the 3.5 million and divided it by 3 to get an annualized budget, and then measured each year as to how far we were getting toward that annualized budget, but realizing that they said only 3 years. The annualization isn't perfect, but it's an indicator --

Ms. Redwood: Okay.

Dr. Daniels: -- if that makes sense. That was -- it seemed like the most reasonable way for us to get an estimate because, remembering that we were doing this each year as we went along, we're only in the position now to look back over 5 years.

But when we first started this, we only had 1 year of data at a time. So that was the best we

felt we could do to try to get an indicator of the progress. So we hope that the red, yellow, and green coding will be helpful to you all in at least getting a quick snapshot of what was happening. And then you'll have to do a little bit more of an in-depth look to try to understand what the picture was for each of these.

Dr. Lawler: Susan.

Dr. Daniels: Sorry. Go ahead.

Dr. Lawler: Susan, this is Cindy. So in terms of the count, you know, 14 projects, however funded --

Dr. Daniels: Yes.

Dr. Lawler: Are those only referring to new projects? Or how did the code, you know, these numbers work for, say, you know, there was a 5-year grant awarded of that? Is that counted in each of the 5 years, or --

Dr. Daniels: Yes.

Dr. Lawler: Okay.

Dr. Daniels: So these were -- again, because we were doing it as we went along each year, the most accurate way for us to be able to do that was just to count the total number of projects each year. So when you see, say, 2008 and 2009 for that

first objective, you have 14 projects in 2008 and 11 projects from 2009. There are going to be some of those that were continuations and others that were new.

Dr. Lawler: Okay.

Dr. Daniels: And in the Web tool, we actually have a way to break that out. But that's not in this particular table. We have a designation for projects that were new and projects that were continuing. But you would have to actually look at the project list to see which ones were continuing and which ones were brand new.

Dr. Lawler: Okay. That's helpful. Thank you.

Dr. Daniels: Sure. Anything else?

[No response]

Dr. Daniels: Alright, well, then, we'll get started, and you may have other questions as we go along. We have, like I said, I think about 15 objectives to go through. But I know Lyn has been through this once and, hopefully, will be able to get through it efficiently.

So let's start with the first one: "Coordinate and implement the inclusion of approximately 20,000 subjects for genome-wide association studies, as well as a sample of 1,200 for

sequencing studies to examine more than 50 candidate genes by 2011." And then the addition of: "Studies should investigate factors contributing to phenotypic variation across individuals who share an identified genetic variant and stratify subjects according to behavioral, cognitive, and clinical features."

So we can see that the recommended budget here was \$43.7 million over 4 years, and the total spent in 5 years was \$38.5 million. So would you agree that the recommended budget here has been partially met?

Ms. Redwood: Yeah.

Dr. Daniels: Each time, I think what we'll do is we'll try to talk about the recommended budget first and then about the projects and your assessment of those. So we'll say that this one was partially met in terms of the recommended budget.

And what do you think about the projects that were funded and how well they addressed the objective and the intent of the Committee for this objective?

Ms. Redwood: You know, Susan, I think it would be important to actually dig into these, and I

know it would take a lot longer than what we have time for today on the call of 2 hours to really determine whether or not we have met this goal. I mean, we've got something that's really measurable, you know 20,000 subjects.

And I know when we were doing this exercise last year there was someone who you put me in touch with that actually was able to provide some numbers in terms of how many subjects had actually been included to date. It would be good to get that information again.

You know, I feel like we're probably fairly close, but the area that I don't think there's been as much focus on is looking at the phenotypic variation across individuals who share an identified genetic variant and how to stratify the subjects, you know, behaviorally, cognitively, and with clinical features. That's the part that I think is really important that we have haven't really accomplished yet.

Dr. Daniels: Can you take a look at least at the 2011 and 2012 tables that we provided of projects? Because that can give you an idea. Most of the groups have been looking at those projects to get an idea, and that's something that you can

kind of glance at on the phone to see if the projects look like they're addressing the question.

Ms. Redwood: Yeah. I tried to look at those before the call, too.

Dr. Daniels: So you felt that looking at the projects that it didn't appear that phenotype was looked at?

Ms. Redwood: Well, I guess what I'm referring to, Susan, is broader than that in terms of the research that's actually come out. Does that make sense? And some of these, when I click on them -- I've got now the 2012 Portfolio Analysis -- it doesn't take me anywhere. So all I really have is the title of the study. I can't really tell how many subjects were enrolled, what they were looking at.

Dr. Daniels: So that one is a 2012. Which study were you looking at?

Ms. Redwood: Well, the very first one: advanced parental age and autism.

Dr. Daniels: Oh, so it was probably new in 2011, which is why the link isn't live yet in the Web tool. So do you feel then that you guys can -- you all cannot make an assessment of this then

without doing deeper analysis? I think most of the groups have been trying to take a look and get a general picture of whether they feel that the question is being addressed by the projects funded.

And we're not talking about outcomes on this call in terms of whether the science was accomplished. We're talking about whether appropriate projects were funded in response to what's in the objective -- not exactly in response, but if there were projects funded that were related to this objective. And if not, what were the areas that we're missing in the portfolio? If you understand what I mean.

So we're not really trying to assess whether there was an outcome. If there was a publication or, you know, the actual scientific objective was achieved, that would be the subject of a future call.

Ms. Redwood: Yeah. I mean, I think we're moving in the right direction. I don't think it's been accomplished yet.

Cindy, what are your thoughts?

Dr. Lawler: I also don't at this moment have access to the application. My, you know, knowledge

from other sources of information is that that type of stratification, you know, looking at, sorting out based on some genotypic characteristics is, you know, commonly incorporated into these kinds of genetic studies.

So I would be comfortable with, you know, pretty good progress on that front, with a caveat that I had not examined the specific [Inaudible comment] that make up, you know, that are represented in this table.

Dr. Daniels: Okay. So then, would your conclusion then be that you think that progress is being made on this, but the objective may not have yet been achieved?

Dr. Lawler: Yes.

Ms. Redwood: Yes.

Dr. Daniels: Okay. So that's the sort of global assessment we're looking for on this call so we can list that for you. And then we can move on to the next one.

So: "Within the highest priority categories of exposures for ASD, identify and standardize at least three measures for identifying markers of environment exposure in bio-specimens by 2011." And in this, we see that the recommended budget

was 3.5 million over 3 years, and the total spent to date is 813,000. And so that one is clearly only partially met. But do you agree with that?

Dr. Lawler: So this is a problematic objective, because it does address a real gap. But it is not a gap specific to autism. So you know, how to capture progress that's being made and exposure assessment?

And there's also, you know -- we have not yet narrowed it down because of the matter of the priority exposures. There are still, you know, many, many good candidate exposures. So while progress is being made, it's not necessarily in the context of, you know, autism research. So I have -- you know -- I'm at a loss as to how we grade this.

Because if it was made in -- we were in some other arena, it wouldn't be captured as an autism brain link and therefore would not contribute to meeting this objective. But you know, we are indeed making progress on the exposure assessment front. And it is really relevant to autism. So, again, this is -- you know -- this is problematic in terms of how to, you know, represent that.

Dr. Daniels: And that information is really

important. What we have been doing throughout all of the other calls is identifying exactly those things. So first we have been looking at the budgets to get an idea of whether the recommended budget has been met or partially met or not met at all.

And then looking across here, we see that there are zero projects for 3 of the years, 1 project in 2012 and 4 projects in 2008. So it's a slim number of projects, but then trying to understand why that might be.

And I think that you've identified a number of reasons that, with this given type of assessment, that we have done in the Portfolio Analysis, we might not be capturing things because some of the work might be being done outside of the autism portfolio and this project only looks at grants and other kinds of projects that are within autism portfolios throughout the Federal agencies and private organizations.

And you identified some possible scientific barriers that might be keeping some of this work from happening.

Ms. Redwood: Hey, Susan. This is Lyn. You know, we had a meeting, gosh, several years ago, I

think back in 2008, with the Institute of Medicine to look at environmental factors, specifically in autism --

Dr. Daniels: Um-hmm.

Ms. Redwood: -- and there was a report published from that that actually helped to identify what some of the candidate environmental exposures might be. And there was

Dr. Daniels: Um-hmm.

Ms. Redwood: Also a paper published just in the last years by Landrigan that sort of identified -- did a literature review and identified -- the top 10 environmental exposures. So I do feel like we have, you know, somewhat of a working knowledge of what those might be that set the same time trends in terms of the exposure having been increased during the same period that we saw and increased in the number of children diagnosed with autism. So you know, I think that we do have an idea and things that we can drill into more deeper.

When I look at those four projects that were listed, which had been the only four, except for one, that was the baby tooth project just funded this year by Autism Speaks --

Dr. Daniels: Um-hmm.

Ms. Redwood: -- I don't even think that those projects really should be in this category. It's hard for me to know. But one of them is called "Genetics of Autism Intermediate Phenotypes." And then another one is "Core C: Analytical Core." These were all ones identified in 2008,

Dr. Daniels: Um-hmm.

Ms. Redwood: And I just -- I don't even see those as even being germane to this objective. There's one that's "Biomarkers as Response to Environmental Structures, Measurement of Environment Exposure to Metals and Chemical Toxicants." And that's sort of the only one, and that funding was 115,000. And there are no Web links, no URLs. There's nothing here to be able to find out what was the outcome of that research.

So, and I would think that maybe NIEHS could provide us with, you know -- Cindy, if you're saying there are other studies in other areas that are not specific to autism where we are making progress --

[Inaudible comment]

Ms. Redwood: -- it would be great if you could bring those to the Committee.

Dr. Lawler: Yes, so as an example I mean we have made a large investment in trying to understand how you measure [Inaudible comment], you know, reliably in, you know, urine samples or blood samples. There are many, many measurement issues that make it really difficult to reliably measure it and to interpret it.

That is not -- you know, would never that -- the research is not being coded in the context of autism. But certainly, you know, as an endocrine disrupter, that would be, you know, an example. And there's some animal work that's ongoing that's in that effects due to some sort of recognition. So that's just one example of, you know, a lot of methodologic work going on to prove our abilities to then to measure an important compound and in biospecimens that is not captured here.

You know, I do have the Bruce Hammock, one of those projects that's a core facility, service and core facility at UC Davis. And they have done a lot of work in that core trying to, you know, understand how to better measure analyzed interests. So I know that that -- you know, that's an appropriate coding. I am not familiar with the middle two that were listed in that.

I think the first one, there's an SDIRS BTR project, I think.

Ms. Redwood: So I guess, Susan, my overall opinion of this would be that - no, you know that based on the information that we have in front of us today, you know -- we're not making progress on this.

Dr. Lawler: But I think the larger -- you know -- the larger issue is that this objective is not written in a way that really allows us to assess progress.

Dr. Daniels: And how is that?

Dr. Lawler: It would be different, for instance, if, you know, there was an objective about applying improvements in similar assessment to, you know, human studies. You know, because that's where, you know, you could perhaps want to make sure that, as improvements are made, that the researchers in autism arena are capitalizing on those improvements and incorporating new methods in the way they assess exposures.

But that's not how the objective is written, so we can't really assess progress. So, I don't even feel comfortable -- I don't feel comfortable -- saying there's no progress. I just, you know,

take issue with that, you know, sort of objective. I don't think that, you know, we can capture or appropriately comment on, you know, progress that's been made.

Dr. Daniels: So I guess, as a summary of this, would we say that, with the objective as it's written, that there has been some limited progress? There has been some progress, but it's been limited in terms of the science of measurement? And that work is being done in that area, but that there are some limitations that are preventing moving forward faster on it?

[Inaudible comment]

Dr. Daniels: Is that -- or you can help me with rewording that.

Dr. Lawler: Okay.

Dr. Daniels: How would you describe it?

Dr. Lawler: Well, I mean, I think there is progress. But we haven't -- we're not -- the way, you know, Portfolio Analysis proceeds, we can't capture that progress.

Ms. Redwood: Cindy, since you work in that area, though, could you provide -- since you feel as though there is progress being made, but we're not capturing it, could you bring to the Committee

what that progress is? I mean, has there been an actual standardized measurement for environmental biomarkers that autism researchers could send you to do assessments --

Dr. Lawler: Again, I think --

Ms. Redwood: -- since that's the whole goal of the objective?

Dr. Lawler: Progress has been made with -- in terms of, you know, the gold standard way of measuring, you know, 20,000 chemicals? No, because we're not there yet. And we're not -- there are always going to be opportunities to include how assessments are made. But there is definitely being good progress in, you know, kind of capturing exposures. So you know, I'm --

Dr. Daniels: So would you say maybe that progress is being made on understanding the measure, or advancing the science of measuring exposures, but further work is needed to translate this to the autism field?

Dr. Lawler: To -- I guess to, you know, ensure that these improvements are, you know, sort of adopted widely by autism researchers.

Dr. Daniels: Okay.

Ms. Redwood: I guess I'd like to still see a

list of what we have. Like what measurements do we have now that we can use? Because that's what this objective is saying: Identify and standardize three measures for identifying markers of environmental exposure.

Dr. Daniels: And that's something that we can do in the future call and workshop. But, Cindy if you would be able to pull anything together about that.

In your write-ups, you'll want to be able to refer to -- for example, I mean, there are other groups that had the situation where work has been done that's not captured in the Portfolio Analysis because it's funded by some other mechanism that's not captured here. And so, that's a part of the text, to just say that progress is being made, but it's not reflected in the funding because it's being done in another way, and these are the, you know, examples of those projects. So, we can do that.

Alright, so let's move on, then, to the third objective.

Dr. Lawler: Okay.

Dr. Daniels: "Initiate efforts to expand existing large case-control and other studies to

enhance capabilities for targeted gene environment research by 2011."

So on this one, \$27.8 million was recommended over 5 years, and 26.9 was spent over the 5 years on projects that are related to this objective. So would you agree that the recommended budget has been partially met, and in fact, largely met, according to how it's written there?

Dr. Lawler: Yes.

Ms. Redwood: Yes.

Dr. Daniels: Okay. So then, in terms of the projects that have been funded, it's still a fairly small number, anywhere between 4 and 10 projects in any given year. How do you feel about how those projects, based on the information you have here, relate to the objective and how well that objective is being covered?

[Pause]

Ms. Redwood: You know, I think we're moving in the right direction.

Dr. Lawler: Right.

Ms. Redwood: I have some concerns about just the studies that are being done in other countries, just because, you know, if we are looking at, you know, gene-environment

interactions, environments in other countries can be just so much different than the environment here in the U.S. So that would be my only sort of caveat to some of these other studies.

Dr. Lawler: I've just seen the one in Korea. Is there another one that --

Ms. Redwood: When I was looking through these earlier, there's a big study that is being funded multi-years out of Sweden or Scandinavia, the Scandinavian study. Let me just share some of the other ones. I can pull them up. I can't remember exactly which questions I was looking at. There's the next one here.

You know the projects I'm talking about, right, Cindy?

Dr. Lawler: No, I don't think so.

Ms. Redwood: In Denmark? The Finnish National Birth Health Court is one.

Dr. Lawler: Yeah, I think that was listed under risks.

[Inaudible comment]

Ms. Redwood: It's listed in the 2009.

Dr. Lawler: Oh, okay, under this objective?

Ms. Redwood: Um-hmm. Yes. "Initiate efforts to expand existing" blah-blah-blah-blah-blah. And

with the targeted gene environmental interactions,
3.S.D.

Dr. Lawler: Oh, I see. Yes. Yes.

[Background Noise]

So that that would lead you to think that it's partial in that? Or -- I mean, as I read it, it meets the mark. I think the, you know, the number of studies is smaller than I would, you know, like to see.

Ms. Redwood: Yeah. Oh, I agree. I mean, I think they're seeing some progress made, but it really needs to be more of a focus.

Dr. Lawler: I'm not sure what you mean, Lyn.

Ms. Redwood: Well, okay. I guess when you just look at the numbers, Cindy, like you said there are not many projects here. The average is for a 4 being a lowest, a 10 being the highest over a 5-year period.

And the spending, when you compare it to some of the other gene studies that we're doing, I mean, the total budget, we're looking at the gene-environment over the 5 years is 26 million, where in the category of "identify genetic risk factors," there are at least 50 people. Over a 5-year period, we've spent 169 million.

So, you know, that's why I'm saying that I really think that we need to be sure that we're focusing on, you know, environmental factors as well, equally.

Dr. Lawler: Well, so, I understand that. Looking back at the objectives, well, part of the limitation of this objective is to initiate efforts to expand existing large case-control and other studies. So while I would have liked to see larger numbers, due to the number of projects, part of the problem is there are not that many large and different studies where we can add on.

So you know, keep that in mind, too. It's not an objective to start, you know, really large studies, which would have been great. It's more to make sure that we're capitalizing on existing studies. So we've probably done a reasonably good job. But you know, there are not that many relevant existing studies we can add on to, as opposed to just, you know, or a new cohort [Inaudible comment] studies.

So you know, I'm comfortable with, you know, good progress on that particular objective.

Dr. Daniels: Okay. So it sounds like then, in summary, that you feel that good progress is being

made on this objective and, you know, work needs to be continued. But one of the limitations here may be that there is only a limited number of existing studies that can be added onto to do this.

Dr. Lawler: Well, yeah, that are well suited to this.

Dr. Daniels: Okay.

Dr. Lawler: Because, I mean, it certainly a large number of studies. But, you know, for this, you know, it's more difficult.

Dr. Daniels: Right. So if you imagine that many of the studies that were amenable to this type of expansion have already been expanded and you've come close to meeting the recommended budget, that you may have exhausted to a large degree this particular objective the way it's written unless you were to start other new studies.

Dr. Lawler: Yeah, I mean I think that that maybe goes a little farther than I'd be comfortable with. I can say that a lot of the obvious places to expand, we've done that. But I don't know that we've exhausted or, you know, that there are not additional ones that perhaps are not

immediately obvious that we could leverage.

Dr. Daniels: Okay. Alright, I think that you've done a good job of summarizing that one. So let's move on, then, to the next one: "Enhance existing case-control studies to enroll racially and ethnically diverse populations affected by ASD by 2011."

[Pause]

Ms. Redwood: It doesn't look like we've really met the funding objectives, if that's the first question.

Dr. Daniels: Yes. The funding recommended was 3.3 million, and 188,000 has been spent. One other thing just to point out here, that throughout this, keep in mind that there may be situations where a project was coded to a different objective, but still partially meets one of the others, because we only coded things once.

We didn't do any double-coding, to avoid double-counting any funding. There might be situations where a project was relevant, but it got coded elsewhere because it was a stronger fit for one of the other objectives.

[Inaudible comment]

Dr. Lawler: -- Are the new ACE centers' coded,

were they funded in 2012 or just 2013? Because one of those isn't one of the UCLA ones -- was a major component to enhance diversity in enrollment for the genetic study?

[Inaudible comment]

Dr. Daniels: Which one were you thinking of?

Dr. Lawler: I think it was one of the Dan Geschwind [Inaudible comment] --

Dr. Daniels: Oh, okay. So that would be coded elsewhere, I'm sure.

Dr. Lawler: It may have been funded in 2013, which wouldn't be included here. I'm not sure when the latest round was funded, whether it was 2012 or 2013.

[Pause]

Ms. Redwood: And when you actually drove to these projects, there are two projects that are multiple-year funding.

Dr. Daniels: I think the new aces are in the 2012.

Dr. Lawler: Okay. So then these were -- it's probably funded -- I mean coded in another objective. I think that was a -- that was a strength.

Dr. Daniels: Okay. We can check that for you

and find out where that study is coded.

Dr. Lawler: I mean, just based on what we have to look at here, it doesn't look like we've done - - we've met this objective.

Ms. Redwood: And it's not clear from the studies that have been funded if they were just looking at a model for how to enroll versus actually enrolling.

But, Cindy, what you're saying is that in one of the Geschwind studies that are actually targeting diverse populations?

Dr. Lawler: I think so.

[Pause]

Dr. Daniels: So, can you think of any reasons why this might not have anything assigned here or why there might not be projects in this area? And you don't have to necessarily come up with this. In the next call, when we have more people around the table, it might be more obvious. But just in case you have any thoughts about it, whether there would be some reason, any barriers that would have prevented this from being able to happen?

[Pause]

Okay. So if you don't have any ideas on that, I think that it sounds like you would both agree

that this objective has largely not been met as yet. That would be --

[Inaudible comment]

Dr. Lawler: Yea, I mean...I think there are probably efforts, good efforts, within existing studies that, to make -- you know -- to cast a broad net and maybe have some extra efforts to really enhance diversity in enrollments. They are just not going to capture it here because the primary focus of the grant is not to do that.

So I think, you know, it's hard to attack this. Certainly, there's not any award, except by [Inaudible comment] two that that was the primary focus which would then make it coded in the objective. I really think it's just hard to know without, you know, looking at a number of -- looking to see what their -- you know, the solution -- what the diversity of the population is, whether it's increased, what kind of effort have they undertaken to try to enhance diversity?

Dr. Daniels: So, it's a question we could ask some of the NIH folks if they might have some thoughts about that. People that know their portfolios may be able to let us know if there are some other studies that may have been coded

elsewhere that actually do help meet this objective. So we can try to gather some information before the next call on that.

Dr. Lawler: Okay.

Dr. Daniels: Alright, so then, let's look at the next objective.

"Support at least two studies to determine if there are subpopulations that are more susceptible to environmental exposures, examples given, immune challenges that are related to infections, vaccinations, or underlying immune problems, by 2012." The recommended budget was 8 million over 2 years, and the total spent in this area was 3.6 million.

It should be green. Right? That's an error then.

[Crosstalk]

Dr. Lawler: Green? S.E?

Ms. Redwood: Why would it be green, Susan, just because --

Dr. Daniels: Never mind. I don't know what was going on in my head there. No. It's partial. Sorry.

It's million; it's yellow. It's correct. So that recommended budget was partially met, and

you're okay with that?

Ms. Redwood: I'd like to see more. I mean, the projects -- when you look at the projects that are being funded -- they look great. But it's just that there's not enough. And it's concerning when you look at the trend over time, that the projects, you know, we had more projects looking at that in 2009 and '10 than we do 2011 and 2012.

So it seems like, you know, the amount of funding was a little bit better. The interest is actually higher in the first 2 years or the second and third years versus the fourth and fifth years.

Dr. Daniels: Right. And we have -- NIH had American Recovery and Reinvestment Act funds in 2009 and '10, which may have impacted funding in those 2 years.

Ms. Redwood: Yeah. But I haven't, let me go and see if I could open up the other five projects that --

Dr. Matthew Carey: This is Matt Carey. Sorry I'm late. I had something going on. But do we have numbers on like that -- you've got projected budgets and where we connect. Do we have numbers on projected number of projects?

Dr. Daniels: No. There was no number of -- I

mean, except for what is written in the objective.
If they say "two studies," you have that number.
Is that what you meant?

Dr. Carey: Yeah. So like, this one in which --
this one is an example, then, right? So, "support
at least two studies" --

Dr. Daniels: Right.

Dr. Carey: Right and we've got 33.

Dr. Daniels: Right. So --

Dr. Carey: Okay.

[Pause]

Dr. Daniels: So, in this case, so, "support at
least two studies." So we've got 33 studies. Are
you feeling like these are addressing the issues
that are described in the objective?

[Pause]

In 2012, it looks like you have projects on
autoimmunity, infectious origins of autism,
susceptibility to environmental toxicants, immune
and physiologic response in children.

Ms. Redwood: Susan, are there any that you see
that are related to vaccinations?

Dr. Daniels: I'm not in front of the computer
to be able to open anything.

Dr. Lawler: So there's one -- let me see. I

don't know what year it is. "Vaccination with regression study" is the title.

Dr. Daniels: What year was that?

Dr. Lawler: Hold on. Let me -

[Pause]

I think that was --

Dr. Daniels: 2009?

Dr. Lawler: Yeah, 2009.

Dr. Daniels: Okay.

Dr. Carey: Robert Davis study, Kaiser
Permanente?

Dr. Lawler: Right. That's the one that jumped
out, from the title.

Dr. Daniels: Okay.

Dr. Carey: Yeah.

[Inaudible comment]

Dr. Lawler: I don't about this "evaluation of
the immune and physiologic response" -- yeah, now,
this is another one there at UC Davis, from Judy
Van de Water.

Dr. Daniels: Okay.

Dr. Lawler: Yeah. And there may be more, Lyn.
I just -- I'm not that familiar with most of them
listed, so -- and I'd have to go in and dig into -
they were directly relevant to the vaccination,

you know, component of this objective.

Dr. Daniels: So then, do you agree that in terms of the number that was recommended, the number of projects was met or exceeded? There are several projects but the recommended budget was not fully met.

Dr. Lawler: Right.

Dr. Daniels: That you feel that further work is needed in this area? Were there any particular gaps? I guess, infections, vaccinations, and autoimmune problems were all covered in those projects. I mean, not saying that the topics are fully covered, but they were at least -- there were some projects that are on those topics.

Dr. Lawler: Yeah, I'm not sure where the basis is for that original budget estimate. It's probably -- many of these made use of existing cohorts and so were less costly than they may have, if you had, you know, developed a study from scratch. So I mean that -- the cost difference may reflect that, that people are being more efficient and they're asking these kinds of questions in the context of an existing study.

So I don't really see that as a gap. But that's what we -- you know, we didn't use the cost

objectives.

Dr. Daniels: Okay.

Dr. Lawler: Because I think there was a good number of studies are, you know, looking at this question.

Dr. Daniels: It does look like the individuals who are making that recommendation for the budget might have been thinking about two de novo studies that were of large two-for-one dollar studies.

Dr. Lawler: Right.

Dr. Daniels: And instead, these might have been supplements on an existing study.

Dr. Lawler: Yeah.

[Inaudible comments]

Dr. Lawler: I mean there's efficiency in doing that. We want, you know, investigators to do that to the extent possible. So I wouldn't consider that a gap, just an explanation for why the amount of funds expended is lower than the cost -- initial cost estimates.

Dr. Daniels: So do you feel then progress is being made on this objective?

Dr. Lawler: Yeah.

Dr. Daniels: Though there's more work to be done?

Dr. Lawler: Yes.

Dr. Daniels: Okay. So then, let's move on to the next one: "Initiate studies on at least 10 environmental factors identified in the recommendations from the 2007 IOM report 'Autism and the Environment: Challenges and Opportunities for Research' as potential causes of ASD by 2012."

And this one kind of relates to what Lyn was talking about earlier with the second objective. So the recommended budget was 56 million over 2 years. And the total spent in 5 years was 10 million, 10.7 million, close to 10.8. And there were a number of projects between 2008 and 2009 and then a smaller number of projects in the following years, probably as some projects that were ongoing finished.

So would you agree then that the recommended budget has been partially met?

Dr. Lawler: Yes.

Dr. Carey: Yes.

Dr. Lawler: But then, I mean, [Inaudible comments] I mean, I know there are some cases, for instance, CHARGE, which is ongoing, which must have been coded somewhere else.

Dr. Daniels: Yes.

Dr. Lawler: But still, the fact that, you know, we're going in the wrong direction with this objective. Because this is where you might capture pilot studies or somebody, you know, looking at a candidate exposure that hasn't been examined before. And you know, to go from 19 to 3 and 1, I think is troublesome to me.

Ms. Redwood: Cindy, if you look at the 2009 studies that were funded, the CHARGE studies are actually in there.

Dr. Carey: Yeah.

Ms. Redwood: There are two of them.

Dr. Lawler: Were these just funded then again? They've been funded continuously.

Dr. Daniels: And so it might be that new objectives arose over time and that those projects ended up being coded elsewhere?

Dr. Lawler: Right. Yes.

Dr. Daniels: And so in that case then, if that is the case, then the objective might not be fully reflecting?

Dr. Lawler: Right. But that's -- still, that's only one study, Susan. So I wouldn't feel any better if 2012 had two projects rather than one. I think that looking at the risk in 2008, it just

seemed like there was a lot, you know, more of the diversity of exposures that were being examined.

Or, you know, just more -- bit larger number. And those are -- you know, those are -- that hasn't been sustained. But I think --

Ms. Redwood: I think we're going in the wrong direction in this one.

Dr. Lawler: Yeah.

Dr. Daniels: By the way, in 2011, just so that you know, when it says \$0 and 3 projects, that those might be 3 projects that were in a no-cost extension or something along those lines. That would be sort of --

Dr. Lawler: Yes. Right.

[Background noise]

Dr. Lawler: The CHARGE may have been in a no-cost extension, that year. They are refunded. But it's possible.

Dr. Daniels: Do you have any sense of why there might have been a lot of projects earlier on and why there are fewer now?

Dr. Carey: I mean, naively, right, I mean, you've got 10 identified factors right away. I mean, in some ways you expect there to be larger.

I mean, I would not expect it to drop off this

dramatically. You got a well -defined - here is 10 identified factors. That's very clear to people to latch onto and start projects on.

And hopefully, the projects would be good enough that, over time, we would cover this and move on to other environmental factors, Alright? I mean, to me. But I don't know if that's exactly why, you know. That I see as a possibility. But I don't see coming from 19 down to 1, explaining that.

Ms. Redwood: The other thing, Matt, is there's 19 projects in 2008 were actually baseline --

Dr. Daniels: Yes.

Ms. Redwood: before the Strategic Plan was developed. Does that make sense? So those were already existing projects prior to the implementation of the Strategic Plan or the Strategic Plan even being approved.

Dr. Lawler: And it looks like the CDC projects were listed under the plan in 2008. And I think those are still ongoing. But they must have switched to be coded somewhere else.

Dr. Daniels: Cindy, can you tell, what are they? CADDRE or SEED or --

Dr. Lawler: They're CADDRE. Well, I guess

[Inaudible comment] morphed into SEED kind of renamed. But --

Dr. Daniels: Yeah.

Dr. Lawler: Those were, according to the Network, they -- you know, there are five of them. So they show up as like five studies. Really, it's one big network. But --

Dr. Daniels: So these projects are still in the Portfolio Analysis, but they may have been coded elsewhere?

Dr. Lawler: Right. So there's some of that.

Dr. Daniels: And that's certainly -- that was one of those caveats I mentioned at the beginning, because in 2008 and 2009, there were fewer objectives. And so, as we grew the number of objectives, in some cases the projects got distributed across a greater number. And so it can give a false sense of a decrease, when there might not have been a decrease.

Dr. Lawler: But again, this is a dramatic drop-off. So, I mean, I think the number of contributing factors -- but I'm still -- sort of concerned, and would like to have it noted that, you know, this is -- you know, this is one that maybe [Inaudible comment].

Dr. Daniels: Okay.

Dr. Lawler: And the new emphasis.

Dr. Daniels: Okay. So then, we can -- okay.

Alright, I wonder, too, also, with the first few years if any of those might have been kind of more pilot-type studies that went out, and then they weren't replaced by larger studies.

But in any case, it sounds like you all sense that more emphasis is needed in this area to maintain or grow the intensity in the area.

Dr. Lawler: Yeah. That would be my -- I'd be comfortable with that language.

Dr. Daniels: Okay.

Dr. Carey: Well, looking back at the first year, right, I mean, you're asking what kind of projects -- there are six different ones that are Center for Autism and Developmental Disabilities Research and Epidemiology. I mean is that what you're thinking of with -- Susan?

Dr. Daniels: Yes. So those are projects that have continued. And those are coded somewhere else, I'm imagining, if they're not in this objective anymore. Like I said, I don't have the data in front of me because I'm somewhere where I can make this call.

Dr. Carey: Right.

Dr. Daniels: So in any case, we can check to see where some of those projects went, but I believe they are somewhere else.

But you're saying overall, you do feel that there's a need to maintain or increase the intensity of research in this area?

Ms. Redwood: Yes.

Dr. Carey: Yes.

Dr. Lawler: Yeah.

Dr. Daniels: Okay. Let's move on to the next one, then: "Convene a workshop that explores the usefulness of bioinformatics approaches to identify environmental risks for ASD by 2011."

And this one is a more discrete and distinct objective that can be met by holding the workshop in question. And that workshop was held in 2011. And Cindy was involved with that.

Dr. Lawler: Yes.

Dr. Daniels: In this case, you know, a workshop is a workshop, so the budget might not be so meaningful. But the budget was met. The recommended budget was met.

And how do you feel about that workshop? I think, Lyn, you were also there for that workshop?

Maybe or maybe not?

Ms. Redwood: This is the one that was at NIEHS?

Dr. Daniels: Oh, maybe. Yeah, I don't remember. It was down at NIEHS, but there were two workshops at around the same time.

Ms. Redwood: I don't think I was at this one.

Dr. Daniels: So, in any case, Cindy, do you feel that the workshop met the recommendation here, the objective?

Dr. Lawler: Yeah.

[Pause]

Dr. Daniels: So are there any other thoughts from any of you about this objective and so forth?

Dr. Carey: This is the most straightforward one, I think, on the whole list, so --

Dr. Daniels: Yes. The workshop ones are pretty easy. They either happened or they didn't happen.

Ms. Redwood: I guess it would be interesting to know the outcome. Cindy, was that presented at one of the IACC meetings, a sort of synopsis of the workshop? Or was that when the Committee was sort of disbanded and then, you know --

[Inaudible comment]

Dr. Lawler: We did produce a report. I can

share that with you.

Ms. Redwood: That would be great. Yeah, send it around. That would be helpful.

Dr. Daniels: I think this one, since it was late 2011, and then the Committee had to go through the reauthorization process again and we had that kind of slow period where we weren't having very many meetings, that we may have mentioned this in a phone meeting in passing, but we didn't have an opportunity to have a more major presentation on it.

Dr. Lawler: Right.

Dr. Daniels: But that would be great, Cindy, if you can pass around --

Dr. Lawler: I can share the meeting report.

Dr. Daniels: Okay. I think we might have a link for it on our Web site as well, from our non-IACC meetings and events page.

Ms. Redwood: Was there anything published from that? Was there a publication that resulted or --

Dr. Lawler: No. There is not a publication. We've used the information in different ways. Just as one example, Autism Speaks from NIEHS created this environmental epidemiology of autism risk network that you know meets definitely in the

context of international meeting of autism research every year.

And we would bring -- well, the meeting, you take the different, a number of formats that -- you know, oftentimes, we invite a sort of a speaker to come and give the epidemiologists sort of a presentation about an emerging area of interest, and so we've incorporated -- a speaker that sort of addressed some, you know, sort of new emerging visualization tools from a bioinformatics perspective to -- again, one of the recommendations was outreach and to help educate the epidemiology for the community and use some of these tools and approaches.

So that would be, you know, one example of, you know, something that we've tried to do with those recommendations.

Dr. Daniels: I don't believe that the report is on our Web site. Is that something that will be on the Web at some point, Cindy? Or if you'd like us to put it up on the Website?

Dr. Lawler: We don't -- we're organizing our own Web site now. I'm going to send it to you now, though --

Dr. Daniels: Okay.

Dr. Lawler: -- and so that you can post it to the IACC Web site. And it should, if it's not already on our Web site, you know, it will be.

Dr. Daniels: Alright. Well, if we receive that, we'll post it.

Dr. Lawler: I'm going to send it to you right now.

Dr. Daniels: Thanks.

Okay. Then, let's move on to the next one:

"Support at least three studies of special populations or use existing databases to inform our understanding of environmental risk factors for ASD in pregnancy and the early the postnatal period by 2012. Such studies could include: Comparisons of populations differing in geography, gender, ethnic background, exposure history -- examples, prematurity, maternal infection, nutritional deficiencies, toxins -- and migration patterns; and comparisons of phenotype -- including cytokine profiles -- in children with and without a history of autistic regression, adverse events following immunization, such as fever and seizures, and mitochondrial impairment.

These studies may also include comparisons of phenotype between children with regressive ASD and

their siblings. Emphasis on environmental factors that include prenatal and early postnatal development is particularly of high priority. Epidemiological studies should pay special attention to include racially and ethnically diverse populations."

That one is a mouthful.

[Laughter]

Dr. Daniels: It's one of the longer objectives.

On this one, the recommended budget was 12 million over 5 years, and 10 million has been spent to date, based on the projects that we were able to collect through the Portfolio Analysis. So I believe that we'd probably say that the recommended budget has been partially met.

And how do you feel about the progress on this in terms of projects?

Dr. Carey: Well, you've got 32 projects, and you were expecting 3, right?

Dr. Daniels: Right.

Dr. Carey: I mean, it sounds like we've got -- with a couple of these, we've got kind of a consistent -- lots of projects and a lot more funding than predicted. So --

Ms. Redwood: But that number is sort of a floor, not the ceiling, and I think we were really low-balling with some of the numbers we came up with. I have a question about ICARE. Can someone explain to that me? Because when you look at -- I think this is the 2009 -- no, this is the 2010 portfolio. A majority of these are for this multi-registry analysis, ICARE Israel, Sweden, West Australia, Denmark, Finland, Norway. Does anybody know what ICARE is?

[Laughter]

Dr. Lawler: Well it is -- I think ICARE was funded by Autism Speaks. It's now incorporated and provides a foundation for one of the NIH Autism Centers of Excellence at Mount Sinai. But the idea -- the idea for ICARE is to provide a means to conduct joint analyses, making use of national birth registries that were available in, you know, a number of different countries.

So I think the awards were made to each of the participating investigators in the different countries, so they appear as different awards, you know, each one incrementing the count and the number of projects. But you know, it's really, you know, an infrastructure to support, you know, sort

of joint analyses.

And as I said, it was, you know, it rolled over into this Autism Center of Excellence that's at Mount Sinai. So the ICARE results would have been the seed the idea. And they did some of proof of principal analyses and try to sort of understand how -- you know -- what methods were needed to kind of harmonize the different data elements umm, you know in the different countries.

So, I'm not sure is that what you were --

Ms. Redwood: Yeah. I mean, that helps.

Dr. Lawler: Yeah.

Ms. Redwood: That helps. I wasn't familiar with it. I was just curious exactly what ICARE was working on.

Dr. Daniels: So how well do you think the topics that were described by the Committee are being covered through the projects that have been funded to date?

Dr. Lawler: I think very well.

[Pause]

Dr. Daniels: Are there any particular gaps you see, anything that is on the list here that you feel isn't addressed or any other thoughts about that?

Ms. Redwood: The studies that are funded look good, and, you know, anxious to see just the results.

Dr. Daniels: Okay. So it sounds like then you feel that good progress is being made?

Dr. Lawler: Yeah.

Dr. Daniels: In terms of funding of projects?

[Background noise]

Dr. Daniels: Is somebody talking in the background? I can't hear it well.

Dr. Carey: I'm sorry. There's somebody behind me in my office that --

Dr. Daniels: Oh, that's fine. I just wanted to make sure it wasn't you trying to talk and say something about this.

Dr. Carey: No.

Dr. Daniels: Okay. Any other comments you want to add to that or --

Dr. Carey: Well, I mean, it's 12 million over 5 years, and we're 3 years into it. So I mean, you know, some of the other ones, other topics, I think, are more clear that they're missing, where this one, you know, it's yellow, but I think it might be on track, you know, if things continue, which we've seen does not always happen, right?

Dr. Daniels: Right.

Dr. Carey: Sometimes, there's a number of projects and funding drop-off. But, you know, this one is kind of on -- this one's on track that, after 5 years, would actually possibly exceed funding. But again -- yeah. You know, yeah, I'm repeating myself. We have seen some pretty dramatic falloff from some of the other ones. We don't want to see that happen here. So.

Dr. Daniels: Right. So then you feel that there is good progress being made?

Dr. Carey: Yeah.

Dr. Daniels: But that it needs to be maintained in order to achieve the objective?

Dr. Carey: Yes.

Dr. Lawler: Yeah.

Dr. Daniels: Okay. Let's go to the next one, number 9: "Support at least two studies that examine potential differences in the microbiome of individuals with ASD versus comparison groups by 2012."

And this objective started in 2010. The recommended budget was \$1 million over 2 years. And to date, \$749,000 has been spent in 13 projects, although, again, because these projects

are counted year by year, there could be overlap. So it's not 13 necessarily separate individual projects. There could be some overlaps between them.

And, Matt, when you missed the earlier part of the call, I talked about some of those caveats --

Dr. Carey: Yeah.

Dr. Daniels: -- just because when we were taking the data down year by year, the best way for us to count was just to count everything in that year. And so there are some continuing projects that were counted again in the next year.

But the funding wasn't double-counted because we were doing the funding annually.

[Pause]

So what are your thoughts about this one and how well the projects are addressing the objective?

Dr. Lawler: So, we're on the microbiome one, right?

Dr. Daniels: Yes, we're on microbiome.

Dr. Lawler: So I mean, I think it's, you know a good start. I'm -- you know, I'm drawn to the fact that we really underspent. And my -- I think some of the sequencing that's needed to do this,

is fairly expensive. So it may be what's being funded are kind of small pilot studies or just, you know, looking at particular aspects of the microbiome as opposed to, you know, a more extensive, thorough characterization. So that might be something to, you know, include in sort of, you know, that data gap.

Because six projects, and all of them, you know, 250,000 in total, that suggests that they're really small pilots and they're not, you know, fully exploring or characterizing the microbiome in a sufficient number of projects.

We just had an NRFA. It was not on autism, but it was, you know, funding a number of studies to begin to look at environmental influences on the microbiome. And I know the technology -- the methodology is very expensive. So I -- you know, I'm skeptical as to how much can be accomplished.

To do six projects would be a total of 255,000. You know, we need, I guess, more fully -- you know, to be able to more fully develop projects.

Dr. Carey: Two of these projects are zero dollars. So they must be carryovers from something previous.

Dr. Daniels: Right.

Dr. Carey: So I don't know how much they were funded before. But, yeah, but I mean, they are very small. I mean, you've got \$25,000, \$87,000, \$20,000. I mean, they're very small. Some of these are very small projects.

Dr. Daniels: And Cindy, you might be more familiar, I guess, with NIH's larger efforts on the microbiome. Is there a possibility that any of this might be covered through that? Although I don't know if they're taking ASD samples at all into their study.

Dr. Lawler: Yeah, I'm not sure either if they funded anything in autism.

Dr. Daniels: Because certainly, that would be a pretty large project.

Dr. Lawler: Right.

Dr. Daniels: And might also help launch some new things after that's completed. But I don't know if they were looking at autism at all in that initial part. And maybe on the next call or in the workshop, some of the other folks who have been involved in that might be able to speak to that.

So it sounds like, from what I'm hearing, that you feel that progress is being made in this area,

but it looks like there are a lot of small studies that may be pilots and that further, larger, and more extensive studies would be needed. And one of the barriers may be the cost of the technology.

Dr. Lawler: Um-hmm.

Dr. Daniels: Okay.

Ms. Redwood: And also, either we limited ourselves by saying "microbiome." I know there's some research going on looking at the biome overall, and also, you know, some treatment studies as well that fit into that with PSO. I don't know if those came up on the treatment calls or not.

Dr. Daniels: Oh yeah, there were a couple of - - I think there were a couple of studies that might be related, but they were in the treatment aspect for some of the GI issues.

Ms. Redwood: Right.

Dr. Daniels: So we could check that to see if there's some overlap there that -- where those studies more appropriately fit in the particular objectives about treatment. But there could be some overlap with microbiome issues.

[Pause]

Ms. Redwood: I think it's an exciting area.

I'd love to see the objective expanded.

Dr. Daniels: Okay. The next one is the 10th objective, 3.S.J, which started in 2010: "Support at least three studies that focus on the role of epigenetics in the etiology of ASD, including studies that include assays to measure DNA methylations and histone modifications and those exploring how exposures may act on maternal or paternal genomes via epigenetic mechanisms to alter gene expressions, by 2012."

And we have a recommended budget of 20 million, and so far, 16 million has been spent. That was 20 million over 5 years, and we're 3 years in.

So do you feel the recommended budget is partially met and on track?

Ms. Redwood: Yes.

Dr. Carey: Yes.

Ms. Redwood: We do see progress.

Dr. Carey: Yeah, we've got kind of green lights on all 3 years for this one, right? And you say it's 5 years. As long as things don't drop off, we're there. We're on track, I think, for funding. And again, number of projects is very much exceeding what was projected.

Dr. Daniels: Okay, so --

Ms. Redwood: it's also nice when you see a combination of Federal funding and private funding for some more initiatives, because I have concerns sometimes that the private funding, you know, typically may not be as robust or as longstanding. So it's nice to see a combination here of funding for this.

Dr. Daniels: And it does look like a good number of projects --

Dr. Lawler: Yeah.

Dr. Carey: Yes.

Dr. Daniels: -- looking at various aspects of this. So then, on this one, would you overall say that you feel that the progress is fairly strong, but you'd like to see it maintained?

Dr. Carey: Yes.

Ms. Redwood: Yes.

Dr. Lawler: Yes.

[Pause]

Dr. Daniels: Great. Okay. So then, let's move on to the next one: "Support two studies and a workshop that facilitate the development of vertebrate and invertebrate model systems for the exploration of environmental risks and their

interaction with gender and genetic susceptibilities for ASD by 2012."

This one has also been in existence since 2010, and the recommended budget was \$1.5 million over 3 years, and so far, 1.2 or close to 1.3 has been spent in those 3, the 3 years that this objective has been underway. And the project number is -- you know, it started at five projects in 2010 and three projects in 2011 and '12. How do you feel about this one?

Dr. Carey: Well, if I'm going to -- the funding levels are on a downward trend again. So I mean, we're very close. But, you know, based on where the numbers have dropped off, there's a risk of us not meeting expectations in the next 2 years.

Dr. Lawler: I agree. I think that, you know, there needs to be renewed focus on the --

Dr. Daniels: Well, how do you feel about the contents of the project, based on the titles and information you have in front of you?

Dr. Lawler: I can only see the five from 2010.

Dr. Carey: There's a separate document that has 2012, right?

Dr. Daniels: Yes. The 2011 and '12 are in

attachments that you received.

Dr. Lawler: I'll have to go back and open those. Let me --

Dr. Daniels: Oh, and actually, they're also on our Web site. If you go to the Meetings and Events page, go to this meeting and click on the materials link, you can get to those documents as well if you need to do it by Web.

Ms. Redwood: Is it the studies, or you know, the funding levels are low when you're looking for the ones for like -- what is this? -- 2012 I have open?

Dr. Daniels: Um-hmm.

Ms. Redwood: 30,000, looking at the roles serotonin and social bonding in animals? Another 60,000 by Simons looking at genetic and environmental reactions. So, I think it's concerning that it's starting to drop off. I think we need renewed interest in this area.

Dr. Daniels: Environmental links.

Ms. Redwood: Has there been a workshop? Because it says "two studies and a workshop."

Dr. Daniels: As far as I'm aware, there has not been a workshop. Are you aware of a workshop, Cindy?

Dr. Lawler: I thought there was a workshop. I mean I, Well, I thought there was a workshop.

Dr. Daniels: Okay. If you find out that there was, if you could let us know. I don't think I attended a workshop or that I'm aware of one on this topic, but that doesn't mean that it didn't take place. So.

Ms. Redwood: Okay.

Dr. Daniels: I think I heard about possible plans, but I don't remember it happening.

Dr. Lawler: Okay.

Dr. Daniels: On this one, in terms of gender issues, those might have ended up coded in another objective that's more focused on gender issues. But this one was talking about environmental risks and gender. So there could be some overlap there, as well. So we might want to check that.

[Pause]

Ms. Redwood: And if we could also check to see if there's been a workshop.

Dr. Lawler: Right.

Dr. Daniels: So then, it sounds like you're -- if I'm hearing you correctly -- that you feel that work has started in this area, but you're concerned about a downward trend in the funding.

But we need more information about whether the workshop took place and information about other projects that might have overlapped some other objective, especially in the gender area --

Dr. Lawler: Right.

Dr. Daniels: Because it's possible with the gender objective that some projects that had a component that was environmental may have gotten coded there because they had other aspects that were closer to that objective.

Dr. Lawler: Right.

Dr. Daniels: Okay. Alright, so then, let's move on to the 12th objective, 3.L.A: "Conduct a multisite study of the subsequent pregnancies of 1,000 women with a child with ASD to assess the impact of environmental factors in a period most relevant to the progression of ASD by 2014."

The recommended budget for this was 11 million, and to date, over 5 years, 15 million has been spent. And it's a small number of projects, but do you have comments about this one in terms of the projects? It looks like the recommended budget was met.

Dr. Lawler: Yeah.

Dr. Daniels: Any thoughts about the content

here and how well it's addressing what was in this objective? For 2012, we have the early study.

Dr. Lawler: So, why isn't MARBLES, the MARBLES project showing up here?

Dr. Daniels: I'm guessing it's probably coded somewhere else. I'm not sure where that is, but we can check, because MARBLES would also address this.

Dr. Lawler: Okay.

Dr. Daniels: I'm just guessing it went with one of the other objectives more closely.

Dr. Lawler: Yeah. And it's not a multi-site study.

Dr. Daniels: Oh. So then, that's probably why.

Dr. Lawler: Yeah.

Dr. Daniels: But it also would address part of this question.

Dr. Lawler: You know, the one study that we have is, you know, doesn't have continued funding right now.

Ms. Redwood: Is that the EARLI study, Cindy?

Dr. Lawler: Yes.

Ms. Redwood: That's really discouraging. And that's the largest. I mean, that's really -- isn't that sort of the only one going on right now?

Dr. Lawler: Right. Right. So I mean, that might be a no, I mean, because it's risky. If you can meet the objective in one study, you know, how to mitigate risk with that one, you know, it's not best to continue.

Dr. Daniels: So --

Ms. Redwood: I guess that needs to be reflected in the update.

Dr. Daniels: Um-hmm.

Ms. Redwood: The main, you know, meat and potatoes of this objective is not continuing.

Dr. Lawler: Well, I mean, we don't know. But it's at risk of not - being able to continue.

Ms. Redwood: Is there anything that -- I mean, I'm just thinking if it's something we put in here that might be helpful in, you know, making sure that project will fund some more, continues. I think we should mention it somewhere in our update.

Dr. Daniels: Right. You can refer to that in your update. You can possibly mention that this objective, in terms of conducting a multi-site study, was met through 2012, but the project that was funded is not currently being funded, and there's a concern about continuing the efforts in

this area.

Ms. Redwood: Yes.

Dr. Daniels: Okay.

Dr. Carey: I mean, the study -- the goal itself says "by 2014." And I mean, part of it would be to say, you know, "This should continue."

Dr. Daniels: Okay.

Dr. Carey: Right? I mean, we don't want to close this off. You know, and say by 2014, we got a lot by 2014, there will be enough -- a lot done. But -- yeah. I don't think you need --

Ms. Redwood: But it won't be if there's cross-funding.

Dr. Daniels: Right, right. Okay. So we'll put that in the notes for this.

Let's look at the 13th objective, 3.L.B: "Identify genetic risk factors in at least 50 percent of people with ASD by 2014." And this one had a recommended budget of 33.9 million, and to date, 169 million was devoted to projects that were related to this objective. So we have 5 years of funding and between 59 and 83 projects per year.

Ms. Redwood: I would have to say this one is pretty much been met in terms of funding.

Dr. Daniels: Um-hmm.

Ms. Redwood: I mean, we've gone way, way over what the recommended budget was.

Dr. Daniels: Um-hmm.

Ms. Redwood: And I don't see how we've come close at all of actually meeting the objective, which was to identify genetic risk factors in 50 percent of people with ASD by 2014.

Dr. Lawler: I would agree. I mean, that's a pretty ambitious statement. So we conducted a lot of large studies that have identified a variety of genetic risks that but to be able to say, you know, in any population, you can identify the genetic risks for half of the individuals in that sample, I mean, I don't know if that's the case.

Ms. Redwood: No.

Dr. Lawler: And I would say no, we haven't done that.

Dr. Carey: Well I think, if you look at this goal and the next one, they both -- they would be -- the language is actually very different from every other goal. Every other goal is conduct a study, support a study. This one and the next one are the only two -- maybe there's others, but the two main ones where it actually says, you know,

what will be accomplished. Right? "Determine the effect" in the next one, you know, "identify the risk factors" in this one. There's actually, you know, a hard deliverable. And yeah, it's not -- I don't think in either of these we can really say that those are met.

Sorry to jump ahead. But I mean -- but it's partly in this -- and they were ambitious goals, but I mean, we need ambitious goals. So I think, yeah. A lot of money spent, and yeah, I don't consider that we've met that.

Ms. Redwood: And I don't know that it's feasible to meet. And I guess that's sort of the other question.

Dr. Daniels: So that would be important to note in the write-up for this -- that it's not clear if it's feasible. It's not clear if it's completely measurable either, because every time they find new genetic factors, the percentages of people estimated to be impacted by that are changing. So it's a little bit hard to pinpoint the number and know whether you've gotten to 50 percent.

Dr. Lawler: Then there's still that question of, What is it? You know, are these etiologic? I

mean, if they're really disruptive mutations, you could make a good case that they contribute a lot to risk. That in a lot of other cases, you know, that's been an open question.

Ms. Redwood: Yes. People have the same abnormalities and don't have autism.

Dr. Lawler: Yeah. Is it really causal? So I think we've made really good progress and spent a lot of money. But I don't think that the objective has been met.

Dr. Carey: Yeah. But I mean - if we are going to say risk ---

Ms. Redwood: I think we need to rethink the objective.

Dr. Carey: If we're going to say risk factor, I mean, risk factor doesn't say completely causal, right? I mean, same thing with environmental. If we have a risk factor, it's not going to cause it in everybody. So I don't think that yardstick can really be applied here directly.

But, yeah, I think, you know, have we identified even risk factors in 50 percent? I don't -- I would say we're, you know, far from that.

Dr. Daniels: Do you feel that this is still,

as worded, the kind of goal that the IACC should be striving to support, to find risk factors, genetic risk factors in 50 percent of patients? Or --

Ms. Redwood: See, I think that focusing more on -- at the genetic risk factors would be the way to go because you can actually modify those. And they're treatable. Whereas, you know, typically, genetic risk factors are not. I think focusing on sort of the combination of, what are the triggers, you know, for those risk factors would be important. But you know, personally, I think we're going to get more bang for our buck focusing on epigenetics.

Dr. Carey: I would actually disagree. I mean, I think there are a number of genetic conditions where you can look at, you know treatments that have come through, like Timothy syndrome. There's been a lot of work on Down syndrome over the past couple of decades. It's improved quality of life and lifespan.

You know, I think just true, you know, simple, you know, as simple as it can get, genetic conditions, you know, are treatable. You may not be, you know, able to completely reverse

something. But there are treatments. And understanding those are very important.

[Pause]

Dr. Daniels: Okay. So I guess, in summary, this one, it looks like in terms of a recommended budget, that it was met and exceeded; that there is a healthy number of projects but concerns about whether the goal of identifying genetic risk factors in at least 50 percent of people is feasible or measurable; and while good progress is being made, that the actual goal of identifying risk factors for 50 percent of patients, or individuals, who are affected has not been met as yet. Is that accurate?

Dr. Carey: Yes.

Dr. Lawler: Yeah.

Dr. Daniels: Okay. Thanks. Let's move on, then, to the 14th objective, 3.L.C, which started in 2009, or I guess 2008, and changed designations. The recommended budget was 25 million to date. That was over 7 years. And then to date, over 5 years, 5.3 million has been spent. So this one appears to have partially met the recommended budget.

And then in terms of projects, 5 to 13

projects per year. And how do you feel about the content of the projects related to the objective?

[Pause]

Dr. Daniels: Oh, and I didn't read it:

"Determine the effect of at least five environmental factors on the risk for subtypes of ASD in the prenatal and early postnatal period of development by 2015."

[Pause]

Dr. Carey: Looking at a lot of the -- to me, a lot of the -- project names, it's hard to see how they -- I mean, they're in the area. But you're asking, are they, you know, how specific are they and how on topic? And for a lot of them, it seems more generic than, you know, something really focused on finding the effect of.

I mean, we've got excellent work going on, but there is only a few that seem to be -- at least I'm looking in 2010, just as one example. I mean, I just see, like, environmental epidemiology for autism, maternal risk factors, you know, in the Nurses' Health Study, those kinds of things.

It's hard to dive into those and say, how specific are they to the goal as written?

Dr. Lawler: Well, I think this is another

example of an objective that's really inelegantly written. I think, you know, to determine the effects of is --

Dr. Carey: Yeah.

Dr. Lawler: -- glib. I mean, you can't do that in an epidemiology study. You're looking for associations and maybe speculating with the causal, but effect to suggest that, you know, there's a direct causal connection with.

Dr. Carey: Yeah.

Dr. Lawler: And I also agree that this is another case where most epidemiology studies, if the data are available, are indeed going to look at subgroups, meaningful subgroups, whether that's -- you know -- is there increased risk of, you know, environmental factor X in, you know, this population of, you know, children?

So that is -- those kinds of hypotheses will normally be incorporated in all of the epidemiology studies that are coded to throughout the Strategic Plan questions. There's nothing about these particular studies that would make them better suited. But maybe they would -- you know -- I'm not sure why we put them here as opposed to somewhere else. And I think that gets

to Matt's questions.

Dr. Carey: Yeah. Much better worded than I put it. Thank you.

Dr. Lawler: But I mean, I don't think that's -
- that's not necessarily a problem.

Dr. Carey: No. I mean, they're good studies.

Dr. Lawler: Yeah. But it's just --

Dr. Daniels: So then, Cindy, you're saying that there may be other studies that are coded elsewhere that are relevant to this objective?

Dr. Lawler: Yes, I think, as I said, you would not do an epidemiology study if, you know, you're going to be looking for acceptable subgroups. You know, is the effect different in boys -- affected boys versus girls? You know, in children who had, you know, preterm births versus those that were full term? You're always going to be asking or trying to look at -- the condition to the effect of your exposure on, you know, these other factors.

In other words, you're looking for, you know -
- is the effect, is the exposure the same in different groups?

Dr. Daniels: And this also might have some overlap with 3.L.A?

Dr. Lawler: Yeah, definitely. As I said, I think, you know, all of the epidemiology studies are doing this --

Dr. Daniels: And those are focusing on the prenatal and postnatal period of exposure?

Dr. Lawler: Sure. I mean, all of them are doing that.

Dr. Daniels: Sure.

Ms. Redwood: See, everything that's concerning -- just looking at it on face value -- and we've identified that there are several objectives, is that the number of projects is dwindling, from 13 to 10 to 10 to 5 to 5.

Dr. Carey: Yes.

Ms. Redwood: Several of those other projects are ongoing without any funding, unless they're no-cost extensions, like the Nurses' Study that's being funded by the Department of Defense. So I don't see any new life, you know, into this. And we're pretty -- we're way under budget.

And if these are really reflected in other categories, then, you know, it seems like we -- that's been sort of a trend, though, throughout our call today, that the projects are going down.

[Laughter]

Ms. Redwood: That's what really was reflected in other categories; it seems as though we would have seen those increase. So, like, if you look at the study right below it, you know, we had 29 projects, and 8, and then 12, and 10, and 10. I mean, that's sort of hanging in there. But it seems like, overall, you know, our projects and funding are dwindling.

And I know that we had that infusion of money in 2009. But still --

Dr. Daniels: Right. And when you go down to the very bottom and look at total funding, you can see the total funding and the total projects. And there has been a downward trend in the funding, in this question. Not to say that there can't be an overlap with other questions, because that's also true in some cases.

Ms. Redwood: Right. But even with the overlap, we're seeing a trend that I think is concerning.

Dr. Lawler: No, I agree.

Dr. Daniels: Okay.

Ms. Redwood: And maybe that could be sort of an overall caveat to this whole, you know, Question 3, when we actually go and look at what was the objective for this question? Does anybody

know it off the top of their head?

Dr. Lawler: I'm sorry. Say that again?

Ms. Redwood: You know, each of our questions in the Plan, you have like an overreaching goal.

[Inaudible comment]

Ms. Redwood: Yeah. Hold on. I'll look up and see if I can put my hands on it real quick. All that update.

Dr. Lawler: I mean it may be that some of this reflects -- I mean, you want to have a healthy mix of larger, you know, fully developed studies and, you know, sort of smaller pilot , exploratory that are, you know, exceeding new ideas, to more, you know, well-developed studies.

And it may be that that's the piece that would have gone down that we've lost. And we have, you know, some very nice well-developed good existing studies. But you know, what's the next generation going to be? I mean, you really want the right balance.

And I'm wondering if, you know, that -- the drop-off in terms of the numbers of projects can reflect that.

Ms. Redwood: And that was sort of the -- you know -- the whole purpose of this exercise is to

take a step back and look at, you know, what transpired over the past 5 years, and where do we need to go from here?

Dr. Daniels: Um-hmm.

Dr. Lawler: And I don't know if that's true either. Because, you know, my knowledge, I mean, I have a good handle -- I think on some of the NIH. But a lot of these other funders, as I looked at over the years were, you know, contributing smaller funded projects, whether it was Department of Defense or, you know, CDC or Autism Speaks.

And you know, whether that's maintained or that's flip-flopped, I don't know. It's just a thought.

Dr. Daniels: And with the private funders, I guess you can also keep in mind the overall fiscal climate has been tight over the past few years. And I think that some of the private funders have not had as much funding to be able to distribute.

Dr. Lawler: So because, I mean, I feel really good that we have a number of really strong, solid projects. But I'm concerned if that's all we have. And, you know, we don't have these other smaller ones going in and out that are more innovative and good at addressing more high risk, high gain.

Ms. Redwood: Yeah. Susan, back to what you just said -- and I didn't look at it this closely either, the pie charts that you created that sort of outline, you know, public funding and private funding?

Dr. Daniels: Um-hmm.

Ms. Redwood: Are we seeing the drop-off in the private funding, too?

Dr. Daniels: We did see some drop-off in the private funding in the past. I don't have those numbers right in front of me, but it's information that we do have.

Ms. Redwood: Yeah. Okay. That would be something to --

Dr. Daniels: I think a lot of the private funders did see some decrease over the past few years just because of the economy.

Ms. Redwood: Right. I still have the operational goals if anybody wants to hear it.

Dr. Daniels: Sure.

Ms. Redwood: It says, "Operational goals for the Question 3 is, Causes of ASD will be discovered that inform prognosis and treatments and lead to prevention, preemption of the challenges and disabilities of ASD."

Dr. Daniels: Okay. Thanks for sharing that.
Are you ready to move on to the last objective?

Dr. Lawler: Yeah.

Ms. Redwood: Yeah.

Dr. Daniels: Okay, so 3.L.D: "Support ancillary studies within one or more large-scale, population-based surveillance and epidemiological studies, including U.S. populations, to collect data on environmental factors during preconception, and during prenatal and early postnatal development, as well as genetic data that could be pooled, as needed, to analyze targets for potential gene-environment interactions by 2015."

And this one, the recommended budget was 44.4 million. And to date, the estimate is that 63 million was spent on projects related to this objective. And the range of projects went anywhere from 10 to 29 projects in a given year, with 29 back in 2008 and then a smaller number of projects in the subsequent years. So you would agree that the recommended budget was met?

Dr. Carey: Yes.

Dr. Daniels: Or exceeded. And how do you feel about the projects that were funded here and how

well they relate to the objective?

Dr. Lawler: I mean, I think they're good. Although, if I look at the listing, it's mostly the CADDRE.

Dr. Carey: Yeah.

Dr. Lawler: We get into that. So that's, again, I mean, they're grants to individual sites. But it's just a network. So, you know, we shouldn't feel as good about that as the numbers indicate, you know, compared to if it were really, you know, that many independent studies being conducted.

Dr. Daniels: Okay.

Ms. Redwood: I agree.

Dr. Lawler: Again, this is where there were many that could have been coded under other objectives. So it's hard to sort out, but we'll [Inaudible comment].

Dr. Daniels: And it is possible that there are some of these projects that overlap. I think this question overall had a lot of different objectives. And so, the projects were distributed more because of that.

Dr. Lawler: Right.

[Pause]

Dr. Carey: Cindy, does that sort of speak to the idea that maybe the large multisite things are the way you keep things kind of -- keep funding levels going? I mean, this is a good example of where we've got kind of flat funding. We've been talking about how funding keeps dropping on all these.

But, maybe, you know, yes, it's all going into CADDRE, but it's going to a lot of different people.

Dr. Lawler: Right.

Dr. Carey: And this is an example where it's kind of held its ground, you know, and we'd like to see that and a lot more of these things going up. I don't know if that -- I don't think there's any way we can make that happen, but, build that into the Plan, right? But to me, this is one -- I'd like to see this kind of funding-level trend more consistent across a lot more of the projects we've seen here.

Dr. Lawler: Right. Well, I think CADDRE is definitely a success story in that respect. And, you know, how we make plans to [Inaudible comment] risk for these very valuable, you know, [Inaudible comment] and other kinds of studies to ensure that

they will, of course, continue and that, you know, the initial return on our investment I think is a question the NIH program officials struggle with all the time.

And, you know, CADDRE has been successful at, you know, doing that and, you know, moving forward and securing funding and meeting objectives. You know, would like to see that happen more often. How to weave that into the Strategic Plan, or you know, with that -- the comments -- how do we ensure that we maintain the infrastructure and the prior investments in these large studies, I think is a key question. I would ask that, in declining fiscal environment.

Dr. Daniels: And I think that's something that would be worth touching on in the final write-up for this. So. And it looks like there's a CDC, NIH, and Autism Speaks in 2012 -- are the funders. So there are a number of different funders involved.

Dr. Lawler: Looking at 2010?

Dr. Daniels: That was 2012.

Dr. Lawler: Oh, okay.

Dr. Daniels: The bulk was between CDC and NIH.

Dr. Lawler: Right.

Dr. Daniels: So then, I think you've made it through all the objectives.

In the "Other" category, which we might end up changing the name of that. Some of the other IACC members suggested that since "Other" sounded sort of unimportant, when in fact, these projects that exist outside of the areas that are gaps that the Committee identified are still very important -- suggested that maybe the Committee consider a change to that name.

And I think something like "Core Activities" or something along those lines will be developed at a future IACC meeting for next year. Or actually, we could put it in this year's Portfolio Analysis if the decision is made in time.

If you go to the summary page for this question, which is one of your last attachments, at the very bottom, we tried to give you an idea of what kinds of projects are categorized in "Other." And we had a couple of examples: Signaling pathways in cognition and history of behavioral genetics are a couple of projects.

But really, there was a pretty limited number of projects in there. It was really in the last 2 years, in 2011 and '12; it was only a handful of

projects. So that was just to give you an idea of what was there. And you have the actual project list for 2011 and 2012.

So you've made it through the task that was set before you today. And the next things that we need to do are that OARC is preparing minutes from this call. It will be about two pages that will summarize the discussion that happened on this call.

And we're also preparing a table for you that will list all the objectives and give a very short snapshot of what the conclusions were that this Group made about the progress in terms of funding for each of these objectives. And we're going to give that back to you.

And then within your Group, is there somebody that would like to work on the write-up for this, aspects of this question? So we need something that would be anywhere from one to six pages. And Dr. Insel actually did a draft for Question 4, and his was two pages. I think he was going for the shorter version, and I can share that with you all.

But we're going to need write-ups for this call and for the next call. So is there somebody

that would like to volunteer? And then whoever does the initial draft will pass it around so everyone else can make comments.

[Pause]

Dr. Lawler: Okay. Tell me again? When you say write something up?

Dr. Daniels: So what the write-ups will encompass is just giving a little bit of narrative about what the Group's conclusions were about the funding in the objectives for this question. And so we'll give you -- OARC is going to give you a table with a very brief summary. But it would be fleshing that out in a more narrative format in one to six pages.

And so you could bring up things like, you know, if you find other projects that are elsewhere that you want to mention, you would put that in the write-up.

Dr. Lawler: And when would this be needed?

Dr. Daniels: Within the next few weeks. I haven't set the deadline yet. We're going to get you the materials you need first, and then we'll set a deadline for the write-up.

And it doesn't have to be the same person to do the write-up from this call versus the next

call. It could be different people, or it could be the same person if someone wants to continue with that.

So is there anybody that would like to take a stab at putting that together, based on the materials? And OARC will provide background materials so that you have that to look at.

Dr. Lawler: I can do that for this call.

Dr. Daniels: Okay. Thanks, Cindy. That's great. So we will be getting you the minutes and the summary table. And then we'll let you know. We have some flexibility. Really, we need all of the write-ups to be in closer to final condition after the workshop. And so, you have some time to work on them.

Dr. Lawler: Oh, okay.

Dr. Daniels: Yeah. So you will have a little bit of time. It's not a big rush. But we don't also want you to forget all of the important points that you may have brought up on your call.

And then these write-ups will become part of the Strategic Plan update for the year.

But I will be sending out more instructions in the coming days. And we'll be setting up the next call, and we will have our invited participants on

the next call, hopefully. And we'll be sending out information about the workshop.

And I think that you've all received notification about travel. We're open to book your travel for the workshop. And that workshop will be open to the public on November 15th. And we've posted information on the Web-site for the public so they can find out more about access to the workshop, public comments, and all of those other things that go along with all of our IACC activities.

Are there any other questions or comments that any of you have?

Dr. Carey: No.

Dr. Daniels: You've done a great job.

Ms. Redwood: Susan, can you tell us who all the -- who are the people that are going to be working with us, the outside experts for this question?

Dr. Daniels: I'm going to be sending that you to you via email, hopefully, this afternoon, to give you an update. I know that I provided an update before the Government shut down. But now that we've had to reschedule the workshop, we had to change a number of the people over because some

of them couldn't make it to the new workshop date.

And so I'll be providing that to the whole Committee at the same time. And then as soon as everything is finalized, we will get all that information out.

Ms. Redwood: Okay.

Dr. Daniels: So you should be receiving it soon. We're working on getting the final few answers from people. But I can give you an update before we get all the final answers if it takes longer.

Ms. Redwood: Okay. I am curious to see who we are going to be working with.

Dr. Lawler: Susan, you've done a great job. I know this is a, you know, visual turnaround and a lot of work to prepare the materials. And you're very in the know, easy to follow, and I think it helps a lot. And I want to thank you for your efforts for the rest of the IARCC staff.

Dr. Daniels: Well, thank you.

Ms. Redwood: Yeah, same here.

Dr. Daniels: I think the team appreciates that. And we appreciate your work on this call. You did a great job getting through all of the objectives and doing your assessments. And so we

look forward to sending you the rest of the information and to working with you on the future calls and write-ups.

So well thank you, everyone. And I hope you have a nice afternoon. I'll be in touch.

Ms. Redwood: Thank you.

Dr. Lawler: Susan, one more thing. You haven't scheduled the follow-up call yet, right?

Dr. Daniels: Yes. We have not scheduled it yet. We're going to be sending out a Doodle poll, hopefully, later today or early tomorrow --

Dr. Lawler: Okay. Great.

Dr. Daniels: -- to let you select a date. Alright, well, thanks so much. We'll talk to you soon.

[Chorus of "Good-bye"]

(Whereupon, the Question 3 Planning Group conference call was adjourned.)