U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTERAGENCY AUTISM COORDINATING COMMITTEE

SUBCOMMITTEE FOR
BASIC AND TRANSLATIONAL RESEARCH

STRATEGIC PLAN QUESTION 1 PLANNING GROUP

CONFERENCE CALL

TUESDAY, OCTOBER 29, 2013

The Strategic Plan Question 1 Planning Group convened via conference call at 1:30 p.m., Susan Daniels, *Executive Secretary*, IACC, presiding.

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PROCEEDINGS:

Operator: Welcome, and thank you for standing by. All participants are in a listen-only mode for the duration of today's conference. This call is being recorded. If you have any objections, you may disconnect at this time. I'd now like to turn the call over to Dr. Susan Daniels.

Dr. Susan Daniels: Good afternoon. I'd like to welcome everyone to this call of the IACC Strategic Plan Update Question 1 Planning Group. We'd like to welcome our listening audience as well as members of the IACC who are on this call.

To start off, I'd like to do a brief roll call so everybody knows who's on the phone. The members of our Group are Anshu Batra. Are you here?

Dr. Anshu Batra: Here. Yes, here.

Dr. Daniels: Thanks. Coleen Boyle?

Dr. Coleen Boyle: Hi. I'm here.

Dr. Daniels: Hello. Gerry Dawson is not going to be able to join us today. Alice Kau?

Dr. Alice Kau: Speaking.

Dr. Daniels: Thank you. Shantel Meek?

Ms. Shantel Meek: I'm here.

Dr. Daniels: Thank you for Linda Smith. And John Robison?

Mr. John Robison: Yes, I'm here.

Dr. Daniels: Great. Thank you. So we have almost all of the members in the Group today here on the call.

So I'm going to be walking everyone through the material today. And the goal of our call is for us to by the end of the call have come up with a status for each of the objectives in the Strategic Plan for Question 1 based on the funding information that I'm going to share, the information that OARC has gathered over the past 5 years about what kinds of projects are being funded and how much has been spent on each of these projects. So we're going to be looking at it kind of in more of an overview format, but you do have detailed information in front of you as well.

So I'd like to start by looking at the document that I think was labeled "Cumulative Funding" in your attachments. And for members who are listening on the phone, members of the public, you can access the materials on our Web site.

They're under the materials for this call if you go to the meeting -- Meetings and Events page. So this table summarizes what has happened over the past 5 years in terms of funding. The first page in the document is a list of details that you might need to know, some caveats when you're looking at the data that explain the data. But to preface this, I will let you know that with -- the objectives that have been created here by the Committee, the goal of these objectives or creating these objectives was to address gap areas that the Committee thought were present in the field.

So the Committee had the understanding that there was ongoing work happening at all of the agencies and organizations on autism, but that there were a number of gap areas that were important that the Committee felt needed to be addressed. And so they took those gap areas and created Strategic Plan objectives around them.

And so the funding that's represented within each of these objectives doesn't represent all of the funding totals for the question area because

there was an ongoing body of research or other types of activities ongoing in diagnosis and screening. But these are the particular objectives that the Committee thought were very important over the past 5 years to try to accomplish.

And so with this question, we have one, two, three, four, five, six, seven, eight, nine objectives. So actually that's a relatively short list, so it should be more straightforward to get through all of them on this call.

Dr. Boyle: Susan, can I ask a quick question? This is Coleen.

Dr. Daniels: Yes.

Dr. Boyle: Yeah. So when you said that there is other funding for projects that are ongoing or are not captured by these objectives, would that then be the total in the last row, the "not specific to any objective?"

Dr. Daniels: Yes. Yes.

Dr. Boyle: Okay.

Dr. Daniels: The total, "not specific to any other objective" -- any objective, and also known as "Other." However, on the other calls that we

had prior to the Government shutdown, we had discussions about "Other," and it sounds like there was, I think, consensus among the different groups that "Other" unfortunately might've been a term that didn't really capture the importance of these other projects that are ongoing because all of these projects are in reality important projects that the agencies prioritized and funded or were outside organizations prioritized and funded, and they form a foundation for work on diagnosis and screening. But they are not necessarily relevant to the gap areas that the Committee identified, but calling them "Other," I think, inadvertently cause people to think maybe these are less important projects.

And so I think the Committee may be looking at this more carefully later and coming up with a different name. We may end up calling it “base funding” or something along those lines that describes more the character of this group of projects as being mainstream foundational funding versus the particular targeted objective that the Committee identified. So I hope that helps clarify

that.

So we have -- our Office has gone through and over the past 5 years has collected data on each of these objectives. And we -- what we've done is we've gone out to all of the agencies and outside funders that the Committee and OARC identified that they wanted to receive information from and collected detailed information about all of the ongoing projects and what their funding level was.

And so, there has been some difference over the years in terms of which agencies and organizations were included based on the Committee becoming aware of other funders that they wanted to make sure got included, or some Government agencies in certain years had projects and then in other years didn't have projects. And so the representation changes a little bit over time, but I think that it still gives you a pretty good idea of what has been happening among a pretty large proportion of these agencies.

2008 should be considered a baseline, and it's looking at the projects that were funded in 2008, and our Strategic Plan came online in 2009. So the

2008 funding really was there to be a baseline to give you an idea of what was happening in those gap areas before the Plan really came into action. So I'd like to go through these with you. Do you have any questions in just taking your first glance at this table? Is there anything that seems confusing or that you'd like me to explain?

[Pause]

Dr. Daniels: I can tell you that the blue font and the red font in the text on the side includes the changes that have happened over the years. So each of these objectives has also changed over the years, not every single one, but many of them have. And that also has impacted what goes into various objectives when coding the projects according to the objectives.

And something else you should keep in mind is that there has been an expansion of the number of objectives over time. And so you may have a situation where in one year you had a larger bolus of funding identified for one of the objectives, but then in the following year more objectives were added, and now some of that funding was

allocated to other categories and so some of those types of changes aren't actual drops in funding. It's really just recoding, but that's because the Committee further clarified and broke down some of the categories.

So I'd like to go through each of the objectives and have you look at the funding levels. So there was an IACC-recommended budget for each of these objectives, and the recommended budget was a part of what Congress mentioned in the law needed to be done. We were told that the IACC had to provide a recommended budget for each objective.

And the purpose of this budget was to give the agencies an idea of how much it might cost to accomplish each of these objectives and also a guideline in case Congress had wanted to provide an appropriation especially for those objectives. But it wasn't directed to the agencies that they must fund the projects with this particular amount of funding. It was more of a guideline, but it did give a sense of how much it might cost. And in some cases, perhaps some of the objectives were

accomplished with less than the recommended budget, and others may have had more of the budget allocated to them.

One other point I should make is that these objectives were developed as a guidance to agencies on priority areas that may need more attention. But the agencies for the most part didn't necessarily take these objectives wholesale and create specific initiatives around them. There are a few cases, for example, with ARRA funding, American Recovery and Reinvestment Act Funding, that NIH received in 2009 and 2010; they actually did look at some of these objectives and specifically created initiatives that would partially address some of these objectives. But most of the agencies really are collecting or they were funding based on investigator-initiated applications. So, but this guidance did provide some information about priorities.

Mr. Robison: Susan?

Dr. Daniels: Yes?

Mr. Robison: How come -- how come we have zero results for conducting studies to understand the

impact of early diagnosis on intervention choice? Is that something that's underway where we have nothing to report yet, or have we truly just done nothing to address that question?

Dr. Daniels: So I can skip ahead to that particular objective. So as we go down, so this is "Conduct at least two studies to identify or to understand the impact of early diagnosis on choice of intervention and outcomes by 2015." And you'll see that OARC was able to identify zero projects and zero dollars that were allocated to projects addressing this question.

And so this means that none of the investigator-initiated projects or specifically targeted initiatives addressed this particular objective. And so far, there hasn't necessarily been progress on this objective in terms of funding, unless it was some type of funding that isn't captured through this analysis.

Mr. Robison: Do you have a sense of why that is? That appears to be the only area of Question 1 where there is a zero response from any of the funders.

Dr. Daniels: Yes. And so that's a question for discussion among the people in this Group to try to figure out where are the barriers, maybe why there hasn't been more attention given to this area, whether it's a matter of the science not being ready, whether there are specific barriers that might make it difficult to work on this area, et cetera.

Does anyone on the call have any thoughts about that?

Dr. Kau: Well, I can speculate. This is Alice. This is about outcome, right, the choice of intervention and outcome --

Dr. Daniels: Yes.

Dr. Kau: -- so you need to do a longitudinal study. It will be probably need to be a larger scale, you know, sample to be able to answer this question. So it's, you know, it's not an easy study to conduct. It needs, you know, a lot of resources.

Mr. Robison: Well, don't you -- do you think the six -- we recommend $6 million of funding toward your asset, which is a significant

resource, and I don’t see anything done, though. I mean, I guess that makes me wonder if we have a fundamental difference of opinion between IACC and what we recommended should be studied and the management of the funding agencies. Do they simply disagree with this priority and not want to act on it?

Dr. Daniels: So John, as you -- I think I want to just clarify. You mentioned that the IACC provided a recommended budget, but it's a budget recommendation. It's not actual money.

Mr. Robison: Right, of course.

Dr. Daniels: So the IACC didn't provide any actual money. So if an agency wanted to do this, they would have had to find that money within their own budgets.

Mr. Robison: Right, but the point of that is that we recommended budget levels for other questions which, in many cases, were significantly exceeded. And so when I look at -- you know -- look at this question, I see that we have nothing done at all. And it just makes me wonder is there something -- is there a reason, for example, that

the management at NIH and CDC might, for example, feel this question is either irrelevant or premature or not timely? Is there something that they might know that we don't that would -- that would cause us to rethink the validity of it?

Dr. Daniels: Or have no investigators come forward wanting to do this type of a study at this point in time?

Dr. Kau: Or the design, you know -- all proposals need to be reviewed, you know. So maybe -- I don't know. I'm really just speculating.

Dr. Boyle: That's probably an important question, and I do feel there have been some studies. Maybe I'm misinterpreting what this is actually saying here. But you know, the work by Gerry Dawson and colleagues on the, you know, the Denver -- the Early Start. I mean, that sort of is captured in here trying to understand early diagnosis and early treatment on outcome.

But you know, maybe it just -- maybe it wasn't funded during this time period. I mean, there's other -- perhaps other things going on as well that might be in that "Other" category.

Ms. Meek: And I think also maybe clarifying the language of what this is really getting at.

Dr. Boyle: Yeah.

Ms. Meek: I mean, you know, if we clarify it and really narrow down what the specific action is supposed to get at, then we might find studies that have or that might sit under there that weren't counted.

Dr. Daniels: So this is Susan. I want to make another clarification. There is a possibility that there might have been projects that would be relevant to this particular objective that were categorized elsewhere because each project can only be categorized once.

Dr. Boyle: Okay.

Dr. Daniels: So it can only belong to one. And so, for example, the Gerry Dawson study that you mentioned, the Early Start Denver Model, was categorized elsewhere.

Dr. Boyle: Okay. Okay.

Dr. Daniels: So it may have addressed this, and so that might be an explanation that you all would want to look into if you know of some things

that really did look at intervention and outcomes. We could look at Question 4 and see --

Dr. Boyle: Okay.

Dr. Daniels: There possibly could be some studies that addressed it in a way, but were categorized elsewhere.

Mr. Robison: It's really surprising to me that we report no studies of that. I guess it's just hard to believe that with all the different stuff we're funding, we're not funding anything in that question. So maybe as you say, we are addressing the question with things like Gerry's research, and it's categorized elsewhere. Maybe so.

Dr. Daniels: Certainly with Gerry Dawson's study, it is categorized elsewhere.

Mr. Robison: How is hers categorized to -- by way of example?

Dr. Daniels: I'm sure that it's in Question 4 on intervention.

Mr. Robison: Oh, is it? Okay. Yeah.

Dr. Daniels: So this one, because it does talk about intervention here, it's in Question 1. But a lot of the intervention -- almost all of the

intervention studies are in Question 4.

Mr. Robison: So maybe that's why it's not here. Maybe it's not really properly a Question 1 objective. Maybe it's a Question 4 objective.

Dr. Daniels: There is a lot of -- there are areas of overlap between the questions and between the objectives. I'm sure you've noticed that as you looked at the Plan and sample.

Mr. Robison: Yep.

Dr. Daniels: It's one of those things that we unfortunately can't perfectly parse. I think the Committee tried their best to come up with seven distinct categories, but there are a lot of overlaps within projects, projects that might be doing both work on diagnosis and something else or other issues like that that create some overlaps. But since we categorize things once in order to make sure that we're not double-counting funding, those types of issues can arise.

Dr. Kau: Also it could be because in order to assess the impact of early diagnosis, you may need to have also come out with a sample that has not received early diagnosis to address the benefits.

And that's probably hard to do.

Dr. Daniels: And this is something we can talk about in the -- in the next call because you'll have hopefully some external experts who will be able to be on that call with you, plus the other Committee members who will be at the workshop. And so, that's something you can bring up because there may be people in the room who actually know of things that are going on related to this and because of the particular methods that we use in the portfolio analysis, namely not double- and triple-coding things.

Dr. Boyle: Susan, will that next call happen before the 15th workshop?

Dr. Daniels: Yes. So we're working on trying to schedule a series of calls before the 15th.

Dr. Boyle: Okay. Great.

Dr. Daniels: And so hopefully we'll be sending out Doodle polls within the next day or so to try to get those set up.

Dr. Boyle: So you'll be on the call 24/7, huh?

Dr. Daniels: We will be, so it's been a little bit of a challenge --

Dr. Boyle: Yeah.

Dr. Daniels: -- trying to reschedule all of these calls and meetings.

Dr. Boyle: Yeah. Well, you've done a great job.

Dr. Daniels: Oh, well, thank you. Thanks to the team for working on that.

So in any case, I think that all of these ideas sound like things to bring up. We can -- we'll note that, and then we can discuss it on a future call, unless you have other thoughts about this that you want to share?

[Pause]

Dr. Batra: Susan, this is Anshu. I guess the only other thought, and clearly when I was reviewing in preparation for this call, as John mentioned, this was the glaring objective that, you know, showed no funding at all or no studies at all and clearly that -- I'm curious why.

But again, you know, as a pediatrician who sees patients every day, to me this is probably one of the most critical questions right here to help me determine, you know, what intervention do

I need to choose based on the presentation of the child. So I think -- again, I think as we -- as we discuss gaps and, you know, as we move -- discussion for how we move forward, I think, you know, we really do have to look at this particular objective to see how we can help either rephrase it or, you know, make sure that it's highlighted.

Mr. Robison: I would have really a question for OARC here, if you shouldn't revisit the data and compare the studies that are in Question 4 to this Question 1 sub-objective. And if it's really true that we have not funded any studies to address that question, I would think that because it is going to take a long time to answer the question, and as we already said on this call, we would need a large sample of children in order to include a statistically significant population who got late diagnosis among our undiagnosed subjects going in. We need a big sample, and it's going to have to run for a number of years to look at outcomes.

I would be concerned that it might be some -- a place where we really drop the ball, not getting

it rolling a few years ago, because it's not going to provide very quick results, but it's a vital set of answers to have.

Dr. Daniels: So that's exactly what the Committee is supposed to be doing in terms of evaluating the progress that's being made. If you feel that the progress isn't adequate on some of these objectives, this process in updating the Strategic Plan will be the time for you to bring that forward and to be able to make an assessment of each objective. And so that's exactly what you're going to be doing.

In terms of OARC, the one thing that we can do is we can go to Question 4 and look to see what studies we think might've had overlap with this area, and that should be fairly straightforward for us to do. We wouldn't be changing the data. We've already worked with the agencies in terms of categorizing every project to the best fit. And so unless there's a real error, we wouldn't be changing the coding. But we could make a note of it if --

Mr. Robison: You know, another thing that

concerns me is that it looks like the sub-questions here are only the sub-questions we started Question 1 with some years ago, and last year we began asking questions about adult diagnosis. I don't see anything in here evaluating the usefulness of adult diagnosis. We don't have any question at all in here about that --

Dr. Daniels: Well, we're only looking at the objective --

Mr. Robison: -- and yet that was a big topic of discussion.

Dr. Daniels: On this call we're only looking at the currently existing objectives. And so that was never --

Mr. Robison: We're not looking at new ones then.

Dr. Daniels: We're not creating anything new on this call. But that's something in the workshop -- particularly if you feel that it's missing in terms of an objective -- you can bring that up at that point. But these are really the currently existing objectives, and the last time new objectives were added to the Plan or revised was

in 2011. And then last year you all did an update that was really just to talk about progress that had been in the past 2 years in terms of research, so you didn't --

Mr. Robison: Yeah. I'd really like to see the questions updated. I think that it's definitely time to actually ask some new questions here.

Dr. Batra: Susan, this is --

Dr. Daniels: So that's something you can bring up at the workshop.

Dr. Batra: Yeah. This is Anshu. If I recall from our last discussion in August when we started this process, that, I think, you know, since it's been 5 years, the focus was really to see -- to really get an accountability report. In 5 years, what has our money gotten us? And you know, that's how this whole -- I think this process sort of evolved to see, all right, you know, we're recommending all this money to be budgeted toward various goals, but then, you know, what has -- what has it gotten us? You know, what projects have been funded, and what have we learned from that?

And I think that's a very critical process that we have to go through to see, you know, if there's any inequity in some areas or, you know, things that are just -- have been already, you know, addressed and we need to, you know, move on and drop those objectives, or, you know, revisit -- again revisit in terms of what should be highlighted in terms of what the needs are for the community, so.

Dr. Daniels: But that's the way the process is going to work. The first step in that process is really assessing what's been there and what progress have we made in terms of the funding and trying to kind of evaluate what we have. And then we're going to go forward to the next steps of thinking about what do we want for the future.

Dr. Batra: Susan, this is Anshu. So in terms of what do we want for the future, is that going to be discussed at the workshop, or is that something --

Dr. Daniels: That'll be the subject of the workshop.

Dr. Batra: Okay. Alright, so that's not

something we're going to talk about today.

Dr. Daniels: No. So my goal is to get you through all nine of these objectives on today's call, so I want to -- and this is the biggest part actually where we're going through each of the objectives and looking at the funding.

Something else that you have at your fingertips -- I didn't tell you about all of the materials -- but you actually have full project listings for Question 1 for 2011 and 2012 in your packets. They're kind of long. But if you had any questions about the details of exactly what projects are assigned to each of these objectives, you have that information in those packets.

You also have links available through the Web tool for the older information from 2008 through 2010. The reason I gave you attachments for 2011 and 2012 is that information has not been activated yet in the Web tool, so that will -- that will come out at a later date. We're still working on getting all of that loaded into the Web tool.

But you have very detailed information. You

can see exact projects, the PIs, the funding, all of that information there if you have a question about what's in any of these objectives or -- in each -- in any given year.

So if it's okay, I'd like to go back up to the top of the page and just go systematically through the objectives and get your feeling on how the work has progressed in each of these areas in terms of the funding. We're not going to be talking about actual research outcomes or community outcomes or anything like that on this call today. That will be the topic of a future call.

So the first objective that's on the list is, "Develop with existing tools at least one efficient diagnostic instrument, i.e., briefer, less time intensive that is valid in diverse populations for use in large-scale studies by 2011." And the red, yellow, and green highlights indicate on an annualized basis how close we came to the IACC-recommended budget. And so if we were at or over the recommended budget in terms of an annualized figure, it's in green, and if we were

somewhat below, then -- within a range -- we were in yellow, and if there was no funding or no projects, it's in red.

So in this one, you can see that in 2009 and 2010, there was, you know, within the annualized figure, we were within the recommended budget and a little bit below that on the other years. And in total, in the last column there you see the total funding that has been spent to date on that particular objective. And we put it in green because it met or exceeded the recommended budget.

So in terms of this objective, how do you feel about how the funding has gone for this and the kinds of projects that are -- that have been funded so far? Do you think that this objective has been covered in terms of what types of projects were launched in the past 5 years?

Dr. Boyle: Susan, this is Coleen. Maybe I'll take the first stab at that. I looked quickly over lunch the 11 and 12 hard copy portfolio analysis that you gave us.

Dr. Daniels: Yes.

Dr. Boyle: And obviously it's -- and I was

just doing sort of a quick perusal of all nine objectives and the projects that were funded. It's very, very variable in terms of -- and I didn't read the abstracts, which obviously you would have to do if you're doing a real portfolio analysis.

But, yeah, some of the projects I think hit the mark in terms of the objective. Others of them are somewhat tangential. And this one probably, based on just the 11 and 12, was a bit more scattered in terms of the actual projects that were funded. Now I didn't go back to 8, 9, and 10, so there may be some much more robust projects that really did directly address this objective. But I'm assuming that's sort of the gestalt that we're supposed to be doing in terms of assessing this?

Dr. Daniels: Yes.

Dr. Boyle: Yeah. So again, I think it would take a little bit of work, but I, you know, just, again, just spent a half hour just looking at the projects trying to line them up, seeing whether or not, you know, the project actually was addressing that, and that we would hopefully in a few years

have one efficient diagnostic instrument based on the body of work that's going on.

Dr. Daniels: Did you feel that there were any gaps in terms of what the Committee was intending here?

Dr. Boyle: Oh, yeah, and I just -- I don't feel like I spent enough time on it to be able to evaluate that.

Dr. Daniels: Does anyone else have an opinion on that?

Mr. Robison: Yes. I think that we have a large gap in all of these questions, and that is that we are really reporting on the effectiveness of translating the answers in these questions into benefit for the population. So for example, we fund research into the development of diagnostic tools, and we think that we have achieved some successes with that, but we do not really have much progress down the path to deployment.

And I think that our public looks at our reporting and says, “How is this going to benefit me?” And unless we answer deployment for every one of these questions, we aren't really delivering

any value to the community. It's not to say that what we've done is without value, but I think when we stop just at the reporting of the basic science, we don't -- we don't accomplish the public's objective.

Dr. Daniels: So John -- so this is Susan -- what you're bringing up sounds like a next step past where the objective kind of ends. So --

Mr. Robison: You know, I agree it sounds like a next step, and I agree that now that we've got the answer, we've got to figure out what to do with it. But I believe that we will be sort of called on the carpet by the public immediately if we don't have that answer in our Plan. I feel like that's going to be an expected part of a plan to be complete.

Dr. Daniels: So what we need to do here is decide whether this objective has been largely accomplished the way the Committee intended it and whether this is now going to be something that we would potentially move off the front burner in terms of being a gap area, the specific items that are called for in the objective itself as it's

written, not additional things we're adding on. Or if you still think that this is really not where it needs to be, and if it's not where it needs to be, what needs to be done in addition? What else needs to be funded here?

Ms. Meek: This is Shantel.

Dr. Batra: This is Anshu.

Dr. Boyle: Oh, sorry.

Dr. Batra: I'm sorry.

Ms. Meek: It's all right. Go ahead.

Dr. Batra: Susan, this is Anshu. I absolutely think that this is, again, a very critical objective that we still need to do to dedicate our efforts toward in terms of, you know, early identification, early diagnosis. There is no -- there is no single diagnostic instrument that I can pull out of my bag of tricks when I'm seeing, you know, a 9-month-old, 12-month-old, 18-month-old that will definitively tell me and help me guide families in terms of a diagnosis and treatment. And so, I think, you know, to answer your question, this is still an objective that needs to be addressed.

And as a practitioner, I think that instead of us focusing a lot of our efforts on new diagnostic tools, I think, you know, we need to be looking at what we already have existing and see how we can then use those tools to capture the features within the ASD population.

And we have some fantastic developmental tools at our fingertips that we as pediatricians use and we have been trained to use to identify delays in development and that have been standardized and validated. And, you know, so I think in terms of -- you know, it's still a gap. It's still -- it's a need. And I think, you know, we have to focus on, you know, on existing tools and seeing how we can utilize them to identify this population.

Mr. Robison: I think Anshu and I are saying much the same thing -- that all of these questions are going to remain gaps until such time as we have deployed the tools to the pediatricians and others in the field. And if that's the case, maybe what we could say is that we have conducted most of the basic research to answer these first questions, and we need to move onto a next step to

now evaluate what is most effective of the things we have developed and how are we going to deploy those things, because until we answer those questions, which I think you could ask of all of these things that we're looking at in the Acrobat file right now, I think that nothing will be accomplished until it's deployed.

And I think actually the first couple of these questions we could treat the same way. I think the next step for us is to evaluate the progress we have made and consider how best to deploy what we have already paid to develop.

Ms. Meek: This is Shantel. I just have one question. So I guess I'm new to the Group, so I'm not exactly sure what the Committee meant by "diverse populations" because I don't see at least in the '11 or '12 -- the 2011 or 2012 project descriptions. And, granted, I didn't take a deep dive into any of these, but did it mean socioeconomic status diversity, language diversity, you know, dual language learners? And if so, how much has the basic research really looked at these, you know, diverse populations,

and do we have tools that are valid and reliable in the language learners or in different languages? So yes, that would be my question.

Dr. Daniels: So that, I think, Shantel -- this is Susan -- I think you've identified a key part of this objective. The Committee did intend it to be in diverse populations such as what you mentioned. And so if you are not seeing that in the projects that are here, that would be an area where, in spite of the number of projects that have been funded, if none of them are looking at diverse populations that would be an area that has not been fulfilled. But you would need to look through the full list of projects.

Ms. Meek: Yes, absolutely.

Dr. Daniels: Sure. So I think that with the Group, in terms of the recommended budget over the past 5 years, $14 million has been spent in this area, and $5.3 million was recommended. I assume that the Group would agree that in terms of the recommended budget, that that was met?

Mr. Robison: Yeah, I think the budget was met.

Dr. Daniels: So that's, you know, one of the

measures that you can check off. And then it sounds like the Group has identified diverse populations as one area that might be a remaining gap and that though basic research has occurred in this area, that further steps to actually develop the efficient diagnostic instruments needs to happen -- and including deployment, getting all the way to that level. And so that's -- those are the next steps of where this area needs to go. Is that -- am I accurately capturing what you have --

Dr. Batra: Yes. Susan, this is Anshu. Yeah, I guess I would want to make sure that we -- and that we have -- that we have not adequately looked at existing tools as potentials for being used to identify the ASD population.

Dr. Daniels: Did you feel that any of the projects that are there are using existing tools or that --

Dr. Batra: None, none whatsoever. There's no -- no one has looked at the ASQ. No one has looked at the PEDs. No one has looked at the Peabody. No one has looked at any --

Ms. Meek: So general developmental screens,

right? Okay.

Dr. Batra: Yes, general developmental screens.

[Pause]

Dr. Boyle: And this is Coleen. I guess some of the projects, too. I mean, having been around for the development of this question, I was really trying to get at a diagnostic instrument and not a screening instrument. So a number of the projects that are listed here are really for screening instruments. And the goal was really to have something that from a more definitive diagnosis perspective was briefer, less time intensive, and could be used in diverse populations. So I don't feel like we're on the mark there.

Dr. Batra: Well, Coleen, I mean, I think that's a good point. This is Anshu. That, you know, one of the issues that we're facing is that there's really -- you know, autism is such a heterogeneous disorder, and that, you know, I think that, you know, we're really sort of shooting at a moving target here. You know, yes, there's a consensus -- an overall, general consensus, yeah, features in language, features in

behavior, you know, et cetera, et cetera. But if you really look at these kids around the spectrum for ASD, you know, that's the problem, that there is so much heterogeneity.

And so we can't target -- you know, we can't develop a tool until we're -- until we really have a better feel for what those -- what those subtypes are, what those phenotypes are within the spectrum.

Dr. Daniels: Okay. So I think that we've looked at this pretty thoroughly. Let's look at the next one. We want to try to get through all of them. "Validate and improve the sensitivity and specificity of new or existing screening and diagnostic tools, including comparative studies of general developmental screening versus autism-specific screening tools in both high-risk and population-based samples, including those from resource-poor international settings and those that are diverse in terms of age, socioeconomic status, race, ethnicity, gender, characteristics of ASD, and general level of functioning, by 2012."

In terms of this one, $5.4 million was recommended over 3 years. In total, $10.7 million was spent. And you see a listing of the projects or the numbers of projects in the table, and you have a listing of projects in front of you. How do you feel the funded projects relate to this objective, and how much of this was accomplished in terms of funding?

[Pause]

Maybe first we could cover -- that the Group would agree that this matter exceeded the recommended budget?

Dr. Batra: Yes.

Mr. Robison: Yeah, I would agree. Yeah.

Dr. Daniels: Okay. So that's one point. What are your other observations or thoughts about this?

Dr. Kau: More development. For example, the M-CHAT revised and with follow-up is -- has, you know, provided additional validation data. But it has not been -- for example, has not met all the criteria listed in the goal. For example, "has not been tried in high-risk population." So you know,

it's partially completed based on, you know, this one instrument that I know well.

Dr. Daniels: Yes. And we probably can expect that there's not likely to be one single project that's going to cover all of this. There might be, but most likely most of these projects cover pieces of this.

Dr. Kau: Right. So I would say there is progress, but, you know, there's still work to be done.

[Pause]

Dr. Batra: This is Anshu. I would agree.

Dr. Daniels: Do you have anything specific about what kinds of things might need to be done that aren't represented in the sample that you have here?

Dr. Kau: Really, again I'm, you know, talking -- making reference to M-CHAT specifically because I know this instrument well. You know, screening in the PI, you know, catchment area, like, you know, University of Connecticut or Georgia State is very different from a population-based screening. So this -- the way this Strategic Plan

objective is written -- has a very high bar. You know, even national children studies, you know, might have to wait that long to get us data. I know we don't have any population-based samples using any of the screening instruments.

Dr. Boyle: Yeah. So actually being able to really evaluate the sensitivity and specificity of the measure would require that.

Dr. Kau: Right. And -- but then -- but then the study needs to start from a smaller area so it's more like extending it and as more -- the more research we do, the more data we accumulate. And we're not there yet, yeah, but, so.

Dr. Daniels: Any other thoughts?

Ms. Meek: This is Shantel, and I say this again with the caveat that I need to do a deeper dive into this. But the one piece that seems to be missing that was brought up in the previous question that's more detailed we've outlined here is the comparative studies of general developmental screeners with autism-specific screening tools. And I don't know if that's been covered.

I think this group of projects and studies does seem to get at the diversity a little bit more than the previous group of studies. But this question of comparative studies with general developmental screens, such as those that have been mentioned -- ASQ and others -- versus autism-specific screens seems to be lacking.

Dr. Boyle: Also --

Dr. Batra: And I -- I'm sorry.

Dr. Boyle: Go ahead.

Dr. Batra: This is Anshu. I think that that has to be really highlighted, that we really, you know, need to be looking at the general developmental screeners as a way to help identify ASD sensors. And I'll just have to say again that very often the verbal and the behavioral traits that very often are in the diagnostic criteria, they're latecomers in development. And I think we're missing a whole category of the early motor signs that very often are in existence and, you know, within the first year of life. And the verbal and behavioral aspects come later.

So I think, again, we have to have -- to not

only look at existing developmental tools, but really look at what we are, you know, looking for in terms of development, developmental --

Ms. Meek: And then also looking at the reach of these because general developmental screens are just more common. Just more people do them in, you know, a number of different settings. And so, if we can use that as, you know, pre-find that there are validity and reliability between the general developmental screen and autism-specific screen. If it's picking up some of our kids with autism, then I think that can have really big implications, so.

Dr. Kau: Right, and vice versa. The autism screen could pick up children with general developmental, you know, disorders --

Ms. Meek: Right.

Dr. Kau: -- and delays our M-CHAT.

Dr. Batra: Yeah, but -- absolutely. And I think -- and that's the whole issue that very often, you know, these developmental screeners, these tools, that, you know, evolve and train to learn about and implement all through medical

school residency and so on, and that we all use it from day zero. And you know, so we pick up these early, early development sort of risk factors. And then autistic features come later.

And so, I think we have to -- we have -- essentially we have -- we have the existence of tools. I think we just have to sort of focus them a little differently to identify the real features of ASD among the development delays that we very often pick up earlier.

Dr. Daniels: Anything else?

Dr. Batra: Susan, I hope that answers your question in terms of how, you know, the next steps or whatever you're asking.

Dr. Daniels: Yes. So I think what I'm hearing here is that the budget was exceeded or met the recommended budget, but that projects might not be meeting all the criteria here because there were many provided that there is a gap in terms of comparison of general developmental screens with other -- with autism-specific screens. And that some of the tools might be missing early signs, especially if they're looking further down

development into the verbal skills area. So there needs to be more of an emphasis on screeners that can pick up early signs. Does that reflect --

Dr. Batra: Right. Yeah, and I would add the motor -- the early motor signs that very often exist in the first year of life and then the verbal and behavioral aspects come later, so.

Dr. Daniels: Okay. So I think that then the overall sense of this one is that though projects have been funded in this area, that there are still these particular items that the Group feels are still lacking. And so there's more work to be done in that area.

Alright, then let's move to the third objective: "Conduct at least three studies to identify reasons for the health disparities in accessing early screening and diagnosis services, including identification of barriers to implementation of and access to screening, diagnosis, referral, and early intervention services among diverse populations as defined by socioeconomic status, race, ethnicity, and gender of the child by 2012."

And so on this one you can see that the recommended budget was $2 million over 2 years, and the total funding over 5 years is less than a million. So that one is -- was given -- a yellow highlight by OARC. And can we -- would we come to a consensus here that some work has clearly happened in terms of funding, but the recommended budget was not met?

Dr. Boyle: Yeah, definitely.

Ms. Meek: Yes.

Dr. Boyle: And also, one of the -- and I don't know if other people are having a problem, but the -- links in some of these don't work, and so it's hard to evaluate what they were really were, like the e-quality measures development by SAMHSA.

Dr. Daniels: Oh, so in terms of looking at 2011 and 2012?

Dr. Boyle: Yeah, yeah. Some of the links work; some of them don't.

Dr. Daniels: So the ones that work are for projects that are ongoing from the previous year because, as I mentioned, the Web tool has not been loaded yet.

Dr. Boyle: I'm sorry. Okay.

Dr. Daniels: And so, anything that's a new project, we haven't made those abstracts and so forth available yet.

Dr. Boyle: Okay. Got it. Got it.

Mr. Robison: I don't feel like we answered this question. I think that more study -- more basic study -- is needed to answer the question. I think if you ask that of any of us right now --

Dr. Daniels: For this one that we're talking about right now?

Mr. Robison: Yes.

Dr. Boyle: Yes.

Mr. Robison: This third one that we're talking about now. I think we just -- we do not know that answer yet.

Dr. Boyle: It looks like there are some small funded studies, but that's about it.

Mr. Robison: And I guess, you know, when I look at the research proposals that we have considered funding and the stuff I've seen looking at NIH and Autism Speaks, I don't recall a lot of people proposing to study this question. And

earlier today when I asked you about the fourth one, why we had zero, you said maybe we didn't get any qualified proposals. I actually think that's the case with Question 3 here. I think there is a great shortage of proposals representing good plans to answer that question.

Is there something IACC can do about that if we just don't get good response from the scientific community with proposals?

Dr. Daniels: I think that will be in the final step of this process in terms of recommendations the Committee has --

Mr. Robison: Okay. Alright.

Dr. Daniels: -- about the next update of the Strategic Plan because the Committee can choose to emphasize certain areas. And so, if this is an area that is in great need and really needs to move forward, the Committee can focus some energy on thinking about how to address it.

So the project number is fairly small here, and it sounds like even among those projects it's really not covering what was intended.

Mr. Robison: My sense is that the projects

that were done did not adequately answer the question.

Dr. Daniels: Okay.

Dr. Kau: Right. There are quite a few articles addressing these areas of need. But in terms of actual studies, there have not been many. But there are other efforts trying to develop other tools to reduce -- to address -- those issues rather than to identify the reasons of health disparities. For example, there are people developing tools to see if we can track those children from the point of screening to the point of referral for services and intervention.

So there is work, you know, kind of in the peripheral, but not directly addressing this objective as it's written.

Mr. Robison: I would agree with you, Alice. There are a lot of -- there are articles that speculate about the reasons for the disparity, but there's no study that gives us actionable information that we could actually use to reduce the disparity.

Dr. Daniels: But I think what Alice is saying

is that there are studies that are actually developing possible solutions or tools?

Mr. Robison: There are? Which ones? Have they finished yet, or are they still in progress?

Dr. Kau: There are people working on that. I can -- you know, I don't know what the status of those applications are.

Mr. Robison: Okay. So they're not complete yet.

Dr. Kau: No. No, definitely.

Mr. Robison: Okay.

Dr. Kau: But there are people thinking about it and wanting to do something about it. That's the --

Mr. Robison: Yeah. Yeah. I think that there's interest in doing something about it. I just feel like it hasn't happened yet.

Dr. Kau: Right.

Dr. Daniels: And in terms of the way this particular objective is worded, "to conduct studies to identify the reasons," maybe some of these types of studies aren't funded the way that -- in a way that -- would be captured here if

it's, for example, like you said, maybe more like review papers that are being written about this where people are speculating versus going after specific data.

Dr. Kau: Right.

Dr. Daniels: So if the intent was here really collecting those data, then there really are very few projects that are doing that. But I think it would be noteworthy to mention that there are projects that are actively trying to develop solutions, although maybe not very many projects.

Mr. Robison: Well, should we go onto Question 6 there?

Dr. Daniels: Yeah.

Mr. Robison: We already kind of did Question 4, right?

Dr. Daniels: Yeah. The fourth one has already been done.

Mr. Robison: Or Question 5 then, I guess, "Conduct one study to determine predictive value."

Dr. Daniels: Yes. So "Conduct at least one study to determine the positive predictive value and clinical utility." Examples given: "Prediction

of co-occurring conditions, family planning of chromosomal microarray genetic testing for detecting genetic diagnoses for ASD in a clinical setting by 2012."

The recommended budget was $9.6 million over 5 years, and in 5 years, $4.1 million was spent. So the Group could probably agree that there was partial -- that the budget was partially met, but not fully?

Mr. Robison: Well, I would agree that the budget is partially met, and if it were up to me, I think I would for the moment drop that question in pursuit of other more pressing objectives. Can we suggest that when we get to our actual meeting on the 15th?

Dr. Daniels: Yes, you can.

Mr. Robison: Yeah, that would be my vote to put that aside because I think we have more pressing -- things of more pressing importance.

Dr. Daniels: So if that's something that the Committee as a whole feels is appropriate, they can recommend that.

Mr. Robison: Does anyone else have a feeling

on that on the call?

Dr. Batra: This is Anshu. I agree with you, John.

Mr. Robison: Okay. So we have two votes for that.

Dr. Kau: I'd like -- you know, this is not an area of science that I track closely. I would like to know, you know, like to be informed of, what we do know, you know, so far, and what we have known so far, are they -- how far in any way is this?

Dr. Daniels: Yes. And so on -- hopefully -- on the next call we might be able to get at that a little bit to get more information about what has happened in the field.

Dr. Kau: Right, because some -- it's a funded, yeah.

Dr. Boyle: Yeah. And I know David Ledbetter has been involved with this -- with this Question in the past. So it would be interesting to hear what the progress has been with his grants.

Mr. Robison: I think that when we look at this Question, I think that every other question that we've asked before on this has been a -- has been

a -- broad question with many implications. This is a very specific question. And I think that if we don't have adequate answers about the deployment of our broad question, I think that renders the specific question like this essentially meaningless. We need to answer the broad question of how we're going to actually deliver value with these results. And this is one very specific thing. We need to be addressing the more general question of how we'll deliver value in Question 1.

[Pause]

I'm sorry to keep returning to that, but I just -- I see that as the criticism of what we're doing. And I feel like we've got to get a better focus on delivering some of this stuff that we've done. Like Anshu said, we've done a lot of research, and none of it has made it to the community, or very little has made it to the community.

Dr. Daniels: So from what I'm hearing so far, does it sound like you all would feel that this -- though there has been some funding dedicated to

this area, there is a small number of projects, even though maybe the full amount of work that was intended by the Committee hasn't happened yet, but this might be a lower priority?

Mr. Robison: I'm satisfied with what was done to date myself, and I would move on. Yes, that's what I would say.

Dr. Batra: I agree. This is Anshu.

Dr. Daniels: Is that how everyone feels or is that --

Dr. Boyle: I think -- I mean, I guess -- this is Coleen. I think we need to have an update from the experts in this area.

Ms. Meek: I would agree with that.

Dr. Daniels: Okay, alright. That's --

Dr. Batra: I guess my concern here, I mean, I think we definitely need an update. My concern is that, you know, the -- very often you have experts who are, you know, basing their updates on their own research. And quite frankly, I feel it's not relevant to the community, and it's not relevant to what -- you know, how is it going to benefit me as a parent of a child with autism? How is it

going to benefit me as a practitioner?
And, yeah, I use microarray testing, absolutely.

But, you know the percentage of positive microarray testing and it being indicative of ASD is slim. But, you know, I tell my parents, I tell my families, send the $2,000 and do it. It's worth it because it's out there, and it might give us an answer. But again --

Dr. Daniels: Okay. So I think that in our -- so we're preparing a set of minutes for you for this call. It'll be a couple of pages that will summarize what we've discussed as well as a table that will kind of summarize all of this. And so, we'll put it in there that you want an update from the experts on this, but that you're questioning whether this is still a relevant question to be pursuing.

So the next one is a fairly straightforward one in terms of the budget. Well, let's go through it first: "Convene a workshop to examine the ethical, legal, and social implications of ASD research by 2011. The workshop should define possible approaches for conducting future studies

of ethical, legal, and social implications of ASD research, taking into consideration how these types of issues have been approached in related medical conditions."

And a workshop of this type was funded in 2011. Alice Kau was the chair at the meeting funded by NIH. I also was involved in that meeting. And the total budget for the meeting was $71,000, and the recommended budget was $35,000, but we had a lot of outside speakers join for that meeting.

So the letter of the law on this one in terms of convening a workshop to discuss these topics or this area was accomplished. But --

Mr. Robison: I am -- as one of the people who was part of that workshop -- I would say, was there action taken as a result of the workshop? What came of it?

Dr. Daniels: Alice, do you have any update from NIH about --

Dr. Kau: Well, I think it raised awareness of the policy issues in autism research in every, you know, area. I'm involved in the High Risk Baby

Siblings Consortium, and, you know, the ethical implications of everything we do becomes part of the, you know, what needs to be taken into account, you know. So that has been done, but not ELSI-specific research has been conducted.

Dr. Daniels: I also should bring up that the Autistic Self Advocacy Network also did a workshop on this same topic in December of 2011. And because we haven't collected data from them, we don't have their funding reflected here or their project reflected here. But they actually did fund a separate workshop. John, I don’t know if you attended that one.

Mr. Robison: I didn't attend it, but I read about it.

Dr. Daniels: Yeah, I wasn't able to attend that one, either, and I don't know if anyone else from this Group did. But there was another whole workshop also that addressed similar questions but had different people involved.

So in terms of this, how do you all feel about this, you know, the --

Mr. Robison: I guess if -- I wonder if we

should do something like this again. Should we do another one?

Dr. Daniels: That's a question for the Committee if you want to recommend a follow-on workshop in this area.

Dr. Kau: -- or do you want to focus on specific areas of --

Mr. Robison: I guess I would wonder, Alice, if you said it raised awareness, should we be doing it every year? That would be what I wonder, if that was its purpose, why just one?

Dr. Kau: I think that -- if that is -- well, a couple, you know. And I actually did one, I think, in other places -- done one or two. So if we're going to do another one, maybe we should pick areas of focus to say, I don't know, you know, early diagnosis, you know, or diagnosing adults who --

Mr. Robison: Well, maybe that's right. Maybe we should have an adult diagnosis workshop. I think that holding the workshops -- I'm not in there in NIH with you every day, but I would believe that a workshop like we did would raise

awareness. And I guess since that was the first thing that came to your mind when I asked what came of it, it makes me wonder if we should convene workshops for some of the other questions, like adult diagnosis. Maybe we should be doing a workshop every year to build awareness for these issues around the community.

Ms. Meek: I think if we --

Mr. Robison: It's certainly not a lot of money. It's a trivial thing in our overall budget context.

Ms. Meek: This is Shantel. I would agree with that, and I think if we do, I think there should be a really intentional dissemination strategy for what comes out of the workshops to inform the community more.

Mr. Robison: I'd like to see that, too.

Ms. Meek: Right.

Dr. Kau: I like that, yeah, Shantel. Yes, excellent. Yeah.

Dr. Boyle: Alice, were there actual recommendations in the workshop?

Dr. Kau: It's --

Dr. Daniels: No, there's not --

Dr. Kau: No.

Dr. Daniels: We have a transcript from the workshop, and we have a summary from the workshop. And it did have -- they weren't formal recommendations, but the group talked about essentially their thoughts about what may be directions for the future.

Dr. Boyle: Okay. And I apologize. This may have happened, but was it reported back to the Committee?

Dr. Daniels: I believe so.

Dr. Boyle: Okay.

Dr. Daniels: I think there was --

Dr. Kau: Yeah, it's been a couple of years, yes.

Dr. Daniels: It has been --

Dr. Kau: We can revisit some of the recommendations or, you know --

Dr. Boyle: Yeah. I think that -- I mean that would definitely be worthwhile, some kind of ongoing process to, you know, understand, you know, what it is that we're trying to change and

what are the implications of it, what are the recommendations, and how do we follow through on those.

Dr. Kau: Right.

Ms. Meek: And then tailoring the dissemination strategy to each sector, so like short policy briefs of the different agencies that are involved in autism funding. Maybe something geared toward practitioners or interventionists for that field, some toward academians, for the, you know, scientific community. So I think that would be a good direction.

Dr. Kau: Yes. Yeah, we should do that. I totally support that.

Mr. Robison: Yeah, I agree.

Dr. Daniels: So maybe some sort of an update at a future IACC meeting on this topic to recap the workshop. I think that we did. It's been a couple of years now, and I can't --

Dr. Boyle: Yeah. I apologize. I don't remember either, yeah.

Dr. Daniels: I think we gave an update at an IACC meeting about this, although -- oh, it

happened right before the reauthorization, so actually maybe --

Dr. Boyle: Maybe not, huh? It got lost in the shuffle.

Dr. Daniels: If anything, it might've been something short because we only had phone meetings.

Dr. Boyle: Okay.

Dr. Daniels: It was probably brought up very briefly, but probably not in any great detail.

Dr. Kau: I do have extensive minutes and the notes, so we can --

Dr. Daniels: Yes.

Dr. Kau: -- something about that.

Dr. Daniels: So maybe we can bring -- revive that at a future IACC meeting to talk about that topic. But in terms of the particular objective, would the Group agree that the objective was accomplished --

Dr. Kau: Yes.

Dr. Daniels: -- and it's possibly something --

Mr. Robison: Well, I think the objective was accomplished, yeah.

Dr. Daniels: Okay. So that is one that we can say was accomplished as the Committee intended, but there might be follow-on activities that the Committee might want to consider for the future.

But let's move onto the next one: "Identify behavioral and biological markers that separately or in combination accurately identify before age 2 one or more subtypes of children at risk for developing ASD and evaluate whether these risk markers or profiles can improve early identification through heightened developmental monitoring and screening by 2014."

Mr. Robison: Well, there again I think that we have -- we have made major strides in identifying those markers. But we have not deployed the tests that we have developed so that we really do not know the effect of improved identification, right?

I mean, we have definitely seen papers showing very promising results, but there are no studies of thousands of children to show what it got us. I guess I think that we did --

Dr. Batra: John, this is Anshu, which goes back to that -- to the Objective Number 4.

Mr. Robison: Yeah, it's the same thing that I -- I sort of feel like I keep harping on this. But we did do the research, but we didn't -- but we didn't deploy it.

Dr. Boyle: Well, I mean, and in some ways, John, that's the second part of that question, "Evaluate whether these risk factors or profiles can improve early identification."

Mr. Robison: Right and we don't --

Dr. Boyle: And that's a very complex question there. There's really -- to me there's really two parts to it.

Mr. Robison: Sure, I guess that's right. We --

Dr. Boyle: -- identify those, and the second is to see whether or not they make -- you know, they make a difference in terms of early identification through developmental screening.

Mr. Robison: Yeah. I mean, I guess I would say we identified a lot of factors, but we don't really know the effect of using the identifications. And the other thing I would say is that the work that we did identifying the factors showed us that there are many more factors

that are as yet to be identified. So I feel like even though we recommended a budget, the job is not done. We identified many factors, but there are many more yet to find. Would everyone agree with that?

Dr. Daniels: So just to be clear, it's not risk factors. We're talking about biomarkers.

Mr. Robison: I'm sorry. Yeah, I'm sorry, biomarkers, yes. I think there are many biomarkers yet to be found.

Dr. Daniels: So this is Susan. My understanding is there have been many studies to identify biomarkers, but we don't really have a robust set of valid biomarkers for use yet to deploy. I don't know if some of you --

Mr. Robison: We do have biomarkers --

Ms. Meek: Right. I was about to say that the technology seems to be way ahead of the practice here, at least at a population level.

Mr. Robison: Right.

Ms. Meek: So a lot of these are like eye tracking, or MRIs, or, like, different -- you know, using different tools that general

populations don't really have access to or --

Mr. Robison: Right. And we haven't really tested those things. I mean, we see the -- we see papers that say that MRI has been effective, different kinds of MRI, genetic studies, blood tests have been effective, the eye tracking, as you say. But --

Ms. Meek: But translation.

Mr. Robison: Yeah. We have that study we talked about last year, the children who were fixated on geometric mobiles instead of faces turning out to have autism. We have many things like that that showed markers, and we haven't done anything to test them with a larger group to see what it's done. That's at least my perception of it.

Dr. Daniels: Alice or Coleen, you might --

Dr. Boyle: I was going to -- yeah, I was just going to say, and, Alice, you can, you know, come from your perspective. But I guess I don't feel like those are ready yet for prime time. So I think this is a field that's still evolving.

Dr. Kau: Yeah.

Mr. Robison: I'm not suggesting they're ready for prime time. I'm suggesting they're ready for broader evaluation.

Dr. Kau: Right, right. More work needs to be done.

Ms. Meek: Yeah.

Dr. Kau: You know, it's obviously not there yet; otherwise, we wouldn't be here arguing.

Ms. Meek: Right.

Dr. Kau: I'm comforted by the fact that a group of very dedicated investigators, who are, you know, interested in it and are conducting research in this area, so it takes time. For example, a lot of work in this -- in an area -- is done with baby siblings who already had one older sibling with autism.

Mr. Robison: Yes.

Dr. Kau: So you find all the differences in all the early markers. But whether, you know, we should use this -- all these findings -- to generate another type of screening for them, it's an empirical question. Maybe other -- maybe M-CHAT can do this. I'm just throwing something, you

know.

So there's some empirical work that needs to be done before we can say, you know -- you know, maybe needs to be done or maybe there is work, you know, underway, I don't know. But I definitely think more work can be done. And more research needs to be done before we can apply them in clinical settings.

Dr. Daniels: Right. And so -- this is Susan -- when I heard the word "deployment," that suggested that things are ready to go and used in the population. And I think that my understanding -- I was at a recent meeting about biomarkers -- is that most of these biomarkers are still very much in the early stages. They have not been completely validated yet and are not ready for prime time, and that more need to be identified.

Mr. Robison: That's my sense, too, that they're not ready for prime time. But I guess I do feel like we have fallen down in the area of casting. I feel like people want to do original research, and they publish a paper with a new technique, but we often don't end up funding or

pressing for the follow-up that really makes it valuable.

Dr. Boyle: And I think, John, that's a good point, and I know that's come up in the Committee discussion about, you know, the continued development of research, you know, the whole progression and making sure that we're -- we're continuing down or continuing to follow up on promising leads.

Dr. Kau: Right.

Mr. Robison: Yeah. That really disturbs me because I feel like we end up wasting a lot of our money when we fail to follow up on promising studies. And I think there are many examples of that in biomarkers.

Dr. Boyle: Yeah. And that could be a general recommendation within the context of some of these broader questions.

Mr. Robison: Yep.

Dr. Kau: Right.

Dr. Daniels: This is Susan. On that one, I think that my understanding is that there have been a number of biomarkers that were identified,

but then some that have turned out not to be valid, and so, people have had to go back to the drawing board.

Dr. Boyle: Right.

Dr. Daniels: And so, it's not really a failure to follow through, but a failure of the biomarker.

Dr. Boyle: Okay.

Dr. Daniels: So they're ending up back at the drawing board with those. So it sounds like with this one, though the recommended budget was exceeded -- met and exceeded -- that there's still a lot of work to be done here because we still don't have those biomarkers at hand, valid biomarkers that we know we can use in larger settings. So continued effort needs to be made there. Is that -- does that capture it for you?

Ms. Meek: Agreed, yes.

Mr. Robison: I would agree, yeah.

Dr. Batra: I agree.

Dr. Kau: Agreed.

Dr. Daniels: All right. Let's move onto the next one: "Develop at least five measures of behavioral and/or biological heterogeneity in

children or adults with ASD beyond variation and intellectual disability that clearly relate to ideology and risk, treatment response, and/or outcomes by 2015." This is the eighth --

Dr. Batra: This is Anshu. This is a loaded question. I think about this, and my goodness, this is like a classic continuum, you know? What problems are there, what do we do about it, how do we treat it, and what are the outcomes? You know, it's everything. It's the whole enchilada put in one. Hmm, I don't know what else to say.

And I think it's an important objective. I think it's getting to sort of -- you know, the variations we're seeing in our individuals with ASD. And boy, would I -- you know, I would love -- I would love to have this question, this objective more defined. It would help me be such a better practitioner in helping guide my patients to the right intervention and, hopefully, you know, optimize outcome, so.

Dr. Boyle: Yeah, and maybe, Anshu, thinking this through for next time, we prioritize, you know, response to treatment and outcome over

ideology and risk. I don’t know. I mean, I'm just trying to think of a way to help because it is a very complex question, and maybe breaking those two issues apart, because obviously treatment and response may not relate at all to underlying ideology. I mean, it could, but we're not sure about that.

[Pause]

Dr. Daniels: So on this one, the recommended -- you see a pretty large number of projects, so the area is not lacking in projects. But what else is needed in this area, or what's not being hit in terms of what was intended by the Committee?

Dr. Batra: Susan, this is Anshu. Can you repeat that, please?

Dr. Daniels: I just said that the recommended budget was partially met, so $51 million versus the $71 million that was recommended, and that there's no shortage of projects in 2012. We see 39 projects, so it seems like a healthy number of projects, although some of them might be a little bit smaller.

In terms of the content here, what do you

think is missing, or how do you feel these projects are addressing what's in the question, what's in the objective?

Dr. Batra: Well, in terms of the content of the projects that are being -- that are being funded?

Dr. Daniels: Yes.

Dr. Batra: Okay.

Ms. Meek: I think it's hard for me to pick out the themes of what this is asking with all of the huge variety of projects that are listed.

Dr. Boyle: This is Coleen. And I guess if I had to -- going through the list relatively quickly, what's probably missing based on the titles here, and I think a more detailed analysis is obviously in need – needed -- but really it's to understand sort of the outcome, sort of the response to treatment and outcomes. So I think there are a lot of projects listed that identify perhaps the phenotype and understanding the heterogeneity, but how it relates to response to treatment and outcome probably would be the one area that clearly needs more attention.

Dr. Daniels: Okay.

Dr. Boyle: And I also have to get off the call in 2 minutes, so I just want to let you know.

Dr. Daniels: Okay, thanks.

Dr. Kau: Right. I think a lot of -- most of -- the studies that I -- you know, I just quickly look over the titles, addresses behavioral or biological heterogeneity, but do not really go -- you know, relate to ideology and risk and even treatment response in all outcomes.

Dr. Batra: Yeah. I mean, there's one -- this is Anshu. There's one about outcome measures and anxiety in youth with ASD, but it's very slim in terms of outcomes, and so. And frankly that's what I need, you know. You know, I would love to have some more guidance in this area.

Ms. Meek: I would agree with what everyone said. That bridge seems to be missing again, so it looks like there's been a lot of heterogeneity identified, but, you know, what you do with it or how you use it for risk, how you use it for treatment seems to be the missing piece.

Dr. Batra: This is Anshu. Now, am I reading it

wrong? If someone could help me clarify this. So that last portion, you know, in terms of treatment response and outcome, I mean, is this supposed to be basically what Objective 4 is sort of asking?

Dr. Daniels: Yes. And so, this is another area where there's some overlap because they -- when they were putting together this objective, it does overlap with Question 4.

Dr. Batra: Okay, good.

Dr. Daniels: And so, there could be some things in Question 4 that might relate to that. But this also might relate to the idea of developing the five measures of heterogeneity, that that in itself was a pretty big question 5 years ago, and it looks like research has tried to address that, but maybe hasn't gotten to the point of applying it to all these other things at this point. That's one interpretation.

And maybe, Alice -- I don't know if you have any thoughts about that.

Dr. Kau: Yeah, I would agree with what you said. I think people are just trying to partial -- you know, to hit -- well, to solve the issue of

heterogeneity. So they're focused on diagnosis -- ADHD, anxiety disorder, and autism. And they use, you know, MRI. They try many ways to approach that. But I don't know if that's what this objective is looking for.

[Pause]

Dr. Daniels: So then it sounds like I hear some agreement here that though the recommended budget was partially met and there are a lot of studies of behavioral and/or biological heterogeneity in children or adults -- I'm not sure about the adults -- that the studies really don't necessarily get to the ideology, risk, treatment, response, and outcome areas that were in the objective. Is that right?

Dr. Kau: Right. I think the majority of the projects cited here are faulting what you have just described.

Dr. Daniels: Okay, alright. So then, let's move on to the next one: "Identify and develop measures to assess at least three continuous dimensions." An example, "The social reciprocity, communication disorders, and repetitive restricted

behaviors of ASD symptoms and severity that can be used by practitioners and their families to assess response to intervention for people with ASD across the life span by 2016."

This one, the recommended budget was $18.5 million, and $10.6 million was spent over 5 years. So would you agree that it's been partially met in terms of the budget, but not fully?

Dr. Kau: Right.

Ms. Meek: Yes.

Dr. Daniels: And then what do you think about the work that has gone on here, the projects that are funded versus what is described in the objective?

Dr. Batra: This is Anshu. Looking at the question and what it's asking, you know, again I think that, you know, identifying measures to assess three continuous dimensions, you know, and targeting social communication and repetitive behaviors, I think I would pose that, you know, there are other measures as well that we haven't been looking at, that I think are very often earlier signs.

And you know, and then the second half of that question, which is response to intervention, you know, that again goes back to I think we're gathering all the data, but then there aren't studies that then give us outcome, you know. So we've developed these measures, but then we haven't applied them to see, all right, what's the response? But I think it's been partially met.

Dr. Daniels: Okay. Other thoughts?

[Pause]

Dr. Daniels: In terms of dimensions that are missing, you mentioned motor. Anything else that you feel might be a continuous dimension that was not addressed here?

Dr. Batra: Visual processing.

[Pause]

I saw some studies -- again, I didn't look at it in-depth, but there were some studies looking at some sensory processing modalities. But again, I didn't -- I didn't see --

Ms. Meek: There were questions of identify and develop measures to assess -- to assess at least three continuous dimensions. So is this getting

at, like, valid instruments?

Dr. Batra: Right, exactly. That's what I'm -- I'm still trying to wrap this around my brain in terms of is it -- so this is very similar to the first objective and, you know, in terms of measures, but then in targeting, what are the features?

Ms. Meek: And then a lot of the studies that are under here look more descriptive than, you know, developing tools or developing instruments to measure either social reciprocity or communication or, you know, either of those dimensions. But I'm not sure if that was what was intended with this question.

Dr. Daniels: I think so. So this is Susan. I think that this one wasn't so much getting at developing specific tools --

Ms. Meek: Okay.

Dr. Daniels: -- but developing the measures or trying to identify the appropriate measures. So it's a little bit more basic than some of those that are at the top of the page.

Ms. Meek: So, for example, joint attention as

an indicator of social reciprocity, looking at the first study, for example.

Dr. Daniels: Yes.

Ms. Meek: Okay.

Dr. Daniels: So with this one, are you feeling that it's similar to some of the previous ones we discussed where the basic aspect of the research is underway, but there's more work to be done to get it to the point of being able to be more applied?

Dr. Kau: Yes, absolutely.

Dr. Batra: I would agree with that.

Ms. Meek: I would agree as well.

[Pause]

Dr. Daniels: Okay. So we have successfully gotten through all of the objectives in terms of your assessments. In the “Other” category, you may want to turn to your subcategory five-part for Question 1.

And we developed these subcategories -- that's OARC developed them -- in response to a comment by a Committee member early on in the Strategic Plan process that in the “Other” category, or hopefully

we'll come up with a better name for this group, that it wasn't clear what kinds of projects are in there because they weren't designed by a specific objective.

And so, the following year, OARC actually took the data and developed a set of subcategories to try to break out what's going on in terms of more obvious umbrella terms for some of the types of work that are being funded. And so, if you look through this, we provided subcategory funding for 2010, '11, and '12. So the first year we did it was 2010. And you can see the breakdown of four subcategories of areas within Question 1 that are covered in the total funding.

Dr. Batra: This is Anshu. Can you just refer it back to the one you're referring to?

Dr. Daniels: It's the one -- it should have subcategories in the title, subcategory pie charts.

Dr. Batra: Subcategory pie charts. Okay. The portfolio pie chart, okay.

Dr. Daniels: And I guess I wish I might've instead given you the “Other” category with the

subcategories because we have "Other" broken down to give you an idea of the distribution there, but I didn't provide that one for you. This one is of all of the funding in Question 1, so 2010, '11, and '12.

You can go through each of those, but there are four subcategories. One is diagnostic and screening tools, one is early signs and biomarkers, one is intermediate phenotypes and subgroups, and one is symptomatology. And so, this gives you an idea overall within Question 1 of what is in the portfolio.

And so, the projects in the other category also relate to these objectives, but it's too bad I don't have that particular pie chart to show you. But you can see that it's relatively -- it's not a huge proportion of the funding that was in "Other," so a lot of it was really focused in some of these areas that are gaps, probably just pointing to the great need for development in this area all along since the start of the Plan.

Oh, I guess I do have -- if you go to the summary sheet, which is -- I think it's probably

called "Strategic Plan Summary" or something like that for the title of the document. If you go to the bottom of that sheet, we have a summary of the 2012 Question 1 projects that were categorized as "Other." And some of the themes in there were sensory systems, social robotics, implications of *DSM* changes on the diagnosis of autism, and language and literacy. It's just if you wanted to know what else was in the "Other" category, those are some examples of the kinds of topics that are covered there.

Dr. Batra: This is amazing, Susan. You guys did so much work. I'm in awe. It's very interesting data.

Dr. Daniels: So that is a rundown. You've successfully completed the tasks that you had today. So our Group is going to be putting together a set of minutes and a table that will show basically a reflection of the discussion we had today. And then what I will need is a volunteer who will help do a, you know, something that's between one and six pages would be maximum.

Dr. Insel actually did it for Question 4, and

he did it in two pages, just to summarize the Committee's or the Group's feel on all of this, but we'll provide you with the backup documents so that you --

Mr. Robison: Did I do that last year? What did I do last year on that?

Dr. Daniels: You did, John. Last year you volunteered. You didn't do --

Mr. Robison: Yeah, I'll do that -- I'll do that again if the Committee wants me to do that.

Dr. Daniels: Oh, okay, great. So thanks for volunteering. So we'll provide all of that information to you within the next few days, and then if you could write something, and it doesn’t have to be very long. It can be, like I said, no more than six pages.

Mr. Robison: Okay.

Dr. Daniels: And it could be as short as a couple of pages just to summarize all of this. And I'll also give you the table and the minutes.

Mr. Robison: Okay.

Dr. Daniels: So for the next call, we'll be sending you a Doodle poll to get the next call set

up. I am going to be sending out an update to the whole Committee at the same time about the invited experts who will be joining us. You got the email from Dr. Insel prior to the Government shutdown just describing some of the issues that were surrounding the meeting -- the workshop that we had coming up and needing to reschedule.

And I've been trying to reschedule everything with the invited individuals because some of them couldn't come once we changed the date of the workshop, and so I'll give you all an update on that. And hopefully those folks will be able to join us for the next call and at the workshop. And we also will be starting to work on your travel arrangements, and information about the workshop is posted. It will be a full day's meeting. We will be having public comment at the workshop, and you'll have a packet of written comments, and then as many individuals as can fit into the public comment session -- oral public comment session -- will be able to present their oral comments.

So are there any other questions or --

Mr. Robison: Sounds like we're good.

Dr. Daniels: Yes. I think you all did a fantastic job. Thank you for your hard work on getting through this material. And we'll be sending up follow -- sending out some follow-up materials, and then getting you together for your next call hopefully in a couple of weeks.

Mr. Robison: I'll talk to you all soon.

Ms. Meek: Thank you.

Dr. Batra: Thank you, Susan, and thank you and your staff for the amazing work that you did.

Mr. Robison: Yes, thank you for everything you've done there, yes. Bye bye.

Dr. Batra: Bye, bye.

Dr. Daniels: Thanks. We appreciate that. Thank you so much.

(Whereupon, the Strategic Plan Question 1 Planning Group conference call was adjourned.)