U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTERAGENCY AUTISM COORDINATING COMMITTEE

STRATEGIC PLAN UPDATE

Working Group 4 – Question 4 – Which Treatment and
Interventions Will Help?

Conference Call 1

FRIDAY, SEPTEMBER 23, 2016

4:00p.m.

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Proceedings:

DR. DANIELS: Thank you. This is Dr. Susan Daniels at the National Institute of Mental Health, Office of Autism Research Coordination. I'd like to welcome members of the public who may be listening in and the members of this working group, IACC Strategic Plan Update Working Group for Question 4 - which treatment interventions will help?

I'd also like to remind everyone as we talk on the call please state your name before you say your comment just because it's difficult sometimes on the phone to tell who's speaking. I'd like to take a roll call and as I read each name if each person can briefly introduce yourself with a sentence or two about yourself and what you do related to autism. I'll start with the chair of this group, Kevin Pelphrey.

DR. KEVIN PELPHREY: Sure. This is Kevin Pelphrey. I am the Director of the Autism and Neurodevelopmental Disorders Institute in Washington DC and also a parent of a child with autism.

DR. DANIELS: Thank you Kevin. Jim Ball.

DR. JIM BALL: Hi. This is Jim Ball here from Cranbury, New Jersey. I'm President and CEO of JB Autism Consulting. I work with agencies, districts, schools and families of all individuals with autism spectrum condition from first diagnosis through my oldest individual that I work with is 65 at this point. And I also am the immediate past President of the Autism Society's National Board of Directors.

DR. DANIELS: Thank you Jim. And Jim is a member of the IACC. Samantha Crane…is not in the call right now and of course Kevin Pelfrey is also a member of the IACC. And Geri Dawson is not going to be able to join us today. Tiffany Farchione?

DR. TIFFANY FARCHIONE: Hi. Tiffany Farchione. I'm sorry I have a cold so I'm going to try not to sneeze or cough while I'm talking. But I am the Deputy Director of the Division of Psychiatry Products at FDA so we review any of the products that would come in for an autism or autism-related indication.

DR. DANIELS: Thanks Tiffany. Do we have Melissa Harris on the line? I didn't think so. Elizabeth Kato? Alice Kau?

DR. ALICE KAU: Yes. I'm also an alternate IACC member from NICHD.

DR. DANIELS: Thank you Alice. Louis Reichardt?

DR. LOUIS REICHARDT: Yes. Louis Reichardt. I direct the Simons Autism Initiative.

DR. DANIELS: Thank you. And also a member of the IACC, Rob Ring, may not be with us today. Tim Buie?

DR. TIM BUIE: Hi. I'm Tim Buie. I'm a Pediatric Gastroenterologist and I'm the Director of GI and Nutrition at the Lurie Center for Autism at the Mass General.

DR. DANIELS: Thank you. Connie Kasari?

DR. CONNIE KASARI: Hi. I'm from UCLA. I study interventions for children with autism, particularly minimally verbal children.

DR. DANIELS: Thanks. Christie Kavulic?

DR. CHRISTIE KAVULIC: Hi. This is Christie Kavulic I'm the - in the Office of Special Education Programs within the US Department of Education. And we administer the Individuals with Disabilities Education Act. And I'm on the

research to practice side which administers
discretionary grants.

DR. DANIELS: Thank you. Alex Kolevzon.

DR. ALEX KOLEVZON: Hi. I'm Alex Kolevzon. I'm
a child psychiatrist and a clinical director of
the Sever Autism Center at Mount Sinai New York
and focus on mainly developing new treatments.

DR. DANIELS: Liz Laugeson.

DR. LIZ LAUGESON: Hi. This is Liz Laugeson
from UCLA. I'm the Director of the UCLA Peers
Clinic and my research is in developing testing
and disseminating evidence based social skills and
interventions across the lifespan.

DR. DANIELS: Thank you. Alex Leonessa.

DR. ALEX LEONESSA: Good afternoon. I'm
recently retired Program Director from the
International Science Foundation where I was
supervising the Disability Engineering Program.
I'm currently Professor of the Genotech working in
the area of rehabilitation and robotics.

DR. DANIELS: Thank you. Beth Malow?

DR. BETH MALOW: Yes, Beth Malow. I am a
Neurologist at Vanderbilt. I am the Director of
our Sleep Division and the Director of our Autism
Speaks Autism Treatment Network at Vanderbilt. My
interest is sleep and autism and I also have two
children on the spectrum.

DR. DANIELS: Thank you. Nancy Minshew is not
going to be on the call today.

DR. NANCY MINSHEW: Except that she is.

DR. DANIELS: Oh you are, great that you are.
Well introduce yourself.

DR. MINSHEW: Hi. This is Nancy Minshew. I'm a Child Neurologist at the University of Pittsburgh and Director of the Autism Research program. I focus for a long time on the cognitive and brain bases of autism and in the past say seven or eight years on developing interventions particularly for high functioning adults. I know we hate that word, and adolescence.

DR. DANIELS: Thank you. Sam Odom?

DR. SAM ODOM: Hi. This is Sam Odom. I'm the Director of the Frankfurt Grant Child Development Institute at the University of North Carolina at Chapel Hill and also the principal investigator on the Center for Secondary Education for Students with Autism. And I'm calling it remotely so I'm going to be on mute most of the time.

DR. DANIELS: Thank you. Mustafa Sahin?

DR. MUSTAFA SAHIN: I'm a Child Neurologist at Boston Children's. I run the Transitional Neuroscience Center here and our research focuses on clinical trials and genetic disorders associated with diverse risk autism such as diverse (unintelligible) and Rhett Syndrome.

DR. DANIELS: Thank you. Fred Shic?

DR. FRED SHIC: Sorry I was on mute. Fred Shic. I'm a Computer Scientist by training. We recently moved to the Seattle Children's Research Institute. I do a lot of work using eye tracking and using new technologies like robotics, video games and apps to help kids with autism.

DR. DANIELS: Thank you. Phil Strain?

DR. PHIL STRAIN: Hi. I'm Phil Strain from the University of Colorado, Denver and I do research on comprehensive early intervention for children with autism.

DR. DANIELS: Thanks. Denis Sukhodolsky?

DR. DENIS SUKHODOLSKY: Hi. I'm Denis Sukhodolsky here at the Yale Child Study Center. And my research has to do with behavioral interventions, a lot of work and core - current conditions in autism trying to understand effects of behavioral interventions on biomarkers and brain mechanisms of autism.

Dr. DANIELS: Thank you. And Zach Warren?

DR. ZACH WARREN: I'm Zach Warren. I'm a Clinical Psychologist at Vanderbilt University. I run our Early Detection and Intervention programs and also work with technologies for individuals with ASD.

DR. DANIELS: Well thank you. And I'm Susan Daniels, Director of the Office of Autism Research Coordination which runs the Interagency Autism Coordinating Committee. And I know most of you know this is a federal advisory committee that provides advice to the Secretary of Health and Human Services on issues related to autism.

So we are going to be talking today about the IACC's update to a strategic plan which was initially launched in 2009. And the last time the committee updated the objective of the strategic plan was 2011 and the committee has done annual progress update on the plan. But this year the committee is going to be doing a major refresh of the plan and developing a whole new set of objectives and we want to update all the information in each of the different areas of the strategic plan.

To start this I'd like to turn your attention to the first item that I put in your materials for you which is the document about the structure of the strategic plan. So just to familiarize those of you who might not have been part of some of our working groups in the past the IACC's strategic

plan is framed around seven consumer based functions that the committee felt were important for the community.

Question one "When should I be concerned?" which is about screening and diagnosis, question two "How can I understand what is happening?" which is about the underlying biology of ASD? Question three, "What caused this to happen and can it be prevented?" which is about risk factors for ASD including genetic and environmental risk factors.

Question 4 "Which treatments and interventions will help?" which is about interventions. And this is a topic of our conversation today. Question 5 – "Where can I turn for services?" that is about services and service systems. Question 6 – "What does the future hold particularly for adults?" which is about lifespan issues and especially issues that affect adolescence and adults?

Question 7 is the cross cutting theme question which involves infrastructure and surveillance so "What other infrastructure and surveillance needs must be met?" And this also encompasses issues related to the research workforce collaboration and outreach. So I've provided you with a structure for the strategic plan document that roughly follows the current strategic plan structure. And we are going to be completely revising the document this year. We'll start with an introduction and then there will be a description of each question area and ask the aspirational goal for the question.

And for Question 4 the aspirational goal is "interventions will be developed that are effective for reducing both core and associated symptoms for building adaptive skills and for maximizing quality of life and health for people with ASD". So that was sort of the long range aspirational goal that the committee set to try to

set the tone for the work related to this question.

Today's call is going to focus on the next section which will - that my office will be putting together based on some of the information that we shared today and the comments that you all make about progress towards the current strategic plan objectives. So the current strategic plan has 78 objectives and my office has been collecting data from all the federal funders of autism research as well as many private organizations and putting it together into in a report. And I'm going to be sharing some of the - those data with you and asking you to comment on them.

For each of the seven questions there's going to be a section that provides an overview of progress that's been made in the field. So this will be split into two sections, one that's going to be a research update which will include the latest advances in science and especially ground breaking findings that have changed the field in the last few years, information about where practice should be informing research and information about gaps, opportunities and needs in the research field.

Something that's going to be new this year is that the progress section is going to include a section on, a subsection on services and policies. So the Autism Cares Act of 2014 which was the latest legislation that reauthorized the Interagency Autism Coordinating Committee requires that the new strategic plan incorporate more information about services and supports.

And so in order to do that we thought that the - one of the ways you could do that would be to involve a section that addresses services and policy issues. So in that section there will be information about new programs and policies that might have emerged in the last couple of years, new research evidence that might be able to be

used to inform policy and service needs, gaps and
needed policy changes. And so this will be the
topic of your second conference call. And that
will be the area in which the group is going to be
writing. And so you will be working on a draft
that summarizes what the progress has been in this
area.

        There will also be a section on progress
toward the aspirational goal. A new section of the
strategic plan will ensure a - will include a
recommendation to ensure non-duplication of effort
and so this was another new requirement in the law
in the autism cares act Congress was interested in
seeing the IACC provides some recommendations for
how to ensure that money is used efficiently and
that there's not duplication of effort that's
unnecessary.

        On the next page of the document that I sent
you the next section of the strategic plan of this
update for Question 4 will involve the new
strategic plan objectives. And that's going to be
one of the tasks of this working group to help
develop new objectives to replace the current
objectives for Question 4. So in the past we've
had 78 objectives across the entire strategic plan
and the committee in its most recent meetings have
discussed this and decided that they would like to
have a more focused strategic plan with fewer
objectives to make it easier to understand for the
public and for Congress.

        So we are going to include three raw
objectives for each of these question areas so
that will allow you to move from once we have a
large discussion of about all of the different
issues that you would like to consider in your
write up to try to prioritize some of these and
develop some broad objectives that can guide the
field over the next few years.

        So I provided the office provided a few
examples of the kinds of broad objectives that

could be formulated for say Question 1 to just get some ideas. And with each of these objectives we can list a few examples of the kinds of projects that would be responsive so that it will be clear what types of research are recommended by the committee.

The plan also must require - must include budgetary requirements for each for the plan. And this is something that's required in the law. And the committee will be - the IACC will be considering how to do the budgetary requirements this year whether they will attach budgetary requirements to each of the new objectives or if they will create budgetary requirements for the plan as a whole. So that will be discussed in a future meeting of the committee. And then the document will have a summary or conclusion. Are there any questions about that?

DR. PELPHREY: No. That sounds good.

DR. DANIELS: So you might want to mute your line if you have other people in your office while you're on the call. So the next document that I actually just sent to you all pretty recently within the last hour I also had our team put it up on the Web site so members of the public could access it too. It's a list of topics that may be included in this chapter just to give you a sense of the scope.

And you all are welcome to propose other things that could be added or to change this around. But this was just a starting place for you to give you an idea of the scope.

And in the past we've covered things like behavioral interventions, medical and pharmacological treatments, occupational, physical and sensory-based treatment, treatments for co-occurring conditions, educational and classroom interventions, technology-based interventions and support, supports in the use of robotics,

complementary dietary and alternative treatments, community-based interventions, parents and giver, caregiver mediated intervention, interventions for minimally verbal individuals with autism, social skills learning, motor skills learning, identification and testing of molecular targets for therapeutics, identifying markers and metrics to measure treatment response.

And in services and policy area some examples were provided as updates you could possibly discuss in your update and is certainly not limited to this but you could discuss access to interventions including disparity issues, tele-help, parent in care mediated interventions, community-based intervention models to make interventions more accessible and cost effective, ethics related to research on interventions, some measures, quality of life measures, disseminating information about effective interventions, uptake in the community and any other important policy issues that you can think of that the committee might want to address in this update.

So I just wanted to give you some sense of the scope. Like that was something that came up on some of the other calls of the other working groups. I think we didn't want to spend too much time debating the scope but I think this might give you some ideas and then you as a group are welcome to expand upon it or modify it. So…

DR. PELPHREY: Susan do you want comments now on - I mean obviously we're going to have ongoing commentary on that list but just in terms of the flow do you want to now or what, start now?

DR. DANIELS: You don't have to really make any decisions but if you, you know, have a timely comment we're, you know, we welcome any comments you have to make. If there's something that, you know, strikes you right now that wasn't on the list that would be really great to include?

DR. PELPHREY: Yes…two things quickly. One is
to - everyone knows I'm going to say this but sec
differences and treatment response. And then the
other being creative ways of combining
pharmacology and behavioral interventions.

UNKNOWN SPEAKER: Yes. And I might also add
that it looks to me that some of those categories
are a little bit overlapping. And so for example I
might say that social skills training are also
behavioral interventions. And I wonder it can have
a topic there that not everybody response to
intervention. So that it seems to me that finding
treatments, new treatments that work with children
who not or respond to existing interventions.

DR. DANIELS: Great, yes. And you can
definitely rearrange things, you know, as you wish
when you're doing your actual writing. This was
just to give you an idea of the kinds of things
we're thinking about. But we'll add these items to
the list. Anybody else anything that you thought
of that wasn't on the list?

(No response.)

DR. DANIELS: Okay. I don't think that the
focus on various age groups was on the list but
that might be - that's another thing that's come
up on other calls is especially of course adult
interventions.

DR. SHIC: Is there space for - I'm sorry this
is Fred Shic. Is there space for kind of meta-aims
for instance like accelerating the pace of
research and/or accelerating the pace of
dissemination of information from these treatments
and interventions or is that more of kind of a
surveillance infrastructure type of question,
Question 7?

DR. DANIELS: It depends. It could fit here. If
it's something that's really cross-cutting we can
certainly take note of it and share it with the

Question 7 group and they might be able to add it to theirs. And we've had that come up on other calls too where people talked about something that probably will end up in another area and wanted to share the information across.

DR. SHIC: Is personalized medicine approaches is that subsumed under any of these so far?

DR. DANIELS: I didn't have it specifically called out so why don't we put that on the list.

DR. PELPHREY: And related to that so the stratification by neuro circuitry refinement studies but we might be getting too specific now.

DR. DANIELS: Okay.

DR. PELPHREY: Adaptive designs, sorry.

DR. DANIELS: No problem, sounds good. So we're taking notes and we'll add some of these things onto the list and revise it because we'll come back to the list in the next phone call. So I've also provided you with some packets of information from our portfolio analysis that our office performed using data from 2013. And the purpose of showing you this information is to have you look at what's been funded and to draw some conclusions about the state of the field based on what's been funded and maybe areas were there might be gaps or needs. And so I'm going to walk you through some of those data. We have the 2014 and 15 data but they're not ready for circulation at this point so this set is the one that's ready and so we'll walk through this.

So on the first page of the data analysis slides that I sent you and that are also available on the Web for anybody who's listening in we have a figure that describes federal versus private autism research funding. So how much of the total funding for all of the areas across the strategic plan in research are funded by either federal

sources or private sources? And as we've been measuring this across the years use of the particular funders that we have gathered data from the federal contribution has been approximately 3/4 in the private contribution has been 1/4 but this is also keeping in mind that there are some family foundations and pharma and so forth may not be included in our data set.

So and we've given the dollar amounts on the bottom of that figure. And if anyone has comments as we go along or thoughts we can feel free to, you know, go ahead and interrupt me and discuss those. On the second figure that I've provided this provides the percentage of 2013 funding by each agency or organization that we included in our portfolio analysis. And so you'll see for all of the areas across the strategic plan that NIH was the largest funder at a little bit over half of the funding.

And there were a number of other large and small contributors to research funding including Simons Foundation, Autism Speaks, CDC, Department of Education and many others. And so we provided the specific figures in the tables to the right.

On the third slide this one shows the distribution of the total funding across all of the areas of the strategic plan. And keep in mind this is a compilation of funding from a number of different funders and it wasn't all planned centrally by one great mind but it was done separately. And this is how it looks when we add it all up.

So for Question 4 it's comprised about 18% of the close to 19% of the 2013 funding and about 20% of the projects. And the specifics are on the table below. The next figure shows alignment with the IACC strategic plan objective. And so just as background the IACC when they develop the objectives in the current strategic plan they targeted those objectives that areas they felt

needed more attention or were good opportunities for building the field and so areas that were well established were not necessarily included in those objectives.

So we expect that the research that's funded in the field that all of it will be related to the objectives. Only some of it will be. But we looked at it in 2013 to see how much of the funded research from the funders that we are deriving data from have projects that are specific to the question - questions and objections of the strategic plan and how many of those projects might not be directly related.

And those were designated as core other by the IACC to try to indicate that just because they're not related to an objective about maybe an underserved area doesn't mean that they're not core to the research mission and foundational to work that might be needed.

It may represent ongoing projects or ongoing fields that are well-established, also emerging research that might not have been a particular focus at the time that the research objectives were created. So this gives you a sense that about 3/4 of the projects that we have in our portfolio relate to the strategic plan objectives and about 1/4 are outside that. When you go to the next figure this just breaks it down across the strategic plan questions.

And you can see the for example in Question 2 about half of those projects are not related directly to strategic plan objectives largely because many of those areas were ongoing or have newly emerged. For Question 4 you can see that the majority of the projects were related to strategic plan objectives.

I'm going to skip the next slide because it's sort of repeated in the next packet. And on this last slide in this packet our office decided to

create a sub categorization scheme for the data
because the objectives are quite specific and in
some cases there's a lot of research that doesn't
fall within them. And we wanted to develop a
simpler ontology to be able to tell you what's in
the portfolio. And so and this is something that
the IACC wanted us to do after the first year that
we did this.

        And so we went ahead and created several
different subcategories and we've been tracking
over the years how the projects that we collect
fit into these subcategories. And so the
subcategories we have are behavioral
interventions, complementary, dietary, and
alternative, educational, medical, pharmacologic,
model systems and therapeutic targets.

        And in the past animal model systems have been
a part of this chapter although I think that
confused a lot of the funders. As we did that it
was just a matter of how the plan was written at
the time. And that aspect may be moved back to
Question 2 which is about basic biology.

        Occupational physical and sensory-based
therapies and technology-based interventions and
supports our categories. And so you can look
across this to see the proportion of each of those
in the portfolio both by funding and by the
project count. And so looking across this
information does anyone have comments or
observations about what you see in the funding
portfolio?

        DR. SHIC: This is Fred Shic. I was just
wondering there's a - of course there's a
discrepancy between the funding percentages and
the project count.

        DR. DANIELS: Yes.

        DR. SHIC: So would another figure be - or I
mean it's you - we could actually do the

calculation ourselves but the average amount per funded project tells us something about the, you know, how preliminary or how kind of more of a pilot these projects are.

DR. DANIELS: Yes.

DR. SHIC: And so it tells us about emerging fields versus more well established fields.

DR. DANIELS: That's right. And that was something that in the last strategic plan update was an observation that the committee brought up that in fact that they felt with some of these areas that perhaps there were - that a lot of the projects that were funded were too small to have the power that they needed to accomplish their goals. So that was something that the committee was concerned about before.

DR. ODOM: This is Sam. Could you talk a little more about the model systems therapeutic targets? And you mentioned that they might be moved over to biology?

DR. DANIELS: So the therapeutic targets may stay but so in the past when the committee was developing the strategic plan it happened to be that the Question 4 group was the one that talked about animal models and wanted to create an objective for animal models because they were thinking of about using animal models to test therapeutics.

And so the objective for animal models got added to Question 4 but as we know animal models are used in all kinds of other areas of biology as well. And so it also is an area that would fit under Question 2. And so there's a possibility that we may just move animal models back to Question 2.

DR. ODOM: Do you want advice from the committee about that or…

DR. DANIELS: Yes, definitely.

DR. PELPHREY: Yes, definitely please. Fire away.

DR. ODOM: Oh I wasn't suggesting today although I think it's a good idea. I think that when I looked at the, you know, the scope and the range of the interventions I think it does make the classification and allocation of resources clear if that movement does occur but that's just my opinion.

DR. PELPHREY: Yes, no I this is Kevin. I think I agree with that.

DR. MINSHEW: This is Nancy Minshew. I had two questions. The first is I noticed the projects are says 2013.

DR. DANIELS: Yes?

DR. MINSHEW: And it would seem to me if we were going to do an update that we would want to know what was in the pipeline now, what's been funded since then even though it's not finished. So that was one thought. And the second was I - as I look through the projects it was difficult to tell what exactly was going on and the numbers of participants that were involved.

And so it seemed like some additional information even - I don't even know if an abstract's enough but to be able to look at that. And I think since this is created for the community that having all of this organized by age groups and then by type of interventions or treatments under the age groups might be helpful although I know some things will transcend age groups. And even the studies are sometimes broad in age.

DR. DANIELS: So to answer the question regarding organizing by age group and so forth so once these data are published where our office is going to be publishing them this year they will be entered into our database. And that database is searchable by, you know, multiple parameters. And so I think that would be a way to get at that without reorganizing the entire project because of course all the questions have different, you know, it would make sense to organize each one differently. And so using the search function you can isolate the ones that you're interested in. So that's the way we've kind of gone about that.

With regard to '14 and '15 like I said we have those data but they haven't been compiled and analyzed as yet. And so I don't know what the possibility is that we would be able to provide anything more recent in the near future. So my plan was only to provide the '13 for this update and then the '14 and because we haven't even finished this report yet. But we can if you have particular questions we can look into it and see if there is an information that we could put together quickly enough to be able to share.

DR. MINSHEW: Well the only thought I had was that…I was on the Department of Defense Review Committee and I know their focus is on treatments for now or services for now which makes their payback supposedly a little quicker. And so they did reinstitute their clinical trials award and did make some awards in those areas that would seem to be pertinent. And many – much of what they've done is probably pertinent to the question. So having 14 and 15 funding projects would probably be relevant.

DR. DANIELS: So yes I'm not really sure what we might be able to do about that given the heavy load that we have with running all of this strategic plan update process and just trying to get the report on 13 out the door. But if there is something that we can do we will try to do that.

And with regard to abstracts in the portfolio analysis project list that I sent you the titles are hyperlinked and so you can see descriptions of the projects under there.

But the abstracts are sometimes not super detailed so if you wanted for example to know how many people were involved in trials I don't know that that information is always in the abstract. But with NIH it takes you back to project reporter. And so there is more detailed information but I don't know if that's true for every funder if they have a lot of detailed information in the project description. So we have that but we haven't analyzed at that level. So but we appreciate your comments. Anything else that…

DR. KASARI: This is Connie Kasari. And I'm thinking about if the projects have linked publications so like so we know what was funded, we know what the point of the project was but do we - is there any place where the actual publications from that project are linked?

DR. DANIELS: So with NIH if you clicked on the link for the project title it would take you to Reporter. And Reporter does track some of the publications with the grants. However if the PI didn't put the grant number in their publication it wouldn't have been tracked. And so our office actually tried to do a publications - well we did a publications analysis back in 2010 and tried to link publications with the projects that were in the portfolio analysis.

And we were really limited by the lack of citation of grant numbers. We only found about 1/3 of the projects had a grant number listed and so it just wasn't good enough data to use for anything. We ended up just doing a general analysis of fields instead of linking directly to our strategic plans...

DR. KASARI: Okay.

DR. DANIELS: …tracking. So but it's something that, you know, our office is interested in revisiting that. I've heard from people working in other fields that have tried it more recently that the citation rate has gotten a lot better so it may be something we're able to do in the future but we don't have that right now.

So what we're planning to do on this call we're kind of talking about the landscape of what's been funded. But on the next call we're going to be asking all of you to contribute your thoughts about progress has been made in the field. And so even though it might not be a complete literature review but for you to point out some really key developments in the your respective fields that we can look to as possible guides to new opportunities.

DR. PHIL STRAIN: Susan this is Phil Strain.

DR. DANIELS: Yes?

DR. STRAIN: You've mentioned earlier I think the term that you used is ground breaking findings related to the treatments. And the new language in the law around non- duplication makes me a little nervous. So maybe you can make me less so. It seems like one of the areas that's so vital to invest in is direct and systematic replication of those really significant treatment studies.

And I'm wondering is there any way to know which studies actually do represent attempts to replicate? And is there going to be any issue around the language of non-duplication with attempts to replicate across different subsets of individuals on the spectrum or using different outcome measures, et cetera?

DR. DANIELS: So thanks for that comment. That is something that has come up on some of our other calls in the IACC previous to this, the IACC that

was in session until 2014. They had some extensive discussion about duplication of effort in response to a report that was put out by GAO, the Government Accountability Administration. They were concerned about the fact that in these different questions and objectives that there were multiple agencies working on them simultaneously. And they were concerned that there should be enough coordination between agencies to avoid duplicating efforts.

And so one effort that we hope is helpful to avoiding duplication is that our office is collecting this information and compiling it together so it can be - you can look at it, you know, projects side by side that are working towards various objectives and even in these different subcategories. And agencies can use that as one tool to see what's happening. Although because it's retrospective it's not current to what's being funded now. So that is one tool.

But this issue of replication has come up. It's come up on other calls and it came up with the committee. And they in fact in their response to GAO did mention that replication was very important. And so that's an important consideration and if it's something that this group also agrees with we can try to convey that back to the committee as they come up with their statement that they'll put in the new strategic plan about duplication of effort that we also need to ensure that there's adequate replication. Is there anything else that's really specific that you want to say about that?

DR. STRAIN: No. That's very helpful to hear. Thank you very much.

DR. DANIELS: Sure. Something that I can do is I can share the IACC's response to the GAO report with you. And if there are certain parts that you feel that you either agree with or you have you would like to add on to regarding replication that

might be helpful to the committee so I can send that out to you as a follow-up. So that's jumped us a little bit ahead into the duplication of effort discussion. Does anyone else have anything to add on duplication of effort as long as we're talking about it already?

So the next packet that I want us to turn your attention to is the multi-year funding table. And in this table the most important column is the final total column to the right where we have indicated in color coding green that indicates that the objective was financially completed in terms of the content of the objective that the committee developed and the recommended budget that they had indicated. If it's in yellow that means that the project was only partially completed in terms of the content of what the committee intended and the recommended budgets that they had developed for the objective. If it was in red that meant that there were no projects at all that were assigned to that objective.

So as you can see with Question 4 all of the objectives had some activity. They were either in yellow or green. And we tracked it across the years and we annualized the budgets and did some color coding on individual years. That was really because at the beginning we didn't have a long enough data set to really look at a trend.

And so that's there just to give an indication year by year whether we were approaching - we were on track to be able to meet the objectives. Does anyone have any comments or observations about any of these objectives what you think has happened with those - the fields that were indicated in the objectives or any comments about the funding?

DR. SUKHODOLSKY: Well this might be a very naive question but how is it decided that the one objective there will be five studies and for the other objection there would be 20 studies?

DR. DANIELS: Yes. So that is something that I think the committee did which, you know, a lot of different working groups and committees around NIH and probably other agencies as well try to provide quantifiable measures of success. And so in order to do that when the committee was developing the strategic plan they wanted to put some sort of numbers on things so that we would be able to measure whether they achieved something.

However it is complex too or it's difficult to assess whether achieving a certain number of projects is really achieving the intended, the underlying intent of the objective to make the science go further. So that was something that they did at the time. With the new objectives that you all will be creating where the committee is interested in seeing those be very broad objectives and so likely won't necessarily be very quantitative in nature but more setting kind of larger goals for where you would like to see the field move.

And then we can provide examples of the kinds of projects but you don't necessarily have to specify how many of different kinds of projects you would like to see. So does that answer your question?

DR. SUKHODOLSKY: Yes.

DR. DANIELS: Any other comments about any of these objective areas or questions about what happened with these?

(No response.)

DR. DANIELS: So as you looked through the last packet I gave you was a listing of projects that related to each of these objectives. Do you have any comments about the types of projects under these objectives or any concerns about duplication of effort as you look through the listing of

projects and the listing of funders that were
involved in each of these areas?

DR. SUKHODOLSKY: One thought that occurred to
me is that there are some multi-site studies that
would involve several universities and then each
site would be listed what would have its own
little link. So somebody might look at that and
say, well there are five projects on the same
topic but this is one project that's conducted by
five universities.

DR. DANIELS: Right that's true. So we in some
cases if the project is a multi-site project that
has a single grant number then we just list the
other projects as subprojects of that big project.
But if they each have their own independent grant
number than they're listed separately.

DR. MALOW: Yes this is Beth. I have a couple
of comments. So I was involved in two of the
projects listed and the - well the Loring Project
was actually not a randomized trial. It was a
pilot, the sleep education program. So it
shouldn't be listed as a randomized trial if
that's the goal to have randomized trials.

And then the other which I think the last
speaker was just alluding to, the Jim Perrin, the
AIRP Network actually funded multiple projects. I
know at least one of them was a randomized trial
because I was involved in that but I think there
were others as well.

So, you know, even though you take away the
Loring project I think several of those AIRP
Network projects were randomized trials. So you
might just want to verify that the trials that are
listed here truly were randomized. The Spence
trial was also I don't know if it was completed
due to limited recruitment. So, you know, just
getting more detail on these trials would be
important before you put them out there as
randomized. And also if it's possible to break out

the AIRP that would be good because that would give you more data about exactly how many projects contributed.

DR. DANIELS: Thanks. So in doing the coding for the strategic plan because the objectives that were created originally sometimes were very specific but then the project pool that we had had a lot of projects that might meet sort of part of the objectives but not the complete objectives at first the first go round we had with the coding we tried to stick to the exact language of exactly what it said in the objective and it turned out that a lot of projects really wouldn't fit neatly and the committee felt like it made it hard for them to see the direction of where this research was going. And so they asked us to try for more of a best fit.

And so there may be - it's possible that the reason if there was not a trial there was not a randomized controlled trial that was in 4SD that we may have put it there because it addressed core symptoms, family functioning and community involvement and it was some kind of a trial even if it wasn't randomized so…

DR. MALOW: Okay.

DR. DANIELS: …that might have been a best fit issue but we're certainly happy to follow-up with you and double check all of that to make sure.

DR. MALOW: Yes that makes sense. I just wanted to make sure that if your goal was to really say how many studies were actually controlled trial randomized - randomized control trials that address co-occurring medical conditions that you actually had, you know, like if you fell short that would be important to know going forward, so making sure that you had that accurate.

It kind of went back to the question that somebody asked earlier about like what's pilot and

what isn't? So for example the Loring Study, she
did a great job but it clearly was a pilot. It was
a $20,000 so we couldn't do a randomized trial in
that. And that might be important I'm thinking for
the IACC going forward to know, okay we did hit
this area of let's say comorbidities but we
actually didn't do any randomized trials in this
particular area and we need to do that, you know,
in the next strategic plan. That's all I'm
thinking.

     DR. DANIELS: Yes. And that's something that
you can highlight when you're writing the progress
section if there are particular areas where you
think specific kinds of research are needed that
are lacking you'll be able…

     DR. MALOW: Okay.

     DR. DANIELS: …to pass that out. So take note
of those and keep them handy for when you all are
starting to write. So yes I did explain that whole
best fit…

     DR. MALOW: Right.

Susan Daniel: …idea but we're hoping that in the
next strategic plan is going to be a lot easier to
assign projects to codes because these will be
broader objectives and there will be fewer of them
and hopefully not much overlap between them. In
some cases in the current strategic plan there is
some overlaps between objectives. And we did try
to count every project only once.

     And so we went for where it fit best and
sometimes it meant that we weren't able to count
it in another place when I was still doing some
significant work there. In some cases we made just
notes of that in our reports so that we can say
for example that for this objective there are
projects in another question area that partially
need it.

DR. MALOW: Okay, thanks.

DR. SHIC: This is Fred Shic.

DR. DANIELS: Yes?

DR. SHIC: I was just wondering is there any representation of NSF in this portfolio?

DR. DANIELS: Yes NSF is in this portfolio. So we didn't have any objectives related specifically to NSF work and so I believe NSF might have ended up in the other area for most of it.

DR. SHIC: Okay.

DR. DANIELS: So but we did collect data from NSF and I have a number of projects especially in the area of developing new technologies and some basic research.

DR. SHIC: And is there any type of - this might be outside of scope of this discussion but is there any transition plan for lifting things from NSF and turning them into NIH projects or is that up to investigators to really navigate?

DR. DANIELS: I don't think that there's anything formal set up but if that's something that the working group wants to suggest that's something that you can think about if you think there is a need for that.

DR. SHIC: Yes it just strikes me that there's probably many more projects that are - then - that are listed here that are related to, you know, this treatment Question 4 from NSF.

DR. DANIELS: Okay.

DR. LEONESSA: This is Alex. Actually as I mentioned I just retired from NSF as of two weeks ago. And the list of projects that Susan is talking about actually I provided that list for.

And I went through quite an extensive search on active projects in Autism and technology and robotic, social robotics and other projects for intervention and that's what I was able to find.

I can tell you that just before leaving we had a workshop with NIH with NCMRR in particular about the possibility of using robotics for pediatric debilitation. And autism was about was among the different kind of conditions that we were considering during that workshop. And the focus of the workshop was exactly how to have NSF with NIH collaborate in terms of continuing in particular with the translational component which are of this technology.

DR. SHIC: Very cool. Thank you for the clarification.

DR. DANIELS: Yes and in the current strategic plan the emphasis on technology is very small and so I think that the committee would like to see a bigger emphasis on that because there is a lot of really exciting new research in that area. And in addition in educational research there wasn't that much of an emphasis on it in the previous strategic plan but we know a lot of important work is going on there too and so want to make sure that that's explored and acknowledged in the new strategic plan update.

UNKNOWN MALE SPEAKER: I have a question about the - about funding column and the zero dollars that are listed for some grants and just why those were included if there wasn't funding?

DR. DANIELS: Yes and so there's some funding agencies that provide all the funds for a project say it's a five year project. And they put all of the dollars in the first year and that the project continues in the out years but it's not receiving an increment of funding whereas agencies like NIH given an increment of funding each year. And so if it's listed as zero dollars that means it was

still an active project that had funding but the
funding had been given to it earlier.

UNKNOWN MALE SPEAKER: Okay thanks.

DR. DANIELS: Sure. So I think that we're
reaching the end of our here. Are there any
emerging research areas that you didn't see in the
current project listing that you want us to make
sure that we cover in the next call?

DR. BUIE: This is Tim Buie. Part of the
question that I would raise is probably overlapped
by biology as well. But when you're talking about
therapeutics there is a great interest in biology
microbiome, metabolome and the impact of
intervention such as fecal transplant or treatment
for intestinal overgrowth. That's - I don't know
because we don't see the other group. Is that
topic covered in your biology group as a bench
piece or is that something that should be included
sort of as a separate topic? It's certainly
receiving a good number of funding resources now.

DR. DANIELS: It is included in Question 2 but
I think that the question about treatments for co-
occurring conditions is still an area that
Question 4 should be covering. But I'm happy to
share the information from Question 2 for you. We
can easily get that for you and you can have a
look at it.

DR. BUIE: Okay.

DR. DANIELS: So as we're drawing to the close
of the hour we really appreciate the good
discussion that you've all had. On the next call
we're going to be talking about updates in
research and policy. And I'll be sending you some
detailed materials about that to get you ready for
that call. And after that call we can begin the
writing exercise. And so our fearless leader Kevin
Pelphrey will help map out an outline for that and
then we can get volunteers who will be willing to

help write different sections. So are there any - sorry any questions?

DR. PELPHREY: This is Kevin. I was just going to say thank you Susan. That all sounds great.

DR. DANIELS: Sounds good. Anything else that anyone else wants to say before we adjourn today's call?

DR. SHIC: I just had one real quick, which is that I was just thinking that there does feel like there needs to - it would be ideal if we could have a greater involvement of actual individuals with autism someplace and this or focus on that as a - kind of an incorporation into this particular question. I think it's very relevant for so many adults with autism who can speak to this.

DR. DANIELS: Yes. Why don't we add that to the topic list under services and policy? That is something that's come up before so involvement of individuals on the spectrum in treatment research.

DR. PELPHREY: Yes that's really great. Thanks Fred.

DR. DANIELS: Great. So well thank you so much for being here and we hope that you all have a great weekend and our office will be in touch with more information about the next call. Thank you.

((Crosstalk.))

(Whereupon, the conference call was adjourned.)