U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTERAGENCY AUTISM COORDINATING COMMITTEE

STRATEGIC PLAN UPDATE

WORKING GROUP 4 – QUESTION 4 – WHAT CAUSED

THIS TO HAPPEN AND CAN IT BE PREVENTED?

CONFERENCE CALL 3

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1:00P.M.

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PROCEEDINGS:

DR. SUSAN DANIELS: Hello, good afternoon and welcome to this conference of the IACC strategic plan update working group for Question 4 on the topic of which treatments and interventions will help. This is the third conference call of this working group and the final one. We welcome the members of our listening audience as well as the members of the working group and our chair Kevin Pelphrey.

For those who are listening on the phone, if you would like to access the materials for this call, you can go to the IACC Website and under the meetings tab there's a working group subtab and you will find question (verse) materials there so you can follow along. So on today's call we're going to be talking about the chapter outline that will help guide the working group in writing some text for this chapter as well as talking about proposed strategic plan objectives for Question 4 and so we will be getting into that shortly. I'd like to do a roll call so that people will know who's on the phone so I will start with Kevin Pelphrey.

DR. KEVIN PELPHREY: Kevin here.

DR. DANIELS: Thanks. Jim Ball?

DR. JAMES BALL: Here.

DR. DANIELS: Samantha Crane? Geri Dawson is not going to be able to make the call today and Tiffany Farchione is not going to be able to make the call. Melissa Harris? Elizabeth Kato? Alice Kau? Louis Reichart?

DR. LOUIS REICHART: Present.

DR. DANIELS: Thank you. Rob Ring is not going to be able to make it today and Tim Buie is not

going to be on the call and Connie Kasari is not going to be on the call. Christy Kavulic?

DR. CHRISTY KAVULIC: Here.

DR. DANIELS: Thank you. Alex Kolevzon? Elizabeth Laugeson?

DR. ELIZABETH LAUGESON: I'm here.

DR. DANIELS: Okay. Alex Leonessa I think is not going to be on the call today. Beth Malow?

DR. BETH MALOW: Yes, I'm here for about 20 minutes.

DR. DANIELS: Thank you. Nancy Minshew?

DR. NANCY MINSHEW: Here.

DR. DANIELS: Thanks. Sam Odom?

DR. SAM ODOM: I'm here.

DR. DANIELS: Mustafa Sahin?

DR. MUSTAFA SAHIN: Here.

DR. DANIELS: Fred Shic? May be coming late. Phil Strain?

DR. FRED SHIC: Sorry, this is Fred, I'm here and …

DR. DANIELS: Oh hi, Fred.

DR. FRED SHIC: … I don't know how to use the mute button apparently.

DR. DANIELS: Oh, it's okay. I know it can be tricky on people's various phones. Phil Strain? Maybe joining us late. Dennis Sukhodolsky?

DR. DENNIS SUKHODOLSKY: Here.

DR. DANIELS: And Zach Warren?

DR. ZACHARY WARREN: Hi.

DR. DANIELS: Hi, great, so we have a good number of our working group. I know that it's always difficult to schedule with everybody's schedules but those who are not able to be on the call today of course are welcome to send-in comments in writing and we'll make sure that those get passed along to the group.

((CROSSTALK))

DR. WARREN: I wanted to say that I had a difficult time getting on the call. There was an incorrect number in the first e-mail that went-out so there may be people coming-on.

DR. DANIELS: Yes, and we've sent-out a couple of e-mails correcting it. It's just the prefix to the number, instead of 888 it's supposed to be 877 so if anyone is on listen-only and you are trying to get into the main call, look at your e-mail and it has the correct number. We apologize for that error. So the first item of business that I'd like to talk about with you is the chapter outline that we provided as one of the attachments in your e-mail or for those who are following along online it's on the Website.

This is an outline that just has the various topics you've discussed throughout these calls and you're going to be wanting to write about progress that's been made in each of these fields as well as what the needs are going forward and directions that you want to go in. And so the way we've organized it right now which can be reorganized however you want is first listing off intervention types to make sure that you cover all of those in your chapter including behavioral and social interventions, medical and pharmacological treatments, educational and classroom

interventions, occupational, physical and sensory-based treatments, complementary dietary and alternative treatments, technology- based interventions and supports as well as the use of robotics AAC and innovative combinations of therapeutic modalities.

And so those were various fields that you talked about on your previous calls and we want to make sure that you include those in what you write about in your chapter and we've put-in some notes from your discussions in-between some of those full lists and across all the intervention types or some of them, there were some other notes.

You talked about parent and caregiver mediated interventions, treatments for co-occurring conditions, interventions that focus on minimally-verbal individuals with autism, community-based approaches, treatment across the whole lifespan including children, adults and adolescents and the fact that more intervention research needs to be conducted in low-resource context including the inclusions of many underrepresented groups. And so those were some of the basic foundational aspects that you talked about on your previous calls and I want to stop there and see if anyone sees anything that's missed there before we move-on to the rest of the outline that you want us to add-in to make sure that we include.

DR. MINSHEW: This is Nancy Minshew. I'd probably add-in cognitive with behavioral. You have behavioral and social …

DR. DANIELS: Okay, sure, uh huh, we'll do that.

DR. MINSHEW: … but also cognitive.

DR. DANIELS: Okay. We'll add that in. Anything else on that first part so those were some of the areas that you want to cover. Some of the issues that you discussed on your last calls were in the

next section. We have generally an umbrella for outcome measures, treatment response and personalized medicine.

So you talked about the importance of identifying markers and metrics to measure treatment response, studies that will address behavioral changes, early indicators of treatment response, moderators, the active ingredients of various interventions and objective outcome measures. You also talked about the importance of looking at sex differences and treatment response and non-response to treatment.

In addition, stratification of patients, the choice of various treatments, tracking treatment response using or based on neural circuitry, personalized medicine ensuring that intervention is tailored to individual needs, trying to identify which interventions are going to work in which age groups and probably that goes along with subtypes as well, research outcome measures, quality of life outcome measures and long-term outcomes and ensuring that outcome measures are meaningful to people on the spectrum or that some of those types of measures are included including interventions that result in increased social relationships or friendships, greater independence, etcetera, some of the items that might be really important to people on the autism spectrum.

And including individuals on the autism spectrum in the planning of intervention research and in trying to develop those outcome measures so in that area are there other important points that you feel were missed? We tried to grab things that were based on your discussion but wanted to make sure that we prompt you on all the things that you want to talk about.

DR. SHIC: This is Fred. I was wondering and I don’t know if this fits in someplace but I was thinking that it might be useful to have a

discussion of opportunity costs within this context as we move towards personalized medicine, you know, the trade-offs involved at an individual level when engaging in one intervention that is perhaps very intensive compared to others as compared to you know, things that are just add-ons to daily living for instance. So just opportunity costs more broadly I think that might be kind of a useful subheading either under personalized medicine or just as a separate bullet.

DR. DANIELS: Okay. Other thoughts?

DR. LAUGESON: This is Liz Laugeson. I think I would also maybe add racial and cultural differences in treatment responses.

DR. DANIELS: Okay.

DR. SUKHODOLSKY: Yes, so it seems to be - this is Dennis Sukhodolsky - it seems to me that outcome measures and treatment response are important but they're slightly in different categories than personalized medicine. It seems to me that personalized medicine is an overarching category that would include the types of intervention and outcome measures and how to make them most appropriate for a given person.

DR. DANIELS: Sure, and so when you're actually writing this, you can separate things out the way you want to. For convenience we kind of grouped some things together that had a few commonalities but you can definitely separate that out into a different section if you want to. Anything else that is related to these topics that you think is an important issue that should be discussed that's not on the list?

DR. MINSHEW: This is Nancy Minshew again. I'd just like to follow-up on the last comment. I thought the personalized medicine is a great objective but when we don't have interventions that are effective, there's talking about

personalizing them is in a sense a little premature but I also thought that some of these interventions are sort of modules addressing sort of the, you know, the (ardoc) type domain.

So that if somebody if you demonstrate efficacy of a program but you find that a certain aspect of people's issues isn't responding to that, then you could bring-in a module from another intervention so I think all of your programs you start with who does it work for and who does it not or what aspects probably of their issues or challenges does it work for and which aspects does it not? And then you can do combinations perhaps of effective interventions or say if somebody has emotion dysregulation, it may interfere with response to any other interventions so you have a module that addresses that first and so like that but I think that's more of the way that I think about personalizing medicine in the context of treatment trials.

DR. DANIELS: Uh huh so I think, you know, personalized medicine of course is aspirational and so you could kind of maybe talk about some of these first and then put that more toward the end in terms of where you'd like to see the field go eventually once you have all of those pieces in place. Anything else with regard to those topics so the third section …

DR. MALOW: This is Beth. I just I wanted to mention too that anything we can do to involve the community, you know, community setting for the research would be helpful because then we can make, you know, generalize the larger population.

DR. DANIELS: Okay.

DR. LAUGESON: I would agree with that, this is Liz Laugeson. I was actually going to suggest the bottom bullet point with the inclusion of individuals in the autism spectrum to maybe

include stakeholders or family members, that kind of goes to that point.

DR. DANIELS: Okay.

DR. MALOW: Yes, I think I agree with that wholeheartedly. What I meant specifically too though was, you know, just doing research in community settings, primary care practices in the community, rural areas, you know, not limiting what we did to let's say our tertiary care academic medical centers.

DR. SUKHODOLSKY: And this is Dennis Sukhodolsky again so there is a bullet point about dissemination of information about evidence-based interventions to parents and providers. I wonder if it would make sense to add the bullet point on dissemination research, how to take effective interventions from research centers and implement them in communities.

DR. DANIELS: Okay.

DR. MALOW: Yes, that'd be great.

DR. ODOM: Yes, this is Sam Odom. I also had a comment about that bullet point and the I think it really understates the need of preparing a workforce or preparing professionals who can actually implement interventions in authentic settings, real-world settings. The dissemination will only get us so far I think because added that may be a different bullet point but …

DR. DANIELS: Yes, so …

DR. ODOM:… but it's a really important one.

DR. DANIELS: … I think that it's fine for you to mention it here. Hopefully Chapter 5 is going to go into that more as they're going to talk a little bit about implementation science so that's

kind of the break point for this chapter versus the next which is on services.

But David Mandell is heading that up and I know that he's planning on including quite a bit about implement in the community and so but I think it's fine for you to mention some things here that will lead into that and he wanted to also serve on this working group but wasn't able to due to time so we'll make sure …

DR. ODOM: I think, yes, I think it's really useful to link the two chapters because the maybe in this way be preparing research interventions and protocols so that they are possible to be used in community settings. It's really an important feature of the research process so …

DR. DANIELS: Uh huh, okay.

DR. LAUGESON: I agree completely, I think that the two while their sort of separated should also be integrated in the wording - this is (Liz Lougason), sorry - so basically developing interventions with the goal to be disseminating in community and educational settings. I think that makes the most sense, just developing interventions that no one can access doesn't make a lot of sense.

DR. DANIELS: Right, okay.

DR. MINSHEW: And I would third that, this is Nancy Minshew. I think that's incredibly important if interventions can get into schools, then that relieves the parents of taking off of work and taking a child in and everything that's involved. But it does also mean that in schools there's going to need to be professionals that are trained to implement these and I think the schools may need to see their mission a little more broadly and not just academic achievement but the kinds of skills that involve social, you know, all of the issues that are issues for people with autism that

quite frankly are also issues for a lot of other students.

DR. DANIELS: Right so again that's an issue that I think would be great to mention here and then I think it'll be expanded more in Chapter 5 so on those that third section of bullets I guess, you know, you've mentioned some of those that we talk about accelerating research and how to increase uptake of and access to evidence-based intervention.

So we've talked a little bit about ensuring that what's developed is going to be able to be practically implemented in the community and that there is a workforce that's going to be available and properly trained to be able to do this implementation. Is there anything more so that things that were mentioned on the previous call, ways to accelerate the pace of research, is there anything specific you want us to point-out in that that we should put into the outline?

DR. MINSHEW: This is Nancy again. I think one issue is that it takes I believe a minimum of two trials demonstrating efficacy to get government approval for reimbursement which is a limiting factor in dissemination and if they're a five-year trial, that puts you at least at 10 years so I wonder if there couldn't be a sort of nested development of trials. So that something that's promising in pilot goes into a clinical trial and if the first two years forced that promise that start a second trial during that second year, you know, so you sort of next the stages rather than first one and then the second and then the third because you still haven't gotten to dissemination yet.

DR. DANIELS: Uh huh. Great. Anything else that you all think should be mentioned in terms of how to accelerate the pace of research or particular barriers?

DR. SUKHODOLSKY: Maybe making it clear statements - Dennis Sukhodolsky again - the endpoint of research is to put treatment, effective treatments in the hands of practitioners in community where they can be accessed by families so children with autism because otherwise it's not very clear what's the end result of research here.

DR. DANIELS: Right.

DR. PELPHREY: Can we also add to this I'll turn it to statistical approaches or methodological approaches? I'm especially thinking about this in terms of the technology interventions that are available.

DR. DANIELS: Uh huh, so sorry, I didn't quite catch what you said.

DR. PELPHREY: I was just wondering if we could add something like I'll turn it to statistical or methodological approaches towards research, especially in terms of just talking about efficacy and specifically if there's different strategies that are available for technology given that the measurement modalities can be very different.

DR. DANIELS: Okay.

UNKNOWN FEMALE SPEAKER: I think a clear obstacle is funding to get these trials going and then of course perhaps having a number of sites to build-in the heterogeneity, you know, related to autism but also people, different socioeconomic, race, ethnic resource groups from the beginning.

DR. DANIELS: So meaning larger cohorts and being able to take advantage of multiple sites?

DR. MINSHEW: You know, I was thinking in don't know if it's feasible but whether you have sites that understand autism that are capable of delivering multiple interventions as a way of

improving accelerating the pace and the number of subjects.

((Crosstalk))

DR. DANIELS: But then as if that doesn't exist, something that has a capacity that would need to be built.

DR. MINSHEW: Yes, I don't know how feasible it is but that would be a way to increase the number of interventions that are being tested and the sample size and it would facilitate use of combination therapies that you've all mentioned, right?

DR. MALOW: So Nancy as you know we've been able to do that with our autism treatment and that worked to some extent and we have received funding from AARP, you know, the HRSA funding but I mean, I think that could be built-out even more and that could be then later numbers of sites and networks. I know it's been very, very helpful in the autism treatment network to have multiple sites because we can pull our data and you know, bring people together from multiple site (childs).

DR. DANIELS: So other items that were on the list here were ways to increase the interest of private industry in helping develop interventions. I don't know if you have any particular thoughts about that.

Strategies for increasing access and we've talked about that a little bit including issues of disparity, delivery methods, telehealth and parent and peer-mediated methods that might be accessible to low resource communities. And yes, and you've talked about how having community-based intervention models can be useful for making interventions more accessible and cost-effective for those communities.

Improvement of coordination of interventions across service providers which of course, you know, as you mentioned just now there are centers that are providing multiple modalities that would be helpful but in addition in coordination between different types of providers. Dissemination of information which we've talked about and large-scale clinical trials so is there anything else in that whole area that you think needs to be called-out?

((Crosstalk))

DR. MALOW: This is Beth. I think the idea of getting industry excited and involved in autism trials is great because I think whenever some of the pediatrics, you know, where they want to get a pediatric indication let's say for a new drug particularly I worked with those who were doing sleeves drug it's…autism isn't always something that is appealing because I think they think there are a lot of side effects and you know, these kids might get into behavioral issues and you know, adverse effects of the drugs.

So sometimes bringing industry together and saying hey, this is such a prevalent condition. This is so important you know, when you think about, you know, particularly with comorbidities, when you think about medications for treating some of the comorbidities associated with autism whether it's EGI, epilepsy, sleep. You know, this is a really important population. I just think having some sort of workshops or something that would really get industry excited and involved would be very good, would be very beneficial to the field.

DR. DANIELS: Great, other thoughts?

DR. MINSHEW: Well, I think for industry it's still a low prevalence disorder and a complicated one and I think the other thing that has challenged them at least looking at their studies

is they pick one primary outcome measure and it doesn't end-up being one that is effective and it seems with the heterogeneity and the complexity of autism that there ought to be, you know, a broader definition of effectiveness. Now in schizophrenia, you know, they use a matrix battery so that everybody uses the same pre-posed assessment measures which is helpful and there's multiple measures. That's really improved progress in schizophrenia and we use it now with adults but I think that's one obstacle also for industry and for adding studies together.

DR. DANIELS: Any other contributions on this area? So we'll take all the notes that we've taken here and add them into the outline and then we'll be talking with Kevin about the outline and you know, Kevin will be able to also do some further work with it and then we'll be asking for various members of the working group to help us flesh this out particularly in your areas of expertise.

So something that you can be looking forward to as hearing from Kevin about trying to get you involved in (unintelligible) infections to this so we will after the call update this outline and then work with Kevin and then you'll all be hearing about what you can do to contribute but we really appreciate all your thoughtful input on this. There have been some really great ideas shared and we'll make sure that you have the prompts you need so that you can write your chapter. We're going to be going for an approximately 10-page or less chapter because we have seven areas and we don't want the strategic plan to be really, really long and just keep in mind that we want to write it in a lay-friendly manner so that a parent or a person on the autism spectrum (unintelligible) that understand it.

DR. PELPHREY: Thank you, that makes sense. I know everybody's looking forward to writing assignments for Christmas and I'll make sure we get those out.

DR. DANIELS: Yes, and so we have an IACC meeting coming-up on January 13th and we'll provide whatever draft chapter you have to the committee to look at - at that time and in addition we'll be sharing all the objectives that are created by the working groups and so this is actually you have the honor of being the last working group call out of the 21 calls that we had scheduled for this call.

And so your objectives will be the last ones we try to put together here for the strategic plan and as you might recall from previous phone calls, the IACC in the new strategic plan they'd like to try to pare-down the number of objectives to something a little bit more manageable. But previous strategic plan grew to a number of 78 objectives which was a little bit tricky to keep track of and sometimes can be a little bit difficult to communicate because it was a large number and so what we decided to do this time is to come-up with three objectives per chapter around these consumer-based questions.

And if you have specific items that you want to include as examples you could under any given objective but the objectives are to be broad and hopefully we'll be able to capture a number of topics but we're also trying to keep the three objectives fairly distinct from each other so that it's easy to determine projects that would fit in that category or not fit in that category so we're avoiding having categories that are overlapping.

So looking at your previous calls it was a little bit challenging to come-up with even more precise draft language for you to look at. With most of the other groups we were able to take things from your calls and come-up with a draft objective for you but I think that you have so many diverse topics you discussed on previous calls, I really wanted to give you an opportunity to try to come-up with what you would like to do on the objectives.

So the way that we have divided it for you right now which you can feel free to you know, propose alternatives if you want to but we thought that maybe you might want to divide it into intervention types because they might have some very different goals for future directions based on the type of intervention. So since we only have three, we grouped together pharmacological, behavioral and complementary interventions into one objective which you can take or leave or leave one of those groups out.

We did hear Geri Dawson shared some feedback with me before the call saying that she wanted to weigh-in saying that she felt like any that the objectives should try to address both core symptoms and comorbidities which I think I've heard from other members of the working group as well so that's something, you know, to consider. We thought that it might be helpful to have an objective around educational interventions which may have a different set of needs and then perhaps one about technology-based interventions but it's really open to you to discuss how you would like to do this and to propose objectives that you would like to possibly pursue so the floor is open.

DR. ODOM: This is Sam Odom.

DR. DANIELS: Yes.

DR. ODOM: We do a lot of work within schools and I know a lot of the work we do in schools are to support behavioral interventions so I guess there's I see an overlap between the Number 1 and Number 2 and so maybe we can sort of think about how sort of how to address that conceptually.

DR. DANIELS: And you know, that's something I thought about as well. You could move behavioral down into Number 2 and have behavioral and educational together. I don't know what makes the

most sense but just I guess it depends a little bit on how you shape the objectives.

DR. MINSHEW: Well I would - this is Nancy - I would go the other way because I think behavioral occurs across context and not just in schools in relation to education and so I would consider this setting as a variant. It doesn't need to be particularly an objective so but I would again add to Objective 1 the behavioral and cognitive interventions.

DR. DANIELS: Uh huh.

DR. MINSHEW: And quite frankly when you were talking about technology-based interventions, I thought you might be including direct brain stimulation but it didn't sound to me from the rest of the document that that was what you were thinking about under that.

DR. DANIELS: No, we were thinking more about some of this robotics, AAC, artificial intelligence, those kinds of things. Direct brain stimulation hasn't come-up on the calls at all but certainly, you know, fair game for you to talk about.

DR. MINSHEW: I think it's very promising, has a lot of potential, needs a lot of development.

DR. DANIELS: Maybe that's something we should put in the outline as something to cover as well.

((Crosstalk))

DR. DANIELS: Go ahead.

DR. PELPHREY: I'll jump in, I'll try not to dominate the conversation or take-up most of our time. The behalf interventions are sometimes thought of as not just applied behavior analysis but things that are sort of non-medical and non-pharmacological in nature and we could include

behavioral, cognitive, you know, there's a whole set of interventions that people are called developmental behavioral naturalistic interventions. So I think grouping those together makes a lot of sense and I agree that those happen in multiple contexts so maybe not characterizing them as educational interventions per se. It might be good (at them).

DR. MALOW: Yes, so this is Beth and I have to go after this, in Number 1 I would just make the argument that we not only look at pharmacological, behavioral and complementary but we look at combining them or integrating them, right? So the idea of a medication that would be paired with behalf might result in a better effect and fewer side effects than isolated so kind of reworking that objective to make it clear that that would be an important area of study as well, looking at combining for example behavioral and pharmacological.

DR. DANIELS: So I think that for combinations I think that that would make a good example under an objective but I don't know that you want to limit your objectives that narrowly because there aren't going to be probably that many studies that are going to be looking at combinations at this point in time because you're still developing a lot of interventions so…

((Crosstalk))

DR. MALOW: Right, no, no, no, and I didn't mean to limit it to that. I just meant to emphasize that would be important, you know, so it could be the objectives for example it could be studying pharmacological, behavioral and complementary interventions and combinations of these to address both but it wouldn't be a requirement that you combine them but it would be something to certainly emphasize and consider.

DR. DANIELS: Additional ideas?

DR. SUKHOLODSKY: Well, this is Dennis Sukholodsky. I'm trying to think about the utility of putting some pharmacological and behavioral interventions into one objective so it seems like even though it's important to research how the combination will work together but those are different approaches to treatment so maybe separating them under two objectives will be useful for the (sig) or for avoiding confusion in people who will be reading that. If this will direct by family so they might think that they will need both, right, to address the same goals so that I would probably try and keep them separate as separate objectives and then adding somewhere down the road that a combination of two with an important research question but has not been addressed very well yet.

DR. DANIELS: Right, and I think that we could do that and so if the working group is comfortable with having these things separated, we got the suggestion of having the second one be about behavioral, cognitive, social, developmental, naturalistic type approaches so we'll have to figure-out wording that's not too complicated but to get that across. So on the first one then do you want to keep pharmacological and complementary both or do you want to drop complementary, what, how do you all feel about that?

DR. MINSHEW: Well, I wanted cognitive added suggested adding cognitive to behavioral.

DR. DANIELS: That's now going to be in the second objective so that's a separate one.

DR. MINSHEW: Okay.

DR. DANIELS: So I have that down there so if we had pharmacological on the top, do you want pharmacological and complementary together to address both core symptoms and comorbidities?

DR. LAUGESON: This is Liz Laugeson. Kind of in addition to that maybe even adding something about just medical because someone mentioned about like neuromodulation or brain stimulation that could fall within that category.

DR. DANIELS: Okay. Yes, so they'll make it have medical, pharmacological and complementary interventions so what …

((Crosstalk))

DR. DANIELS: Go ahead.

DR. PELPHREY: Instead of medical just because I'm not sure how that …

DR. DANIELS: How that might be interpreted?

DR. PELPHREY: … fairly differentiates them pharmacological but can we say neuroscience informed or cognitive neuroscience based?

DR. DANIELS: Sure.

DR. PELPHREY: And that way we're actually introducing a new notion into the chapter, you know, kind of what behavioral interventions and pharmacological let's talk about neuroscience informed.

DR. DANIELS: Yes. I think we can do that. Now with that area so if we're going to talk about cognitive neuroscience-based pharmacological and complementary interventions that are going to help core symptoms of comorbidities, what do you think is the most important direction that you want to give for that field? What needs to happen there and although we can kind of give a little bit more direction to the objective?

DR. SUKHOLODSKY: So also just to comment on Kevin's point and this Dennis Sukholodsky again. I think that behavioral interventions can also be

informed by neuroscience and ideal educational interventions should be a two. So that I wonder if instead of breaking-down objectives by sort of how they are delivered, would it make sense to think about interventions that are already developed and tested and then interventions that may need to be developed and then innovative interventions such as role (but derivative) therapy that will be aspirational goals so that treatment …

DR. PELPHREY: Yes, I like that, yes, because one would hope that any pharmacological intervention or behavioral or educational would have some reference to the brain so yes, I think that's better and kind of get away from lumping things and pharmacology, behavioral or medical or you know, and not create a new category, right?

DR. DANIELS: So if you do things based on their kind of state of development I think that the concern is if the strategic plan is going to last over five years, that might be fluid and so we also use these in the office, the Office of Autism Research Coordination, we use the objectives to help code the research portfolio and so I think that if we start doing it based on how well developed we think the technologies are the interventions are, it would make it really difficult for us to be able to do any meaningful coding so that would be one concern I would have that it might not be …

DR. PELPHREY: Got you. Yes, no, that's important. And Dennis…

DR. DANIELS: That was one reason that we were leaning towards trying to separate-out things that we think are fairly distinct that, you know, you would find a few projects that might be combining more than one of these but a lot of them will be on one of these tracks.

DR. PELPHREY: And Dennis what if we had a unique section of the chapter that describes the need to begin to incorporate these different

approaches and maybe that would allow us to develop a new code that's, you know, across disciplinary multi-approach?

DR. SUKHOLODSKY: That makes sense. Can you comment a little bit more?

DR. PELPHREY: Not yet.

DR. SUKHOLODSKY: Okay, okay.

DR. PELPHREY: I'm just thinking that that kind of takes care of the issue you raised is that it is really good one without overly complicating the other uses of this …

DR. SUKHOLODSKY: Sure, sure.

DR. PELPHREY: … and while still kind of attending for the way much of the field still sees (bens) in category.

DR. SUKHOLODSKY: Yes, yes.

DR. DANIELS: That might actually make a really good way to introduce the chapter. I know some of the other groups have come-up with kind of crosscutting aspirations as kind of an introduction to their chapter and if you want to talk about how cognitive neuroscience is now informing a number of different treatment modalities and needs to be incorporated more or something along those lines, we could have a whole paragraph on that to introduce your chapter.

((Crosstalk))

DR. MINSHEW: So the idea seems to be something about mechanistically anchored approaches?

DR. DANIELS: Uh huh.
DR. PELPHREY: Yes, just …

DR. MINSHEW: Is that the idea that we wanted to begin linking to mechanisms?

DR. PELPHREY: … right, I think so, that as we're kind of lumping things out or splitting things out that we're not blindly ignoring the fact that all of these must address some set of mechanisms.

DR. SUKHOLODSKY: Right, right, right.

DR. ODOM: This is Sam. I'm wondering if, you know, it looks like on the agenda there's a discussion about aspirational goals. I think today at least with the behavioral developmental interventions, there's been very limited association I'd say with neuroscience. I think it's a great aspirational goal but there's not a lot of research about of that mechanisms to this point so thinking about that as aspiration seems great.

DR. PELPHREY: Yes, I would agree with that.

DR. DANIELS: That's a terrific though so why don't we put that on our list so when we get to the aspirational goal to talk about that and maybe how we could revise the aspirational goal to incorporate that idea so back to Objective 1 so for when you talk about medical, pharmacological, complementary interventions, where does that general field need to go? What are some directions that you want to see it go in in the five years or beyond? I mean, you could have something very generic that just says you'd have to support more research on such and such but …

((Crosstalk))

DR. SUKHOLODSKY: But just to continue on the previous comment is that if we can see more understanding of the brain basis of effective treatments and also if we can see more understanding or how to put effective treatments

into hands of practitioners so to me those are two sort of important aspirational topics for the next five years.

DR. SHIC: And I don't know - this is Fred - I don't know if this is subsumed under one of the categories we're already talking about but, you know, just as a return to outcome measures and I think that that might be something that we also I don't know at what level we would want to focus on the need for really good outcome measures that could be used across a variety of studies for comparability. I think that's something that we really do need in terms of treatment in general. It's just some better, more sensitive, more robust ways of measuring change in outcome.

DR. REICHARDT: That's one of the big disincentives for pharmaceutical companies.

DR. SHIC: Right.

DR. ODOM: And as kind of, you know, something on the other side of really understanding things mechanistically I would say this idea of focusing on very practical outcomes also has its, you know, certain utility that may be really valuable to the community and in returning a little bit to personalized medicine for, you know, and this is all of course interlinked with being able to come-up with the right types of not just outcome measures but predictive measures to figure-out, you know, which treatments and for whom. I think it's a longstanding objective that's kind of been raised multiple times through the years and it could be neuroscience that is giving us the next breakthrough in understanding for which populations, which treatments go best.

DR. DANIELS: So it sounds like these three areas so if you want to talk about trying to elucidate mechanisms, improving outcome measures, predictive measures, focus on practical outcomes,

putting more in the hands of practitioners or being able to effectively implement …

DR. MINSHEW: Sort of translational in dissemination.

DR. DANIELS: … right, right so those go across multiple like all of these categories so but we could if you have a few of these types of themes, I guess we could try to play with it and structure it so that you have these different categories but these are some common themes that you want to see addressed in all of them.

DR. LAUGESON: This is Liz Laugeson. I want to also highlight again I think the importance of the dissemination and of this like translational research of you know, what's the point in developing these interventions if nobody can access them. And I think that that fundamentally become a funding issue because a lot of times I think we think that dissemination is, you know, writing scientific papers and not necessarily writing manuals that people can access or conduct trainings that people can attend. And I don't know where all this then fits into what we're doing but if there's some sort of a mandate in order for this research to be disseminated on a more practical scale, I think that would be very, very useful. I think that it does become a funding issue. It's difficult to disseminate on that level if there's not support, financial support for that.

DR. PELPHREY: This is Kevin and that's a really good point.

DR. MINSHEW: Yes, I think - this is Nancy - the other side of that though is a lot of money is being spent already on services for which we don't know if they work. I was really stunned to find-out that the military spend more money on treatment of autism than it does on head injury in their active servicemen and they don't have active

ingredients or early predictors or objectives outcome measures so I think that's kind of the broad state of things. So to me the issue is can we convince some people who are funding the services like Health and Human Services or education that you're already spending a lot of money. Let's see if we can spend it on interventions that are effective, more effective or at least have effectiveness demonstrated.

DR. SUKHOLODSKY: Right, right and also this brings-up a question of how to track effectiveness so if services that are already delivered, right, so how do people know they're receiving effective services or not effective and how do providers know if there is a change in symptoms so they're trying to influence.

DR. DANIELS: Right, I think that lends itself more to writing than to an objective because it would I think you would need more than a short phrase to convey all of that but it's something also that Question 5 I think will be looking at as well so are there any other major common themes that you think these areas have or do you feel that there are any of these areas that have their own specific needs?

(No response.)

DR. DANIELS: So I know that technology-based interventions is kind of new for the strategic plan. We've never had a focus on that before. Is there anything unique about that that would make you want to have a more specifically worded objective or would you say that these same issues are the issues that you face there? I know that on previous calls you've talked about the need for more coordination between agencies that fund the earlier-stage research and the more translational type research with regard to technology-based interventions but I don't know if there's a …

((Crosstalk))

DR. REICHARDT: I actually think technology is really important, it would be very important for getting the objective outcome measures that pharmaceutical companies want and it may be extremely useful for providing therapy at a time when it's needed, you know, through automatic monitor and behavioral stress and so on.

DR. SHIC: I would totally second that and I would add that, you know, unique to technology and technology-based interventions, there's this capacity for data recording - automatic data recording - and very dense data recording that is really unique just by the kind of the design of these underlying technologies.

And so I think an appreciation and kind of the statistics, the mathematics, the mining of this data, combining this with advances in computer science and then being able to develop this into something that is appreciated I guess. That's something that I think we still have some ways to go and without overstating because that's been a big problem, right, it seems like every other week I read about an app that claims you know, 100% ability to diagnose autism and these are things that we know cannot be true.

So we really need to have some way of rigorously evaluating the systems and attaching to them the right type of machine learning methods if those are available, having a translation layer so that this can be appreciated in the context of clinical trials and really to bring these modern methods into the fold. And I'm not sure about what's the best way of phrasing that objective but I know that it's multifaceted and multipronged and it's really going to require a lot of coordination across different disciplines.

DR. DANIELS: So what you've talked about so far sounds like it also might lend itself more to language in the chapter than to the objective if

you're going to try to name these three areas and have a common set.

DR. PELPHREY: Yes, and I think Fred you just nominated yourself to write a great paragraph.

DR. ODOM: Yes, I think - this is Sam - from what I'm hearing it sounds like this category has sort of different layers related to technology from assess one of which is it sounds like is assessment. Another it sounds like might be data management, data mining. A third might be sort of delivery of an intervention approach through the use of technology like as the telemedicine for example. The fourth area that I think we've started to talk about is how technology is actually used indirectly in interventions with individuals with autism (spectrum) disorder so I think making and there are emerging - it is emerging quickly emerging - literature. So I think our being sort of clearer about sort of the layered or multidimensional topics that exist within this technology - general technology - areas (of core).

DR. SHIC: And I would agree, it would be very important to get a lot of different perspective on that piece, you know, to make it something that is really applicable for the ultimate outcome of making it effective.

DR. DANIELS: Great, so any other thoughts about it looks like I have four crosscutting themes that you've come-up with. Is there anything else that we've talked about understanding mechanisms, robust standardized outcome measures, predictive measures and practical outcomes, trying to get well, I guess it's three, dissemination and translation? So is there anything else that you think is a key crosscutting theme that you want to emphasize as a direction for the committee?

(No response.)

DR. DANIELS: I think of the things I've heard, well I guess the translation part of it incorporates community-based approaches or making sure that what's being developed is going to be able to be useful in community settings?

DR. LAUGESON: This is Liz Laugeson. I guess one other thing I might add to the assessment piece is follow-up so assessing the durability of treatment outcomes over time. I'm not sure if that would be appropriate here but it just seems rather relevant.

DR. DANIELS: Okay, I'm going to put that in the chapter in the section that has the things about treatment outcomes as a part of that. Something that isn't covered here that I don't know if you want as a crosscutting theme that you've talked about is just addressing heterogeneity, the different needs across age groups and different communities.

DR. SHIC: I wonder if the heterogeneity question could be part of that outcome prediction section and the communities could be part of that translation dissemination piece? I mean, it is a little I can see how it can standalone also but I could see it, just to keep it a little parsimonious.

DR. DANIELS: Uh huh.

DR. MINSHEW: I think that's a good thought, a good way of looking at it. The only other thing that I see is that we don't exactly with those objectives touch on things like adaptive function and function in community life roles. You know, for adults it's ultimately employment and independent living so I think measure, maybe we roll it in there by encouraging measures of inclusion of measures of adaptive function and delineating mechanisms of adaptive function. I know that's emerging.

DR. DANIELS: Okay. What we can do with that, something else that came-up a couple of times on today's call was an aspiration toward working toward combination therapies and I think if you have that as a fourth item if that's something that you think is important to prioritize that would apply across all of these as well?

DR. PELPHREY: Definitely.

DR. MINSHEW: I think the issue is really how do we identify the optimal treatment for an individual and maximize effectiveness in the shortest period of time?

DR. DANIELS: Uh huh.

DR. MINSHEW: You know, so how do we get them to the treatment they need at a particular time point in their life and enhance the effectiveness of that treatment?

DR. SHIC: I really like that as an objective because I feel like the outcome measures prediction could be actually underneath that, you know, the goal is to optimize the means by which you do it are, you know, outcome measures and predictive models.

DR. PELPHREY: Yes, I served that - this is Kevin.

DR. DANIELS: I think we can do that so then the objectives themselves so we would have these four crosscutting themes that apply across these different fields. The objective would probably be worded fairly simply as like, you know, advancing the science around each of these areas and then with these four bullets that describe the major directions that you want to see things go in.

DR. SHIC: Just as a I'm just wondering where you know, this kind of stakeholder input where that might fit in, you know, specifically

perspectives from individuals with autism and also you know, their family members kind of at a high level and also how this shapes the decision-making process and you know, the various complexities and trade-offs surrounding the decision-making process. I'm thinking, you know, like is there a place where that could go because it seems like it's a little bit overlooked and it's important in terms of defining value at a very high level?

DR. DANIELS: I think it's something - and this is just my opinion - I think that it would be something easier to describe in a chapter than than as an objective because I'm not really sure how we would measure whether that's being done or not, you know, with the objectives we're going like our office will be responsible for trying to help identify projects where this is happening and I think that that is something that's a little bit more abstract and it'll be something that I think you all in the community who are experts will be able to kind of comment on this (unintelligible) rather than us trying to measure it through projects so …

DR. PELPHREY: And I wonder along the lines of - this is Kevin - of what Fred just said, having perhaps a section of proposals where you address how stakeholders were involved in the proposal design, how you intend to keep them involved and, you know, what role they're playing at each stage of the research process would be worthwhile. I think people do that now, you know, voluntarily but maybe it could be part of call to research proposals.

DR. DANIELS: Yes, I think that that's something that you could definitely flesh-out in your chapter.

DR. PELPHREY: Yes.

DR. DANIELS: So good so are there any other final thoughts before we it sounds like you I

think you've done some good work here and so what our office can do is try to put what you've said together and then get it back to you so you can see what it looks like. But it's not if there aren't any more comments on that, then I'd like to move on to the aspirational goals and it sounds like we had some ideas about possibly updating that so currently the aspirational goal reads 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.

And what I heard from the group is that you'd like to incorporate something about connecting this more with mechanisms and modern neuroscience so do you have any proposals of how to do that?

DR. MINSHEW: Well, you could introduce a phrase after the first core and associated symptoms and say identifying mechanisms of efficacy.

DR. DANIELS: Uh huh.

DR. MINSHEW: So you could add that there and then I thought the last part was a little too big, maximizing quality of life and sort of to me the word that comes-up is meaningful outcomes and then you get to meaningful to whom and I think it really comes back to the stakeholders.

What's meaningful to them in terms of function and function across life roles, not just function but satisfaction may be the word?

DR. DANIELS: Uh huh.

DR. ODOM: So this is Sam, the I actually like maximizing quality of life but it can be stated I think it could be stated maybe in health in a more sort of definite way. I'm wondering about whether we could move those positive statements up toward the front of this phrase. I do believe this comes-

off as sounding as beginning at the beginning it's sounding like a disease reduction aspirational goal and if you are going to have stakeholders from the autism community, advocates, I think they're going to talk about that right off the bat so …

DR. DANIELS: I didn't catch the first part of what you said.

DR. ODOM: … so the first part was that I liked the idea of maximizing either the quality of life or meaningful outcomes or in life and health for individuals with autism and, you know, trying to put those more positive statements up towards the front of the phrase in an effort to avoid thinking about an aspirational goal sounding like a disease reduction goal.

DR. DANIELS: Okay.

DR. ODOM: Because I believe that stakeholders will if we have individuals with autism (spectrum) disorders involved and in reviewing or wanting to identify with these aspirational goals, that may jump out at them.

((Crosstalk))

DR. MINSHEW: That's a really good idea. I think that's a really good idea because that would mean that what follows is not just reducing core and associated symptoms but also building adaptive function and employment and you know, whatever else you put there so it's reducing one but also building the other.

DR. DANIELS: So we want to keep it very like a simple statement. It's not going to be able to be a whole paragraph. They're all - all of these - are just kind of the way we use it in the document is the aspirational goal is usually at the front of the chapter as this is sort of the overall direction that we want this area to go and it's

something very simple, high level so and that's fine.

We can try to build some of these things in but I don't think we can get into all the issues of employment and all of that. It would get too complicated so we'll have to come up with a way to word it that kind of brings it to a high level so do you have a proposal how to do that?

DR. PELPHREY: By high level do you mean a more generalized statement rather than our sort of this is a goal and then there may be specific more targeted objectives that address the goal?

DR. DANIELS: Well, we're not going to have a list of specific targeted objectives under the aspirations so it's just a simple statement to kind of describe this overall direction that the field should move in that's associated with this chapter. I unfortunately I don't have the rest of the strategic plan right in front of me right now to read you other examples that the other chapters have. Let me see if I can get a hold of it. We can get them but we want to make sure that we're parallel with how the other aspirational goals are.

DR. PELPHREY: It could be that by talking about maximizing quality or meaningful outcomes in life and health that that may subsume the idea of reducing core and associated symptoms, maybe. I'm not sure about that. I'd have to think about that.

DR. DANIELS: Do you think that just for example deleting the reducing both core and associated symptoms would help although I think the reason the committee had that there before is they wanted to make sure that these co-occurring conditions got some attention because I think they felt that it at times that that wasn't enough of an emphasis.

DR. PELPHREY: I wouldn't necessarily remove it from my perspective but I would just put the positive things more towards the front of the statement.

DR. WARREN: Yes, I would argue for something that was more around some optimization of neural developmental trajectories across a lifespan and as sort of the aspiration you could, you know, you could add-in saying that talk about minimizing the impairments associated with the symptoms but I think I would echo what was said previously.

I mean, stakeholders I would react to the statement from years ago in terms of sort of are you reducing me or you taking me out of the picture or are you talking about optimizing sort of my engagement across the lifespan and minimizing the impact of the impairments associated with core and associated features.

DR. DANIELS: So what you just said a second ago …

DR. WARREN: That was Zach Warren by the way, sorry.

DR. DANIELS: Yes, thanks Zach so you said alter neural developmental trajectories across the lifespan and then you said something else that I didn't catch.

DR. WARREN: Optimize actually so what I was thinking something like that, I mean, I just wanted to echo that, you know, interventions will be developed that optimize neural developmental trajectories of individuals with autism across the lifespan and then you could add-on something, you know, inclusive of you know, minimizing impairments associated with core and associated features, something like that's just off the top of my head though so …

DR. DANIELS: So I think that the way the current objectives, I mean, the current aspirational goals are worded, most of them have kind of the what are we doing and then the why at the end so you know, I mean, we could switch it to have the why before it but it would take it a little bit out of alignment with some of the others.

For example the while this is of course current, I don't have all of the new aspirational goals right in front of me either because all the groups have been working on them but for example in Question 7 the old one was develop and support infrastructure and surveillance systems that would advance the speed, efficacy and dissemination of ASD research.

So, you know, what they want to do and then kind of the overall goal and purpose of why they want to do it.

DR. MINSHEW: So in this context you might say develop a range of interventions with interventions or programs that enhance function?

DR. DANIELS: Uh huh, for that optimized …

((Crosstalk))

DR. MINSHEW: … and something about …

DR. DANIELS: …optimizing developmental trajectories?

DR. MINSHEW: Well, I think to me neural developmental trajectories, we know what that means but I'm not sure what it would mean to a lay group, a non-professional group so it's sort of optimize functions across the lifespan to achieve I hate to say desirable …

DR. DANIELS: Meaningful outcomes?

DR. MINSHEW: …yes, thank you, that's it.

DR. DANIELS: Meaningful we could say meaningful outcomes. You still want to say something about quality of life and health or is meaningful outcomes enough?

DR. MINSHEW: I'd say meaningful life outcomes and you could say across or you could say meaningful outcomes across life roles. That could be a little bit too specific language but would you read a whole sentence now?

DR. DANIELS: Or you could do something like achieve meaningful outcomes that something like that allow people to engage fully in their communities or something like that? I think that's partially what you're getting at so develop a range of interventions that optimize function across the lifespan to achieve meaningful outcomes and then something else.

DR. MINSHEW: There's the piece that I feel is missing is to not just optimize but in a timely manner, you know, faster than what happens. Does it need to take 30 or 40 years before a person with autism gets to the point that they have a job that they can do? Can't we maximize the impact of interventions and really enhance function sooner?

DR. DANIELS: Sure and it sounds like …

DR. MINSHEW: And somebody else has to come-up with the words.

DR. DANIELS: …with your intervention some people though might be getting their interventions later in life and so but you want to optimize them too if they're getting, you know, interventions in the adult, etcetera.

DR. MINSHEW: Right, whatever we do, let's be very effective and very efficient, effective and efficient.

DR. DANIELS: So we could say effective interventions so develop a range of effective interventions that optimize function …

DR. MINSHEW: That demonstrated efficacy, a range of interventions with demonstrated efficacy?

DR. DANIELS: I think that starts getting a little bit too long.

DR. MINSHEW: All right, effective.

DR. DANIELS: I think effective is like pretty lay-friendly for just …

DR. MINSHEW: Okay, agree.

DR. DANIELS: Okay, develop a range of effective intervention that optimize function across the lifespan to achieve meaningful outcomes.

DR. MINSHEW: Perhaps you could add in a timely manner.

DR. LAUGESON: I don't know if anybody would really understand what that means without more context.

DR. MINSHEW: Maybe you just stop there and we kind of mull it over for a while.

DR. DANIELS: Yes, maybe we could think about that a little bit and see if there's some other proposals but does anyone else have any input on this and other things that we need to consider?

DR. MINSHEW: The only thing you could add is outcomes relevant to each page of life or each, something like that?

DR. DANIELS: Because you already say the lifespan so that kind of indicates …
((Crosstalk))

DR. DANIELS: …different stages of life. I think you're covered there. Let's try to put this together and then we'll over here in the OR we'll think about it a little bit. You all can think about it and see the draft language and then make any suggestions but this is a very good start and I think it needs just like another little phrase and then it would be good.

So in terms of the chapter title, the current chapter title is which treatments and interventions will help which is what the original consumer base question that the committee wanted to kind of focus this chapter around. Do you feel like there's any need to change that? Do you think that that's still applicable now?

DR. LAUGESON: I think that works.

DR. ODOM: Yes, I think it sounds fine.

DR. DANIELS: All right, I think that in my opinion I think it's still seems relevant to how people are thinking about this now and what you've all discussed as you've been working on the outline for your chapter. I think we'll answer more questions about which types of interventions and treatments are even under development or available now because I think in our previous strategic plans, we just had a smaller pool of folks contributing and so we didn't flesh-out some other areas that I think we will in this version of the strategic plan which I think will be very helpful to the community.

So I guess if there are no other comments, wanted to wrap-up and we'll reiterate that I will have our team work on updating this outline and updating the language on the objectives and the aspirational goal and we will get that over to Kevin, have him look at it and then we'll be working with the group. And we can circulate some of this language that we've been discussing on the

objectives and the aspirational goals to the working group so that you can have some input.

We have an IACC meeting coming-up on January 13th and so we'll be looking to see at least a partially drafted chapter by then and certainly we'll share the objectives that you've come-up with and the aspirational goal for review by the committee and they'll be adding their input. And if we need additional input from the working group, we will be contacting you after that so are there any questions about anything?

DR. PELPHREY: No, that sounds great.

DR. DANIELS: Well, thank you …

DR. ODOM: Thank you.

DR. DANIELS: …first on this.

DR. PELPHREY: All right, bye - bye.

DR. DANIELS: Thanks, everybody. Thank you. Bye - bye.

DR. PELPHREY: Bye, everyone. Thank you.

DR. LAUGESON: Thank you. Bye.

DR. REICHARDT: Bye, everyone.

GROUP: Bye.

(Whereupon, the conference call was adjourned.)