U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTERAGENCY AUTISM COORDINATING COMMITTEE

CO-OCCURRING CONDITIONS PLANNING GROUP

CONFERENCE CALL

TUESDAY, MAY 27, 2014

The Interagency Autism Coordinating Committee's Co-Occurring Conditions Planning Group convened via conference call at 11:00 a.m., Thomas Insel, M.D., *Chair,* presiding.

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PROCEEDINGS:

Dr. Thomas Insel: Good morning, Tom Insel here. Let's find out who's with us in speaker mode from the IACC on the phone.

So can you go ahead and quickly take attendance, and we'll get a sense?

Dr. Susan Daniels: Yes. So I'll go through the attendance for this call.

So, Tom Insel?

Dr. Insel: Right.

Dr. Daniels: You're here.

Lyn Redwood?

Ms. Lyn Redwood: Here.

Dr. Daniels: Idil Abdull?

[No response]

Dr. Daniels: Anshu Batra?

[No response]

Dr. Daniels: Sally Burton-Hoyle? Is that Sally?

Unidentified Speaker: Hello,

Dr. Daniels: Hello? Is that Sally?

[No response]

Dr. Insel: I guess not.

Dr. Daniels: I can't -- I couldn't hear

whoever that was, if you can speak up?

Dr. Matthew Carey: That might have been my -- this is Matt Carey. That might have been my son in the back of the car. I'm driving him to school. So I apologize.

Dr. Daniels: Oh, okay. No problem. Okay. Matt. All right.

So marking Sally Burton-Hoyle as not here.

Judith Cooper?

Dr. Judith Cooper: Yes, present.

Dr. Daniels: Thanks. Jan Crandy?

Ms. Jan Crandy: Present.

Dr. Daniels: Oh, good. Thanks.

Geri Dawson?

Dr. Geraldine Dawson: I'm here.

Dr. Daniels: Great. Thanks.

Alice Kau?

Dr. Alice Kau: Present.

Dr. Daniels: Donna Kimbark?

Dr. Donna Kimbark: I'm here.

Dr. Daniels: Walter Koroshetz?

Dr. Walter Koroshetz: Here.

Dr. Daniels: Alison Singer?

Ms. Alison Singer: I'm here.

Dr. Daniels: Hae Young Park?

Ms. Hae Young Park: Yes, I'm here.

Dr. Daniels: On behalf of Laura Kavanagh for HRSA.

And Larry Wexler?

[No response]

Dr. Daniels: Okay. Larry might be joining us a little later because he sent an email this morning sounding like he wanted to be on this call.

All right, so we have [Inaudible comment].

Dr. Insel: All right. Thanks. So this is Tom again. And it will be helpful because we have many people listening in if you can just identify yourself when you speak up.

Thanks, everybody, for getting together on relatively short notice. We've been trying to hammer out the details of this Co-Occurring Conditions Workgroup, our meeting that had been talked about. We had a discussion about this at the last meeting and a discussion about it at the meeting before that as well.

It became clear in the emails that went between the group members afterwards that there was still not a real consensus or a real

understanding of what this meeting would be and who should be invited and what the purpose was, what the deliverable would be. So I think both for Susan and myself it was important to get us all together and make sure we are all on the same page before we get into the details of finding the venue, the time, and the people to be invited because I don't think we have agreement about any of those things.

So the purpose of this session this morning in the next half hour or so is just to get everybody back to the table virtually and think through the issues of what it is we're trying to accomplish here. What is the scope of this effort, this meeting? And what do we want to have come out of it?

So I'll leave it there. There was an additional email that came this morning from Lyn with some additional details about recent abstracts. You should have received that in the last hour or so.

Dr. Daniels: So, a comment on that. We didn't receive those in time for them to be distributed to the public. So, in the future, if anyone on the

group wants to distribute information, you need to send them to OARC at least 2 business days in advance so they can be put up on the Web.

Dr. Insel: But we can do that subsequently.

Dr. Daniels: After the fact.

Dr. Insel: Yeah, so we'll put them up so people can see them. But with that as an intro, let me just invite the members of this Planning Group to sort of weigh in about what it is they would like to have done here. And it does sound to me like the conversation goes sort of back to where we started because I'm not even sure that everybody on the workgroup is in agreement about what we're trying to do with a meeting.

Dr. Koroshetz: Yes, so this is Walter. Thinking this through, I think it's probably the first node in decision-making is really to kind of decide on what is the overall goal and in looking at the materials, you know there's a lot of things to do. The question is what -- you know, what are we going to do?

It seems to me there are two main paths. One is a path which is trying to understand what are the medical issues that are plaguing the kids and

the parents with autism that need research to improve the symptoms of autism? The second one is which -- so I thought that that was kind of the track we were on.

But there's also in a lot of these materials things that go toward, you know, what is the biology of autism? What's the cause? What's the immune basis or metabolic basis that causes autism itself? And I think that what we need to do is decide, you know, where do we want to go with these two general areas?

Because if we mix them up, it gets pretty -- it's hard to stay on track and do something productive, I think.

Dr. Sally Burton-Hoyle: And hi, this is Sally Burton-Hoyle. I just got on the line, and I would thank you for letting me hear that last comment.

After reading, after watching the IMFAR webinars, it informed me greatly of something I already knew, and that is those basic things that are the anxiety, the depression, the hypertension, those are the things that are killing -- killing people, and the obesity and the -- and it's directly attacking quality of life for adults, of

which the research is so depressing.

So I guess I am hopeful and why I got on this Committee was so that that part could be furthered.

Ms. Redwood: This is Lyn. Walter, I have a question. I'm not certain that I'm really following you in terms of breaking it out --

Ms. Singer: Hello?

Ms. Redwood: -- into two paths. Can you hear me? This is Lyn Redwood.

Dr. Insel: Yeah, we can hear you.

Ms. Redwood: Okay. Walter, I had a question in terms of what you were saying about the first path, which is trying to understand the medical --

Ms. Singer: I can't really hear anything. Hello?

Ms. Redwood: Can you hear me now?

Dr. Insel: Yeah. Who was saying they couldn't hear anything? Was that Alison?

Ms. Singer: That's me. It might be my phone. I might have --

Dr. Insel: Yeah, we can hear you fine. So, but were you able to hear the comments from Lyn just now?

Ms. Singer: No, I'm sorry. I couldn't.

Dr. Insel: You might want to try to call back in.

Ms. Singer: I can hear you, but for some reason, I can't hear Lyn.

Dr. Insel: You want to try again?

Ms. Redwood: What I was asking is if -- Walter, if you could clarify in terms of the two paths that you think are critical for us to define, the first being understanding the medical issues that need research. And then, if I heard you right, you were saying then there was also information in terms of understanding more what causes autism and what some of the pathways might be and metabolic abnormalities or immune system abnormalities.

Dr. Koroshetz: Yeah.

Ms. Redwood: Because I see those two sort of fitting together, and that if we identify those distinct abnormalities that they could lead into targets for treatment. And some of those abstracts that I sent actually had some, you know, guidance in those areas in terms of what things might be done to treat some of the immune system

abnormalities, things that you can do to correct, say, oxidative stress, which, you know, has documented an improvement in behaviors, too, in some of the research on oxidative stress.

So I was confused by seeing those two things as being separate paths because, to me, they -- they're combined paths.

Dr. Koroshetz: Yeah, well, I think if we did something like that, then I think we -- you know, it would be a mix of improving symptoms and research into the pathogenesis of autism, and that would restrict us to basically a subset of things to go after. Because it would be quite complicated, and there's a lot of things when you're dealing with both of those issues.

And that would leave, you know, the issue of how to improve symptoms in persons with autism due to these medical complications -- when the symptoms are due to those medical complications. We wouldn't be able to get into that, that entire spectrum.

That's my point is that if we do -- if we do something like you were mentioning, doing a metabolic and immune and going after the

pathogenesis and how you might treat those to improve the pathogenesis of autism, then that's a full -- that's a decision that would limit us to, you know, maybe two things like you said.

But it wouldn't allow us to get at, you know, the GI problems, the autism problems, the hypertension problems, the other things we've talked about as co-occurring conditions. So I think -- I'm not saying one is worse than the other. I'm just saying that that seems to be the decision tree as I see it.

But other people may -- may –

[Background noise]

Dr. Dawson: So this is Geri Dawson. I just wanted to provide some background information just so we can have it on the table as we go through this decision-making process.

So my action item from our last call was to reach out to the folks at the ATN, or maybe this was an action item from our last IACC meeting. But in any case, I did and to find out what they're doing in terms of an immune and metabolic kinds of research and guidelines. And so, I wanted just to report back on that briefly.

So I heard both from Jim Perrin and from Dan Coury, and it turns out that AIR-P and ATN are not at present working on medical guidelines focused on either metabolic or immune-related conditions.

They are continuing to do work in this area in terms of research, and they are involved in developing a review of some of the research on a range of medical issues that includes immune systems.

In terms of the research that's going on, they mentioned that the Lurie Center in Boston has some activities in those areas. Alessio Fasano is continuing his GI mucosal and integrity work and its relationship to immune function and ASD symptoms. And that's -- and then Chris McDougle at Lurie is studying neuroinflammation in adults with autism, and then he mentioned some work being done at the MIND Institute by Ashwood and Van de Water and at Caltech by Patterson and Sarkis Mazmanian.

And then Jim also mentioned a project that David Beversdorf at Missouri is doing, examining children with and without GI symptoms. That is examining a series of inflammatory markers, and this is being done in collaboration with Jeremy

Veenstra-Vanderweele.

And so, those are just some of the things that are going on. I just thought I would throw those on the table. So it sounds to me like that there's very well -- little in the way of guideline development. I'm sure that people are perceiving that as premature, but there is quite a bit of ongoing research in this area, and so we could certainly have a meeting where we highlight some of the work in this area that's ongoing.

[Pause]

Ms. Redwood: Thanks, Geri. That's really helpful information to have.

Dr. Koroshetz: Geri, are they working on medical guidelines at all?

Dr. Dawson: Yeah. So I think that the medical guidelines right now are focusing more on the area of neurology in terms of seizures, and but again, this email to them was specifically asking about metabolic and immune. So it's not that they have stopped doing guidelines. They're just not at the point yet to develop guidelines for metabolic and immune.

Dr. Koroshetz: Thanks.

Ms. Redwood: And didn't they also do ones for GI, sleep, ADD, ADHD? So those are already available.

Dr. Dawson: Yeah, so those are already out -- GI, sleep, and ADHD. Although remember that for GI, we're really talking about the treatment of constipation and diarrhea.

Dr. Insel: Geri, this is Tom. Was the reason that they're not pursuing this area, the inflammatory/metabolic, was it because they didn't think the data were sufficient or because they simply hadn't gotten to it?

Dr. Dawson: So it says -- well, Jim Perrin says we're not, you know, doing a great deal of work in the network related to immune and metabolic at least that would lead to guidelines.

And then he says they've had a few projects. They've looked at evidence of creatine deficiency syndrome in children with ASD, which turned out to be a negative study. They also funded a study by Alvin Loh and Jill James, looking for evidence of inflammatory markers in children with regression.

And then he said essentially this turned out to be a negative study. It was a pretty small

sample. There was one marker that was mildly positive, but correcting for multiple comparisons made it not so.

Those two papers are --

Dr. Insel: Do you know if that's published?

Dr. Dawson: He says these two papers are close to submission.

Dr. Insel: Okay.

Dr. Dawson: So, I think that, you know my assessment is that this is still an area that is, you know, early in its development in terms of research. I think the only -- in terms of immune, I mean, there is a study that I think Alessio Fasano is conducting where they are conducting a probiotic study to look at the impact.

And then, of course, you've got the study on the worms, the worm treatment. Those, I think, are still ongoing, and I saw Eric Hollander recently at IMFAR and asked him about that. And you know, he's continuing to work in that area.

Dr. Insel: So I have two questions. One -- this is Tom -- for Walter. I mean, this must seem very familiar because you've done -- there's been similar suggestions for just about every CNS

disease around inflammation and oxidative stress.

Is there someone who's run this to ground in any CNS disorder where it's been useful and where you could be convinced that the tools are ready?

Which leads to my second question, which is, is there a way to falsify this idea, or are we at a point where it's everybody is still contributing to building the hypothesis, but there's really no way to rule it in or out? And I bring this up because certainly for almost every mental illness, we've had similar questions that have come up, and it's been difficult to ever fully eliminate them.

But I know there's a lot more that's going on for Parkinson's and for ALS and for a variety of neurodegenerative diseases.

Dr. Koroshetz: Yeah, so, you know, it's kind of a question that, you know, the answer is always yes because in dealing with any condition in which there's cell death, there is likely going to be reactive oxygen species involved, and there's going to be an immune response. And the immune response is involved not only in creating trouble, but also in repair.

I mean, I think if I had to point to something

that really broke, it's these conditions which we saw, you know, maybe four or five a year of people who are encephalopathic in status and have been found to have antibodies to various brain proteins, NMDA receptors, potassium channels and you know, often, you know, once it was discovered, the treatments, you know, became more aggressive, and people responded.

So, in terms of the immune system, there's clearly a lot of activity going on, and there are some new techniques to look at the immune system in the brain. There's new evidence that it's involved in synaptic pruning and moving stem cells into injured areas. So there's a lot more going on in the immune system.

The problem with the mitochondrial disorders, which we ran into, you know, a couple of years ago, I think that still remains. You know, we have genetic identifiers for mitochondrial mutations, and there's a wide spectrum of symptoms in people with these, including no symptoms.

And the techniques to identify the abnormal metabolism in individual people, there's some things which are clearly wildly abnormal, but then

most of the people fall in this middle range where the techniques have not been standardized among different places, and people get different results. And so, still pretty much of a quagmire there.

You know, I think in autism, you know, the things that come to mind in terms of the immune system is, you know, the Geschwind paper, where immune genes -- a whole network of immune genes was seen in the autism brains, which was not seen in the GWA studies. And then the studies of maternal antibodies that have been coming out of California certainly pique interest.

And then the issue of what, you know, the new science about microglia role in brain development is new, but tantalizing in the sense that there's a focus now for the immune system to interact in brain development. So those are the kind of things I see that, you know, look like they're really interesting areas for research.

Now what I don't see is a lot of -- you know, a lot of stuff on is there increased infection or is there immune problem in people with autism? You know, is there a metabolic disorder in folks with

autism, such that their symptoms are related to the infection -- you know, co-occurring symptoms, as opposed to the autism symptoms, are due to the metabolic or immune problems.

I mean, Geri, does that sound right to you that the -- if we go into metabolic and immune, we're really looking at autism pathogenesis and not necessarily co-occurring disorders in terms of symptoms?

Dr. Dawson: Well, I guess, you know, the question would be if you get, as you've mentioned, into autoimmune conditions. And you know, there is this emerging literature that there might be -- I mean, there actually likely is and there are some case studies of kids who have this autoimmune encephalitis as an etiology for autism.

I know that there's been some case studies that have been published, and we actually have a pretty active autoimmune encephalitis clinic here at Duke and have been actually seeing quite a few kids show up with autism to that clinic where they do have, you know, clear markers that indicate that that process is going on.

But again, this is a very -- you know, these

are very early emerging findings. And then I guess the only other question is if you wanted to get into GI-related inflammatory processes and, you know, start getting into the probiotic, some of the work on probiotics and that literature.

Dr. Insel: So, Geri, this is Tom again. I guess when Lyn and I first were trying to push this group -- this work-group; I don't think the idea was that we were thinking this was going to explain all of autism. But that there -- and I shouldn't speak for Lyn here, but my own thought was that if this turned out to be a pathway that would help us understand some subgroup, and maybe it would ultimately explain 5 percent or 10 percent, that could still be enormously helpful.

And what I've been trying to figure out here is whether there are some areas that we could borrow from. So maybe to have the kinds of people at this workgroup who have never actually studied autism, but who really know a lot about developmental neuroimpathomunological issues, and that could include everybody from people like Beth Stevens, who are mapping out what microglia do in the developing brain, to people who are working on

clinical syndromes of encephalopathies where there's an immune mechanism.

Dr. Dawson: Mm-hmm.

Dr. Insel: And even the recent work with narcolepsy, which is just extraordinary for giving us, you know a very detailed mechanism. And because it does feel to me like if you -- if we only invite or if we only bring to the table the people who have worked on autism, this is going to be a very shallow pool and a very early set of data.

But there are other areas that have kind of worked this up, and that would give the group, I think, a better sense of what's the rigor we would need here? And what would be the level of evidence that would actually make this become useful to define a subgroup?

Is that helpful at all? Does that look like it would be workable?

Dr. Dawson: Yeah, I mean, I do think that the two areas of the ones that you're talking about that would be interesting. One is, you know, the animal model work that's being conducted that is looking at prenatal environmental influences and

how that affects microglial activation and ends up influencing fetal brain development and ultimately, you know, postnatal behavior.

So there's really a nice literature that's emerging there. I think it's that literature that motivated the Simons Foundation to put out an RFA looking exactly at those kinds of mechanisms.

I know here at Duke, Staci Bilbo is doing some of this work where she's even looking at environmental stressors like air pollution and how that influences microglial activation during fetal development and so forth. So that's a pretty interesting group.

And then the other one, you know, would be more the autoimmune encephalitis approach, and but I would say even outside the autism field, that's still a very new field. But Sue Swedo has been, you know, quite involved with that group, and she would be very up on what's going on in that area.

Dr. Insel: We just had a meeting here in the last 3 weeks on developmental neuroimmunology, which we had Staci Bilbo and Beth Stevens and about 10 other people, Tracy Bale, a few others who work in this area. It was -- it was actually

spectacular.

Dr. Dawson: Yeah, I think that work is phenomenal, too.

[Pause]

Dr. Insel: Other thoughts?

Ms. Redwood: Dr. Insel? This is Lyn. At our last IACC meeting when we discussed this, I left thinking that the goal was to be a workshop that would take place sometime in either: July, August, or September, where we would pull together, you know, the experts in these areas and try to further define what are the research needs? You know, what areas, as Walter was saying, are mature? And which areas need more research, which could then feed back into the strategic plan for autism research.

So I just wanted to put that idea back out to the group again. And I was thinking that Geri was reaching out to the American Academy of Pediatrics and the AIR-P people in terms of participating in that. And that when we left the meeting, we were trying to identify the people that we would bring together for this workshop, and it seems as though that's sort of, you know, gotten off track.

So I'm throwing that back out again as being sort of a direction we would take moving forward.

Dr. Koroshetz: Yes, so that -- problem

Dr. Insel: Let's hear from some of the others because I think that part of the reason for this phone call is I'm not sure that everybody had the same understanding or agrees that that's the way to go forward.

Dr. Koroshetz: Walter, here. So, Lyn, that's what confused me because on the one hand, it was engaging pediatricians to understand what the clinical problems are that the kids are having that they're having trouble managing, what the families are complaining of. And it's very much symptomatic based.

I think if we get to know the previous discussion we just had, you know, on the immune system and development of autism, that's a completely different -- it seems to me to be a completely different group of people, and that's what I was having trouble meshing, and that's why I said we should decide which way we're going to go. I don't think we can go both ways.

But anyway, that was why I brought it up to

begin with, but --

Ms. Redwood: I read back over the minutes to the last IACC meeting when we had this discussion, and I think where that came in, Walter, was when I mentioned the DoD model and how, you know, they combined those like clinicians and scientists and all the stakeholders and how, you know, sort of that blend can result in more information being shared. And there might be a pearl that, you know, a stakeholder would share with a researcher or scientist that they hadn't thought of.

So that's why I put that idea forth at the time because I do think there's so much rich information, you know, that parents and individuals with ASD can share with researchers.

But if you feel as though those things are both mutually exclusive?

Dr. Koroshetz: No, I think that's fine. But I think the point of, you know, getting them engaged, and we've often discussed, you know, picking things that could turn into practice guidelines, that's a -- that would be a much --

Ms. Redwood: Yes.

Dr. Koroshetz: -- jump into the symptomatic

zone. It seems like we're going more to the pathogenesis zone, which is fine by me, if that's okay with the group.

Dr. Insel: So I would like to invite other people to talk about this. My only contribution here -- again, this is Tom -- is if we're going to down the etiology/pathogenesis subgroup route that we don't focus exclusively on autism, but that we bring in people who have worked this out in other areas.

Because I don't think at least the literature that I've read in this field that's clinical is strong enough yet to merit really a serious debate. I think most of it is it's all too positive. We need people who have really brought the rigor to this area in another disease entity and can tell us what it is that one would really need to do in order to provide compelling evidence. I'm not sure we have that yet.
Let me hear from other people who are on the workgroup.

Ms. Crandy: This is Jan Crandy. Is it possible that we can invite the doctor from the American Academy of Pediatricians because that could drive

them to go further once they hear what our group does say?

Dr. Insel: Sure. I think we could invite anybody we want. Yeah.

Ms. Crandy: And maybe that could drive them to do guidelines?

Dr. Koroshetz: Not going there, though.

Dr. Insel: Yeah, I think you've already heard they're probably unlikely to do that with the current evidence that's out there. I think the question really is who can bring to the table what the evidence level ought to be to support coming forward with a clinical guideline plan.

So we're not ready for that. But I think we could be ready to have the discussion about how one studies these systems in children at a very high level.

Other thoughts?

Dr. Burton-Hoyle: Yes, this is Sally. Is there not going to be any focus on the issues of adults? We've read -- I've read and listened to pretty compelling evidence about the issues with adults, and that's something that's seemingly dismissed. So what about that?

Dr. Insel: Yeah.

Ms. Redwood: I think a lot of these problems do extend into adulthood, Sally. I just don't think they're being acknowledged or investigated.

Dr. Burton-Hoyle: Well, but what about all the --

Ms. Redwood: And we don't know if some of those abnormalities may very well result in some of these other conditions like obesity, for instance.

Dr. Burton-Hoyle: What about this compelling data from Kaiser Permanente about the things, I mean, the things they know are the issues? The anxiety and the depression and the hypertension and that, you know, those things which are certainly things that are affecting and impacting quality of life, and it's adults who have been -- not had the same attention as children.

Dr. Koroshetz: Right.

Ms. Redwood: I guess, Sally, I'd probably just say that there's already guidelines in place for treatment of hypertension and depression and anxiety for everyone, regardless of whether or not they have a diagnosis of autism. So, to me, with

that, the problem seems more to be recognition in the autism community of those comorbidities versus needing treatment guidelines.

Dr. Koroshetz: So that's the tension between the symptomatic approach and the etiologic pathogenesis approach. So if we go to pathogenesis, we're not really co-occurring conditions. We're actually talking about contributions to autism from metabolic and immune dysfunction.

I mean, they're all good things. You know, the problem is we just have limited time. You have to do one thing at a time.

Dr. Anshu Batra: Susan, this is Anshu. I've been on the call listening, and I apologize for coming on late.

You know, I don't see how you can -- how you can separate out pathogenesis from the symptoms because, again, you know, as a pediatrician and I see these, you know, patients coming in with certain complaints, whether it's, you know, ASD symptoms or, you know, individuals with ASD with GI symptoms, you know, it's -- it's my job to sort of, you know, sort of piece it out and figure out,

you know, how to treat that patient, whether it's the symptoms or, you know, overall the ASD.

So I guess I'm not understanding, I mean, how we're going to be able to, you know, sort of parcellate them out. From my standpoint, I mean, I see these kids. I see these individuals, and my own son included. And there are -- they are co-occurring symptoms here.

And very often, you know, the autoimmune and the metabolic and the mitochondrial dysfunction is what, at least in our area, with the help of Richard Boles, who's at Children's Hospital in L.A., we've been able to identify kids who present with certain symptomatology and link it towards mitochondrial dysfunction.

And these individuals come in with ASD diagnoses plus other symptoms, and treatment of the mitochondrial dysfunction helps them function better, as well as improve their ASD symptoms. So I guess -- I guess I'm not understanding what the question is here. I mean, how -- you know, how can you separate these two?

I think from what I'm hearing from Lyn is really, you know, the need to have some guideline,

first of all, number one, you know, understand that these symptoms that the individuals with ASD commonly will have these other associated co-occurring conditions.

And then, as a pediatrician, I would want to know, you know, what do I do about them? How do I -- first of all, how do I identify them? And then what do I do with them to help the patient feel better, improve?

And so, which I know, you know, the AAP doesn't have that. The AAP does have the guidelines for ASD and ADHD. You know, there is the guidelines for ASD and constipation. But this is more than just that. So --

Dr. Cooper: This is Judith Cooper. If we're going to be focusing on co-occurring symptoms, I guess -- and it sounds like it may be -- sounds like the Association of Pediatrics thinks we're too premature at this point to be developing guidelines, I need somebody to say is there a reason to just focus on one of the co-occurring symptoms? Or would the Committee be criticized for saying, yes, this is a problem, but there are these other problems that, boy, it would be great

if we had guidelines?

And so, maybe it would be helpful to have -- I think somebody already suggested have somebody who either represents or has been involved in the development of guidelines for some other condition to come and speak about here's what it takes. And then -- then we would talk about what kind of research needs -- I mean, what kind of research agenda or issues do we need to address in these co-occurring symptoms to prepare us to develop the guidelines?

Or maybe, maybe the one we're talking about is the only co-occurring condition that doesn't have guidelines. And so, if the pediatric association thinks it's premature, it'd be great to hear what kinds of research would you need in order. That's something that would help me in trying to decide how this should be focused.

Dr. Kimbark: Hi. This is Donna Kimbark. I'm a little bit confused.

I think one of the things we really have to do, or maybe I just missed it with this whole thing, is what is the point of the Subcommittee itself? I didn't think we were going to put guidelines for

treatment or anything like that because we're not a medical body, per se.

So I think that in order to figure out how the scope of what we're trying to do is we have to know our end goal, our end story. What do we want to do? And what do we want to produce as a product and an outcome of this Subcommittee?

And then we can streamline it and get a better idea of what we should focus on, whether it be etiology or symptom management or what not. I think it's really important to have an idea of what our end goal is, you know, what the game is. Before we start, you know, get an idea of how to parse it down.

I think we're kind of lost in the quagmire of how complicated the entire question is.

Dr. Daniels: Donna, this is Susan. Listening to the conversation here, in terms of guidelines, this kind of a group would not be capable of putting together guidelines. That is a job for a medical body.

For this group, you can identify some of the issues. You can potentially put together research agenda ideas or something like that that would be

able to support something future in the area of guidelines. But at this point, if it's so premature, that's not -- the guidelines aren't going to be forthcoming anytime soon. So the research would need to be done, and that might take several years.

But you could put together some ideas in terms of what types of research are needed.

Dr. Kimbark: I agree. So, I mean, if we're working as a group on co-occurring conditions, I know that the DoD, one of the things that we put out in our program announcements that are out right now is that we want studies on co-occurring conditions, and that includes all of the co-occurring conditions that are within the ASD.

And so, I think it's important that we focus more on that rather than, you know, the -- something that's beyond our scope.

Ms. Singer: So this is Alison. I just -- I wanted to ask about the timing. At IMFAR, Lisa Croen presented very compelling data that quantified the magnitude of some of these psychiatric comorbidities. Do we have this data for some of these other physical comorbidities?

Like, do we have The Lewin Group data yet? Because I know that was one of the tasks for The Lewin Group. Do we have that yet?

Dr. Insel: Yeah, this is Tom. We do have the data on comorbidities across a range of medical diagnostics. Now that's in -- that's in children, not in adults. And I think the numbers are in that 35,000 range in terms of the number of kids that recover by the health plan with a primary diagnosis of ASD.

Ms. Redwood: One of the problems with that, though, that I just want to point out is that what we're hearing from parents over and over and over again is that a lot of these underlying issues, especially involving metabolic or immune, are not being recognized. And therefore, you're not going to have a diagnostic code in the medical record that The Lewin Group would be able to data mine.

I think Anshu said that a few minutes ago that, you know, clinicians are just now starting to recognize some of the symptoms of these subtle mitochondrial abnormalities, whether it's low muscle tone and things like that. So maybe even developing just a questionnaire that clinicians

can use to be able to even have on their radar screen some of these other issues.

But I don't think relying on these large databases that are just administrative, basically billing records for the insurance companies, is going to really pick up on these types of disorders because they're under recognized.

Dr. Insel: Yeah, I guess I see your point, Lyn. I think if people have come in for care, there will be something that can be pulled out, even if there isn't a mitochondrial disorder.

Actually, that raises an interesting question, which I don't know the answer to. Walter, you may know. In children that have a bona fide mitochondrial illness where it's been diagnosed and documented, is there a high rate of autism, or did they show other kinds of behavioral abnormalities?

Dr. Koroshetz: You know, there's different types of mitochondrial disorders. There's a small subset that have definitely been linked to autistic symptoms. The majority -- you know, there's a muscle group, you know, that seem perfectly normal except the muscles are weak.

There's another group that affects the brain stem, and some that affect the eye.

So it's a very heterogeneous population. But I think a clear subset definitely had autistic features.

Dr. Batra: Yeah, Tom, this is Anshu. Yeah, I don't think that anyone has published that data that you're describing. But again, you know, clinically, that's what we're seeing out in the community is these -- because now we're understanding that there is this association.

And again, it might actually help, as we're thinking about bringing experts on to help us work through this and get a better awareness. You know, in Los Angeles, Richard Boles, who is a geneticist and mitochondrial expert at Children's in L.A., has really helped our group and the other physicians in our area to have greater awareness and understanding of how -- you know, what are the symptoms, and then how do we work them up and see -- and what we're finding is, yes, there is a subgroup.

I can't give you a number in terms of percentage of, you know, mitochondrial

dysfunction. I mean, over the last 5 years in my practice, I am seeing more and more of it. I would say, you know, at least -- at least 10 percent. Again, that number might be -- I might be under shooting here.

And these kids present either with -- they come in with a diagnosis of ASD already or ASD-like symptoms or, again, because we have someone in our area that is focused on this and has given us better understanding and guidelines locally, it's the individuals who come in with some tone issues. You know lower tone than usual. Fading in and out of behavioral patterns. Skills that are waxing and waning, which it doesn't make sense, you know?

Ms. Singer: So, Anshu, this is Alison. I'm just curious. When you see that in your practice --

Dr. Batra: Yes?

Ms. Singer: -- do you note it in the medical record?

Dr. Batra: I note it in my chart. But you know, as Lyn said, there really is not any -- any coding for me to, you know, to use because, you

know, there isn't. So I would use ASD, or I would use, you know, some other diagnostic code.

And so, again, a group that's using, you know, chart review and coding review as a way to identify, you know, percentages of diseases, I don't think it's going to reflect it accurately.

So --

Dr. Insel: So we did have this earlier meeting on just this topic, on mitochondrial dysfunction/disorder and ASD and that we circulated that report. And now that was 4 or 5 years ago, and it may be that science has advanced enormously since then.

My guess about this, though, is that the same conclusion that we had then would be the conclusion we'd have now, which is that there are these hints that there is a relationship. But it's very difficult to rule out mitochondrial dysfunction in the kinds of symptoms or the kinds of tests that people are using now. Like signs of oxidative stress are proving positive. In virtually every CNS disorder anybody wants to look at, you can find evidence for that.

It's hard to know what would be specific about

autism in that respect, and it would be hard to know how you would ever convincingly falsify the hypothesis that there's a mitochondrial dysfunction in this disorder or that you could show that it was part of an etiology.

And maybe something has changed in the last 3 or 4 years, but that's where we were when we brought the experts together to try to answer this question. Now I should add I'm not sure --

Dr. Batra: Well, I do think a lot --

Dr. Insel: Let me finish because I think that's not the same as saying that it's not worth studying inflammation or other mechanisms. I think as we -- you know, we're talking about at least three different topics -- mitochondria, metabolic disorder, inflammation -- and those don't necessarily overlap. They could, but they don't have to.

Ms. Redwood: Tom, this is Lyn. Just back to the comment about the mitochondrial workshop. I think was that in 2006? I mean, that -- or maybe 2008? That's been like 6 years ago, and I do think the science has advanced in that area and that what they're seeing in the children with autism is

not your purely genetic type of mitochondrial disorder, and it's more a milder, subtle mitochondrial dysfunction.

And some of the markers that they're looking at, I can send these to you, there's been -- I think that Richard Frye and also Dan Rossignol have been the people who have been doing the most research in this area in terms of the markers that they see that are abnormal. And it's not the oxidative stress markers. It's more the energy-producing markers.

So I can send some of that research to you. I just can't cite it off the top of my head, but there are things that are --

Dr. Insel: There was a paper -- yeah, a paper just out on this. So there's an actually very nice paper looking at lactate twins, lactate species in the brains with neuroimaging done at Columbia, which showed -- does look like it's increased in kids with ASD.

But again, the question I keep coming back to is there anything specific to ASD here? Because we've seen so many reports like this in other areas.

Dr. Dawson: So this, I know we're coming to -- did we have an hour? Is that what we have today?

Dr. Daniels: We did set it up for an hour, but if you --

Dr. Insel: I have to leave at noon.

Dr. Daniels: Okay.

Dr. Dawson: Yeah, so I just wanted to throw, you know, a suggestion on the table that we either have a workshop that really brings in scientists that are understanding the role of the immune system in autism or other in terms of the developing brain that is focused more on the etiological and mechanisms that might underlie some immune factor in autism, where we would bring not only autism folks in, but folks from outside autism.

And then the other suggestion would be to have more of a clinical focus where it's more -- there's been quite a bit of large-scale studies on the natural course and prevalence of medical comorbidities in autism, and so we would bring in people like the Lisa Croen and perhaps have presentations from the Lewin project and others where -- and there's some very interesting work

that's coming out on, you know, early development, and it's also adults.

So more of a clinically focused on the epidemiology and nature and life course of these medical comorbidities in autism because I think those are two areas where we'd have enough literature and scientists to actually have a meaningful workshop.

So I'm just throwing out a couple suggestions.

Dr. Koroshetz: That's how I thought of it, one of those two. So do you want to do poll right now?

Dr. Insel: Other, other ideas here? I mean, is that -- what I'm really looking for is consensus from this Planning Group because I thought that we had that, and then it fell apart in the emails after the last meeting.

Dr. Daniels: Right. We haven't heard from a number of folks that seemed to have really different ideas on the email, unless that has kind of changed and people are more onboard with this idea now.

[Pause]

I think some of the other folks that had other ideas were Matt Carey and Donna Kimbark, Sally.

There may be some others, but do you all feel that this is coalescing for you in this direction?

Dr. Koroshetz: I think we got to make it tight --

Dr. Carey: This is Matt. Can you guys hear me? Hello?

Dr. Daniels: Yes.

Dr. Carey: I'm going with Sally on this one. I mean, I think we -- I think we moved into the granularity of this very quickly without actually answering our initial question, which is we've got a huge number of comorbid -- you know, co-occurring conditions. We picked three, leaving behind more than we know.

Whether the ones we picked are underdiagnosed or not, we know these other ones are very prevalent within this community, and we're just -- we're just walking right past them. And I think that's a mistake, quite frankly.

I think, if nothing else, we have to sort of look at this -- I mean, even though we are sunsetting, we have to sort of look at this as an ongoing project, not the co-occurring conditions meeting, but the first of, hopefully, a series of

these.

So when we go forward, you know, maybe we'll do one on these three. Maybe one or two of these three. And then, hopefully, keep moving with the idea that we will come back to some of these others.

I don't think we have the time to do all co-occurring conditions, but we have to acknowledge the fact that there are these very prevalent and very serious co-occurring conditions that are not really being addressed here.

And then if I could add one small thing, if we go on with immune dysfunction, I'll send the abstract out from Carlos Pardo at IMFAR. He had a very interesting abstract saying basically immune dysfunction is not pathogenic in autism. So, again, that would be, you know, a very -- I think that shows that this is not an area that's gelled yet. We're not really at a -- you know, we are still developing ideas. There are still very different ideas out there.

And I think bringing him in would be very interesting, considering I think he's the only person I've heard say that so far.

Dr. Kimbark: This is Donna Kimbark. I have to agree completely with what was just said.

[Pause]

Dr. Batra: So, Susan, this is Anshu. Can you -- can you review what's on the table right now in terms of, you know, what -- what the focus for this group --

Dr. Daniels: The goal of the call was to try to develop a focus for the group. We did talk about a focus at the last IACC meeting, and we were talking about doing something on immune and metabolic conditions, and it sounded like there was consensus because nobody really disagreed at the IACC meeting.

But then afterward, via email, a lot of people came forward with other ideas of -- you know, I mean, there are a lot of different co-occurring conditions that are important to a lot of people, and so people raised concerns about focusing exclusively on one set. And so, we came back to this call to try to get some of those ideas on the table and talk about whether we can choose to focus on something.

And it sounds like right now there are two

proposals that are here, either to work more closely on the neuroimmune and metabolic conditions and related to etiology and symptoms, or to do something more generalized on the prevalence of a variety of different comorbidities in the population and look at epidemiology, the life course, and bring together experts that have looked at a number of different comorbidity areas.

That's what I heard.

Ms. Redwood: Could we not do both of those?

Ms. Singer: [Inaudible comment] look more deeply at the data that Lisa found.

Ms. Crandy: This is Jan Crandy.

Dr. Daniels: Sorry. We couldn't hear. There were a number of people talking at the same time.

Alison, what did you just say?

Ms. Singer: I was saying that I thought there was also a third option that was raised, which was to try to dig deeper at some of the data that Lisa Croen presented at IMFAR, which was focused on she really quantified the magnitude of some of the psychiatric comorbidities, and I think a number of us were really shocked at things like the high suicide rate and the prevalence of anxiety and

depression.

And now we have good data there. So that was, I think, raised as a third possibility.

Dr. Daniels: Okay. I had thought that was maybe part of the second one. But anyway, go ahead.

Ms. Crandy: This is Jan Crandy. I like the idea of a series, if we could plan -- and I know this Committee is not reauthorized yet. But if we had the mindset that this would be the first one of a series that addressed all the different ones.

Dr. Insel: So I think with the timeframe that we have left with the current Committee, and we can't assume there will be a reauthorization, we can't really plan a series.

But what I'm hearing is a little bit different from where we started. It sounds like people would like or where the consensus seems to be is to have a more general meeting around co-occurring conditions broadly writ, which could include a range of things, including immune, metabolic, mitochondrial disorders.

I do think the group would be missing out if it didn't hear some of what's going on in the

world of inflammation and brain development. It's just too exciting to not put in front of the IACC and to suggest that this is an area for renewed interest and for focus with a strategic plan.

Part of what we want the IACC to do is to highlight areas that are breaking quickly and that are giving us new insight, even if they're not yet directly being studied for autism. And this is an area that really is moving very fast. So it'd be wonderful to be able to include that in terms of basic mechanisms.

Ms. Redwood: Tom, this is Lyn. One of the things that I'm having a difficult time with, and I understand that all of these other comorbidities are incredibly important, but that the ones that I'm hearing already have diagnostic codes. They already have appropriate treatment guidelines.

You know, for example, suicide and depression and anxiety and obesity and hypertension. And if we're wanting to focus on the things that are, you know, late-breaking and new insights, you know, we already have this data that's been presented by Lisa Croen at an international meeting. To me, regurgitating that over again doesn't really move

the ball forward the way it needs to.

So that those are my concerns about, you know, focusing on these broader comorbidities, maybe even separate out the ones that we don't have treatment guidelines for or have it be a focus on the recognition, you know, clinical recognition of some of these comorbidities. But, to me, they should be diagnosed and treated, you know, automatically if you have an astute healthcare provider.

Dr. Batra: This is Anshu. I have to -- you know, I have to say that that's what I need as a clinician in the community, and I know that's what parents are asking for. You know, the issues around -- I mean, there are, I think, countless co-occurring conditions that we haven't even mentioned here today that people are suffering through.

And I think the issue here is to, number one, validate and, you know, support the fact that, yes, there are co-occurring conditions because very often, you know, my -- pediatricians that I work with, that call me for -- to either send me a referral or ask me, you know, what to do with

their child with autism, they very often aren't even aware that there are co-occurring conditions associated with ASD.

And you know, what we need in the community is, again, you know, that affirmation, that validation, and then some guidance in terms of, you know, how do we recognize something clinically, you know? If a child comes in with this clinical pattern that, yes, we should be considering ASD, but also there are some associated -- some associations with ASD, such as mitochondrial disorders and autoimmune issues.

And you know, not to say -- I think everything is cutting edge right now, clearly. And so, I don't think that we should limit ourselves or prevent ourselves from moving forward on this because we don't have enough data because, you know, we don't. That's the problem.

And I think the focus, you know, should be that, well, we need -- you know, we need more research in this area, and that way, you know, at least from my standpoint, you know, in the community, parents who come to me every day, patients that I see every day that I struggle

with, what do I do about this?

And so, you know, I would like some movement forward in this in terms of, you know, just clinically recognizing these co-occurring symptoms. And I agree, I think the issues around suicide and mental health issues, you know, I think that there have been some -- I think that that's a little bit more recognized and partly because there may be a little bit more research associated with it.

But in the other things that we've mentioned here today, there isn't. There just isn't much on it because very often it can be subtle. And, but I think that's the important thing to also recognize is that it is subtle and that we should be aware of it and that it's a spectrum, just like ASD is.

So --

Dr. Daniels: Okay, well, I think -- this is Susan. We're running out of time. Is there anyone else that has a really important comment to make before we try to close?

[No response]

So I've heard a number of different ideas on this call, and once again, it just sounds like

there's really not consensus around exactly what we need to do. So I'm going to propose that I send out a list of some of the ideas that I've heard on this call today and that we try to have another call in the next few weeks to try to finally nail down a direction for the group.

Does that sound agreeable?

Ms. Redwood: Yes. Susan, that just keeps extending it longer and longer. I mean --

Dr. Daniels: The problem is that there was no consensus here. There isn't any consensus about what the direction is. I mean, we've heard really different ideas.

Ms. Redwood: But I don't know that 2 weeks is going to actually change that. And then I was reading through the minutes, and you actually said in the minutes, if we don't have something on the books by the end of May, it's not going to happen.

So I'm just -- I'm really concerned that we're running the clock out. And by again postponing the decision in terms of what we're going to focus on, it's just -- you know, it won't happen.

Dr. Kimbark: Susan?

Dr. Daniels: Yes?

Dr. Kimbark: This is Donna Kimbark. I would defer my -- my reservations on this completely as long as we acknowledge with whatever we put out that we are narrowing our focus and that there are other co-occurring conditions, but this team was only working on, you know, what conditions that we picked out here, and that's it.

I realize that there's no way that we could do just all of the co-occurring conditions, and as well at this point in time, we can't tell whether or not we're going to be renewed.

So I just want that acknowledgment, and then I would defer everything else.

Dr. Daniels: Right. Well, there never was a specific charge that this group was in charge of trying to unravel everything about every single co-occurring condition by September 30th. So I don't think there's a necessity to put out a statement about that.

We -- this group can really focus on any area within the umbrella of comorbidities that they'd like to, and so is there consensus to work around the immune and metabolic type conditions? Or do people --

Ms. Redwood: I don't feel that --

Dr. Daniels: -- still have concerns about wanting to work on psychiatric conditions or something else?

Ms. Singer: I mean, just because we want to work on psychiatric doesn't mean we don't also want to work on the metabolic and immune. So, you know, I think just because people raised other issues doesn't mean that we couldn't achieve consensus on this.

Dr. Daniels: So we need to focus on really a more narrow set probably, unless we're going to do something generalized on all the co-occurring conditions, as one of these ideas that Geri put forward to look at a clinical focus and prevalence and so forth across a number of different co-occurring conditions.

That could be a broad focus, or we could focus down on one of the areas and go into depth. So what does the group think that it would like to do?

[Pause]

Dr. Batra: This is Anshu. I'd like the metabolic and immune issues that are seen in ASD.

Ms. Redwood: And this is Lyn. I agree.

Dr. Burton-Hoyle: And this is Sally. I don't agree because I don't think that just because information has been conveyed at IMFAR that it would be regurgitating because the community at large and even the data indicated the medical community doesn't understand. And they are not even asking colleagues about -- you know, at very, very low rates, they're asking colleagues about potentially coexisting disorders with an individual or even if it's autism.

So I don't think the information, you know, from IMFAR is common knowledge, and I think for it to be focused on more specifically I don't think would be a waste of time.

Ms. Redwood: Would having a workshop on it, though, as part of an IACC meeting be able to get that information, though, widely distributed the way it needs to be?

Dr. Burton-Hoyle: No. But it would be a beginning, and I think that people don't understand. And I think that if you had an adult in your life that was suffering from obesity and all these other things, and the anxiety and the

depression and how everything snowballs, I think you'd think differently.

Dr. Daniels: So can we say that maybe there are two ideas, talking about clinical recognition of various co-occurring conditions, the ones that especially are not so well recognized now, or focusing on something with neuroimmune issues and etiology?

Those seem like pretty different ideas to me.

Ms. Redwood: Yes.

Dr. Daniels: So then within the group, with this idea about doing something with clinical recognition of currently rather unrecognized co-occurring conditions, would that be a path that everyone could agree to or most?

[Pause]

Or do we still need to keep these two options on the table and defer?

Ms. Singer: Could you say again what you said, Susan?

Dr. Daniels: So we could do some sort of a workshop on clinical recognition of currently less well-recognized co-occurring conditions that would be a little bit broader in focus and could include

a number of different conditions, and it could include immune conditions as well as other kinds of conditions and talking about what we can do in the community to try to get these better recognized and what types of research might be needed to support better understanding of these conditions.

Or we could have a workshop that really focused specifically on neuroimmune/metabolic type conditions in people with autism and bring in some of those outside experts that Dr. Insel talked about, people from other disease areas that have worked on those types of conditions in other CNS disorders.

So between those two options, should we try to see if we can get a count here for who would support which one? So we'll call one the broad clinical recognition workshop and one will be the neuroimmune workshop.

So if I go down the list, Lyn, you would support the neuroimmune or --

Ms. Redwood: Yeah. I mean, Susan, yeah, I would. But I also, you know, agree with what Sally said. The other issues are hugely important, too,

and you know, I wish we could do both.

Dr. Daniels: There's not going to be enough time between now and September 30th to do two things. So we need to -- we need to make a decision about what we're focusing on. So, between those two options?

Ms. Redwood: I would go for the metabolic and immune, just because I do think that they're completely under recognized and that they can feed into a lot of these other abnormalities that may very well be downstream from those.

Dr. Daniels: Okay. Anshu? It's a little bit awkward trying to do this on the phone, but since I can't see you to see hands raised or tell who it is if you're just saying "yes." Anshu, which of those two ideas?

Dr. Batra: I think -- yeah, I have to -- I would love both. But again, as I think about sort of what the needs are and, you know, to cover all populations involved here. I mean, I think with number one we would be able to sort of accomplish some parts of number two, as you've mentioned. So I will say I'll vote for number one.

Dr. Daniels: Okay. Sally?

Dr. Burton-Hoyle: If number one is the broad category, then I vote for number one.

Dr. Daniels: Okay. Matt?

Dr. Carey: I would go with making it more broad.

Dr. Daniels: Okay. Judith?

Dr. Cooper: Yes. I go for the broader approach.

Dr. Daniels: Okay. Jan Crandy? Jan, are you with us? Sorry, we can't hear you well.

Jan, number one or number two? I'll come back to you.

Geri, what are your thoughts? Do you prefer the broad workshop or the neuroimmune-focused workshop? Geri?

[No response]

Okay. Geri seems to have left the call. Alice, are you still there?

Dr. Kau: Yes. I will vote for the metabolic and neuroimmune workshop.

Dr. Daniels: Okay.

Dr. Kau: It's very difficult to decide, but that's the one I'll vote for.

Dr. Daniels: Okay. Donna?

Dr. Kimbark: Broader, please.

Dr. Daniels: Okay. Walter?

[No response]

Walter might have left the call. Alison?

Ms. Singer: I'm going to vote for the neuroimmune.

Dr. Daniels: Okay. Is Hae Young on the phone?

Ms. Park: Yes, this is my first call, and I'm really filling in for Laura. You know, I'm not sure that I really should vote for one, but just based on HRSA's investments in the autism intervention research work on physical health and their ongoing efforts on addressing the more clinical, you know, and their feeling that there is an ongoing need in addressing those needs of the families, you know, if you would like to include my vote, I would vote for the first one.

Thank you.

Dr. Daniels: Okay. So right now, we have one, two, three, four, five, six for number one. We've got three for number two, and we have four people that are not -- unless, Geri, are you there? Jan?

[No response]

So it's -- by a vote, I can't really tell

right now. I would need to follow up by email, if that's okay, to try to get the rest of it. But then, once we have a decision on either way, we could work via email and probably scheduling another call to talk about who to invite to such a workshop and also trying to find a date.

Okay. So I think that's where we'll need to leave it for now because there weren't quite all of the people left on the call to complete this.

But I will follow up by email, and we will schedule our next time to talk.

Thanks, everyone, for being here.

Bye-bye. Thanks.

[Whereupon, at 12:20 p.m., the Planning Group adjourned]