

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTERAGENCY AUTISM COORDINATING COMMITTEE

SUBCOMMITTEE FOR
SERVICES RESEARCH
AND POLICY

STRATEGIC PLAN QUESTION 5 and 6 PLANNING
GROUP FOR SUBGROUP COMPARATIVE-EFFECTIVENESS
RESEARCH AND PATIENT-CENTERED OUTCOMES
RESEARCH (CER-POR)

CONFERENCE CALL

THURSDAY, OCTOBER 4, 2012

The Planning Group convened via teleconference, Denise Dougherty, *Co-Chair*, presiding.

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PROCEEDINGS:

Ms. Gemma Weiblinger: Thank you very much. Hello, everyone. As the operator said, my name is Gemma Weiblinger, and I am temporarily acting as the designated Federal official for Dr. Susan Daniels, who is currently out on maternity leave.

Welcome to the IACC's conference call to discuss the update of Questions 5 and 6 in the IACC Strategic Plan. This team will particularly focus on comparative effectiveness research and patient-centered outcomes research. So now I'll turn the meeting over to Dr. Denise Dougherty, who will lead the discussion.

Dr. Denise Dougherty: Thank you very much, Gemma. And thank you all for being on the call. And my understanding is we have Dr. Lisa Simpson, Dr. Tristram Smith, and Jan Crandy. And Lisa and Tristram are our experts on our call. And Jan is a member of the Services Research and Policy Subcommittee.

And there are other members of that Subcommittee who are working on this subtopic who are not able to join the call. And that would be Idil Abdull and David Mandell.

And also, another member who is an expert may or may not be able to join us during the hour, and that is Zachary Warren from Vanderbilt University. So, just let me give you a little background. And Elizabeth Baden, who is also on the call, she works with Gemma from OARC - a little bit of background. They can jump in if I get something wrong.

Our group here is a group that has the task of coming up with some answers to two questions: what have we learned in the past 18 months that's critically important and what do we need to know to develop a research agenda.

So this comparative-effectiveness research, patient-centered outcomes research group is one of five subgroups of the Services Research and Policy Subcommittee of

the Interagency Autism Coordinating Committee that is run out of NIH, NIMH specifically. And we can get you more information on the makeup of that group.

So the Services Research and Policy Subcommittee, one level up - well, which is a sub of the IACC is one of two subcommittees that is working to develop the IACC 2012 Strategic Plan for Autism Spectrum Disorder Research. So that Plan is due to Congress at the end of December this year, 2012.

The Committee actually came together at the end of July. So the OARC staff and the Committee and Subcommittee members have been working on this effort to come up with the 2012 Strategic Plan since the beginning of August. So I know that you're feeling rushed if you looked at the timeline we gave you. I just want to put us rushing you into that context.

So, Gemma or Elizabeth, perhaps you could explain what the Strategic Plan for 2012 is designed to do. And then it's going

to be a limited effort is my understanding. You can explain that. And then there will be another opportunity in 2013 for the 2013 Strategic Plan to be more expansive about research recommendations. Do I have that right?

Dr. Elizabeth Baden: You do. This is Elizabeth. And while I'm thinking of it, whenever you speak on the call, if you could just identify yourself so that we can know who is talking that would be great.

And Denise, you're exactly right. The 2012 Strategic Plan is going to be in the form of an addendum, which if you look at the 2011 version of the Strategic Plan, you will see at the end of each chapter is a specific 2011 addendum. And so this is designed to be modeled after those, the ends of those chapters.

And as you said, it addresses basically the two questions of what have we learned since the last Strategic Plan, since about January of 2011, and then what are the

remaining research gap areas.

Dr. Dougherty: Right.

Ms. Weiblinger: And I would just add to that that, since this is very time limited, just to remind everyone that there will be a more comprehensive look at the Strategic Plan in 2013. This is, as Elizabeth said, an addendum. And so it will be brief, very brief.

Dr. Dougherty: Great. So are there any questions on that? I just wanted to set that context before we actually do introductions so that you can understand who you all are and how we'll be working together.

Dr. Lisa Simpson: This is Lisa Simpson. I had a question about - you mentioned that the SRP is one of two Subcommittees of the IACC. I was interested in what the other Subcommittee was charged with.

Dr. Dougherty: Sure. That's the Biomedical and Translational Research Subcommittee. So they have Questions 1 through 4 in the 2011 Strategic Plan.

So we can go through, march through if you want, what those questions are and which our group is addressing and which the other group is addressing if you'd like.

Dr. Tristram Smith: I think that would be helpful to me.

Dr. Simpson: Yes; it would be extremely helpful. And I have to admit - is there a document other than the draft? I missed the Strategic Plan. I have the CER-specific document that was sent.

Dr. Dougherty: There was - under that document, there was a reference to something online, but I certainly don't expect anybody to have had a chance to absorb that at this point.

Dr. Simpson: Ah yes, I just pulled it up. Okay.

Dr. Baden: This is Elizabeth. We can send around a link to the Strategic Plan.

Dr. Simpson: I have it. It was in the -

Dr. Baden: Okay.

Dr. Dougherty: I sent it, Elizabeth.

Dr. Baden: Okay, great.

Dr. Simpson: I just pulled it up. I have it in front of me now.

Dr. Dougherty: Yes. I just sent it yesterday or something, so -

Okay, so the Biomedical and Translational Research group, which actually used to be the group that was most focused on research questions, covers the following questions, just broadly: Question 1, when should I be concerned? That's about the symptomatology of autism spectrum disorders. Question 2, how can I understand what is happening? Question 3 is what caused this to happen and can it be prevented? Question 4 is which treatments and interventions will help? So those are the questions for the BTR Subcommittee.

Our questions, we're kind of - David and I and with the permission of Tom Insel who is both the Chair of the IACC and the Co-Chair of the Biomedical and Translational Research group have actually modified our questions a

little bit, though we're going to try to insert these as addenda under these question labels because of the time limitations we have.

So our questions we have then: Question 5 is where can I turn for services? And Question 6 is what does the future hold, particularly for adults? So, those are not - well - nothing is obviously a research question here.

But what we are trying to do in this Subcommittee with our five different topics - and I can tell you what those are - is to combine those two questions at this point and focus both on children and adults. Because the way it's turned out, Question 5 tended to be mostly about children with autism spectrum disorders, and Question 6 was about the transitional issue and adult services. So, you got that so far?

So we have - in order to try to address both those questions for children and adults with a reasonable number of subtopics related

to services research and policy - we have divided our Subcommittee into five different topic-specific groups.

The first is access and coverage; second is quality of care; third is education and employment; fourth is family support; and our task-specific group is comparative-effectiveness research/patient-centered outcomes research.

So, are there any questions about how this is organized? We should probably send you an organizational chart - send everybody in all these groups an organizational chart at some point.

Dr. Smith: Yes; I think that would be helpful. This is Tris. Just because it is difficult to tease out those questions from, for example, topic 4 in the Strategic Plan. So, just to make sure we know what our purview is.

Dr. Simpson: Yes. I would just add to that, it sort of seems like, given that we're focused on CER/PCOR, Question 4 seems the

most close to what we're tasked with.

Dr. Dougherty: So this is Denise. And actually David and I had this conversation about what we should focus on in terms of CER/PCOR. And the big question that I actually included in this very drafty thing I sent out is should we focus on clinical CER/PCOR questions or delivery system questions. So that's really the question, right? Because the BTR group for Question 4 is likely to focus on the clinical questions.

So, David's recommendation -

Dr. Simpson: But they might focus on clinical questions sort of, you know, more upstream and not the sort of T2/T3 questions.

Ms. Jan Crandy: This is Jan Crandy. I think there would be some crossover, especially in the delivery.

Dr. Dougherty: Yes. This is Denise. And well, what David's thought was, and we can have this discussion, you know: Where is the boundary between the upstream questions and the CER-type questions? Because for the - his

view is that for a clinical CER question, you need a topic, a clinical topic or an intervention that is very - not circumscribed - but very clearly defined.

And to make it a - given the tools we have today to do CER for clinical research that you can't have an intervention - that is something like what's typical of many of the autism interventions that is highly variable in its implementation.

So if you wanted to look at a registry, for example, and see what interventions a child got and then link that to the outcomes - or an adult got - and then link that to outcomes, you may be looking at something that was designated as ABA or Floortime or something else, but you really wouldn't know what that intervention consisted of. We don't have that information yet. So that it would be very difficult to do CER on the clinical questions.

So that's where we were as of yesterday when we had this conversation, actually. So

it might be good to hear from others about this boundary - not that we can't have overlap with Question 4 - and if we come up with great clinical questions, they could either go under Question 4 or under Question 5 or 6 depending on the population.

Ms. Crandy: This is Jan Crandy. Could we be looking at community provider outcomes versus clinic outcomes versus a Medicaid outcome - kids that are getting services through those entities.

Dr. Dougherty: This is Denise. We could, but I think David's argument would be that we'd be looking at the outcome in relationship to a highly variable - variably defined intervention. So, if you were looking at, you know, sort of comparing different state Medicaid programs and how they do in outcomes related to the interventions that they support, you really wouldn't have a firm definition of what the interventions are - so that comparing the outcomes across the states or different community settings would be

difficult.

That's why we have you experts and - I think there's no clear answer with CER/PCOR. People are still defining it.

Dr. Smith: This is Tris. Just to state it in different language and see if it still sounds right: So, for Question 4, it's largely university-based efficacy trials around specific interventions. And for us, it might be more community-based effectiveness trials or pragmatic trials or observational studies, maybe including ongoing services rather than - and not just interventions that have a discrete starting and stopping time. Does that kind of capture it?

Dr. Dougherty: Well, I think based on what David was saying, and I see his point, even that might be difficult. So I guess - this is Denise - I was thinking of questions for CER/patient-centered outcomes research might be more around the organization of services and their delivery, for example, comparing different approaches to the

transition from adolescence to adulthood with autism. What has the better outcome? So they would be more services questions than - even though services, of course, includes the clinical components - they'd be more services questions.

So Lisa, do you want to try and jump in here and explain how you see the difference between the clinical and the service delivery questions?

Dr. Simpson: Sure. And I think that there is definitely crossover as somebody earlier said. I guess it's - one way that I think about it is not, you know, the question of what works in terms of outcomes and effectiveness, and comparative effectiveness of this approach versus that approach is sort of more the clinical question. And all kinds of pragmatic trials and designs can be implemented to answer that question of what works for which patients, you know, under what conditions.

But then there are more services

questions around how do you implement an effective intervention for a broad population in the delivery system. Or how might you deploy your workforce to identify, manage, and refer these children effectively and look at different models of workforce deployment.

Particularly in rural areas, you might ask questions around access to specialty care and the role of telehealth platforms, which I know, are being used increasingly with psychiatric services. So, that's what comes to mind off the top of my head.

Ms. Crandy: Another one that comes to my mind - this is Jan Crandy - is looking at those kids that are on waiting lists. There are some states that are implementing different services to do while a child's on a waiting list for direct treatment. Are there studies out there that look at that and what happens to those kids while they're on the waiting list?

Dr. Simpson: Different models of how to organize, you know, how to integrate the

patient-centered medical home with adequate screening and developmental and referral services and a system of care.

One question I have, Denise, is to what extent are questions of payment reform and payment design within scope, since PCOR had to walk completely away from that?

Dr. Dougherty: That's an excellent question.

Dr. Simpson: This would be an opportunity - if the IACC is not precluded, obviously - the extent to which services are covered in benefits and the level at which they are reimbursed to the provider, and how much copay and financial risk the families are exposed to - are all going to drive the utilization of services.

Dr. Dougherty: Yes. That may come out of the access and coverage group - but potentially not. I think these are - these are questions - and Jan can weigh in here - that are really in the forefront of the minds of people whose family members have autism.

Ms. Crandy: We definitely - because I am on the access committee - and we definitely will be addressing that because that's a huge problem - is being able to - the barriers to even getting your insurance coverage when you have insurance coverage. There are so many barriers to actually getting services.

Dr. Dougherty: So will you be comparing them, Jan - different payment approaches? And even if they're hypothetical payment approaches and their potential impact on service utilization, quality, and outcomes?

Ms. Crandy: Yes. And even the increase in cost to treatment once - insurance billing in our state has, is actually increasing the cost of treatment because of the cost of going through an insurance company. It's interesting how that's changing.

But I think that we do need to look at in this Committee comparing community-based services. And I know one of our other members that's not on here, and it's a strong concern of mine too is the Medicaid outcomes. Because

most of the Medicaid programs are not even covering ABA, and that has the most research behind it. So what are the outcomes of kids that can't have any - that have no other resources except for Medicaid?

I don't know, Tristram, what kind of research you've seen out there for those long-term outcomes for kids that are Medicaid kids.

Dr. Smith: Well, I think there are - yes, there's not that much. And I think there are some interesting questions with insurance legislation coming in. For example, you know what is covered through Medicaid or public schools versus insurance. So those may be - it sounds like those may be topics that we'd want to summarize the current state of the art and science and give some recommendations.

Ms. Crandy: And I think that needs to be some of the questions that come out of this group, as what questions do we still need answered that we don't have in research as of

today. Because we do need that comparative look.

Dr. Dougherty: So could a question in this area then - and it probably doesn't matter at this point whether there's overlap between us and access and coverage because it'll all be put into one addendum anyway - you know, whether different states' approaches to the essential health benefits make a difference as a research agenda item.

Ms. Crandy: And I will tell you, that's a huge problem in our state. I've been going to those meetings, and we have an autism insurance mandate which we had a cap. So they want to remove the cap. We also put in our bill you can't limit the number of visits, but they want to look at making it equal to what the cap was and trying to define what that number of visits is. We really need comparative studies on the intensity of hours; those kind of things need to be done.

And comparative for different models of treatment, too. That argument comes up over

and over again about - between ABA, Floortime, Denver model. They actually need to do comparative studies pairing all those against each other so that we can really see what's the better outcome, where should the money be going.

Dr. Dougherty: Okay. Well, I think we've really gotten started on our charge here.

Dr. Simpson: Right.

Dr. Dougherty: So, maybe we can step back and you know - go forward, actually. What we were thinking of as our next step - because this is a brief call - what we were - now that we've had this kind of discussion - is to have each of you come up with what you know about that first question: What do we know based on research from the last 18 months or approximately. And not every piece of research, but you know, key items. What do we know about some of these questions and then what else do we need to know?

My own personal opinion, and you can all weigh in here, is that I think this group in

particular is going to be very heavy on the what do we need to know using CER and PCOR. Since, if we're focusing on the health care delivery issues as opposed to comparing different clinical interventions, that there won't be a lot of that kind of knowledge available at this point. So most of it will be in a future research agenda. But that's not to stop anybody if they know of something to actually add that to that part of the two sets, the two questions.

Ms. Crandy: This is Jan Crandy. Too, another thing is looking at what - because every state is doing it different. Some states are offering slot programs, Medicaid waivers. Some are taking funds out of general funds to pay for treatment. What treatments are available in states and how is that looking, too. What services, you know.

Dr. Dougherty: Okay.

Dr. Smith: I'm going to have to go in a minute.

Dr. Dougherty: Oh, is this Tris? Is that

Tris?

Dr. Smith: Yes.

Dr. Dougherty: Okay. Well, let me just cut to the chase here. What - everybody sent their time of their availability for calls next week. Unfortunately, most people are available on Tuesday, October 9, which is only basically one working day from today.

So what we were originally planning to do is have each of you come up with your own sets of questions and then we would get them out to everybody and discuss them on the October 9 call before we turn something over to actually me and David who are the Co-Chairs of this Subcommittee to polish up and perhaps go back to you with additional questions and get something to OARC so they can distribute it in time for the workshop.

So, you know, we're not limited by this timeline here. I think we're just brainstorming. At the workshop, we will be able to go into more depth, and then, you know, we'll have a plenary session where the

access and coverage group will be with the quality group and the CER group and the other group so that we can come up with a nice set of responses to these questions.

So, not everything has to be done over this weekend, but it would be nice I think for the OARC to have something to start with at the workshop.

Dr. Smith: Okay.

Dr. Dougherty: That's the aim. Right, Gemma and Elizabeth?

Ms. Weiblinger: Yes. That's right. That's right. And if we can get the finished products from the groups by October the 22nd, that would give us enough time to put it together and send it out to all of the Subcommittee members to review before the workshop.

Dr. Dougherty: So given that I know that we were all aiming - every group, every topic group is aiming - to have some sort of document that the Co-Chairs can work on the week of October, what is it, a week from --

October 15.

Could we possibly, to give this group more time and the other Services Research and Policy topic groups more time, perhaps have our calls on October 15th? Then the onus would be on David and me to kind of polish it up and get it into a publicly available document by October 22. I just don't see how anybody is going to be able to really think about these questions and come up with something by Tuesday that would be our draft publicly available document.

Ms. Crandy: This is Jan Crandy. I agree, 10/15 is probably more reasonable.

Dr. Smith: I am not able to join that day but -

Dr. Dougherty: Or October 15th or 16th, something like that?

Dr. Smith: Right. I'm at a cross-site meeting all day those days, so - But it's going to be hard to get everybody together, so -

Dr. Dougherty: Yes. And there's always

the opportunity. We will get it, you know, circulated among everybody a few times so that you can add your comments.

Dr. Smith: Okay.

Ms. Crandy: And, Tristram, you couldn't do the 12th? The 12th didn't look good for anybody?

Dr. Smith: The 12th was okay for me.

Dr. Dougherty: Okay. I can send out a calendar request again for the 12th, which would mean that you all would have to get in your drafts, you know, just some bullet point questions, to me for circulation by say close of business next Wednesday or noon next Thursday.

Dr. Smith: Okay.

Dr. Baden: Denise, this is Elizabeth. Just so you know there's already two calls scheduled for the 12th from other groups. One is from 9 to 11 a.m., and the other group is looking like it will be somewhere between 2 and 4 in the afternoon.

Dr. Dougherty: Okay. So, you and Gemma

will be very busy that day.

Dr. Baden: Yes.

[Laughter]

Dr. Dougherty: Yes, if we try to squeeze it in.

Dr. Smith: I better sign off now, but I'm flexible that day, and I can work on things between now and then.

Dr. Dougherty: Great.

Dr. Smith: All right; thank you.

Dr. Dougherty: Thank you.

Dr. Smith: Bye.

Dr. Dougherty: So Lisa, you haven't weighed in on that timeline, and Elizabeth and Gemma, either. But I just don't see that anybody can get in a bulleted set of recommendations by Tuesday that we could discuss on Tuesday.

Ms. Weiblinger: Okay. Well, yes, this is Gemma. And just a reminder that - I mean, we can certainly squeeze something in if that's the only day that's going to work. But we won't be able to do a call with this group

between 9 and 11.

Dr. Dougherty: Right.

Ms. Weiblinger: And then probably somewhere between 2 and 4. That hasn't been definitely determined yet in the afternoon.

Dr. Dougherty: Right; that's what Elizabeth just advised us of. So we would have from 11 to 2, basically.

Ms. Crandy: But, Lisa, can you do a call on the 12th? Do we still have Lisa?

Dr. Dougherty: Lisa may be - well, I'll send out a calendar item for a couple of days and see.

Ms. Crandy: I can make the 12th work, and I can definitely do the 11th or the 15th, but I would like to have Tristram on.

Dr. Dougherty: Okay. Okay. Well, we will do that as a next step then. And give the, send a note along with the assignment for you all to brainstorm what kinds of questions in each group.

So now I'm trying to find my agenda for this call since I've been looking at

different pieces of paper. So is there anything else?

We didn't get to the introductions. I assume, Gemma and Elizabeth, at some point you're going to ask all of the experts for bios and circulate them?

Dr. Baden: Yes, we will do that. And they should be in the packets for everyone at the workshop.

Dr. Dougherty: At the workshop, okay.

Ms. Crandy: I just wanted to ask one question. And if I missed this, I'm sorry. It doesn't just have to be - it can be research from anywhere in the world, correct? That we can be pulling abstracts to answer these questions. Or are we trying to keep it.

Dr. Dougherty: Well, I think what I heard at the IACC meeting - this is Denise again - that you know, a very - that nice book that the group put out really shows that there's been a lot of good research from other countries so that you wouldn't limit anybody's looking just to the U.S.

Ms. Crandy: Okay.

Dr. Dougherty: When we get to these financing issues, it can be a little tough to find a comparable situation.

Ms. Crandy: Right.

Dr. Dougherty: Do you agree, Gemma and Elizabeth?

Dr. Baden: I'm sorry, what was the last thing you mentioned?

Dr. Dougherty: Is it okay to, when we're looking to see what we've learned in the past 18 months or so, to look at non-U.S. research.

Dr. Baden: Definitely. If there are good studies anywhere in another country that have been done, then certainly you could include those results.

Again, just as a reminder, we are looking at sort of seminal studies that are - not every study that's been published since January of 2011 but the most important results that sort of really advance the field. Or also, of course, raise more

questions.

Ms. Crandy: Understood.

Dr. Dougherty: Okay. So is there anything else? Then we - I'll just write up a little note and have Gemma and Elizabeth take a look at it before we send it out to make sure we got all the important points and assignments here.

Dr. Baden: That sounds great, Denise.

Dr. Dougherty: Okay, terrific. Well, thank you everybody for being on this call. It's been really good.

Dr. Baden: Thank you.

Dr. Dougherty: Okay; thanks so much, Jan. Take care.

(Whereupon, at 12:37 p.m., the Planning Group for Question 5 and Question 6 on subgroup CERPCOR adjourned.)