

INTERAGENCY AUTISM COORDINATING
COMMITTEE

FULL COMMITTEE MEETING

WEDNESDAY, JANUARY 16, 2019

The full Interagency Autism Coordinating Committee (IACC) convened in Rockville, Maryland, at the Hilton Washington DC/Rockville Hotel & Executive Meeting Center, 1750 Rockville Pike at 9:00 a.m., Joshua Gordon, M.D., Ph.D., Chair, presiding.

PRESENT:

JOSHUA GORDON, M.D., Ph.D., *Chair, IACC*,
Director, National Institute of Mental
Health, (NIMH)

SUSAN DANIELS, Ph.D., *Executive Secretary*,
IACC, Office of Autism Research Coordination
(OARC), NIMH

DAVID AMARAL, Ph.D., University of
California, Davis (UC Davis) MIND Institute

MELINDA BALDWIN, Ph.D., LCSW, Administration
for Children and Families

JAMES BALL, Ed.D., B.C.B.A.-D, JB Autism
Consulting (attended by phone)

JUDITH COOPER, Ph.D., National Institute on
Deafness and other Communication Disorders
(NIDCD)

GERALDINE DAWSON, Ph.D., Duke University

PRESENT: (continued)

MELISSA HARRIS, Center for Medicare and Medicaid Services (CMS)

JENNIFER JOHNSON, Ed.D. Administration for Community Living (ACL)

ALICE KAU, Ph.D., (representing Diana Bianchi, M.D.) Eunice Kennedy Shriver National Institute of Child Health and Development (NICHD)

LAURA KAVANAGH M.P.P., Health Resources and Services Administration (HRSA)

CHRISTY KAVULIC, (representing Larry Wexler, Ed.D.) U.S. Department of Education (ED)

WALTER KOROSHETZ, M.D., National Institute of Neurological Disorders and Stroke (NINDS)

CINDY LAWLER, Ph.D., (representing Linda Birnbaum, Ph.D.) National Institute of Environmental Health Sciences (NIEHS)

KEVIN PELPHREY, Ph.D., University of Virginia

LAURA PINCOCK, Pharm.D., M.P.H., Agency for Healthcare Research and Quality (AHRQ)

LOUIS REICHARDT, Ph.D., Simons Foundation Autism Research Initiative (SFARI)

ROBERT RING, Ph.D., Vencor Therapeutics

JOHN ELDER ROBISON, College of William and Mary

STUART SHAPIRA, M.D., Ph.D., Centers for Disease Control and Prevention (CDC)

PRESENT: (continued)

ALISON TEPPER SINGER, M.B.A., Autism Science
Foundation

JULIE LOUNDS TAYLOR, Ph.D., Vanderbilt
University

CHERYL A. WILLIAMS, (representing Melissa
Spencer) Social Security Administration (SSA)

NICOLE WILLIAMS, Ph.D., U.S. Department of
Defense (DoD)

CARRIE WOLINETZ, Ph.D., (representing Francis
Collins, M.D., Ph.D.) National Institutes of
Health (NIH)

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PROCEEDINGS

DR. JOSHUA GORDON: Good morning.

I want to welcome everyone to this meeting of the Interagency Autism Coordinating Committee. As you know, I am Joshua Gordon, Director of the National Institute of Mental Health and Chair of the IACC.

I want to welcome all of the committee members and public attendees. I especially want to welcome Melinda Baldwin. Where is Melinda? Is she here yet? Not yet. Who is going to be representing the Administration for Children and Families at HHS.

I also want to welcome a new alternate, Ms. Cheryl Williams. Are you here? Hello, Ms. Williams. Who will be representing the Social Security Administration. We are very pleased that SSA is joining us. Thank you.

And I want to note that Ms. Melissa Spencer, who served as a representative of the SSA over the past year, is retiring this month. She really appreciated the time that she had to serve on the committee and we'll miss her, but we are very pleased to have Ms. Williams.

Ms. Williams, would you like to just introduce yourself briefly, tell us a bit about yourself?

MS. CHERYL WILLIAMS: Good morning. I am Cheryl Williams. I am the Director of the Office of Medical Policy within the Office of Disability Policy at the Social Security Administration.

I have been in my current position for the last ten and a half years. We do have a specific body system in which the purpose of this discussion lives, I like to say. In fact, today, with me, I have Elena Ness, who

is a supervisor of the mental disorders body system. And we are glad to be here.

DR. GORDON: Welcome to the both of you. Thank you for coming.

I also want to just take this moment to remind everyone what Ms. Williams did so excellently, which is to please use your microphones. You need to press the button until you see it burn red and then speak directly into the microphone so that everyone not only in the room can hear you, but, importantly, we, of course, have people all over the US and perhaps, all over the world - I don't know - listening in today through the webcast. We also take careful minutes and so it helps to speak clearly into the microphones.

With that, I am going to turn the mic over to Susan Daniels, who is going to do the roll call and the minutes.

DR. SUSAN DANIELS: Thank you. Good morning. So, I will take the roll call for the IACC. So, first on my list, Joshua Gordon.

DR. GORDON: Here.

DR. DANIELS: Judith Cooper.

DR. JUDITH COOPER: Yes, good morning.

DR. DANIELS: Alice Kau.

DR. ALICE KAU: Here

DR. DANIELS: For Linda Birnbaum, Cindy Lawler?

DR. CINDY LAWLER: Yes, I am here.

DR. DANIELS: Or for Linda Birnbaum and Alice for Diana Bianchi.

Carrie Wolinetz.

DR. CARRIE WOLINETZ: Yes, here.

DR. DANIELS: For Francis Collins.

Elaine Hubal. Tiffany Farchione is not able to join us today from FDA. Melissa Harris.

MS. MELISSA HARRIS: Here.

DR. DANIELS: Jennifer Johnson. And I think Jennifer has an alternate who may not be here yet.

Laura Kavanaugh.

MS. LAURA KAVANAUGH: Here.

DR. DANIELS: Someone for NINDS for Walter Koroshetz. Not here yet. Laura Pincock.

DR. LAURA PINCOCK: Here. Good morning.

DR. DANIELS: Morning. Marcy Ronyak is not able to join us from the Indian Health Service.

Stuart Shapira.

DR. STUART SHAPIRA: Here.

DR. DANIELS: Melissa Spencer or Cheryl Williams.

MS. WILLIAMS: Good morning. I am here.

DR. DANIELS: Christy Kavulic for Wexler.

MS. CHRISTY KAVULIC: Here.

DR. DANIELS: Nicole Williams.

(no response)

DR. DANIELS: David Amaral.

DR. DAVID AMARAL: Here.

DR. DANIELS: Jim Ball.

(no response)

DR. DANIELS: Samantha Crane.

(no response)

DR. DANIELS: Geri Dawson.

DR. GERALDINE DAWSON: Here.

DR. DANIELS: David Mandell is not able

to join us today.

Kevin Pelphrey.

DR. KEVIN PELPHREY: Here.

DR. DANIELS: Edlyn Pena.

(no response)

DR. DANIELS: Louis Reichardt.

DR. LOUIS REICHARDT: Here.

DR. DANIELS: Rob Ring. John Robison.

MR. JOHN ROBISON: Here.

DR. DANIELS: Alison Singer.

MS. ALISON SINGER: Here.

DR. DANIELS: Julie Taylor.

DR. JULIE TAYLOR: Here.

DR. DANIELS: Is there anyone I have missed? And is there anyone on the phone that wants to let us know that you are on the phone listening in? All right, I think -

DR. JIM BALL: Can you hear me, Susan?

Jim Ball.

DR. DANIELS: Oh, hi Jim. Yes.

DR. BALL: Okay. Thank you.

DR. DANIELS: Thank you. And if anyone else is on mute, but you are going to be joining us, you can let us know that you are here.

So, thank you very much. We will move on to the minutes.

So, the minutes from the last meeting in October are in your packets, the draft

minutes. Did anyone have any comments? Is there any discussion about the minutes?

So, hearing none, can I have a motion to accept the minutes? Second? All in favor of accepting the minutes as drafted say aye.

(Chorus of "ayes.")

DR. BALL: Aye.

DR. DANIELS: Any opposed? Or any abstaining? So, then the motion carries to accept the minutes as drafted here. And they will be posted on the web shortly after this meeting. Thank you.

Welcome, Walter Koroshetz.

DR. GORDON: With that, we - next we are going to have a report from Dr. Ann Wagner. Dr. Wagner you have all met at a couple of meetings, is the Chief of the Biomarker Intervention Development Branch for - in the Division of Translational Research at NIMH. But more importantly, for this audience, she

is the National Autism Coordinator as named by the Secretary for Health and Human Services. Dr. Wagner is going to talk to us about what she has been up to.

DR. ANN WAGNER: Good morning everybody. Thank you.

Some of this background is just here for - on the record for people who weren't here at the last meeting. So I am not going to go over it again, but I will mention and say thank you to the representatives from the various federal departments and agencies who are participating on the Federal Interagency Workgroup on ASD, what we call FIWA, which is a vehicle for me to do my job coordinating across departments.

Last time, I told you that my first order of business was to meet individually or in small groups with all of the various players on this working group so that I could

get a better understanding of how things work in - particularly in the services agencies because it is very different from - from NIH. At that point, at the last meeting, I had met with about half of the players. Now, I am happy to say I have met with all but one. The previous slide were the HHS programs involved, and these are other departments involved, as well.

This has been incredibly informative for me. And one of the things I have been talking with people about is strategies that they use - that federal programs use to make influence at the state and local levels because, in most instances, it is not direct. So - so I have been learning a lot about that and we actually devoted our last FIWA meeting to discussions about the various strategies that are used in different federal programs.

I have divided them into three categories for today and I am not going to go into detail because I don't have time and this is far from exhaustive or comprehensive, but I wanted to give you a flavor of the kinds of things that people - strategies that people are using because it was informative to me.

In our meeting - so, one category is direct engagement with state and local entities. Michael Reardon from the Department of Labor described - Labor with state and local associations and councils on disability employment initiatives and policy. So, these are organizations like National Governors Associations and National Conference of State Legislatures.

Marcy Ronyak from the Indian Health Service described a project - an initiative they are involved in now called the National

Hope Committee, which is addressing the opioid crisis. She described this as an example of bringing together local providers, community leaders, and federal partners on critical, health-related topics.

A second category are targeted grants programs. And Jennifer Johnson from the Administration on Community Living talked about several flavors of what they called system change grants that support efforts to make positive changes in social systems and service delivery programs. And they support things like the University Centers for Excellence in Developmental Disabilities and other state councils on developmental disabilities and programs to - to support state protections and advocacy systems.

So, I am going to let the people around the table who run these programs talk with

you either offline or at a later date about specifics if you want them.

Then the third category is education and professional development. Larry Wexler at the Department of Education talked with us about their professional development grants programs that support 8,000 Master's and doctoral-level scholars. Education also supports IRIS Centers to create free online learning modules to teachers. And they support an autism-focused program, which is called AFIRM, which also is the development of resources and modules.

And Hae Young Park at HRSA described the way the - their LEND Program, which is Leadership Education in Neurodevelopmental and other related Disabilities and their programs for developmental and behavioral pediatrics, the ways in which those are providing continuing education and training

and technical assistance to people in the field, as well.

So, that kind of background I think is very helpful to us as we continue our ongoing activities, one of which is to focus on the supports and services recommendations from the 2017 Report to Congress on Transition-Aged Youth with ASD and Adults with ASD.

We also are continuing to work on two projects that I mentioned last time. One is evaluating government-sponsored survey datasets that - collecting data on this age group, transition-aged youth and adults with ASD, in order to look at where there is overlap, where there might be gaps identifying potential places where data might be combined.

And then we are also gathering information on outcome measures. The report talked about the dearth of outcome measures

or functional measures for this age group of people with ASD and the need for more. And we have identified some investigators supported by the Department of Defense, the Administration on Community Living, and NIH, who are developing such measures. So, we are planning - we are meeting to plan a special FIWA meeting in which we will invite those people to give us updates on their projects and also look for potential collaborations, avoid duplication, look for other areas that might still be missing, and think about ways to facilitate for the development in that area.

That's my five-minute overview. Thank you very much everybody. And thanks to everybody for participating on this working group.

DR. GORDON: Thank you. Do we have any questions from the committee for Dr. Wagner?

We will move right along then to our first presentation of the day. And Melissa Harris is the Acting Deputy Director for the Center for Disabled and Elderly Health Programs at the Center for Medicare and CHIP Services at CMS. She is going to talk to us about the HCBS Final Rule.

MS. HARRIS: Hi, thank you. So I am really happy to be with you, here, this morning. I have been on the phone for the last several committee meetings.

And so I wanted to share with you, today, a regulation that has come up a few times in IACC conversations. I thought it would be helpful to have a dedicated conversation about it. And I am happy to field any questions - oh, thank you. I am happy to field any questions if I can today, or take them back to my team and get an answer back to you as soon as we can.

So, let's see - there's a lot of information on these slides. And if they weren't contained in the materials sent out already, I am happy to send them to you. So, please don't feel like you have to take notes.

But the regulation that we are talking about is one that was published in January of 2014, so right around five years ago. And then it was effective in March of 2014 with the exception of the provision that we are going to talk about right now, which is the criteria defining a home and community-based setting for purposes of Medicaid payment.

But this regulation did a lot of things that are in effect right now. And we will touch on those just briefly, but it tends to be known as the Home and Community-based Settings Regulation. And so that's the provision that gets the most attention. And

so that's what we are going to focus on today.

And so we embarked on this regulation years before 2014. We actually used a vehicle that we don't use very often. Typically, when a federal agency is going to be issuing a regulation, they release a proposed rule saying here is what we are thinking about regulating, solicit public comments, and then use those comments to inform any changes that take place in the final rule.

We actually backed up a step in this regulatory adventure and issued what is called an Advanced Notice of Proposed Rulemaking, saying that we are thinking about regulating in this space and give us some ideas of what stakeholders want to see as the criteria of a home and community-based setting. Then we used those public comments to inform a proposed rule, again solicited

public comments, and then used those comments to inform the final rule that was published in 2014.

We realized, as we were able to read through public comments, that as - in many cases, viewpoints were all over the map in terms of the role that the federal government should have in defining a home and community-based setting, the types of issues that stakeholders felt were most important, be they safety of individuals, be they freedom to make an individual's own decisions, how to blend those two. Certainly got a lot of conversation in the public comments.

We realized that whatever set of criteria defining a home and community-based setting we ended up with would take some time for providers to be able to implement and states to be able to oversee. And so there

was a transition period built into the regulation.

It was initially a five-year transition period. And so that would have expired in two months from now. The original end date of the transition period was March of 2019. We ended up extending that a couple of years ago and so now, the transition period runs through the middle of March 2022.

And so we are going to focus on, today, what the regulation actually says for the criteria of a home and community-based setting. I will touch a little bit on some of the decisions that are made at the federal level and some that are delegated to the state Medicaid agencies. And then where I see us going from here.

But we really - one of the key reasons that - that set us off down this path of - of issuing regulations is that even many years

ago, we could see the trend of expenditures and the provision of long-term care services in Medicaid increasing more in the direction of home and community-based services. In 2013, we finally crossed that threshold in the Medicaid program, in which more money under the umbrella of long-term care, was spent in home and community-based services than it was spent in institutional care.

And that was a big benchmark, a big optic, but it also kicks off a lot of questions. As more and more money is going toward the provision of home and community-based services, what is the federal government buying with taxpayer dollars? What kind of criteria are defining the settings that are receiving funds for home and community-based services? What is the difference between that type of setting and an institutional setting, both in terms of

individual freedoms, federal oversight, et cetera? And so, those were some of the roads that were converging to make us know that we had to move forward in this space.

Over time, there was an enormous amount of variation across the states in the types of settings that were providing home and community-based services and receiving Medicaid funding for those services. States would need to describe to CMS in the primary coverage vehicle, which was the - a waiver program at - found at 1915(c) of the Social Security Act. That's a coverage authority that's been in existence since the early 1980's and was at - for a long time and really still continues to be the primary coverage vehicle for long-term care in Medicaid.

States had enormous variety to describe to CMS the types of providers that were

receiving Medicaid funding, the types of settings that those services were being provided in. There really was no standardization. And so someone receiving home and community-based services in one state could be living a very different life from someone receiving those same types of services in another state with regard to the amount of flexibility they had in setting their own schedule and determining what they did on a daily basis, who to interact with, those types of things.

And so we - we felt as more and more dollars were being put into the home and community-based services arena, that we needed to really understand what we were buying and how individuals were living. And so the main goal of the regulation was to bring a mixture of standardization and person-centeredness into the mix to really

facilitate some beneficiary autonomy and some movement in the facilitation of person-centered care.

So, the next couple of slides walk through the actual criteria that has been outlined in regulation. There's a couple of different components of the settings criteria.

This first cohort applies really to any setting that wants to be a provider of Medicaid-funded home and community-based services, whether it is a residential or non-residential provider, whether these services are being provided in a assisted living setting, for example, or some kind of day program or some type of group home or whatever. And so in some ways, these characteristics are very basic.

The individual needs to be supported to have access into the greater community. The

individual needs to select the setting from among setting options. There need to be opportunities for an individual to pursue competitive, integrated employment. And it's - the services need to be provided in such a way that the fact that an individual is receiving Medicaid services does not set up any type of barrier to receiving services. There shouldn't be any real difference in how Medicaid services are provided versus non-Medicaid services are provided.

That's really what the criteria in the bottom left category is. It sets up a bit of a comparison between how other individuals in that same community who are not receiving Medicaid services receive care, interact with the community, and make their own decisions.

And so, again, these criteria apply to all types of settings. You will see references to privacy, dignity, respect,

freedom from coercion and restraints. The individuals are based on - sorry, the setting options are based on an individual's needs, preferences, resources, particularly when room and board is necessitated at a residential setting, and, again, facilitating individual decision-making and autonomy.

You see the first reference in the top left to a person-centered service plan. And we are going to talk more about that as we get further into the discussion. That continues to be the foundation of how an individual is to be supported in receiving services and how providers are to be determining how services are going to be provided to one individual as opposed to another.

The next couple of slides talk about some additional criteria that applies to a subset of home and community-based settings.

And these are provider-owned residential settings. So, here, we could be talking about a group home, an assisted living facility, any kind of variation on that theme, any kind of host home. States have all sorts of different titles for different service models in which someone is living in the home of the - the company, the provider, the individual who is furnishing services to them.

And there's an additional set of home and community-based criteria because it is so - the where you are living is so intrinsically linked, especially if you are receiving services in the place that you are living and from the individual from whom you are renting a space. It - that has some key implications for how you are exercising day to day decisions and autonomy. And so based on stakeholder comment, we developed this second set of criteria.

And it includes things like an individual needs a legally enforceable lease or in the absence of a lease, something else that carries the weight of law in that particular jurisdiction. That talks about responsibilities of residing in a particular place, rights of people who are living in a particular place. This is all to prevent inappropriate discharge and evictions.

And then you see here on this second slide a list of a myriad of different types of requirements: privacy in sleeping or living units, an individual having the ability to lock their doors with only appropriate staff having keys, choice of roommates if an individual needs to have a roommate, the ability to decorate your own space, the ability to have access to visitors at any time, the ability to have access to

food at any time, the requirement that the space is physically accessible.

Some of these things, you know, don't seem all that complicated, but we've actually needed to have many, many conversations with stakeholders to make sure everyone understands what we mean.

For example, the access to food at any time, that doesn't mean that individuals need to have access to a hot buffet 24-hours a day, but it means that if there is a meal time at a particular time and someone misses that meal time, they are not prohibited from eating until the next scheduled meal time. There are snacks available. The ability to have a sandwich if you are not in love with what's on the menu that night. The ability to grab a piece of fruit in the afternoon if you are hungry.

The same food decisions that you and I make on a daily basis, that is what really this is getting at here. It doesn't mean anything more formal or more complicated than that.

And then there's similar conversations, really, that we could have about any of these criteria: the choice of roommates. Certainly, you know, if we all think back to our college days, if you are having a real hard time living with someone in a shared space, that can present a lot of problems.

And so this is not designed to say if you and your roommate are arguing, you - there has to be some sort of permanent solution made, but - as we talk to providers, it's certainly - it is reiterated to us time and again that if you've got an inherent clash between individuals sharing a space, the provider is going to have to devote a lot

of attention to make sure everybody is okay. And so this is just really to say if two people are really not a good mix to be sharing a space, then there really should be some actions taken to - you know, to maximize the ability for people to coexist together.

And then the lockable entrance doors to individual units - you know, we will get into, again, the role of the person-centered plan in a minute, but this doesn't prohibit staff from having access to individual rooms. It just means that the - that if I am living in a unit in one of these residential settings and I want to be able to have some privacy, I should be able to lock my door and have staff knock and be granted permission to enter my space if and when they need to get to me. And we'll talk about some safety precautions in a minute that we can get to on an individual basis.

But this is all towards provider mentality. You know like making - helping providers recognize that the individuals that are living there are really living their life with those providers and they need to be treated as independent individual people and not just charges that the providers can come and go at will and make such basic decisions for people.

And I will say - you know, so we have had conversations with providers. They've been really receptive to these criteria. They have questions. They want to make sure they understand what the federal expectations are that are behind these criteria. But when we really get behind what a lot of these are talking about, there is large acceptance and understanding of where these came from and a recognition that with some modifications, if necessary, providers really can adhere to

these. And our goal is to make sure that whatever technical assistance is needed at the state level, at the provider level, is happening.

And so here we will get into a little bit more of the person-centered plan because any time you are talking about the Medicaid population, you are inherently talking about a lot of different people with a lot of different needs. Individuals receiving Medicaid-funded home and community-based services are literally at every place along the lifespan from a newborn to an older adult. They have very different diagnoses from individuals with developmental or intellectual disability to a traumatic brain injury to physical disability, a mental health issue, and they present with very different and very individual needs and preferences and support requirements.

And so the ability for the federal government to have a one-size-fits-all cohort of criteria is not possible and was not the goal of us embarking on this regulation in the first place. And so what is really at the crux of all of this is the development of a person-centered plan.

And the regulation has a lot of narrative about what goes into the development of a person-centered plan, the ability of the individual, and those who need to make decisions for that individual or with that individual either through formal arrangements or through informal selection by that person, how they need to be at the table, and how they need to be supported in making decisions.

There is discussion about the need for providers to be at the table, so providers can confirm that they have the ability to

provide the types of services that individuals need. But providers shouldn't be driving the bus and saying because you need these services, you will receive them in this way and you will live your life in this way.

And so it is in an individual's person-centered plans that any modifications to the regulatory criteria that I just walked through would be documented. And so if an individual really should not be able to lock their room, it would be in that person's person-centered plan that that conversation would happen and there would be a discussion about the individual's needs that make that person having a key to their room not safe, not medically supported, whatever.

If someone should not have access to food at any time based on some sort of health diagnosis like Pica or Prader-Willi, that should be documented in the person-centered

plan along with whatever - other modifications or what other kinds of activities or services should be implemented because of that person's health status.

So you will see here that we have just a quick discussion of the fact that - that modifications based on an individual's needs and health care diagnoses are expected. This is not meant to be a regulation that sweeps under the rug the fact that some individuals need some fairly significant supports. It's meant to be a recognition that individuals are going to vary.

What one individual needs as a safeguard, other individuals living in that same location or receiving services from that same provider might not need. So, this isn't an issue of kind of going down to the lowest common denominator and having the same kinds of safeguards in place for everyone. It's a

recognition that individuals are different and they need to be receiving services in a different way.

So here you see again some requirements in the regulation for how any modifications should be documented in the person-centered plan. This is not meant to have someone spend their life documenting. Some of these requirements we have been told look a little overwhelming for documentation.

And we recognize that some health needs that require modification of our regulatory criteria are not going to change over time. They are not going to improve. And so we certainly want to be reasonable as the documentation requirements are concerned so individuals are not spending an inordinate amount of time writing down in a person-centered plan why an individual's diagnosis that will be with them for their entire life,

has not changed over the course of the year. So we are happy to have those kinds of conversations.

But there are people who will need time-limited modifications. And so this is really meant to say, you know, if there is something preventing an individual from being able to interact with their community such that they are not able to be supported to fully experience the community the way you and I do, let's take a periodic look at that and make sure that we are not just continuing those kinds of restrictions because they have been in place for a while. We need to make sure that any kind of restrictions are really linked to an ongoing health issue.

So, to go from a - the philosophical discussion and a walkthrough of what is in the regulation to more of an operational angle, because there is a transition period

and because there will be activities needed at the state level and the provider level and the stakeholder level throughout the transition period, we developed requirements that the - each state submit a statewide transition plan to CMS to talk about the activities and the timeframes associated with those activities that would need to happen throughout the transition period.

So we - that kind of organically shook out into two different types of approval of a state's statewide transition plan and we will talk about those in a second. But you see that 43 states - and in this case, there's 51 states. There's 50 states and the District of Columbia. And so we are missing initial approval that I will walk through in a minute, of eight states. And we have 10 states who have gone on to receive final approval of their statewide transition plan.

And I'll flip back to this slide as we get a little bit further and get more into the details of what a statewide transition plan is.

And so, you know, we talked about in the regulation that within a year after publication of the Rule, states should be submitting their statewide transition plans to us and we have been reviewing them ever since. And so the - we asked the state to make sure that their plans were submitted to us, at least in their preliminary state, by March of 2015. And that largely happened. Not every state got their plans into us, but it has kicked off a rather extensive negotiation and collaboration period with the states as they and we have learned over time the types of information that needed to be contained in a statewide transition plan.

And so we talk here about what is necessary for a state to receive initial approval of their STP. Those activities are really focused at the state level. The state should be looking at their state regulations, any administrative codes, provider manuals, managed care contracts, whatever kinds of enforcement infrastructure a state has with their provider community, licensing and certification standards, et cetera, to determine what needs to change to make sure that the state requirements are in line with our federal regulation.

It is not that we expect the state to totally regurgitate back our regulatory language, but we need to make sure that any state - state requirements are not in conflict with our regulations. And that is so providers are set up with their best foot

forward as they meet state requirements and federal requirements.

And so what we talk about here as a systemic assessment is really a state looking at their state-level processes and figuring out what needs to change. And then figuring out the timelines associated with those remedial actions.

A key component of all of this is stakeholder engagement. The state should be issuing their public - their statewide transition plan out for public comment, walking their stakeholders through the actions that they need to take and the timelines for doing so, both at the state level and then, as importantly, if not more importantly, as states are moving toward final approval.

Final approval is when the state walks through the actions that providers need to

take, the timelines that providers will need to take those actions, how a state is going to be working with their provider community. Often times, states are permitting providers to do self-assessments of how a particular provider adheres now to the regulatory criteria and what kind of changes will need to be made by the end of the transition period.

But the statewide transition plan should be walking through how the state is going to be confirming a provider's self-assessment and the state getting to a comfort level that by the end of the transition period, the - those providers will be in compliance with the regulation.

You see the final bullet on this slide, the statewide transition plan should identify how a state is going to work with settings that are presumed to have institutional

characteristics. We'll get into that in a second, but that tends to be another component of this regulation that takes up a lot of mental space and energy. It's - you might have heard the phrase "heightened scrutiny" and that links to this provision of settings that are presumed to have institutional characteristics.

The regulation - and I am not sure how - let's see - yes. Let's see, what slide did I just skip over?

Oh, so here's some other components of what a statewide transition plan would need to have for final approval. Certainly, talking about ongoing monitoring and compliance even after the end of the transition period.

And something at that - that top bullet speaks to something that we hope happens in a minimum of cases, which is when a state is

aware - either they have made a decision proactively or as time is passing they become aware that a provider may not be in compliance with our regulatory criteria by the end of the transition period and then decisions have to be made.

It is a true statement that after the end of the transition period, which is March 17th, 2022, Medicaid cannot use home and community-based services funding to reimburse for services provided in settings that don't meet our regulation. That doesn't mean necessarily that all Medicaid funding is cut off, but it does mean that conversations need to happen between the state and CMS. And if there is no path forward for the continuation of Medicaid funding, then there needs to be some conversations that happen between the state and the provider to determine what next steps might need to happen so individuals

residing or receiving services from a provider understand what their universe of options are. And we can spend a little more time on that in a second.

So, the regulation defines some settings that are not home and community-based. Most of the real estate in the regulation is designated to talking about what home and - home and community-based setting is. There are some settings that are not home and community-based.

Most of them are pretty straight forward. They are institutional settings. Institutions are legitimate locations of Medicaid-covered services. They have their own coverage authorities. But they are not home and community-based.

And so here, we talk about a nursing facility, an institution for mental disease, which is worthy of its own conversation in

the Medicaid program. It is actually a type of setting in which the federal government is not permitted to reimburse for services due to a statutory payment exclusion. But those institutions do exist.

Intermediate care facilities for individuals with intellectual disabilities and hospitals are all types of institutions that are not home and community-based.

Then this last bullet is where we get into heightened scrutiny because it talks about other locations that are not formal institutions, but may be acting as one and providing services in an institutional manner. And so locations that are determined to have the qualities of an institutional setting are by their nature not home and community-based. And that has led to the need for CMS to have quite a bit of guidance issued on what types of settings are those

that have the - that are presumed to have qualities of an institution.

And, you know, we've - we have quite a bit of guidance on our website, but it's also safe to say that we have been having some new conversations in this current administration. The regulation defines three types of settings that are presumed to have the qualities of an institution. Two of the three are determined so based on their proximity to an institution. The third one is not.

So, the first category is settings that are on the grounds of or adjacent to a public institution. And here we could be talking about a cottage on the grounds of a public ICF IID. That setting is not precluded from being a home and community-based provider, but because it is on the grounds of an institution, it is presumed to have the

qualities of an institution and there needs to be a special look at that type of setting.

The same goes for settings that are in the same building as a public or private institution. So here, we could be talking about a wing of a nursing home that is an assisted living facility, a wing of a nursing home that is an adult day center. Again, there is no strict prohibition on those settings being home and community-based, but because they share space with an institution, there needs to be a special look to make sure they really are home and community-based.

And then the last category is settings that isolate HCBS beneficiaries from the larger community. And here, we're not so much talking about settings in a rural location. People live in rural locations by choice. But here we're talking about more by the service model that a setting uses. Could it be

restricting access for those individuals to engage with their larger communities?

That third category, those isolating settings, has required the most subregulatory guidance from CMS. And it's required the most time for us and our state partners and some other provider stakeholders to really come together and flesh out a bit more.

So, let me - let me walk back a couple of slides to the status chart of the statewide transition plans. And so, again, 43 states - 42 states and the District of Columbia have received initial approval of their statewide transition plan, which means they have laid out all of the activities and the timelines associated with correcting any provisions at their state enforcement level. And again, that is state-level regs, statute, provider manuals, et cetera. It is not that

they've done all of those actions, but they've laid out the timing of any remediations across the transition period.

Ten states have received final approval, which means not only have they done that, they have also laid out a process and timeline associated with working with their providers so providers can do self-assessments, the state can verify those assessments, and the providers can accomplish the necessary remediation.

So, we still have a ways to go on the final approval. We have many statewide transition plans that are in-house now. And we hope, you know, even in six months that that number will be significantly higher than ten.

It does mean, though, that if you are a stakeholder in one of those states, you should know the status of your state's

statewide transition plans. And it's a statement of fact that some states are better than others in engaging their stakeholder community. And so if you are in a state that has not been great at publishing their statewide transition plan and notifying the public that it is out for public comment, we do want to hear about that. We are aware of some states, but if this is all kind of foreign to you and you've never heard of a statewide transition plan and certainly don't know what your state's might look like, then we can certainly have those conversations.

We do have links to - on our Medicaid.gov website. We do have links to the most recent version of each state's statewide transition plan, but those can get outdated at times. And so I am happy to have a state-specific conversation with you.

So, this is - is the last slide, besides I think some contact information coming up. So I will end here and open it up for comments. I will say a couple of things.

There's a lot of uncertainty associated with the reg. There's a lot of fear associated with the reg. When it first came out, I think several types of providers thought that the reg was specifically designed to end their business and to make a statement that their service model was not appropriate for the continued receipt of home and community-based funding.

We did issue some guidance in 2015 that tried to give examples of what CMS meant by an isolating setting or a setting that isolated HCBS beneficiaries from the larger communities. And in that guidance, we gave some specific descriptions to different types of settings that fell under the heading of

intentional communities, be they farmsteads or any type of gated community where there was a combination of residential and day services, vocational services, entertainment services, whatever, all in one location. We said these are the types of settings that we meant when we said a setting that could be isolating.

Well, we heard a lot of feedback from that. And it was not good. And so those providers took real issue with the fact that we were kind of painting them in an especially isolating light and said it is really not fair for the government to kind of lump all of them together under this flag of being potentially isolating.

So, we did take that to heart. And for the past year, we have been working on revised guidance on those heightened scrutiny provisions.

I should say that a setting that meets any of those three categories of being presumptively institutional, the state needs to take a special look at those settings and provide some documentation as to why that setting overcomes its institutional presumption and meets our reg and then they need to submit that information to CMS and we need to take a look at that as well.

That CMS review of a specific setting is called heightened scrutiny, a Heightened Scrutiny Review.

And so, there's a lot of providers who are really hopeful to avoid heightened scrutiny and I'm not sure if that is where the energy should be. Heightened scrutiny is a pathway for us to say - the royal us, a state and CMS, to say, yes, you are on the grounds of an institution; yes, you are inside an institution; yes, you may have been

isolating to individuals as you formerly provided services, but you do, in fact, meet the settings criteria and you are a home and community-based provider and your funding stream, as such, will remain intact.

So, it's - heightened scrutiny is not supposed to be a paperwork exercise for CMS just to delay a verdict of no, you are not home and community-based. It is really meant for the states and CMS to take a look at one setting as an individual setting and figure out how that location is providing services to individuals.

We like to think we are going into this with an open mind. We have been receptive to the feedback that we heard from those providers who found themselves highlighted in a way they didn't appreciate in our earlier guidance. And so we have taken a crack at walking back from having specific examples of

an isolating setting and having a more criteria-based conversation about what an isolating setting is, in terms of how its way of providing services really infringes on an individual's ability to interact with a community.

If you are a setting that might see yourself still in that criteria of an isolating setting, there is time to make some changes to no longer be an isolating setting. And CMS is here to provide that kind of technical assistance.

What we're really hoping to do is avoid disruption. We are not going to declare success if many providers cannot meet this criteria and individuals receiving services need to find another provider or individuals need to, you know, make some kind of wholesale change in the way they're living their lives in a way that does not create

meaning for them. That is not the intention of this reg.

It is meant to say we need to take a look at the way services are provided and make sure we are doing so in as person-centered of a way as possible. So we are not treating everyone with the same diagnosis or the same condition in the same way, recognizing the differences across individuals. But the need for CMS to be out and about, talking with stakeholders, is not going to end any time soon, to try to combat misinformation, indicate - you know - what are federal decisions, what are state decisions.

States have a lot of flexibility in this. A state can determine whether they want to continue doing business with a particular provider or a particular service model. And they could decide to use this regulation as a

catalyst for some changes in their provider makeup. That's okay. CMS is not going to prevent a state from doing that.

A state could decide that a setting that falls into a presumptively institutional category does not overcome that presumption and should not be submitted to CMS for a heightened scrutiny review and that provider will no longer be a home and community-based provider. It doesn't mean that there's no other Medicaid category for them, but it means they won't be a home and community-based services provider.

So, you know, I would encourage you to understand your state's rationale and your state's vision for implementing the regulation. Find your state's statewide transition plan. Ask questions of them. And then at the federal level, I'm certainly available to be the conduit into CMS and to

the team that is engaged in working on this regulation at a national level. And I am happy to open it up now for any questions.

I've totally lost track of how much time I have for that Q&A session. So I'll - Susan, I'm going to rely on you for help. So, thanks.

DR. GORDON: So we do have just a few minutes, unfortunately, for questions because we had so much information presented there. It was wonderful. Alison.

MS. SINGER: Thank you. I really appreciate your presentation today. It was a lot of really good information.

I just - I want to express my appreciation for CMS' flexibility with regard to the intentional community rules. We are really looking forward to the new guidance and hope to see that new guidance quickly, particularly because we are facing a capacity

issue and that new guidance is really important for building new settings and giving people the new options for - more options to live with if that is what they choose to do.

I wanted to talk a little bit about the transition plan and specifically about the people who are involved and who are very much affected by these transition plans. I am going to quote data from my own state of New York, just because that is where I live, but in New York, in our plan, New York has identified 72 settings that cannot be modified, which affects 6,900 beneficiaries, and 243 settings that fall under heightened scrutiny and an additional 336 that could be.

So my question is really how is CMS prepared to ensure that those individuals receive their necessary benefits? Are you working with states to build new capacities

so that there are ways for individuals who need these benefits to continue to receive them?

MS. HARRIS: That's a really - that is - that's the question or one of the main threshold questions associated with this regulation is we need to make sure at the end of the transition period that not only have we done all of this work to make the providers compliant with the regulation, but that we still have an array of providers designed to meet individuals who are at whatever part of their lives and whatever part of their diagnosis that they need the most supports for.

To continue using New York as an example, what we would do - and so, New York is a state that has initial approval of their statewide transition plan. That is relatively new. They received that in the last couple of

months, I think. They do not have final approval.

So, New York is one that has a whole lot of providers. One of the things that they needed to change was a requirement that - and I don't want to get too specific or I will be wrong, but there was a particular type of provider that needed to be located inside of a nursing home. And so that, right there, is at cross-purposes with figuring out what types of settings need heightened scrutiny if those settings are located inside a public or private institution.

The numbers that they were giving us for the - the numbers of settings that might require heightened scrutiny were a little alarming because of some of the way their state statute is read or state statute is written. And so we are working with them to try to figure out how best to crack that nut

in terms of heightened scrutiny. And, again, that would mean the state has made a determination that the setting falls into one of those three categories of presumptively institutional setting, but, nevertheless, the setting overcomes that presumption and then information will be sent to CMS.

There could be - and it sounds like there is in these other 72 settings - a determination made by the state that the provider can't come into compliance with our reg by the end of the transition period or the provider has communicated to the state they don't really have the intention to make changes necessary to come into compliance.

And depending on the provider and the percentage of Medicaid funding in a particular setting, it might be that the provider doesn't find it financially viable for them to make any needed - or doesn't - or

has a fear that it wouldn't be financially viable for them to make any remediations necessary to comply with the Medicaid requirement if a lot of their money isn't coming to them through Medicaid. That is a very provider-specific articulation they would need to make.

I don't know what's behind these 72 providers that the state has said can't make modifications. And so is it - is it in the state's mind that those 72 providers will no longer be home and community-based providers after the transition period? Maybe. In which case, the conversation would flip to - I should say that the regulation applies to services provided under three coverage categories in the Social Security Act.

That service is provided under the 1915(c) Home and Community-based Waiver, the 1915(i) Home and Community-based State Plan

Option, and the 1915(k) Community First Choice State Plan Option. It is all alphabet soup, but it's services authorized under those three authorities that are required to be provided in a home and community-based setting.

Other Medicaid services don't have that requirement to be provided in a home and community-based setting. And so it could - and so there are other coverage authorities like the institutions and then there are this middle ground of services that could be authorized under those home and community-based authorities, but they don't have to be. And so you've got home health services, personal care services, some private duty nursing services, rehab, which can authorize a lot of mental health, substance use services.

My point being is that if a setting cannot meet the home and community-based services criteria and cannot receive funding under those three main HCBS coverage authorities, there could be other Medicaid authorities that don't require adherence to that regulation that would still authorize Medicaid funds.

That, again, would be a very provider-specific conversation to figure out what services they're providing now. Is there a crosswalk of those services to non-HCBS coverage authorities? The answer could be yes. It could be no.

If there will no longer be Medicaid funds at all coming into that setting after the transition period, what does the - what is the state and CMS collectively going to do about it? Could the state be picking up those services under state-only dollars? Maybe yes.

Maybe no. The strength of that maybe will depend on the state that we are talking about.

And so there are a lot of downstream conversations that need to happen if there is doubt or certainty that a provider will be able to adhere to the regulation by the end of the transition period. And those are the conversations that even though we still have three years left in the transition period, do need to be happening now, if not in a - by what date in the next six months will we be making hard and fast decisions, at least some kind of process or plan needs to come into place to figure out at what point are we going to say, all right, a change needs to happen.

That is not - at some point, that is a plan and a process. But as time passes, that is going to get very specific to individual

people and will certainly not be an academic conversation. It's impacting how people - from whom they are receiving services, perhaps where they live, how they live, and so we don't want that to be rushed as the transition period is winding down. And so that is why you will see, as one of the required components for a statewide transition plan to receive final approval, the state needs to articulate a process for communicating with providers that have either already made a decision that they won't be in compliance by the end of the transition period or the state is doubting that they will be.

We don't want - to be pulled prematurely and people to be either physically relocated or to find new providers earlier than they have to, but we also don't want, like I said, the waning days of the transition period to

see a lot of decisions needing to be made in a hurry, which is never, you know - which is never a good way to do things.

All of this is a long-winded way to say, you know, what's happening in New York I am sure is happening in other states. And it speaks to the need to - for states to take advantage of the full transition period and for the state and CMS to be in communication about what they're seeing as the transition period moves on. You know, it really comes down to figuring out how many people are involved and what other options are going to be available to them.

CMS most likely won't get into decisions that impact where a particular person moves. That is more a state and local decision. But we can walk through all of the potential options for maintaining federal Medicaid funding and then what options are available

in the absence of Medicaid funding that could have some pretty direct implications for how conversations with individuals play out.

DR. GORDON: Thank you. There's a lot more questions and comments, but I am afraid we are going to have to move on.

MS. HARRIS: I will be here for the rest of the day and I think my email address is probably somewhere associated with these materials. I am happy to rattle it off now if you'd like to contact me as a follow-up.

DR. GORDON: If there is time in the schedule, we'll - we can return to this conversation later in the day because I know there is lots of interest, but we have other speakers with time constraints.

MS. HARRIS: Okay. Let me quickly give you my email address and then I'll stop and then you can feel free to grab me throughout the day. It's Melissa.Harris@cms.hhs.gov.

DR. GORDON: Okay. Thank you.

Next on our agenda we have a presentation from TRICARE, which, of course, is the military healthcare organization for active military. I welcome Captain Edward Simmer, the Chief Clinical Officer of the TRICARE Health Plan at the Defense Health Agency in Department of Defense, and Krystyna Bienia - I hope I'm getting that close - a Clinical Psychologist and Senior Policy Analyst at the Defense Health Agency.

Thank you both for coming today and we look forward to your presentation.

DR. KRISTYNA BIENIA: Great. Thank you. My name's Krys Bienia. I am a clinical psychologist and I work at the Defense Health Agency. And I am the clinical lead for the autism benefit that we have under TRICARE.

CAPT. EDWARD SIMMER: Nice to be here. I'm Captain Ed Simmer. I'm a psychiatrist.

And I am the Chief Clinical Officer for the TRICARE Health Plan, which basically provides coverage for all of our military beneficiaries.

DR. BIENIA: Okay, I'm not going to go through the "Our Agenda" line by line, but, essentially, we are going to talk about the military healthcare system, the TRICARE benefit, how one gets medical services under this benefit, and then focus mostly on the history of ABA services under TRICARE and then really our way forward and hopefully - my apologies - we will glean information from everybody here, in the audience.

CAPT. SIMMER: Thanks, Krys. So, I am going to just give you a very brief introduction to what the military health system is, what we do, the kinds of things that we cover.

So, we are a worldwide system.

Obviously, we have service members and their families in over 160 countries worldwide and we have to ensure medical care in each of those locations.

And we are focused both on health and readiness, very importantly. We have about 9.5 million people who rely on us for their medical care. That includes not only service members and their families, but also retirees and their families because anyone who serves honorably for 20 years or is medically retired before that and their immediate family get medical benefits for the rest of their lives from us.

So we have a lot of folks who are - who come into our system at birth. They are born into a military family. They choose to join the military, themselves. They then retire. And they may be with us from age 0 to age 100

and we are responsible for their care over that entire lifespan.

We have both a direct and a purchased care system. We will talk a little bit about that. A direct care system is 55 hospitals right now and 373 clinics around the world. Those are facilities that we actually run ourselves and staff with military employees, some active duty like myself, also civilian employees and contractors.

And then we also have a large purchased care system, where we contract with civilian providers to provide care. About 70 percent of our care is provided through the contracts, through the civilian providers, and about 30 percent in our direct care system.

Obviously, our - the number one reason the military has a health system is to make sure that our military can go to war, can

maintain the peace, do all of the things that our military has to do. That is why there is a military health system.

So, we talk about two things that are really our vision. We need to, number one, have a medically ready force. That means that our troops are ready to deploy on a moment's notice and have all of their medical needs met. Their vaccines are up to date. They're medically fit. They're ready to go and do what they need to do anywhere in the world on a moment's notice.

But we also have to have a ready medical force because we have to have medical folks who go with them to take care of them. So, it is very important to us to maintain our medical forces so that they are ready to provide whatever treatment is needed. And certainly, sometimes battlefield medicine is very different than typical civilian

medicine. And so we have to make sure that we're keeping those skills up and that is another very important part of our mission.

You see that we have an enterprise approach. We are very much right now focused on moving the network care and the direct care, the care in our own hospitals, closer together. In the past, those benefits have been different. You could get different things in military hospitals than you could through our civilian program. We are trying to change that, and we are trying to make those rules the same. That is going to be a process, but we are certainly moving in that direction.

We also - as you can see, our priorities and goals, I think the first two really apply to autism, specifically. So, we are working to optimize our operations, become as efficient as possible, but also very much

focused on moving towards a high value system of care so that we are providing high value care, care that is proven effective, and minimizing the use of low value care.

So if I can give you a medical example, we want to encourage the use of vaccines so we don't have to treat as much illness from folks who aren't vaccinated. So, that is an example of high value versus lower value care.

Of course, we want to create outcomes for health, wellbeing, and readiness, because we realize that family readiness is what - what is really what we are going to be talking about here today with our autism care, very much depends on - very much impacts on service member readiness. You know, when - I'm a psychiatrist, as I mentioned. When I have been deployed, I have seen any number of soldiers or sailors come

to me and one of their primary concerns and reasons that brought them to me was they were worried about the health of their family back home. So when we take care of the family, we are actually making a service member more ready, too.

I think we have one of the most generous medical benefits of anywhere in the world. If you are an active duty family member in our HMO program, there is basically no cost to you for any medical care. Your prescriptions are free. All of your medical care is free. Basically, you get everything at no cost. There is no copay. There is no cost share. No deductibles.

Even for our retirees, the catastrophic cap right now is \$3,000. So even if you need a million dollars' worth of care, you will never pay more than \$3,000 in a year. So, it is a very generous benefit.

So, I mentioned we support 9.5 million beneficiaries. We are not health insurance. I think that's a very important distinction. We are an earned benefit. People deserve this benefit because of the service they provide to their country. And I think that's an important distinction.

And we are governed by law and congress does from time to time, and has with the autism care program, as we'll describe - can be very much into the weeds and tell us exactly how they want us to administer the program. So we do have some statutory requirements that tell us how to do this.

And you will notice that because, you know, we have a lot of young active duty members, we have a lot of children. So about 2 million of our beneficiaries are actually under the age of 21.

We have the Basic Benefit. The Basic Benefit is what we cover for everyone. Unlike most civilian insurances, you can't buy different types of TRICARE. You can be in TRICARE Prime, which is the HMO, or TRICARE Select, which is more of a preferred provider network. Other than that, everybody gets the same benefit. Everybody gets the same coverage, the same things that are covered, the same cost shares and that apply to the retirees. There is one level of benefit in our program. So, that is kind of a difference from most civilian insurance.

We cover all medically or psychologically necessary treatments. And we will talk about what those criteria are, how we determine that. You can see the definition there in the law, but let me move on because I think it's important to look at both -

let's talk about what's covered under that - this definition and how we got to that point.

So, we cover medically necessary, evidence-based treatment. And we'll talk on the next slide about how we determine what is evidence-based.

But for children - and actually, we do have some adults, too, in the autism care program. They can get OT, PT, speech and language therapy - all of these are evidence-based for autism - obviously, primary care, of course. In an HMO system, the primary care manager actually manages all of that care. And then we certainly have robust mental health benefit. In fact, we just expanded that significantly. And as I mentioned, all medications, prescription medications are covered, usually without a copay, especially if you are getting them through a military treatment facility.

We also, for active duty family members only - one of the challenges for active duty families is Medicaid waiver programs and a lot of children with autism utilize those. A lot of our families, they move every two to three years. That is the nature of military service. So, by the time they get to the top of one of these Medicaid waiver waiting lists, it is time to move again. They move to another state and guess what? They go back to the bottom of the list. So, they can never access the Medicaid waiver services that they are entitled to because of the way the waiting lists are.

So, we have what is called the Extended Care Health Option, which provides specific benefits only to active duty family members because they are the ones moving around a lot. And that does provide some additional benefits to children with autism, respite

care being one. But there's also other things you can get through that program such as modifications to a vehicle, so you can get a wheelchair lift, translation services. There's a number of things you can get through that program that is specific for active duty family members. And a number of our children with autism do use those services.

So, let's talk about how we determine is something a covered benefit. Are we going to cover something for a child with autism, specific to this audience?

So, you can see there it is actually governed by federal regulation how we determine what's a benefit. And these are in order of importance. And we actually have a whole team out in Aurora, Colorado, that does nothing but look at the new research, monitors the journals, and reviews all sorts

of different treatments and things to determine what should we be adding to the benefit and on rare occasions, even what should we take out of the benefit if the research shows something we thought worked actually doesn't.

The number one thing is well-controlled studies with clinically meaningful endpoints. We are looking for that to be in a peer-reviewed journal. We prefer controlled and blinded studies when possible.

But we also realize, especially in the pediatric population that you are not always going to get a lot of that because there are both ethical and practical reasons why that kind of study can be difficult in a pediatric population. So, especially in pediatrics, we tend to rely on the other four things you see there on the list, as well.

I'm not going to read through them all, but basically, what we are looking for is things that are well-grounded in evidence. It has to be well done research. You know, all of the other things there have to be research-based. So, if we are looking at a technology assessment, a report of a national professional medical association. If it's just somebody's opinion, we are not going to give a lot of weight to that. But if that is a well-documented report from a professional association and they say this is what we recommend and this is why, so it is like a clinical practice guideline, we're definitely going to consider that in our deliberations.

If this - if this standard is met, that becomes a covered benefit and all of our beneficiaries are eligible to receive it if they have whatever diagnosis is appropriate.

So, let's talk about how we determined what is and is not a covered benefit for autism. Because you'll notice on that list that I showed you with the OT, the PT, and all of that, applied behavior analysis is not on that list. Applied behavior analysis, which is commonly used for autism, is not part of our basic benefit because it does not meet our hierarchy of evidence standard. The evidence does not - is not strong enough to support its use.

And we actually did a very extensive literature review, as you can see here. We have - if I go to the next slide, we have found that the studies do not consistently identify ABA. They are not - there is not a consistent way of providing the ABA. It - there is lots of variation in the studies that are out there in terms of the type of provider, the education of the provider, the

way they are providing the service, the age of the children in the study.

They are generally not well controlled with a lot of case series or even single case studies or maybe two or three or four subjects. And that is just not sufficient research to make a determination is this an effective treatment by our standards.

Again, very small sample studies. Often, the populations are very limited. They are very specific in nature, which makes it hard to generalize to a population like ours. And they are not always showing effectiveness. There's conflicting findings across these studies. And often, there could be outcomes may not be clinically meaningful because we not only look for statistical significance, we look for clinical significance, as well.

If I could use an example of a depression study, if the score on the

depression scale changed from 8.2 to 8.5, if you have a large enough sample size that might be a statistically significant change. But did it really make any difference to the patient? Did it make a clinical difference? And we look at that, too.

And what we have found is that, by and large, the studies of ABA just don't meet that level of rigor.

So, looking at the gaps in research - and this is where, you know, a group like this, we are very excited to hear about the work that you are doing because we are constantly watching for new research. As Krys is going to talk about, we're also sponsoring some research because there were some gaps that we didn't see being filled and so we thought we need to put - you know - DOD money behind that.

But, you know, so what are we looking for? Knowledge regarding specific ABA interventions. Comparative effectiveness studies. I can tell you - you may know - if anybody has been on one of our autism calls, you know that I often site some work that's been done - now, it's not rigorous research. It doesn't meet the hierarchy of evidence standard for sure, but we're aware of a group that surveyed 8,000 people or more, parents of children with autism who were signing up for basically a blog, and they asked them what helped your child with autism the most.

Number one thing was occupational therapy. Number two was speech and language therapy. And then number three, about 15 percent of parents said what was most helpful was ABA. So, we'd love to see some comparative effectiveness studies. What's

best for the child: OT, speech and language, ABA, maybe some combination of those?

Even more importantly, how do we know in advance which child is going to benefit the most from what? Right? It would be great if we could identify using a - some sort of technique, children as they come into our program, and say this is what's going to help that child the most. Then we can target the right treatment to the right child up front and help them reach their maximum potential in the most efficient way possible. And that is really important.

And right now, the science just doesn't support us doing that. And that is kind of frustrating.

Obviously, how much treatment? You know, we have a lot of kids in our program who get 40 hours of ABA a week. As we'll talk about, although we don't provide it through the

Basic Benefit, we actually have a demonstration project that lets us bend our rules a little bit and provide things that maybe are not fully evidence-based. And that's how we're providing ABA to children with autism through TRICARE right now.

But we have kids that get 5 hours a week, 40 hours a week. There's really no rhyme or reason who gets what. We are very much looking to determine how we can better manage those kids to determine who should get what level of service and what type of service, as I mentioned.

Again, what's the therapist experience? Is a high school-trained behavior technician really qualified to do this? Are they going to get the same outcomes as a board-certified behavior analyst? We don't know. The research just doesn't tell us that.

I mentioned patient-specific predictors of outcome. We mentioned the small sample size problem.

And last, a lot of heterogeneity. There is no commonly used outcome measures. We actually will have some and Krys is going to talk about that. We have some outcome measures that we are now using to help drive treatment planning that we think are reasonably reliable. But the studies are all over the place on what their outcome measures are. It would be impossible to do a meta-analysis, a good one, of ABA studies because there are so many different measures, you wouldn't get enough studies using the same measure to get reliable evidence.

So, with that, let me turn things over to the Krys, who is going to talk about our Autism Care Demonstration.

DR. BIENIA: As Captain Simmer mentioned, this is a demonstration benefit. Because the research doesn't meet the hierarchy of reliable evidence, we, like Captain Simmer said, can bend the rules under a demonstration. And ultimately, our goal is to figure out how do we move these services to be a medical benefit? What must happen? And so I'll talk a little bit about that.

The other thing to point out is Captain mentioned - Captain Simmer mentioned the difference between direct and purchased care. Most of the ABA services that are rendered under the TRICARE benefit are in the purchased care, meaning our network and non-network providers who are contracted through our regional contractors, Health Net in the West and Humana in the East. We won't spend much time talking about them, but certainly feel free to ask me questions.

Briefly want to talk to you about the history of ABA services under TRICARE. We started providing services in 2001 as an educational benefit. And you can see throughout time, we have evolved from an educational to other than educational to now other than medical. And hopefully, we'll figure out how to move the services that we provide to a medical benefit.

You can see right now the 2019 - why I included that is there was a CPT Code change. I'm not going to spend a lot of time talking about that today, but that is a huge milestone for us because prior to this year, they were Category III codes and prior to that, we were using non-standard code usage. So, again, the evolution is moving us more towards medical benefit, but CPT Codes are just one component of that.

And then our demonstration authority ends December 31st, 2023. So, we need to figure out what we're going to do between now and then.

A little bit about our benefit currently. So, I have here that about 15,000 beneficiaries are receiving ABA services under the demonstration, but I want to highlight we have about 30,000 beneficiaries under TRICARE who have a diagnosis of Autism Spectrum Disorder. We don't know why the other 15,000 or so aren't utilizing the benefit. We have guesses. Perhaps - you know, maybe they've aged out of services. Maybe they don't need the services. Maybe they're receiving services elsewhere.

This is a gap we're trying to address. And Captain Simmer will talk about - later in the slides - about our movement forward and what we're going to try to do for that.

We currently have about 25,000 ABA providers. I believe it's somewhere around 10,000 Board Certified Behavior Analysts and then the assistants and the paraprofessional level make up the other 15,000.

Lastly, on this slide, our annual cost of the ACD is \$268 million per year with an expected growth of - to about \$400 million by the end of the demonstration. So, we are really trying hard to be good stewards of taxpayer dollars when we talk about ABA services, medical necessity, and our beneficiaries and their improvement.

I'm not going to go line by line here, but I wanted to highlight some of the covered elements of our benefit. Really to highlight the Autism Care Demonstration has no limits. We have no age limits, no dollar limits, no duration limits, and no caps on any of the services. That wasn't true about five or ten

years ago. We had other limits. But in the spirit of Mental Health Parity, which TRICARE is not subject to, but we are aligning as best we can, there are no limits.

Essentially, we - the key is - and we will keep hearing this as we continue through, we want to - to be a medical benefit, we have to be providing medically necessary services.

Captain Simmer mentioned outcomes. Outcomes have been a challenge for us over the course of time. And we are finally at a place where we have outcome measures in. And how - the three that are listed up here, the Vineland, the Social Responsiveness Scale, and the Pervasive Developmental Disability Behavior Inventory, those are essentially parent surveys, but we had to select measures that were applicable to all beneficiaries, they had access to those measures, and we had

a resource of providers who were able to deliver those services.

Being devil's advocate, are they the best? Maybe. Maybe not. We talk about the inconsistency across literature. And they talk about the ADOS or maybe other measures that could be - lend itself to better information, but we don't have the provider pool to be able to render these or deliver these measures.

So, right now, this is where we're at. And ultimately, it's about driving treatment. We want to know at these intervals are our children getting better. And loosely, I'll talk about getting better. Are they improving in symptom presentation? Are they becoming closer to their developmental age, as opposed to developmental and chronological age, are they matching up?

The other thing to point out is our diagnostic measures. Again, specialty fields in pediatrics, is a limited resource. There are limited providers out there. And we have inconsistent use of the diagnostic tools. You know, well baby visits, they use the M-CHAT, standard measures through all pediatric appointments, but the specialists are inconsistent also in their usage, whether they are doing the ADOS or they are not.

So, we have a lot of variability here. And, hopefully, going forward, we are looking for information on how do we diagnose our kids as early as possible and get them the right services when they need them most?

And we'll come back to this question at the bottom to the group here is are there other measures we should or could be using, again, keeping in mind the provider pool and

the accessibility to all of our beneficiaries.

I am going to go through this slide quickly. We have several initiatives that are going on within the Autism Care Demonstration and the Defense Health Agency.

We have a significant engagement with our stakeholders, whether it's ABA providers, advocates, lobbyists, internal and external - so like the developmental pediatricians within our military health system. Lots of engagement to provide us good information resources, even research, up and coming research.

One of the other ways that we communicate, and I will highlight because I want to give you the email address is our ACD mailbox. This is for program policy questions that providers, stakeholders, anyone interested who can reach out to us and ask us

any questions. I am going to share that email address because I think if you all have ideas after today or we don't get a chance to go over them, I would love to hear from you.

The address is really easy. It's DHA - so Defense Health Agency - .ACD - Autism Care Demonstration - @mail.mil. I will say it again, DHA.ACD@mail.mil.

It's a great way for us to communicate. And it goes to several people at the Defense Health Agency, so we monitor that daily.

UNKNOWN SPEAKER: (inaudible comment)

DR. BIENIA: M I L - mail.mil - as in military. Yes, ma'am. ACD - I'm sorry. DHA.ACD@mail.mil. Thanks - thanks for clarifying.

Two other activities that we have on this slide. We have Quality audits that are - we have contracted out an external reviewer to look at what's going on in our Quality

metrics. That is an evolving topic for us because the - well, I'll talk about Quality in a second here, but that's a huge effort on our part to ensure that we're providing quality care.

And the last thing that, you know - on this slide - 2017, we hosted an Industry Day to really solicit best practices and ways of delivering the most efficient services. Again, moving us closer towards that medical benefit.

Spend a little bit of time here. The directs - direct care has four locations now where we're providing some sort of resource on a military installation, so at the hospital.

And I'll point out that Fort Belvoir Community Hospital here, in Fort Belvoir, Virginia, and then Walter Reed National Military Medical Center up in Bethesda - I'm

sorry. Those both have programs that are engaging with parents directly, exposing them to the resources, the services, the availability not only within the military health care system, but their local resources. Connecting with schools. Connecting with Medicaid services.

So, we really are trying to leverage this passing on of knowledge. I'm sure everybody here has had an experience or knows somebody who - you know, receiving the diagnosis is very tough on that family in those first few - well, for quite some time, but especially those first few days. And it is overwhelming information. We are trying to provide a resource where we can disseminate and put out and contact with all of what we have available.

Joint Base Lewis-McChord at the Madigan Army Medical Center offers a

multidisciplinary clinic where they do a lot of the in-house assessment. We are trying to figure out how to replicate that military-wide.

And then Wright-Patterson Air Force Base has the P.L.A.Y Project. I think it's Play and Language for Autistic Youngsters Project. And that's a parent-mediated program based out of Ohio. I think Dr. Solomon is the lead on that concept. But Wright-Patterson Air Force Base has taken the initiative to do these parent-mediated programs as a supplement or possibly an alternative to some of the ABA services.

The next on here - I am going to go to those slides because they're important to us. The Department of Defense Office of the Inspector General did two audits, the North and the South regions. I won't spend much detail on this, unless you are really

interested, but, essentially, we found that based on medical records documentation that two-thirds of our reimbursed services were inappropriately paid. And that's basically because there was either no documentation, insufficient documentation, or absent - or inappropriate, so copy and paste.

We find that we're trying to move these providers from an educational to a medical benefit, so they're learning some of the ropes of how to provide medical care, to include how to write a medical record.

The links to these are - I mean they're publicly available. So if you're interested, feel free to download that information.

But the last thing that I want to spend time talking about is - the most exciting part for us is the Congressionally Directed Medical Research Program. And Nicole Williams is our POC for that, so thanks, Nicole. But

it was - the study was awarded in the fall of last year to the University of Rochester. And it's - the abstract is available at that link.

But really, for us, we see this as the potential to be an incredible study looking at - comparing standard of care, so early intervention - early intensive behavioral intervention with an adaptive model. So, an hour bifurcation here.

They are really looking to address four key questions. Do kids improve as well as or better - right - for the adaptive model? What's really the impact on the families of this adaptive model? Can we predict any of this information - are there any predictive factors that we can glean from these kinds of - types of delivery? And then, ultimately, what helps or hinders a company from providing these types of services?

So, hopefully, they will be able to answer those question.

The next slide is - I think is what's most important to community at large. Five items that we're hoping to identify.

The first is how does it compare and does - how can we give families more choice. That would be a huge contribution, I think, to the field.

The second one is knowing that ABA works well, it can provide us more justification. If we can get to those clinically meaningful outcomes - like Captain Simmer said, obviously, this is not an RCT, but it's - we're moving closer with a larger sample size. I think the anticipated - or the projected n size is 130, which I think for any one study is pretty large when it comes to autism research.

The next one is for family selection. What works best for the family? This is intensive on the family. People go into these family's homes and spend lots of time. You know, can we do this more efficiently?

The last one - or number four is can we do - can we provide services at a lower cost? Like we said, we have 263 or 68 million annually right now. Can we provide better, more effective care at a lower cost? Not reducing reimbursement rates, but can we get to a more meaningful outcome from a different model?

And then lastly, I think, not only for TRICARE, but I think this will provide information to all funding services on ABA services. So, we have great hopes.

It's a five-year study. There'll be annual reports. And at the end, obviously, we are anticipating some sort of a published -

well, hopefully, a peer-reviewed journal to talk about this five-year study.

Captain Simmer?

CAPT. SIMMER: Thank you. All right, so the last thing that we wanted to cover before we give you some questions is a little bit about where we are hoping to go next with the Autism Care Demonstration.

Let me just say upfront that, you know, I'm responsible for all medical in TRICARE, so although autism is probably the single program I spend the most time on, it succeeds because we have two really outstanding people. Krys is one. We also have Ms. Amy Hinds down in San Antonio. But all these kids get their care because of their work. So, I just wanted to really shout them out and say what a great job they do and recognize them.

So, this is where they are taking us next. This is what we want to do next.

We want to have a truly comprehensive benefit. If you read the Autism Care Demonstration - and you can go to the TRICARE manuals. We have 5,000 pages that tell you what TRICARE does online. If anybody is really bored, go read them. But we actually use those.

And in there, if you go to the TRICARE Operations Manual, you'll see in chapter 18, there is a section on the Autism Care Demonstration. And right now, it is very focused on applied behavior analysis and it is very provider focused. How do we take care of the providers? That needs to change.

TRICARE is a beneficiary and family-focused program and service member. Right? We talked about that. So, the Autism Care Demonstration needs to become a beneficiary and family-focused program and that is where we are going next. And you are going to see

some very dramatic changes, I think, to the Autism Care Demonstration between now and July. That is really our goal to get all of these changes published and announced.

And the biggest thing there is going to be we are going to be a much larger parental and family component. You know we cover parent training right now. Less than half of our families actually receive it. That really bothers me. That is a failure on our part and we are going to change that.

So, we are going to make parent and family support because we know what is the number one evidence-based intervention for children with autism? Taking care of their family. Taking care of their parents. We need to do a better job of that and we are going to do that. We are going to expand the benefit that parents have available, the services that parents have available, and we

are going to incentivize their use. And we are going to go to the providers that aren't doing it and say, why not and we are going to hold them accountable for that.

We are going to have a more holistic, beneficiary-centered approach. What are we providing for the beneficiary? So, it's not just going to be ABA anymore. I mentioned that that is the number three thing that parents found helpful. So, we are going to incorporate occupational therapy, speech and language therapy. All the other things that are evidence-based that help children with autism, we want to bring that into one program, not two bifurcated sides like we have today.

And really make it so we have treatment team - we are going to require treatment team meetings and require a single team to be working with that child for the child's

benefit and the family's benefit. That's going to be a change for us.

We're going to expand respite care. We know these families do well when they have respite care, so we want to expand that benefit. We want to see if there's a way that we can legally offer that to our retiree families and not just our active duty families. We're working on that with our - there are always statutory issues, but as Admiral Bono has told us many times, our director, tell me what's right and then we'll figure out how to get there. So that is what we're going to do here.

Case management/care coordination. We really want to beef that up and make sure, again, that we're looking at the child as the focus and everything is coming in to make that child - help that child reach their

maximum potential and that everything's focused on the child and not on the provider.

Utilization management, I mentioned that already. Right, we've got some kids that get five hours of ABA and some kids who get 40 hours a week. We have no evidence that their outcome is different. The CDMRP study is hopefully going to help us get to some of that, but we can do some of that now, too. That's why we have some outcome measures.

One of the questions you are going to see on our next slide is what do you recommend we start measuring so that we can identify and target the right services to the right child? Maybe this child is going to do better with occupational therapy. Then let's do that. And this child will do better with ABA. Then let's do that or some combination. We need a better way to manage the

utilization in such a way that it serves the child and the family.

Quality oversight. We are going to have a big focus on that. One of the things we're doing on a large scale in TRICARE is moving to value-based care. That's not just in autism. That's in lots of things we do. We have a number of value-based care initiatives. And we're focused not only on incentivizing providers, but also incentivizing patients and encouraging them to use the highest value care. And that's going to get built into this care demonstration.

We're going to identify the things that are the most needed for that child and then set up the financials and some of the non-financial incentives, too, so that we can ensure those children get the - again, the best thing for them.

So, questions that we'd like to ask you. One, if you are aware of any research or any data that would help us with that utilization management piece, what is the dose response, how can we identify - because we know Autism Spectrum Disorder is not one illness. Right? It's a variety of different things that all kind of fall under the same thing in DSM-5 and the ICD because it's very - right now, the description is really symptomatic, not based necessarily on the underlying etiology.

What other outcome measures can we use? Because we definitely want to measure the outcomes. We want the treatment plans to match the outcomes. And if we're not getting the outcomes we should be, then the treatment plan needs to change and we need to hold those providers accountable to make that happen. And we have the authority to do that

from congress, but we need good science to base that off of.

And finally, what are medical necessity criteria? Kind of getting - you'll notice these questions all kind of interrelate. We want to be able to look at the science and use that science to develop treatment plans for these children that will help them reach their maximum potential, help their families adjust the best way possible to having a child with autism, so that we are using - you know, we put a lot of money into this program and that's great if it's helping the children. We don't mind spending the money if it helps the children, but let's make sure we're making the best use of the resources that we're expending and that - again, that we're using the most recent science and evidence that we can to get to where we need to go.

So, with that, we're going to open it up to discussion.

DR. GORDON: Thank you very much. I see John and Geri and Lou. Go ahead, John.

MR. ROBISON: Thank you for your presentation and for the efforts in autism care. I would like to suggest that for many people in the autism community, the first priority is actually something you did not even mention here and that is identifying and treating other serious medical problems that accompany autism.

We have had many meetings and discussions here at IACC about how in the case of children, intestinal pain, various other causes of pain, are the root cause of serious behavioral problems. And for many with autism, those are unidentified and untreated. Epilepsy is probably a major cause

of death for autistic people and that wasn't mentioned.

So, I would suggest then with all due respect that that's a fundamentally different priority that might well be incorporated into what you're doing.

The next thing that I would question is you talked about occupational therapy and speech pathology or speech therapy as being the two first things. ABA is the third. And then the whole presentation was about ABA.

Here, at IACC, we have sat year after year and we have watched billions of dollars be invested in autism research and from some of those billions, we have evolved new therapies. And I think many people would say that ABA is more than 50 years old. It is like the sulfa drug of autism treatment. There are many other things.

And it concerns me that you didn't mention trying that. And I see a risk that we're going to be trapped with one treatment for autism that TRICARE covers and that is ABA. I would very much hope that that does not happen.

And the final thing that I would ask you all to consider in evaluating ABA, speech and occupational therapy, too many of the studies that evaluate those things are based on parent report and clinician report. And we are - we've now been - we've got 20-30 years of all of those things being administered in big numbers to autistic children. And the autistic children who receive, in particular, ABA, often, when they are adults, they have strikingly different opinions about the value of those services than their parents did. I would urge you to look at that when evaluating what we should do.

CAPT. SIMMER: Well, great comments and let me tell you I agree with all three of your points, first of all.

So, absolutely, we are aware - in fact, we are looking - we maybe should have put this on the slide. You know, one of the things that we're very concerned about is feeding disorders in children with autism. How are we building that into their treatment plan?

Certainly, a third of children with autism have seizures. In fact, we have some requirements that the community doesn't like, I will add, that all of our autism providers have to have CPR or BLS training. Why? Because these children have medical complaints. They have things like seizures where you might need that training. It's amazing the number of folks in the community

that aren't real happy with us for that, but we have that requirement. But, absolutely.

Now, they - now, you know, as I mentioned, we have a very comprehensive medical benefit so those things will be addressed, but I appreciate your feedback. And I think that's good feedback for us. We will look to make sure that we're incorporating all those medical issues, not just the things we talked about, as we rewrite the Autism Care Demonstration. So, completely agree with you on that point.

So, I think in regards to the medical issues, absolutely, yes. And your - you know, I tried to get to this and if I didn't very effectively, I apologize. You are right. This is an ABA focused program today. ABA has its place and I think its an important component of a treatment plan. It is one component. There need to be many others.

And that's what I was trying to say here is that what you're going to see over the next six months is this is not going to be an ABA-focused program anymore. It has been in the past and that has not been to our credit. So we - that's why we're going to build in the OP - the OT and the speech therapy and other things, too, like the P.L.A.Y therapy that we're now testing out at Wright-Patterson Air Force Base, or some of the things that we're doing at Madigan out in Seattle.

We are going to have actually a summit with our direct care providers, who are testing out some of these new and innovative things to bring them in and let's see if we can expand those things across the entire MHS so that all of our children can benefit from this.

So, completely agree with you on that point. And we are absolutely wanting to make this a - again, ABA has its place. We are not going to - I'm sorry. We're not going to eliminate ABA, but we are going to make this a more holistic program and not only focused on that. So, completely agree.

And actually, do you want to take the third one?

DR. BIENIA: Sure. I think the - the comment about parent and clinician-based feedback, that is absolutely one of the issues we're trying to take as just one component because - when we talked about outcomes, like I said, the three that are on there are provider and parent surveys. We want to go beyond that. We want to go beyond what's self-report, essentially.

And I think that's a critical component of moving forward and also getting us to

include other evidence-based services that are out there. We know there are a whole host out there, but like Captain Simmer said, we've been driven - external forces have driven us to focus predominantly on ABA services.

And we think we're finally at a good enough place where that is settled. Let's evolve. Let's keep growing. Let's provide what the child actually needs. Because long-term, we want them, like Captain Simmer said, to be the most well-functioning individual and, you know, possibly contributor to society, right. So I think we want to keep evolving and keep growing and moving in that direction.

DR. GORDON: Dr. Dawson.

DR. DAWSON: First of all, I am thrilled about your new - new program that you're developing that is looking at the efficacy of

early intervention and the new program out of Rochester. I just think that's fantastic.

And I actually, you know, recall being at the senate, you know, hearing around TRICARE Benefit and testifying at that and having Kirsten Gillibrand suggest that the review that apparently now has been done be conducted to understand the evidence base. So, it's interesting to see how it has evolved.

I just have a few comments. One is - and this was - other people had mentioned this to me, so I am saying it also on behalf of others, which is that I think it's important to keep in mind that ABA is a very broad term. Sometimes people think of ABA as discrete trial training or discrete trial teaching and - but ABA actually encompasses a very broad range of evidence-based treatments, including the play-based and

naturalistic, you know, types of developmental/behavioral interventions that are now being used in many cases.

The other thing I wanted to say is that although I completely agree the evidence base needs to be stronger, should be stronger, I guess I respectfully disagree that it's quite as weak as perhaps it was portrayed. That I do think there have been very high-quality randomized clinical trials. And that those trials have shown meaningful outcomes.

So, for example, I am aware of one very well - a randomized clinical trial where the outcomes were IQ, language ability, adaptive behavior. Children were followed for two years afterwards, after having received two years of intervention. And the gains were sustained for two years. And, again, cognitive, language, adaptive behavior,

symptoms, all continued to show benefit, as well as analyses of the cost-benefit.

So, even people on this committee tracked the services that children who received two years of intensive intervention, meaning, by the way, 15 hours - so it's not 40 hours - a week for two years. That after that, they required fewer services and the cost-savings was estimated to be about \$19,000 a year after having received the two years intervention. And it was estimated that by age 10 that the costs were fully, you know, recouped because fewer services were required.

The other thing is just to say that NIH has funded a number of studies that are - will be coming out in the next year or two. There is a study in press, which is a multisite randomized clinical trial of intensive early intervention, which I will,

you know, just say that we - that there was benefit found in meaningful outcomes. And I won't, you know, disclose too much because it'll be coming out soon.

As well as there is a study funded by NIH that is I think close to being done where they are comparing more play-based versus traditional types of ABA interventions at two dose levels, so that we can start to get some information about dose.

Thank you.

DR. BIENIA: Sure. I very much appreciate those - the comments and the feedback. I agree that there are - for our review, we identified six RCTs in that 2013 - actually, I believe it was the 2015 - but we had identified six RCTs that were - as part of that medical benefit determination. While there were some great findings in there, one of our challenges is replicability. One study

finds some great outcomes and then we don't see another one that replicates the same criteria, the same outcomes, the same population, the demographics of the children studied.

So, yes, there are - totally agree there are some good studies out there. It's the big picture here that we struggle with.

DR. DAWSON: Just one more quick comment is I do remember at the time that I was working on this more actively in an advocacy role, Tom Insel made a comment to me as we were walking in to talk to some of the people who make decisions around insurance. And he said, it's always amazing how mental health benefits require a higher standard.

So, for example, has there ever been a randomized clinical trial of speech therapy? So, I'm just saying that there - six trials. So the outcomes were a little different. I

think that the standard for some reason for these kinds of benefits is higher. And I just think its unfortunate because a lot of people are waiting while we require these incredibly high standards.

CAPT. SIMMER: I'd say two things if I could. One, you know, we certainly - we're always looking for new studies. I think we've probably seen the ones you referred to, but if you could send us the references that would be great. We'd appreciate that. So, if you could use DHA.ACD@mail.mil and we would love to communicate with you some more. I think that would be really helpful, so I would ask you to do that.

I will tell you that we do apply the same standards to - those hierarchy of evidence standards that we mentioned do apply to everything that we do. And I am aware of some randomized control studies of speech and

language therapy where some children - and adult, both, but mostly children - got it and some didn't, and they compared the results. So, yes, there are some studies like that. I can't cite them off the top of my head, but I know they're out there.

And I think we are pretty good about using the same standard. As I mentioned, we actually use a slightly lower - I don't want to say lower - a slightly different standard for pediatric studies because we know that the same level of evidence doesn't always exist for pediatrics as adults and that doesn't mean that the treatment is not helpful.

So, I think if anything, we do have a slightly different - and I certainly would not say higher standard for pediatric research than for adult. It is just a little bit different.

DR. BIENIA: One more comment I wanted to
- sorry, I will be quick. I promise.

The comment about the number of hours -
it's interesting for us right now and this is
why we're looking for medical necessity
criteria, is that these providers in the
community make these recommendations and that
is essentially what we go on. So, there is
nothing out there for us to go back and say,
really, why did you decide 40 hours? How come
you're only - and then billing us for 10? If
you thought 40 was medically necessary, we
need to figure out a way to get 40 to get
your child - you know, the logic, to me, is
that if you are under-providing what your
recommendation is - it's just like any other
service. Right?

If I have my Z-Pak of - you know,
because I'm ill in some way and I take five
out of the seven pills, well, I haven't done

the dose response. Right? Now, that's a little bit different because we know some of that information, but these recommendations, we - we're trying to move so we can make better decisions on what is the right amount of care for our kids. And we just don't have that yet.

DR. GORDON: So, I am going to go to Dr. Reichardt in a moment. I just wanted to make a comment, which is in a similar circumstance, which is the use - recommendation by the U.S. Preventative Services Taskforce for Screening for Autism.

We've been engaging in a dialogue with them about the kinds of research that they would find compelling enough to change their recommendation to - in favor of universal screening for autism. And we have designed a research program to answer those questions.

So I think engaging with you and other health care funders around the kinds of evidence that you would find compelling - would it be a repeat of the kind of study that Dr. Dawson mentioned, et cetera - might help us. In addition to, of course, awaiting the results of the study that you identified, which has the potential to replicate the earlier findings.

I think continuing this dialogue will help over time. And in fact, I already sent off an email to Ann, who runs the NIH-wide research program to ask, well, what do we have in this area and to send that information to you.

So, we'll engage in that dialogue going forward. I want to give Dr. Reichardt the chance for the last question or comment before we move on.

DR. REICHARDT: (inaudible comments)

DR. GORDON: Can you - the mic.

DR. REICHARDT: All right. Excuse me. I enjoyed and appreciated your presentation. I think one comment I would have for you to consider is that in terms of analyzing future risk, actually, genetics is one of the best prognosticators about what else might happen to something. And you might consider incorporating this, which is now quite low-cost and would probably provide some comfort to the families. You know, knowledge is always helpful for families.

The second thing is I'd hope that maybe we could talk about some incentive to persuade your families to participate more widely in autism scientific research, which again may be of future benefit. I mean there are a lot of new drugs that I think are on the horizon for improving cognition and so on. And it - particularly knowing as much

about these people, their characteristics, IQ, genetics, and so on, may be very important in determining who is most appropriate for inclusion in such trials.

Thank you.

DR. GORDON: Thank you. I am afraid we're going to have to move on. Susan has some announcements before our break.

DR. DANIELS: Thank you. Thank you so much for your presentation.

DR. GORDON: Let's thank TRICARE for their presentation.

(Applause)

DR. DANIELS: So, I have a very important and happy announcement. Sam Crane sends her greetings and she wanted me to announce to you that her baby arrived today, so she has a good excuse for missing the meeting. But she said she is sorry she can't be here, but she is well occupied and doing well.

(Applause)

I also wanted to welcome Nicole Williams and Rob Ring. I didn't get a chance to do that earlier.

Wanted to mention that Marcy Ronyak and Tiffany Farchione are not able to be here because of the absence of federal appropriations for their agencies. They wanted you to know that they are not just missing the meeting for other reasons.

And we will have a photo of the Committee during this break because we have a number of new members and want to update our website. So, if members would please step to the side here, we will get that done as soon as possible and then we will come back.

Josh, what time would you like?

DR. GORDON: I think we should come back at 11:10. Does that give us sufficient time for business? Yeah.

DR. DANIELS: Yes. Good.

DR. GORDON: So, committee members, where should we meet for the photo? In the back here. And we'll reconvene at 11:10. Thank you.

(Whereupon, the Committee members took a brief break starting at 10:55 a.m. and reconvened at 11:13 a.m.)

DR. GORDON: Please take your seat we are going to get started again. We want to make sure to use the full amount of time for committee business that we need.

So, before - the next item on our agenda is committee business. I'm going to turn the microphone over to Dr. Daniels to proceed. I just - before I do that, I just want to mention that I have an obligation during the lunch hour over on main campus, so I'm going to be leaving a few minutes early from the business session and I will be back hopefully

not too many minutes late into the public comment session. But I'll be hopefully back here by 1:15 at the latest.

And in the - during that time, of course, Susan will chair the session.

DR. DANIELS: Thank you. So we'll move onto IACC Committee business.

Just to start off, thank you to the OARC staff, again, for all the work that they put into preparing for this meeting and preparing the many publications and projects that you're going to see presented here. In particular, this time, we are going to be talking about the IACC ASD Research Portfolio Analysis Report. And thank you to all of them for all their work on this.

So, first, I wanted to talk about a new option that the IACC has for submitting public comments. Last time, we had a discussion about public comments and,

particularly, about remote public comments. So, just to review, since 2008, the IACC has had two methods for public comment. One is written comments, which are a form of remote public comments that can be submitted in advance and can be sent from anyone around the country, around the world. We also have oral public comments that are presented in person at the meetings.

And these two methods are used by the vast majority of federal advisory committees across the government. And there are - on the GSA website, they say over 1,000 federal advisory committees. We looked at a sampling of these federal advisory committees and did find that they use these traditional methods of public comment.

So, we wanted to explore whether we could offer a different - an additional option for public comment. So, we've

established a new one. It's called the live feedback form. This option will provide additional flexibility to those who are not able to attend the meetings in person to submit a written comment - or - and that cannot submit a written comment in advance.

The live feedback comments can be submitted online from 9:00 - 11:00 a.m. on the day of the meeting. And today, it's already past 11:00 a.m., but we're going to keep it open just a little longer so that anyone who would like to submit a comment via this online form can do so. And I'll show you that in a minute.

And these comments must adhere to the guidelines and will be collected and presented to the IACC before the public comment session in the afternoon. So, the IACC members, you will receive a packet

during the lunch hour that will have these live feedback comments in it.

So, just to show you the form, when you go to the IACC webcast that you can access from our website - from the IACC website or from NIH Videocast - when you go down to the bottom of the videocast, there is a little link that says live feedback. So you have to click on that. And then it'll open up this form and you can submit a comment right online.

So, the advantage of this is that you don't have to do it in advance to a deadline. So, this can be done on the day of the meeting. And you might even be able to comment on early sessions of the meeting.

And for the guidelines, again, there's a link there that is provided for you.

So, we hope that this will provide a little bit of additional flexibility for

those who are listening remotely. We really appreciate the many people around the country who do listen to our meetings and have important feedback and information to share with the committee.

I also wanted to give you an update on disability accommodations, as this was a topic of discussion at a previous meeting. Just to reiterate, closed captioning is always available through the NIH VideoCast. And you can access it through the little CC button at the bottom of the videocast - or it might be at the top. I think it's at the bottom of the videocast. And that has always been there since we started videocasting back in 2009.

We also initiated a new feature. A quiet room started in April 2018 at our IACC meetings and events. To date, we've only had one user of the quiet room in one of our

meetings, but perhaps it hadn't been publicized enough. We did put it on our materials. But just wanted to announce it here that we do have a quiet room for those who might need it. And you can ask for information about it from any of the staff who are in the meetings.

We also started in October 2018, providing CART services, as this was brought to our attention that it might be helpful for certain individuals who are attending our meetings. Last meeting, it was provided as - within a remote application, a web application, and that is still being provided. But this time, we also added a screen that is over to my right and anyone who needs it can use it. Today, it looks like we have no users in the room. However, there may be people logged onto the app and you are welcome to use that.

If you need information, please email our office about that for future meetings and any other disability accommodations may be made available upon request.

Just moving right along, I'd like to make an announcement that we have the 2016 IACC Autism Spectrum Disorder Research Portfolio Analysis Report that has just become available. This was just released.

This is the first portfolio analysis report that is coding projects to the 23 new objectives in the Strategic Plan that you all put together in 2016 and '17.

And to accompany the report, detailed 2016 project data are now available in the Autism Research Database that is accessible via the IACC website. So you are welcome to look at that.

And, members, you have a draft - or a preview copy of the report at your table. We

have not done the full printing run of this. If there is anybody out in the audience who wants a paper copy, please leave your address with us and we'll mail it to you or anyone out there in the public who's listening in, you can just email us and send us your address and we'll send it.

So, just to give you very brief highlights of the report, the Analysis includes data from 18 federal agencies and private organizations. And in the 2016 dataset, we found that research funding totaled \$364 million and included 1,360 projects. And federal agencies supported 80 percent of the overall funding that was analyzed in this report, which is similar to previous reports. This was the ninth report that we've done in OARC for this.

So, in 2016, federal agencies and private organizations supported research in

all seven of the IACC Strategic Plan question areas. And in 2016, Question 2 (Biology) continued to be the most highly-funded research area. And this pie chart shows you in more detail what the funding was for each section.

I wanted to give you an update on the budget recommendation that the IACC made in the Strategic Plan. The 2016-17 IACC Strategic Plan calls for a doubling of the 2015 ASD research budget to \$685 million by 2020 and this would cover federal agencies and private organizations that are funding research. To accomplish this goal, the Committee recommended a nearly 15 percent annual increase in ASD research funding.

And just to give you an update on what is happening with that, since 2015, funding for autism research has increased 6.3 percent

in funding. So, there's a similar figure inside the report.

This table I'm not going to give you all the information, but I put it in the slide set. It does not appear in the report, but it gives you an update on the funding levels for each of the Strategic Plan objectives and the project counts. So, anyone who wants to go back to this information can find it on the slide set when we post it on the web.

In addition, the 2016 IACC ASD Research Portfolio Analysis Report includes: a map displaying institutions involved in ASD research across the U.S.; a list of countries that are receiving U.S. funding for ASD research; funder contributions aligned with the seven Strategic Plan questions to give you an idea of the mission areas that are being accomplished by each of these funders; a subcategory analysis for each Strategic

Plan question to show you what types of scientific and services research are being done; and ASD research funding trends from 2008-2016 arranged by Strategic Plan question.

And at the bottom we have a link to the full report and you are welcome to look at it there. And we have information that's also been sent out and will be going out about this report to make it available to everyone.

Next, I would like to share with you an update on the Autism CARES Act Report to Congress, which is required in the Autism CARES Act. So, this report will detail progress on activities related to ASD and other developmental disorders across the federal government.

On behalf of HHS, OARC is coordinating responses from federal departments and agencies and we've prepared this report. The

report is in the final stages of completion. And we expect this report to be out shortly. And so, you can be looking for this and we will, of course, share it with you at the April IACC meeting.

In addition, I wanted to share an update with you about the IACC Strategic Plan Update, which is required by the Autism CARES Act, as well. And we discussed this last time.

The Committee agreed that we would provide a short summary report of activities from 2018 within the IACC and progress has been made on the Strategic Plan. And this report would include a summary of Health Outcomes Working Group activities and the workshop that was just held, a summary of the IACC Portfolio Analysis Report, which I just shared with you, and a summary of the Autism CARES Act Report to Congress.

Committee members will receive a draft for review and comments. The reason that you have not received it before this meeting is because we are waiting for this Autism CARES Act report to Congress to be cleared and published before we can share the information with people who are not part of the federal government. So, we hope that we will be sending that to you shortly, but we have it basically ready to share with you as soon as that happens.

And we expect the final publication to be in Spring 2019. So, we'll also be presenting that report to you in April.

Other reports that OARC has in preparation include the 2017 IACC Portfolio Analysis Report. We really appreciate the contributions of many federal agencies and private organizations to this report. We've collected the data already and we expect the

final report soon. So, we hope that this spring, we will be able to share that report with you.

We also - sorry, that one is not expected in spring. That's expected this year.

In the spring, we expect to share the 2016 International Portfolio Analysis Report with you. And that covers the U.S., Canada, and the UK. And we will give you an update on that as soon as we have that.

So, the next update, just keeping us moving here, is Improving Health Outcomes for Individuals on the Autism Spectrum Working Group. So, this working group has been meeting. So, the IACC, again, voted to convene a working group on health and wellness issues for individuals with ASD. And Dr. David Amaral and Dr. Julie Taylor are our co-chairs for this working group.

And the Working Group is exploring ways to: support research to better understand the health conditions that affect individuals on the autism spectrum; to increase community and provider awareness of these conditions and their treatment; and to foster development of practice guidelines, policies, service approaches, and other efforts to improve the health and quality of life for people on the autism spectrum and their families.

So, the scope that we went over last time is listed here - health and general wellness, co-occurring conditions, premature mortality, patient-provider interactions, and parental/family mental health.

Just to summarize activities that have happened, we had a Working Group conference call on September 5th. We had a very nice workshop that I went over with you at the

last meeting on September 27th. And we had a very nice discussion here, in IACC, about that, which was helpful. And the Working Group had another conference call on December 17th and they discussed plans for their written product and plans for a workshop on mental health issues in ASD.

So, the remaining activities of this working group include working on this written document - and we are working together to develop a workshop around mental health conditions that will be taking place in spring 2019. We'll keep you updated on that as we develop the agenda for that and the dates and we'll get those dates out to you as soon as we have them finalized.

We also will be continuing discussions in the Working Group via conference call and IACC full committee meetings. And Working Group activities will run until September

2019, which is the term of this iteration of the Committee.

Next, I wanted to give you an update on the Housing Working Group.

So, the IACC voted to convene a working group on housing issues for individuals with ASD. And it was very timely, today, having an update on some housing policies from CMS.

The scope of this Housing Working Group will be research and best practices on housing, implementation of current federal regulations, and housing issues faced by autistic individuals with more severe disabilities.

Alison Singer has volunteered to serve as a chair of this working group.

So, this is a draft mission statement that has been developed for the Housing Working Group, but it's subject to further

refinement once the working group has been convened.

So, this draft is: In the autism community we face a mounting housing crisis, with growing - a growing population of autistic adults with diverse needs lacking appropriate living situations. The goal of this subcommittee is to examine a wide variety of housing options and service models for people with autism, and to develop strategies to achieve a broad array of supported housing options throughout all of our communities that enable autistic individuals to achieve person-centered outcomes.

So, the activities will include: working group phone calls, possible in-person meeting or workshop, and potentially, written documents. And the activities will run through September 2019.

I have sent out an email to the Committee asking for your nominations of individuals from the public stakeholder community as well as from federal agencies who would like to serve on this working group. If you have nominations to send me, I'm taking nominations for another couple of weeks. I gave you a deadline in my email. So, please feel free to share those with us. And we will be convening this working group and getting started on this activity very shortly.

So, I think I did well on time getting through the information for this update. And now, we have time for discussion.

DR. GORDON: Is there any questions or comments on any of the materials that Susan presented or on the Housing Workgroup?

DR. REICHARDT: I just wondered if there was any way we could get these portfolio

analyses when they were less out of date in a sense. I mean this is obviously hugely useful. It would be more useful if it were 2017.

DR. DANIELS: Of course. The challenge for us is that we wait for federal data to close and that doesn't happen until that fiscal year is already over. And there are some agencies that have even additional restrictions that don't allow us to even collect the data before a certain time. So, that's kind of what creates that lag because we have to have finalized data from federal agencies.

But we do our best to collect it quickly. And we really appreciate that many of the private organizations here and federal agencies do their best to get us these data as quickly as possible. And the data analysis also takes time.

But we recognize that we - that it's always a little bit behind where you would feel is current. But because of the need to close the data out, we can't really start analyzing it until those data are available to us.

DR. REICHARDT: I mean I think this update is simply terrific - tremendously useful. I mean it's just trying to make something that's really good a little - where possible.

DR. DANIELS: Sure. We appreciate it. And we hope that you will find it useful. And we are working on 2017 now. So, thank you for sending in your data.

Geri.

DR. DAWSON: I just want to say how much we appreciate these analyses. And I can only imagine the work that goes into this, but - and even - of course, it would be great to

have it - you know, last year's data, but really, it's a beautiful analysis. And thank you for all that hard work.

DR. DANIELS: Thank you and thank you to the OARC team for all the incredibly hard work they do to make this analysis as accurate and comprehensive as possible.

John.

MR. ROBISON: I would I guess just like to voice my disappointment that our working group on housing and our conversations on housing seem to have had very little effect on the government's position that somehow, a person who is not developmentally disabled, but who is receiving government housing assistance, is able to live anywhere that has a certificate of occupancy that the government can pay rent to and somehow, an autistic person does not have that freedom of choice.

And it is very troubling to me. I understand that there are some autistic people who are very disabled and they have guardians and the guardians choose in what they believe is the autistic person's best interest. But outside of being under guardianship, it is not clear to me why this continues to be a matter for debate within the government. Why can we not choose freely where we wish to live if we are able to do so?

And I just - you know, I don't know if it was you that I asked - I don't mean to seem, you know, offensive, but I said to the last person who made this presentation, why can't we get a straight answer on where autistic people - why can't we be free to choose where we want to live? Why does the government feel the need to interfere? And I'm still very disappointed.

And I certainly don't speak for every autistic person, but I speak for a lot of autistic people who tell me that.

DR. GORDON: John, just so I am clear on what you are talking about - is the regulations that were discussed earlier today, for example, on the needs to meet certain sets of criteria in order to be eligible for this disability housing - et cetera. That's - these are the restrictions that you are talking about?

MR. ROBISON: Right. That is what I take issue with Josh. Because a person who is not developmentally disabled can receive government assistance, whether he wants to live on a farm, live in an apartment complex, live in a free-standing apartment. The only restriction I believe the government places is he can't live in a tent. He's got to live somewhere that's a legitimate residence.

DR. GORDON: A legitimate residence does have definitions, different definitions than the ones that were elucidated earlier, but I would imagine has to have heat and running water and all the rest. Right?

MR. ROBISON: Correct. But it doesn't have definitions that we apply to developmentally disabled people. We don't tell somebody in an apartment - we don't tell a college student who else will have access to his room when he locks the door. We don't tell people who are on welfare who can enter their apartment and who can tell them when they can and can't eat. I just think that we're losing sight of basic human rights here.

DR. GORDON: I'm wondering if you might like to just - a bit.

MS. HARRIS: Sure. And I think I would say a couple of different things. I would

assume that we are not treating individuals with a developmental disability - well, let me start out by saying that the regulation I was talking about this morning for individuals receiving Medicaid funded home and community-based services applies across the board, regardless of why an individual is receiving those services.

So, the same criteria apply to individuals with a developmental disability, individuals who have aging-related health care issues, individuals with a mental health or substance use disorder, physical disability, traumatic brain injury, whatever. And so those same regulatory provisions, the same requirements for a person-centered plan, the same settings that could be determined to be - to have institutional characteristics, those apply across all of the HCBS populations.

The types of settings that we talked about in the guidance that gave examples of those that could be isolating, like farmstead communities, intentional communities, by and large, we have heard about those settings developed to provide services to people with an intellectual disability and sometimes specific to people with autism. That's - that's not to say that we intend to implement those regulatory requirements in a more restrictive way for people with developmental disabilities than other populations. It could be that a farmstead for people with a mental illness or substance use disorder looks the exact same way as a farmstead for individuals with an intellectual disability and we would apply the regulation in the same way to both of those types of farmsteads.

Partly, the regulation is designed to do exactly what you talked about, to remove the

fact that you are an individual on a taxpayer-assisted program from infringing on your ability to decide when to eat, what to eat, who to interact with, whether to go to a particular place that day, whether to go to a different place from the place where the van associated with your setting is going. The ability to make your own decisions is exactly what's at the heart of the Home and Community-Based Settings Rule.

As it relates to housing - and I have a lot of interest on being on the Housing Work Group. I don't have an official clearance yet to do so.

As it relates to housing, the goal of the reg - much as we hear the criticism that the reg is infringing on choice and restricting the opportunities of people to receive - to choose to - where to receive services, my pushback to that would be to say

there's no reason that any of the settings that are in business today, receiving Medicaid funding - whether they are a farmstead, whether they're a group home, whether they're independent living, whatever type of variation of independent living, there's no reason that they can't meet this regulatory criteria and continue to be an option for people to receive services in perpetuity.

The settings criteria was not developed to "weed out" - and I put that in air quotes - any particular type of facility providing day services or residential services. It was designed to make the person-centered planning elements front and center in a way that they probably weren't before. But because these settings are providing services to people with all different types of disability needs, it's really to make that - it's really to

elevate the requirements of the reg without saying we've made them so hard that we don't expect you to meet them.

DR. GORDON: So, are there other comments or questions in this topic area? I think this is nice because we have the time. We can return to this.

Dr. Dawson.

DR. DAWSON: So I was really struck by thinking about the transition plan and then, you know, giving the example of New York. And there were many - many options that may then not be supported in the future.

Maybe this is something that the Housing Committee can think about, but certainly, it seems like that the government should be thinking about this. Is - I think we really need a transition plan that analyzes the impact of the change in philosophy around, you know, what is a supported, you know,

housing option and what shouldn't be supported on just the number of options for people.

Because I think, you know, having - running an autism clinic and dealing - you know, walking - with families every day that are trying to find places for their - you know - adult child to live or an independent - you know - adult, him or herself, finding a place to live, there just aren't enough options. Right?

So, to me, I am so concerned that we are trying to do something good, but actually, the impact is going to be fewer options for people and that that - the overall impact will be negative on families and individuals with autism.

So, I feel like that has to be part of the plan. Right? That we actually say the net gain is - not just that we like - you know -

this - we have this philosophy and now we feel good about it, but really - you know - that we have limited the number of options.

MS. HARRIS: I totally agree with that. And it's a shared goal to make sure that's not the outcome of this regulation. And so when I hear scenarios of, you know, a state saying this many existing settings won't be able to be in business after the end of the transition period - you know, I wonder what has gone into that to know three years in advance of the end of the transition period that a setting can't be in - can't eventually be in compliance.

Now, like I said, the states have a lot of discretion. Maybe the state is wanting to take the provision of HCBS in a different direction.

Many times, though, we hear from a variety of audiences, the federal regulations

won't let this provider continue or CMS won't allow me to continue funding services in x provider type. That is probably not true. It could be the state or whoever is speaking, it could be their genuine interpretation of the reg, but that doesn't necessarily mean that we, CMS, have had a hard and fast statement to say we agree with you that this provider will not be able to be in compliance.

That's why these conversations are so critical. And I would - I would hope that the housing subcommittee or the housing working group would delve into these exact things.

DR. GORDON: I appreciate this discussion and it is really important to think about the impact of the regulations. And its wonderful that we have at least the forethought to provide this transition period and ask states to be thinking three years in advance, you

know, how their facilities will or won't be able to respond.

I want to point out that John was just asking a slightly different question, I think, than the question that's being addressed by the questions - by these responses. I wondered, John, whether I'm missing the mark or not, but what you were saying is why - you know, why have - if you have a housing program to support those individuals with autism, why not give them the full freedom of choice that is afforded anyone else who gets a housing program through Section 8 or other programs.

And I think that deserves a specific answer. I'd imagine that part of the answer is that this - you know, that an individual with autism who would otherwise qualify for one of those other programs can go ahead and do it, but this is an extra added service

being provided for those with I guess the better way to put it would be health reasons to require housing. And therefore, that service needs to address the health needs of those individuals who are getting that service.

But I wonder if there are any other thoughts or comments addressing your point, specifically, about - about why there are any restrictions, if you will, added to this program or other programs aimed at those with autism and other neurodevelopmental disorders.

Do you want to make a -

MR. ROBISON: Yeah, I just would say that I received some tweets here from Sara Luterman, who is an autistic person who is frequently in attendance here. And she makes the point that there is a - there is on the one hand, the issue of free choice. That we

should have the right to choose where we live. But Sarah also says that she is concerned about the risk of weakening CMS rules such that autistic people are institutionalized against our wills.

And so I think that we have to be clear whose free choice are we talking and does the ability to choose mean that someone else could institutionalize us? I think we have to be mindful of that.

DR. GORDON: Or I think the point would be that you might have free choice to end up in a housing situation that is, for a myriad of other reasons, not just inappropriate, but actually harmful.

MR. ROBISON: I think what I would just say without going on and on on this with respect to your housing thing is that if you look at the comments such that I see and our Committee gets, its clear to me that despite

your best intentions, the issue is far from settled. And we don't really have a consensus about exactly what you should do, but it seems like there is a consensus that what is proposed is not what either camp wants. And I think that more work is needed.

DR. DANIELS: Alison.

MS. SINGER: I think we just have to be careful about the use of the word institution. You know, I think we all bristle at that word. My brother was in Willow Brook. I have first-hand experience of seeing it. No one would recommend that we go back to any sort of situation like that.

But the intentional communities that are built today for people with autism are nothing like the institutions that we saw in the 1970s. Many of them provide important opportunities for socialization with peers,

active participation in the community. They have to be part of the spectrum of choices.

And I think some of the fear was in the 2014 regulations and guidance, there were specific examples of types of intentional communities that were called out. And I - I'm sort of getting from what you're saying now that in the new guidance, which we're looking forward to seeing, there won't be those specific call-outs. So no type of intentional community would be off the table. Is that - is that what you're saying?

MS. HARRIS: That's right. And so, in essence, this would level the playing field of an intentional community with any other type of setting for the state to make a determination of whether that particular setting, be it a farmstead, be it a group home, be it a whatever, whether that setting is isolating to HCBS individuals.

And we will have some criteria about what an isolating - what CMS would consider an isolating setting to be. And it's not by virtue of location, necessarily - it's just tucked away in a rural setting. It's more like the method of service provision does not facilitate an individual being able to make choices to leave that intentional community.

For example, you know, in some cases the intentional community will have a host of resources available on that campus. And if I'm living on that campus and I want to avail myself of the resources and the service options or entertainment/recreation options on that campus setting, I should be able to do so no problem. And nothing about our regulation says you shouldn't be able to access on campus activities.

But, if I also want to interact with my family and friends who live off-campus and

use the resources of my community, the problem comes in when my service setting, my service provider, says you don't need to access the community. We've got those types of resources here. And so then it starts to become very insular and very isolated and I'm not encouraged as an individual person to exercise my choice to go off-campus.

It doesn't necessarily mean that the provider has a fleet of vans to get me off-campus whenever I want to. It might mean that the setting - and in my individual plan, my friends and family who live off-campus and are my natural supports are part of the equation to come get me and take me into the community, but nothing about the way that setting operationalizes its services makes it - works to prohibit me from being able to leave campus. That's the kind of thing we're

talking about when we're talking about an isolating setting.

We did go down the pathway several years ago of providing some specific examples and it caused more problems than it solved. And so we are taking a step back and saying now we're not going to show specific examples of an isolating setting, we're just going to provide you with criteria of what one would look like.

So, an intentional community and a state could say I don't meet that criteria of an isolating setting. I don't need to be elevated to CMS for heightened scrutiny. Now, it might be that there are stakeholders in that state who don't agree with that - with the state's position that a particular setting does not require heightened scrutiny. There's a lot of different viewpoints around

this issue and everybody is attached to their viewpoint with a lot of strength and passion.

And so we are aware that a state could say I looked at this farmstead. It does not meet the definition of isolation. I'm going to work with it to make sure it complies with the settings criteria by the end of the transition period, but I'm not sending it forward for heightened scrutiny. And there could be stakeholders who disagree with that decision.

CMS probably is not going to get involved in a disagreement between the state and the stakeholders. We've left open the possibility of us - for us to get involved if there's a really - you know, kind of sustained disagreement between stakeholders and a state about a particular setting. What that looks like I think we'll all kind of

need to work out operationally as time passes.

We hope that the new guidance - and we've been saying it's coming for about a year. We are in the final stages of clearance. It is at least partially impacted by the status of the federal government. And so we all hope to be able to have that released as quickly as possible, but we hope that that will really demonstrate the fact that we've heard some of the criticism of prior guidance.

We're not walking away from the fact that the regulation talks about an isolating setting, but we're taking a different tack at defining it and not calling out specific settings over others.

DR. DANIELS: Thank you. Additional questions or discussion? Or any remaining

questions from any of the earlier sessions in the meeting?

John.

MR. ROBISON: I would like to raise another comment with respect to our TRICARE folks and their presentation.

Louis raised a good point about how genetic information could provide valuable insight and also comfort to families. And there are 30,000 such families receiving assistance under TRICARE, according to what we just heard.

What I took away from all that is that genetics also tells us that with those 30,000 kids receiving some kind of autism service under TRICARE, there are most likely 60,000 parents, many of whom are part of this broader autism phenotype that genetics has shown us.

And we look very hard for communities that we can study, looking at autism over generations. And we also look at adults that we can study. We talk, for example, about screening adults for autism and the difficulty of doing that in the United States. And in the Armed Forces with the TRICARE population, we may have a large group of potential folks to study that could be tremendously important to science.

And I never really thought that until listening to his presentation, but, you know, with the congressionally mandated autism research, that's a thing. We could just right on with that.

And we might be able to do some really high-impact studies of broader autism phenotype among TRICARE families. And I just didn't want the meeting to continue without

that. And Louis, you're - as always, you always help me see the value of genetics.

DR. DANIELS: Thank you for that comment, John. And do we have another question over here or any other comments?

All right. I'm seeing none. So, that means we can break a little bit early for lunch, which I think will be welcome to everyone.

There is a restaurant here, in the hotel. So, you're welcome to go there to get your lunch. And we will meet back here at one o'clock for public comment. Thank you.

(Whereupon, the Committee recessed for lunch at 11:53 p.m. and reconvened at 1:00 p.m.)

DR. DANIELS: Welcome back from lunch and looking forward to hearing from our public commenters.

Today, we have five oral public comments and so I would like to invite Dr. Eileen Nicole Simon first to the podium to give her public comment. Welcome.

DR. EILEEN NICOLE SIMON: Thank you. Language disorder is the most serious problem of children who receive a diagnosis of autism.

I am attending the IACC meeting in person to add emphasis to the many written comments I have submitted for discussion by members of the IACC.

Many parents of non-verbal children have come here to plead for attention for these most severely affected victims of this affliction. I cannot understand the need to look for adults who were not diagnosed with autism as children, and who did not have problems learning to speak.

The IACC was formed as part of the effort, 20 years ago, to seek out reasons for the increase in autism that became evident in the early 1990s. Why has this mission been set aside?

My oldest son is now 56 years old. Too many people have tried to tell me I should be more accepting of his autism. Does anyone believe that childhood cancer should be accepted?

Autism is a serious neurological disorder. Autism, like cerebral palsy and spinal cord injury, must be made the focus of research on ways the brain can become damaged in the perinatal period. And, what measures can be adopted to prevent brain damage, in children as well as adults?

Thank you.

DR. DANIELS: Thank you, Dr. Simon. Are there any comments from the committee?

All right. And we will have more discussion time later. So then we'll move on to the next public comment. Thank you, Dr. Simon.

And now, I call Shari Chase to the podium to give a comment. Welcome, Shari.

MS. SHARI CHASE: Thanks everybody. I am putting a picture of my two sons up here. (inaudible comment) babies in the world. One was frozen. That's Alec, 22, the younger one with autism. And the other one is now a biomedical engineer. It's amazing, you know, how far we come in the world.

But thank you for having me. First of all, I'm a mom of two young men. One has Autism and is 22 and has fallen off the cliff since leaving high school last year. His days are not meaningful. Normally, he thrives when being creative and accomplishing meaningful jobs and roles.

My son Alec is an extremely bright young man but he is ruled by mood swings and meltdowns. These meltdowns come in a moment's notice and he sometimes has no control over them. His neurologist has told us he has something called SUNCT headaches and that these are secondary and common to people with autism.

Often, people with autism end up pulling their own hair out of their head, smashing their heads with their fists, and screaming. These headaches last for 15 seconds to 15 minutes over and over again, and they're like an ice pick stabbed into your face. And there is no cure.

I searched for years to find something that can detect some of the precursors that are non-obvious prior to various biological symptoms that occur before not only SUNCT headaches, but also meltdowns, something like

an early warning system, so we can utilize some of the resources we have, including breathing techniques, removing someone from a situation, et cetera. But until recently I saw no hope.

My older son, Brent, who is 24, is a biomedical engineer at Northwestern and he is now completing his master's degree. He's devoted a great deal of his life to finding ways to help people on the spectrum that have meltdowns and give them back the ability to steer their own life and self-advocate.

He has done this through his own startup called Gaia Wearables via a device that detects premarkers of anxiety. It's excellent. I've tried it and so has my younger son. It was voted the number one medical device for college students a couple years ago. Top eight startups and coolest in Inc. Magazine. And now, he will - for the

second year, will be presenting at Southeast Southwest. Very exciting.

We need to find direct funding sources for our brightest students for they're the ones with open technology minds doing what others think is impossible. My son has given up an income to make this a reality.

Excitement for this so needed device is a shining bright light in the future for those people on the spectrum and those who suffer from anxiety and other meltdowns. It will be more than a life preserver. It's a springboard to being able to rise to a person's fullest potential. For often, as is the case in my younger son Alec's life, the meltdowns actually prevent him from working and attending college, which is what he wants to do so badly.

But it can't stop here. We must find ways, internationally and nationally, and

share these techniques through some type of web base on a current basis - that work and those that don't work, so that we don't waste our valuable, precious resources and time.

We need to be more functionally coordinated and directive. And I'm not saying this committee. I am saying all of us, everyone that has a stakehold in this.

Watching your child, whether 8 or 22, smashing his head with his fists is a cry for help. And I, personally, am pleading for assistance from everyone. Let's all dig in. The damage is not only to those innocents on the spectrum, but to the families and the caregivers.

Sorry. Excuse me one second. I got out of order here. Look at that. Well, look at that. I don't have the proper organization. Can you give me one second so I can get my other page? Pardon me.

I apologize. Please forgive me. I am so sorry.

All right, well, anyway, these emergencies can't be pushed to the side and there is no more time to discuss us taking action.

One partial solution I can offer is CBD oil, which for us has been a life-saving supplement, along with Chinese herbs for many need other types of things. The problem is CBD oil is considered against the law for a caregiver to utilize on federal property. It can calm, though, with no side effects and can assist in replacing atypical psychotropics, opiates, and other addictive harmful drugs.

Next, I want to alert you all to a lack of health care professionals to deal with those on the spectrum from psychiatrists that really are not in the know, to internists, to

most recently, what I found out when my son had a TBI that was caused at Kennedy Krieger due to being locked into a room with screaming sounds and waterboarding him, where he got a head injury at the NBU, every doctor that I have approached in Maryland, D.C., and Virginia, has said to me I understand your son has traumatic brain injury, but he has autism and we don't know anything about autism so we can't treat him.

That's not fair. Just because if I had - and I did have cancer. But if I had autism, too, could you not treat my cancer because I have autism? We need to really educate rehabilitation doctors and really put some funds back into giving our doctors the information they need across the board in all fields to be able to deal with people with autism. It's only the right thing to do.

Next, we need a national job training program for those with autism. It needs to be presented visually. Starting to learn your skills in a classroom following by moving through the skills into a practical application as an apprentice with a mentor and finally in an independent job.

We can use our retiring workforce as trainers and create - recreate the old vocational schools. Anybody here remember those?

It will be a win-win situation. This can be further paired to a work, live and play environment. There is a slow movement right now to create paired retirement and special need communities. I'm looking for those interested in pairing with me to create a nationwide community brand.

We need to change our focus. Early detection is fine, but how about those

adults? We must make sure these programs and the people who are willing and able to provide devices/therapies are covered by some sort of social program and timely publicized.

We can't leave people behind that can really become contributory citizens for that is not only a waste of life, but it's a drain on society that does not need to happen.

Let's work together to find programs to help find ways for individuals to control their meltdowns and other tics that prevent them from being completely employed and integrate into society.

This will springboard for those with ASD to earn an income that make them self-sufficient, gives them back the pride of control of their own body, and it will also - takes eventually a burden off society because these individuals that are on the spectrum

will become contributory citizens and will give back. They'll become the heroes.

This can give those that do not have the ability to currently - nor do they have the right mindset to have vocational and behavioral training modifications.

I'm not saying - and I want to be clear on this. I'm not saying to erase the characteristics of autism. What we need to do is to be able to give a hand to those that want the ability to be able to assimilate so that they can reach her own fullest potential.

So, finally, housing. It is an extremely important subject. I have been preaching the model of pairing individuals that are at retirement age with those people that have autism in a housing unit similar to a residential wonderful campus community.

I believe you can attract businesses, physicians, and therapists to open on campus with the obligation to provide the majority of jobs to the community.

The workers who are retiring most likely will need more funds to enjoy the lifestyle they're used to and can pass their expertise on that is second to none, for hands-on training usually is the most effective with individuals on the spectrum.

Just imagine a viable community where you live and work and play with no ways to be locked in, but only ways to springboard out and enjoy a full life and always feel welcomed and accepted. Those people who are senior citizens eventually will be in need of physical companions and, perhaps, others will need cognitive help. You will now have a workforce with those people with ASD that are living there that were personally trained on

the property. This bond and our AST - D community will be pre-trained by those individuals to assist the aging and they will become the heroes.

I do not believe in complaining without offering solutions. I, personally, have a television show - it's on public access - called Making a Difference. And I am going to be dedicating and highlighting those treatments that work and also those that don't via public access on a show that will be accessible through cable and the web.

We all need to contribute and take our own abilities - what we can do - to make immediate actions.

I ask you to take these very important needs that are not being met and make sure they are met in the most expeditious way. I do realize that many of these appear daunting tasks, but they're not things that we can say

we will work on committees anymore. We have to take action and push forward immediately.

I thank you so much for all of the dedication all of you have put into this. And I hope that my son will come on and speak to you about what he's creating to make people's lives better.

I just want to close with this - I know we have psychiatrists that are in the audience and hopefully, listening in. My son, Alec, had two different Rx's that were prescribed to him. In both situations, he ended up going into rage and literally taking his fist and trying to smash his head open.

We thought it was the SUNCT headaches. And we kept on blaming it on that. And then we said, oh, it must be the head injury. We blamed it on that. And I have to say that I, personally, feel very responsible. My

education should have made me listen and look at little further.

I started to time when these would happen and they all happened within 20-30 minutes of taking - one time it was benztropine and then the next time was clonidine.

I went to his psychiatrists and they insisted there was absolutely no way these Rx's could cause rage. None. They're supposed to take anxiety away. But I took him off the medicines and - the Rx's and each of them, like clockwork, within a day, the rages stopped.

But his psychiatrists were insistent that I was wrong. I went as far as speaking with the manufacturers, generic and brand to find out -

DR. GORDON: Ms. Chase, I'm sorry. You're well over time. I'm going to have to ask you to wrap up.

MS. CHASE: Okay, I'm closing.

DR. GORDON: We really appreciate your remarks, but in - for fairness -

MS. CHASE: You're welcome. I'll just close with this. Just be a smart researcher, yourself. If you see something that's wrong, don't necessarily always listen to your doctor. Go the step further.

So, I took him off that and, now, thank goodness, he's not raging.

But thank you again. Sorry I went over. Obviously, I'm passionate. And, you know, bless all of you for really trying to make a difference in people's lives. Thank you.

DR. GORDON: Thank you very much. Are there comments or immediate questions about

this presentation? We'll have time for discussion at the end, as usual.

Okay, then we'll move onto the next - next public comment is Dr. John Martin, if you could come to the podium. Not here? John Martin, M.D., Ph.D.? Okay. We'll give him a chance at the - next then is Aimee Doyle.

MS. AIMEE DOYLE: Hi there. I'm Aimee Doyle. I'm an attorney. I'm an autism mom. And today, I am testifying on behalf of SafeMinds. I am going to read the statement.

I am pleased to present my testimony on behalf of the national autism nonprofit organization, SafeMinds, to the Interagency Autism Coordinating Committee for its January 2019 meeting.

SafeMinds remains concerned about the federal government's lack of urgency related to autism disability. Urgency and a commitment to rapidly improving outcomes are

desperately needed due to the increased prevalence of autism over the past 18 years, from 1 in 150 American children in 2000, to 1 in 59 today.

Improving outcomes are also desperately needed due to the significantly increased mortality of those with autism and the lower quality of life associated with autism.

In an effort to obtain feedback from the autism community on the Federal response to the autism crisis, SafeMinds, in collaboration with Autism Action Network, TACA, and the Thinking Moms Revolution, developed an online survey and sent it to their constituencies in the Summer of 2018.

We received 1,405 unique responses via Survey Monkey. The autism community stakeholders who completed our survey included people with autism, caregivers of people with autism, family members of people

with autism, autism service providers, physicians, and others.

Today, I will share the themes that arose from the survey results. They center around effectiveness, responsiveness, and accountability. Concerningly, almost half of the respondents had not even heard of the IACC before they completed the survey.

In their optional written answer sections, respondents said they were concerned that the IAC has not coordinated or promoted research that would identify the causes of autism, how to appropriately prevent or treat autism, how to effectively ameliorate or eliminate commonly co-occurring conditions such as epilepsy and gastrointestinal issues, or how to help address the commonly co-occurring mental health issues such as anxiety, depression, and suicidality.

By way of example, a person who self-identified as a retired school psychologist, whose job included diagnosing people with autism stated I don't think the IACC is doing enough to uncover the causes of the explosion in autism cases since the mid-eighties.

The survey results show that many autism community stakeholders feel disenfranchised by the IACC. Almost 94 percent of respondents said that they had not provided comments at an IACC meeting. Of the respondents who did provide public comment, over 95 percent thought that the IACC had not appropriately addressed their concerns or issues.

These respondents further stated that they were not given an opportunity to discuss their concerns with the committee and were not provided enough time to properly explain the context and relevance of their issues.

Over 46 percent of 1,400 respondents reported that the IA - that the work of the IACC has affected their life either not at all - that was 24 percent - or negatively - that was 22.21 percent. Conversely, only 4.93 percent stated that the work of the IACC has affected their lives positively.

Further, over 56 percent of 1,370 respondents said that the work of the IACC is not improving the lives of people with autism and their families. 38 percent stated that they did not know if it was. Conversely, only six percent stated that the IACC is improving the lives of these stakeholders.

When asked if the IACC members represented their interests when it comes to addressing autism in the United States, nearly 60 percent of the 1,402 respondents answered no. 33.38 percent of respondents said, I don't know. Conversely, seven percent

of respondents found that the IACC members represented their interests when it comes to addressing autism.

By way of example, a self-identified service provider to people with autism stated, the autism community is not being well-represented by the IACC. If the IACC wants to make a positive difference in the lives of those suffering from autism and their family members, you must seek out and listen to organizations which represent that demographic.

It seems that outreach to the leadership of the many autism nonprofit organizations representing people with autism and their families would be in order.

When asked if they think the IACC is accountable to its autism community stakeholders, 56 percent of the 1,375 respondents reported that they did not, and

31 percent stated that they didn't know if the IACC is accountable to its autism community stakeholders. Twelve percent of the 1,375 respondents answered that they did think the A - IACC was responsible to autism community stakeholders.

It appears that there is much to be done to improve the efficacy, responsiveness, and accountability, and responsiveness of the IACC. We hope that we can work together during the year - during the year to move forward together, as a community.

The full report is available on SafeMinds' website, www.safeminds.org.

Thank you.

DR. GORDON Thank you for your comments. Thank all - actually, before we do that, is Dr. Martin here?

Okay, thank you very much to all of the commenters. We really appreciate you making

the trip and giving us this feedback. We will have a discussion period momentarily.

John, you wanted to say something now?

MR. ROBISON: I just wanted to speak to what we just heard from SafeMinds.

There has never been a time in my government service that I haven't felt that we should be doing more to provide positive, definitive help to families and individuals living with autism. And I don't think there's really anyone here on the committee that would disagree with me that we all want to do a better job for people living with autism.

With respect to us not being responsive to autism community stakeholders, one thing that troubles me a lot is that over the years we've had SafeMinds represented on the committee, Autism Speakers, Simons, Autism Science Foundation. We've had a number - The Arc - we've had a number of - Autism Society

of America - I got to keep listing them, but, anyway, there's a bunch of them.

And they've all had representatives on the committee. And I've enjoyed talking with every single one of them. And yet, it seems like out in the public world, all of these communities are at each other's throats.

We heard thoughtful comments from SafeMinds, but SafeMinds represents only a fraction of the community. And we have ASAN, who represents a fraction. And Autism Speakers, a fraction, and so on.

And if we could pull together as a group, we would get a lot more done than if we were all at each other's throats.

The final thing I would want to offer with respect to that is that we heard a couple comments beforehand from Ms. Simon and Chase. And it made me think of something Susan said to me at lunch, which is that

people come here and they offer us thoughtful comments like the Simons comments on premature cord clamping and could that be a cause of brain damage. And I don't know whether it is or it isn't, but I know that, as Susan said, we can't study that question unless a researcher proposes it.

And one thing we offer here, at IACC, is a path for the public to come here and express their concerns. And I hope that researchers listen and some of them think about what they hear and remember that these are things we could propose to study. And if you are a researcher looking for people in the autism community that would want to help you in your studies, every single person that comes to comment before us is most likely such a person.

And I wish that that was a resource we made better use of because I think it's safe

to say that every single one of us wants to be more responsive and provide more help to autistic people.

DR. GORDON: Thank you. David.

DR. AMARAL: So, I just wanted to make a comment, again, to Ms. Doyle's testimony. And that is I find it sort of disheartening that there are well-intentioned - well-intentioned approaches to trying to solve some of the issues that Ms. Doyle brought up.

So, the workshop on improving health outcomes for people on the autism spectrum that we have talked about - you know, we had a wonderful workshop. It was open to the public. We addressed issues like gastrointestinal problems and epilepsy and sleep disorders.

It was open to the public for comment. And there was a lot of positive feedback and we're trying to have a second one to deal

with the mental health issues like anxiety and depression and suicide. Yet, we heard in the testimony that IACC is not doing anything in this.

So, there's a disconnect where there is work that we're trying to do and somehow, that's - you know, not either being translated to the general public or - so, I would welcome hearing from folks that are listening to us how can we translate that information better? I'm sure that Susan would welcome other efforts to try and get the words out to the public.

But I don't think it's so much that we - the members of the committee aren't well-intentioned and trying to address these very difficult issues. It seems to me more that we're trying to do that, but yet, our efforts are not getting out there somehow. And

probably we need to do a better job about translating it to the general public.

DR. GORDON: Okay, again, we can return to have some discussion at the conclusion of the public comment period.

Now, we're going to have the reading of the summary of the written comments. And I want to remind folks - although, I imagine this is duplicative. Susan probably already did - about the needed comments - we'll do that after. Okay.

Go right ahead. Sorry, who am I - who's giving me - Oni Celestin, thank you, from the Office of Autism Research Coordination, will be summarizing the written comments. Hi, Oni.

DR. ONI CELESTIN: Good afternoon. Excuse me.

Since the October full committee meeting, the IACC - IACC has received written public comments from 17 commenters. For the

purposes of this presentation, we've organized these comments into five broad topics. The Committee has been provided the comments in full, but they will be summarized briefly here.

The first topic is concern about medical practices and potential causes of autism. There were five comments received on this topic.

Dr. Eileen Simon thanks the Committee for discussing her comments submitted to the October 2018 IACC meeting. She encouraged the IACC to investigate several factors that could be contributing to autism symptoms.

In particular, she would like the IACC to discuss the importance of the inferior colliculus and its susceptibility to damage. She believes that brain injury is caused by Wernicke's encephalopathy, Bilirubin

exposure, or umbilical cord clamping may contribute to autism.

Mr. Dwight Zahringer expressed concern about the potential contribution of glyphosate to ASD symptoms. He also wrote about changes in his son's symptoms following modifications to his diet.

Ms. Josefine Krapp is concerned about the use of electroshock therapy at the Judge Rothenberg Center. She recommends that the IACC advocate for changes to the standard of care for individuals with intellectual and developmental disabilities.

Ms. Caroline Rodgers expressed concern that prenatal ultrasounds and x-rays may be contributing to autism symptoms.

Dr. Linda Papadimitriou-Varsou is concerned about the potential role of electromagnetic radiation in autism.

The second topic is vaccines and autism. There were four comments received on this topic.

Mr. John Best believes that autism is caused by mercury in vaccines. He also expressed frustration with the IACC.

Ms. Resa Warner is concerned about the association between autism and several environmental toxins, including mercury. She requests that the IACC call upon the Department of Justice and the Department of Health and Human Services to investigate allegations of fraud and obstruction of justice in the Omnibus Autism proceeding.

Ms. Margaret Ewell expressed concerns about child - about the childhood vaccination schedule. She believes that autism is caused by vaccine injury and that the National Childhood Vaccine Injury Act of 1986 should be revised.

Mr. Dan Fergo believes that a clinical study should be done to compare children that have been reported to regress into autism versus neurotypical children. He also expressed concern about the three-year statute of limitations in the National Vaccine Injury Compensation Program.

The third topic is the role of the IACC and the Federal government. There were four comments received on this topic.

Mr. James Kilpatrick shared a link to an online commentary expressing concern about the progress of the IACC. The commentary recommends the formation of a new autism taskforce and a vaccine safety commission. The commentary also recommends amendments to the Individuals with Disabilities Education Act, or IDEA, to provide more options for special education.

Mr. Dwight Zahringer requests that the IACC facilitate a survey of autistic parents in order to better identify research needs. He also requests that the IACC make a formal request to Congress to investigate the CDC whistleblower issue.

Ms. Michelle McCormick believes that the IACC should work harder to identify causes and treatments for autism.

And Mr. Marc Spilo also requests that the IACC increase its focus on identifying causes and treatments of autism.

The fourth topic is service needs, resources, and policy implications. There were three comments received on this topic.

Ms. Whitney Ellenby shared a link to an online commentary she wrote advocating for an increase in sensory-friendly opportunities.

Ms. Caryn Harb shared several concerns with the committee, including the need for

group housing with properly-trained staff. She is also concerned that public school special education programs are not able to meet the needs of the increasing autistic population in schools.

Finally, she wrote seeking assurances that the SSI and SSDI programs would continue to be available as her teenage grandson and others with ASD age into adulthood.

Ms. Jill Escher shared a press release announcing the creation of the National Council on Severe Autism, a new organization that aims to advocate for the needs of autistic individuals with severe disabilities.

The final topic is transition to adulthood and adult service needs. There were two comments received on this topic.

Mr. Robert Johnson shared a blog post detailing the experiences of a young man with

ASD who has started his own woodworking business.

Ms. Benedetta Stilwell wrote about the various employment challenges her adult son with autism has faced.

This concludes the summary. Thank you, again, to everyone who submitted written comments.

DR. GORDON: Thank you. Are there questions or comments by the Committee on any of the written or oral comments that we've heard today - oh, sorry.

DR. DANIELS: There we go. Can we also just add the Live Feedback comments right here before we discuss?

DR. GORDON: Sure.

DR. DANIELS: So, just to bring to your attention, our first set of live feedback comments are at everyone's place at the table. We received three: one from Karla

Shepard Rubinger, that was a question about the TRICARE presentation, a comment from Rose Walker with concerns about ABA, and a comment from Sara Luterman about employment issues.

So, just wanted to bring those to your attention. And we're going to be putting those up on the web shortly for anyone out in the audience. So, just wanted to add those in for discussion, as well.

DR. GORDON: Yeah, Kevin.

DR. PELPHREY: I wanted to - I read with great interest the - Caroline Rodger's comment.

DR. GORDON: Could you just get a little closer to your mike?

DR. PELPHREY: Oh, sure. I read with great interest Caroline Rodger's comments about prenatal ultrasound.

I had done a lit review because we were utilizing or planning to use ultrasound for

studying brain development. And so, I had recalled when I was at Yale, Pasko Rakic and I had a conversation about ultrasound and autism. So I went back through that literature.

It's an interesting hypothesis. And the - Caroline - or Mrs. Rodgers is looking for research on the topic. So, I wanted to bring to her attention and the Committee's attention, there was a - a couple of studies done by Pasko's group looking at a mouse model where they actually administered ultrasound. It was an R01 that was funded by NIH.

And the results were very interested in a sense of changes in migration as a result of very intense ultrasound, so about 30 minutes of continuous ultrasound to a mouse brain - a fetal mouse brain. So, you can imagine the analog to that would be a really,

really long series of ultrasounds for a human brain.

They published this in PNAS. Dale Purves was the contributor of that. That sparked a lot of interest.

And then the studies that have followed this up, one just came out recently in JAMA Pediatrics. The overall results were negative. There was no association. You kind of dug into the data very intensely with the associated risk of finding things that aren't really replicable, there were some associations between certain parameters of the prenatal ultrasound.

But the problem with that study and many others like it is that unlike the mouse model, there isn't a randomized experiment that you could do with prenatal ultrasound in the sense that if you are getting more ultrasounds, usually there's a reason.

And so those reasons - so, for example, in my daughter's case, she was developing slowly and very small for the time period. So, she was prescribed additional ultrasounds. I don't think it caused her autism. I think that whatever caused her kind of very slow development also caused her autism.

And so, there's always those types of third variable problems. So, I think that while its an interesting hypothesis, we're not really able to do the studies that are required to unambiguously put this to rest. But the studies that have been done so far, even with that confound, which would tend to make the results say, yes, there's an association, are saying, no, there's not an association.

So, I think the - the conclusion would be - wouldn't recommend somebody forgoing an

ultrasound that is deemed medically necessary because of a concern about autism. Again, it's always a risk-benefit ratio. And you want to say what's the purpose of this and what's the likelihood that it could do some harm. The likelihood looks like it would be very small and the information gained could be very valuable in facilitating the child's development in other ways. So -

DR. GORDON: Alison.

MS. SINGER: I'll just add that Lisa Croen also studied this and found no association.

But I wanted to talk about the press release from the National Council on Severe Autism. I'm really excited that this group has now been launched. I'm thrilled to serve as a member of its founding board.

The group is really trying to focus on the needs of a population of people with

autism who have been left behind, those whose autism is severely disabling, which includes those with cognitive disability, severe verbal impairments, severe deficits in adaptive functioning, and self-injurious and aggressive behaviors.

The needs of this population are very different than the needs of the broader autism community. And these are individuals who rely in many cases on their parents to be their voice because they are not able to come to the policy table and advocate on their own behalf.

So, I'm - in the first - in less than a week since this group has been launched, we've already had almost a thousand people sign up on the Facebook page and on the website to get more information. So, we know this is a ground that's really looking for support.

I encourage all of you to look at the new website. There, you will find position statements on very important topics that are facing the autism community, including guardianship, vocational options, personal safety, and abuse prevention, access to appropriate health care, including crisis care, HCBS residential policies, educational placements, and the need to include this population in research, which we know from a study published last month from Dr. Siegel's group in Rhode Island, this population of individuals with autism are also - are often excluded from research studies and, therefore, most autism research that we look at does not even apply to this population.

So, this organization is already hard at work to make sure that the needs of this population are accounted for at the policy

table, at the research table, and at the services tables.

DR. GORDON: Thank you, Alison.

David.

DR. AMARAL: I wanted to make a comment now because I won't be here for the round robin, but it also relates to Dr. Simon's request for more post-mortem research.

So, I wanted to give an update on Autism BrainNet. Autism BrainNet is a program started initially by Autism Speaks and the Simons Foundation and now is one of the programs within the Simons Foundation Autism Research program.

It's a program that asks individuals to consider providing post-mortem donations of brain material in order to carry out research that leads to better understanding of the causes and treatments of autism.

So, we've been doing this for now a number of years. We've had 146 donations, both of brains from individuals who had autism during life as well as appropriate control donations, as well.

And what I wanted to mention is that we've been holding off doing any distribution to researchers until we thought we had a critical mass of cases and controls, but now we do. So, we will be announcing in the next few days that all of this tissue will be open to researchers worldwide to carry out research.

There's a process, if anybody's interested, on our website, autismbrainnet.org. There's a tissue catalogue that itemizes the cases and some of the characteristics that we can release to the public. But researchers can select from that catalogue the cases that would be most

appropriate for their research and then put in an application for tissue that goes through a peer-review process, an independent peer-review process. And if it's approved, the tissue is distributed to those researchers free of cost.

We will - this is an ongoing process. We're continuing to request donations so that if any of our listeners would be interested in getting more information about Autism BrainNet, please consult our website. People can sign up for a quarterly newsletter. There's no obligation to signing up for the newsletter. It's just information.

But we are trying to do our best to get that critical mass of tissue that would allow not only the kinds of studies that Dr. Simon requested, but all the others that will allow us to understand the genetics as well as the neuropathology that's associated with autism.

So, thank you.

DR. GORDON: Thank you, David.

Other comments or questions? Stuart.

DR. SHAPIRA: So going back to the public comment about the association between ultrasound - prenatal ultrasound and Autism Spectrum Disorder, so at CDC's Study to Explore Early Development, or SEED, there are data collected from maternal interview as well as medical record on prenatal ultrasound.

SEED has, in addition to those - the group - the case group of children who are affected with autism, two control groups, so children from the population who don't have autism and then a group who have other developmental disabilities, which isn't a group that's included in most studies and there are probably prenatal indications for a

number of children in those groups to have prenatal ultrasounds.

So, we're looking at the ultrasound data that have been collected and hope to have a report about this in the future.

DR. GORDON: That will be very helpful. I wanted to make one additional comment that both of these issues raise. So, as Kevin suggested, it is hard, if not impossible, to obtain definitive data ruling out certain predisposing factors, such as ultrasound. Although, the data would suggest that if there is any risk, it is extremely small.

We can hope by using some of these other methods to be able to gather further correlative evidence that would suggest the risk is, indeed, small.

There's a cost to doing further research, to the extent that it is possible, on any of these hypotheses. And this is an

issue that I've raised before in response to some public comments about a number of different theories.

One thing we don't lack in autism is a collection of hypotheses. What we lack is a collection of hypotheses that are strong enough to pursue.

We are now - I should say what we have lacked. We are now in the position where we actually have a fair number of strong hypotheses that are based in excellent correlative data and this would include, of course, genomics and genetics, but also environmental factors, that we can actively pursue.

And the question is with the funds that we have available, which, although growing, we have to acknowledge we can't do everything, do we spend x amount of dollars pursuing a very, very low likelihood with a

very, very low impact, the definitive question, for example, of whether ultrasound raises a risk, versus some of the stronger hypotheses that we have available to us?

In general, just like a doctor wants to choose the highest impact treatment for the patient, a researcher or someone like myself, in charge of setting priorities for research, wants to try to choose the highest impact research.

And all evidence would suggest that the ultrasound question is a low impact. Although, of course, as additional evidence arises, we can revisit that question later.

All right. John.

MR. ROBISON: Having heard about high and low impact research tradeoffs, and your announcements about the severe autism group. I think that this should really remind us all that while we agree, I think, in principle,

that there are people who are very severely impacted by autism and their needs, in many cases, are very different, for example, than my needs or my son's needs. I don't think there's any doubt that autistic people who are self-injurious and have really serious medical problems or violent - that's a big challenge. And we need to help those people.

But I'm concerned that we do not know what the balance is in the autism population. Is this severe group 2 percent, 5 percent, 10 percent, 40 percent of the autistic population? It's all speculation.

And I would urge everyone to be thinking - and I want to take this up at a later IACC, but I would just urge all of you to think about the need for learning more about the profile of the autistic population as we age, so that we can make well-informed, good decisions about how best to help these

different populations. I don't think there's any question that help is needed, but how to do it? We need to know more.

Something went wrong. Nobody's saying it.

DR. GORDON: Thank you, John. I think - you know, I don't have the data. offhand, I think, to some extent, we do know some of these things, but we tend to know them rather in limited aspects.

So, for example, we know the distribution of IQs in those who are diagnosed with autism from reasonably sized collections. We know there's a range. Right?

And we know, similarly, there's a distribution of social functioning in those diagnosed with autism. Although, of course, it's lower than children who do not carry a diagnosis of autism, there is still a range.

I think what you're asking for, which is the percentage of individuals who have severe autism, I think that's really a challenging thing to decide because it depends upon the threshold you choose.

But I will agree with the sentiment that we don't - I don't know that we have a handle - and maybe my subject matter experts could correct me if we do - on the distribution of those who would meet say a specific disability threshold or the percentage of those who don't have - develop language by age x. I don't know to the extent that we know that, but we might.

Kevin, do you have any insight in terms of whether these things are known or anyone else on the Committee?

DR. PELPHREY: Well, when I was listening to your comment, what I was thinking about is exactly what you brought up, which is, you

know, we know something about the IQ distribution. We know about social symptoms. We know from extensive work on the Vineland, as a measure of adaptive behavior, what's a clinically meaningful difference, what's severely impairing. So, we've got that data.

But it's a - the other issue you highlighted is it's a shifting definition. You know, what do you mean by severe autism? We used to mean that - you know, or I learned in graduate, well, a lower IQ, severe adaptive behavior problems, often presence of seizures and lack of language development. That, even then, would be debated depending on where you went to graduate school.

It's sort of - I think the bigger frustration is we don't have - it comes back to John's point, which is defining the spectrum. And it even comes back to John's earlier point about an underlying unity to

what we're talking about when we're thinking about autism so that we're not creating artificial boundaries and pitting groups against each other.

And so it kind of - those two comments I think are interrelated.

DR. ROBISON: The ask is is the - is the autism that Alison described a few minutes ago, is that medically or biologically the same autism that I describe in my life? Because, certainly, I think you would have a very different view if it were as I am, but more impaired versus being a totally different condition at a low biological level.

DR. GORDON: David, you had a comment?

DR. AMARAL: I think that is a good question, but I also want us to all remember that autism is a developmental disorder, so it changes over time. So, if you take a slice

of life and you ask, you know, is a child at three severely impaired, that child might actually improve dramatically over the next three to six years and at six, not be dramatically impaired.

So, maybe it's something like kids who don't show improvement over time, which there's a substantial portion of kids who don't do that.

But, you know, I think that this general issue of how - how do you define a severely impaired individual with autism - if it's somebody who has good receptive language, but no expressive language, is that a severe impairment? Or is it somebody who is self-injurious?

I mean I think we need to develop some metrics to be able to answer that. But, again, I want to just remind us all that you can't just take a slice of life. You have to

look at the course of the individual's life over time.

DR. ROBISON: I think if Sam were here -

DR. GORDON: Sorry. I want to give other members a moment. And I see Alison with her hand up. And I think given the fact that you've spoken on behalf of this organization, perhaps you might comment on what the organization -

MS. SINGER: So, I think the idea here is that individuals with severe autism have different service needs than individuals whose autism enables them to participate at the policymaking table or even enables them to be interested or able to look for and hold down a job.

I mean this is an organization that is seeking to bring the voice to the table of people whose number one goal is really to reduce self-injury because that is incredibly

debilitating in terms of any opportunity to participate meaningfully in the community or even to just prevent physical injury.

It's also necessary because, frankly, in the DSM-5, everyone was lumped together as having Autism Spectrum Disorder. So, the term Autism Spectrum Disorder has now come to really be seen in the general media and in - by the general population as people who have very high-functioning autism. Those people who are depicted in the media, who are on shows like *The Good Doctor*, people look at that and they say, oh, that's autism. That's not so bad. Why do you need research? What do you need to raise money?

Higher-functioning individuals with Autism Spectrum Disorder are, as I said, able to participate on the IACC, which is great. They are also the ones who are able to

comment in the media when studies are published and give their opinion.

Whereas, this particular segment of the autistic population is left behind because of the nature of their disability. And the purpose of this organization is to bring a voice to that group that has been left behind because in many cases, they have the most severe medical needs, they have very intensive service needs, and we have to make sure that we remember them when we are talking about research, services, and policy. So, that's why this group was formed.

DR. GORDON: Thank you. John, did you want to make another comment or question?

MR. ROBISON: I would agree that we have to be mindful of autism in all of its forms. And I am always concerned in my own advocacy that because I am so clear and articulate in my speech that I could - I create a false

impression and there are, in fact, many autistic people who are not blessed with that.

And I wish that - I wish that I knew a perfect answer to give voice and help to that.

DR. GORDON: So, I wanted to, myself, answer the question at least partially that you posed about is severe autism - and let's for now call it less severe - I don't know if that's quite the right way to put it - autism, are they the same thing?

And I think we are getting some answers, at least from one domain that help clarify the relationship.

So, in one sense, those with severe autism - by - here, let me be very explicit. The data refer to those with intellectual disability in addition to social disability. That they have a higher preponderance of rare

mutations in the genome that are - with big effect sizes. To some extent, you might say, oh, that means its somehow a different disorder. It's one that's caused by a different kind of mutation than the ones - than individuals with less severe intellectual disability.

On the other hand, though, when you look at those rare mutations, the bulk of the evidence would suggest that most of those rare mutations don't automatically give you a diagnosis of autism. That in order to have a diagnosis of autism, even if you have one of these rare mutations, you tend to have a higher load of common mutations which are associated with all of autism.

So, in other words, those who have severe autism, those who are in that severe end of the spectrum, have some genetic differences that set them apart, but also a

significant, if not most, of their genetic liability that is in common with those with less severe forms.

So just like the answer is that autism is on a spectrum, the notion that ends of that spectrum are the same is on a spectrum, itself. And that what - that's what makes it so thorny to figure out where is the dividing line.

And let me tell you, as those of you around the table who do more than just work in autism know, this is true throughout the mental health spectrum. It's probably throughout health spectrum, but doctors in other disciplines tend to ignore it or have better ways of classifying. But, you know, we have the same issue with schizophrenia, with bipolar disorder, with dividing bipolar from schizophrenia. And in fact, globally, as our colleagues at SAMHSA will tell you, we have

the same issue with deciding what severe mental illness means compared to the rest of mental illness.

So, I think these are common themes when talking about brain disorders that have tremendously complex, multifactorial etiologies.

Louis, did you want to say something?

DR. REICHARDT: I just wanted to say - I mean while you can say that certain - tremendous hits to function, which would automatically give you low function, in fact, it's a probability thing. There are many people that this has not been identified in. And, you know, one of the challenges is you say it's an under-researched population.

DR. GORDON: Thank you. Are there other comments or questions about other oral comments? We have been focused on a couple of them.

Walter.

DR. KOROSHETZ: I would just say that the comments to the IACC about how we've been inadequate in terms of responding to the patients, I think I agree. And I think we all - we all agree and we all feel really bad about it.

I just think that for the people listening, I'm sure everybody around the table feels the same way. That we're as frustrated as anybody at the slow progress that we've been able to get at. So -

DR. GORDON: Okay. Thank you. So, it's now two o'clock. Our Department of Justice presentation is due to start at 2:15. I suggest that we take a - are they here right now? Yeah, so why don't we take a 10 minute break and be back at 2:10 and try to start up then so we can get ahead of the curve if there's more discussion on that item.

So, we'll be back here at ten minutes after two.

(Whereupon, the Committee members took a brief break starting at 2:00 p.m. and reconvened at 2:15 p.m.)

DR. GORDON: Okay, so next up, we have a presentation from the Department of Justice on Kevin and Avonte's Law and Disability Programs. And to introduce this presentation, I welcome our own Alison Singer, the President of the Autism Science Foundation and an IACC member, to introduce the panel.

MS. SINGER: Okay, so I am going to give just a brief five-minute sort of historical look back at the issue of wandering as it relates to the IACC before I introduce the panel.

So, in 2018, the most recent year, we had 224 cases of autistic individuals wandering and it resulted in 19 deaths.

That's about the same number of cases each year. We have approximately 20 searches per month for individuals and, unfortunately, we have about two to three deaths per month.

And trends are pointing to an average increase in age of the people who die as a result of wandering. We are seeing more deaths among teenagers and adults who are wandering.

Overall, I'd say we're seeing more training and better awareness about water risk, but there are still many agencies in rural areas, particularly, who are unaware of this particular phenomenon. And many agencies that continue to request training.

So, here's just a look at the timeline. Back in October of 2010, the issue of wandering was first brought to the attention of the IACC during public comments by Lori McIlwain, the President of the National

Autism Association, who will be on the panel today I'm thrilled to say.

And immediately, we formed a safety subcommittee to investigate wandering. And that subcommittee was chaired by Lyn Redwood of SafeMinds, and by myself. The following month, a consortium was formed. The consortium members included the Autism Science Foundation, Autism Speaks, the Autism Research Institute, the Global Autism Collaboration, and the National Autism Association.

And we immediately wrote and distributed a survey to study wandering utilizing the Interactive Autism Network. So, it took us about two months to design that survey and by March of 2011, the survey was released to the community. And it surveyed 1,218 parents of children who had ASD and 1,076 of them also had non-affected siblings.

At the same time, we also drafted a letter to then Secretary of Health and Human Services, Kathleen Sebelius. And the following month, March 2011, we received a letter back from Kathleen Sebelius, thanking us for alerting her to this issue.

I think this is a great example of urgency and of response to urgency because five months after we released the survey, we presented preliminary data to the IACC about the problems of wandering.

And what these data showed were that 49 percent of kids with autism spectrum disorder had attempted to elope at least one time after age four, which was four times the rate of their unaffected siblings. We used unaffected siblings as our control because we didn't want to look - to have an issue of this being the result of bad parenting. So, the idea was if you were a bad parent, your

non-autistic child would be just as likely to wander off because of neglect than your autistic child.

53 percent of the kids who eloped were missing long enough to cause concern. Also, I want to point out that from age 8-11, 27 percent of children who were diagnosed with Autism Spectrum Disorder eloped compared to only 1 percent of the unaffected siblings.

I also want to point out that I always think this data looks like a shoe sort of for wandering. Okay.

Six months later - I mean just six months from the launch of the presentation by the National Autism Association, the CDC had already worked to get an ICD-9 medical subclassification code for wandering. And this was another way for us to get better data on the extent of wandering because now, we had a medical code where doctors would be

able to make a notation in medical records. So, thank you, again, to the CDC for those efforts.

In May of 2012, the data from the wandering study were presented at the International Meeting for Autism Research.

And in October of 2012, those data were published in Pediatrics. And this study was later included in the 2012 IACC summary of advances of one of the key studies in that year.

The study, when it was published in Pediatrics, got a tremendous amount of press coverage, including USA Today, U.S. News & World Report, the New York Times, ABC News, and Good Morning America.

But despite that, parents were still reporting that they were not receiving any anticipatory guidance from their health care providers. Over 50 percent said they had not

heard from their pediatrician that wandering was a risk related to autism. And these data are also from the Interactive Autism Network.

So, in response, the Safety Subcommittee reached out to the American Academy of Pediatrics, which is an organization that represents 65,000 pediatricians. And the CDC, again, worked with the American Academy of Pediatrics to develop these factsheets about wandering to be included in the American Academy of Pediatrics Toolkit.

These factsheets were designed for parents. So, they were designed for pediatricians to give to parents as part of anticipatory guidance so that parents would know that if they had a child with autism, there was a risk for wandering.

But we realized that it was just as important for us to be educating the

pediatricians, themselves, because many of them were not aware of these data.

So, in 2017 - and this took some time, from 2013 to 2017 - we were finally able to have the American Academy of Pediatrics have a presentation at its annual meeting, which is the meeting that all the pediatricians go to - not just a workshop, but a keynote presentation on the issue of autism and wandering. And that presentation was done by Dr. Susan Hyman and Dr. Susan Levy.

In addition, they published an article in the AAP magazine in 2017 and another article is planned about autism and wandering in the 2019 - in this calendar year.

And then finally, in March of last year, we finally - thanks to the advocacy of many people in this room - finally were able to pass Kevin and Avonte's Law.

Now, Kevin and Avonte's Law revised and extended the Federal Missing Patient Alert Program. So, this was a program that was initially established to meet the needs of Alzheimer's patients, but through this law, which expanded to cover individuals with dementia and developmental disabilities, and was renamed the Missing Americans Alert Program.

Through Kevin and Avonte's Law, the DOJ, the Department of Justice is now also authorized to offer grants to be used for the purchase of tracking technology. And we've heard a lot about tracking technology at the IACC. And I believe we'll hear more about it from the panel.

And, finally, the Law enables the Department of Justice to issue grants to non-profits and law enforcement agencies to develop training and emergency protocols for

first responders and for school officials, so that they can be trained in the unique aspects of wandering that are related to autism.

Unfortunately, we still do not have an appropriation for funds for Kevin and Avonte's Law. We have an authorization, but still no appropriation. And again, I want to thank the many advocates who are here in this room who are working hard every day to try to get that appropriation.

With that, I would like to introduce the other members of the panel. So, Lori - I'm sorry. I don't have the sheet in front of me. Could the other speakers just come up? Lori is going to start from here.

DR. DANIELS: So we have Lori McIlwain from the National Autism Association, Maria Fryer from the Bureau of Justice Assistance at the Department of Justice, and Leemie

Kahng-Sofer, the Program Manager at the Missing Children Division at the National Center for Missing and Exploited Children. Thank you all for being here.

MS. LORI MCILWAIN: Thank you. So I'm going to do a quick update. Over 1,300 cases since 2011 for missing and found missing cases in the United States. 180 reported fatalities.

On average, 20 cases per month, 2-3 deaths per month. Drowning remains the leading cause of death.

This is what it looks like from year to year. 2013, 2014, we're not sure why that's so low. Monitoring was the same. We looked at weather patterns. We looked at other factors. But it continues to increase.

Average - this is from our six-year sample. And 2016, the average age was 13.

It's now 15. So, that average age for the fatalities has risen.

Also from our six-year sample. Not much has changed here. Residential settings, times of transition, heightened response to stress, all of those factors remain what increases the risk of these cases.

So, this is what it looks like on the ground. Last week, 37-year-old Wendy was found dead in a creek. Accidental drowning is what the autopsy showed.

And this isn't - there was, you know, a couple jokes about the Utah - we talked about a Utah case before where police training led an officer to nearby water to find a missing man in Utah. And it was a Utah dessert. So there were some jokes about, well, of course he would go to water, the missing man, because it's the dessert.

That's not what's happening here. These kids and adults are going to water in the winter when it's 20 degrees out. And that's what happened here.

A week before last, this is Xavion. He's seven-years-old. Was found in a nearby pond.

More notable cases - this was Maddox Ritch. He was missing for five days. He was at a park with his father when he got away. There's a lot of speculation about the father's involvement in this particular case. And even within my own circles of how could this child get away so quickly? I don't understand. I think the father did it.

And looking at these cases all the time, every day, we knew how this case would end. And he was found dead. It was accidental drowning. But this is another case that shows just how quickly they can get away.

So, this little boy was missing for an extended period of time, was found, treated by EMS, got away while he was under the supervision of EMS staff. So, that's how this is happening. These kids get away quickly. It doesn't matter if it's a parent, a teacher, or EMS, or a police officer.

So, training on that side, once the child is found, it's very, very different from a typical missing child. They're found. They want to be found. Right? Not the case with kids with autism. So, that training is necessary as well.

This was Trevyon Rowe, 14-years-old, out of New York. He went missing from school. This was very similar to Avonte Oquendo's case and it was compared to Avonte Oquendo's case.

Once this case came up and we looked at some of the details, it didn't seem right

because he was, to us, higher functioning. And once it came - once he was found, we were very confused. But this kind of brought it - made a little bit more sense.

So, this is happening, and we don't have much data on how often it's happening. And it seems to be - so, he was upset that he lost his cell phone. So, we are seeing this, and I am seeing this in my own son. Reactions that are out of proportion to the event. Right? So, my son, it could be a computer virus, the dog barking can make him run, and actually verbalize that he wants to die.

And it's a very acute reaction, very acute suicidality. It's not - these children aren't going to write a note. They're not going to tell a psychologist or somebody that they're thinking of killing themselves. An hour after the meltdown has happened or the shutdown or being upset, they don't want to

die. It's very in the moment. And so we don't have a whole lot of data on these cases or information, but that's another - adding to the complexity of these cases is something that we need to discuss.

There's been a ton of work on this. And a lot of it is thanks to IACC. So, you guys really took this issue - Alison, Lyn, Geri, Susan, you took this issue - and Kathy Rice, I love her - and you got the data, which opened a lot of doors for resources. So, I know - I know that this committee could do really great things very quickly. So, I'm very proud of that.

So, you know, once we got that data, a lot of resources came together. We've sent out nearly 50,000 Big Red Safety Boxes with life-saving materials in them. Over \$100,000 provided to agencies for Project Lifesaver. Friends at Autism Speaks have done similar

things. But, you know, that's limited when we don't have the proper funding. So, that's why we need Kevin and Avonte's Law to be appropriated and for us to get that funding.

Prevention is essential. These are some of the survey results from our Big Red Safety Box recipients. We'll get emails and comments from parents saying, you know, just that door alarm saved my child's life because he got out and he was heading towards the road, but because I heard it, I was able to get him, you know, before he could really get away.

So, we get a lot of that. And it's not that hard, these little door alarms and giving them out. And we also do it for schools, as well.

Project Lifesaver is - and another radio frequency - not GPS, but radio frequency trackers - more reliable and run through law enforcement agencies. So, if the child does

get out, if the child is missing, this is sort of the gold standard. And after Maddox's case, a lot of people wanted these tracking devices. But a lot of times, they're just not available.

If they are available, some still have age exclusions. So, this was a case out of Michigan. A mother had called. She had lost her son to drowning. He had autism. His brother also had autism and she wanted to get a tracking device for her other son, but there was an age exclusion. They had to be 60 or older. Right?

Now, this county worked with me, but they had to jump through some hoops to make that happen. And that shouldn't be happening. It should be open for everybody.

IACP - I love this initiative. It would be great to have something similar for autism. You know, 40,000 members getting

training, getting collateral pieces, do's and don'ts. Just search water first. Just that one little tip. 40,000 members. It's easy. We could do this tomorrow. It's easy, but IACP needs the funding so, once again, we need to get that appropriated.

Still an urgent issue. There's less notification to NCMEC, but there are more cases overall. That's because of the age. Ages are going up.

There's major differences in Alzheimer's versus autism. Similar resources are needed.

There's an increase in average age of lethal cases.

More agencies requesting interaction, training especially.

And mental health or comorbidity is adding complexity to this issue. And we really need to talk about that and the

unique, hidden challenges that these children face.

So, risk contribution really - risk contribution. You know I think 56 percent have intellectual disability or borderline intellectual disability. And then there's how many who are non-verbal - I've seen 25 percent to 40 percent. That contributes to risk. And then wandering, 50 percent. That contributes to risk. And suicidality, so nine times - you know, Sarah Cassidy is doing great work on that. That contributes to risk.

So, we are really looking at risk here and that's what I feel like is being underrepresented. And that's where the voice - having that voice comes in. Because there are so many hidden challenges - families like mine, where we have to live apart. We have to live apart to keep our kids safe. And you don't hear about these challenges because we

don't talk about them. We're not here. We're in survival mode.

So - but this, this is a good - this is a good place to talk about that and to get families like mine represented on this committee so that we can really look at those risk factors and make those a priority. It's not about high/low. It's about risk.

And right now, there's a lot of risk out there, a lot of families going through some complicated issues and they're not represented. So - thank you very much.

(Applause)

MS. MARIA FRYER: Oops, going backwards. Okay. Good afternoon. My name is Maria Fryer and I am the policy advisor at the Department of Justice Bureau of Justice Assistance. And I oversee the Justice and Mental Health Portfolio.

I'm here today to just talk about some of our initiatives and some of the work that I've been engaged with over the last four plus years at BJA. And, hopefully, just kind of laying some groundwork for some of the things that we've been involved with and sparking some interest and looking at some of this - some of these programs and initiatives as sort of foundational to moving forward with additional programming and addressing the needs of vulnerable populations.

So, today's discussion is basically here. Just overview of what I would like to cover.

So, BJA, just to begin a little bit about the organization, the Bureau of Justice Assistance supports, like I mentioned, many initiatives and programs that help communities address their state, county, local, and tribal responses to people with

mental illness and intellectual and developmental disabilities.

And I hope you forgive me - I am going to stick to my notes because of the timeframe. I know we have a certain amount of time to get through a lot of material. And I won't freewheel it because I'm trying to make sure that I impart some of the programs that we've got. So, bear with me on the notes.

But my hope today is basically to - you know, going forward, to just share our programs and initiatives and services with all of you and to start by learning from you. And I was so grateful for the presentations today and being able to take all of that in and gather that information, especially the work that's been done thus far and also seeing BJA as funding some of the initiatives already through IACP. So, that was very encouraging.

We've had similar, but different experiences with vulnerable populations. So, it's up to me now to gather what's been done to date in the justice system, note what's been done well, what needs work, and note where the gaps are and how we need to be effective moving forward.

I skipped.

So, the National Center on Criminal Justice and Disability and Serving Safely, these are two just kind of growing and building on this theme of response in terms of vulnerable populations. NCCJD or the National Center grew out of a need for response to the numbers of people with disabilities in the justice system.

It began to provide advocacy at the intersection of criminal justice reform and the advancement of disability rights. But it grew with work towards helping victims,

witnesses, defendants, on issues facing those persons who have been charged with crimes or find themselves in contact with the justice system.

And according to NCCJD, people with disabilities represent 4-10 percent of the prison population. 2 in 10 prisoners, 3 in 10 jail inmates report having a cognitive disability. People with disabilities by age 28, face a 43 percent chance of arrest compared to those without disabilities at 29 percent.

The greatest risk of arrest falls to men of color with disabilities. 55 percent will be arrested by the age of 28.

People with disabilities experience higher rates of victimization, as many of you in here are aware, three to four times higher rates. And if you've maybe perhaps have listened to the NPR series recently about

NPR's Abused and Betrayed Series, seven times higher for the risk of sexual assault.

Serving Safely was awarded in 2017. It took them a little while to get up and running as a National Center with many experts and objectives, but they bring expertise to local law enforcement, prosecutorial districts, on improving responses to people with intellectual and developmental disability and mental illness. And they actually just began and got up and running in May of 2018.

Now, NCCJD, who has formerly had a direct relationship with us, is now up under the National Center, which is called Serving Safely. And you'll hear me talk a little bit more about that further on.

So, the National Center on Criminal Justice and Disability - a little overview of what they offer. They offer a training for

law enforcement called the Pathways to Justice.

So, given those limited numbers that I just shared, coupled with a few national instances where police interactions ended tragically and the need for the National Center was more and more pronounced. They opened their doors in 2013 under BJA.

And their mission is to ensure equal access to justice, ADA accommodations, and effective treatment for both defendants, victims, and witnesses with IDD who come in contact with the justice system.

So, why is this important? I know I'm in very good company here. I've felt at home all day. And I probably don't need to go into those details, but they are overrepresented in the jails and prisons. They are often a hidden population as we're not identifying them at the front door at jail booking, often

times. And there is confusion and misunderstanding about mental illness and intellectual/developmental disability and the differences and where they coexist.

They are more likely to be victimized and used by others in correctional settings. That's very important. So, we want to divert on the front-end as much as possible and connect to treatment and services.

So, again, why Pathways to Justice? Almost all people with intellectual and developmental disability now live in the community. And we had lots of conversation about that earlier today. More and more are transitioning.

Community living, much like for people without disabilities, can lead to involvement in the criminal justice system, whether they are victims, witnesses, suspects, defendants, or incarcerated persons.

As victims or witnesses, assumptions about ability to recall events or testify effectively may lead prosecutors and others to ignore crimes that should be prosecuted. The rate of violent victimization is not only double, but triple. Cognitive disabilities equals greater risk, and we just heard about that. Children are more likely to be abused or bullied at school. One of the most at-risk groups, of course, to be trafficked, as well.

As suspects, individuals with IDD are frequently used by other criminals to assist in lawbreaking activities without understanding that a crime is being committed or that their actions have legal consequences. They may also have a strong need to be accepted and may agree to help criminal activities in order to gain acceptance.

So, the good news, after all of that bad news, is that we are developing more and more responses. We are engaging more and more law enforcement agencies and communities across the country through disability response teams.

And these teams help raise awareness and debunk myths related to disability. They help criminal justice professionals identify disabilities, help provide supports/accommodations, create and sustain and refer to local resources, and sustain training efforts. So, I thought it's important to move on to the solutions.

The impact has been tremendous. We have many, many resources to help local communities, law enforcement, prosecutorial districts, and advocates.

To date, NCCJD, through the ARC, has trained over 500 participants. And Pathways

to Justice held over 20 webinars, 4,500 participants to date, 250 requests for assistance over the last year. Currently, NCCJD can be accessed through our partners at Serving Safely.

Again, a little bit about Serving Safely. So, in May of 2019, as I mentioned, BJA officially launched a new National Center to assist law enforcement in their response to people with mental illness and intellectual and developmental disabilities. It's called Serving Safely, which is supported through a cooperative agreement.

Serving Safely is currently taking training and technical requests from law enforcement, agencies, prosecutors, and other community stakeholders with a variety of needs and requests.

Here is a little bit - a quote and a way to request training and technical assistance. So, I hope the slides will be shared.

So, I'm just going to move right along with some of the products. I'm going to kind of do a lightning round because there's so many that kind of, like I said, sort of build that foundation, which I hope will help to inform the way forward.

The Justice and Mental Health Collaboration Program was authorized - you may have heard - through the Mentally Ill Offender Treatment Crime Reduction Act, affectionately known as MIOTCRA. And it was reauthorized by the 21st Century Cures Act.

Typically, funding levels have been between \$10 and \$12 million per year. It's grown substantially in 2018. We were increased to \$30 million. And through JMHCP, our focus has increasingly shifted toward a

more system-wide level of improvement, bringing on more and more partners and learning to address issues of people with mental illness and intellectual disability in the criminal justice system in a more systematic way.

There are three categories of grantees or how folks apply to JMHCP. Since its inception, JMHCP has been promoting the development and implementation of system-wide change. In many ways, it's been the Firestarter in many communities, getting people around the table, multiple community stakeholders.

It's very broad in its application to states, tribes, and communities. And it has been the mechanism that opens up the lines of communication, often times, between justice and juvenile justice, mental health, substance abuse treatment systems, and all

other treatment providers and meets local needs and grows the strengths that may already exist in a community, as far as a community response goes.

So, JMHCP requires that grantees partner - by the name, itself, collaboration. You have to partner with your mental health authority and with a criminal justice entity.

Oh, I didn't advance that slide. Okay.

So, like I said, there's three categories. Category 1 is more of a county collaborative. That actually really encourages data collection and really looking at preventing people with mental illness and co-occurring disorders from moving deeper into the criminal justice system.

Category 2 is primarily focused on law enforcement and the needs of law enforcement for training and response and improving response.

And Category 3 is for an already established program that's any place in the criminal justice system, any place along that criminal justice continuum from very first contact right on through - you know, as much as we can, we looked at putting resources on the front-end to prevent people from moving deeper into the criminal justice system.

But in the event where it's appropriate and folks are incarcerated, then it also provides the resources necessary to make sure that re-entry is done very thoughtfully and very carefully and there's connections and comprehensive case management with the community to prevent and improve recidivism rates. We don't want people to return. We want them to be successful in the community.

So, the Law Enforcement-Mental Health Learning Sites - this is one of my favorite BJA initiatives that I oversee. The BJA

supported Law Enforcement-Mental Health Learning Sites Initiative delivers peer-to-peer learning through a cooperative agreement with the Council of State Governments' Justice Center.

There are currently 10 agencies in the sites above. They represent a diverse cross-section of model strategies and examples of police-mental health collaboration. And agencies can visit these sites. They can spend a few days with them. They can copy their policies. They can ask their questions. They can help agencies - law enforcement agencies to devise a collaborative strategy with their community partners to respond to people with mental illness and co-occurring disorders.

And then in 2016, we launched the Police-Mental Health Collaboration Toolkit. One of the things that we found from a really

intense focus group of multidisciplinary partners was that there was no one place to put all of these BJA resources, all these really important foundational documents and things like that.

So, we went ahead and launched the toolkit. It's growing. We're adding this year more of a behavioral health perspective, people with lived experience, and law enforcement executive needs. It focuses on planning a response in your community, on implementing a response, on managing that response, and sustaining it, training - and adequate training and performance measurement.

The need for data collection is critical in order to show impact and to continue to sustain programming and obtain resources. So, we help with that, too.

Excuse me. Another sentinel document that's just about ready to come out is the Police-Mental Health Collaboration Framework. This framework document basically takes the lessons learned. It's more of helping leadership to plan and sustain their response. And it runs through these core metrics and helps to plan to collect these metrics.

And it asks law enforcement leadership and helps provides guidance based around six basic questions: Is our leadership committed to response? Do we have clear policies and procedures to respond to people who have mental health and co-occurring needs? Do we provide staff with quality mental health and stabilization training? Does the community have a full array of mental health and co-occurring and support services for people who have special needs? And do we collect and

analyze data to measure the Police-Mental Health Collaboration against the four key outcome measures up here? And do we have a formal and ongoing process for reviewing and improving performance?

We're always improving performance. And using the data to improve performance is really important.

Stepping Up is another BJA initiative, actually BJA-funded. It's an initiative that's a collaborative between BJA, the Council of State Governments' Justice Center, National Association of Counties, and the American Psychological Association Foundation. And its intent is to reduce the number of people with mental illness and co-occurring disorders in local jails and to help coordinate response.

To date, we have 400 - get to my notes - 461 counties that have passed resolutions to

work on the four key outcome measures within this initiative, which is to reduce jail bookings of people with mental illness and co-occurring disorders, reduce the length of stay, increase connections to treatment, and, again, reduce recidivism.

So, I just encourage you to just put Stepping Up Initiative in your Google app and just see all the resources that we have to offer and all the counties that are doing just some tremendous work out there to reduce the numbers.

And, of course, we wouldn't ask you to pass a resolution without guidance, lots of guidance. So, we have the Six Questions Guide. And, again, this is to help counties to reach their goal of reducing those numbers. And you can see the six questions there.

There are also other guidance that's provided through the Stepping Up Initiative to reach this goal - a county online assessment, the Coordinator's Handbook, tools that assist with screening and assessment, which is critically important. We ask that communities reach a goal of 100 percent for screening and assessment. I hope one day that we can get there also with other vulnerable populations and people with intellectual and developmental disability.

So, again, some more additional resources. And this is where I just kind of put some questions up there because it's really important for me - I kind of breezed through all that so quickly because, like I said, gathering the information going forward, this is a - Kevin and Avonte's Law is going out in a solicitation. So, it's a competitive year right now. I can't talk

about what's in the solicitation because it is competitive and we want, you know, a wide pool of applicants and a really strong pool of applicants.

But it's really important for us to hear from you in this work. And so I thought, you know, putting some questions up there and having a bit of a listening session would be wonderful.

Just exploring what's been done, what works, what doesn't work. I've learned a little bit about that today, but I'd like to learn more. What do we know? What do we don't know? Where are the gaps in knowledge? Where are the gaps in services? And how can we leverage what resources we all have to make this better?

These are some additional resources. I didn't bring them all with me today. I had intended to do that, but I thought you might

appreciate them electronically versus paper to carry home. So, let me know if we can put those out on a web link, something that interests you.

And here is my contact information. I would love to hear from you. This is just so important to us and we want to be successful and just learning a little bit about the initiatives that we have thus far, I'm hoping that that will provide sort of that groundwork moving forward.

So, thank you very much for your time and attention and all the work that you've done. Thank you.

(Applause)

MS. LEEMIE KAHNG-SOFER: Hi everyone. I am here from the National Center for Missing and Exploited Children. I am with the Missing Children Division. And we really greatly appreciate the opportunity to be here. And

our Vice President of the Missing Children Division, Bob Lowery, he has been very, very passionate about this issue and has been a visionary about it. And so what we wanted to do was just at least go through some of our efforts since this topic came to light for us.

So, this is just a basic slide. I'm not going to go into exactly, you know, who we are and all of our resources, but - so there are some bullet points up there.

We are a non-profit organization. And we were founded in 1984. And so we have a number of different divisions and we have different programs of work and we're partnered with the Department of Justice to perform 22 specific tasks.

So, I'm here with the Missing Children Division and I'm going to talk to you about

what we've seen in terms of children with autism who have gone missing.

That current slide and the photo in that is a new building that we just moved into after about being in our other location for about 20 years. I'm here from the Austin, Texas regional office and we do have other regional offices that are listed there, as well.

Okay, so, Lori gave some data and I think - I believe Alison also gave some data. So, I just wanted to start with what we have seen.

And please also understand the context in which this data is presented because these are cases that have come to us. These are cases that were reported to us. We very much understand that there is a broader context and that there are tragedies and there are missing events that never make it to us

because either the recovery happened before or the tragedy happened before it ever got to us.

But this is data within the last 10 years, going up to December 31st of 2016. So, we had - up until that date, we had 952 children with autism reported missing to us. And then the majority of the missing children with autism were male. So, you can see that that was 74 percent.

We have a case classification called Endangered Runaways. And so they made up 61 percent of our cases with children with autism. And then the second most common case type was 20 percent and those were of our case classification, Lost, Injured, or Otherwise Missing, where there are insufficient facts or - to tell us exactly what happened. Maybe the child disappears without a trace or there are risks that

increase what would happen to the child and the vulnerabilities and that's what we classify as a Lost, Injured, or Otherwise Missing.

And then in terms of additional data that we've seen during the exact same period of time - so, we saw, in terms of duration and how quickly a child was recovered, that 48 percent of the children with autism reported missing to us were recovered within a day of going missing. And then 70 percent were recovered within a week.

So, when we're talking about deceased children, again, in that same period of time, we saw that four percent of our total of 952 children were recovered deceased. That was 43 children.

We have some updated statistics not yet in this publication, but between 2017 and

2018, we're at about .07 percent in terms of children who were recovered deceased.

And then 72 percent of the time, the manner of death described was accidental. A high percentage of that were due to drownings. That you can see here. And it's interesting that Lori, you mentioned suicides. In this publication - everything is on our website and I did bring some samples, which is in my manila folder that I will have with me, but 2 percent were reported suicides, in terms of the deaths.

So - and then moving forward, Lori also mentioned this case. This is Xavion. This was really the first deceased case that we had very early on in January of 2019. And when she talks about time is of the essence or it happens in the blink of an eye, it was reported that his mother was in the bathroom. He wandered out. And he was reported to like

feeding a particular goose near a retention pond. And so, unfortunately, his body was recovered I believe the day after that he was reported missing and was our first drowning victim.

So, what has NCMEC's response been to everything that we have been seeing? And I do remember, Lori, when you and Wendy came to NCMEC many, many years ago, that really launched our collaboration and initiative and really building awareness within our center, in terms of what the phenomenon is and the wandering and elopement and the tragedies that can really befall these children.

So, we started looking at things in 2012 and really started the Collaboration with NAA, Autism Speaks. From there, we made a number of different efforts, including our own internal protocols and then getting awareness materials together, as well as

awareness material and checklists for law enforcement, as first responders.

In terms of our internal protocols, they do start with our Call Center. So, with all of the materials that we have created throughout the years, we make sure to get that to law enforcement. Whether we're able to intake a case or not, then our case managers know, in terms of the criticality and the risks that these children face. So, we have our case managers also trained and follow particular protocol when it comes to children missing with autism.

And then I'm going to talk to you in a little bit - in a few slides - about our Team Adam consultants, but they are also a group of retired law enforcement that we have as consultants and who go and physically deploy on many critical - Critically Missing Children cases, including those on the

spectrum and those who are at high-risk for fatality.

Then throughout the years, we've had some other initiatives. We did a "Train the Trainer" and that was in partnership with Autism Speaks. Again, in terms of awareness materials and publications. In 2016, we held a focus group to try to relook at the protocols and the checklists and see if there is anything else that we, as a group, and all of the participants there could do.

In 2016, also, we held our first Sensory Friendly First Responder event. That was down in Florida. And that was in partnership with the school and the Palm Beach County Sherriff's Office. And that was exposure for the children who had autism with first responders so that they could get used to the sights, to the sounds. And it was reported back in terms of the event, that it was

really quite an amazing spectacle to see where - there was a teacher who was able to get 30 children with autism to look into the sky to see the helicopter that was flying above them that was a part of this.

So, we continue with partnerships and with trainings. One of the things that we did see and I have - I think one of my last slides has to do with data with children in the foster care system, but last year, in conjunction with the Autism Center - Center for Autism at Texas Tech with Professor Wesley Dodson and a pediatrician, Dr. Michael Gomez, we did a three-part series for caretakers. And it was a regional conference for special needs.

And what we are trying to do is - what we saw was in terms of children in foster care - and we have seen fatalities of children in foster care, as well, and

drownings - that we wanted to get the word and the awareness out there in that community, as well.

So, in terms of notifications and the efforts that we take - so, NAA, National Autism Association - so they're the one agency that we take notifications from. So, Lori emails our Center. She comes across a case and it's a news article. She will email it to our Call Center. Our Call Center will then respond appropriately.

They will make outreach to law enforcement. And then they will try to intake the case, offer resources, offer the protocols and the checklists, and then if law enforcement is not necessarily responsive, depending on the nature of the case, then we will force that intake and we will get it assigned to whoever is on-call in terms of

the case manager, so that we can deploy our resources immediately on these cases.

Another partnership that we have had is with NIXLE. It is a community notification service. And we have had this in place with them for many, many years. And - so it is not only just notifications on children missing with autism, but on missing children, in general. And so they also - it is - residents can sign up. It is a free service to law enforcement. They get weather alerts. And they also get missing child alerts.

And so, we've had a number of notifications from NIXLE. It's been very, very helpful because Lori brings attention to cases to us that may not have made it to us, as well as NIXLE. And we've had several instances where we did not have notification of that incident and we were able to intake the case and move accordingly.

Recently, in 2017, we also partnered with Next Door, who wanted to help in any way that they could. And so I don't know if anybody is on Next Door. It's web-based or application-based. And so it is another one of those community notifications. So, you'll see various different topics, but one of the things that we do is when we come across an incident - a missing child incident, whether we have it intaked or not, then we will send it to Next Door so that they can disseminate the information, as well. And it basically reads something like we need your help, this is urgent, and then it will be a description of the missing child and the circumstances involving the missing child.

So, we've had a number of notifications that we've already sent to Next Door, including those involving children with autism.

So, this is one of our last cases. I started with Xavion, which was one of our first cases in the new year. This is one of our last cases in 2018. There was a successful recovery in this one. And I wanted to just bring this to light because it is one of the last cases that I think, Lori, you sent us an email about.

And so we were able to reach out to law enforcement and deploy one of our Team Adam consultants. And eventually, he was found. He was actually found back in his home. And then there were some thoughts of him being neglected and so the parents were placed under arrest, but he was found successfully, alive, and in his home.

So, when I referenced Team Adam consultants, they are our set of retired law enforcement. So, we do have them around the country and you are going to see a map in the

next slide. And so you'll see where they are around the country. But they physically deploy onsite in our Critically Missing cases. And they provide law enforcement a number of different resources.

And then they will also make referrals to the families to our Family Advocacy Division, who assist our families, and then also make a Team Hope referral, if necessary and needed. And that is our group of parent/family volunteers who are specialty trained, but have also encountered within their own family a missing or exploited child, so that they can relate in a way that if you have not undergone that - in a way that those people cannot.

So, one of the other things that I wanted to mention about our Team Adam is that we also have an initiative and CART stands for Child Abduction Response Team. So, that

is just a map, in terms of the red start, depicting our Team Adam consultants around the country. And then the shaded areas are where there are CART teams that are available.

And so we now have NCMEC liaisons - TAC liaisons, who are assigned to CART, who get included in trainings, who get included in exercises. So, when we're talking about collaboration and communication, it is all with the goal of streamlining communication between agencies, between entities. And so, this is another initiative that has also proven helpful in those cases involving children missing with autism.

This is a - this is a publication also on our website and I have a sample. It's about 55 pages. But this is the Sensory Friendly First Responder Event kind of how-to

guide. So, I just wanted to show you what the image looked like.

And then the other thing that I just wanted to touch upon very briefly - so, often times, we're talking about the lower functioning, very high-risk and very high-risk victims of accidents and fatalities and drownings. But the other thing that we are also trying to raise awareness on and something that we discussed back in the conference that I did in Texas at Texas Tech was that we also have high-functioning individuals who are able to go online, but they also have a number of different vulnerabilities.

So we have had older children, juveniles, who meet people online, who are lured, who have become victims of crimes, of sexual assault, of sex trafficking. And so we are very much aware of this and keeping an

eye on it and also responding critically as necessary.

And then, as I mentioned, in terms of the foster care community, we want to make sure that we are spreading awareness in that community, as well. As they are accepting children into their foster home, what is their level of awareness of those who have autism?

What we did see - and this is, again, from that same publication with the same period of time - that 15 percent of reported children with autism were missing from foster care. And then of those, the older teens, we had a mean age of 15. And then a little over half, 54 percent of children with autism who were missing from a group or foster care, they were recovered within a week after they went missing.

And then this is my final slide I guess before we get into the discussion points, but one of the things that I know that we are really focusing on is training awareness and that is a part of Kevin and Avonte's Law, and getting that training and level of awareness out there to all levels of our community, our society, whether it's parents, caregivers, foster care, law enforcement, hospitals, first responders and -

So, when I reference the Train the Trainer Initiative that we had back in 2015 and ended in 2016, we reached over 1,300 first responders/law enforcement. And we received an extremely impactful email from a state trooper who had gone to that training.

What he wanted to relay to us was that - you know, he went into the training. He sat through it. He thought this is really interesting, great stuff, but it's never

going to happen. It's not going to be relevant to me.

Twelve days later, he encountered a young girl who had gotten on a chair, was able to unlock the door. Her father was sleeping. She was supposed to be sleeping. She left the home. She was running down the street. Thankfully, there was a passerby who saw her running and reported to law enforcement.

She was headed towards a lake. Law enforcement was able to quickly track her down. And through tips that they had gotten through the Train the Trainer piece, that he was able to engage her in a way that kept her attention. They were able to find her family members. And he said it was the most rewarding night of his career.

And that, you know - he walked away thinking it's not going to be something that

he was going to need to use, but he wanted to articulate to us that he stood corrected and that he was humbled. And so that is what we are striving for.

And, again, thank you very much for having us here. You know, moving forward, we are looking forward to collaborating with anybody in the community. And as much as we can get that kind of awareness and even if it's - we reach one person, that is a success. Thank you.

(Applause)

DR. GORDON: So, thank you very much to the panelists for each of your talks. I think there's plenty of opportunities now for questions and comments regarding these presentations.

Louis, do you want to start us off?

DR. REICHARDT: Yeah, I just wanted to ask you about a slightly different topic - I

mean, which I say relates to justice and diminished capacity and so on.

I mean we know that brain function is very important for control of emotions, for responsibility of the implications of crimes, and so on. So, it strikes me that many individuals, particularly the more severely affected on the autism spectrum - in fact, we know they - many have less - have more difficulty controlling their emotions and so on.

And how does this enter into sort of planning or activities at the Department of Justice? It seems like it's an important issue, at least for individuals that are tied up in the legal system.

MS. FRYER: So, you're absolutely right. Often times, law enforcement have - they are called to a scene. Patrol is dispatched. Sometimes they know what they have. Sometimes

they don't. And if - you know, if the situation where there is heightened emotion, things - you know - if there's a family member, you know, they might be able to explain, you know, hopefully.

But Pathways to Justice, they talk officers through that. It's very - it's very educational in terms of, you know, types of disabilities that law enforcement might encounter, strategies to de-escalate, how to connect someone to treatment, and so on and so forth.

But we're making these efforts - so we have that program. And currently, we're almost complete with an advanced - if you've heard of - there's several different response models for police, in terms of responding to people with mental illness or co-occurring mental illness/substance use or mental illness and intellectual and developmental

disability - crisis intervention. Team training is one. There's co-responder model. There's mobile crisis team. Co-responder model is where behavioral health professional and law enforcement travel together in a patrol car and respond.

So, these are some of the techniques. There's another model response called a mobile crisis team, you know, that are out in the community where they can respond. And they know, you know, who - kind of satellite. You know, they are out there and they know who's in that area and - so, there's so many different strategies.

I'm recently exploring agencies around the country that do sort of a - sort of an informational forum for law enforcement if they have someone in their house that's severely mentally ill or a severe - severely disabled in some way. I know those are

controversial. And, you know, just - there's just so many different approaches. But I hope that answers your question.

DR. REICHARDT: Well, it answered part of it, but the other part of it I guess is once you're in the justice situation, what's an appropriate punishment? I mean I imagine that such people are more likely to falsely self-confess, for example.

MS. FRYER: Exactly, and that's where - we have, through Serving Safely, the National Center - that's - you know, the bulk of the TTA requests that they have been getting is from prosecutor's offices, which I am so happy about because that's a huge need.

And out of those training and technical assistance requests, they are learning. They're learning as they go out.

We've got prosecutors as part of the subject matter experts as part of the

National Center. They're learning. And they have plans, along with disabilities rights and the ARC and other researchers, to develop products and guidance for prosecutors on, you know, deferred prosecution and other ways to sort of look a little bit deeper as to what's going on, what's the underlying reason for the behavior, and to really come up with an appropriate response.

Non-traditional to what we've been seeing, because the numbers are showing that the number of people with disabilities is increasing in the jail population.

DR. REICHARDT: Thank you.

DR. GORDON: John.

MR. ROBISON: I have a question for our Justice representative.

So, we've heard about tracking kids that run away and we've heard about various programs to train law enforcement. Everything

that I heard you talk about either related to behavior of children or how to deal with or manage the behavior of people in crisis situations when police are called.

I serve as an expert on autism and behavior in some federal court cases. And I get a lot of correspondence from families of autistic people in trouble. And one of the things that I hear about most often, which you did not actually say anything about, is sex crimes and, in particular, child pornography.

That is a thing nobody really wants to talk about in the autism community, but the real threat there, in my experience, is that people with developmental disabilities may see children as peers when they are older and, therefore, their ideas about romance, friendship, sex, or whatever are illegal.

And whether that is played out with downloading illegal pornography online or whether it's played out with your 19-year-old child who's maybe - maybe he's not even living with you. He's in a group home and he goes out on the street and he says something to an 11-year-old girl and the response is to call the police. And we have no - we have no real system to deal with that and all too often, the prosecutors think that these people are horrible animals and we should lock them up and throw away the key. And, you know, there is no question there are dangerous child sex predators, but it's not, by and large, in our community.

Does Justice have a view on that?

MS. FRYER: I can't say officially - you know, views of the Department of Justice. I can speak through the work that we've done.

And through the advocacy and - that's provided through Pathways to Justice, which is under The Arc, which is the National Center for Criminal Justice and Disability. That's the bulk of the advocacy - a lot of the advocacy that they provide to parents and families and prosecutors are people with disabilities charged with sex crimes. You're absolutely correct. Spot on.

And think about - think about when you - it's trying to explain to your own children like boundaries and what's acceptable and what's not acceptable behavior in a relationship. And people with disabilities, they want relationships, too. And they like romantic relationships just like anybody else.

But in its - it's a challenge. I actually was just talking to one of the providers through Pathways to Justice just

recently for a middle school child that was in need of - parents of a middle school child that was in need of some guidance. And they actually - there is some literature written.

Through the National Center, if you need guidance from the Pathways to Justice program, there is guidance on talking to your kids, if your child has autism or some other disability, about relationships and boundaries and things like that. Because having some kind of understanding is very helpful. To be preemptive with children is also very helpful to help set those boundaries.

But, you are right. Very difficult. And often times, don't end well where there's a lack of understanding. And how things - how situations are described, how events are described, when police are called in, it can get very confusing very quickly.

DR. GORDON: So - sorry, it's me up here. I don't know if you can see me. I recognize, as a federal employee that often has to wrestle with this issue of authorization without appropriation that it can be tricky for the federal panelists to comment on this. But there was the - there's an elephant in the room that was not discussed, which is that that first two speakers mentioned that the Avonte Law was authorized, but not appropriated.

And yet, the two federal representatives from the Department of Justice were telling us about initiatives that you're able to carry out - to carry out the - Avonte's Law. I don't know if you can or could talk about the support that you are getting through the Department of Justice to carry out these programs and how extensive is the reach with the current level of support.

And - you know, one of the things that we, as a committee, are charged with by Congress is recommending resource levels for the things that we recommend. And so we would like to hear if you're not asking Congress, we're just asking you, how much more demand is there than supply. That's something that we talk about all the time with our grants, so it's probably something you guys could talk about.

MS. FRYER: Let's see if I can dance around this carefully.

So, the programs that I described have already been funded. That's why they're - they're out there.

And, you know, the current situation that we're in, cooperative agreements, they've already been awarded. Those folks are out there doing this work. So, that's ongoing.

The new legislation that just came down the pike - I want to say December it was. That's been added to - under our portfolio on my team. And that is - that has not - we have not received that yet.

Under JMHCP - well, Justice and Mental Health Collaboration Program is authorized, as I mentioned, through MIOTCRA, which is authorized up to \$50 million. We - it started when the first program - it was first authorized in 2004. First programs went out the door in 2006. It was like \$7 - between \$7 and \$9 million. It steadily increased up to \$10 - \$12 million in 2014. Then it dipped back down for a little while and then it climbed back up again.

And then in 2018, like lo and behold, it increased three times to \$30 million. And I think that was, in part, because of advocacy groups and non-profits and things like that

knowing the work that's been done across the country.

And under the Justice and Mental Health Collaboration Program, it funds - not only it funds through a competitive grant process, but it also funds training and technical assistance. And there is a cap on that. There's a percentage cap on that per the legislation. So, you know, our hands get tied at a certain dollar amount as to what we can do.

So, we try to make those dollars go as far as they can with the things that we - the initiatives and things that we try to do - try to make large impact. We have moved from funding smaller, kind of one-off programs - not that they're not valuable. They are. But looking at more system-wide change so that everyone can reap the benefits, taking those resources and stretching them further.

DR. GORDON: Like training the trainers rather than just training the -

MS. FRYER: Exactly. And, you know, system-wide approaches and policy and things that - you know, how can we help states leverage what states can provide to local communities so that, you know, we can kind of figure out, you know, what are the levers, what are the push and pull at the state level to help support what we can fund at the local level.

Change happens at the local level, but we really tried to figure out how to make those dollars go as far as they can. I hope that answers the question.

DR. GORDON: That answers it. I have a couple of follow-ups, which I'm pretty sure you can answer because they're kind of things that we can answer. So I'm pretty sure you can as well, but if you can't, that's fine.

MS. FRYER: Okay.

DR. GORDON: So, one is what - do you know what percentage of your funds go to programs which are aimed at autism, in particular, or wandering, in particular?

MS. FRYER: So, currently, it is really all of intellectual and developmental disability, not just autism. But autism is a part of that.

The percentage or the dollars really - it's really what falls under Serving Safely or under what we - we're recompeting the National Center to support law enforcement in their response to people with mental illness and intellectual/developmental disability. We are recompeting that this year. And it will be up to \$4.5 million and that includes intellectual and developmental disability.

DR. GORDON: Then the programs that you mentioned that are capped or that are - you

know, that you have limited resources to meet, do you know how many you've turned down or what - or if it's not - you know, you get 100 applications and you fund 20? At what point during the year do you end up running out of the cap?

MS. FRYER: Sure. Can give you some estimates there.

So, the solicitation for JCHCP comes out in usually early spring - late - around this time - February timeframe/March timeframe. We typically get between 120-150 applications. Of those say 120-150, we typically can fund between 35 and 45.

Last year, we funded 55 because the Category 2, we actually tried to provide small planning grants to law enforcement to help them get up and running with their response. So, we kind of scaled back the

dollars and tried to fund more of them, but -
I hope that helps.

DR. GORDON: That helps a lot. Just so
that I am getting it right, out of the safety
- sorry, I forget the name.

MS. FRYER: Serving Safely.

DR. GORDON: Serving Safely program,
about \$4.5 million for developmental
disorders and intellectual disabilities -

MS. FRYER: Right.

DR. GORDON: Of which, you know, a lot of
that is relevant to autism. Not necessarily
specifically focused at it.

MS. FRYER: Yes.

DR. GORDON: And then for this program,
is this part of the Serving Safely or is it a
different program, the 120-150 applications?
That's a different program?

MS. FRYER: That is different. That is
under JMHCP. That is under Justice and Mental

Health Collaboration. So, there's two separate funding streams.

DR. GORDON: Got you. And you're funding about a third of that.

MS. FRYER: Yep. The National Center for both Mental Illness and Intellectual and Developmental Disability, the funding stream comes through Edward Byrne Memorial Fund.

DR. GORDON: Right. And for those of you not familiar with it and those of you listening, if you're thinking, oh, a third of the program - that's very small. NIH funds less than a fifth or about a fifth of the grant applications that come in.

So, that's actually not terrible in terms of supply/demand ration. Although, many of us at NIH feel like we would love to be able to fund more than the 20 percent that we are able to do.

Anyways, I want to make sure that the committee gets a sense of the resources and the demand that's out there for those resources because, as I said, one of the obligations Congress has given to us is to make recommendations on future funding levels.

Are there questions or comments for the panelists or that you'd like the panelists to hear or that you'd like to spark discussion amongst the committee?

(No response)

DR. GORDON: Alright, I want to really thank you. We've been anticipating the Department of Justice presentations for a while. It's wonderful to have you here.

And we hope we can keep the lines of communications open. Many issues arise here at IACC that are of relevance to Justice. And your information is of great relevance to our

considerations, as well. So, thank you very much.

(Applause)

DR. GORDON: Thank you to the non-profit panelists, as well, for raising the issues and for discussing the historical background, which was really helpful.

Okay, it is now 3:30. We're actually 15 minutes ahead of schedule. I'd like to say we should take our break now for 15 minutes, so 3:45, and start up the next phase, the Summary of Advances Discussion at 3:45. So, we'll stay 15 minutes ahead.

Alright, see you all in 15 minutes.

(Whereupon, the Committee members took a brief break starting at 3:30 p.m. and reconvened at 3:45 p.m.)

DR. GORDON: We seem to be missing some of our Committee members, but they'll trickle in, I hope.

So, this next component of the meeting is discussion of the 2018 Summary of Advances. And Susan is going to take us through the process as a reminder, although this is I think the third year we've done it this way.

DR. DANIELS: Thank you. So I will give you an overview of what we're going to be doing to complete the 2018 Summary of Advances.

So, the Summary of Advances is an annual report required by the Autism CARES Act. It includes lay-friendly summaries of the 20 most significant advances in ASD biomedical and services research as selected by the IACC. And this typically includes articles addressing all seven topic areas of the IACC Strategic Plan. And you can see we already have a cover ready for our new publication.

So, the process includes monthly emails to solicit article nominations from IACC members. So, you've been receiving those and responding to those and sending us your nominations. And the advances are compiled quarterly and discussed at IACC meetings and we have a set of them to discuss at today's meeting.

And in today's meeting, we will discuss the top articles among all of those nominated - among the ones that were nominated this round. The others have already been vetted.

And then we're going to be sending you a ballot to be able to vote on the top 20 articles to be included in the final publication of the 2018 Summary of Advances. And we're going to set a due date of February 1st to receive our ballots back. And we will do a tie-breaker vote if necessary.

So, in the process, we will be selecting - taking the selected articles and summarizing them. And the nominated articles that are not selected will be listed in the appendix. There will be a draft publication that will be prepared and sent out to committee members for a very brief review. And for those of you that may be authors on any of the publications, you'll get a chance to look carefully at your summary to make sure that it's accurate.

And the final publication will be prepared for release for the April 2019 meeting in Autism Awareness Month.

So, so far for the year, 10 IACC members submitted a total of 43 nominations, which is a smaller number of nominations from last year. Last year, it was about 80 nominations or so.

And we had 6 in the Question 1 area of Diagnosis and Screening. 8 in Question 2, Biology. 14 in Question 3, Risk Factors. 3 in Treatments and Interventions, Question 4. 5 in Question 5 on Services. 3 in Question 6 on Lifespan Issues. And 4 on Question 7 in Infrastructure and Surveillance. So, you will have a variety of articles to choose from in the final publication.

So, with that, we're ready to talk about the most recent round of nominations. And I'll turn it back to Josh.

DR. GORDON: So I - just one comment, I think perhaps one of the reasons for the lower number of advances is because we've been, over the last couple of years, socializing each other about what we think are significant advances. And I'm pretty impressed with the nominations that we've been receiving over the past year. And I

don't think I have to draw many red x's through them as I did in the past in my own mind and - as such.

So, we have a number of nominations that are included in the summary overall for the entire year. And, in addition to that, we have the ones that were nominated just this past month. So, you have I think both. Is that correct?

DR. DANIELS: Right. On the bigger listing, you have the ones that are highlighted are the ones that have recently been nominated. And the ones that are not highlighted are ones we've previously discussed in other meetings.

DR. GORDON: So, I think what we have done in the past is gone through and, of course, we would welcome, in particular, the comments that were nominated most recently. But if you have strong - if you'd like to

make lobbying on behalf of any other applications to remind people of their strengths so that we can consider those comments when we go and vote, we'd love to hear about it.

So, first, we'll tackle Question 1, which is Screening and Diagnosis. That's on page 1 and the top of page 2 and - if you're looking at the paper. And - paper descriptions. And these are the two - is that correct - that have been nominated in the past month.

It looks like Geraldine had to leave. I think I saw her leaving earlier with her bag. But she nominated the Ozonoff article on Diagnosis of Autism Spectrum Disorder After Age 5 in Children Evaluated Longitudinally Since Infancy. So, this is a descriptive paper that attempts to look at those who get late diagnoses by retrospectively looking at

their longitudinal follow-up to figure out what might be different about them.

I haven't read the article, myself. I don't know if anyone at the table would - can comment on it.

DR. DANIELS: Her justification is included in the packet for anyone who wants it.

DR. GORDON: She wrote rather shortly, ASD is manifest after age 5 in some children. The description's not all that good. We'll have to ask her to qualify it if we want to go further with it.

The Wolff paper, which is the one that we nominated from NIMH, is a longitudinal study of parent-reported sensory responsiveness in toddlers who are at-risk for autism. So, this is trying to explore the symptom space in this group of what we consider high-risk toddlers, 12-24 months,

looking for signs and symptoms that might be relevant for the progression. And this one focuses, in particular, on sensory-related features, which as we all know are a significant feature of Autism Spectrum Disorder.

The main conclusion is that in the high-risk group compared to those who receive a clinical diagnosis, there are significantly higher scores - sorry, those who go on to receive a high-risk - a diagnosis have a significant - have higher SEQ scores than others in the sample.

So it's, if you will, relative progress in our efforts to try to be able to identify those with autism earlier. That's part of this effort.

Are there any other comments on any of the others in Question 1 before we move onto Question 2?

Okay, so Question 2 is understanding the biology. We have also two more nominations. Is that correct? Yes.

And both of them were made by Walter or NINDS. I don't know if Walter, you'd like to comment on either of these two that are on the screen?

DR. KOROSHETZ: I guess before I do that I give a heads up - David Amaral study, which was nominated before, looking at neuron counts in the amygdala, showing an excess in early childhood and ASD and then a fall-off in adulthood. And I don't know who had the - counts, but hats off to them, David.

And then the new one is a paper from a Canadian group, where they looked at using IPS cells and they basically did a knockout of a whole bunch of different ASD-associated genes in these induced pluripotent stem

cells, which enable them to see what the effects were on different networks.

And they saw some similarities in some of these molecular networks and the different CRISPR knockouts and also in some of the physiological changes in these IPS cells.

So, kind of a new way of looking at phenotype in human cells in a dish.

And then the second one is a really interesting paper looking at Fragile X. So the Fragile X protein binds to transcripts of messenger RNA.

And they actually looked at this in fruit fly oocytes because the theory - their theory is that the Fragile X protein is necessary - necessary for messenger RNA storing and then keeping it stable so that it can be then transcribed into protein. This occurs in the synapse, but it also occurs in

these fruit fly oocytes, which is much easier to study.

They did find some things that were counterintuitive to what had previously been thought to be the function of the Fragile X protein. So, really interesting paper with a kind of different method that may have some really important insights.

DR. GORDON: I would just make the comment with regarding the Amaral, which is the first paper in your - in this Question 2 on page 2 of the packet that you got that Walter mentioned that has been nominated earlier. That this is - addresses one of the comments - the public comments made about the need for post-mortem studies.

And just to point out that, indeed, the research community as well as IACC is trying to respond to some aspects of the public comments where we can.

Alison, did you want to make a -

MS. SINGER: I just wanted to ask about -
I know there was a study published last week
in Nature Neuroscience that looked at the
growth rates of stem cells in a dish of
people with autism versus - so, that was in
January of this year. Was there a prepub? Or
is there any way to nominate that so that we
don't have to wait a year?

DR. DANIELS: So, if you can send it to
us, we'll see if it's eligible. And if it is,
we'll put it on the list.

DR. GORDON: I would make another
editorial comment with - regarding the two
new nominations by Walter, which is that
these papers highlight that you need
sometimes different experimental systems to
answer different questions. Right?

So, the frog oocyte doesn't seem like a
very good model for the brain, but, in fact,

it is a great model for studying biochemical processes that take place inside of cells that are affected by genes, which affect brain function.

The big question then is if we learn something from that is it relevant to brain cells and is it relevant to human brain cells? That's obviously going to need further experiments to figure out. But you can't make these basic discoveries as quickly or as easily if you stick to more complicated situations.

Similarly, the first manuscript, the Deneault et al., that used human stem cells - human induced pluripotent stem cells, which are taken, as you know, from adults, to explore synaptic connectivity between neurons, there you, number one, need neurons to explore the role of autism genes in connections between neurons because only

neurons make connections between neurons. And number two, if you can, it's best to do that in human neurons because human neurons may have different synaptic substrates than mouse neurons or other animal neurons.

And so, where the technology exists and you can explore questions, you do try to do it in as relevant a system as possible. Again, though - even though this is human neurons and human connectivity, it still asks the question, well, what is the role of this during development of an intact human brain, which would require additional and different kinds of studies.

So, this is something that we try to emphasize across our portfolio at the National Institute of Mental Health and what we try to emphasize when we're interpreting these results. Different scientific questions require different models and each of those

models then requires different levels of interpretation, validation, and confirmation to know how they apply to the human condition.

Any other comments on any of the other nominated papers, which were previously nominated and discussed in Question 2, which goes through page 5 in the packet?

Okay, so we'll move onto Question 3. And here we have 1, 2, 3, 4 - 4 nominated questions on page 5-10. And the first 2 of them are here on the slide, the Andrews et al., Stuart, was nominated by you. And the Question 3, of course, is Risk Factors.

DR. SHAPIRA: Yes. So, this was from CDC and as many here are aware, when you do genome-wide types of studies, it's often difficult to make any conclusions from samples from one single study because you run into problems with - even if you have a lot

of samples, you run into problems with small numbers.

And this study was unique in that it looked at samples in three different studies. Two of them were with blood samples from SEED data, the Study to Explore Early Development, and the Simon Simplex Collection. And what was done was to do genome-wide methylation analysis from blood samples. And methylation is actually a signal for genes being upregulated, so more highly expressed, versus down-regulated, turned off.

And they looked for differences between individuals with autism and controls who don't have autism and did identify statistical significance in seven sites. And then another sample that was looked at was actually brain-based DNA. And they found that the same sites that were identified in blood

were also methylated similarly in brain samples.

So, the findings of the analysis have the potential to show that one could use blood samples for methylation analysis and as a resource for looking for differences in gene expression.

DR. GORDON: The next one is a manuscript by Gandal et al., on transcriptome-wide dysregulation in ASD. That was nominated by Walter.

DR. KOROSHETZ: Right. So, Josh may be able to talk more to this, but this comes from a really big project that NIMH funded looking at the transcriptome combined with genomes in patients with different neuropsychiatric conditions, primarily schizophrenia, bipolar, and ASD.

And by looking at the - in this study, looking at the transcriptome combined with

the genome, they can see patterns of gene expression changes that - some of which overlapped among the different diseases. But some of them, and particular the one I point out is that the networks involved in innate immunity in the brain, particularly the microglia, that network was highly different in people with autism as compared to the other disorders and as compared to normal.

So, again, it points to something that the genome studies didn't show, themselves, that there's something going on in the innate immune system in the brain in autism. And, again, as Josh mentioned, these kind of studies with these new technologies can only be done with brain tissue, which highlights the importance of really kind of putting out a big effort to obtain brain tissue for this technology.

And there are now much more powerful technologies coming on to look at single cells. So, you could actually look at the microglia, themselves, with the new technologies.

DR. GORDON: Yes, so as Walter mentioned, this is part of a larger project that the NIMH has been funding for a few years now called PsychENCODE, which tried to understand the relationship between genes - right - that's our DNA code that codes - that instructs the body on how to build a cell and the transcription of those genes - that's conversion of genes into RNA and the RNA then tells us what proteins to build and actually build the machinery of the cell.

And so this and actually a number of other papers that were all published together provide not just these interesting findings, such as pointing out the possibility that

microglia are a particularly important locus for autism genes - although, there's a little problem with that. Sorry - for autism expression, right, expression of those genes.

But the - but also provides a resource on top of which lots of other investigations, including the paper that Stuart nominated, can build their results and figure out where and when in brain development are these genes acting.

The one issue I have with the finding about microglia is that at this stage, we don't have a lot of single-cell data from the neuronal populations. And it may be that, actually, neurons are even more important than microglia, but they don't separate out from everything else with this level of analysis.

But this group and other groups are going through that dataset - those datasets

now on a neuron by neuron basis to try to figure out whether there might be equal evidence for specific neuronal cell types.

You look like you might want to say something, Louis.

DR. REICHARDT: Just say that you shouldn't be over-optimistic about the single-cell technique because of its depth of coverage. I mean there was a very creative paper from Mike Greenberg's lab a few months ago illustrating that. That he - which is of general use for what I call - for excellent genes.

That he - that it turned out the MECP is not expressed at high enough levels to detect reliably by the single-cell technology, but what he did was he identified SNPs in genes that were expressed at much higher levels that he could use to identify the cells and then use this level.

And so there - I think there's still huge value for the whole tissue, which you can - yeah.

DR. GORDON: Yes, and indeed, in fact, the next incarnation of this project actually compares directly single cell and bulk tissue expression to try to get a handle on what the advantages and disadvantages for each.

We've gone and geeked out a little bit as molecular biologists sitting over here. So, we'll move on to the other studies.

But I think the important take-home from this nomination and from Stuart's is that these really high throughput, relatively inexpensive techniques to interrogate the molecular components of the risk factors for autism are making steady progress. We don't have any, you know, definitive answers, but we have clues now, even more so than we had last year, in terms of not just the genes,

which, now, we've known for a while some of the genes, but actually where they - where and when they might be acting and how they might be exerting some neuro effects. So, these are promising developments.

Geri Dawson had nominated the next one, which is on the next slide, Janecka et al., Association of Autism Spectrum Disorder with Prenatal Exposure to Medication Affecting Neurotransmitter Systems.

I actually saw this article, although I didn't read it carefully. It's another look at electronic health records. I believe we talked about a previous study last year looking at exposure to - I can't remember the details, actually. And I don't know if it was selected or not for the highlights.

But this points out that using these EHRs, you can determine that exposure to medication during development at least is

correlated with alterations in risk for autism. The risks are actually quite small, but they are there. I shouldn't say they are there. They are hinted at by these large studies.

So, I don't know if anyone has any other things to add to this.

Okay, and Stuart, you nominated the next one, as well, which is autism spectrum disorder and birth spacing.

DR. SHAPIRA: So this is a risk factor analysis from the Study to Explore Early Development, or SEED. And it's actually looking at birth spacing, so the length of time between a pregnancy that did not have ASD/autism and the next pregnancy, which did have ASD, and looking at both long and short birth spacing to determine if there's an increased risk. Because there had been studies out there about this in the past.

There are a number of methodological limitations with those studies. And so this one is more comprehensive using a much larger sample than in previous studies. And not only could they look at the basic assumption, does a short or a long birth spacing increase the risk, but also they had data to assess various subtypes of autism and to examine factors possibly in the causal pathway for this association.

And the exciting thing was that the associations that were found in this study were unique to autism because SEED is well-positioned to look at any associations between those with other developmental disabilities that don't have autism and does that affect birth space - I mean are those increased with birth spacing. And that is - it was only - the associations were only seen with autism for those where the birth spacing

was less than six months or more than 60 months. In those cases, it's definitely a u-shape distribution.

And although the American College of Obstetricians and Gynecologists already has recommendations and information for birth spacing, what this study does is actually helps to inform those recommendations further for families to consider the length of time between having children.

DR. GORDON: Stuart, do you know what those earlier recommendations about birth spacing - which obviously not based on autism risk, but other factors, what they are recommending - why the recommendation is for that medium length birth spacing? Is it based upon health outcomes or other factors?

DR. SHAPIRA: Do you remember? I am trying to remember if it's related to preterm birth or other issues, other growth issues

with the child. So, I'm not the expert in that area, but the College does have recommendations, which, actually, again, is less than 6 months, but then longer than 18 months.

The association in this study was really very long birth spacings for more than 60 months, but also less than 6 months.

DR. KAVANAGH: More than 18 months.

DR. SHAPIRA: I'm sorry. So they had - so, it should be - it's more than 18 months between the - well, it's less than 6 months or more than 18 months -

AUDIENCE MEMBER: (Inaudible comment)

DR. SHAPIRA: As my colleague, here, was in Division of Reproductive Health.

DR. GORDON: And you were saying it's based upon concerns about low birthweight and preterm labor, which would suggest, perhaps, if this is related to that risk, it might be

about growth - growth more globally, perhaps affecting brain development. It's intriguing.

Are there any comments about any of the other nominated papers in Question 4, Risk Factors?

So, I just want to point out this is now the second year in a row at least - it might be go back further - where we've been gaining more information about risk factors. Again, now, we have environmental risk factors. We have genetic risk factors.

I would also make the editorial comment and we should make sure - although, I think we usually do - that the Summary of Advances reflects this. This evidence does not help us yet really guide parents. Right?

So, although the previous paper that we discussed suggests the possibility of a linkage between prenatal neurotransmitter - medications that affect certain

neurotransmitter systems and autism, it is not at all clear that the right advice from that would be that mothers should avoid medications belonging to those classes that affect those neurotransmitter systems.

Nor is it, despite the ACOG recommendations based on other thing, clear that we should recommend that parents to avoid having autistic children should have a midrange interbirth interval because we don't know the causal relationships between these factors.

So, the importance of these advances is not because now we know you should avoid x or y or z, or now, we can use this genetic information to diagnose autism. We can't do those things yet. The importance of them is to point out the places that scientists should be looking for causal relationships.

So, while I certainly do appreciate the public comments, as we talked about earlier, about hypotheses about what factors cause autism, those hypotheses should be rooted in the kinds of facts that are represented here, in these and other papers we've referred in the past on risk factors. Those risk factors that are really strongly statistically significant, those are the ones we should be exploring for causal relationships.

Okay, Question 5, Services - oh, sorry, Question 4 is Treatment Services. We have one nomination and Alison, you made the nomination.

MS. SINGER: So I think this is one that does fall into now we know. This is the study I referenced earlier. This is, in my opinion, a critically important landmark study that, for the first time, identifies in the literature that children who are severely

affected by their autism are dramatically underrepresented in our studies.

This was a rigorous review of 367 treatment studies, looking at three domains of severity: communication ability, cognitive ability, and adaptive functioning. And as I said earlier, this is a type - this type of study is important in order to increase awareness and make changes in our inclusion policies in studies so that we are not getting an unbalanced picture of autism in the scientific literature.

DR. GORDON: I think this is a really important study. And note that the findings of the study are that rate of individuals with - who are "severely affected" - that is communication ability, cognitive functioning, adaptive functioning - has been decreasing over time from 1991 to 2013.

I want to point out a little counterargument at the risk of inciting a comment about who is important within the autism spectrum. Because John's essentially right that we don't know what the rate of these - of the individuals in the overall autism or general population is, we don't know if we were under-representing or over-representing in the past. We only know that things are changing.

That doesn't obviate the need to make sure that our research has adequate numbers of those that are severely affected to evaluate the effects of treatments on them because if we're evaluating treatment studies only in a high-functioning population, we're only going to see results in that group.

What's important about this study is that it points to the need to ensure that we maintain a large enough sample of severely

affected individuals that we can evaluate the effects of those treatments on those who are severely affected. Otherwise, we're only serving a portion of those with autism spectrum. So, the point is well-taken.

Okay, Question 5 - oh, sorry, are there any other comments on the other nominees we have - two other nominations from the year in Question 4?

And at this point, I would say that we like to try to include at least one advance from each of the questions, so as you're doing your voting, even though there's only three, don't skip over Question 4 because there's only three. You know, one of those may very well be amongst your top 20. And we want to try to encourage everyone to evaluate each of the questions.

Question 5: Services. In Question 5: Services, we, again, have one new nomination

and this comes from NIMH. And it's a study of healthcare service utilization and cost among adults with Autism Spectrum Disorders in the U.S. Integrated Healthcare System.

And this really looked at healthcare utilization records to begin - really, this is the beginning of an attempt to describe how adults with ASD use general healthcare and how they - and how that compares to those in the general population and also a comparison group of adults with ADHD.

And the main finding is adults with ASD had significantly higher rates of utilization across most healthcare services.

You know, we, here, have talked about, though, that - the adverse outcomes. That is the increased mortality in individuals with autism. One possibility would be because that they're not actually utilizing services. This data would suggest that's not the case.

But then the additional analysis suggests maybe a hint about one of the reasons why. So, the last line in this summary that my staff - I have to admit I didn't prepare it - my staff prepared for me - was that women with ASD were significantly less likely to have gynecology visits and have screening for cervical cancer.

So, it's not about overall contacts or overall utilization of the healthcare system, but perhaps, what happens when they interact with the healthcare system. Perhaps they're not getting the kinds of treatment and the kinds of screening services that other adults are getting.

Are there any other summaries/comments on the other nominees in Question 5? There's four or five other ones. We'll move on to Question 6 then.

There were no new nominations. I do point out there were four nominations in the past in Question 6. Are there any comments or highlights from those applications? This is Lifespan Issues.

Okay, Question 7: Infrastructure and Surveillance. Here, we have a number of new nominations, which is good because, apparently, we had no nominations before December in this area. But we now have four nominations, two from Stuart and two from Geri.

Stuart, why don't you take us through your two, which are the first two?

DR. SHAPIRA: The first two are the two surveillance reports that look at prevalence of autism spectrum disorder and other characteristics that came out this year that are quite complementary and they use

different approaches and, therefore, can answer different types of questions.

And the first one is from the ADDM or the Autism and Developmental Disabilities Monitoring Network, which is in 11 sites around the United States. So, it's not nationally representative, but it's representative of those 11 states that contribute data to the ADDM Network.

And it's a very thorough review of both health records and educational records in order to look at behavioral characteristics of individuals who are 8-years-old at the time and determine if they fit the surveillance diagnosis for Autism Spectrum Disorder.

And so this is where the number 1 in 59 that folks have been using - that's come about. And so the 1 in 59 is higher than what

was - so more prevalent than the estimate from two years prior.

But the report had a lot of interesting and important information noted in it. And the first thing is that there has always been a disparity between the prevalence in non-Hispanic whites versus non-Hispanic blacks and Hispanic.

And, finally, probably through better recognition and referral to services, that those who are non-Hispanic black have on - almost equal prevalence to those who are non-Hispanic whites. So, that's part of the reason for the prevalence increase is better recognition. And the disparity or the difference between whites and Hispanics is also narrowing.

So, that's good news to show that, hopefully, individuals in all of these groups are getting referred for services.

Also, those with - looking at the proportion of those with intellectual disability and the change over time is that there is a - now a higher proportion of the total which do not have intellectual disability, but do have autism - so a higher functioning proportion. So, it's just showing that those who are at the milder end of the spectrum are being identified more likely, which wasn't the case in the past.

And then the other important component of this analysis, it was the first opportunity to compare making diagnosis under DSM-4 versus DSM-5. So, there's the change in the diagnostic criteria and there's been a concern, would that change the prevalence.

And, overall, there - the difference, by applying DSM-4 versus DSM-5, there were similar overall, as well as when stratified by sex and race/ethnicity. So, that's

reassuring to know that moving forward with the change in the diagnostic criteria is not - there won't - there is unlikely to be a significant impact in the prevalence and people losing services that would previously have had a diagnosis.

The second -

DR. GORDON: Stuart, sorry, before you move on, there was a line in there that I'm not 100 percent sure I fully appreciate, but I want to underscore. And I'll give the background first, of course.

A big concern with the increasing prevalence rates has been why. Right? And there are competing hypotheses about why. One might be the increase or prevalence of risk factors. And another might be the increased case ascertainment. That is that we - and there's been statements that perhaps the reason why we're realizing more cases is that

less severely affected individuals with autism are being identified at higher rates.

I think you said something that touches on that last hypothesis, so I'd like you to repeat that.

DR. SHAPIRA: So that is, again, that because the - of the overall - so, if you look at the proportion of intellectual disability of those identified who have ASD, the proportion is shifting so that there - it's a higher proportion of those without intellectual disability who are higher functioning. So, as it - as it's increasing, you're seeing a higher increase in those who do not have intellectual disability and, therefore, to some extent, making up the difference in the prevalence increase.

So, that's also good news not only decreasing the disparity between black and white and Hispanic and white - and we have no

biologic reason to suspect that autism should be more prevalent among non-Hispanic white individuals than among black or Hispanic individuals. So, it's nice to see.

And in fact, in some of the sites, it was completely the same for all three racial/ethnic groups. So, where they're doing seems to be a better job of identifying and getting people into services, we're seeing no disparity between those groups.

DR. GORDON: So I think it is safe to say that while these results are not definitive, the recent evidence suggests that - at least the possibility that a partial reason for the increase might be case ascertainment as opposed to increased prevalence of risk factors. Although, you know, this question I would say is not definitively answered yet.

DR. SHAPIRA: Correct.

DR. GORDON: Okay, sorry to interrupt.
You can go on with the next one.

DR. SHAPIRA: And the other surveillance report is - was instituted - funded by HRSA with collaboration from CDC and - in both our center and the National Center for Health Statistics.

And it's using a national survey in order to assess the prevalence of Autism Spectrum Disorder. So, this is asking parents in a survey has your child ever been diagnosed with autism and does your child currently have autism.

This is nationally representative because of the way they designed the survey. And - but their age range is different than for the ADDM Network. It's 3-17 years of age. So, it's a much broader age range. And this is based on parent-report. Does the child have a diagnosis from a provider of autism?

So, they found instead of 1 in 59, 1 in 40, but this is, of course, a different analysis.

But the value of this survey was they could look at other characteristics with regard to treatment of children, which can't be assessed with the ADDM Network. So, looking, for example, at autism-specific drug and behavioral treatments.

And they found that 27 percent of children with autism were taking a medication for their autism-related symptoms and 64 percent received behavioral treatments in the past 12 months. And there were some variations based on sociodemographic factors and other characteristics and whether or not there were co-occurring conditions.

So, they can look at other characteristics in assessing autism in children in the population, 3-17 years of

age, and can do lots of stratification and slicing and dicing.

DR. GORDON: Thank you, Stuart. Geraldine Dawson nominated the next two. McDonnell et al. and Schendel. Can anyone - anyone else have familiarity with these two articles?

So, McDonnell et al., the comment from Geri is population-based study finds that children with ASD and/or intellectual disability are at heightened risk for maltreatment.

And the fourth one, Schendel and Thorsteinsson, is the cumulative incidence of autism in Denmark in adulthood, which is interesting.

And it meets a need for us to understand - I just quickly drew up the abstract. I must confess ignorance as to the content of the paper. And it doesn't really tell me what the autism - autism prevalence is at 2 and 2.47

percent in school-age children. Previously estimated from parent data - cross-sectional - I can't quite make heads or tails of it from the abstract, I'm afraid to say.

So, please do take a look at those manuscripts, yourself, and make decisions about the voting.

So, any other comments about any of the papers that we didn't discuss just now? Okay, so you'll be getting a ballot in the email from Susan or the OARC staff. And please pick out your top 20 and send them in.

And if you have specific comments about things that you think are important to include in the summary that would help our team, email them - I don't know if there's room in the ballot for comments. But if not, just email them to the OARC staff.

Okay, so that's the Summary of Advances and the last item on our agenda is a round

robin. I believe two people had pre-registered, if you will. Is that right? They're already finished.

So, are there any other round robin comments? Let's just go around the table.

Stuart, do you have anything else to add?

DR. SHAPIRA: So quickly, on January 1st, CDC began a new phase of funding for the ADDM Network, which I mentioned. And it's a collaborative group of programs that estimate the number and characteristics of children with autism and other developmental disabilities in multiple communities in the United States.

So, CDC funded the ADDM Network at 10 sites moving forward. Eight were existing sites, so they were funded previously or in the last cycle. There's one new site, University of California, and one previously

funded site, University of Utah, that wasn't in the previous funding cycle.

And if folks are interested, you can ask me later who the ten sites are.

All ten sites will monitor eight-year-old children, but there are three sites that - Johns Hopkins, University of Arkansas System, and University of Utah, which will follow-up on adolescents aged 16 years who are previously diagnosed with ASD by the ADDM Network.

And also, the Intramural Site in Georgia through the CDC will also follow up adolescents at age 16. So, four sites will do that.

And by completing the follow-up of adolescents at age 16, they will be collecting data on autism co-occurring conditions, limitations, and activities and

educational delivery. And also looking at planning for transition to adulthood.

DR. GORDON: Wow, that's really great news. This is a new - new aspect to the program.

DR. SHAPIRA: Yes, this is new. It hasn't been done before.

DR. GORDON: So, again, in response to the public comments that said that IACC isn't accomplishing its mission or isn't addressing the concerns of the public, I think this is a perfect example.

I mean we, in the IACC, have been talking about transition age and adulthood for a while now. And although it does - the wheels of government sometimes move slowly, here, we have a perfect example of how we've influenced the CDC, as well as I'm sure our non-profit partners who have been asking the CDC to do this.

We should get some really nice data on adolescents through this study.

Any plans or thoughts on moving into adulthood or is that a little bit too much beyond the capabilities of the current - current moves in CDC?

DR. SHAPIRA: Well, I can't answer that because it all depends on appropriations and funding, as you're well aware. But we have been listening and have been thinking about options for moving into the adult.

DR. GORDON: I think this is a major step and we should really be proud and pleased with the CDC for making this move. That's great.

Moving along the table, anyone else? Yes, go ahead.

DR. COOPER: Okay. So, I am with the National Institute on Deafness and Other Communication Disorders. And so I want to

just mention a few things about my institute and what we've been doing because communication comes up a lot and has today.

Certainly, our focus - the research that we support has to do with characteristics of language and communication development and treatment, predictors of success in the development of functional communication, the basis of why some of these children do have communication disorders and differences.

The second thing I wanted to say was we've talked about and Alison was mentioning it about the - those on the more severe end of the spectrum and how they've been ignored. And I would say individuals who are minimally verbal have for years been almost excluded from many of the research studies that NIH investigators have utilized. They are - by their minimal abilities, they are ineligible to participate in a lot of research studies.

So, NIDCD has made minimally verbal - research focused on minimally verbal children as a priority. In fact, we have it in our strategic plan as an area that we'd really like to see more and more applications in. And we have, in fact, seen an uptake in research submitted to the NIH on that.

And then the last thing I wanted to say was I was looking at the research that we supported last year, specifically looking at beginning investigators. Because the pipeline of researchers is something that concerns everyone here, at NIH. Are we going to have the researchers that we need to take us forward?

And I was very encouraged to see the number of beginning investigators, whether it's in fellowships, but more career development. We even have a program for early stage investigators. And a lot of those

awards that we made last year were in the area of autism. So, I'm very encouraged by the next generation. So -

DR. GORDON: Thank you, Judith. It's a shame that Alison I guess had to leave because I'm sure she'd like to hear about those programs you - she's aware?

DR. COOPER: I talked to her during the break.

DR. GORDON: Very good. Good. I believe, Alice, you had something to add?

DR. KAU: Yes. In the last IACC meeting, I mentioned that NICHD has started a process to revise our research strategic plan. After a year of working with internal and external stakeholders, now we are ready to solicit feedback on a set of priority themes, objectives, and goals under consideration for a new NICHD research strategic plan.

And as I was listening, I was - I just, you know, look at the themes that are right now under consideration. One of them is improving health during the transition from adolescence to adulthood. Obviously, we did not mention just autism, but that is one of the themes. So - and I had nothing to do with the creation of the themes. So, that's really good news.

DR. GORDON: Thank you, Alice. Let's come up this side. Any updates? Louis?

DR. REICHARDT: Yes, I do. One thing of some general interest is during the past half year, we evaluated the success of our different categories of grants over the last decade. And before - through this past year, we funded one-year explorer, two-year pilot, and three-year research awards.

And when we analyzed things - and I need to speak carefully about this - when we

looked at the impact of the two-year pilots and the three-year research awards, that they had significant impact. The publication/citation indexes were actually about double that of the NIH, actually.

Also, about two-thirds of the grants resulted in follow-up funding, either from us or from the NIH.

So, what we've done - this was not true of the one-year awards. And so we've abandoned them. We've gone to a cycle of two-year pilots. And we've now made the research awards four-years long. So, we've extended it by a duration.

We've gone through one cycle of the pilots. But we just announced the research awards. And so I'm not - we're beginning to read the research awards rather. So, anyway, this is a significant change.

Over the last several years, we've had roughly 110-130 research publications a year plus a number of reviews.

SPARK, which is our autism cohort recruitment effort - I will just say currently, we have more than 57,000 individuals with autism that have enrolled. About 149,000 total, almost 15,000 trios. We've sequenced almost 29,000 individuals. This has resulted in a small number of new genes, about three, that were returning results.

And, importantly, I think we have now 36 research studies that people have applied to use this - individuals in the SPARK cohort. 36 have been approved and are ongoing. And 13,000 individuals with autism in the SPARK cohort are actually participating in research studies. So, this may prove to be its bigger impact.

Autism BrainNet, I think David covered that so I won't say anymore.

We have a Clinical Research Associates, L.L.C. - primary is to pursue the possibilities for Arbaclofen - is a therapy. We're now providing the drug to Canadian and European AIMS Phase 3 trials for this. So, in fact, our involvement is happily low. We're just paying and giving them the drug.

We are in planning stages to look at the 16p11.2 deletion. And this is based on some very promising animal data, but also on effects of Arbaclofen on binocular rivalry, which there's an alteration that is seen in autism which seems to be suppressed by this drug.

So, that's our status.

DR. GORDON: That is great. Thank you very much. Any other updates? Laura. Walter.

DR. KOROSHETZ: We just have a couple of clinical trials to mention. We're testing an mGluR5 negative allosteric modulator in Fragile X, looking at language development in three to six-year-olds.

And we're treating TSC patients when they development EEG abnormalities with antiepileptic agents even before they have seizures to see if preventing the epilepsy could have an effect on the development of the child.

And then a - may or may not be relevant - a study of vasopressin, one AR antagonist and for irritability in - actually in Huntington's Disease, but the idea is if it worked there, it might work in other things, as well. So, we'll see.

The last one is finished. So, we're just waiting for results.

AUDIENCE MEMBER: (Inaudible comment)

DR. KOROSHETZ: It's from Azevan. The company is Azevan.

DR. GORDON: All right. I guess from the NIMH, we talked in the past about our efforts to develop research into screening in the first year of life and those programs are well underway. We're getting applications and looking forward to be able to fund some efforts in that area.

So, that's most the update that I have for you from the NIMH. In addition, of course, to the program we discussed earlier of PsychENCODE. That was really a landmark, having a number of papers out in the area. I think it was over seven of them all in top journals. But, more importantly, releasing that data to the public so that scientists all around can use it to try to figure out the relationship between genetics and neurobiology.

So, with that, I think we can close. Any closing remarks, Susan?

DR. DANIELS: Just thank you for excellent presentations and discussion today. We'll be in touch about our working groups and follow up on Summary of Advances.

And our next meeting is going to be Wednesday, April 17th, and we'll be back at the Neuroscience Center down the street.

So, thank you all for coming and we wish you safe travels. Thanks.

(Whereupon, at 4:40 p.m. the meeting adjourned.)