NWX-OS-OPHS-OEP-OER

Moderator: Syreeta Evans
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11:00 am CT

Operator: Welcome and thank you for standing by. At this time all participants are on listen only for the duration of today's conference. This call is being recorded. If you have any objections, you may disconnect at this time. I would like to now turn the call over the (Sue Levine). Ma'am, you may begin.

Dr. (Sue Levine): Thank you. It's Dr. (Levine). We're going to do a roll call. (Susan Levine) here. (Adrian Casillas)?

(Adrian Casillas): Present.

Dr. (Sue Levine): (Alissa Koch)? (Dane Cook)?

(Dane Cook): Here.

Dr. (Sue Levine): (Donna Pearson)?

(Donna Pearson): Here.

Dr. (Sue Levine): (Gary Kaplan). I believe (Gary) will be getting on shortly in time for his presentation. (Faith Newton)?

(Faith Newton): Here.

Dr. (Sue Levine): (Jose Montoya)? (Lisa Corbin)? (Rebecca Collier)? (Mary Anne Fletcher)? Okay, now the following are liaison organization heads. (Carol Head).

(Carol Head): Here.

Dr. (Sue Levine): (Steve Krachik)? Now for a list of ex-officios. Would you identify yourself please? Social Security Administration?

(Michelle Shaffer): (Michelle Shaffer) here.

Dr. (Sue Levine): NIH?

(Vicky Whitamore): (Vicky Whitamore) here.

Dr. (Sue Levine): CDC?

(Elizabeth Ungar):(Elizabeth Ungar) here.

Dr. (Sue Levine): PMS?

(Jeff Kettleman): (Jeff Kettleman) here.

Dr. (Sue Levine): AHRQ?

Woman: (Unintelligible) here.

Dr. (Sue Levine): (HIRSA)?

(Erin Fowler): (Erin Fowler) here.

Dr. (Sue Levine): FDA.

(Janet Maynar): (Janet Maynar) here.

Dr. (Sue Levine): And okay. Okay, thank you very much. All right. (Nancy) do you want to go ahead with the webinar logistics?

(Nancy): Sure. And thank you all for the - we apologize for the delay. There were some issues getting everybody on the committee to where they could see what they needed to see. But I think we're getting there very quickly. So I hope people have seen the agenda. The agenda is posted on the (CISAK) website as well as call in information for listeners. That's on the website too. Note that there will be a different number - different weblink for tomorrow's website than for today's.

We have this webinar is being recorded. We will archive it on the (CISAK) website. That takes a few weeks to do that. We also have someone taking - (Deborah Eby) who has done many minutes for us in the past is doing minutes for us today as well. Those will be available within 60 days. And if you have any concerns, you can send me an email onto the (CISAK) email address and I will monitor that.

I'd also like now to welcome Dr. (Karen Scott) who is with the Office of the Assistant Secretary for Health. She is the chief medical officer. She's new to the job and she has been working with me and with Dr. (Disalvo) the Acting ASH on (CISAK). So (Karen).

Dr. (Karen Scott): All right (Nancy), thank you very much. And I want to welcome everyone to this advisory committee webinar on behalf of Dr. (Karen Disalvo) the Acting Assistant Secretary for Health and myself again as (Nancy) said in this new role as chief medical officer at OASH. I'm also new to the Department of Health and Human Services so it's been an exciting time and opportunity to me to learn about a whole range of activities and I certainly look forward to listening today and tomorrow and learning more about the chronic fatigue syndrome advisory committee's work and what you have been doing over I know a number of years to help elevate the focus on CFS on behalf of all the patients with this debilitating and concerning disease.

My own training background includes training in preventive medicine and public health and I've held positions in public health policy, focused on access and quality as well as senior positions in large health systems, focused on quality improvement patient safety. So from a number of perspectives I'll be very interested in hearing the discussion today.

I'm also have had a chance to spend some time with Dr. (Lee) as well as with Dr. (Sue Levine) in New York and begin to learn about much of the work and activity, particularly over the last couple of years and understand that the committee really deserves significant credit for propelling the work forward from the work of the Institute of Medicine and the release of their reports last year to NIH's pathways to prevention program and I think we will hear more over the next couple of days in terms of activities that are getting underway and building on the IOM and NIH work so far.

Similarly, CBC has convened a technical work group to develop educational materials on CSF in collaboration with a broad range of stakeholders and we'll hear more about that on the webinar as well.

So again, I know the committee has contributed to making sure that all of these efforts have gotten underway and continue to be developed and I look forward to hearing the recommendations of the committee that come out of this webinar as we continue to see how we may support these efforts.

Thank you again for your time and commitment and all of your efforts and I will turn this back over to (Nancy).

(Nancy): And then we can turn this back over to (Sue). Thank you very much (Karen).

Dr. (Sue Levine): Okay, thank you, (Karen), for those remarks. As (Karen) said, I enjoyed meeting her in New York and now I'm just going to do a brief overview of what we plan to do for today. And if at any time there is some extra time left over, we will try to fit some other things in that are perhaps not on the schedule right now. But we want to stick to a pretty tight ship here.

We will first of all hear some agency updates from the various agencies here and then we will get some updates from liaison organizations, in particular (Carol Head) and from south CFS and hopefully (Steve Krachik) from IACFSME will be on the line. And then we will look forward to hearing some public comments and then we will get to hear a report from (Gary Kaplan) the head - the working group chair of the Centers for Excellence working group. And then we'll take a short break and have some discussions regarding the recommendations that come from his committee. I'm not sure - (Nancy), do you know how many recommendations (Gary) had planned or?

(Nancy): There's one big recommendation with details on it.

Dr. (Sue Levine): Okay. And one other thing I meant to ask you -- is somebody white boarding this or?

Woman: Yes, yes. We are white boarding it. But that's not going to happen until we get to the discussion of it.

Dr. (Sue Levine): Sure.

Woman: Or the recommendations. But the white board everyone should be able to see and we should be able to wordsmith.

Dr. (Sue Levine): Okay. And then we'll have a brief discussion on plans for day two. Okay? So any other comments? Okay, with no further ado, let's proceed to (Beth Ungar) please.

(Beth Ungar): (Nancy) will somebody be advancing the slides?

Woman: Yes, just say "next slide please."

(Beth Ungar): So there's a problem. The slide looks kind of all wonky at least my view. I mean I'm only seeing the top part of it. It's like off centered.

Dr. (Sue Levine): Yes, it looks kind of enlarged here.

Woman: Is that a better view?

(Beth Ungar): No.

Woman: I think we're seeing the whole thing now.

(Beth Ungar): My still isn't.

Woman: Mine doesn't show the whole thing, either. Just the bottom of the page.

(Beth Ungar): Yes, I don't know why it's doing that but if you click the minus sign at the top you get it fixed.

Woman: It's their problem, not ours. You go ahead.

(Beth Ungar): I don't think it's our problem because yours was perfect. So something is weird about how this was loaded.

Woman: There. Does that help?

(Beth Ungar): Didn't change it.

((Crosstalk))

(Beth Ungar): People are having trouble seeing it, if they use the little minus sign they can shrink it and then you see the whole thing but it's like off center in the view. So there's a big white space and then you get to the top of the slide.

Woman: Don't record it, it's not the presentation.

(Beth Ungar): Perhaps, I don't know, I sent the PDF as well as a Powerpoint. Maybe it's the wrong one that got loaded?

Woman: No, we can't load the PDF. I think that the solution is to hit and plus and minus thing do you all see that? That's it.

Woman: Where (Nancy)?

Woman: Well it looks like it's in the upper right.

(Beth Ungar): You can't have the full screen view. You have to go back to the view where you've got the comments and the people.

Dr. (Sue Levine): Right, I've got that one. Where it's like the screen is split in half?

(Beth Ungar): Yes.

Dr. (Sue Levine): And you're on the left.

(Beth Ungar): You need to go minus for the view. And then you get it so it fits.

Man: Minus for the view?

Dr. (Sue Levine): What minus? I'm sorry we're being so naïve here.

Operator: Excuse me, this is the operator. If I may interject. Across the top of the screen you see below file, edit and share. You click start event and then the titles of your slides. Right below the titles of your slides is the number one and a little arrow which will advance the slide. Over to the right is the plus and minus in and out and then if you click the four arrows that all face out, that will hit the viewer and then if you do the two slant arrows that makes it fit the whole screen.

Dr. (Sue Levine): Okay, why don't you proceed (Beth), I guess for the time being. I guess they'll be working on it while you're speaking.

(Beth Ungar): Well I think you're going to have to adjust your screen.

Woman: I think you have to do it yourself.

(Beth Ungar): Everybody can see the whole slide. But this one just says the (unintelligible) ex officio member Dr. (Ernie Filay) and he sends his regards but he could not attend today so I'm going to be presenting the report on his behalf and thank you for the opportunity to share some of CDC's work. Can I have the next slide.

I don't have control, right?

Woman: You just tell Syreeta and she will advance it for you.

(Beth Ungar): Okay, very good. So this slide lists some of the activities that - or the activities that we've conducted since our last (CISAK) meeting in August. All of these have been introduced to the (CISAK) committee in the past and most represent ongoing activities directed toward awareness, education and data collection to improve our understanding of MECFS. I'm going to talk about several of these in a little more detail. Next slide.

Public health grand rounds was held on February 16th this year. And this was a significant accomplishment for the program and it indicates CDC's commitment to addressing MECFS as a public health problem. These rounds are held monthly and the topics are selected through a very competitive process. Grand rounds have a good reputation in the community for providing concise, significant information on the topic that's being presented.

Our session was introduced by Dr. (Harold Jaffe). He is the Associate Director for Science in the office of the director. The session was one hour and included four speakers along with time for questions from the audience, both in person and online. The session was webcast live and is archived online at the web address on the slide. The session can also be found by going to the CDC webpage and searching for public health grand rounds and then looking under past sessions.

In addition to the grand round sessions, Dr. (John Iskander) who is the scientific director of the public health grand rounds program conducted an interview with Dr. (Anthony Komeroff) and this is featured as a video clip called "Beyond the Data." That feature brings additional take-home messages to the audience in a different format. The session is accredited for continuing medical education and this will be available for two years there with an arrow on the slide. It is two years. Next slide.

So, we do have some metrics on how we did with the public health grand rounds. The system collects this data and there was very good participation on the day of delivery with more than 1200 participating in the live webcast, 87 in the audience in person, and 417 on IPTV. The session was also distributed to a broad range of electronic distribution systems that reached physicians and other health care workers as well as public health departments. As of the end of April there were almost 5700 views of the session video, 2000 views of beyond the data and 7300 views of the archived (unintelligible). Next slide.

The CME program provides additional educational outreach for the public health grand rounds. An evaluation of the content is part of the CME process and we'll use this feedback to inform our future projects. To date, 69 credits have been issued. We are also planning to prepare an article based on the public health grand rounds for the morbidity mortality weekly reports. MMRW is a series of publications prepared by CDC that's available free through electronic subscription, often called the voice of CDC. This will be an additional forum to continue awareness in education about MECFS. Next slide.

Now I'm going to shift to RPPCOCA and PCOCA stands for "patient-centered outreach and communication activity." This is an outreach to the U.S. patient community using a free call in number. These are held twice annually and they're spaced to occur in between the (CISAK) meetings to allow regular updates. The format that we use is that CDC provides a brief update on activities and then we invite an outside expert or experts to give a talk on the topics of interest to the advocate community. This is followed by answers to questions submitted by email. Our last call was in October and was given by Drs. (Lap), (Campbell) and (Black) on managing MECFS SEID learning to pace. Our next call is scheduled for June 23rd and Dr. (Jared Younger) will be speaking on current and future research on MECFS treatments and updates from the field. Next slide.

Given the importance of disseminating the IOM recommendations on diagnosing MECFS, CDC decided to seek broad stakeholder input into the process of developing educational materials for the webpage as well as to prioritize additional educational needs. The stakeholders include patient advocates, medical professional organizations, medical educational organizations, clinicians with expertise in MECFS and government. During the process of stakeholder engagement we hope to improve communication among all the groups. In addition, if medical professional organizations are part of the process it is more likely that the information will be disseminated to their members and adopted. The logistics of this project is being facilitated by a contractor, (McKing) Associates. Next slide.

The technical development work group has been established and it includes 11 medical professional organizations, seven educational organizations and educational providers, ten advocacy organizations, six foundations or research organizations, and two (CISAK) representatives. Included among these are seven physicians with MECFS expertise including two who served on the IOM committee and three who were reviewers of the IOM reports. Slide.

We provided the technical development work group copies of the IOM report, the IOM guide for clinicians, the NIH P2P report, (CISAK) recommendations on the IOM and P2P reports, and FDA's voice of the patient. Has led small group discussion calls designed to identify topics to be discussed and prioritized for the face-to-face meeting which is now being planned for the last quarter of the fiscal year. Slide.

Just a brief reminder about our multisite study. We are now using the acronym MCAM. This has been presented to CISAK before so this is just kind of a reminder. We are continuing follow up of enrolled participants and are increasing enrollment of pediatric and adolescent patients, comparison groups both ill and healthy, severely ill patients and those with onset of illness less than two years. We are also building a viral repository of samples that will be available for hypothesis testing by investigators. Next slide.

We've prepared our second newsletter for study participants and the first paper describing the methods in detail has been cleared by CDC and was just submitted to the journal for consideration of publication. We completed our pilot study on NK cell function testing and learned the results on peripheral blood and mononuclear cells isolated from blood shift overnight correlates well with the gold standard method established in Dr. (Fletcher)'s laboratory, that is same-day testing of whole blood. We plan to perform NK cell function testing on a larger group of study participants. Next slide.

Finally, I want to give a little brief update on activities related to the (CISAK) recommendations. Both the MCAM project and the technical development work groups begin to address some of the recommendations. We recognize there is a need for treatment guidelines but this is beyond the scope of this year's technical development work. CDC is collaborating with the National Institute of Neurologic Diseases and Stroke facilitated through (CISAK) ex officio (Vicky Whitamore) to develop MECFS common data elements. This project is important to improve standardization of data collection and will facilitate research sharing.

Finally just a brief comment on the ICD 10 CM. The National Center for Health Statistics reports that this was implemented in October 2015. Changes to coding are made through proposals to the ICD 10 CM coordination and maintenance committee. Proposals presented in 2016 are being considered for October 2017 implementation. The date input that NCHS has received does not indicate consensus on how to change coding. Thank you very much.

Dr. (Sue Levine): Thank you (Beth). Okay let's move on. (Vicky) please.

Woman: (Vicky) is not scheduled to give her comments until tomorrow.

Dr. (Sue Levine): Okay.

Woman: So look at the agenda. I think the next comments are from CMS.

Dr. (Sue Levine): Okay.

(Jeff Kettleman): Thank you, this is (Jeff Kettleman) representing Medicare and Medicaid. I'd like to mention the exchanges and we have no updates since our last meeting.

Dr. (Sue Levine): AHRQ. Are you there?

Woman: This is (unintelligible). I too am hoping everyone can see the slide. The first slide is just has the name and the date. If you wouldn't mind going onto the next slide.

Now in December 2014 AHRQ released its (unintelligible) review on treatment and diagnosis of MECFS (unintelligible) NIH P2P workshop and the way that was systematic was designed was to include patients that were diagnosed with (unintelligible) or MECFS or just CFS using any criterion. At this point I wanted to remind you that this review looked only at the peer review literature. The interventions that were covered in that included pharmaceutical drugs, complementary and alternative medications, counseling and behavioral therapy, exercise (unintelligible).

Woman: Excuse me, is everybody able to see these slides? I can't see them, that's why I'm asking.

Woman: It's the same thing, you have to do the little minus sign.

Woman: Okay, okay. Excuse me, I'm sorry. Go ahead.

Woman: The outcomes that were focused in the report were (unintelligible) function, employment and global improvement and quality of life. May I have the next slide please?

Since the publication of the report and the P2P report that was informed by the systematic review we have a lot of input from the patient community requesting that the (unintelligible) be separated by case definition. In response to this request, we are indeed doing a subgroup analysis where we're looking at outcomes of all interventions and separating outcomes based on studies that use the Oxford criteria and studies that use the CDC or any other criteria. In addition, we received input that perhaps it wasn't the best to pull together studies that used cognitive behavioral therapy and counseling since they defer both in terms of their objective and in the content of the intervention itself. So in response to that concern, in addition to separating results by Oxford and CDC criteria, we will also be looking at the data and separating them up - excuse me, for CBT and counseling. So this work is currently underway and we hope to release it in the form of an addendum. Next slide please.

We think that the addendum will be ready and posted in the summer. That will have the subgroup analysis as well as the breakup of results from CBT versus counseling and other behavioral therapy. This is the bulk of the work that was being done related to MECFS at ARC. In addition we continue to work with CDC and participate in their work group related to education materials. Thank you.

Dr. (Sue Levine): All right. I think we have one more agency to hear from. Social Security. Go ahead. Who's representing Social Security?

(Michelle Shaffer): This is (Michelle Shaffer). I'm representing Social Security and I'm happy to speak with you today about the new Social Security ruling we have. It's SSR 16-3T. It's on symptoms evaluation and disability claims. The SSR was published and was effective as of March 28, 2016. Next slide please.

The SSR supersedes SSR 96-17 which focused on assessing credibility of an individual's statements when evaluating symptoms in disability claims. So I guess what the question is, why the new SSR and what has changed with our symptoms evaluation policy? I'd like to give you some background on why we made this change. We solicited in the independent study from the (unintelligible) United States (ACIS) on (unintelligible) disability claims.

Operator: I do apologize. Her line just dropped.

Woman: Hopefully she'll get back on.

(Steve Krachik): This is (Steve Krachik). I was glad to join. Sorry about the technical difficulties, but I still can't get online to see the slides or anything either. Same trouble as (Sue).

Operator: (Steve), this is the operator. I will pull your line and help you.

Dr. (Sue Levine): Okay, and then I think if there are any questions from the group for the ex officios we can have them after this presentation is done. Hello?

Woman: This is (Nancy). Could the operator try and call (Michelle Shaffer)? I don't know if you have the ability to do that. Maybe (Sue) just start the questions now and then when (Michelle) gets back on?

Dr. (Sue Levine): Sure. Are other people on the line? Okay. Does anybody want to ask the ex officios any questions?

(Carol Head): Yes, this is (Carol Head). I have one question for the representative from AHRQ.

Dr. (Sue Levine): Go ahead.

(Carol Head): You had noted at the end of your presentation that there was no consensus about the change to the ICD code that would next be updated in late 2017. Certainly I know I'm interested in learning more about where there is a lack of consensus. Obviously this is a very important issue to many of us. What's the best way to better understand the arguments on either side if you will and the process for reaching consensus so that code can be updated?

Woman: This is (Beth), I think that was a question for CDC and it's the NCHS part of CDC and it's my understanding that the proposal or proposals need to be developed and the feedback that NCHS has had you know, hasn't been in the form of a proposal but there have been a number of interested parties contacting NCHS about this. And I don't think anyone has advanced a proposal yet. And so it's just kind of not clear where it's going.

Woman: So (Beth) would we contact you if we were interested in putting forward a proposal?

Woman: I would be forwarding your request to NCHS but I could help you with that.

Woman: Thank you.

Dr. (Sue Levine): Well I had one question for the representative from AHRQ about - it kind of flew by me too quickly really, but I didn't understand how or anything about which subgroups of patients were chosen for the study in which you performed the cognitive behavioral therapy. Were those a wide range of MECFS patients and from what part of the country or where they - how did you choose those people and why did you choose that type of therapy to study?

Woman: Dr. (Levine), this is (unintelligible). In our systematic review we only reported on studies that had been published. So we didn't perform the study, we just took all the studies that had been published and pulled them together and did a (unintelligible) analysis on the result. So in the original report...

Dr. (Sue Levine): Why did you choose that particular type of therapy to study? Why did you do that kind of poll, that type of treatment?

Woman: We looked at all studies that had been published with any sort of - that looked at any sort of intervention for MECFS. So if the study called it a behavioral therapy, we reported it as a behavioral therapy. If the study called it a cognitive behavioral therapy, we reported it just as the study also had reported it. We didn't change the names of it.

Dr. (Sue Levine): No, I understand that, but I didn't understand what the basis was for your choosing, you know, that type of - I know there's not much out there published on therapy for CFS but this I think a particularly controversial area for our community. So I guess that's why I wanted to get an explanation.

Woman: So the authors chose to include any study that said their intervention was for patients that included either under the CDC criteria or the Oxford criteria. So the authors said that if it was a CBT that was modified for CFS patients or unmodified it was still included. Depending on how the authors presented it.

Dr. (Sue Levine): All right. Okay. Well, does anyone else have any questions about that aspect or I guess we can move on. Okay (Steve), you're here now.

Man: Yes I am.

Dr. (Sue Levine): I can't see my agenda very well but I think (Carol) may be first and then you go next to present, you know, your update. Go ahead. I think (Carol) right?

Woman: (Unintelligible) I am thrilled that the (unintelligible) is doing this subgroup analysis. I'm hoping it's going to make a big difference. My question is hoping that we found that the CDC is most effective in groups that where they use the Oxford criteria. Do we have agreement that that group is not represented (unintelligible) or IOM and if so, does that mean that we will be able to get that information off of CDC and other websites? Because it doesn't apply to these patients is the gist.

Dr. (Sue Levine): Yes, I would agree with that but...

Woman: Does anybody have - maybe there are no answers yet but I'm hoping somebody maybe knows something about that.

Dr. (Sue Levine): Well, I mean I think we have something on the record that indicates that you know, at least most of the members of our group I'm thinking, unless somebody says not, are not so fully in agreement with this being a definitive treatment for MECFS patients. At all, or possibly for a very small subgroup of patients. So we don't you know, I think we don't really want to highlight it necessarily as the only treatments going forward. Like I said, it's a controversial topic and...

Woman: It's (Faith). I have a question. So I think the question being asked was why CBT, why not another intervention?

((Crosstalk))

Dr. (Sue Levine): I'm not sure she understood that but that's...

Woman: And I would like to know the answer to that question too, because...

Dr. (Sue Levine): Well, I don't think there's much published out there. Because really we having had enough funding or resources whatever to run other trials with other therapeutic interventions. But I hesitate therefore in that regard to just highlight this as I think an area where, you know, it just I know it doesn't work in most of my patient so...

Woman: Correct, and so...

Dr. (Sue Levine): But I don't want to use this platform to, you know, what I think. But still I think it does a disservice to our community to suggest that that's the only treatment and we're going to stick with that. You know, let's put it that way.

Woman: The problem is that CBT studies have been funded and the psychologists or whomever it is that believe in it, you know, have kind of led the charge on it and because it's the only, you know, the majority of funding is going to that, that's all the HRQ had to look at. And unfortunately as has been mentioned, it hasn't been done on patients with this disease that we can tell.

Dr. (Sue Levine): Well I guess I just wanted, I mean I don't want to negate all those efforts. Of course you're right about that, but I think even in speaking to (Fred Freburg) who has conducted some of those studies, he believes that in only a very small subgroup of those patients does it have any positive benefits. So I wanted the qualification to show that this was not the only treatment out there that was being considered. I mean, of course, what you're saying is true. But I guess if you don't mind, let's move on. (Carol) I think you things were being loaded. Your slides.

Woman: Sure, I'm ready.

Dr. (Sue Levine): Go ahead.

Woman: (Unintelligible) slides for the (unintelligible) initiative and I see that they're there. So thank you all very much for the opportunity to speak briefly today. This is sort of a two partner. I primarily wanted to stock our new registry but I also always try to bring forward a story of a patient and generally those are quite as you can imagine difficult and heartbreaking when I talk with patients. So next slide please.

In this instance (unintelligible) I had a very interesting conversation with an unusual patient. I talk with many, many patients in the course of my work and this is a conversion story from a doctor, Dr. (Amrik Shazad) who is now a patient with MECFS and the irony is that a physician, a trained physician, she learned nothing about this disease, had not ever explored it and in fact did not believe it was real. And now as a patient obviously she has a very different perspective. And I love some of these quotes from speaking with (Amrik) despite her profound disability with this disease, she says I am my own patient hero. And because of my unique position I have a lot of dots that I need and want to connect and I cannot walk away from this exploration. So like so many patients, Dr. (Shazad) demonstrates extraordinary resilience and positive attitude in the face of enormous difficulty. So glad I could tell that quick story. Next slide please.

So the core of what I want to talk about today is the new national patient registry for MECFS that we are just now beginning to build. And this is directly relevant to (CISAK). I refer back to (CISAK)'s recommendation number four from that last August and I will quote it. We recommend this quote, "A development and ongoing use of a patient registry in order to reduce one obstacle to MECFS research. We request that NIH institute a plan for the development and long-term maintenance of an MECFS patient registry." And then we received a response and then an updated response and it was equivocal. To quote from the NIH response it says, "Because funds are typically directed to hypothesis-driven investigator initiated research, funding opportunities for patient registries are limited. But many disease organizations" -- that would be us -- "Many disease organizations support valuable registries for patients they serve." So the NIH clearly is beginning to make an effort in this arena and we applaud it. They refer now in their updated response to the development of common data elements and they're working with CDC on that and we continue to have conversations with NIH and CDC and I just - the upshot here is that the trans (unintelligible) MECFS working group is exploring the cost and feasibility of the data coordinating center as part of research (unintelligible) going forward and we applaud that.

And at the same time we are impatient. The patients are impatient. We understand that the suffering and the need is extreme and therefore we applied for a grant to fund a national patient registry. And like so many other patient organizations for other diseases, it is indeed very common for patient organizations (unintelligible). So that's what we've done. Just the slide here why. Obviously this is (unintelligible) that need in every (unintelligible) community. We hope with this registry to reduce a key barrier to research. This is staff recommendation that has been made time and again and as (unintelligible) and frankly understandably we can move faster as a private nonprofit than the government to make this a reality.

So what it is that we're developing? It will be, our intention is a comprehensive new MECFS patient registry using a robust time-tested platform. It will be open to qualified researchers every. We are collecting demographic data and so forth. We'll be conducting targeted surveys and the intent is to generate verifiable and large data (unintelligible) with specifically powered metrics to influence policy. Next slide please.

This was funded in partnership with the Robert Woods Johnson Foundation and the genetic alliance peer program and through collaboration with a number of other members of the MECFS research and patient communities outside our organization and that's critically important. I would note that the grant came in the form of genetic alliance raising the fees for our use of the peer program. We have supplemented that with funds from our own organization to hire an individual who will be building this registry in the coming months and our target date for completion and being able to announce that the registry is open and having begun to populate it with information is November of this year. We have a great deal of work to do. So there are many obviously potential applications for this. Clarifying the natural history of the disease, promoting research, influencing policy, and so forth. We are looking forward to working with folks at NIH and CDC to use common data (unintelligible) to best understand their work and how to integrate it. So our intent is not that this is our organization's national patient registry. Our intent that it is truly a resource for the community and that is a very important element of what we've done. This has been spearheaded by Dr. (Zahar Nali) who has been with our organization for about a year and has done an extraordinary job of reaching out to (unintelligible) both at other private research organizations and in the federal government, and I think his outreach and successful application for this national registry is important for all of us and we are cautious about over-committing because this is a significant undertaking and at the same time very grateful that we do have the knowledge and resources to move forward in this way. Next slide please.

So that is the core of what I wanted to say. I also just (unintelligible) you know, we give a pitch at the end that we do offer resources at no charge to anyone, both our printed chronicle and our free monthly newsletter and you see on the screen there now to sign up for those and we encourage everyone to do so. I would also note that we do webinars roughly every month. In fact we have one coming up day after tomorrow featuring Dr. (Jared Younger) who as we know has been doing some extraordinary work. So we're happy to talk about that. Next slide please.

So simply thank you. As a private nonprofit institution we seek to be nimble and we are delighted to take this early step to create a registry that will become a resource for all both public and private. So thank you all.

Dr. (Sue Levine): Thank you (Carol) for that very nice presentation. (Steve) why don't you do your presentation and then we can have questions for you both at the end of that.

Man: That would be great. Thank you (Susan). Finally I'm on. I wanted to let everybody know that the IACFS annual meeting is scheduled for October 27th through 30th at the Westin Fort Lauderdale beach resort and we'd like to request that the fliers that we have for the event be available on the ICFS on the (CISAK) website if possible. So people, both patients and providers can have access to it. That's the main thing that I wanted to say so I'll keep it short and stop there. Any questions.

Dr. (Sue Levine): Well the other thing (Steve) you've extended your deadline for submission, I know what.

Man: Right, right.

Dr. (Sue Levine): So there's still plenty of time for people to submit their abstracts and post their presentation.

Man: Absolutely. And I just don't have the deadline that it's extended to. I know it was...

Dr. (Sue Levine): June 19th I think.

Man: (Unintelligible).

Dr. (Sue Levine): Well listen, I think both of these organizations are absolutely fantastic. I've been treating patient with MECFS for many years and I think Solve MECFS and IACFS are both just wonderful organizations and they've you know, brought our patient community a lot of information over the years and they you know, brought us all together. Researchers, clinicians alike, patients can participate, and you know, (Carol) I really applaud you for putting that patient registry (unintelligible) of course as well. Putting that together because I think that's going to be extremely important like you say to develop the natural history of this illness and you know, hopefully encourage some diversity in terms of selecting you know, patients from other ethnic groups and like, you know, the very sick patients and (unintelligible) patients, etc. But I think both the organizations are really wonderful. And like you say, in the absence of a strong but emerging NIH funding presence they really held us together for many years. And hopefully they can continue to work in partnership with the NIH. Okay.

Woman: Thank you.

Dr. (Sue Levine): With that let me open up the floor to any other questions and then may I ask is (Gary) on the line yet?

Man: I am.

Dr. (Sue Levine): There you are. Okay. All right. Well let me see if any of our members or anybody else has questions for either (Carol) or (Steve) and if not, then I believe you can proceed with your presentation.

Woman: Well this is (Nancy). We have public comment at 1:30 and we shouldn't - we can't start that early so we have about 20 minutes and I'm glad to see that (Gary) is back on. (Michelle Shaffer) did you ever get back on?

(Michelle Shaffer): Yes I am, I'm sorry, something happened with the technology and I got thrown off.

Woman: Would you like to - should we let finish (Michelle)'s presentation, (Sue)?

Dr. (Sue Levine): Totally. Yes, let's do that. Go ahead (Michelle).

(Michelle Shaffer): Okay. Well, so we decided to publish this new SSR based upon an independent study from the administrative conference of the United States ACUS. We asked them to look into symptoms, evaluation and disability claims and in March 2015 ACUS published a report with specific recommendations for SSA. And the report is on ACUS.gov website. If you go to Slide 3 on there. I think it's the next side.

The ACUS report recommendations included removing the term credibility from our subregulatory language and more closely reflecting the language that we have in our regulations and actually our regulations do not have the term credibility in them. So we revised our language and talked about evaluating symptoms as evidence-based analysis. And that's in line with our regulations. Next slide.

We still define symptoms the same so that hasn't changed. We did publish the SSR 16-3P, removed the term credibility and clarified that symptom evaluation is evidence-based analysis to determine whether the nature, intensity, frequency, or severity of an individual's symptoms affect the ability to work for an adult or affect the child's ability to function. The guidance we have in the SSR 16-3P on symptom evaluation is consistent with the guidance we have on SSR 14-1P on evaluating cases involving ME and CFS. So that's a good thing to know. We still have the same two-step evaluation process for symptom evaluation. I have included in the slides just so people can see it, but these are the next couple slides.

And we also have the seven factors so you can see what those are. Those haven't changed either. So go to the next slide and the new SSR emphasizes that when evaluating the effect of the individual symptoms, we consider the consistency of individual statements about the symptoms, resulting limitations and all evidence in the file and it emphasizes that symptoms can vary in intensity or persistence and their functional effect may worsen or improve over time. It may fluctuate. So there is the possibility that person can have a favorable decision without considering all the symptoms, say if you (unintelligible) or something like that but otherwise we go through a full symptom evaluation and the next slide emphasizes that the SSI adjudicator must clearly provide specific reasons of about how the individual's symptoms were evaluated in making the determination or decision. So you can see that analysis. That's our overview for the new SSR we published. Thank you.

Dr. (Sue Levine): Thank you.

Man: (Susan) this is (Steve). I have a question or two.

Dr. (Sue Levine): Go ahead. A question relating to what? This last presentation or just a general questions? Go ahead.

Man: If a person gets a CPAT or a silk table test as positive, will those be considered enough to get somebody Social Security?

(Michelle Shaffer): Well, testing is considered but it's not in and of itself enough at this point, no.

Dr. (Sue Levine): My question was (Michelle) whether or not you use the language post-exertional malaise or any of the other features of the said definition? Is that incorporated in the assessment or?

(Michelle Shaffer): Well, we updated the language and the chronic fatigue SSR and I'm not sure it uses that exact term but it was...

Dr. (Sue Levine): Because I think it's key to say post-exertional malaise as opposed to just fatigue. You know, because a lot of our patients don't feel anything right away but maybe the following day they will, and a I think unrefreshing sleep and so on. And have they done away with the need, the requirement for the elevated Epstein-Barr titers? Previously that was like a titer of 1 to 5020 or something like that was required but...

(Michelle Shaffer): I don't think that's required.

Dr. (Sue Levine): You don't need any objective findings are necessary?

(Michelle Shaffer): Well, you need certain findings but you need to establish if a person has a medically terminal impairment.

Dr. (Sue Levine): But you don't specifically outline which ones. It's up to the physician or whoever's writing the report to make a case?

(Michelle Shaffer): Yes.

Dr. (Sue Levine): Okay, okay. Does anyone have any questions for either the ex officios or the organization heads? And does anybody want to make any comments before we proceed? We have about ten minutes or so before we proceed to public comments.

Man: I don't want to hog but I have a question and it's for (Carol) and (Vicky) I suppose. We know that the NIH was looking into the possibility of a data sharing platform. Does what the SMCI is doing they replaced that need or is it something that would be done together or complement each other or how exactly would that work?

Woman: This is (Carol) (unintelligible) my answer has to be that as we were just awarded this grant literally three weeks ago, it's simply too early for us to know. But certainly we, you know, have a good relationship with (Vicky) and the NIH and we'll want to make that work together. But I'll let (Vicky) respond more effectively for NIH.

Woman: Hi. So I think from the NIH perspective, what we - any kind of data platform would be to collect data as part of the research study. But I would hope that we can work with (Carol) and Solve MECFS to make sure that the data bases are compatible and are collecting similar data with similar data elements. I'll talk tomorrow more about our common data elements project that we are just getting started and now we intend to go forward with that, but would really welcome Solve MECFS working on that project with us to make sure that everything is being coordinated across both what NIH is doing and what Solve MECFS is doing.

Dr. (Sue Levine): Thank you. All right, any other comments from anybody?

Woman: This is (Vicky) and I have a question for (Carol). Thanks, (Carol). I think the data base you're putting in place in the registry is really wonderful. Are you going to in any way link this to your bio repository and collect (unintelligible) specimens in addition to the information that will be collected in the registry?

Woman: I missed one word of your question early on but I think I got the gist of it, (Vicky). So as many of you may know we have had a bio repository for some period. Which you know, is helpful in our understanding of the issues involved generally as we build the right patient registry. Our intention is to integrate the two. We expect that there will be many, many more individuals in the registry than who have contributed physical samples from the bio repository. But we would hope that the bio repository becomes a subset of the patients in the registry. (Vicky) did I answer your question?

Woman: Yes, thank you.

Dr. (Sue Levine): (Carol), I had one question for you. In terms of both the registry and the bio repository, has there been any attempt yet to get follow up samples on any individuals or follow up information and how did you determine what the right sort of follow up time would be? I mean, it is standardized. In other words, would you contact everyone in the registry for instance like a year later or when something happens to them say, would they reach out to you or how have you - I'm trying to determine if you've thought about how to develop a longitudinal kind of a narrative of each person that you have in the registry.

Woman: Yes, (Suzie), these are all great questions and the short answer is this is very new for us. We have if you will a roster of you know, 20 or 30 planning questions that will help us focus and drive forward the registry from the beginning with the uses and the end in mind. And so the issues you raised you know, we are cognizant of. We understand that it will be important for us to reach out to those people rather than waiting for individuals to necessarily you know, proactively contact us. But there really, sadly, this is so new for us. There are more questions than answers. So we'll be happy to report on our planning for that as we figure it out.

Dr. (Sue Levine): Great, thank you.

Woman: Thank you.

Dr. (Sue Levine): All right (Nancy), we have about eight minutes or so for public comment time.

Woman: Sure.

Dr. (Sue Levine): Do people want to take like a three-minute stand up break?

Woman: Sure. And I was just wondering, did Dr. (Montoya) join? I sent him an email.

Dr. (Sue Levine): Do we need him? Does he make up the quorum or?

Woman: Well, I would hope. We need as many members as we have but we have a quorum at the moment.

Dr. (Sue Levine): Okay.

Operator: At this time Dr. (Montoya) (unintelligible).

Woman: I beg your pardon?

Operator: At this time Dr. (Montoya) is not on.

Woman: Okay, thank you. I just sent him an email.

Dr. (Sue Levine): Okay may I suggest it's 1:22. Can I just step and get a quick glass of water and be back like about 1:28.

Woman: Yes, that works. And then we'll start the public comments.

Dr. (Sue Levine): Okay I'll be right back.

((Crosstalk))

Dr. (Sue Levine): Hello guys. I guess it's about 1:26. A couple minutes I guess we can dial the first of the people. Is that how it works? Hello?

Man: (Unintelligible).

Dr. (Sue Levine): Hello? Anybody on?

General: (Unintelligible)

Man: This is (Steve).

Dr. (Sue Levine): Hey (Steve). Just don't want to go over time.

Man: (Unintelligible) is terrible.

Dr. (Sue Levine): What the allergies?

Man: I got knocked off again.

Operator: Excuse me, this is the operator. We have the first three people were open here.

Dr. (Sue Levine): Okay. (Nancy) are you on? I guess we have to wait for (Nancy). And who else is on the line?

((Crosstalk))

Dr. (Sue Levine): Are you guys on again? I think we need to wait for (Nancy) before we can - we need a federal official on the line.

Woman: Is (Beth) on?

Woman: Yes I'm here.

Dr. (Sue Levine): I'm not sure of the protocol exactly but...

Woman: I don't think I count, though.

Dr. (Sue Levine): Okay.

Woman: It was a good try.

Dr. (Sue Levine): Is that right, I'm not sure. Operator do you know? Do we need to have Dr. (Lee) on?

Operator: I would imagine so, yes.

Dr. (Sue Levine): I'm sure she'll get back on in a second. (Gary) are you on? (Gary)?

Woman: (Sue), are you there?

Dr. (Sue Levine): Yes, is that you (Nancy)? Hi. Okay we were waiting for you and then I guess we can proceed with dialing the first.

Woman: Right. Just to say Dr. (Montoya) I think has been on the listen only line so I'm going to send him the correct information but he should be joining us shortly too. So go ahead. Syreeta, will you help with getting the operator and then we can begin. (Sue) will announce who the next speaker is.

Dr. (Sue Levine): Did you send me?

Woman: I sent you that.

Operator: This is the operator. We have the first three people for public comments. (Dinsher Meister), (Bobby Onsibel) and (Mark Hamondstein).

Woman: (Sue), I sent that to you yesterday. Do you not have it?

Dr. (Sue Levine): I don't, I'm trying to get it on my...

((Crosstalk))

Woman: I will go ahead. The first speaker is (Janet Burmeister). Ms. (Burmeister), go ahead.

(Janet Burmeister): Can you hear me okay?

Dr. (Sue Levine): Yes.

(Janet Burmeister): This is (Janet Burmeister). Twice a year HHS gives some of us three minutes to comment only to ignore the solutions proposed by patients and to continue to disenfranchise them. Therefore, rather than provide substantive comments I would like to use my time today to ask the committee and those on the call to observe a moment of silence to honor and acknowledge all those who over decades have suffered with this disease or even died. So let's please use one minute of my time to reflect in silence starting now.

Thank you.

Woman: (Sue), do you want to go to the next person?

Dr. (Sue Levine): Okay. I didn't know she was going to use the whole time for, sure.

(Janet Burmeister). Thank you I appreciate it.

Woman: So the next speaker is (Bobbi Auserbel).

(Bobbi Auserbel): Hello?

Dr. (Sue Levine): Hi, go ahead.

(Bobbi Auserbel).Hi, I was just very moved by the last comment. I'm (Bobbi Auserbel). My daughter has been sick, very sick for 26 years and has spent most of those 26 years homebound and bedridden. I wanted to tell you that on Wednesday, May 25th. ME and CFS patients and advocates are going to be protesting at the U.S. Department of Health and Human Services in Washington, D.C., headquarters as well as regional Health and Human Service offices and other locations in Atlanta, Boston, Dallas, Philadelphia, Riley, North Carolina, San Francisco, my city, and Seattle. That's eight cities. And this is groundbreaking first for the MECFS community and the patients joining the protests and demonstrations are demanding the U.S. government make a serious commitment to addressing MECFS including funding, research and promoting appropriate clinical care for patients. We've (sic) also waiting for a response to a meeting request with Secretary Burwell of HHS. And we're calling these protests the hashtag millions missing protests because millions of dollars are missing in research funding to find effective treatments, millions of medical and healthcare practitioners who fail to provide adequate care, and millions of MECF patients missing from their careers, school, social life, families and if any of you can get on that website hashtag millions missing you can join us.

Patients can be more functionally impaired than those with congestive heart failure, multiple sclerosis, renal disease, but the NIH funding is much less than illnesses of similar disease burden. Why? Remarkably little research funding. And because of this neglect, academic researchers and pharmaceutical companies don't want to come near us to do research in this disease. The government and medical communities have neglected and stigmatized MECFS for the last 30 years and we demand our government finally respond with vigor, urgency, warranted by the devastation of this disease. And that's what the demonstrations are for. I'm finished.

Dr. (Sue Levine): Thank you for your testimony. Thank you. Call please.

Woman: Next caller is (Mark Kamenzein).

(Mark Kamenzein): Hello, this is (Mark Kamenzein). Thank you so much (Bobbi) and I'm going to put my other phone on mute. I am basically a volunteer/advocate for R&D to cure myalgic encephalomyelitis (sic). I am representing myself and my son who is severe affected by ME. Up to two-and-a-half million in the U.S. have ME. That's roughly the size of the U.S. standing military. So you see military people. Think for every one you see there's an equivalent person sentenced to life imprisonment with this disease without much chance of parole for doing nothing wrong. It could happen to you before any of the hundreds of millions of other Americans because there are no great predictors for this disease. It's happened to many people we know around California where I live.

My son was a straight A Stanford computer science student, class of 2016. He worked very hard to get there and we were quite proud of him and his very promising future. He was an Eagle Scout, took 50 mile bike rides, back packs, senior patrol leader, marching band, science polls, robotics, grand cross-county. He had zero medical issues. Highly productive, motivated. Not lazy. He became ill two-and-a-half years ago with three illnesses over three months starting January 2014, maybe viral, maybe we'll never know. He took medical leave from Stanford as he degraded and became extremely ill and is now bedridden 24/7 with severe ME, lack of energy, complete brain fog, up to 9 liters of urine a day, that is not somatoform illness, that is a medical illness and we need to treat it as such. (Tom) would love to watch this but he cannot tolerate any light. He sleeps with a pillow or shades over his eyes 24 hours a day. And he'd love to tell you his story but he cannot speak anymore. Two years ago he was a straight A Stanford student. He'd love to listen to this but he cannot tolerate any sound. In fact, he spends every day alone in a dark room with the door closed to keep out sound and wearing industrial-grade earmuffs 3M designed to be used at a rifle range. Even wearing this, if I say good morning to him quietly he says "Shhh" because that is aggravating because of the neural inflammation. He can only communicate with us with special hand signals. He's developed six pages' worth. He actually can still think, he can't communicate. Two thumbs down means take me to the emergency room. We've had ambulance trips. (Tom) would love to eat normal food but he cannot chew so all foods must be ground up, sift so they don't plug his straw and sipped through a large straw to have less difficulty sipping, and he cannot hold his cup because he's too weak so I or my wife have to help him be available 24/7 to help him, leaning over his bed which is very difficult on the back. And so this affects not just him but also parents. He's 22 years ago. Where were you and your family when you were 22 or your children? He will not be graduating next month with his Stanford classmates. Without more R&D funds he and others may never graduate, never get well, and contribute, and may not even survive ME. The death rate for people dying of ME is likely higher than the death rate of automobile accidents in the U.S. Thirty-five thousand auto accidents (unintelligible) death rate from this disease on the order of 60,000 is an estimate.

MECFS is the most common chronic disease to my knowledge causing drop out of high school or college with many never able to return. (Tom) has zero productive days. My wife and I must care for him 24/7 so we lose another person equivalent there. The cost of MECFS to the U.S. economy due to direct medical expenses plus lost productivity is estimated $51 billion per year by the CDC grand rounds by (Beth Ungar) February 2016. Imagine the return on investment for R&D to cure this. AIDS is 75 percent male and gets $3 billion a year funding even though this is now a rarer and less severe disease and that was money well spent and we applaud NIH and others for helping make this a treatable, livable disease and a great success. But now it's treatable and at this point MECFS which is by the way 75 percent female gets a piddly $6 million per year. That is a 500 fold sexual discrimination that cannot be tolerated by government. So this is gross discrimination for three decades against women ME and is unacceptable. We need similar funds per patient vs. MS which is a somewhat similar disease. So 2015 was a stellar year in some ways. IOM, P2P, (Francis Collins) announcing more emphasis which was phenomenal, Dr. (Knapp) getting some leadership on the NH which is fantastic. (CVAX) and (Susan Levine) chairing this is great. But the funding is grossly inadequate. Zika and Ebola get billions of dollars of funding overnight and we can't fund even 100 or 250 million for this two million people affected in the U.S., whereas these other diseases overseas have almost no people in the U.S. affected. ME Action Network, ME Advocacy and groups demand $250 million NIH funding per year and they've been asking this for a while. Anything less is unfair and discriminatory. We will educate 100 senators, 435 congressmen on MECFS which is going on now and so each clearly understands the gross discrimination and ask their support of $250 million per year. Anyone not supporting this at this level or higher is grossly discriminatory and has no place in office for both current people and also incoming representatives during the upcoming election. So we need to put each to the litmus test. I hope to get 100 percent passage of 100 percent of the senators and the congressmen. Any federal employees perpetrating discrimination also do not deserve to be in office and need to be replaced. Starting from the top down instead of what we've been doing which is the bottom up that hasn't worked as well as desired. So we hope you can increase funding and leadership for biomarkers understanding, training, CME courses, clinical trials, and eventual cures. NIH is amazing but it needs to fund extramural studies. It does not have all the people, knowledge and expertise...

Dr. (Sue Levine): Thank you but we have to wind down a little bit, we have other people. Thank you.

(Mark Kamenzein): Okay, thank you so much.

Dr. (Sue Levine): Thank you. Okay.

((Crosstalk))

Dr. (Sue Levine): I think we have a few more callers, don't we? We have three.

Woman: Yes. So the next caller is (Mary Dimick).

Dr. (Sue Levine): Hi (Mary). Go on.

(Mary Dimick): Thank you. Hi. Can you hear me okay?

Dr. (Sue Levine): Sure, yes.

(Mary Dimick): Thank you for the opportunity to speak today. Earlier you talked about the problems for the Oxford definition because it includes other patients. You also talked about the problems with (unintelligible) treatment that is CFS are based on the assumption that the disease is the result of a (unintelligible) condition. Clearly the IOM said that this disease is not deconditioning or a psychological problem. And the P2P explicitly called for Oxford to be retired because it could cause harm and yet medical information and clinical guidelines including those from the CDC continue to be based on Oxford studies and studies of the nonsensical psychogenic theory behind the bulk of CBT and (unintelligible) studies. For instance, the new guidelines from up to date recommend the IOM criteria for diagnosis and then recommend (pace) style CBT and GET. Those guidelines displaying poor prognosis on a patient's belief that they have a physical illness. Another example is CDC science clips published in February of this year. The references provided also represented CBT and GET blame the diseases (unintelligible) on a patient's perception, attributions and coping skills and included statements on pediatric patients based on the study of nonspecific chronic fatigue. I'd add that the clinical presentation of the CDC grand rounds failed to adequately describe the diagnostic and treatment implications of the systemic intolerance at the IOM (unintelligible) core to this disease. Regardless of the statistics of how many watched that presentation, how many of the doctors are any closer to understanding the disease that (Mark) and (Rifka) described a few minutes ago? This is so wrong. Clinical guidelines are supposed to be based on studies in patients who actually have the disease. Clinical guidelines need to adequately describe the key features of that disease. The guides being provided for this disease today are confusing doctors and putting patients at great risk of harm. This would never be tolerated in any other disease. (Unintelligible) patients CDC must provide the leadership to fix this mess in its own guidelines and provide the leadership for other medical education providers to do the same.

Second I want to address the upcoming recommendations for Centers of Excellence including both the research and clinical care component will best jumpstart the research and drug development that's so desperately needed. But the clinical care component is also desperately needed to address the crisis we face in clinical care, made worse as our disease experts reach retirement age. HHS you must find the creative way to fund both research and clinical care component.

The last concern I have is the lack of urgency in HHS's response to date. Yes steps are being taken, but those steps are nowhere near the magnitude or the urgency response that is required. This disease is destroying peoples' lives and it has been for the last 30 years. You need to act as though one of those lives is your son or your daughter. After 30 years of neglect to sustain you owe these patients at least that much. Thank you.

Woman: The next speaker for public comment is (Leah Williams).

(Leah Williams): Hi.

Dr. (Sue Levine): Hi, (Leah), to ahead.

(Leah Williams): Both of my children have MECFS. My son now aged 20 became sick when he was 12. He had what seemed like an ordinary cold except that he never got well again. Instead he suffered increasingly from headaches, joint pain, unrefreshing sleep, overwhelming fatigue and difficulty concentrating. He missed most of high school because he was too physically sick to attend school. His health has improved somewhat over the last few years and he is now applying to college but he will have to attend part-time. My daughter now age 17 also became sick at around the age of 12. Her symptoms were similar and equally debilitating. She is enrolled at our local high school but is much too sick to attend. She is taking online classes and has a tutor at home. My children have lost an enormous amount. Their health, the social experience of high school, and the ability to participate in sports. They are smart, creative young people and would if healthy be making a contribution to their school and their community. It is incredibly frustrating that there is no treatment and certainly no cure for MECFS. I fully support your efforts to promote centers of excellence which would help focus research on this illness. We have seen many, many doctors over the last eight years. Some have been sympathetic, many more have been dismissive, and a few have been cruel such as a psychiatrist who wrote a ten-page report about how MECFS is not a real illness and we were abusing our daughter by preventing her from going to school. Centers of excellence which help educate doctors and provide sorely needed places for MECFS patients to get appropriate care. Thank you for this opportunity to comment and thank you for all of your efforts on behalf of patients and their families.

Dr. (Sue Levine): Thank you.

Woman: The next person for public comment is (Michelle) or (Michael Lee).

(Michelle Lee): Hi there, thank you. (Michelle) actually. As a preliminary point I really just want to recognize what I think is absolutely truly exceptional work of the CSAK committee. You've trudged along tirelessly and I think with precious little glory and there's no question your effort and those of Solve ME and other researchers who focus in this area and advocate groups and so forth have been phenomenal, as has the work of individual government committees, workshops, the FDA really fabulous. But this effort is in such a stark contrast to the entrenched and boots stuck in the mud inaction of the CDC at large. I do research in the basic environmental and energy policy area and I have done investigated illness patterns relating to environmental toxic exposures. I'm also author of the first peer-reviewed journal study analyzing application of the Americans with Disabilities Act. So I pop in and out of research in your area, which I find fascinating, but I've been very immersed in other areas, Fukushima and Chernobyl issues that have some up in the last year so I've been out of this field for a year and just popped in for this particular meeting. And frankly, just astonished that we're - that they're still trying to get through the same barrier. So let me try to just illustrate my point with a story - case history of two actual patients and, I think, you draw your own conclusions from these.

The first one - well, both individuals, first of all, were in robust health before falling ill, both were working full time, both very physically active, both had high caliber health insurance, both lived in major metropolitan regions with high, easily accessible medical care.

Okay, patient Number 1, call her C. Headed non-profit, her career was skyrocketing, she had - it was a very exhilarating time for her, she was burning the candle at both ends for months, and then she was struck with a flu-like virus. Then boom, then hit with proverbial truck, and in a very short period she developed the symptom profile that could have been lifted right out of the (CCC) criteria.

She was diagnosed very early on by a colleague who is also a friend and a physician and knew her well and, therefore, delved into the research. However, her internist refused to accept the diagnosis because her internist deemed that the patient was not depressed and didn't sufficiently display a draggy, fatigued demeanor.

And so, therefore, the patient was sent out on a very long, heavy testing regime with mammograms, MRI, chest x-rays, whole body CAT scan, dispatched to multiple specialists and so forth. All absolutely huge waste of time.

Patient Number 2, Call her T. She was the former Vice President of one America's largest corporations. Made a small fortune then went on to work closer to her heart in the non-profit arena.

A few summers ago she began to feel sluggish and gradually developed trouble sleeping, began to experience headaches, joint, body pain especially the neck, back, hip. (Unintelligible) felt a little blue, husband was away on business a lot of the time and so she went to her doctor and then she got sent to physical therapy. She went to acupuncture, she was put on antidepressants.

She didn't get better so eventually she went on the web to do her own research and she found the CDC (Fukuda) criteria and decided well, that fit her. And following the wonderful advice that she saw online then traipsed off to a behavior psychologist. Then one day she collapsed in the middle of the street because what she had was cancer and her spine was riddled with it.

So what I hope you take away from these two stories, because I think they are almost at the opposite end of the spectrum is that we have an illness that can be identified with precision if effort is made to, you know, to focus attention on the granularity of the symptom profile and the case history.

I'm glad that's beginning to be done but until web pages, until information is update and doctors and patients can easily access the information and easily access the more detailed symptom profiles set forth in the CDC or the (ICC) or the (SCID) criteria you are going to have many, many more cases very similar to these two patients. Thank you.

Woman: Thank you. Okay. With a few minutes to go we have two more people on the list, the first is (Denise Lopez Mahano).

Woman: Okay.

Woman: Hello?

((Crosstalk))

Woman: You actually have (Courtney Miller) on the open line.

Woman: Is (Denise Lopez Mahano) there?

(Denise Lopez Mahano): I am here.

Woman: (Denise), go ahead.

(Denise Lopez Mahano): Okay. Thank you. As a result of a meeting with a health care professional (HCP) who had never knowingly met patients with severe myalgic encephalomyelitis, I've been thinking about some of the things health care professionals (unintelligible) in order to help patients. Health care professionals must know the differences between definitions for CFS and disease definitions that require post exertional malaise, PEM, as part of diagnostic criteria.

They must know the range of disease severity and how to assess frequency and severity of symptoms. They must know that the Institute of medicine diagnostic criteria has not yet been correlated to any treatment which means existing treatment guidelines may well be inappropriate. As an example, those based on Oxford or other definitions.

They must know that PEM (unintelligible) is not fatigue. PEM is a system exacerbation of symptoms following even minimal cognitive or physical exertion lasting anywhere from days to months and not alleviated by rest.

They must have detailed information about PEM including examples of how it further disables patients. For example (unintelligible) each breath requires conscious effort, or the inability to make decisions or use a toothbrush, and so on.

PEM cannot always be avoided but careful pacing can keep it at bay, sometimes. ME forces patients to lead tightly circumscribed lives because minimal cognitive or physical exertion can cause extensive repercussions. Getting back to their typical illness baseline is the best patients can hope for.

Health care professionals must know how to educate patients about pacing. Pacing is not graded exercise therapy. Accurate education about pacing must reflect the nature of energy metabolism impairment and the patient's lowered aerobic threshold.

They must know how orthostatic intolerance manifests and how it compounds disability. They must understand that cognitive impairment is common and it's evident in impaired working memory, slowed processing speed, difficulty with decision making, slow speech, and so on.

The intelligence is still there but accessing it oftentimes seems almost impossible. Health care professionals much understand that cognitive impairment has dramatic negative impact on patient's lives. Also necessitating that caregivers speak for patients because the mere act of getting to the appointment has already exhausted their cognitive and/or physical resources.

They must treat symptoms, including sleep problems, appropriately to see what else can then be treated with the goal of improving patients' level of function and quality of life. Health care professionals must know that children get this disease also.

Children with ME have unique problems and there are far too few pediatric specialists. Like adult patients they may be housebound or bedbound. They may be too sick for homebound tutoring. Care professionals must know that even though they get ME as a child that doesn't mean they will get better.

And there's much more that health care professionals must know. Obviously this is much more than individual advocates can address to effectively educate health care professionals.

Un-pieced quilt patches randomly spread across the bed, piecemeal education of health care professionals by advocates, these are the few quilt patches knowledgeable health care professionals gathered across the country and no way to effectively piece them together to cover the patients who have no access to the few knowledgeable health care professionals.

Under the current model, as the years go by and the experts retire, more and more patient care with fall to uneducated health care professionals and their teams. The reality is the more patients are undertreated the greater the rates of disability. This cannot be allowed to happen.

Education about ME for health care professionals must be improved and now medical school curriculum must include accurate information about ME. We also need centers of excellence for ME to provide clinical care and to train health care professionals because patients alone cannot train enough of them.

These centers of excellence must be staffed by recognized disease experts. Standards and protocol for centers of excellence certification must be developed by recognized ME experts. Certified centers of excellence for ME would greatly enhance the quality of life for patients as well as ensuring appropriate training for health care professionals to replace the aging population of current specialists.

We urgently need more medical education about ME and we urgently centers of excellence for ME to provide more appropriate care for greater numbers of adult and pediatric patients and educate health care professionals. By improving level of function and thereby reducing disability, centers of excellence and more appropriate overall patient care constitutes a cost saving measure for the overall economy. Thank you.

Woman: Thank you (Denise). Touché. I couldn't agree more. Okay. Last call on the line and then we have (Gary)'s presentation.

Woman: Is (Courtney Miller).

Woman: Okay, go ahead (Courtney).

(Courtney Miller): Thank you Dr. (Levine), members of the committee. My name's (Courtney Miller) and I'm calling from Reno where I've moved my family twice in 15 years so my husband can access (Ampligen).

This year has been one of change and new directions at the Federal health agencies and my family is hopeful. The IOM and P2P reports were published a year ago and they've created a new mandate at NIH and (HHS). They were pivotal initiatives and the recommendations were better for the high level of expert and patient engagement in them, an important point right now.

Last fall Dr. (Colms) announced a new commitment at NIH, pledging to increase funding and conduct intramural research. We embrace his new commitment. I am encouraged that Dr. (Kourshets) and his team have jumped in with both feet and thank (Vicki Whitmore) for being the face of that effort.

We can see early evidence of this leadership but there is a lot of ground to make up. I applaud the use of supplemental grant awards as a creative expansion of funding yet we expect and need RFAs to follow.

The intramural study is a huge opportunity. It is instrumental to our future as patients and the future of research on our disease. That was the cytokines, proteins, genetics, brain imaging, pre-and post-exercise testing, neuron research, mouse models. This is exactly what we need to seed a research program that can bring us diagnostic tests and medicines.

I can't stress enough how critical it is to enroll well diagnosed patients. I would ask (unintelligible) or recommend that patients for the intramural study be selected and diagnosed by expert doctors who have participated in the (XMRV) or CDC multi-site studies.

Dr. (Nash) has said most patients will come from those clinical sites and I believe your support for this recommendation would reinforce, for the whole research team, how important expert diagnosis is to a credible and meaningful study.

On centers of excellence, we are running out of time to integrate our expert doctors into translational research as they approach retirement. I urge you to stress the ticking clock and urge the Secretary of Health to integrate expert doctors and patients during the planning stages for centers of excellence.

We need structural help to build bridges between expert clinicians who employ sophisticated diagnostics and pioneer the treatments and universities which have scientific infrastructure. Centers of excellence can't have one without the other. We must train new clinicians as a key goal and to do that we need funding mechanisms that reach existing doctors and clinics, not just universities.

Lastly, I believe we have an obligation to push these new directions hard and smart enough to create change in what patients' experience, which has yet to come. NIH must prioritize and fund clinical trials for treatments. Pharma will only invest in our disease when FDA approves the first medicine for ME. That's the short term goal.

Our community has expertise that can help make the most of this new investment and avoid pitfalls that we cannot afford. Integrating us into your planning will pay dividends.

To conclude, I ask all of us to work harder and faster, learn from each other, embrace and expand new commitments aggressively and plan collectively so that NIH's new investment produces treatments for patients as soon as possible.

Thank you all for your work.

Woman: Thank you (Courtney). I guess with that we're ready to move on.

Woman: (Sue), I have a couple of technology issues.

Dr. Dr. (Sue Levine): Sure.

Woman: Number 1, Dr. (Montoya) are you on a speaker line now? No. So Dr. (Montoya) has been on the line and I've sent him the number again and that's the number and he's still apparently not able to speak. I was going to ask the - (Jennifer), the Operator, to see if she could get him moved over.

Operator: Excuse me, this is the Operator. Dr. (Montoya), if you could please press star 0 and highlight your line. Press star 0.

Woman: Dr. (Montoya), star 0. We'll try that. And while they're working on that, a number of people would like to listen directly on the computer instead of going through the phone line. We were told by Verizon that was possible. Now…

(Dr. Montoya): Can you hear me now?

Woman: Yes, hello sir.

(Dr. Montoya): Yes, just for the record, I've been on the line since 9:10 am, 12:10 pm waiting for the phone call to start and I had been on the phone call the entire time.

Woman: Good. Thank you. Well, email always works so I got hold of Dr. (Montoya) via the email finally and we established he was there.

(Dr. Montoya): Thank you.

Woman: So we're still trying to figure out if there's a way - we were told several times by the people running that own the webinar technology that we could either listen on the phone or on the computer. We're working on that. We'll see what we can come up with because I know some people would like to do that. But we're trying.

Woman: Okay, thanks (Nancy). So go ahead (Sue).

Dr. Dr. (Sue Levine): Okay. (Gary), have you - now you're going to give kind of dual presentations or…

(Gary Kaplan): Yes, so the way we're going to be set up - can you hear me?

Dr. Dr. (Sue Levine): Okay, great. So the way we're going to be set up is I'm going to give an overview of what we're doing, I'm going to present the justifications for the centers of excellence. (Mary Ann Fletcher) is going to present part of the structures and (Dane Cook) is going will also talk about the structures of the centers. And then I'll come back on and go over the specifics of the proposal we have for the committee.

Dr. Dr. (Sue Levine): And (Mary Ann) is not on the call. She told me she was going to be in Alaska.

(Gary Kaplan): Right, but she said she was going to do a voiceover that was supposed to come with her slides or, I don't know, perhaps (Dane) decided he was going to pick it up. It was - the two of them were going to decide what they were doing on that.

Dr. Dr. (Sue Levine): (Dane) what do you - what's going to happen?

(Dane Cook): She did say she was going to do a voiceover and then she emailed a couple of weeks ago asking (Jose) to give the presentation. I don't know what happened following that.

Dr. Dr. (Sue Levine): Is that true (Jose)?

(Jose Montoya): No, I don't have that.

((Crosstalk))

Dr. Dr. (Sue Levine): Well why don't we play along and see what happens. Are you - (Gary) you're familiar with her - you've read it?

(Gary Kaplan): I have the slides in front of me, I've got everything.

Dr. Dr. (Sue Levine): Okay, so if need be you can say it aloud if we need it, you know...

(Gary Kaplan): Not as elegantly as (Mary Ann) can but I'll be happy to go through it.

Dr. Dr. (Sue Levine): Sure.

Man: And I'm happy to weigh in. A lot of what she is saying is somewhat - it overlaps quite a bit with what (Gary)'s going to say, what - and what I'm going to say.

Dr. Dr. (Sue Levine): Okay...

((Crosstalk))

Dr. Dr. (Sue Levine): Okay go ahead and get started then whenever you're ready.

(Gary Kaplan): All right, great. So what I want to emphasize here - we're going to end up repeating a few things over and over again but one of our goals was to make sure we had excellent documentation in terms of what centers of excellence - why they were needed, and also what they could potentially do.

And so we spent a lot of time in - if I could have the next slide please. Okay, so what we did to begin with was I split the committee actually into two working groups. One was for creation of justification for the centers of excellence, the other was for creating - talking about the specifics of the structure of centers of excellence and then we got back together and created the recommendations that are at the end of this presentation.

Next slide please. The committee has been quite large and I want to thank everybody for, truly, a lot of contributions. We've had a number of phone conferences working out the specifics of each of these justifications and structure issues as well as the final reports. It really has been a team effort.

I particularly want to thank Ken Friedman who did the justifications for (ME/CFS) centers of excellence, who did an unbelievable job of research and laying this out for us. And then (Mary Ann) and (Dane) who took over chairing the component of the structure of the (ME/CFS) centers of excellence.

But thank you to everybody. It really has been a lot of work, on part of many people, to bring this presentation. Next slide please.

Though we originally the centers of excellence committee was created in June, 2014 (SOSAC) meeting. And so, just briefly what's happened since then, we obviously had the NIH P2P report, we had the 2015 (IOM) report, and then we gave a preliminary report at the December, 2015 (SOSAC) meeting and today we're going to present our final recommendations.

Next slide please. Do I have control over these slides?

Dr. Dr. (Sue Levine): No, we're doing it from here.

(Gary Kaplan): Okay, so...

Dr. Dr. (Sue Levine): So just say, "next slide." Syreeta's great at this.

(Gary Kaplan): So, you know, the first issue, of course, is the prevalence. We all - we know these numbers. We're looking at somewhere between 836,000 to 2.5 million Americans. Fully 25% of these people are either housebound or bedbound...

Dr. Dr. (Sue Levine): Excuse me (Gary), do we have references for this?

(Gary Kaplan): Yes, at the very bottom you'll see Source: CDC Public Health Grand Rounds, February 2016.

(Sue) Okay. Thank you. Sorry to interrupt. Go ahead.

(Gary Kaplan): Yes, the illness is more disabling than heart failure, multiple sclerosis, or end-stage renal disease. It affects all age groups, racial ethnic groups, and socioeconomic strata. (Unintelligible), the cost, which has been stated several times today, is a massive cost to the US economy, somewhere between $18 to $51 billion annually and yet despite these huge numbers in terms of number of patients affected and the cost to the economy, Federal support for research in ME/CFS only averages about $5 million a year.

Next slide please. Though ME/CFS continues to be a (unintelligible) which has controversies regarding a precise case definition it is difficult to diagnose because of this. It's difficult to treat, it's misunderstood or not recognized by many health care providers, rarely included in medical school curricula, and under-treated or not treated in many parts of the United States.

(Sue) you had asked about references for this, I do want to point out that Ken Friedman provided an extensive slides and details with regards to the justification component of this which has also a lot of references in it backing up all of these slides.

So, next slide please. Though, you know, NIH P2P in 2014 defined disease parameters, it created - called for the creation of new knowledge, improved methods and measures, provide training and education, finding new funding resources, and conducting clinical trials and improved treatment, these are all things that they identified as deficiencies and things that need to be rectified.

IOM did a similar set of issues though they specifically defined new diagnostic criteria with new terminology. They were calling for increased research, increased funding, and dissemination and knowledge, establishment of collaborative centers which we will read as centers of excellence, and improved patient care. CDC Grand Rounds in February 2016 again reviewed all of this data and again reiterated the needs for more research.

Next slide please. Though Dr. (Arger) mentioned the multi clinical assessments of ME/CFS, this has been an important contribution to our understanding of the disease but what I wanted to emphasize simply on these slides is that these are treatment centers and they're not centers of excellence. This is different than what we're calling for in our proposal.

So next slide please. So basically two questions we were posed with: What are the unmet needs that centers of excellence could fulfill, that is, the justifications for centers of excellence for ME/CFS, and second, how do we meet those needs and that's the structure component of centers of excellence for ME/CFS.

So if we could go to the next slide please. Okay, so Justifications for Creating the Centers. Next slide please.

Again, I want to thank Ken Friedman for truly an amazing amount of research and effort in the process of compiling this. I'm summarizing a lot of his work and, again, would refer you to the extensive slides and data that he's provided as - not as part of this but it will be available on the website.

So, basically the justifications are one, you know, centers of excellence work, they're successful for other disease complexes. (Unintelligible) is, social and economic burdens of these disease, we've got big illness, we've got big cost to the economy and they need big study commitments.

There are significant research deficiencies. There are significant clinical deficiencies. There's denial of equal access to participation - to participate in society and medical care, patients suffering with these conditions, and there's a unique and comprehensive approaches to these problems with ME/CFS centers of excellence can provide.

So we've got, you know, a very complex problem. It needs a multi-specialty interest in the process, the stakeholders in the process of examining and working on this condition. And we also have an interesting problem that Ken had put forth about denial of equal access. And we'll talk about that coming up.

Next slide please.

So, if we look at simply the first issue with the success of centers of excellence for other complex diseases, the beauty here is that NIH has a well-established funding process for creation of centers of excellence. All right, there's a research project grants which are (PO1)'s, there's center care grants which are (P30)'s and (P60)'s specialized center grants. The point is we don't need to reinvent the wheel. We have a process which we can work through that already exists.

Funding mechanisms for centers of excellence already exist for Parkinson's, autoimmunity genomics, pain, multiple sclerosis. Again, we're not reinventing the wheel, we're simply applying a well proven process to ME/CFS. Without question centers of excellence dramatically advance research. Centers of excellence provide comprehensive rapid advancement in caring of people suffering with complex disorders and centers of excellence also provide centers of education for physicians and researchers.

Next slide please. The socio and economic burden of the disease, as I stated earlier, this is a disease that affects somewhere between 836,000 to 2.5 million people. The economic costs are huge, between $18 and $51 billion loss annually. And then 25 to 29 percent of ME/CFS patients are either house or bed bound.

Next slide please. Research Efficiencies. Well we lack biomarkers, how do we make a diagnosis of this disease - clinical diagnosis but we need biomarkers. There's insufficient understanding of the path of physiology of the disease. There's no approved pharmacological treatments of the disease, there's no prevention protocols, there's no cure, and there's a lack of training for researchers so these are things that centers of excellence can, in fact, begin to address.

Next. Next slide please. Thank you. There's clinical deficiencies. We have insufficient physician training for both clinicians and medical students. We have severe deficiencies in access to quality medical care by patients. We have confusion and misunderstanding of the disease by clinicians resulting in harm to some patients. We have a lack of treatment protocols and we have no prevention guidelines.

Next slide please. This is an interesting study that - talking in terms now of this denial of equal access to participate in society and medical care. Right? This is actually the Public Health Service Act of March 13, 2013 mandates the treatment of medically underserved populations and Ken has made a very strong argument that this is a medically underserved population.

Looking at a paper by (Tidmore Nicholson), look at the satisfaction of patients who have ME/CFS versus multiple sclerosis. You see the patient dissatisfaction with care with 54% - over half our patients' struggling with ME/CFS, versus less than 10% of the patients with multiple sclerosis.

Patients receiving specialized care, only 11 - quite 12 percent of patients suffering with ME/CFS are receiving specialized care, whereas 41% of patients with MS were.

Patients reporting impediments to health care, way over 50% for the ME/CFS patients, about 11, 12 percent for the MS patients. Comprehensive Care Centers, ME/CFS essentially none. We have 122 for multiple sclerosis and, again, the number of patients, because it's a shocking piece of information at 2.5 million for ME/CFS, and we're only talking about .4 million for multiple sclerosis.

This is not to say multiple sclerosis isn't a very important disease that deserves its funding and treatment centers but it is to say that, in comparison, ME/CFS is at best the poorer (unintelligible) and desperately needs more attention especially in the way of funding and research.

Next slide please. This is a - next slide please. This is a particularly astonishing slide. If you look at this, you're looking at - this is an argument that says ME/CFS is an underserved population and divided across census regions in the Pacific, only 13% of people who suffer with ME/CFS were seeing people who were specialists. In the Western North Central area, the number was 0%. As you look across the country I think a very strong argument can be made that this is an underserved population. And by that argument alone should receive special funding for research…

Dr. Dr. (Sue Levine): And was a survey conduct - how did they determine this - these...

(Gary Kaplan): So this was again (Nicholson). If Ken is on the line Ken can give more details about this.

Dr. Dr. (Sue Levine): Did he call up people or call physicians or how did he...

(Gary Kaplan): I believe it was a phone survey.

Dr. Dr. (Sue Levine): Okay. But he just like calls like random people in those different geographical areas and...

(Gary Kaplan): People identified with ME/CFS.

Dr. Dr. (Sue Levine): That's curious. I've never seen anything like it.

(Gary Kaplan): It's an amazing and depressing slide.

Dr. Dr. (Sue Levine): And so we're seeing in the middle of the country, what's going on there.

(Gary Kaplan): Yes, as far as people seeing specialists for ME/CFS it was next to none.

Dr. Dr. (Sue Levine): Wow, that's amazing.

(Gary Kaplan): It is astonishing.

Dr. Dr. (Sue Levine): Okay, I'm sorry. Go ahead.

(Gary Kaplan): Next slide please. So basically we're arguing that ME/CFS centers of excellence situated in academic university settings with access to health professionals are an environment that can offer unique and comprehensive solutions. It can conduct basic and clinical research, it can provide for patient care, it can provide social services for patients.

This is something, again, where if we're looking at an underserved population, and I believe we can make that argument, social services become essential for these people in order to be able to get access to care and in order to be able to get access to benefits that they deserve to be receiving by virtue of the disability imposed by the disease.

Offering medical students medical residence and medical health care providers education and the ability to monitor the effectiveness of these programs. We can provide lay public education, we can conduct health surveillance of ME/CFS adding other disciplines as needed, this becomes extremely important and we've had a number of conversations about this and (Dr Montoya) has made this point repeatedly that it's extremely important that we have multiple specialties available to look at this disease because frankly it's not owned by any one specialty. And we need neurology and immunology, amongst others, should be able to look at this disease and across disciplines. So consulting and developing partnerships with external groups is another thing that these centers will do.

So, next slide please. I believe we're up to (Mary Ann)'s. (Dane) do you want to do this piece or would you like me to do it?

(Dane Cook): You're welcome.

(Gary Kaplan): Hello?

Dr. Dr. (Sue Levine): Hi. Go ahead.

(Dane Cook): Go ahead (Gary), I'm not as familiar as you are with this slide presentation.

(Gary Kaplan): Okay, next slide please.

All right. So this is all put together by Dr. (Mary Ann Fletcher) and so she had talked about what the structure of the centers of excellence should look like and what needs to be done there. She's citing the same studies we had cited previously with the NIH PB2P and the Institute of Medicine.

Next slide please. So, again she's summarizing these, I'm going to skip over this because we really discussed this in terms of what they've done.

Next slide please. And next slide after this.

And so, she talks about some of the deficiencies that have been noted in the disease both through the NIH P2P workshop and the Institute of Medicine. She said that the expert committee at the Institute of Medicine, the committee was unable to find subgroups of patients or even to clearly define the natural history of the disease. There's a paucity of data to guide clinicians in distinguishing among these disorders, the gap that urgently needs to be filled.

The literature is unable to clinically distinguish (NACFF) patients from healthy controls using symptom based diagnostic criteria. Huge gaps in our diagnosis of this disease and huge problems with the literature.

Next slide please. Next slide after this and we'll get more to - and she was talking about definitive recommendations which we had also gone over previously so next slide.

So centers of - so what constitutes a center of excellence. Okay, so we need center of excellence investigators, clinician educators working together and in collaboration with a wide international network of center of excellence fellows, an integrated program which combines clinical, research, and education missions. A multidisciplinary approach to a multidisciplinary disease.

Next slide please. It's important that these not be standalone entities. Okay? Without the clinics there's no patients. Without access to patients there's no research - bench to bedside policy approach for ME/CFS research. Meaning that, as was emphasized by one of our speakers earlier we need - this needs to be a clinical entity as well as a research entity. We need to have basic science occurring alongside of clinical research occurring alongside clinical treatments occurring alongside of education for both clinicians and for patients.

Next slide please. So, if you're looking at this, the core - creating a critical mass integrated into critical space. So you have an administrative core which is made up of the advisory committee and the steering committee and their job is to bring together all of the information from systems biology and information management. This ultimately is a big data issue and so will need to be managed as such. Genomics and molecular medicine, therapeutic sciences and the clinical care.

So this is basically the structure of what a center looks like in terms of the necessary components of it.

Next slide please. Cross Disciplinary. Okay, so we need clinic immunology, endocrinology, neurology, infectious diseases, exercise physiology, environmental medicine, toxicology, integrative medicine.

Again, this is not a disease that we are going to solve the problem with and, quite frankly, I think increasingly we're going to find this with more and more diseases by a single specialty but rather we're going to need to break down the silos and have everybody cross disciplinary looking at these patients, providing their expertise to come up with better answers.

So, expert care for ME/CFS patients regionally, nationally, and internationally on-site and virtual. Okay, we'll talk about that specifically in our recommendations because we have people who are not able to get back and forth to the centers. We have people who need to be treated in their communities and so being able to do that we're going to now have to utilize the telemedicine components that are now becoming widely available in order to reach the largest number of patients and educate the largest number of physicians.

We're going to have to subject - assessment and recruitment on physiologic and behavioral profiling. We need critical assessment of treatment of the candidates so that we know what we're doing and why we're doing it. We need to provide hands-on and virtual education opportunity for health care professionals.

This is one thing we talked about in the committee a fair amount is because we do have a population that can't get back and forth to the centers - is virtually reaching out and spreading the information as fast as possible to clinicians and also helping to guide care out in the community away - at some distance from the centers. Patients must become active participants in their overall care.

Next slide please. Core Competencies, we're talking about cellular biology, genomics, virology, proteonomics (sic), you know, chemistry, the neurosciences, and we need clean and certified labs. They provide expert relevant clinical lab testing, biomarker development which we talked about earlier, the assessment of an illness, specific changes in immune (unintelligible) cell populations and (unintelligible) functioning.

We need to define the pathogenesis and mediators of resistance in this disease. We need longitudinal studies for progress immune exhaustion and dysfunction. We need educational opportunities for undergraduate, graduate, and postdoctoral students.

Next slide please. Again, the Core Competencies, the computational genomics and systems biology. Again this is a big data problem. We need to have the appropriate backing of computational and engineering biophysics and high performance computing in order to really make these centers effective and move data out of them in a very rapid manner.

Also centralized data management will need to be done, registry and repository for a patient sample. So this is - the next piece is simply reiteration of what I just talked about.

Next slide please. Core Competencies again, integrating computer and experimental models with in vitro and in silico testing to develop clinical treatment trials, development and use standard in vitro models. This is all about standardizing our - not just our treatment protocols but our research protocols so that we can share data much more rapidly so that we're comparing apples to apples.

And the centers - part of what needs to happen in all of these centers is these centers need to be connected to one another because if they're not connected to one another we're getting too much duplication of research and not moving forward ahead as fast as we possibly can.

Next slide please. Development of Targeted Therapies. Obviously improving cellular energy, enhancing antiviral functions, reducing neural inflammation, reducing pain, quieting immune activation, enhancing adrenal function, finding and eliminating antigenic triggers.

Next slide please. New Strategies in Design. All right, so we need dynamic challenge studies. We need genomic monitoring for early results. We need in vitro modeling. Red cap platform for assessment and computational biology and modeling. We already heard from a number of people in the communities that it's not uncommon to have several members of the family affected by this disease. There's clearly genetics involved in this. And there are also sub classifications of this disease that we're going to find as we get more precise in our diagnoses. And hopefully with those sub classifications also get more precise in our treatments.

So this is what we're looking to come out of these centers and to be able to truly define these from a biologic standpoint and also individualized treatments as much as possible so we get the best possible result.

Next slide please. The core will support the centers of excellence, and this is the administrative core, and the investigators in their collaborative clinical and research activities by ensuring organizational and administrative management of the overall program. Coordination and communication within the program with related university programs with scientific community patients and their advocates. So the core has a lot to do in terms of pulling all of this together.

The use of most appropriate methods for monitoring progress in the projects and effective use of shared resource cores. This is the nitty gritty of how you create a centers of excellence is everything that (Mary Ann) has gone through with this.

Next slide please. She talks about some of the funding that is presently available through the National Institute of Health, the R01 (P30), P50 grants and how they're defined. Currently we have a funding limit of $5 million per grant but we can take $5 million per center and that would be lovely.

Next slide please. Other funding sources that she was proposing, the Department of Defense, one of the largest funders for breast cancer research is the Department of Defense interestingly enough, I'm not sure how that happened, but the point is we can look outside (HHS) for other entities that are capable of funding this: U.S. Department of Veterans Affairs.

So there's a number of other places that we can look for funding in addition to (HHS).

Next slide please. So the establishment of centers of excellence offers the unique opportunity to create an integrated fabric of ME/CFS that unites clinical, laboratory, and computational sciences in a truly translational effort for discovery and deployment of effective treatment courses, while training the next generation of expert clinicians and providing a national resource for patient care.

Now that's the end of (Mary Ann)'s presentation. (Dane)?

(Dane Cook): Thanks (Gary), that was very well done and I know difficult with someone else's voice not there. So my presentation is intended to be a simple presentation of the basic working parts of a center of excellence.

It's a distillation, by myself and others, of the most representative aspects of a centers of excellence so, as (Gary) presented to you all (Mary Ann)'s idea a big center, how it could be conducts - that's kind of a rooftop view, I'm giving you sort of the ten thousand foot view of really the integrative parts of the science clinical care and education and community outreach.

Next slide please. So one of the more powerful aspects of centers of excellence is that they can force integration and if that integration is effective, they solve problems quicker than independent programs such as if an investigator had an R01 research project. So as (Gary) said integration is critical in this communication and each component within a center is designed to inform the other components. So you can enhance research participation, provide real world information to doctors and researchers, and engage the community.

And in the end you achieve, basically, more than the parts of the center if they were conducted in a vacuum so the whole of the center is greater than the sum of its parts. You achieve things that you couldn't have achieved if you hadn't had these types of clinical research and, as I'll talk about, outreach and education components.

Next slide please. So one of the nice things about centers is that they can grow. So you can grow a center within itself and then you can add centers across the country to really accelerate knowledge. So a complex disease such as ME/CFS requires multiple centers of excellence to accelerate progress towards understanding the pathophysiology of the disease and for eventually finding a cure.

So these centers are designed to solve complex questions through integration and collaboration and then the diverse expertise within centers of excellence allow for the vetting of ideas, fuller testing of hypotheses, and development of novel approaches for the study of the disease.

And, the incorporation of the state of the art knowledge and formation of new collaborations really provide a fertile ground to train the next generation of ME/CFS physicians and scientists.

Next slide please. So now, basically the center components that (Gary) specifically alluded to and, again, more the ten thousand foot view to look at these potential cores. I'm providing examples with the understanding that no single center will encompass all of the clinical scientific and educational resources necessary for ME/CFS.

These are examples of the most common cores and their constituent parts. Core is being the principal component of a center and, as mentioned previously, they work together to solve these complex problems.

Next slide please. So before we get into the actual core component parts I want to talk about the leadership structure of centers so there are defined leadership structures and these can vary from one center to the next. But most often a core will have a principal investigator, or team leader, that is kind of the vision of what the core overall wants to accomplish, the big umbrella.

Often a core will have a bunch of sub-leaders. For example research cores may have several principal investigators, clinical cores would likely have several clinical leaders. And then specific cores will have specific subcomponents. For example outreach cores may maintain a patient registry or, as now it is being termed, health surveillance of patients.

Clinical cores may host grand rounds to teach other physicians or have a clinical training program within it. And then the key personnel within each of the cores facilitate communication among the cores so that you maintain integration.

Next slide please. So all of the NIH centers have a research core. And this is led by a primary investigator who has a vision of how to study a particular disease. So they bring their approach to the NIH, they get reviewed by a panel and if it's meritorious enough they'll get their center funded on that idea or vision.

It will likely include several scientists either working independently or collaboratively and the collective disease expertise will often dictate the research questions that are being addressed. And so that's a really important part of centers of excellence is that the type of expertise you put together really dictates the type of questions you can ask.

So the research core can be themed or have independent research questions and then there are pilot research programs that are often housed within research cores and these provide a really excellent opportunity to train junior scientists. And one of the positive aspects of at least most of the centers of excellence that I researched is that data sharing is often a requirement.

So, for example, in the Alzheimer's disease research centers they have big data sharing and when they have like measures they're able to combine those and really ask bigger questions. And this is something that could greatly benefit ME/CFS.

Next slide please. So within the research cores there are often services to support particular research projects. So these provide the critical infrastructure to ensure productivity and that we use best practices when doing the types of research that we want to conduct.

So you might have personnel and expertise necessary to conduct state of the art neuroimaging, you might have exercise physiologists that are available to do state of the art exercise testing. You might biostatisticians to provide support to the (PI)'s. You might have epidemiologists to do proper survey research. You name it. So these are services that can occur within the cores depending on the center's expertise.

Next slide please. So clinical cores are often designed to house disease specific medical expertise and to apply current state of the knowledge with respect to diagnoses, patient communication, treatment, and medical education for physicians.

They also collaborate closely with research and education cores. So these medical experts may see patients, they may work to improve accurate diagnoses of disease, and educate the next generation of medical specialists.

They may also conduct research themselves and are really critical for collaboration with other centers and, as part of the center of excellence, they can work towards developing and implementing telemedicine models for patient care. So as (Gary) mentioned earlier this outreach and this ability to reach patients that can't reach you can really be accelerated by centers of excellence.

Next slide please.

So the term used by many NIH centers of excellence now is really a combination: outreach recruitment and education cores working together. So these cores really include the (unintelligible) leaders and sub-leaders and they're the life blood, or engine, of the center of excellence. This is where (Mary Ann) talking about an administrative core would probably be housed. This is also the likely home of the heath surveillance within the center and then these cores are critical for engaging the patient community, maintaining a web presence, leading an organized recruitment for research and patient scheduling, as well as coordinating seminars, symposium, grand rounds, etc.

They are also a critical component of the outreach to the medically underserved communities and for developing educational content. So again the integration - this core is going to learn from the clinicians, is going to learn from research, research is going to learn from this core as well as the clinicians will learn from it.

Next slide please. So really depending on the size of the center and its specialty there could be numerous other types of cores. Centers are really, again, designed by the expertise that's brought together by the principal investigator.

So (Mary Ann) put together a lot of the cores that are probably common, or currently existing, at (unintelligible) South Eastern so they probably have an immunology, I know they have biostatistics, I know they have a big data type of cores. But you could also have a neuroimaging core. You can have a graduate student and post-doctoral fellowship training core. You can have a physician training and mentoring core so they - really again, depends on the strength of the application and the expertise that is brought together.

Next slide please. So I think the justification that Ken Friedman put together was fantastic. I think it's clear that centers of excellence for ME/CFS are critical if we are to make substantial and timely progress towards solving this complex disease. Thank you.

(Gary Kaplan): Outstanding (Dane). Thank you.

Woman: Thank you. Very good.

(Gary Kaplan): Next slide please. So we get to the Executive Summary and then specific recommendations. So this is the stuff we're going to want the committees who approve and eventually pass on to the secretary.

So begin with is ME/CFS is a debilitating complex disorder that severely impacts lives of 836,000 to 2.5 million Americans. At least 25% of these patients are either housed (sic) or bed bound during the course of their illness. The illness is more disabling than heart failure, MS, or end-stage renal disease. The loss to the U.S. economy produces ME/CFS is estimated to be between $18 to $51 billion losses in direct and indirect costs.

The disease has received comparatively little research and clinical support from the U.S. government. For example, MS, a disease to which ME/CFS is often compared in published studies and which effects a fraction 250,000 to 350,000 of the estimated - compared to the estimated 2 million ME/CFS patients receives an average of 94 million a year while Federal support for ME/CFS averages only 5 million per year.

Next slide please. The extremely low Federal funding has resulted in inadequate research and very few specialized health care programs.

Therefore, ME/CFS continues to be an illness which A, lacks precise case definition; B, is difficult to diagnose because of a lack of biomarkers; C, is difficult to treat because of a lack of targeted illness specific treatments; D, is misunderstood or not recognized by many health care providers; E, is rarely included in medical school curriculum; F, lacks a medical subspecialty which takes ownership of the disease and provides continuing medical education to physicians; G, is undertreated or not treated in many parts of the United States.

Clearly, current approaches to ME/CFS research and care remain insufficient. To overcome these impediments centers of excellence are desperately needed.

Next slide please. Two recent expert panel reports recommended a multidisciplinary approach to gain understanding of ME/CFS. The NIH P2P and the IOM. ME/CFS centers of excellence are the ideal response to these recommendations because they create an environment necessary, that is, expertise, infrastructure, and medical facilities, to achieve a multi-disciplined understanding of ME/CFS.

Two, creation of ME/CFS centers of excellence satisfies the longstanding and unfulfilled goal to the CDC's CFS Awareness Campaign.

Three, centers of excellence can also provide regional expertise to health care providers in the communities who need help with their patient with ME/CFS. This will enhance the overall understanding and awareness of ME/CFS.

Four, medical schools do not have adequate ME/CFS curriculum content. In some cases it's misleading and incorrect.

Five, centers of excellence being proposed for ME/CFS are similar to other centers of excellence currently funded by the Department of Health and Human Services.

Next slide please. The Chronic Fatigue Syndrome endorses the recommendation to establish ME/CFS centers of excellence. These centers should be comprehensive and include outreach recruitment, social services, patient education, medical professional education, clinical and research components.

Given the complexity of this disease, one of the funding requirements of an ME/CFS centers of excellence should be that the institutions assemble a designated multispecialty team to provide - for the provision, it should read, for the clinical care of ME/CFS patient.

Next slide please. Acknowledging that NIH and other cooperating agencies will ultimately determine the Federal investment, the CFS (SysAc) recommends $60 million of direct dollars to be dedicated to fund 12 centers which will serve patient communities across different regions of the U.S. based on scientific, clinical, and geographic factors.

Funding for each center should be for a minimum of five year period. Centers should be housed in or near academic centers with medical education, research and patient treatment facilities capable of providing health care, professional and community education, and access to additional academic disciplines as needed.

Next slide please. That it? Next slide. Should be one more.

In addition to the provision of onsite patient care it is recommended that centers of excellence develop the capacity to develop telemedicine services to patients who, due to the disability imposed by ME/CFS, are unable to travel to a center of excellence.

It is also recommended that centers of excellence be required to develop the capacity to support community-based physicians at a distance from the COE with both consultative and educational support via telemedicine or any other viable methods to facilitate the delivery of health care to patients within the patients' community.

That's it. That's our recommendations. I do want to emphasize that the $60 million that we're proposing in funding, okay, is specific for centers of excellence. This is not what we're suggesting should be the total funding for research and treatment of Chronic Fatigue Syndrome. So, questions.

Dr. Dr. (Sue Levine): Well, you know, I think a terrific presentation by all of you. What I'd like to say is that, yes, everybody ask their questions and then we'll, I guess, go - we'll discuss specifically the recommendations. The one thing I wanted to ask - sort of say, (Gary) and (Dane), I think the piece that really needs to be emphasized, which you did bring up quite a bit, but I'm not sure what the track record is, say, in other diseases like (Dane), you mentioned Alzheimer's centers of excellence, is outreach. Because really very few patients are really be able to just walk out their door and take a train or drive to a centers of excellence.

I think a lot of effort has to be spent on this outreach bit - piece and, you know, getting the doctors in rural communities really invested in wanting to refer their patients to these centers of excellence. In other words we must work on getting support of these outside doctors who don't know much about ME/CFS in the first place.

What would be their incentive to send patients there, how would they even learn about these centers of excellence? And that whole thing - that link has to be strengthened. In other words you talked a lot in the presentations about, you know, all the different components and those are all fantastic. The bioinformatics and all the fancy stuff, but really, we really need to reach out to those people who may not know about ME/CFS and get them invested in sending their patients to these places and continuing to send them to these places, you know, of excellence. I mean, like, sort of a marketing idea of - so that they're aware that such a place exists, you know (unintelligible) that's (unintelligible) I think is important.

But otherwise, excellent, excellent presentations.

((Crosstalk))

Man: I'd like to comment on that. So here at the Alzheimer's Disease Research Center UW Madison as well as the (unintelligible) center, their continued funding is, in part, predicated on how many people come through their doors.

Dr. Dr. (Sue Levine): Okay.

Man: And who they're serving and how they're interacting with the community. And so they have really done a fantastic job of educating physicians, hosting conferences where citizens are invited in to learn about state of the art technology that they're using and research findings that they have.

They have community events and they really spend a large amount of time engaging the community, reaching out to underserved populations, reaching out to minority populations, and really working that into the centers. It really is an integral part.

Dr. Dr. (Sue Levine): Yes.

Man: And I would imagine that any (RFA) from the NIH, that that would be very strongly emphasized.

Dr. Dr. (Sue Levine): Yes. I do think that that's a critical point. And, of course, all of us have heard about Alzheimer's Disease and fewer clinicians even have heard about ME/CFS or think it's important enough to want to refer a patient there. Do you know what I'm saying?

Man: Right. And I think that is incumbent upon the team to communicate well with the physician community.

Dr. Dr. (Sue Levine): Yes.

(Gary Kaplan): One of the reasons we put in specific recommendations for telemedicine - we envisioned it in a couple of different ways. One is providing seminars to doctors who can't come into the centers and want easy access to it in their office. The second, however, we had this concept of the specialty team being able to provide support at a consultative basis to the physician in distant communities so that they can step up their game in terms of treating these patients.

I think at the basis, docs want to be able to do a good job and they're finding frustration also at not being able to appropriately diagnose and care for these individuals. And now, if we hand them a resource that the center - and we're asking in the creation of the centers of excellence mandate that you actually do community outreach, that you actually have a telemedicine presence so that you can get to more people, fully recognizing that lots of people can't get to you.

Dr. Dr. (Sue Levine): Yes.

(Steve Krachik): And this is (Steve). I think those of us who were on the (unintelligible) years ago with (Debra Woods Dillinger) talked about the (ECHO) program where a doctor could call in to a specialist and actually have a virtual meeting and consult, and that was part of this concept of telemedicine.

Dr. Dr. (Sue Levine): Yes, I think it was hepatitis C.

Man: Yes that is correct. I remember this.

Dr. Dr. (Sue Levine): But I think just given the lack of visibility of our illness, unfortunately. You know, hepatitis C, you know, there are advertisers in the subway for that. Everybody knows about that but the idea that a clinician would actually take the time to, you know, reach out to a center of excellence or, you know, you have to somehow make it very interesting and palatable for that rural clinician.

(Gary Kaplan): I think you reach out to them.

Dr. Dr. (Sue Levine): Right, and give them incentive to keep coming back and continue - because sometimes they'll do it like the one time deal. I've seen that near my office that some clinician will be interested after I send them a consult note.

But then will they follow up or -- this cuts, you know, I just have to -- I think you really have to work on that piece.

But anyway, enough said.

(Gary Kaplan): (Sue) is there a specific wording that you want to put in there or something you want to add?

Dr. Dr. (Sue Levine): Well I guess we'll all discuss that - I'm trying to decide whether we should take a - (Nancy) can we take an early break and then come back at 3:10 say?

(Nancy): Well our break is supposed to begin at 3:00 so it's not that early and we just learned -- this is a new technology we've learned and we thought we could copy and paste things on the white board. Syreeta is going to type them on the white board at break so, it won't be that long. Just the recommendations and then we'll be able to wordsmith and add to the recommendations, take away, whatever you all want. But we do need the break so that we can get these things typed up on the white board.

Dr. Dr. (Sue Levine): Sure, so, like...

(Nancy): So I think it's a good time so...

((Crosstalk))

(Nancy): ...why don't we just come back at 3:15?

Dr. Dr. (Sue Levine): Perfect. Okay.

Man: Thank you.

Dr. Dr. (Sue Levine): All right, thank you.

(Gary Kaplan): Okay, thank you.

Man: (Unintelligible) nobody answering the phone so I'll try to call back...

Man: (Unintelligible) I just called the main line and nobody answered.

Man: Did anybody talk to you on break or?

Man: (Unintelligible). Oh, that's right, anybody in?

Man: I have to go on. Okay, I'm on with (unintelligible) advisory committee. (Unintelligible). They used to go to (unintelligible) these things. The webinar is (unintelligible). You'd think they'd have that nailed down. Still on track to do (unintelligible) tomorrow? Yes, I'll be in after two o'clock. Their East Coast thing (unintelligible) which I (unintelligible). All right, let me talk to (Jen).

Man: I'm calling (unintelligible). I was trying to give you to her, I got lost. Hi (Jennifer) it's (Steve), just checking in. How you doing? (Tom) talked to me yesterday and was wondering if the front desk person could handle some closing process.

Man: Hey (Steve), we can hear you.

(Steve Krachik): When are we getting back together, does anybody know?

(Dr. Montoya): Three fifteen pm or that would be what your time 3:15 pm. This is (Jose Montoya).

(Steve Krachik): About 12 minutes. That'd be in about 12 minutes?

(Dr. Montoya): That's what I heard, yes.

(Steve Krachik): Thank you.

Woman: Hi (Jennifer) are you on the line?

Woman: (Jennifer) are you on the call?

Woman: I'm sorry, (Jennifer) are you there?

(Jennifer): Yes, I am here.

Syreeta Evans: So a quick question while I'm on the white board, the only way to edit - so if you can see what I'm doing the only way to edit is to completely erase the sentence?

(Jennifer): No, you should be able to click your cursor on the thing that you want to edit.

Syreeta Evans: So when I do...

(Jennifer): So, like, okay along the left side you see that you have your different icon options? The second to the bottom is an eraser...

Syreeta Evans: Yes.

(Jennifer): So if you click on that and then highlight, click and drag the section that you want to delete.

Woman: Is there a cut and copy and paste one too?

(Jennifer): Copy...

Woman: Just practice with it Syreeta, see if you can make it work. We just did something that deleted a whole line which, she didn't want that.

Syreeta Evans: Cuts it off and then if I show it in full screen here. So see here, (Jennifer), if I wanted to put a space in here and continue on I can't do that. Is there any way I can?

(Jennifer): So you see the options along the left hand side again?

Syreeta Evans: Yes.

(Jennifer): One of them is the lower case A.

Syreeta Evans: Yes.

(Jennifer): So you click on that and then click your cursor where you want the space and then hit space.

Syreeta Evans: No, it didn't insert. Yes, I'm on the double A here, see it's highlighted. I got to where I want to go and I'm not going anywhere.

Woman: Can you tell what's happening (Jennifer)? (Jennifer).

(Jennifer): I am not seeing it, no. Just a second here and let me take over host control and then - it's been a while since somebody asked me about white board. Hold on.

Woman: Okay.

Man: Maybe for practice on the first line, comprehensive is spelled wrong. Need to take the S out, maybe that would be a good test to see if you can edit it. That's not good.

Woman: Yes, that's what we're trying to avoid.

Man: Yes, that didn't work too well did it?

Woman: No, well it happened once before. Oh, there it is.

Man: It is much easier with in-person meetings isn't it?

Syreeta Evans: (Jennifer)?

(Jennifer): Yes, I'm still here.

Woman: Hello it's (unintelligible). Sorry.

Syreeta Evans: I'm sorry. What I'm going to do is I opened up a Word document here of the recommendations instead of using the white board and I'm just going to share that screen so I can edit from there, make it easier.

Woman: Okay, whatever you think.

(Jennifer): You can totally do that, yes. So you can - let me give you host role back.

Syreeta Evans: Okay, thank you.

Woman: Hi, anybody on the line?

(Gary Kaplan): This is (Gary).

Woman: Hey (Gary).

Man: Yes, (Donna).

((Crosstalk))

(Nancy): We should probably - since this is the voting part -- this is (Nancy) -- we should probably do a role call again.

Woman: Okay, let's see. (Adrian)? (Adrian Casillas)?

Woman: (Adrian)'s line has dropped.

(Nancy): Okay, well hopefully he'll be back. Can we contact him somehow? Or should I just wait another five minutes?

Woman: I'll try to call. I have a phone number for him.

(Nancy): Thank you. Okay, (Dane)?

(Dane Cook): Here.

(Nancy): Okay, (Donna)'s here, (Terry)'s here. (Faith)? (Faith Newton)? (Jose)?

(Jose Montoya): On the phone. Here.

(Nancy): Okay. Who else do we have that we - waiting for (Faith) and (Adrian), hopefully they'll return.

(Gary Kaplan): Then we have a quorum, yes?

(Nancy): Yes.

(Gary Kaplan): Good.

(Nancy): Oh, how many total f do you have?

(Gary Kaplan): Just one.

(Nancy): Oh, I see.

(Gary Kaplan): Just one, the first is the Executive Summary and the second part of it is the specifics of the recommendations.

(Nancy): I got you. Yes. Good. Yes.

(Gary Kaplan): Did you get Ken's email with the details of how that map got created?

(Nancy): Yes, yes. No, it's interesting. Yes, yes because I haven't seen anything like that.

(Gary Kaplan): Yes, he did truly outstanding work.

(Nancy): Yes, yes.

Man: That map was quite striking.

(Gary Kaplan): Yes, I think it was a picture's worth a thousand words, right?

(Nancy): Yes, yes.

So do we have (Adrian) back?

Man: Even the good areas didn't have much penetration.

(Nancy): Yes, urban areas.

And I guess what we'll do, (Gary), is have you read, you know, the first couple of lines and then we can make comments every couple of lines, I don't know, we'll see how it goes.

(Gary Kaplan): Okay.

((Crosstalk))

(Gary Kaplan): I'm sorry?

Man: Oh, it's a technological question. Right now I have it as a small screen in the middle of my...

(Nancy): Right.

Woman: So (Adrian)'s trying - he's on, he's trying to get connected back into a speaking line. So now I'm going to call (Faith) unless (Faith) has joined us.

(Faith Newton): I'm here.

Woman: Okay good.

(Faith Newton): It's (Faith), I'm here.

(Gary Kaplan): You know we could do an entire genomic sequence on a human being in three days now? And we're having trouble communicating with this thing.

(Nancy): I know.

Woman: So (Nancy) I suggested that (Gary) read like a couple lines and then people raise their hands.

Woman: We're here to help. Syreeta's got it up on Word so she can make edits, so you all decide how you want to do it.

Woman: So explain to me again, (Gary), so you've got, like, the main recommendation and then you've got the supporting kind of materials.

(Gary Kaplan): So, prior - so the first several slides are essential the Executive Summary from everything we had done before.

(Nancy): Okay.

(Gary Kaplan): So the first three slides are just the Executive Summary of what we had just talked about. And, so then, specifically we have the slide that begins with the

Chronic Fatigue Syndrome Advisory Committee endorses the recommendations to establish ME/CFS centers of excellence and that's where we - that's the point we're ultimately going to have vote on.

(Nancy): Okay.

Dr. Dr. (Sue Levine): And can you all see that text that's up on the screen now?

(Nancy): Yes.

Dr. Dr. (Sue Levine): You should be able to see it. (Gary) can you see it?

(Gary Kaplan): Yes.

((Crosstalk))

(Adrian Casillas): Yes, hi it's (Adrian), I'm here now.

((Crosstalk))

Dr. Dr. (Sue Levine): So all you really need to do is just decide if you want to keep these different parts of the recommendation at written or if you want to wordsmith them, add new, etc.

(Nancy): Yes, I tried to recall how we've done it previous times. I don't know why it seems like it's been so long ago and then we had...

Dr. Dr. (Sue Levine): Well, I think it differs with each set of recommendations because each of them are…

(Nancy): Yes.

Dr. Dr. (Sue Levine): ... sort of in different formats, etc. So you all just decide. I sent these to everyone yesterday in the form of the PowerPoint so they could look but they can also look at what's on the screen now. I also sent everybody the PowerPoint -- well, I think I thought -- I sent something yesterday and then I know I sent the PowerPoint, this whole PowerPoint, earlier this afternoon so it's available to the members.

(Gary Kaplan): And I need to warn you at the - in the process of crafting this recommendation I went back and forth several times with the committee. I'm betting somewhere around half my committee are editors and English majors so moving a comment is at your peril.

(Nancy): Well I think (Gary) and tell me if you guys disagree that you should, like you did with your discussion just now, is maybe provide the rationale at the top, you know...

Woman: That will be sent to the secretary as part of this.

(Nancy): You want to do that as a background thing, okay.

Woman: We have been sending forward a rationale or a background with each of these sets of recommendations.

(Nancy): Right, right. So you think - I'm just trying to decide the order of the little sentences that you have underneath that first sentence. So, does anybody - I guess what we could do is decide, I mean, not only on the wording or whether the order is appropriate or should certain things be said first. Should certain comments be made first? Or...

(Gary Kaplan): Whatever you think is...

(Nancy): No, I'm asking for all of you guys to just give us some input.

(Carol Evan): This is (Carol Evan), I'd just make a comment and perhaps I'm stating the obvious. You know, obviously this is really important and centers of excellence have been proposed by (SysAc) in the past and we really, I think obviously, want to do everything we can for (HHS) to come back with a positive on this.

So I would say, and this has been worked in much detail by the committee, I think this the place - if there's ever a time when we need the (unintelligible) who are (unintelligible) now. You can help serve us by noting elements here that may be red flags in your organization. Maybe sensitive issues within your organization, and not that we would necessarily change these in order to accommodate what you're department would desire but I think it's helpful for us to at least be aware of where the sensitive issues are so we can potentially address them here before they go to (HHS). So I would really encourage our seven (unintelligible) friends to speak up here on sensitive issues.

(Faith Newton): That's a really good point (Carol). This is (Faith).

Dr. Dr. (Sue Levine): Yes, I agree with that also and I think, furthermore, that - I have one more question and I know that the time is getting tight but (Gary) or any of you, have you envisioned somebody quarterbacking the multidisciplinary team. In other words like when you - so you send a patient to Mayo Clinic or something, there's usually like a doctor that, you know, or internist or somebody who just takes everybody's information and puts it together. Like, in other words, will the patient, for instance, and this is a detail, be assigned to one kind of doctor that collects the information from the different specialists and then sends it to, let's say, the referring doctor.

(Gary Kaplan): Ultimately I think there has to be, unique to each individual center in terms of how they manage their patient flow and their information. I don't know if we can specifically - or should we because I'm not actually sure what the absolute best way to do it is.

Dr. Dr. (Sue Levine): I know because when you say designate multispecialty team, I'm wondering is there a head person on that team to kind of collate the information and put it together - I don't know, for some reason that's important to me but maybe it doesn't have to be in a recommendation really but I'm just trying to envision the structure better so that there can be better communication, you're not going to communicate with all the members of that team, but with one person to the outside world. But, anyway.

(Gary Kaplan): (Dane) you going to address that?

(Dane Cook): I'm not sure I understood it fully.

Dr. Dr. (Sue Levine): Yes, you know how like, obviously, because this is such a multi-systemic illness you have, and I've seen it before where, let's say, a family practice physician or an internist will sort of quarterback, meaning be accountable for all of the multi-specialty input on a specific patient. Let's say that person goes to gastro, cardiology, neurology. That he or she will be in charge of getting the consult reports from all those different people and perhaps threading it together in one narrative report that then goes out to the referring provider. I don't know. I know it seems like a detail but I'm just...

(Dane Cook): I think I agree that in practice that's how it would. I don't see how it fits in the recommendation though.

Dr. Dr. (Sue Levine): Right, right. But I think I just want to be precise in the language. Instead of saying designated multi-specialty team. I'm not - but feel free to jump in and I guess let's get started on, do we like the order as you have it here? Why don't different people weigh in on that?

Man: (Sue), it would be helpful if they'd make it a full screen so we can see the entire Recommendation.

Dr. Dr. (Sue Levine): I agree.

Man: You can make it a full screen, I found at the very bottom that there was a thing called - so at the very bottom in the - there's a percentage sign in the middle of the things and you can, if you click on that, it's a Zoom In, Zoom Out, Fit In Viewer, or Percentage. And if you do that...

Dr. Dr. (Sue Levine): So that's 70%, right?

((Crosstalk))

Man: And we have the whole thing in my viewer. I actually just hit Fit to Viewer and the whole thing was there.

Dr. Dr. (Sue Levine): Okay. I see it. I got it. Yes.

Woman: She has now shared a Word document and you should be able to see this. I'm looking at the webinar and I'm seeing the whole thing very nicely...

((Crosstalk))

Woman: ...based on what Syreeta just did.

Dr. Dr. (Sue Levine): Okay, why don't I do this? Why don't you, (Gary), read the first two lines and why don't people just chime in to see whether we want to keep that or not. Does that make sense or - that's how we'll get through it.

(Gary Kaplan): Actually, before we did that I want to go back to something (Carol) was saying as the other advocates are taking a look at this, is there anything glaring on this that you're looking at, saying, "Boy, they missed this, or this should have been put in, or this language is going to give us trouble."

So is there anything just at the quick overview of this on these seven recommendations. Is there anything from the patient advocate groups that are sitting there saying we disagree with this or no this looks okay.

Man: Or the (unintelligible).

Woman: I think you must have accessed the (unintelligible) - the department (unintelligible).

Man: The (unintelligible) yes I'm sorry.

Woman: I just want to echo that - I mean we could certainly go through this sentence by sentence - you know, at the end of the day this is not going to fail or pass at HHS because of a word or a comma. What I would really ask is you know what are the odds of this being approved - what do we anticipate as a group from a top down perspective is being the impediments to this being passed and make sure we cover those issues.

I'm not sure of the answer to that other than - I mean or perhaps the answer is just so obvious it's the elephant in the room. We've got to help - NIH has to find $60 million. I mean at the end of the day is that the issue here?

Man: Yes.

(Stath): That's a really good question (Carol) - this is (Stath) - I would agree. Is that the ultimate question at the end of the day regardless of the recommendations we make.

Man: It has always been.

(Gary Kaplan): Yes it is and you know, but so we've - we asked what we considered big on this because we want 12 centers, if they give us eight centers we can talk but we gave them what we felt would be the ideal situation within reason.

So we certainly - you know ideally we want we ask for and we're giving them some guidelines to go by. I can tell you that my sense at NIH is that their receptive to this - how much money they're going to give and what the budgetary constraints are I don't know.

But I also tell you that the other place that this can go is that the community can then use this document to help advocate their position and say here's the specifics of what we're looking for. We don’t want just more funding, here's what we want the funding to do and here's the specifics how we can do this.

So if you're going to Congress and you're going to your representatives and saying you know this is what we'd like to see happen. This is a reasonable ask. That make sense.

Man: Yes well…

Woman: Amen to that (Gary) - I mean you guys have nailed it with this proposal and we will certainly use this document in that way and at the same time - you know let's get the money.

So you know, that's really kind of my core question here. I think the case you've made for this is just water tight. You know that is irrefutable. So I just want to make sure we're focusing on the right thing.

(Gary Kaplan): Well that was our objective - our objective was to make this as tight as possible with the evidence available and say okay here it is. B2B said it, I've said it and by the way we have an underserved population which I think was a brilliant argument on (Ken)'s part and time to allocate the funds. We got a big problem, needs serious funding.

Woman: Do you have anything in there about the underserved population in this - on these two pages. I do think that's a strong aspect of it.

(Gary Kaplan): It's in the executive summary above.

Woman: Okay.

(Gary Kaplan): Let me see if we specified down here. Yes it's in the executive summary above.

Man: It goes with the recommendation as the justification.

(Gary Kaplan): Right.

Woman: Can you tell me (Gary) is the $60 million expected to cover the five year period or is it $60 million per year times five years.

(Gary Kaplan): (Dane) you best came up with that answer - I think the answer is five years, but (Dane).

(Dane Cook): It's five million per center, so that's 12 times 5 would be 60 so that'd be a million a year per center.

(Gary Kaplan): Right.

Man: That we are arrived, too, correct - yes.

(Gary Kaplan): Yes.

(Dane Cook): Per year or five years.

Woman: One million per…

(Dane Cook): One million per year.

Woman: Got it.

(Dane Cook): Per center.

Man: One million per year for five years per center correct.

(Dane Cook): That's correct. So each center would get five million bucks to spend over the five year period.

(Gary Kaplan): And I want to also emphasis that (Dane) has up to put in the direct dollars which is a very important phrase because the institutions skim off 40 to 60% of the grant for their operating expenses. So whatever they want to skim off they can skim off, but we want a million dollars left after that per year for the center to do what it's supposed to do.

(Dane Cook): So in realty you're talking about another 50% on that that the NIH would have to budget.

(Gary Kaplan): Correct.

Woman: So I would only recommend with the wording that maybe we would want to say (unintelligible) recommends 60 millions of direct dollars to be dedicated to fund 12 centers for a minimum of a five year period or something like that just in case it's a question to others. I don't know that…

(Gary Kaplan): Number four right under that says funding for each center should be minimally be for five years.

Woman: Right.

(Dane Cook): But it doesn't.

Woman: (Unintelligible) I thought you wanted five million for the next coming year and then another - you know per center. I thought you wanted five million per center. I don't know if anyone else…

Woman: You should work on wordsmithing that.

Man: I had the same issue too.

Woman: You did too.

Man: Yes, how do you just say 60 million to direct funding dollars to be dedicated for 12 centers over a five year period.

Woman: Right.

Man: In five years.

Woman: Okay does anybody want to capture that.

(Dane Cook): I think that's a mistake because you don't want - we need to have the opportunity for renewal. You need - the minimally for five year was very intentional.

Man: Okay, but I think you need to say (unintelligible) which is a million dollars per year per center or something to explain what the five years is.

(Dane Cook): I don't - I mean if it's an NIH center we are talking very standard language there.

(Gary Kaplan): Yes that language is - was used specifically to be in conformity with the way NIH funds things.

Man: Okay.

Woman: You're saying (unintelligible) it.

Man: But it doesn't say whether it's $60 million per year for five years, one million dollars per - I mean it doesn't specify what it is and that is confusing.

(Gary Kaplan): Not the NIH. (Jose).

(Jose Montoya): I think it would not hurt if we specify that what we're asking is one million per year for at least five years per center times per center. The idea of making it least five years is because when you get the funding it takes about one year to assemble the team and everybody so the first year is kind of gone.

Between year two and year three you are collecting the data and year 4-5 is to the analysis because we are talking about the big data. So the centers will have a fair shot for five years to demonstrate that they have the capacity to use to advance.

And meanwhile because if the center proves by year five that they are performing at a high level then obviously should be open to renewal, but I think that it is there and maybe (Gary) would just specify further so that there is no confusion, but minimal five years you need to have that fair shot that time and meanwhile because if the center is performing that it should be renewed or could be renewed.

(Dane Cook): The only thing I would say to that (Jose) is that if you don't get 12 centers applying you've limited the other centers to less than $60 million.

Man: What you could do is in the one where it says funding per each center should be minimally $1 million a year for a five year period.

(Dane Cook): That's better.

(Gary Kaplan): Okay.

(Jose Montoya): That's better sure.

(Gary Kaplan): So we need the wording on it.

Woman: So (unintelligible) see $1 million per year for a five year period.

(Gary Kaplan): So funding for each center should be minimally $1 million.

Woman: Per year.

Woman: You know how it should minimally be. I think it's should be provided at a rate of one million - I don't know - doesn't that dramatically sound. I don't know.

(Gary Kaplan): I'm not going against this group of English majors. I'm here to tell you I've already been there. So whatever you guys think sounds proper English, but certainly putting in funding for each center should be at a minimum of $1 million for a period of no less than five years.

((Crosstalk))

Man: And that means if they choose to do six centers they still have a funding base for it.

(Gary Kaplan): Yes so can somebody put that in.

Woman: So no less than a five year period.

(Gary Kaplan): No less than a five year (unintelligible). But how does that now get put on the board.

Woman: (Unintelligible) is working on it.

Woman: (Rita)’s working on it. I think she's got $1 million per period and it should say $1 million per center.

Woman: Right.

(Gary Kaplan): Per year.

Woman: Per center, per year.

Man: (Unintelligible).

Woman: There we go.

((Crosstalk))

Woman: I don't know she wanted to keep in the five year.

Man: Yes.

Woman: For a five year period.

Woman: What did we say for at least a five year period, right.

Man: Right.

(Jose Montoya): Yes also for a minimum of five years.

(Gary Kaplan): Okay, but I've got no changes coming up on my screen.

Woman: Oh you don't.

Woman: (Gary) some people had to sign off and sign back in I've been told. We're all seeing this editing going on if you're not.

Woman: Did it come up as sharing (Gary). If it came up as sharing, hit the sharing. That's what I found I had to do.

(Gary Kaplan): Where was sharing.

Woman: Right here.

Woman: For a minimum of five years I think.

Woman: Just right click on minimum it'll spell it correctly. There you go.

(Gary Kaplan): I got nothing. So where am I.

Woman: So you're not seeing this.

(Gary Kaplan): I'm not seeing any changes no.

Woman: So (Jennifer) can you help Dr. (Caplan) with this to see - because he unlike the rest of us is not seeing the editing going on.

(Jennifer): Yes I can pull his (unintelligible).

Man: Do you need a little (unintelligible) about where they're housed. You lost your bullet or whatever it was.

Woman: What did you say.

Man: Where the next paragraph right below where it is the center should be out - you lost your bullet.

Woman: Oh a little hash thing yes.

Man: He lost his (unintelligible). There you go.

Woman: I think it should be for a five year period.

Woman: Or a minimum of a five year period.

Woman: We already said minimum.

Woman: (Unintelligible) for at least five years I think, at least five years.

Woman: I leave the English majors to it too then.

Woman: Yes it's for a minimum of a five year period. So for a minimum of and then A should be in there - five year period.

Woman: There we go.

Woman: Please scroll up and see maybe start - so we don't start in the middle maybe. I know we zeroed in on it because that's where the money is, but…

Woman: Can we number them too.

Woman: That's a good idea.

Woman: Like the first one.

Woman: That's a very good idea yes.

Woman: The first recommendation or something.

Woman: That's a very good idea.

Woman: Well I'll jump in with two questions. The first one is it says that we are endorsing the recommendation. I'm assuming you mean we're endorsing the work group recommendation, but my understanding from last year is that's not how it should be wording.

We just recommend - we at (unintelligible) recommend establishment of centers of excellence. Unless you're saying you're an endorsing something that the P2P said or something that the IOM said, but I don't know that they were specific about that.

(Dane Cook): I think (Donna)’s right on that one.

Woman: Yes I do too. (Donna)’s right. We need to take out the endorsed word and just say…

((Crosstalk))

Woman: … somebody recommends the establishment of ME/CFS centers of excellence.

Woman: And then after the (unintelligible) we put in (unintelligible) in parenthesis I think right after that. Don't you think so that way that's how we can refer ourselves in the rest of the thing.

Woman: (Unintelligible) can we recommend.

(Gary Kaplan): The establishment.

Woman: The establishment of and she can delete the rest.

Woman: I'm looking forward to hearing what the (unintelligible) says too. I just want to ask one last question. Do you have any idea how many patients you expect each center of excellence to be able to serve.

Woman: Well I guess we could estimate from the background document which shows the population distributions at least according to that one reference. I guess that's something that belongs - that's in the background documents.

(Gary Kaplan): Yes.

Man: Hello do we have information on chronic fatigue patient's by state.

Woman: Well that nice geographic document which was (unintelligible).

Woman: Yes (Ken Freidman)'s geographic document I think is great if we can use that.

Woman: You all can put together a background document that contains the information you'd like. I recommend against it being a power point presentation and rather should be a text document which can have photos and graphs and what not and maps.

Woman: And that could be done separately outside this meeting correct.

Woman: Yes because they are not recommendations they're just a background document.

Woman: All right so we don't have to worry about that now.

Woman: I guess my question is - we know that they're long waiting lists to see Dr. (Montoya) to see Dr. (Klimas). If we were so lucky to have 12 centers of excellence provided and we have more than a million patients. How many patients do we think are going to be able to get care through these 12 vendors. I mean what dent will we make in this is - do we have any ideas is the question.

Woman: Well presumably with the telemedicine piece you'll be able to reach out to even more people, but I'm not sure how one can estimate that number. And it sounds like maybe certain communities will have a greater density of these places, like if we're not seeing many people that's really true in the middle of the country - you know the higher prevalence might be - for whatever reason - I don't really buy that.

You know what I mean - like I think there should be a couple of (unintelligible) closer together where there's a denser population of MECFS people, but I'm not sure how accurate that document is. I don't know how to assess it.

Man: (Unintelligible) per center.

Woman: What did you say.

Man: I said (Daniel Kloss) in Michigan at the - in the area where there's a zero (unintelligible) so I doubt that's accurate.

Woman: Yes I would find that odd, but I mean it's interesting, but anyway I'm sure that would be a factor that you'd have to estimate the prevalence to decide whether it's worth your while. But I think the telemedicine component reaching out to these other communities will be important in terms of the funding.

Like as you say if you make the centers countable for how many people they can grab in from the outside communities they can get correspondingly more funding if they see more people at their center, they can ask for more funding. But all those people don't have to come in physically to the center if they do this outreach thing. Do you know what I mean.

Man: Maybe we could…

(Gary Kaplan): (Unintelligible) affect from these things.

Man: Maybe we should look at the (unintelligible) they got for the ECHO program for just hepatitis C and multiply it.

(Gary Kaplan): Well, but I don't know - there's actually - let me bring up a different topic for a moment because actually I don't know that we're going to be able to come up with those numbers. But (Lilly Chu) just sent me an email - she sent it to several of us - did you see that.

Woman: Yes.

(Gary Kaplan): Saying the median amount given per year for one center of excellence was $1.7 million in 2002 equaling $2.2 million in 2006 dollars. IOM report 2004. So $5 million over five years for one center is not a lot. In fact for five years 25 million would be better. (Ian Lipkin) has suggested five million per year per center when I spoke to him in 2014.

Woman: Okay and how does that fit into what we're writing right now that we want to focus on better.

(Dane Cook): Your saying our number seems low.

(Gary Kaplan): Yes.

(Carol): This is (Carol Head). You pull out your calculator and you do the math and you know it is clear that 12 centers will not be able to accommodate every patient in America. So I'm not sure that's - you know - I think the issue is I think we ought to go forward with this. I think getting 12 centers would be phenomenal. That will not be sufficient, but we grow from there.

((Crosstalk))

(Gary Kaplan): Once you've got centers around - first of all this (unintelligible) disease once you've got centers of excellence. Second is you start educating everybody in sight about this stuff by virtue of the moneys being there. Money by the way attracts both clinical and bench researchers.

So I think there's a huge multiplier effect by virtue of COE's. You don’t need to worry about them servicing everybody, but rather them creating the opportunity for everybody else to get service.

(Jose Montoya): It's a way to start right from basically zero. I've seen the COE's is the most expedite pass for finally connecting any CFS patients with 21st century medical care innovation and research and then one of the components of the COE's is the location. So you could also ambition having (unintelligible) from other places coming and spending four weeks seeing patients at each center and then taking that doc to the community center - the patient.

But we have to start somewhere and I think that because all what is happening in this disease for 35 years there is a lot of things that are happening in medical and in research obviously and new technology that has never been connected to any CFS patients. So this is the most swift and expedited way to finally have these patients getting the benefits of what we call - you know 21st modern medicine.

Woman: Yes I agree. I think it's a good place to start.

Woman: So the question is the dollar figure enough.

(Gary Kaplan): That I think is the more pressing issue.

Woman: I don't know how we would ever know that. You know how we would ever know.

(Jose Montoya): Well I think the only thing is like you could make a (unintelligible) of an older centers of excellence, but they had already - they are already established and I think when you start from scratch - you know you always need a minimum amount of money, but I think as a starter I think that's a good option. Perhaps we can have a statement where should the center prove to be productive and have growing needs.

That the amount of funding be considered to be (unintelligible) later on. But I think that you know throwing 2 or $3 million per year in a center when there has been nothing - all these centers are going to start from scratch right, maybe here a sample we have some (unintelligible) we have been kind of like modeling after centers of excellence kind of idea, but most people, if not all our (unintelligible) will start from zero.

So I think that you have to throw out a reasonable amount of money that you are taking a risk as well. I think that one million per year is reasonable as a starter.

Man: At the base of (unintelligible) emails she points out that we paid 35 million for one (unintelligible) or at 35 (unintelligible), so maybe we do two less (unintelligible).

Woman: I only concern about not asking for enough money would be to them have failure because of insufficient funding and then it looks like the centers of excellence didn't work. So I don't know if there's a way to make sure that we're asking for enough money without being - you know without over pricing ourselves right out of getting any consideration whatsoever.

(Carol): This is (Carol). One question is a million dollar per center per year appropriate and I would ask those two are more knowledgeable than I about cost to establish these kinds of facilities. If there (unintelligible) from other centers of excellence. A million dollars per year per center sounds low to me, but I don't have any data to back that up.

(Dane Cook): This is (Dane). In my research of the centers throughout the NIH and going into private centers and things like that, it was often centers where five million a year, but I would imagine - I would not be surprised if (unintelligible) choose number that the median was much higher than that - I would not be surprised if that was true at all. If you look - I was just searching really quickly.

Current use of center awards and just brushing through the median in 2004 or the average in 2004 was like about two million a year. But it depends on the center mechanism used. If it's a U mechanism or a P mechanism. So there are a lot more variables than just - you know - it's a center of excellence and this is exactly what it should cost. I would view the million dollars a year as a minimum as (Jose) pointed out to get started.

Woman: So recommends a minimum of 60 million of direct dollars. I don't know if that covers it.

Woman: And then you want to tack something on to be - and afterwards if there's some indication that more is needed or that the money has been used successfully. I don't know how to phrase that exactly.

(Dane Cook): I think we're talking about two different things. I mean if we want to get the - if we think 60 million is a useful target and we could fund either more centers or less centers per year or do we think that 60 million is a low target and we should be doubling that. I mean...

((Crosstalk))

(Dane Cook): We struck a balance between a reasonable request, something that we felt was needed and was really a minimum of where to start.

Man: And that 60 million is not 60 million. That 60 million is direct dollars.

(Dane Cook): Yes it's probably like 100 million.

Man: Yes.

(Dane Cook): In reality because we want the cost for the…

(Gary Kaplan): (Unintelligible) skimmed 60% off the top. I don't know what Stanford is taking. Georgetown takes about 45%.

(Dane Cook): I think UW's around 58 so.

Woman: Well do people want to think about that.

(Dane Cook): Listen (Gary) they don’t take it off the top, they take in addition to.

(Gary Kaplan): In addition to yes.

Woman: I think it makes more sense to put out there that depending on how the centers perform than that amount can go up. I mean.

(Dane Cook): Oh I don't - that's a rabbit hole you don’t want to go down.

Woman: Okay.

Man: (Unintelligible).

Woman: Well since you all were saying that - you know - we're not asking for enough I thought - you don’t want to be too greedy or that’s not the right word, but you know. You want to show them that you want to prove yourself that you're going to work hard at this and then you know when you succeed you can get more money. You know - I don't know what the right approach is.

(Gary) Well once you've actually got these things funded you now have a lobbying group and so they're going to be going back saying we need more money for this. Now you've got to get constituency.

Man: You'll also have a lot more data.

(Gary Kaplan): Yes.

Woman: That’s why it seems to me we should ask for more money. I mean we've used this argument in the past asking for I think a seven million dollar RFA hoping that it would do something and we still got the same answer.

That was two years ago, but what amount of money do we really need to make this successful and to have it make a difference. I don't want to just throw in a low number because we know that they're not going to give us any money. I want to say what we really think is needed to do the job.

Woman: But I (Donna) I just - my problem is I don't even know how we arrive at these numbers.

(Dane Cook): I mean you can start to think about from individual project perspective. I could say that the research program alone could be a million dollars a year and that - you know that is not counting in what the clinical core would cost or what the outreach in education core would cost. So we could be low here and it's really - but the exact number - no one knows what the exact number is.

(Nancy): I have a question and that's based on sort of my ignorance of how academic centers are funded. So you and (Jose) and some of the others might have a better idea. My understanding is that a center of excellence is really a base or a core funding and the expectation is that the investigators particularly for the research part of that function, the investigators make additional applications for specific research.

(Dane Cook): Yes that and so…

(Nancy): So this is a core grant.

(Dane Cook): So this is true - that's true in part (Nancy). So the original chronic fatigue syndrome centers were the center itself was made up of an application that included individual RO1 applications. And so it is true that you would have a core amount of money, but the application itself would also have research dollars in it initially, but it also true that individual investigators would also be expected to grow their research program independently to grow the center.

(Gary Kaplan): Right typically...

((Crosstalk))

(Dane Cook): You are going to have some research dollars within in a center of excellent.

(Gary Kaplan): Right.

(Dane Cook): And you're going to have clinical dollars and you're going to have infrastructure dollars as well. Does that help.

(Nancy): Yes it's that the researchers are expected to contribute additionally to the center of excellence.

(Dane Cook): Most often.

(Gary Kaplan): Right your researchers typically have a percentage of their salaries covered by any one grant. It's very rare that a grant covers all of somebody's salary.

(Dane Cook): So in my researching of all the different centers of excellence and the different models that were used, there is a lot of diversity in how they are conducted even within just the NIH, but also outside of the NIH. There isn't - there wasn't a cookie cutter recipe that I could find.

(Gary Kaplan): (Jose) how far would a million dollars a year go at Stanford.

(Jose Montoya): Yes so the NIH (unintelligible) rate here is between 56 and 60% , but that's not what we're talking about.

(Gary Kaplan): No.

(Jose Montoya): And I think that - I think it was (Nancy) who said it right that money - the $1 million that you have in your hand to distribute to pay other faculty - the times (unintelligible) fellows to pay for projects. You came up with the idea that there is another MRI technology or technique that could see things in the brain of the patients that have (unintelligible) and you have to obviously pay for the actual MRI's.

You have to pay for the fellows who are performing it, for patient recruitment. All of the things that this research costs, but also you need to during that period that you are being funded apply for research grant. So you're not going to stay with just the $1 million a year, but you have to multiply that money by applying to other funding sources.

So $1 millions, it is on the low side - something that an anonymous donor gave us about seven or eight years ago - $1 million a year for five years and that really helped us a lot. But it is on the low side, but on the other hand we want to strike a balance with not being too greedy and going nowhere.

Maybe should we just say $1.5 million a year for five years minimum and start there. So that's the money that - you know if you look at RO1's and RFA's in general for grants for (unintelligible) grant this is - you know two hundred thousand, three hundred thousand dollar project that leads you very - they allow you to go very little far. So for something like that I think that one million - 1.5 million should be enough to start. I'm not talking about functioning at a higher level later on, but to start.

Woman: Did you guys say you wanted some of the (unintelligible) like maybe (Vicky). Do you have any comments. Estimate. (Vicky) on the line.

(Vicky Whitamore): Yes I'm on.

Woman: Okay what do you think. Do you want to comment.

(Vicky Whitamore): Well it's difficult to comment I think because when we, for example would put together a request for applications we think about the specific components that we're asking for and then try to determine what the appropriate funding level is.

So and I think - you know as (Dane) said - these centers or whatever they're called across NIH can have very different infrastructures and structures to them because they are composed of very different things. Cores, databases, whatever. So I think to be honest and to comment in general on the NIH budget everybody is very nervous about the budget right now.

Not knowing what our budget is going to be for fiscal year 17 and not knowing who the next president is going to be. So I think being realistic, but being not greedy is the word that you've been using and I don't mean that in a bad way. But being realistic about what you think would be required to run a center is where you should land and I think - you know I think it's - in my mind a million is the minimum.

I don’t' think you could so what you're proposing here for any less than a million. You certainly could always do more with more funding right. So I'll just kind of leave at that. I think the only think that I'm a little concerned about at this point in your discussion is that NIH typically does not fund clinical care.

So if you just think about a center that we might establish there could a clinical component that would have clinical protocols and would bring patient's in to participate in a clinical protocol which could include a lot of testing, a lot of things to come to a diagnosis and helping to develop or to test a treatment but that's different than clinical care. Great clinical care.

So I think you just need to keep that in mind as well as you're talking about this because like I said NIH is not going to fund clinical care. We would fund clinical studies and clinical research.

Woman: Right, right.

(Dane Cook): That's a good point.

(Gary Kaplan): Yes.

((Crosstalk))

(Gary Kaplan): It sounds like we need to ask for more money.

Woman: So I think what you - here's my opinion and this is my opinion not necessarily others, but I think what you have here is good and I think that if NIH were to take this and now develop a center of excellence they're going to say - they're going to look at what is the minimum dollars that would be needed to make it be successful. And I heard that discussion and I think that - you know certainly NIH would want to set up center of excellence with insufficient funding such that they all would say that would be a (unintelligible) exercise. So I think you're wording here of a minimum of a million per center is sufficient.

(Dane Cook): Thank you.

Woman: Thank you.

Woman: Does anyone know why the centers of - I think there were some centers of excellence in the 90's that apparently either failed or didn't continue to get funding.

(Dane Cook): They discontinued the funding.

(Vicky Whitamore): This is (Vicky) again. Those were funded by NIAID, National Institute of Asthma and Infectious Diseases and we've had discussions about that. My understanding from them is that they were independent centers.

There was no communication or collaboration between those centers such that they felt - they felt and obviously this is before my time at NIH - they felt that they were not successful because each one did their research, but there wasn't a network that was established. And I don't know if there is more to that story likely so, but that's what I know about that.

(Dane Cook): This is (Dane). I was involved with one of the centers, the one in New Jersey. To my knowledge that's fairly accurate. There was not a lot of cross communication between the centers other than I think a couple of meetings that were had. And so yes it was largely driven by the PI's idea of what types of RO1's needed to be put in for each center and I think there were four per center that were funded for RO1's per center.

(Gary Kaplan): So quick vote are we happy with this number in leaving it here as the beginnings of this process with NIH or do we want to increase the number.

Woman: Well I'm happy with it. I think you know (Vicky) knows what's right and you know - of all of us I think she's got a good idea of what's reasonable. So I think I'd go with that myself.

(Jose Montoya): And I think we are saying a minimum, we're not saying one million. I said a minimum.

(Dane Cook): I think historically speaking we are asking for 12 times more than we currently get annually just for the centers of excellence. So I'm kind of weighing that in the back of my head because I was a little swayed to increase the money because I do think a million is a minimum, but we're also asking for 12. So I agree. I think that this is a reasonable start.

Woman: And we just the word minimum in front of 60 million as well then just so that they correlate. (Unintelligible) recommends a minimum of $60 million and then later we say again it's a minimum of one million per center for five years.

Woman: Yes that change should be made.

(Dane Cook): Yes I agree. That's fine.

(Gary Kaplan): Good, completely agree. And then the other question I have is number four when we put a minimum of one million percentage per year, should the million also reflect as above direct dollars.

Man: Oh yes.

Woman: Yes, yes

(Gary Kaplan): And then Number 4, we go to at a minimum of 1 million.

(Steve Krachik): Four should be, funding efforts should be (unintelligible) x dollars at a minimum…

((Crosstalk))

(Gary Kaplan): That's $1 million of direct dollars per center of direct dollars. Yes, you don't need to put the word dollars in there.

Man: Yes.

Man: Yes.

Woman: Yes, you would…

((Crosstalk))

Man 6: We'll put million dollars in direct costs.

(Gary Kaplan): Direct cost, yes, I'm sorry.

Man: (Vicky), do you think there's wording in there that makes it sound like we are trying to set up clinics as well then? Or do you think it's clear the way it's written? Because I didn't understand it, obviously.

(Vicky Whitamore): So I think referring to clinical care, I don't see it in your recommendations, but it - I do remember hearing it somewhere.

Woman: Well, maybe in number one, where it says clinical and research components, maybe - oh, well we're not...

(Vicky Whitamore): I mean may…

Woman: … asking for money for that though. Okay. I don't know.

(Vicky Whitamore): I mean maybe it was more in the way you were talking about the number of patients that could be seen per center and to me that part of your discussion sounded more like you were seeing patients for clinical care.

(Steve Krachik): Well look at Number 2…

(Vicky Whitamore): Not…

(Steve Krachik): Number 2 says that I think.

(Vicky Whitamore): Clinical care, right. To provide clinical care. And I think that that is something NIH is not going to fund is providing clinical care. They would provide funding for - individuals with NECSS to participate in clinical studies…

Woman: Clinical research. Yes.

(Vicky Whitamore): …and clinical research.

Man: So, change the phrasing to multispecialty team…

((Crosstalk))

Woman: But I mean, you're not asking for that money from NIH, but you're still going to provide clinical care, right (Gary)? I mean, you still envision it as providing clinical care even though that money won't be from NIH that's covering that aspect of it.

(Gary Kaplan): We - without question, we would like the Centers of Excellence to have a clinical component to them.

Woman: So I think it's okay to leave it in. You're not asking for money from NIH for that, you're just describing your center.

(Steve Krachik): Yes, and the tele medics portion is going to be for both research and clinical so that's part of it and that's going to require…

(Vicky Whitamore): So you're - you're saying (unintelligible) requirements in Number 2. So to me that reads that you're looking to fund clinical care.

Woman: Right, that's true. Yes.

(Vicky Whitamore): But I don't disagree that it's important to have a clinical care component of the centers, but that's - you know, and like I said, there's certainly a way to develop clinical protocols where patients come in and get lots of tests and results of those tests and all kinds of things are part of research but that's different than providing clinical care.

Woman: So if-given that we do want a clinic - we would ideally have clinical care at each of the centers and NIH doesn't provide funds for that, what agency is most likely to provide funds for the clinical care at these COEs?

(Vicky Whitamore): So typically, what I'm familiar with is that a center would access insurance and other ways to pay for things that are routine clinical care. There really isn't an agency, unless someone else knows something I don’t, that will just give funding for clinical care that's not part of a research study or a clinical trial.

I was looking and the majority of the - for example, the MS centers and the clinical care there is supported the MS Society. So I think that there are just a lot of different ways that clinical care can be provided for beyond NIH funding. So it might even just be…

Woman: So it might even just be a private hospital system?

(Vicky Whitamore): It could be, but I would think that even a private hospital system would want reimbursement for things that were considered routine clinical care.

Woman: Yes.

((Crosstalk))

Woman: They make profit on seeing patients so they need to figure out how to do that in the COE. I would think that Number 2, we could just remove the word funding and then we're just requiring that the COE assemble a team to provide care. Maybe we can say also they need to figure out how to fund it, I don't know, but we don't need to ask for funding for it. So if we remove the word funding, does it accomplish what we want?

(Steve Krachik): But you could always remove the care and put clinical research, then you got to have patients in clinical research to get that...

((Crosstalk))

Woman: I like that idea.

((Crosstalk))

Woman: Make that into clinical research of NECSS patients?

(Steve Krachik): Because to do clinical research, you've got to provide clinical care.

Man: No, you don't.

Woman: Not necessarily.

Woman: No, you don’t, no.

Man: No, you don't.

Man: No, you don't.

Woman: No.

Woman: Is the word funding the problem (Vicky) or no?

Man: Yes.

Woman: I think you're right, I think I would remove the word funding.

(Vicky Whitamore): Yes, I think - the way it's stated there, yes, I think it is. I would either - so it's really two things right? You want to fund clinical research and in order to do that appropriately, you'd need a multidisciplinary team to do that for NECSS. But you also, at that center, want either those or other physicians healthcare providers who will (unintelligible) about NECSS and provide clinical care and partner with….

Woman: The training program?

(Vicky Whitamore): … and partner with the research program or be part of the research program. So I think you're - it's two things right? Providing the clinical care as part of a - and also a multidisciplinary team, but also providing access to clinical research in that center and having funding for the clinical research.

(Steve Krachik): What if you say clinical care and research? (Unintelligible).

Woman: Yes, that makes sense. Clinical care and perform clinical research? Or ...

(Steve Krachik): And clinical research.

Woman: And engage in clinical research relating to NECSS. Or, I don't know.

((Crosstalk))

(Vicky Whitamore): Yes. No, I think that sounds good.

(Steve Krachik): Clinical care and clinical research of NECSS patients. Don't make it more complicated.

(Gary Kaplan): Good.

Woman: I think in one, number one, that what's nebulous is that recruitment - I mean we know what we're talking - what we mean, but recruitment of what? Recruitment of patients? I would say specifically include outreach recruitment of patients, right? Not just recruitment, I think. It shouldn't be a stand-alone.

Man: Recruitment both.

Woman: Of both what?

((Crosstalk))

Woman: Clinical research subjects and patients or how - I guess think about that.

(Gary Kaplan): We're actually recruiting physicians, we're recruiting patients, we're recruiting researchers.

Woman: To my eye, but maybe not to others. It should be - you know recruit - you should say something after recruitment to kind of - too broad, I think, to say it… Recruitment of medical professionals, clinical subjects, and patients. Or, you know, maybe spell it out. I mean...

(Steve Krachik): And you're talking about physicians, researchers, and patients?

(Gary Kaplan): (Dane), this was a particular wording I think you had in here. What's your thoughts?

(Dane Cook): For the recruitment?

(Gary Kaplan): Yes.

(Dane Cook): I think it - we had it as a stand-alone for exactly why you said, because it wasn't specific for a single purpose.

Woman: Well I think to someone who's just reading and who's not as close to it as we are, maybe it requires some, you know, explanation or…

(Steve Krachik): You could put (unintelligible) and parentheses after it and that would work.

(Dave): I mean, that's fine. I will say that, you know, we can wordsmith all day and no one's going to be happy so…

Woman: Right. Well, I mean I think the major - I think the big, biggie was the money aspect of it and I think you did a good job on that.

Woman: Speaking of the money, does a HRSA ex officio know if there are any ways to fund clinical care or any of the ex officios if it's not the NIH? Anybody at all?

Woman: (Aaron) are you still on the phone? (Aaron)?

(Nancy): This is (Nancy). There are HRSA funds federally qualified health centers.

Woman: Yes.

(Nancy): And I don't know if there's - if there - if HRSA funds other than that. These federally qualified health centers are generalists, they're placed for general medicine and if there's lots of - you know, if there's a - somebody develops a more complicated disease, they're generally referred out, I believe. But that's the clinical care that comes out of HRSA.

Woman: So since this recommendation essentially goes to the secretary and all of the agencies look at it, as they did with our last batch, I would assume that each of them would look at each of these and see what applies to them and how they - and what their response might be.

(Nancy): Right. But I think that it - because this is about Centers of Excellence, it's not about the federally qualified health centers.

((Crosstalk))

(Gary Kaplan): I think the most important thing is to hit the keynotes. Because when all is said and done, NIH, for instance, is going to put it into its process and fund it accordingly.

Woman: You're right.

(Gary Kaplan): (Unintelligible) and so directed to do so.

Woman: I have a question (Nancy). What did you mean by that this goes just to NIH and nowhere else?

(Nancy): Well, I don't know if it goes to other parts of HHS. I'm just telling you that the federally qualified health centers are not part of a research network, for example.

Woman: Okay. Thanks.

(Nancy): Does that make sense?

Woman: Yes, I got it now.

(Nancy): And I don't know if the other research - generally the research funding agencies that apply to this committee etcetera is CDC, ARC, and NIH. And if the other ex officios want to speak up, they can. But that's in general who funds research that's represented on this committee.

(Beth Unger): Yes, and, you know - sorry, this is (Beth Unger) and CDC has not had an extramural program for research. And we don't to my knowledge, I can check, have any mechanisms for funding clinical care. But, I think the - kind of the point, I mean indirectly, that we're making is that once one of the HHS agencies gets a project ongoing, it would behoove us to try to build on to that.

So, for example, if, you know, we can build on each other's and create synergy and perhaps get the, you know those community care centers to be referral sites and get the Centers of Excellence to work with the community care centers. I'm just talking off the top of my head, but… But, I think that's beyond what your trying to accomplish with the recommendation and, again, rather than focusing so much on the money, I think what you're going to be trying to sell to HHS is the concept and the importance of the concept.

And, as (Vicky) indicated, the amount of money that they will be able to devote to it depends on a lot of things that are kind of beyond our control at this point, but they, you know, are good at knowing what it takes to be successful. And I'm sure they would not fund a program at a level that would be incompatible with actually getting something done.

Woman: The only other question I had for (Dane) and (Gary) is, talk about not so much just profession education, but professional development of training of fellows say. Let's say somebody wants to train to become an NECSS, you know, knowledgeable person or professional and then leave and go somewhere else. I'm not sure that that's so clear in here (unintelligible) because I think that's a big role...

(Gary Kaplan): I think that's just a natural outcome of any Center of Excellence is the curation of Fellowships, but the Fellowships will not be funded, at least I don't believe they're funded by NIH, but…

Woman: No, I'm - again, not about the money so much, but about just what you will provide or - you see, right - professional and community education, I'm looking at number five. Should it also be professional development or the training more than education? I'm just throwing that out there. I don't know. Because I think that will - professional and community education means - I don't think is as strong as saying, like a training program, which might then attract funding. Because...

(Vicky Whitamore): This is (Vicky). And there are mechanisms, for example, I know that NCATS, in their Rare Disease Clinical Network, provide funding within each of those networks to support fellows that - who do research as part of that center. So I think there are mechanisms to include that into an actual center application say. You know, and I think also there are many different training mechanisms. And I mean, I think we would want, at NIH anyway, to absolutely encourage that at these Centers of Excellence.

Woman: So would you put that in a different wording kind of? Say in number five? I don’t know.

Woman: Do you think the wording is adequate the way it is? I read it as being - I don’t think - I don't know that we need to get into this little tiny detail stuff. I guess that would be also a question for (Vicky).

Woman: Well that's why I mean training of, you know, an actual somebody who carries out the legacy of our, you know, - as we gray and get older, the NECSS doctors.

Man: Professional education, that's what that is isn't it?

Woman: Yes. You see to me, education means you just go to a grand rounds and you learn about the disease, but you don't really, you know...

Man: Oh, I see. Recruit actual people who might want to be specialists.

Woman: That's sort of what I'm getting at, but I don't - you know, I think that's an important component to this and not just a small detail.

Man: So I think you could just, after education, say and training. I think we've made it pretty clear in the background document how important it is to have fellowships to train future generations ...

Woman: Right, right. But I think if you could - yes…

Man: … of physicians and scientists so, yes, I mean, I think that's a simple fix.

(Vicky Whitamore): Yes, I agree. I think just adding training there is good.

(Gary Kaplan): Good. And by the way, we are so done with this conversation about aging specialists who will be dying off rapidly. I'm sorry, I'm planning to stay in practice for a few more years. (Unintelligible). So quit writing us off so quick.

Woman: But I feel that way. I mean, how many of us have had students rotate through the office and they're so interested in the first couple of weeks and then the interest peters and then they go on to do like radiology or dermatology or something. Anyway…

Man: Well, yes, because in the community (Gary), you're probably one of the younger people who do it. We look for help and a lot of them came from the original outbreaks or some historical connection to it and there aren't a whole lot - I mean, I think there's (Dr. Younger), but other than that, can we really name very many young people? I don't think so.

Woman: And, it's really - I think we need to work on making it more interesting. And I think it is interesting. But you know what I mean? I don't know if people know that at the outset. Anyway, that's a different conversation.

(Gary Kaplan): Well I think the interest comes at - look, if we've got research dollars, then we can do - I think the fact of the matter is, the breakthroughs that are potential here are massive. And so, I think if you've got the money to do the research and the proper studies, the interest will be there.

Right now the problem is, yes you want to do this and you're told your career is over. I mean so, the Centers of Excellence automatically give gravitas to the field and give money - and I think the whole thing about Centers of Excellence is getting them established is a multiplier. It sets in motion a whole bunch of things, it starts attracting people who want to look at this disease. It starts attracting - it starts getting education out into the community. It makes it real as opposed to - you know, the reports are lovely, but if you've got a center where - and they're doing research on this stuff, docs want to stay somewhat up on what's going on and they don't want to be left behind.

So this is the imprimatur NIH saying, "yes, look we're serious about this stuff, here's the money", because the money is ultimately about where it's at.

Man: (Unintelligible).

Woman: But do we want to wordsmith this some more or are people satisfied and they don't want to do anymore nitpicking or we got the basics down? Go ahead.

(Gary Kaplan): I'm concerned about the first sentence again there because we've done - so the center should be comprehensive include - outreach recruitment of physicians?

(Steve Krachik): Don't need providers.

Woman: You could say other medical professionals and - or medical professionals, perhaps, to cast a wider net.

(Gary Kaplan): Yes.

Woman: Or medical providers, possibly.

(Gary Kaplan): Or researchers.

Woman: And researchers.

(Gary Kaplan): Providers and researchers. Yes, I mean...

Woman: And patients.

(Gary Kaplan): Providers, researchers, and patients. Yes, okay.

(Steve Krachik): I'd put it in parentheses.

(Gary Kaplan): And I would agree with that also, with Steve. Just stick it in parentheses.

Woman: Provision of social services.

Man: Recruitment of providers, (researchers), -we've lost physicians there, - researchers, - which could be clinical or - researchers and patients. Clinicians, researchers, and patients.

(Steve Krachik): We need to take the words of providers out.

Woman: Perhaps clinicians, you want to say recruitment of clinicians?

Woman: Recruitment, clinicians, researchers, and patients.

(Gary Kaplan): There you go.

Man: Can we put a period after each numbered item, we have some periods and then others don't. I think they may be - maybe they're not all sentences. I don't know, but we should be consistent.

(Gary Kaplan): We have - where do you want periods?

Man: So like number four has a period after it. Number two doesn't.

(Gary Kaplan): They all have periods after.

Man: (Unintelligible)...that's why I'm asking.

(Gary Kaplan): No, they all have periods after them. One period, two period, three period.

((Crosstalk))

(Gary Kaplan): On mine they do.

Woman: Is (Karen Scott) still on the line, our Chief Medical Officer for HHM? I was just going to ask if she, or if any of the others of you from the agencies, see any other red flags or issues or concerns that would impede this going forward.

(Nancy): (Karen)'s not on the phone any more, this is (Nancy).

Woman: Okay.

Woman: I think that the last clinical and research components on number one may be repetitive. Or, how do - do people - how other people feel? And I think we can delete that.

Man: No.

Woman: No? You think that's different from clinicians, researchers, and patients?

(Steve Krachik): That's just recruitment.

Woman: Okay. Maybe it's the way it's worded, and have clinical and research components. I'm just trying to - I'm sorry - I'm not an English major, but…

(Gary Kaplan): But, (unintelligible) one on T.V.?

Woman: That's funny. And have clinical and research components, no? Am I wrong?

((Crosstalk))

(Vicky Whitamore): The way I would restate that as, the centers should be comprehensive and include clinical and research components as well as outreach, and all the rest. Does that work?

Man: Yes.

(Steve Krachik): (Unintelligible).

(Vicky Whitamore): So that should be then after components, as well as.

Man: Delete (unintelligible) and put in...

(Vicky Whitamore): Yes, right there.

Woman: Syreeta and I are getting a little ... I think Syreeta is doing a great job.

Syreeta Evans: One at a time please.

Woman: It's hard, it's hard to do.

((Crosstalk))

Woman: And plus you don’t know, but she's got me yelling at her too so...

((Crosstalk))

Woman: So yes, right where you're at, as well as is what you got to add in there right?

(Steve Krachik): Right.

Syreeta Evans: As well as.

(Steve Krachik): Right where you are.

Woman: There you go, perfect. Now you need to put an and before the last thing, and medical professional education.

(Steve Krachik): That looks like a camel, that's great.

(Vicky Whitamore): So can you scroll down because I would like to see number six. So - I guess my question here would be, I understand that you want to be patient care at each of these centers and what you're trying to say in this is that there should be the capacity to provide telemedicine for patients who are unable to get there. That's what you're saying in the bullet right?

Man: Correct.

Man: Yes.

Woman: Yes.

Woman: Yes.

(Vicky Whitamore): Okay.

(Faith Newton): This is Faith. But I'm a little confused, didn't we just say that patient care was (unintelligible)?

((Crosstalk))

Woman: Well it's not funded, but that doesn't mean they can't have it there. I mean it's not funded by NIH directly kind of, but…

(Vicky Whitamore): Well, and I think - I mean there are places I think where telemedicine could be funded and could be - funding for telemedicine could be incorporated into these centers so I think it's okay the way it is. I just couldn’t read that whole thing.

Woman: I think so that - I think there was something kind of awkward sounding in two, like that institutions thing on line two. There's some kind of slash there after the n before the s of institutions so you want to remove I think. And perform clinical research on. I don't know. I don’t like the last (unintelligible).

Person: I think the - is throwing you off.

Woman: Okay.

Person: We're talking about the requirements of each (unintelligible), right?

(Gary Kaplan): One thing I heard loud and clear from the community was that they want to make sure that clinical care is a component of what we're doing in the COEs.

Woman: Certainly.

(Gary Kaplan): Grant you, we're not going to be able to get that piece funded through NIH. But, nevertheless, a clinical component of what - we need to make a statement about the need for clinical components in the COEs.

(Steve Krachik): Should institution be replaced with COE?

Man: Word institution in two.

(Steve Krachik): We're talking about the Center of Excellence right?

(Gary Kaplan): Right.

(Steve Krachik): COE.

(Jose Montoya): If it somehow can be explained that the funding that is being at NIH is for research purposes, but for centers to get the benefit of that funding they have to have a clinical program open. But because I think that if we mix the two that the two activities for funding purposes, it may go nowhere.

So I think what we could be saying is, the funding is for the research activities, but the center to apply to be (unintelligible) they will have to have a clinical program with all those components.

Woman: Yes, that makes a lot of sense.

(Steve Krachik): (Unintelligible) and change it to support and add the words, after clinical care to support clinical research of any CFS patients, and that would take care of it.

Woman: Did you guys want to put - add on? Or you can corporate that into an existing bullet point?

((Crosstalk))

(Gary Kaplan): Less is always more, so you know Steve's think will solve the problem, provide clinical care to support clinical research. You get rid of the land and replace it with to support.

(Steve Krachik): And put to support, you got it.

Woman: I think the word assemble maybe shouldn't have the s.

Woman: Right.

(Gary Kaplan): (Vicky) does that create any issues for you? Not there.

(Vicky Whitamore): Sorry, I was muted. No, I think that's fine.

(Gary Kaplan): Okay.

Woman: Somehow, that the COE thing is mentioned twice in the same sentence bothers me, but I don't know how to fix it.

(Steve Krachik): Leave it alone, we're done.

(Jose Montoya): Just go, let it go.

Woman: Okay. Okay, okay.

(Gary Kaplan): Certainly we could put a semicolon in somewhere.

Woman: Sorry. We'll let it go. I'll let it go.

(Gary Kaplan): All right, do these hit the key notes? And are there any big things that we've missed?

((Crosstalk))

(Faith Newton): This is Faith. I like it, I think it looks good.

(Steve Krachik): If we're actually going to put research in, we ought to put research somewhere (unintelligible).

Woman: Put it where?

(Steve Krachik): (Unintelligible).

Woman: What number do you want it in (Steve)?

(Faith Newton): The first number?

(Steve Krachik): (Unintelligible).

Woman: It is in there.

(Steve Krachik): (Unintelligible).

Woman: You want to write clinical research?

(Steve Krachik): No, just research.

(Gary Kaplan): No, no, no, no, no, research because research needs to be both bench and clinical. We love our PhD's right (Dane)?

(Jose Montoya): (Gary), because you are asking for some big things now, I wonder if for point three, which would say our recommendation for when, because if we say, you know, this time (unintelligible) for this level for this center, it could be 2020 or 2021. Should we say, you know, (unintelligible) start in 2017. Something like - so that people look for a date to start this funding or to open at least the funding request.

Woman: That's a good idea.

Man: It could say on the card, their next budget cycle.

(Vicky Whitamore): I can tell you then that 60 million in fiscal year '17 is not realistic.

Woman: Depends on who gets nominated right?

(Vicky Whitamore): I think, you know, looking at it that way, if you're asking for these to be launched in fiscal year '17, I guess realistically, funding might not begin until Spring, depending how fast things happen, wouldn't begin until a year, possibly even in the fiscal year '18, but like I said, with the NIH budget, it's just totally unrealistic to think that 60 million could be found for fiscal year '17.

I know many of the institutes are already working on their fiscal year '19 budgets. So, it just - something will have to essentially go away to find the $60 million. That's not going to happen quickly.

Woman: So we shouldn't put a date on it or a year. Okay.

Man: Yes.

((Crosstalk))

(Gary Kaplan): I'll tell you, the one way that you can circumvent that is if Congress decides to create a special allocation for funding. But other than that, you are absolutely correct that the agencies can't do anything.

(Vicky Whitamore): It might be realistic to start some centers, but it certainly wouldn't be realistic to set up 12, for example.

Man: Yes.

Woman: Okay, do we want to vote on this? Are we ready to vote…?

Woman: Yes.

Woman: …Or do people want to make more changes?

(Gary Kaplan): I would vote.

Woman: Okay. Let's start with (Gary). Of course, yes, right?

((Crosstalk))

Man: Wait real quick, should we change direct dollars to cost on number three?

(Steve Krachik): It's in there.

Man: No, it says direct dollars.

(Gary Kaplan): Well, but that's a specific term utilized in....

Man: Okay, all right, because we put cost in the other one.

(Gary Kaplan): Yes.

Person: We're inconsistent in three and four is the problem.

(Gary Kaplan): So use direct dollars, number four.

Person: Yes.

(Gary Kaplan): (Dane) you coined the phrase, direct dollars, you good with that on both those?

(Dane Cook): I think NIH actually uses direct costs, but I think it gets - you know, it seems synonymous to me to be honest, but - I think they're going to get it either way.

(Vicky Whitamore): They are one in the same. Direct cost is the term we use, but….

(Dane Cook): Right.

(Vicky Whitamore): …direct dollars, as (Dane) said, means the same thing.

(Gary Kaplan): Okay.

(Donna Pearson): This is (Donna). (Vicky) can you explain just, I don't understand about the funding thing and, you know, every report says this is urgent and when does it become something that gets put high on the priority list? You know, like an Ebola outbreak comes and we've got zillions of dollars, and this disease, we can't even get in the budget for next year. I'm not sure I understand how it works, maybe you could enlighten us just a little bit. Put you on the hot seat.

(Vicky Whitamore): Well, I mean, clearly those decisions are made at much pay levels, grade levels than mine. But, you know, I think - so I think there's different kinds of urgency right? So there's the urgency for Ebola because people are dying and it's spreading and more people might die. And for Zika, there are more babies that will be born as the Zika virus spreads and more pregnant women become infected, so there's a more immediate need to act and I think that's what people will react to.

That's different than what I would say is the urgency to direct dollars to research on NECSS, which is critical, but well - and people are dying, so that's not a fair comparison - that's, I can't say that, but it's a more chronic disease and I think we all understand the importance and the critical need for research dollars, and increased research dollars, but it's when there's these massive, potentially global outbreaks that things get mobilized at a very high level.

(Nancy): Let me just remind people that at 5 o'clock we will lose the webinar. We can - I don't know if we can still use the phone. I don't know we can still use the phone. So you all need to wrap up your business.

Woman: So should we take a vote (Nancy) and then just spend like two minutes talking about tomorrow?

(Nancy): Well I - if you all - I just want to make sure everybody is through with this and then we do need to have a vote. What is that noise? Do we know? All right.

(Gary Kaplan): I would move to have a vote.

(Faith Newton): This is Faith. I would second it.

Woman: Okay. I want to do roll call. (Adrian)?

(Adrian Casillas): Yes?

Woman: Yes or no?

(Adrian Casillas): Yes.

Woman: (Donna)?

(Donna Pearson): Yes.

Woman: (Dane)?

(Dane Cook): Yes.

Woman: (Gary)?

(Gary Kaplan): Yes.

Woman: (Faith)?

(Faith Newton): Yes.

Woman: (Jose)?

(Jose Montoya): Yes.

Woman: Okay. Me too. Did I leave out anybody? I don't think so. Okay. So great.

(Steve Krachik): Congrats, it was unanimous.

(Faith Newton): You know, I want to say a comment. This is (Faith). You guys did a really nice job on this document and your presentation. It was very succinct and clear. I thought it was very well done.

Man: Thank you.

Woman: Yes. I thought so too.

((Crosstalk))

(Gary Kaplan): Thank you. It was a lot of people working hard.

Woman: Yes. No it looks like it and I like the idea that you broke it up into those components, that made it...

(Steve Krachik): Take the word draft off the top of the document.

(Gary Kaplan): Oh, yes.

(Steve Krachik): (Unintelligible).

(Nancy): (Gary), I'm going to let you take the information, or whoever you want, to take - maybe you can get back with your workgroup ultimately, but whatever was in the presentations today on the PowerPoint that you want to include in the background document, please go ahead and get that to me - there's not a huge rush, you know, in the next week or two is fine. And if you just want it to be the executive summary and that other page at the end, that's fine too. You all decide what you want to submit, because what you submit will go to the secretary.

(Gary Kaplan): So we shouldn't be submitting PowerPoints, is that what you're telling us?

((Crosstalk))

(Nancy): No PowerPoints.

(Gary Kaplan): Okay.

(Nancy): It should be a Word document or a PD - it's easiest if it's a word document because then we can print it off in the formats. There's all kinds of funky rules about how we present documents to the secretary so.

(Gary Kaplan): Okay. Can do.

Woman: Okay folks, so I don't have my agenda in front of me, but I know it includes (Donna)’s group is going to give a presentation, we'll have more public comments, and more comments by ex officios.

(Steve Krachik): (Unintelligible) Eastern Standard Time?

Woman: Pardon?

(Steve Krachik): And we start at 9 o'clock Eastern Standard Time?

Woman: No, I don't think so. Back at noon Eastern Standard Time. Did I leave anything out (Nancy)?

(Nancy): Just to remind people again that do try to get on a few minutes in advance because we were able to troubleshoot with the operator. We will probably have a different operator tomorrow.

(Steve Krachik): What time (unintelligible) start tomorrow?

(Nancy): Eleven thirty Eastern Time is when you can sign on. Remember also to sign on for the committee members with the number that I emailed you. The phone numbers that are on the website or that pop up when you open up the webinar are for the people who are in listen-only mode. So to speak, which I think as you've seen, it's been very helpful for everybody to be able to speak and give their comments on the recommendations. You need to use the phone number and the passcode that I sent you yesterday. You will use the link to the webinar that says May 18 on it. Not May 17. And we'll - hopefully it will be smoother technologically tomorrow.

We're still working on - I feel badly that some people had to listen on their phones when they were counting on listening on the computer. We were given incorrect information by Verizon and so I don't know if we're going to be able to fix it, but that was something that was very important for us to have and so we will continue to make sure that future webinars have the ability to listen on either the phone or on the computer. Anything else, Syreeta, that I need to add?

Woman: (Nancy), I have one question. If we have a proposal for future working groups, should I send that out to the committee tonight or should I just wait and do that tomorrow?

(Nancy): You could send it out tonight and people could think about it.

Woman: Yes, all right. That's what I'm going to do.

(Nancy): Yes, that'd be fine.

Woman: All right.

(Nancy): Also, I have - that reminds me, I emailed everyone on the committee earlier today a copy of the PowerPoint presentation that (Donna)’s workgroup will give so that you can look at it in case you're having trouble on your computer.

And I think I'll also send out - after this, I'll send out the PowerPoint from the ex officios that I have so that it make it easier. I apologize that it's been a little bit hard to read on the webinar. Maybe we should do it in sharing mode tomorrow? So that should make it easier. Syreeta has figured out how to do the sharing mode and so that hopefully will be - make it easier for everyone, including those who are in listening mode, to review.

And then lastly, of course, we will have - this will be archived and you can listen in and at least for the PowerPoint that are easy to convert into 508-Compliant documents. If they have a lot of photos and a lot of charts and stuff, we can't convert them to 508, but we'll do our best to get the PowerPoints put up on the website. Ultimately, it takes some weeks to do that.

(Steve Krachik): (Nancy) this is (Steve), can you send me the PowerPoints too?

(Nancy): I did send them to you (Steve). I did.

(Steve Krachik): I believe you.

(Nancy): You have to look for them.

(Steve Krachik): I will.

(Nancy): Thank you.

(Gary Kaplan): All right, are we wrapped?

Woman: Sounds like it.

(Gary Kaplan): Do we have to officially adjourn?

Woman: I think we do. Sue?

Woman: All right, yes, Sue?

(Steve Krachik): She adjourned.

(Gary Kaplan): Move to adjourn?

Woman: They might have gotten disconnected.

(Faith Newton): So moved. Does somebody want to second it? This is (Faith).

(Jose Montoya): Second it.

Woman: Sue are you on the phone?

(Faith Newton): Yes, I wonder if she got disconnected.

(Nancy): Well I think that I'll just take over so that you all - you all deserve a few minutes of rest, you've worked very, very hard this afternoon. And I've got a picture of Syreeta I'm going to send to everybody. She's been working so hard. She had - I just want to thank her for all the effort she's put in the last few days, because it's been quite an experience for us both.

(Gary Kaplan): She's been also great support for the COE workgroup and I want to thank her for that as well.

(Nancy): She has. She has been a great support to all of us.

(Dane Cook): Yes, wonderful.

(Nancy): So, we'll start up tomorrow at 11:30 Eastern time. And then 12 o'clock, the people in listen only can sign in about that time and we will begin.

Woman: Thank you.

(Gary Kaplan): Great. Thank you.

(Nancy): Bye, bye.

(Faith Newton): Thank you. Have a nice evening.

Operator: That does conclude the call for today. Thank you all for participating. You may disconnect at this time.

END