

## **NWX-OS-OPHS-OEP-OER**

Moderator: Syreeta Evans  
June 30, 2017  
11:00 am CT

Coordinator: Thank you for standing by and welcome to the Chronic Fatigue Syndrome Advisory Committee Meeting. At this time all participants are in a listen-only mode until the question-and-answer session of today's conference. At that time you may press star 1 to ask your question.

I would like to inform all participants that your conference is being recorded. If you have any objections, you may disconnect at this time. I will now turn the call over to your conference host Mr. (Gustavo Seino). Sir, you may begin.

(Gustavo Seino): Thank you (Catherine) and welcome, everyone. A quick announcement. We have sent out via the list-serve an ME action has posted on the Facebook page a new link our policies but we're using a new link from the one we used yesterday, the operator made an announcement.

So if you are having any problem or if you cannot find the link please and if you are on the list-serve on the (sifsac) list-serve, just send us an e-mail and we will send you the correct link for those listening in the public. We have for today share Faith Newton, Dr. Newton and Dr. (Levine) will be joining us in a few minutes.

She's running a few minutes behind but we have update from NIH, from HRSA, from HARQ and then from the Department of VA Affairs and then we will hear from Gary Kaplan, Dr. Kaplan a member of the committee has been working with some other members of the community and members of the committee on medical education, then we'll take a break.

We'll just come back and discuss some recommendations based on Dr. Kaplan's work and with his committee and then we'll discuss (sifsac) SOP moving forward to be approved by the entire committee. At this point I'd like to conduct a quick roll call. Sue Levine said she will be late, Faith Newton?

Faith Newton: Here.

(Gustavo Seino): Dane Cook?

Dane Cook: Here.

(Gustavo Seino): Dr. Kaplan and he will be joining in these, (Alisa Cox)? (Alisa) if you are listening in the public can you please dial star 0 to get the operator so she can pull you as a speaker. Jose Montoya? (Donna)?

(Donna): Yes.

(Gustavo Seino): (Ted) from HARQ? (Beth Infirmes) from CDC?

(Beth Infirmes): (Beth) is here.

Man: MES is here.

(Gustavo Seino): (Janet Maynor)?

(Janet Maynor): Here.

(Gustavo Seino): (Joel Neirsa)?

(Joel Neirsa): Here.

(Gustavo Seino): (Michele Schafer)?

(Michele Schafer): I'm here.

(Gustavo Seino): Vicki Whittemore, NIH?

Vicki Whittemore: Here.

(Gustavo Seino): And Drew Helmer from the VA?

Drew Helmer: Present.

(Gustavo Seino): Our (non avoidance) liaison Leah Williams from Massachusetts ME FNSOC?

Leah Williams: I'm here, I'm here. I'm here.

(Gustavo Seino): (Courtney Williams), (Cimarron Research)?

(Courtney Williams): I'm here.

(Gustavo Seino): (Van Servarge) from (mini action)?

(Van Servarge): I'm here.

(Gustavo Seino): Welcome, everyone. Faith, is (Carmen) going to join us today or not.

Faith Newton: No, she's unavailable today.

(Gustavo Seino): Okay, well I'm turning it over to you for any opening remarks. Otherwise, we can go directly into the agency updates.

Faith Newton: I am looking forward to listening to (unintelligible) I think we've got an exciting afternoon planned. Why don't we start with the agency updates? I think we have starting with NIH?

(Gustavo Seino): Can we start with the VA Vicki if you don't mind with ...

((Crosstalk))

(Gustavo Seino): ... no, he doesn't have slides.

Faith Newton: Sorry (unintelligible) no problem.

(Gustavo Seino): So Drew if you don't mind going first because she has other commitments.

Faith Newton: Thank you, Vicki.

(Gustavo Seino): Drew, you might be on mute. Drew? Oh, well. I'm sorry Vicki, I guess you're back on. He e-mailed me earlier and say if he could go first and I say okay but now he's not doesn't seem to be on so we can start with NIH if you don't mind.

Vicki Whittemore: Yes, that's fine, thank you so thank you everyone and it's a pleasure to join and give you an update from NIH today. Next slide, please.

So to start with I would like to draw your attention to the funding from NIH for ME/CFS research the Fiscal Year '16 data was recently released and you can see that we're inching up toward \$8 million in Fiscal Year '16 and hopefully with the funding of the new centers and the data coordinating center will certainly break that and hopefully break records, right, and keep on this upward trend and the next slide?

I would like to bring your attention also to the fact that we recently and NINDS recently funded a new fellow so this is (Rakib Ryhan) who works with (James Aranmuk) at Georgetown Emmet Howell University.

He's an MB Ph.D student who recently received a Fellowship Award to study the neural (crellas) of fatigue in ME/CFS so funding will start this fall and will continue through August of 2021 so we're very excited about this opportunity to fund a new young investigator. Next slide.

So just to remind you that NIH is open for business and open to the grant applications at all times from investigators so to give you a way to see and to search any funding opportunity announcements you can go to that Website link on our NIH Website.

There are what we call parent announcements and these are the standing grant announcements for all of the mechanisms so this includes the R series of grants which are investigator-initiated R grants at the RO1 and R21 and RO3.

For the F series, those are fellowship awards for undergrad, graduate and post-doctoral fellows and then there's the K series which are primarily used for clinician scientists and all of those parent announcements can be found on the Website.

If any of the investigators have questions about any of the mechanisms, they can contact me or the appropriate person from the appropriate institute who's a member of the trans-NIH working group or if you can't figure-out who to contact, they can contact me and I can point them in the right direction.

There I would also like to announce that there will be coming-out a new funding opportunity to specifically look at dynamic neuroimmune interactions in the transition from brain function to dysfunction and this is going to be released by the NIAA Institute the Alcohol and Alcoholism Institute but with sign-ons from all of the neural science institutes including NINDS as well as I believe (nyad).

To really look at what is happening in the brain when the neuroimmune system goes awry and so I think this could potentially be a mechanism for investigators studying ME/CFS who are interested in this aspect of the disease and in the next slide?

In terms of I was asked to address what we see as future funding potential for ME/CFS and as many of you know for fiscal year appropriations for Fiscal Year '17 which we received at the end of April.

So this is funding that will take us through the end of September, we actually received an increase of funding so NIH received a total of \$34.1 billion which includes over \$300 million for the 21st Century Cures Act and of that you can see and NINDS received \$1.8 billion.

The President's budget as we are all aware is calling for a significant reduction in the NIH budget so it's \$7.2 billion decrease overall for Fiscal Year '18 but what we are very uncertain

about what that budget will look like and when we will actually receive a budget as has happened in many of the past years.

What happens at the end of September is that we get a continuing resolution which means we function at the same budget level as we did the previous year until the time a new budget is actually passed and signed for that fiscal year.

So we really don't know and I have to say it's causing great concern and it's causing leadership across NIH to be very conservative about what we're funding not knowing what our out-years meaning if we award a grant in this year, we pay that first year out of Fiscal Year '17 funds but not knowing what the future holds, everyone's a bit concerned and nervous about that.

We could be hopeful that we'll get an increase like we did in Fiscal Year '17 but we won't know that until we see the budget and in the next slide so as you all know, we've been operating as the trans-NIH ME/CFS working group at NIH since October of 2015, is that right, yes, I think so.

And it continues to be chaired by Dr. Koroshetz and I'm working with him to coordinate the group. Again we're still represented by 24 institutes, offices and centers. We continue to meet monthly and have ongoing discussions in-between those meetings and rather than planning we're now implementing our goals and strategies to stimulate and support research on ME/CFS.

And in the next slide so what have we accomplished? Well, in Fiscal Year '16 we're able to award seven administrative supplement awards and these are awards that were given - supplemental funds - that were given to existing NIH-funded grants that buy from NIAID and two investigators funded by NINDS to supplement the work that they were doing either on ME/CFS or in one case an administrative supplement went to (Mark Davis) at Stanford that's really allowed him to expand his research into looking at T cell dysfunction in ME/CFS and he's I think moving forward with what seemed to be some really promising and interesting and exciting results.

We've also used the request for information that was provided to help guide us and shape the research focus and priorities moving forward and as you've heard yesterday together with the CDC NIH is moving forward with a common data elements project and I'll talk about that in a little more detail now in the next slide.

So NINDS started their common data element program several years ago and this was carried-out with a contract. Currently the contract is with (emmis). It's in the process of being re-competed at this time but is a project that has now been carried-out across many different neurological diseases.

And several other institutes at NIH have also participated in their own common data elements project and the goal of developing common data elements is to provide standardized data collection so investigators can systematically select, analyze and share data.

So the idea is that rather than one lab collecting and reporting-out the outcomes of a specific test in one way and another lab doing it a different way, this allows for collection of those same elements in the same way so that data can be compared and in many cases pooled across different studies.

So the next slide you can see that these are all of the subgroups that are working across all of these various domains of ME/CFS so some of the folks on the call today and many of the investigators, those researchers, clinicians and advocates are participating in this effort and I have to say I've been very impressed with the work that's carried-on so far and the very thoughtful discussion and work that's being carried-out.

So in each of these areas what they do is they begin by looking at what are the tests for instruments or measures that are utilized in this particular area and come to some consensus on what they recommend as being those tests that would be most suited for research on ME/CFS, then moves to looking at well if this particular test is being used, then what are the outcome measures or data elements that would be collected and how should those data elements be reported-out?

So we're moving forward with all of this and in the next slide this is the timeline we pushed this out a little bit because we had a little bit of a lull in activity while everyone was busy writing their grant applications.

And so we've now pushed this out such that we are hoping to have this first round of all of the common data elements ready to push-out to the public for comment this fall with then coming back and revising those and finalizing those common data elements and in December timeframe such that they can begin to be used in the new centers and in other NIH-funded research as well.

There have been some discussions both within the individual - amongst the individuals - who are participating on all of these subgroups as well as outside of this as to what is the role of the case definitions as we're moving forward in developing the common data elements?

And what we started-out this project being naive to case definition being used but they're real I think in some of the internal discussions we've been having at NIH realizing that this has been such a huge issue and concern in the community we're going to have to address this in terms of saying if you're using X case definition which you should then utilize the following test instruments and here's how we would request that the data be reported-out.

We see that this is something that is a discussion that needs to be had in the community and something we will task the new collaborative centers and the data management reporting centers to lead in the discussion.

This isn't something that we feel should be NIH telling the investigators this is what to do but the investigators will come to a consensus once we bring everyone together this fall, once the centers are funded so in the next slide, additional things that we've been involved in.

I together with my colleague (Andrew Breeden) attended the invested ME conference both the colloquium, the scientific conference and the day-long conference that specifically developed for the lay community, patients and patient advocates and other clinicians and (Sue) reported-out on some of the interesting findings from that conference.

And I have to say I think we came away from that conference very enthused about the research that's going on and the developing information that really is pointing toward various different subtypes of ME/CFS that may be based on whether the individual has dysfunction in B cells or T cells or another aspect of metabolism and so I think that this is really exciting research that will really blossom within the next couple of years.

We've also participated in sessions on ME/CFS at professional scientific conferences so it's first at the Suite 2017 meeting, Joe Breen from NIAID and I were asked to be part of this session that was specifically focused on sleep, fatigue and cytokines (has to not) talked about ME/CFS directly.

And yet the rest of the folks talked about various aspects of fatigue and cytokines and Joe and I really filled-in in terms of what NIH's interest is in both ME/CFS and in general fatigue research going forward. That session was organized by Janet Mullington and (David Raison).

We also Joe Breen and I also organized and had (accepted accession) at the Federation of Clinical Immunology Society in Chicago and that in that session Beth Unger gave a very nice overview of ME/CFS and was followed by (Mark Davis), (Tonar Riley), (Ian Lipton) and Jose Montoya talking about various research aspects specifically focused primarily on immunology.

And I think although we were a bit disappointed by the numbers of people that came to the session, the people that came were very interested and were very motivated I think and excited about the research and where the research community is headed in ME/CFS and the next slide.

So one of the other things we've been working very hard on this year is to foster collaboration and communication regarding research activities on ME/CFS both between federal agencies and nonprofit organizations as well as the foreign-funding agencies so we've had discussions with the Canadian Institutes of Health Research.

When I was in England I recently met with reps from the Medical Research Council in England in the U.K. in the National Institute of Health Research and (for) these folks are all very interested in supporting worldwide collaboration and open communication between researchers to really move the field forward as rapidly as possible.

We were also recently contacted by the research funding agency in Australia and are beginning those conversations as well and then the next slide, what was a major accomplishment for us and hopefully for the community was that we released the new funding announcements in January of this year.

And these were two different announcements, one to develop multidisciplinary multi-site collaborative research centers and a second to fund a data management coordinating center so this was a collaboration across NIH institutes offices and centers where we will support \$6 million per year for five years for ME/CFS research.

And so we think this translates at least tentatively now to funding two to three centers as well as the data management coordinating center so our goal for these centers is to foster the use of common protocols and data elements across sites so that we can begin to look at larger cohorts of individuals with ME/CFS.

To enable and support research and academic centers, as many of you know many of the clinicians who see individuals with ME/CFS are in private practice or are not at academic centers so we're pleased to see actually that many of them are involved and included in the applications and so this was hopefully a way to bring that expertise into partnering with researchers in academic centers.

And where possible we hope that they can leverage the clinical science translational awards which are awards that come-out of (centac) the national center for accelerating translational research at NIH and these centers can help to provide them with significant

amounts of infrastructure, help with IRB approvals, all kinds of standard things that go on within an academic center that won't need to be copied over and duplicated in the centers but can utilize the resources that are already there.

We also hope that these centers will encourage the involvement of young and new investigators both basic scientists, clinicians, clinician scientists and one of the key pieces of the applications was that we required each applicant to include community engagement and involvement in their applications such that they will be informed by the community and partner with the community in all aspects of their research going forward.

And as I mentioned earlier we've been in discussions with some of the other foreign funding agencies and looking at ways that we can partner and collaborate with them to expand the center and to expand research with utilizing funding from each of those resources but we're all working together to really address the goals of the centers and in the next slide.

So overall our research interests include but aren't limited to determining the etiology and pathogenesis in ME/CFS studies to help identify subtypes of ME/CFS based on biological markers or symptom classification, longitudinal studies to understand the course of disease over time to better characterize the manifestations and develop and validate outcome measures for future intervention or clinical trials and the identification of potential treatment targets for ME/CFS and next slide, please.

So our timeline here is that the announcements were released in January. We received letters of intent for those planning to submit applications in April, the full applications came-in in May. The applications will be reviewed in late July and our funding recommendations will be reviewed at the appropriate NIH institutes advisory committee in September.

And I put hopefully here we will get the funding announcements out the door if everything aligns perfectly and we have no glitches, we should be able to fund the centers in September. You never know when somebody has a problem with getting IRB approval or there's some glitch.

But our hope is that we will fund the centers and the data coordinating center in September and then have a sort of all hands on deck investigators' meeting in early fall to bring them all together to really launch this new initiative and then the next slide.

Just quickly the NIH intramural study, as many of you know this study has now been ongoing and actually my numbers are now out of date. They've brought-in more than five healthy controls in study participants. They're coming-in weekly or biweekly at this point and so these people have now completed Visit 1 which is the careful genotyping, lots of studies that are being carried-out.

And those they will begin calling those individuals back for their second visit which will be exercise testing and post-exertional malaise evaluation beginning in July as they're continuing to bring-in the newer studies out study participants.

There was extensive analysis and biospecimen collection happening and today everything has seemed to move along quite smoothly and then the next slide, for those who know (Brian), this is (Brian Vastag) who has ME/CFS and recently came to NIH to participate in the study.

So you see him in one picture there with Francis Collins who went over to the clinical center to meet with (Brian) while he was there and then in the other we see (Brian) on the tilt table participating in that particular test.

I met with (Brian) after he was through the protocol and he was very positive about his experience there, a little exhausted I think but very positive nevertheless so I think we are very appreciative of all the people that are participating from many different institutes to make this a successful study at the NIH clinical center and then the next slide.

The ME/CFS special interest group continues to bring an outside speaker for their seminar series and coming-up in July in (litgen) we'll be visiting NIH on one I believe July 12th and then (Sonia Marshall Gradvisnik) and (Don Stanes) from Australia will be visiting toward the end of July.

And these opportunities really provide wonderful exchange of information both in a sort of more seminar presentation format and then the individuals spend time visiting with each of the appropriate individual investigators through a part of the clinical study.

So it's been a very successful program and many of the folks on my side in extramural also attend these seminars to really hear what's going on and understand more about the clinical aspects that are being looked at in the clinical study and the next slide so our plans going forward we have a stakeholder conference call coming-up on July 10th.

We're working as I said toward completing the CBE project toward the end of December, launching the collaborative center and the data management coordinating center and fostering collaboration and communication between foreign and U.S. agencies as well as the nonprofit and advocacy organizations going forward.

We are working toward an interagency collaborative group that will we're hopeful could bring together those people specifically interested in research on ME/CFS and the status of that is that that's currently being reviewed by Francis Collins' office and as soon as possible we'll be able to say more about that moving forward and in the next slide.

Our long-term goals haven't changed. We're still continuing to stimulate support research, grow the pipeline of researchers and investigators, support and expand the collaborative researchers as funding becomes available, support development of new therapies and treatments, support clinical trials of ME/CFS and ultimately to improve the quality of life for all individuals with ME/CFS and the next slide.

I'll stop there and I don't know if you want to take questions now or wait until the end of the session but here is the link for the ME/CFS Website as well as my e-mail address and so please contact us or check-out information on the Website as you have the interest so thank you very much.

(Gustavo Seino): Thank you Vicki. We will take questions at the end like we did yesterday after the agency updates.

Vicki Whittemore: Okay.

(Gustavo Seino): So we'll take questions from the committee at the end and then open the line for the public. Drew, are you on?

Drew Helmer: I am, can you hear me?

(Gustavo Seino): Yes, sir, so if you want to go ahead and give your updates from the VA.



Drew Helmer: Yes, thank you and I apologize for disappearing briefly there so I have a very brief overview of the VA reports. I think I'd like to start by saying the VA does not have a strong explicit focus on ME/CFS but actually considers it a distinct entity under an umbrella term that we use commonly in the VA called chronic multi-symptom illness or CMI.

We do have a little bit of data about the prevalence of ME/CFS mostly from claims data from within the Veterans Health Administration and I would say the summary of that experience as reported in the literature is that the prevalence of ME/CFS is a little lower among veterans than the general population, now these are not direct comparisons.

But in some groups particularly veterans who were deployed to Operation Desert Shield and Desert Storm in 1990 and '91 also known as Gulf War veterans, the rate of ME/CFS or ME/CFS-like conditions is higher or equivalent to the general U.S. population.

So the VA has focused to a large extent on that cohort that was deployed in 1990 to the Persian Gulf region and uses the term Gulf War illness or Gulf War veteran illnesses to differentiate this condition.

Also considered under this broader umbrella label of chronic multi-symptom illness and obviously there are some similarities to ME/CFS but I think many people feel that it is not the same condition or it is a subgroup of broader group of diseases.

Regardless, Gulf War illness is a very high priority for the VA and this is expressed in kind of all three branches of the VA, we have our benefits administration, we have the health administration which includes the research but also the clinical care so across benefits, clinical care research we see a high emphasis and a high priority for Gulf War illness in the VA.

Some recent activities related to chronic multi-symptom illness within the VA include the development of provider education video discussing a VA DOD and interagency clinical practice guideline for the management of chronic multi-symptom illness.

The guideline itself was an update - it was completed - in 2014 at the end of 2014 and was an update from an earlier clinical practice guideline that was entitled management of medically unexplained physical symptoms.

But very recently we actually completed an educational video for providers and a promotional video to disseminate the, you know, awareness or to increase awareness of the availability and the presence of this clinical practice guideline as well as a frequently-asked questions sheet and so there's toolkits to, you know, further disseminate the clinical practice guideline has been enhanced and that is all being finalized and launched as the (unintelligible).

In addition the war-related illness and injury study center which focused on medically unexplained conditions related to deployment offers monthly Webinars to providers within the VA system and we're also developing on-demand online e-learning modules on both chronic multi-symptom illness and generally and Gulf War illness more specifically.

All of these activities are accredited for continuing education for various providers. Another important development and I think this is going to be of interest is that the VA Office of Research and Development is currently reviewing and updating its strategic plan for research related to Gulf War illness.

The last time this was done was in 2015 and there is a federal advisory committee to the VA Secretary on Gulf War illness and that committee has been engaged with the Office of Research and Development in updating the research strategy.

Finally I think, you know, maybe a little bit of an editorial comment I think from where I sit in the war-related illness and injury study center and as a clinician researcher very engaged in chronic multi-symptom illness care and research, I think we tend to take lead from other agencies in particular the NIH and I'll commend my colleague for that very thorough and illuminating presentation.

And I think what we can do is take some of that information and start to apply it to both our research activities and our clinical care patients within the VA and so I really appreciate the opportunity to be an ex-officio member of this committee. I would be happy to present a more-detailed overview of the VA's activities related to CMI and Gulf War illness at the December meeting.

I kind of put this out here today as a feeler to see if the committee thinks it would be of interest and relevant and obviously it would be helpful to know whether some of the clinical and provider education activities would be of more interest or the research activities related to CMI and Gulf War illness.

So I'm going to stop there and I should be able to hear any questions or field any questions or hear any comments at the end of this session. Thank you.

(Gustavo Seino): Thank you Drew and so we will hear from members of the public as to whether or not they want to do that presentation in December and also interesting to hear how many of them are actually veterans and receiving care through the VA after we're done with all the presentations so moving on to HRSA, Commander (Nelson)?

Cdr. (Nelson): Good afternoon (Gustavo), yes, good afternoon, (Gustavo), thank you and good afternoon to the group. I really appreciate the opportunity to present this afternoon to provide a couple of updates from the last meeting from HRSA but also essentially based on a recent meeting I had the opportunity to meet with Carol Head and Emily Taylor from the (salt) MEC event CFS initiative.

And based on that meeting, it occurred to me that it would probably be helpful to give this group a general overview of HRSA and the work that we do to help sort of inform the recommendations that you make for the Secretary in the context of the work that we do at HRSA as a part of the Department of Health and Human Services.

So wanted to spend if we could go to the next slide, please, just spend a little bit of time talking about broadly about the work that we do, give some examples of impact of our work and highlight some maybe opportunities where you all might find room to align a recommendation with our focus.

So the Health Resources and Services Administration or HRSA as I mentioned is an agency within the Department of Health and Human Services and we support grants programs, over 90 programs actually that provide healthcare to people who are geographically isolated or economically or medically vulnerable.

So essentially the bottom line is our focus really is on that geographically isolated in other words rural communities and populations and the underserved and we do that through as I mentioned grants, cooperative agreements and contracts that we award through funding

opportunity announcements which are derived from authorizing statutes, legislation such as the Public Health Service Act as it relates then to the Ryan White Care Act for HIV/AIDS programs and then the Social Security Act.

Those documents - those statutes - really inform the work that we do and Congress then appropriates our programs in order to execute those missions. Every year we serve millions of people including those special populations such as those with HIV/AIDS, pregnant women, mothers and their families and children and others who otherwise have challenges essentially accessing healthcare. Next slide, please.

With a few legislatively-based exceptions such as the National Hansen's Disease Program and the Ryan White HIV/AIDS program, our focus really is more on a macro or a global level with respect to access to care and in services and related services.

And our work is organized essentially into these five overarching areas which are increasing access to high-quality healthcare and health services, strengthening the health workforce both by adding new members to that workforce.

But also training current providers, making sure that they are well-trained especially in work with rural and underserved populations, third, focusing on building healthy communities and fourth, reducing health disparities and thus improving equity.

And then finally focusing on the proper management of our programs, strengthening program operations, ensuring alignment with our authorizing statutes and any additional guidance that we receive from Congress, monitoring the performance of our award recipients and providing technical assistance to ensure we maximize the impact of that investment and then of course trying to reduce burden on (unintelligible) grantees.

So if we go to the next slide, we'll sort of unpack these agency goals and talk about some of the component programs and the impact of those programs so under Goal 1 increasing access to care, essentially we focus on as I mentioned rural underserved populations and so I think it's interesting to highlight that one in 13 people nationwide utilize HRSA-funded health centers.

You may be familiar with the term federally-qualified health center. One in 13 people within the country rely on health center services for preventive and primary care needs but when you dig deeper, one in three people living at or below the poverty level utilizes the services provided by health centers for their primary medical care.

Over 50% of people diagnosed with HIV receive care through the Ryan White HIV/AIDS program and which is a comprehensive system of care which was first enacted in 1990 and 10 million people living in health professional shortage areas receive primary care, dental or mental healthcare through the National Health Service Corps program.

Yesterday Leah mentioned that she coordinated her activities within Massachusetts and that she had interacted with our Office of Regional Operations and I think that's a good point to highlight that there are while, you know, we are obviously based out of Washington, D.C. there are plenty of opportunities within the region more locally-based for engagement with our offices and so I would encourage folks to engage at that level as well.

Next slide. Half of pregnant women and 1/3 of infants and children benefit from the Title V block grants under our maternal and child health bureaus and MCHB also focuses on

their home visiting program. You'll see a little further down the slide that, you know, they got 150,000 parents and children participate in that program.

We have the federal Office of Rural Health Policy which focuses on access to care in rural communities and nearly 14 million rural Americans received health services from a HRSA-funded provider in those rural communities so again ensuring that those communities have access to not only a healthcare facility but also to well-trained providers familiar with their needs.

We do within our health systems bureau operate Division of Transplantation so if you're interested for more information on that, you can visit [organdonor.gov](http://organdonor.gov) but we facilitated about 30,000 organ transplants including 6000 blood to stem cell transplants last year so some really interesting work happening there. Next slide.

With respect to the health workforce, HRSA trains medical, dental, mental and behavioral health providers through the National Health Service Corps and then Nurse Corps programs.

And this is one area where it's really sort of one of our flagship programs and we trained about 11,000 students, residents and health providers through the National Health Service Corps scholarships program last year specifically focusing some of those on integrated health where there's certainly a nexus with ME/CFS. Further we support through Title VII and Title VIII those are Titles VII and VIII within the Public Health Service Act.

That's the authorizing statute for various programs in interprofessional care, mental and behavioral health, programs that focus on increasing the workforce diversity so programs some of them by name the regional public health training center program, primary care training and enhancement program, the nursing workforce diversity program.

As mentioned, over 90 programs funded through HRSA but many of them are focused specifically on training health professionals specifically for work with rural and underserved populations. Next slide.

We support a national center for interprofessional practice and education and really focused on a priority of training multidisciplinary teams so but multiple provider types all working together to deliver high-quality care and we supported primary care training residencies, primary care residency programs, approximately 60 locations for those and last year trained over 550 residents.

Further we also focus on training mental health providers and clearly there's a huge focus currently on opioid crisis and last year we trained almost 6000 new mental health providers. With respect to training for clinicians, I do know that at the last meeting there was a question regarding any ME/CFS handout that was produced by a HRSA grantee.

And did want to provide the update that we circled-back with the National Center for Integrative Primary Care and wanted to update this group that that draft document is currently being updated based on feedback received and the contractor has worked with CDC to sort of refine some of that material.

They hope to have a draft ready by the end of July at which point I know they're already actually in touch with (Gustavo) but they will circle back at that point to connect with this group and to receive any final feedback on that.

Of course it will likely be a living document but really appreciate the input and the opportunity to take that back and to make some refinements to that program. Next slide.

HRSA also focuses on building healthy communities and I mentioned our Office of Rural Health Policy which focuses on access to care for rural populations which include the viability of rural hospitals and so a huge part of what that office does is to coordinate healthcare activities for the approximately 60 million Americans who live in rural areas.

They also support other types of initiatives which help increase access to care such as telehealth, telemedicine and other health IT initiatives and the last line there, a little bit more with respect to our maternal and child health bureau's work focused on perinatal health outcomes and trying to reduce disparities between racial and ethnic groups by using community-based service delivery. Next slide.

Gulf War as I mentioned and sort of echoing the last bullet point from the previous slide is to reduce health disparities and HRSA does that by providing enabling services such as housing, food services, nutrition counseling, job support to over two million patients nationwide and I mentioned the HIV/AIDS Bureau, the Ryan White HIV/AIDS program focuses among many programs of course on outcomes related to viral suppression and have improved those rates from 70 to 79% since just 2010.

And another example of ways to reduce health disparities through the 340B drug pricing program, 340B is a reference to the section of that authorizing statute. Through that program they saved qualified safety net organizations approximately \$5 billion annually negotiating reduced prescription rates for safety net provider organizations.

And on the next slide, this is just a sort of an overview of the various components of our organization. HRSA is run by an administrator, Dr. George Sigounas, actually recently arrived about two months ago and sends his regards.

You can see then around the rest of the perimeter of this slide the other offices and bureaus that do the work that I just described and so hopefully this has been helpful to sort of set the stage for the type of work that HRSA does through our statute through our sort of legislatively-derived program but there are certainly areas where our mission overlaps with your work in ME/CFS.

And I think the few things I would highlight is to say that nonprofit entities are eligible to apply for our funding opportunities and so if you are not already signed-up at grants.gov any nonprofit organization can come-in for most of our announcements and that's a great way to track new opportunities and also they may not explicitly state ME/CFS as the focus.

As I mentioned most of our work is on a global access to care or health workforce development level, certainly as a vulnerable or medically-underserved community I think there are ways to make the case to tie that into the overall mission or even to partner with a prospective applicant such as an academic institution or another healthcare facility to that end.

And we will continue to work on ME/CFS awareness and training initiatives for all of our workforce development programs but I think as much as we can and that provider education material will really be key in doing that.

If you go to the next slide, you can see my contact information there and I'm happy to serve as the nexus back to HRSA although we mostly work through (Gustavo) here but at the bottom of that slide, you can see some resources.

If you want to get more information about our programs, you can visit our Website at [hrsa.gov](http://hrsa.gov). Follow us on Twitter of course or through Facebook and those resources can help to link you to other pages such as [grants.gov](http://grants.gov) that I mentioned or [organdonor.gov](http://organdonor.gov) so with that I'll pause and I guess defer for questions at the end. Thank you.

Faith Newton: Thank you, Cdr. (Nelson).

(Gustavo Seino): (Pat) are you on? I guess not. He e-mailed me and told me he was going to be on and off and I'm not sure if he has any update from HARQ so let's Faith turn it over to the rest of the committee to ask questions of either Vicki, Drew or (Joe).

Faith Newton: Yes, that's a good idea, let's do that. While folks are coming-up with their questions, I want to comment on Vicki's presentation. I thought it was very thorough and very well done. I was really excited to hear about the common data elements project and the work that you're doing ...

((Crosstalk))

Coordinator: To ask a question by phone, please press star 1 on your touch-tone phone.

Faith Newton: ... and multidisciplinary, multi-site (to lack of) research centers and also looks very exciting (unintelligible) so I think we've done a lot with what you're doing and just wanted to commend you on the presentation and the collaboration with the other agencies, the CDC, etcetera, with Beth Unger and all of that. I thought it was well done. Questions from other (sifsac) members?

(Courtney Miller): This is (Courtney Miller). I have a comment and a question for Dr. Whittemore.

Faith Newton: Okay, go ahead.

Vicki Whittemore: Yes, go ahead.

(Courtney Miller): So Dr. Whittemore I wanted to thank you for your work, thank you for the detailed presentation and I know I haven't been on this body before so I wanted to take the opportunity to say that having watched NIH presentations over probably 15 years (sifsac) certainly the last year of presentations and today has been far more substantive than anything in my memory.

So I want to thank you for your work on that work, Dr. Koroshetz, Dr. Collins for shifting and renewing the program and I want to thank Dr. Koroshetz for the comments he made at I think it was at NIH advisory council meeting acknowledging that this is a start and we probably need 10 to 20 times the current funding levels to adequately address ME/CFS in the research field.

And his comment was in response to Dr. (Lifkin) raising the dollar amounts from the (unintelligible) and as you know, we support my husband and I have supported (Cimarron) has supported the center grants, the request for applications, the intramural study, the initiatives that have been taken.

So but we (also) want to recognize that the funding levels even with those grants need to increase to be as productive as we need and my question really goes to something I raised

yesterday with Dr. (Mayerd) in the FDA presentation, how can NIH and FDA work together on a plan to move forward an initiative to do clinical trials in ME/CFS?

It is the third leg of the stool. We're in a chicken-and-egg situation. It's (unintelligible) research site and applying any treatments and there's never a study of existing treatments to figure-out what's working for whom and there's a considerable amount that can be learned on the question of subsets about who responds to particular kinds of treatments even on a small scale.

And so I really (unintelligible) figure-out and I'd like to hear a, you know, thoughtful plan put together that has our federal agencies really moving forward, a clinical trial program, seeding it in the way you're doing with the RFAs for the clinical centers, the collaborative centers.

We need to change the current cycle which has left patients without treatment for 30 years to my question is to Dr. Whittemore I also want to ask the chairs, the co-chairs of (sifsac) how do we participate in putting forward a real program that has the potential to create clinical trials and treatment options for patients?

Vicki Whittemore: So make sure, I'm not muted, I don't think.

Faith Newton: No, you're on, we can hear ...

((Crosstalk))

Vicki Whittemore: Okay, thank you so thank you (Courtney) first of all for your comments and for your question so I would I think echo or repeat what I said yesterday in discussing potential clinical trials with investigators and with program staff at NIH.

What seems to be the missing piece at this point in time is how is there a way that we can better predict who would respond to a particular treatment so that we're not enrolling individuals into trials that may in fact be harmful to them.

So I had long discussions with this with the folks from Norway and if you look at the data, the preliminary data that they're released and they tell me that this looks to be the same in the blinded study although they don't of course at this point know who's getting drugs and who's getting placebo.

But there are certainly people who are responders, who respond very well, very consistently, continue to have a good response to the treatment. There are people who showed no response whatsoever so either those are non-responders or people who are getting placebo and then there are a lot of people in the middle.

And so what we feel would be helpful would be eventually get to the point where you have a person that would come-in and we would be able to identify the underlying cause or causes or their ME/CFS such that they would then be put into the appropriate clinical trial so that we have sort of a battery of trials ongoing or treatment interventions that could be tested in this population.

And so one of again one of the things that was very clear to us when we began to look at what to put in place which was did the RFAs for the collaborative centers, is that many most of the training clinicians are not at academic sites.

It would be best for NIH to fund clinical trials through academic centers so we needed to put this initial infrastructure in place that can lead then to future clinical trials.

And again as I said yesterday we don't see this as five years in the centers before we even begin to think about clinical trials but putting this infrastructure in place that will lead to clinical trials and lead to investigators being able to come together to think about the best way forward to present these clinical trials and submit the applications to NIH.

The last thing I'll say and then I'll see if you have comments back to me about this but I think the other thing that will be important is what the CDC and FDA have been working on which are the outcome measures so that we have very clear outcome measures so that when a clinical trial is done, we know what the objective outcome measures that will be that will tell us if the trial is successful or not and what those meaningful outcomes for patient function and health are that can be utilized in those trials.

So I think what they're doing is also critically important and all of these pieces hopefully will be coming together in the next year to two that will really help to boost our ability to do clinical trials in this area.

Faith Newton: Thank you Vicki. Do you have a follow-up, (Courtney)?

(Courtney Miller): Just that we'd have to start with what we have. We do have certain treatments being used by certain clinicians and we could have data on who's responding if your point about the (unintelligible) of trial in Norway but we have to figure-out if we can't really rate until we identify the underlying cause for five different subsets so we do have a place we could be starting.

The importance of the outcome measures goes back to the question of who's engaged in producing those so ...

Vicki Whittemore: I'm sorry (Courtney), who they what ...

(Courtney Miller): ... who is engaged in ...

Vicki Whittemore: ... sorry, I missed a word.

(Courtney Miller): ... coming-up with those. It's great that we're using data. Some of the clinicians know that to be the most that they have to be part of that process and so I think if we do have the ingredients that come together over the next year, we should figure-out now how do we inform that plan and how do we lay it out so that people have targets to whether it's investigators or drugmakers so start looking at our disease.

So I guess from the (sifsac) perspective, you know, can we consider when we come to the end of a meeting for our agendas for the next meeting you know, working group to put some real substance into making a plan and I don't think if we don't start making the plan this year, it won't happen for two to three more years and we have to do something to attract study and investment by the pharmaceutical companies who have shunned this disease. I'll leave it at that.

Vicki Whittemore: I understand what you're asking and the question that I am going to want to have an answer from the rest of the members on this committee as well as the ex-officios is we don't want to put together a recommendation or a plan that has no - that will not be funded - so this and that's what's happened in the past.

Where there have been recommendations that have been made that either are not realistic or that have no that there's no possibility of them being funded so I think what we're trying to do is (explain) how (sifsac) works and that we are all starting to work together with all



the ex-officios and the different agencies to see what is realistic and what can we move forward?

So I don't have an answer to that question but I think that as we start, you know, with all of us (starting on) how to move forward I think that we will get there but I want to hear from the ex-officios as well as to is that realistic to start a working group on that moving forward (unintelligible) quickly too fast (unintelligible).

Faith Newton: This one's, Vicki, go ahead, Vicki.

Vicki Whittemore: So you know, I'm saying this as an ex-officio and I guess I would like to hear from the committee and other ex-officios but it's not clear to me that that's really the purview of (sifsac).

I think and other ex-officios could you chime-in that as I said NIH is open to talking to investigators about funding clinical trials. We don't have set aside money for any clinical trials. Any investigator or group of investigators can come-in and submit grants for review for a clinical trial.

In my mind what is needed are these clear outcome measures plus looking at and bringing-in potentially and again I don't see this as the purview of (sifsac) but maybe a purview of us federal agencies to bring-in people from the pharmaceutical company and say were you to look at a clinical trial in this area, what's missing?

What would encourage you to participate or and even fund a clinical trial for ME/CFS and to really I mean, if that is I think the plan you're talking about (Courtney), I think that's certainly something that we could engage in and we could certainly do to better understand what those pieces are that would both make it more feasible for NIH to fund clinical trials and make it more attractive for pharmaceutical companies to be interested in supporting a clinical trial.

Faith Newton: Thank you. Other comments from other members of (sifsac)?

(Ben Seeburger): Hi, this is (Ben Seeburger). I have two questions for Dr. Whittemore. One's just a small one about the thank you very much. It was a very substantive presentation. I really appreciated all the information you provided.

On the second (side) just a small formatting thing. I would when I reviewed this the NIH funding slide in advance, I had a little trouble putting together the information that you provide in that slide with what I was aware of some of the funding so it would be helpful maybe in addition to the bar graph lines if you put totals for each year so I could be more clear on that.

But let's just say a smaller technical thing and I think the larger question that I had of course, you know, has any (action in) the patient community I think in general is also very concerned about the budget cuts or the future budgets or agencies and what that means for our work going forward.

But I guess the main thing the key question I have is how do we get ME/CFS to get a fair share of whatever budget is available? I recognize there's a lot of uncertainty around what budgets are going to be but given that historically in the past ME/CFS has not had a share of funding commensurate with its disease burden and I think still everyone would recognize that the funding is still not commensurate with disease burden.

You know, it's not reasonable to ask this community to wait, you know, for answers about that until, you know, future times that budgets are going to slow down so what I'd like to hear are what assurances can you give and what steps are being taken at the NIH level to assure that whatever the pie is that you're dealing with that ME/CFS gets a fair and commensurate share of that funding.

I know there's been some incremental increases but what are we going to do to change that situation so that there is the funding that's commensurate even if the pie isn't as big as what we would all like. Thank you.

(Gustavo Seino): Vicki, this is (Gustavo). Before you reply, I got an e-mail from a note taker and she reminded me to please say your name before you speak for the sake of the minutes. Thank you.

Vicki Whittemore: Okay, this is Vicki Whittemore.

(Gustavo Seino): Okay. Sorry, I was just going to say was (Ben Seeburger) at any action.

Vicki Whittemore: So thank you first for the (four vetting) comments. I will take that under I will make sure to do that better next time so thank you for that comment so it's difficult, right, so we at NIH unless Congress directly tells NIH we're going to appropriate funds for a certain amount of dollars for a certain disease.

All other diseases are essentially put into a research area, not even diseases, basic research and translational research is funded out of general funds based on the scores that grants obtain in grant reviews so I think what my observation has been if you look back historically there were people doing research on ME/CFS that fell by the wayside because they lost interest and/or couldn't get their research funded, whatever the reasons were.

And I was very encouraged by the response we got to the RFAs with centers and the number of people that expressed great excitement about this as well as people from outside the field who said (unintelligible) I do something related, perhaps I could move into doing research on ME/CFS because NIH clearly has an interest in this area.

So the way we are thinking about it is that as Dr. Collins said at the directors' advisory council meeting we see this investment that we're making now in the centers and the research we're currently funding through investigator-initiated grants as just the beginning.

And as more is known as we bring more investigators into the field, the top the part of the pie that goes to ME/CFS will just expand and it's our job as (people) at NIH to really help foster the research and to help investigators put-in the best applications as possible.

And so, you know, I think that is probably how I can best answer your question at this point and if you look historically at other diseases that started-out with very little funding, very few people, sort of a critical mass of research (goals) starting to happen, things exploded.

And I think that's sort of where I see that ME/CFS research is just at the cusp of this hopefully explosion of bringing new interest, new people, increased numbers of applications and some to this research area.

So you know, I wish that we could say we want this part of the pie dedicated toward ME/CFS but especially with the uncertainty of the budget, the number of really directed initiatives is really decreasing at NIH because we're leaving the bulk of the money open to investigator-initiated research.

Faith Newton: Thank you Vicki. Any question for any of the presenters, the ex-officio members?

(Donna): This is (Donna), can I ask a couple questions of (Janet) or FDA ex-officio?

Faith Newton: Go ahead, (Donna).

(Donna): Okay, Number 1, we know that the rituximab trial results will be published hopefully in the near future. If an when the results show that yes, there is a subset of patients who respond, what is the process for the FDA to then approve that drug in the United States for use for this specific disease? My understanding it is approved for use already but not for this disease?

And then my second question I'll just throw it out there is the one and only drug that we know about that's tried to get approval specifically for this disease of course is Ampligen and it was reviewed by the FDA in 2012 and that was before the FDA did the voice of the patient and gleaned a whole heck of a lot of knowledge about it and it was before the IUM and it was before the P2P.

And it I think most people would agree that if the FDA had had the information about devastating the disease is, it is likely that that drug would have been approved because we've seen so many other drugs being approved for other conditions like multiple sclerosis where they believe that the quality of life is so horrible they even take more risky drugs and give them approval.

Whereas this disease was found to be relatively safe so my question is - my second question is - is there any kind of (unintelligible) where the FDA having new information about a disease takes a drug that has previously been denied, looks at that same information and is able to consider approving it without the need to go through, you know, , multimillion dollar trials moving forward, and other words.

(Janamina): Hi, this is (Janamina) from FDA. So I guess I can give a general response that can hopefully address both questions and then may be dive into both separate questions.

So both of your questions are essentially how can we get a drug approved, be that rituximab or Ampligen, or really, any drug to help the (pieces) who are suffering with NECSF, correct?

((Crosstalk))

Man: Yes, that's correct.

(Janamina): Yes. So the way it would work for either rituximab or Ampligen or any pharmaceutical company that wanted to seek approval of their drug for MECFS, what they would do is they would submit information to FDA. Generally how pharmaceutical companies do that is if they have promising results.

Let's say they have a trial where it looks like the drug really works in a certain subset of patients. Generally they would give just sort of a high level of that information to the FDA and we would meet with a pharmaceutical company to talk about sort of the high-level results and then advise them whether or not it was felt that those data were adequate to support approval of the drug.

But it's really up to either the pharmaceutical company or if it was individual investigators or whoever sort of generated that data, they would be the ones who went submit that information to FDA and sort of make their case why they thought the data were adequate.

And we would work with either a pharmaceutical company or the investigators to sort of give more specifics about what would be needed to actually support approval of the drug for MECFS.

So I think that could really apply to any potential drug. I mean, FDA is very open to working with any either investigator or pharmaceutical company who's interested in seeking approval for MECFS.

And really what we need is just for people or companies who are interested in that pathway to come to us because I think we have the highest likelihood of success if we have sort of communication and dialogue with the different stakeholders to make sure we're all kind of on the same page knowing what data is available so that we can work together.

So I think that pathway could be - probably be different in each exact situation. It would really involve a dialogue working with pharmaceutical companies. And we're very open to working with whoever would be interested in pursuing a drug approval for MECFS.

Man: So just be clear, the maker of rituximab would approach the FDA once they had the information about the trial results. And that would just begin the process. For that particular drug, being brand-new, for consideration, how long would the process take?

(Janamina): I'm sorry, I missed the last part of your question.

Man: Along with the process take?

(Janamina): To actually sort of meet with the FDA and have those discussions?

Man: Yes, and to have the drug approved for use. You know, it wouldn't be off label use. It would be for use for this disease in this (unintelligible).

(Janamina): Right. So the timeline really, just the kind of what needs to be done, so if clinical data is already available and it's felt that that data could be reviewed and potentially support approval, then the timeline would be more just how long it would take a pharmaceutical company to submit the information to FDA.

And then, depending on exactly what was submitted, it would have a different timeline of review, but it would just be review of that information. So I guess it's hard for me to give, like, an exact timeline because it would really depend on the situation and the type of information that was being submitted.

Because obviously if a drug company started a clinical trial today, it would take a long time to generate all the data to support the drug approval, but if the data is already available and we're just - they're just admitting that data, it would be more of them getting the information to us and then us reviewing the information.

But the FDA does have sort of very clearly articulated times that it takes us to do different things, like in terms of how long it takes us to have a meeting with a pharmaceutical company or how long it takes us to review data that's submitted to support drug approval.

So I think there would be a lot of transparency with the pharmaceutical company about how long things would be - it (wouldn't) necessarily take, and so it wouldn't necessarily be a very long timeline just depending on the exact situation we're talking about.

Man: So, again, do you mean, like, it would maybe be a year or maybe be five years? What do you mean by not a long timeline?

(Janamina): Well, I guess I'm trying to say that the situation just depends, right. If you were...  
((Crosstalk))

Man: Right, but what's closer? What is it closer to, a year, or five years, or three months? I mean, sometime in the range I guess I would be looking for.

(Janamina): Right. So, I mean, again, it depends on what is submitted. It was sort of a drug that's already approved and then they're submitting the information that's already - let's just say there's already information gathered and that could be - it could be submitted, like, tomorrow.

Then it could potentially be sort of less than a year. It just depends on - because the limiting factors aren't always necessarily FDA's review of the data (unintelligible) pharmaceutical companies need to organize and get the data ready to submit to FDA.

And depending on what they need to do, that can involve some time. So it's just - there are a lot of sort of variables that would make it impossible for me to say exactly how long it would take, right.

But clearly, if you have existing data that could be easily submitted to FDA to review, then it's not nearly as long of a timeline. Does that make sense?

Man: Okay. And then on the Ampligen thing, and I'm not up-to-date on Ampligen or where they are in any approvals are any trials, but am I clear in understanding that you're saying they could just resubmit the same information that is already present to the FDA with? And now that you have - you would look at it again now knowing more about disease?

(Janamina): No, I guess what I'm saying is that we are totally open to working with any sponsor and that includes, you know, sponsors who have already performed trials and have data available.

So I think it's totally reasonable for companies to talk to us about their specific situation.

Man: Okay.

((Crosstalk))

Woman: Go ahead.

(Gary): This is (Gary). Can I pop in for a sec?

Woman: Yes, go ahead.

(Gary): One of the things I want to emphasize is that even with FDA approval of the drug, the insurance companies may still not cover it. We run into this all the time with increasing frequency.

And, so yes, there's a piece of - of a question where we want to get it through the FDA for approval if it's appropriate but you're going to hit a big road blockade when you run into the insurance companies being willing to pay for it. It's a financially, the drugs may still be unavailable (to you).

(Stacy): And I have a - this is (Stacy). I had a question also, (Janet). Do advocacy groups petition the pharmaceutical companies to submit drugs to the FDA? I mean, do they go in that group to try to get drugs supported?

(Janet Maynard): So this is (Janet Maynard). I think there has been a variety of different situations from sort of patient advocacy groups working with pharmaceutical companies to help support drug approval.

You know, I think probably there could be lots of different examples and I do think, you know, as has been mentioned I think a lot yesterday also was the importance of stakeholder communications.

So I agree that if the patient advocacy group would like to sort of work and support the pharmaceutical company to help them understand the significant unmet need of patients with MECFS, that to me, seems reasonable.

Woman: Thank you. Are there any other questions from any of the other (CISAC) members? We're at about 1:35, and I believe Dr. (Levine) is also on now, the other co-chair.

(Gustavo): I think we have to - what we have to do now, we have to have the operator contact - or Mr. (Miller), if you are on, press pound zero so you can provide your public comments.

Following Mr. (Miller)'s comments, because we have more time for public comments, Syretta has put up on the Webinar the questions that were drafted by the medical location workgroup for members of the public to address.

And then, last but not least, is (Charmaine) and (Mary Demick) - are listening. Can you also press pound zero. They're members of the subcommittee and they wanted to address any questions that the public might have. So let's start with Mr. (Miller), if you are on the line.

(Ben): (Gustavo), this - sorry, this is (Ben). Did you mean to say star zero? You said pound zero.

(Gustavo): Oh, I'm sorry, star zero.

Woman: Thanks, (Ben).

(Gustavo): So, operator, do - (Charmaine), Mr. (Miller) and (unintelligible).

Coordinator: (Charmaine)'s line is open.

(Charmeon): This is (Charmeon) (unintelligible).

(Gustavo): How are you?

(Charmeon): Okay, thank you.

Woman: (Unintelligible).

(Gustavo): Is (Robert Miller) on the line? Can you press star zero?

Woman: (Charmaine), do you have a question or comment?

(Charmeon): I had a question. Are we still able to get questions on the previous updates?

Woman: Yes, you can go ahead, correct, (Gustavo)? She's fine.

(Gustavo): Well, I'm letting (Charmaine) speak because she was a member of the workgroup and (Mary Demick) asked that if she and (Charmaine) could be able (unintelligible).

Woman: Okay.

(Charmeon): It's (Charmeon), not (Charmeon).

(Gustavo): (Charmeon). Yes, sorry, English is not my first language. So - but if you have a question for any other presentations, go ahead.

((Crosstalk))

(Charmeon): That's okay? Okay, that would be great. Thank you. My question is for (Drew Helmer). First of all, I'm delighted that the VA has an ex officio on this committee because I

think there're tremendous opportunities to understand better the prevalence of MECFS in the veteran's population.

And I think the VA being a centrally managed organization, medical organization, with outreach to a very large patient population and potentially comprehensive and organized medical education gives us tremendous opportunities in working with MECFS.

So thank you for being here. I hope you will become even more involved over time. I do have a concern, however, and what you said about MECFS currently being under the category of, I believe you called it chronic multisystem disease.

(Drew Helmer): Yes, chronic multisystem illness.

(Charmeon): Yes. Because MECFS has particular characteristics and many studies have shown that it is different from Gulf War illness, for example.

And so to - we - I think we need to be very careful particularly with diagnosis and also with treatment to make sure that MECFS is separated out and treated appropriately, for example, (graded) exercise therapy which is often recommended for chronic medically unexplained illnesses and so on.

Is - we know now is not an appropriate treatment for MECFS and can actually harm patients. So I think there's good reason to take special care and make sure that the VA is applying appropriate diagnostic criteria for MECFS and that the treatment guidelines are unique and specific for MECFS and not general ones for chronic multisystem illness.

I don't know that you meant that from what you said, but it sounded like that confusion could arise. The second part of my question is, you mentioned that there was some education already on chronic multisystem illness and that it might be applied MECFS.

Is that something that those of us in the patient community could look at to see what the content of that medical education is and perhaps give you some feedback on whether we feel that it is appropriate or perhaps not for MECFS?

(Drew Helmer): Yes, well, thank you very much for the comments. I think you're highlighting the reason that I kind of dipped my toes into the conversation today with a very brief overview, and I really appreciate the feedback.

I agree that there is a lot of - there's actually a lot of concern about, you know, how does this (chronic) multi-symptom illness label fit with the distinct entities that are better defined like MECFS or even Gulf War illness, for that matter.

So I think that's an area of active inquiry and continued understanding, search for understanding. With regard to the educational materials, they are publicly available. We have them on the (risk) Web site.

And maybe I could work with (Gustavo) to disseminate some of the links to the Web-based version of those. The e-Learning modules that I mentioned, which are being developed, are actually going to be publicly available to the (train) platform.

The other Webinars and, you know, some of the other educational materials we have are on a VA only platform that's not generally accessible by the public, but I can certainly find some way to share those with you.

(Charmeon): That would be wonderful. Thank you.

Woman: Thank you. I believe now we're going to go to the public for questions, answering the medical education workgroup that are posted right now.

(Gustavo): So operator, if you don't mind announcing to the members of the public how to speak to the rest of the committee.

Coordinator: Thank you. If you would like to ask a question, please press Star 1. And we have a question from (Roberta Davis). Your line is open.

Woman: Thank you. Go ahead, (Roberta).

(Roberta Davis): Yes, hello. Thank you so much for the presentations this morning. A technical question I would have is for our next meeting, will you have the slides available for those of us who are the patients likely that an earlier meetings?

I love looking at this stuff and, Syretta, but I would also appreciate seeing the slides that the presenters are showing everyone else and visually it would help me with my concentration and focus.

Woman: You haven't been able to see any of the slides this afternoon?

(Roberta Davis): No, and yesterday either. All I'm saying is the room where they're sitting.

Woman: (Gustavo), can you give her a little direction on that?

(Gustavo): Do you click on the Webinar link using Google Chrome which was sent via the listserv? I'm not sure if you are on the listserv.

(Roberta Davis): Oh, maybe I (unintelligible) the right - oh, I didn't use Google Chrome probably. All right, so that was probably a mistake on my part. Okay, thank you. (It's too late now).

Woman: You're welcome.

(Roberta Davis): Here's my question and it's probably for NIH. Realistically, as a patient, I understand that you need this critical mass of researchers who are going to submit applications.

How do we help connect our practitioners or entice our practitioners to want to connect with the academics and get into this translational process and apply for these grants?

How, realistically, do we do that? And to which of our specialists do we direct our attention? I mean, should it be our primary? Should it be the neurologist? Should it be the gastroenterologist? I mean, which of our doctors should we try to entice into this circle? Does that make any sense?

(Vicki Whitamore): Yes, this is (Vicki Whitamore). Thank you for that question. That's a very good question. So the way I would answer that right now, and I - this may change after we fund the centers, but I'm hoping that this is what will happen - it's likely that once the centers are up and running, they will begin recruiting participants for various studies within the centers.

And it will be really helpful for all of you to be able to get the word out to other individuals with MECFS and to clinicians to help to refer individuals into those studies.

So I think that that is a way that a clinician who sees individuals with MECFS, regardless of the specialty, is if they know of someone that could participate and they really benefit from being part - or they always tell us you don't benefit from a clinical trial, right, or a clinical study.

(Roberta Davis): Okay.



(Vicki Whitamore): If they could qualify - that's the word I'm looking for - qualify to participate in a clinical study, that would be a really superb use of clinicians across the country.

So I think we'll work with - probably through (SIFSAC) as well as through other federal agencies as well as the advocacy groups to begin to get the word out as soon as we're at that point.

(Roberta Davis): Okay.

(Vicki Whitamore): Does that make sense to you?

(Roberta Davis): Yes, that makes very good sense. Yes, and the centers - where are they located again?

(Vicki Whitamore): We don't know that yet.

(Roberta Davis): You don't know that yet.

(Vicki Whitamore): So the applications will be reviewed and we'll be able to announce that after they're approved in council in September.

(Roberta Davis): Okay. Okay. All right. Would you be able to speak more about the subset of patients that are beginning to be recognized? Would anybody be able to speak more about that?

(Vicki Whitamore): I can, but I think not to tie up time, one of the things that I might suggest, if this is okay, (Faith), would be that we could have that the a presentation at the next (SIFSAC) meeting.

(Faith): That sounds like a good idea, actually, a very good idea.

(Vicki Whitamore): Okay.

(Faith): So we will - let me just write that down quickly, and (Vicki), I'll send you a follow-up email to make sure I got it right.

(Vicki Whitamore): Sure.

(Faith): Thanks.

(Vicki Whitamore): And I likely would ask my colleagues who are - especially the immunology folks and the neuroscientists to participate so that they can be more knowledgeable and answer questions better than I could about that, so.

(Roberta Davis): Okay, that - terrific. Thank you so much. I won't take up any more time. Thank you.

Woman: You're welcome.

Woman: Thank you.

Woman: Thank you for calling in.

Woman: Thank you.

((Crosstalk))

Coordinator: Our next question comes from (Sue Ellen). Your line is open.

(Sue Ellen): Sorry, I do want to take time, but it's administrative. I cannot - as they did yesterday - click on the link for the Webinar nor see - even get to your site or see the slides. Could someone just email me the information or tell me how I could overcome that? I was fine yesterday. Sorry.

Woman: Just give us your email please.

(Sue Ellen):` Yes. M-R-S-T, like, Mrs. T, like T, 2222, at Gmail.com. Mrs. T, four 2s, at Gmail.com. Sorry, but I'm...

((Crosstalk))

Woman: I have to see it visually too. And having the slides ahead of time, also, I echo that, would help us cognitively impaired folks greatly. Thanks for that question, (Roberta).

Woman: And our next speaker please, operator?

Coordinator: (Samantha), your line is open.

(Samantha Lyons): Hello, can I be heard?

(Gustavo): Yes, go ahead, please.

(Samantha Lyons): All right, thank you very much. My name is (Samantha Lyons). I'm currently 24, out of Ohio. I had three short questions or really points to consider.

The first is, I've actually been suffering gradually worse since I was around 16 years old or went into puberty, but it wasn't until about two or three years ago that I finally got diagnosed after a lot of testing, and only because I had a very experienced nurse practitioner.

But even until now, I'm still constantly learning things. So the idea is kind of, there could be like a beginner's manual or information, some sort of, like, online booklet or something for people who have been diagnosed to figure out, you know, what are parts of this disease, what are common ailments, that would be pretty awesome.

Because I'm pretty sure many of the people listening no, information is pretty spread out and it's hard to get a clear idea of what could be part of this and what could be random.

The second one was, this was kind of asked a couple minutes ago, but the study volunteers, like, I would personally be interested but I've heard there's a study that will be looking into, like, treatments with (crisper) and such since its mitochondrial.

And do any of you guys now anywhere, where like, they're posting looking for volunteers for these studies or anything?

(Vicki Whitamore): All right, let's - this is (Vicki) - I'm not aware of those studies but I can investigate that for you.

(Samantha Lyons): Thank you. All right, and just the last point was something I have seen again and again is many organizations are looking for a different name for the disorder because of the (state) of people brushing off, like, chronic fatigue syndrome thinking it's the symptom, et cetera.

And I just - I don't know if this is the right venue for it, but I just had a thought of one thing you could be renamed to would be (Ia) syndrome after the character (Ia) who is the main character from (Parasite Eve) which, the short story of it, is it has a lot to do with mitochondria.

And since they're saying this is a mitochondrial disease, it seemed rather fitting. So, that was all. And thank you guys very much for your time.

Woman: (Sue Ellen), thank you. If you want to email me, we can help you set up - get you some information out about the disease and link you up with some of the advocates.

My email is F, as in (Faith), Newton, N-E-W-T-O-N, at DESU.edu, and it should be posted somewhere. So again, F, N-E-W-T-O-N, at DESU.edu, or (Gustavo) will have it. You can just email the (SIFSAC) we will see what we can do to help you out. Thank you for your time and for your suggestions.

(Beth Unger): And this is (Beth Unger). Could I just mentioned something?

Woman: Yes, go ahead, (Beth).

(Beth Unger): The IA CFS ME primer is available for download on their Web site, and the pediatric primer, even though it's - the caller was in the pediatric patient, has also very good information and that has just been published. And that's a good area.

Woman: You know what, you would think I would have thought of that. Thank you, (Beth), very much. Yes, the - yes, we can send you a link to the pediatric primary. You can just look it up. Even though you are 24, a lot of it is applicable, and the adult primer also is applicable. Again...

((Crosstalk))

(Samantha Lyons): And where could I find those?

Woman: Say that one more time.

(Samantha Lyons): Sorry, where could I find those were what was that email again?

Woman: The email is F, Newton, N-E-W-T-O-N, at DESU.EDU or you can just look up (frontiers) in pediatrics and the primer, this pediatric primer, should bring it up.

(Samantha Lyons): Thank you very much. You all have a wonderful day.

Woman: You too, and thank you very much for calling in. Do we have any other speakers on the line?

(Charmeon): This is (Charmeon). My husband, (Alan Gerwin), has a question.

Woman: Go ahead, (Alan).

(Alan Gerwin): Okay. In listening to this telecast, or auto-cast, it seems to me that what has not happened yet is that the federal government, and its various health agencies, have not declared simply and clearly, that ME is a biological illness.

You imply that by all the good work that I hear you're doing but it hasn't declared definitively that this is an organic illness. We here in Massachusetts have a terrible time finding physicians or knowledgeable and placing patients with them.

And it's because of the false information that was spread by British psychiatrists about the psychological nature of ME. It is not psychological. It is an organic illness.

And unless the federal health agencies so declare, we are facing a very powerful uphill battle.

Woman: Do any of the ex-officious want to comment - Dr. (Whitamore) or Dr. (Unger) or (MI)?

Woman: I mean, it's a very good point. I think the ION was very clear on saying that and I think that the materials coming out, too, help clarify this and definitely we'll keep that in mind.

(Alan Gerwin): Thank you.

Woman: Thank you. Thank you, Dr. (Gerwin) for your comments. Do we have any other speakers on the line? Do we want to move on to - (Gustavo), do we want to move to...

((Crosstalk))

(Ben Seborger): This is (Ben Seborger), if I could ask one follow-up question for (Vicki).

Woman: Go ahead, (Ben)

(Ben Seborger): Thinks. So, (Vicki), you talk in your presentation about increasing collaborative efforts with other organizations, private organizations, that would fund research.

And I wondered if you could clarify, are there any efforts underway for the NIH to also increase collaboration with organizations that don't do funding or is this - are you only looking at collaborating it - collaboration in terms of organizations that will fund research?

(Vicki Whitamore): So, a very good question. No, we are open to working with and partnering with all groups. And so, typically if we set up a group, it has a focus. So, for example - the example I've used before that we are thinking of modeling our MECFS group after is ICARE.

It's a group that comes together to talk specifically about funding for epilepsy research. But, you know, that can also entailed discussions about training new investigators, training, you know, the upcoming clinician scientists, can really involve other discussions.

So that's a long way of saying we are not just interested in partnering with - focus on research, but with partnering with all advocacy groups. So I'm sorry if I implied that.

(Ben Seborger): No, thank you. That's very helpful. And, sorry, if I could just ask one more question. This is x-ray to Dr. (Unger). Some of the patients in our network brought up to me a question that they've been trying to ascertain through the Freedom of Information Act to request what's the amount of money that the CDC spent on the previous IOM report.

And to my knowledge, so far, it's been years and they still haven't received any answer about this. Is that a piece of information you could provide us with that, now that this report has already been finished several years ago?

Can we have that public information on how much has been - how much the CDC spent on the IOM report contract?

(Beth Unger): Sorry, this is (Beth Unger), and CDC was not the sole funder of this report. It was - CDC did make a contribution and how to disclose that information, I think it's a little beyond where I'm at.

But we did provide the information to (Gustavo) and I assume there's going to be an HHS response. But it's - it definitely was not solely funded by CDC.

(Ben Seborger): Sure. But so you provided the information to (Gustavo) on what CDC's contribution was?

(Beth Unger): YEs.

(Gustavo): Yes. It was a contribution between - my understanding - this also pre-dates me and it goes back to (Nancy Lee) who was the DFO - but it was funded by this office by (OASH) with contribution from NIH and CDC.

Woman: And are you sure none of the other ex-officious contributed? There might have been somebody else in there. I don't know.

(Ben Seborger): So, (Gustavo), in the interest of time, could I follow up with you later to get some of that information on what the contributions for that report?

(Gustavo): Yes, yes, send me - you can send me an email. We can talk on the phone.

(Donna): This is (Donna). I'll just add, although the figures are not disclosed, the (IM) report actually lists all the agencies that contributed to funding it. It was definitely - and maybe four, five, six or seven. I don't remember how many, but there were a number of them.

Woman: Thank you, (Donna). I thought that's what it was.

(Ben Seborger): Thank you.

(Gary Kaplan): (Gustavo)?

(Gustavo): Yes sir?

(Gary Kaplan): Hi, this is (Gary Kaplan). (Gustavo), can I address some of the questions here that are on the medical education workgroup because we have a number of respondents prior to the conference and wanted to give just a brief summary of the data that we got back.

(Gustavo): Sure.

((Crosstalk))

(Gary Kaplan): So with regard - I'm sorry.

(Gustavo): Do you want us to put up your presentation or...

(Gary Kaplan): No, stay right here for - because what I'm going to do is just a brief summary of the respondents to these questions that were put out.

(Gustavo): Okay.

(Gary Kaplan): And then we'll move on to the presentation.

(Donna): So, (Gary), this is (Donna).

(Gary Kaplan): Yes.

(Donna): Did you get my documents?

(Gary Kaplan): I did not.

(Donna): Oh, I wrote up a document for you. (Nora) was supposed to send it to you. Okay.

(Gary Kaplan): Okay. No, I was in transit most of today. So I apologize for not getting that. But what I'll - let me summarize what I've got in the, (Donna), you can add to that.

(Donna): Okay.

(Gary Kaplan): And then we'll go on from there.

(Donna): All right.

(Gary Kaplan): So, you know, we had about 17 people respond and I want to thank everybody who did so. You know, listening to the stories and reading through this stuff is truly heartbreaking and I'm (foundly) embarrassed of my profession.

The way people who have this disease are treated as shameful. And it's just gut-wrenching. And I'm so sorry that you had to endure this family will hopefully make this better as we move into the future.

The first question was with regards to what are the three most important things you want your physician and other healthcare providers, nurse practitioners, physician's assistants, registered nurses to know about your disease?

You know, and overwhelmingly the answer came back that the disease is real, it's not caused by lack of (motivation), (unintelligible). They want people to understand - their physicians, their caretakers - to understand that this is a systemic disease, that it's not just, you know, fatigue, but rather it involves issues with brain fog and (pots) and gut disorders.

And so it's a very complex problem that is multi-systemic. They talked about wanting to have access to telemedicine, thus, you know, one woman had said that, "I was forced past my energy envelope and had a nasty flare-up for a month. Just going to a doctor shouldn't have to make us sick."

The doctor doesn't see what's going on or we leave the office. I mean, these were not unusual comments. Then the other thing - their comments were the necessity of getting out

good therapy data because the (graded) exercise therapy, the (pace) trials have proven harmful.

And we really need to get the message across to physicians and first, do no harm and certainly following these, our recommendations are doing harm. The other problem, of course, is that people will always run into, doctors should not rely on the patient's appearance because the illness (will vary), because the illness fluctuates. That was just some of the - a quote from one of the other commenters.

Question two, since P2P and IOM reports, have you found the access to clinical care easier, harder or about the same? Unfortunately, pretty much across the board, the answer was not easier - the same, no difference.

So they don't - we're not seeing in the field, at least from this limited survey, the impact that PCP and IOM in clinic of care. And one patient wrote back and said, you know, doctors tend to make me feel unwelcome when they learn my diagnosis. This is just a disgrace.

Question three was, do you believe that the physicians that you're saying are interested in learning about MECFS? Now, this was - this question was inspired actually about a comment we had on the phone and one of the (unintelligible) meetings and (Kent) particularly brought this comment up - question up.

He said, you know, what - we can do all this stuff but if we don't have a willing audience, who are we talking to? And so I decided to pose this question to the community and say, okay, what are you finding?

And the answer was, "No, I don't believe my physician is interested in learning about this stuff. There's too much deep rooted prejudice against the illness."

This is another barrier that were going to have to figure out how to overcome in terms of providing education and we need people who want the education. And then do you believe this attitude has changed much since (P2P) and IOM?

Unfortunately, the answer for the most part was not at all. There was one particularly interesting comment that said only and researchers and journalists. So we seem to have made a dent actually in getting the researchers on board and wanting to be interested in this and journalists. But we are not, again, getting to the clinicians the way we need to.

Number five is, do you believe that social workers, psychologists, and/or psychiatrists are interested in learning about MECFS? And, if yes, what specifically would they be interested in learning about?

Some felt that this was a little bit too much for (the healthcare) providers. They'd like to see where they could help but they felt, quote, "it was a step too far for other healthcare providers even though (they must) learn about the disease."

One particular pointed comment of (Kate Brown) that caught my eye was, I would like to not be the expert in the room when I'm (talking to the healthcare provider).

So we've got a lot of work to do. And while I think P2P and IOM are extremely important and groundbreaking in terms of moving the disease forward and more to the forefront, we have a long way to go in order to be able to get care to people. (Donna), do you want to add to that?

(Donna): Yes, I kind of crossed off the things that you mentioned and I'll just - I'll point out a couple of other things. Again, and this is worth stressing because pretty much everybody said this - they want providers to know with absolute certainty that this is a biologically-based disease and that it causes multi-systemic dysfunction.

It's high on the morbidity index and it results in a greatly diminished quality of life. And they really want educational materials to actively repudiate the psychosocial narrative and make it abundantly clear that the disease is not (mopped) and it's not a diagnosis of exclusion.

The other thing that was high on the list was for doctors to understand that PEM is very real and that a patient's definition of overexertion is not that of a normal person, and also that physicians should respect the patient's knowledge of their own energy limits.

And you did talk about this, (Gary), where - I mean, I know this happens all the time. People go to the doctor and they crash. And then the third most frequently mentioned thing is doctors need to know that it's not just about fatigue.

It needs to be clear that it doesn't revolve around the teak but, rather, around limited energy creation or energy reserve. And that it also has unusual sensitivity to stressors of all kinds and they typically destroy the patient's life due to the limitations it imposes.

And one person suggested that the (metabonomics) research should be shared in medical education materials. And then I just don't want to leave out the neurocognitive dysfunction.

Not as many people as the debt, but at least three or four people did say that providers need to understand that. A couple other comments about that, that rapid diagnosis, early intervention and ongoing support is the best care.

And proper diagnosis is extremely valuable, whether or not treatment exists. And one person said, "I'm not even looking for them to cure me. I just need their help to live the life of any quality." I think that's pretty important for doctors to know.

On the - one (unintelligible) got a little bit more detail, and that's do you believe the physicians are seeing or are interested in learning about the disease? Most people, as you said, (Gary), feel that they don't. But I had one person who wrote a really good comment and that was, one has to make them be interested.

I think it was (Margaret) who did this. And she lists things that would help. I know the committee has (seen) that but I tend to agree. We need to make them interested (by) getting the right information out there, letting them know what their responsibilities to treat, rejecting the false narratives of the disease, giving them some idea of how they can help patients. And that's it. Okay?

(Gary Kaplan): We have a lot of work to do. (Donna), thank you. We clearly have a lot of work to do. (Gustavo), can we move onto the presentation?

(Gustavo): Yes, Syreeta is going to bring it up. We'll (move the) slides for you, (Gary).

(Gary Kaplan): Okay, you'll move them forward?

(Gustavo): Yes.

(Gary Kaplan): Please. Okay, so if we can - so if we go on - okay, so this is the group of people who are participating in this committee. It truly takes a village that I want to really acknowledge the fact that everything on this list has contributed in significant ways and everybody is working very hard.

This is an interim report. We are not ready to ask for specific approval for movement or recommendations from the advisory committee at this point. We will have that ready at the next meeting.

But we have - you know, as I go through this you'll see there're a lot of issues that we have to address and still need to address, as we go through this. So if I can - so I just want to make sure I acknowledge and thank everybody on this committee because everybody has been participating.

Next slide please. So the committee's original charge was to formulate a series of recommendations to the secretary on how to improve education for healthcare providers and MECFS.

We took that and, if you'll go to the next slide, and we kind of broke that down into three sub-questions, clearly overlapping but allowing us to combat it from a couple different directions so we could begin to understand, not only the potential avenues for providing education, but more importantly, the barriers that we're facing.

So we had one group of people doing - provide progressive MECFS education to healthcare providers. Another was looking at disseminated clinical practice guidelines and best practices.

And the third was identifying potential mechanisms to expand the base of providers capable - able to diagnose and care for persons with MECFS. Next slide please.

Next slide. Great. So with regard to that first point - provide progressive MECFS education to healthcare providers particularly (Terry Wideler) (unintelligible) worked very hard on this particular area, and looking at providing a wider array of progressive MECFS education, training, resources and tools to healthcare providers.

And we expanded clearly, not just to physicians, but to also (to natural paths) and physician's assistants, nurse practitioners, RNs, social workers, psychologists, psychiatrists.

Basically we're trying to get the whole array of people who potentially come into contact, especially on a first line basis, with people struggling with this disease.

And the other was including continuing education options to incentivize participation and specialist support for healthcare providers and experience in the field.

So this starts to address this business of, okay, how do we make our audience interested in what we're talking about? Certainly provision of CME is one thing. Continuing medical education credits.

That always seems to attract physicians. But we need to figure out how do we get people wanting to have this information? Next slide please. So potential solutions, and I want to say that (Terry), in particular, has a great deal of experience with this in New York using a model with AIDS.

And so we talked about toll-free MECFS line to connect healthcare providers to highly knowledgeable specialists regarding the disease, training and conferences on MECFS and related topics, MECFS Project ECHO.

So Project ECHO is Extension for Community Healthcare Outcomes. This is pioneered at the University of New Mexico specifically looking for trying to disseminate information for the



treatment of hepatitis and taking them model and potentially utilizing it for people struggling with MECFS.

And what this does is, it connects an expert in the field with people out in the community, positions out in the community, mostly through telemedicine conferences, and give them ongoing guidance and support in terms of treating patients out in the field.

Looking at MECFS intensive mini residencies, practicing medical providers, so that's bringing people in for a week, two weeks, to be able to learn from an expert how to treat these conditions.

We have a similar model to this in Lyme disease where an (I lab) is set up in one to two week (intensives) with experts in the field of Lyme. The point is that we have models we can follow and develop.

Technical assistance and clinical tools, always empowering our providers so that they actually feel like they can accomplish something, and guidance on Web sites.

Now, these are potential solutions to beginning to address the dissemination of information. Next slide please. Next slide. So in terms of disseminating some of the practice guidelines and set practices - best practices, (Charmeon), (Elizabeth) and (Robin) were spearheading this effort and produced a huge amount of information that we're going to need to consolidate but which gives us a really wonderful basis for vetting information out and understanding within the government structure we can disseminate this information.

So the first thing was, what existing mechanisms are available to disseminate clinical guidance, best practices for care with people with MECFS? What educational content or resources are available? And again, perhaps most importantly here, as we get to this - to the end, or what are the gaps?

Next slide please. So compiling a database, an idea grid, which may actually have the beginnings of - and it's a big grid and it's extremely useful - of disseminating options, tools for prioritizing and identifying gaps.

So evaluate audience geographic scope, program type, cost, funding plan, who is responsible, obstacles to success, difficulty conducting, impact assessment plans.

So this is a little servicing in terms of, in a sense, interactive. You're identifying who your audience is but you're also getting some feedback from the audience in terms of understanding with their needs are.

And this also talks about who's going to be doing what, and what their responsibilities are. And that's extremely important because if we just come up with ideas because we don't have mechanisms for true implementation, then nothing happens.

Critical need for approved content for dissemination - this is the biggest (obstacle), and we'll come back and talk and talk about this in a minute, but criteria for content.

Evidence-based clearly whenever possible, and if not, then based on expert advice gathered and evaluated systematically. (Treatment needs) to be included in content.

Message should be consistent across federal agencies, certainly a problem we've encountered and must be tailored to the audience. So, again, who are we addressing?

Are we addressing physicians? Are we addressing nurse practitioners? Or are we addressing the public? So the information needs to be at the appropriate level to the appropriate audience.

Next please. Identify potential mechanisms to expand the base of providers able to diagnose and care for persons with MECFS. (Ted) and (Mary) did a great deal of work on this.

Identifying barriers to access to clinical care along with potential solutions, and expand the base of providers able to diagnose and care for patients with MECFS.

Next slide please. So the barriers, and these are the things that we really need to focus on, I think, in the - in our upcoming meetings and how we're going to fix this.

Anticipated loss of disease expertise and lack of providers - one of the things that's happening, unfortunately, is we've not seen lots of new young physicians moving into this area, but rather, we have a lot of physicians who have been treating these conditions for many years.

They're starting to age out, and we are at really serious risk of losing an incredible wealth of data from these experts and need their clinical (expertise) in terms of guiding treatment as we move forward.

So we need to figure out some way to capture that data. The Institute of Medicine, this P2P, reports the validity to the disease and guidance to diagnosis but provided no treatment recommendations. And this, again, speaks to the first problem as well.

Without treatment recommendations, we have a massive problem because we don't know what to tell people what to do. And there's nothing more disempowering to physicians than saying congratulations, you have - and I remember this from training.

I walked into a patient's room. We had just diagnosed him with (Younkins Creutzfeldt) which is a degenerative neurologic condition and, congratulations, we know what you have. You'll not have any memory of this conversation and there's nothing we can do for you.

That does not encourage physicians to want to go treat these things, and so we really have to put some tools in their hands so that they can feel empowered so they feel good about being able to effectively interact with patients who are struggling with this disease and provide the appropriate guidance and treatment.

Negative attitude, stigma, disbelief and misconceptions - a huge problem within the field that needs to be addressed. And MECFS is endorsed by the community but incompletely accepted by major medical groups and large medical societies.

So what we're going to have to do here is we're going to have to figure out a way, first, what's the message? What is it we want to tell them? Okay, we've got good guidance from IOM and P2P in terms of diagnosis of the disease, but then what? How do we treat it?

And we have to get that information into the medical community, and that can be done predominantly through lectures at major society endorsed conferences, and also in major society endorsed publications.

But again, we need to know what that message is. We're going to have to figure out how to do that. Limiting medical practice - medical office practices and financial challenges - you know, everybody is squeezed at this point.

These five, ten minute visits which are dictated by insurance limitations are not acceptable to truly being able to understand and treat diseases as complex as MECFS.

And then, of course, we're always struggling with the lack of research data. But that's going to change and we've now got NIAH ready to fund these centers and we've got real money starting to move into the system to make that.

So there is much reason for optimism. It's not moving anywhere near as fast as we wanted to and need to, nevertheless, this is a major sea change from where we were just two years ago.

Next slide please. Some potential solutions - defined criteria for identifying acceptable sources of content for clinical guidelines. Certainly we have the IACF and the primer that's a few years dated at this point in time and needs some sprucing up, and the new pediatric primer.

It's a place to start and maybe that - we can come to an agreement, but somewhere along the line, we have to come to an agreement about what it is we're going to be putting out in terms of not just diagnosis, but treatment recommendations.

The provision of telemedicine to underserved - unserved areas, and I do want to emphasize the unserved, not underserved. I - one of the women who responded to the questionnaire said that she had moved to New Mexico and found that there was no provider available for her in the entire state who could address her condition.

And she literally had to move out of the state in order to get care. This is an unbelievable severe problem. Proactive knowledge retention programs - this is going back to picking up the skills and wisdom of the clinicians who have been treating these conditions for years so that we don't lose that data.

Provide remote support for medical providers by disease experts - again, we're going to have to figure out where we're getting those experts from and what - and agree upon what the appropriate data is.

You know, you start getting somebody who decides they're an expert in saying (pace) is the way to go. Again, it's the way to go. We have a problem. So that - we've got to get on the same page and we have to try to understand how we can make appropriate recommendations to the secretary to be able to accomplish this.

Experts presenting at key conferences at the (influence of providers) - again, that something else that we want to be seeing. And I think the very first thing, if you go to the next slide, I think that's (it).

They - the real challenge here is trying to understand what the message is. And that's what we're going to be addressing over the next couple of months to understand how to get - all right, we've got the treatment guidelines - we've got diagnostic guidelines at least.

Now we need an officially sanctioned treatment guideline, and it's going to have to draw both on research, which unfortunately, is fairly scant, but a lot on expert opinion.

And we have to figure out what the mechanism for that is going to be within the government in order to be able to get on the same page and then be able to disseminate this information. I'm open to any questions. Next slide. Yes.

((Crosstalk))

(Mary): (Gary), this is (Mary). Can I add on? Can I add on to what you just said?

(Gary Kaplan): Absolutely.

(Mary): I want to speak to the clinical guidelines. One of the challenges that we face, and I don't quite know what the solution is to this yet, but our clinical guidelines across the board, and I'm not talking CDC specifically, I'm talking about across-the-board, different guidelines and guidance, still includes (CBT and yet), still includes the biopsychosocial theories.

And the problem we have is that those studies continue to be pumped out and they have, like, a virtual pipeline right into clinical education. And so we need to find a way to, very pro - and it's going to take a lot of leadership from HHS and the medical societies to proactively break that link.

Because until we do, it's going to be very difficult to address the stigma and to address mistreatment of patients. And that's probably one of the biggest challenges we face.

And it actually - to go back to the case definition discussion we had earlier, it links back to that because we still have case definitions that are overly broad that are producing guidelines and ending up in medical education. Thank you.

(Gary Kaplan): Completely agree. Any other members of the working group on to come and add on because you guys have been doing a lot of work? The deafening silence.

(Beth), I'm going to put you on the spot because you guys put together a huge flowsheet in terms of how we can disseminate this information. But I'm trying to get some understanding about one government mechanism.

Once upon a time we had (intensive) conferences at NIH. What - mechanisms that we could potentially work within the government in order to get consensus on treatments by utilizing expert opinions.

(Beth): This is (Beth), and I would say that we aren't - we - there's not a formal-formal process or not one only process and this is something that we are discussing. So we don't have an answer yet.

We just recognize is the need. And it's particularly challenging because the traditional methods for consensus rely on published literature and we have to find a way around that because, in this particular case, the literature is only part of the picture, and a minor part of the picture.

(Gary Kaplan): Anyone else want to add on? (Terry), (Ted)?

(Mary): This is (Mary). I had another follow-up question. Is there - one of the key issues we face is the magnitude of the stigma that's holding everything back. The IOM recently produced a report that was reported on the educational initiative that CDC ran about what it takes to overcome that stigma.

Is there any program anywhere within HHS that could be leveraged that's been used to address that magnitude of stigma in the past that we could use as a model?

(Gary Kaplan): So you're hearing the challenge. We are struggling to find a (mechanism). Is somebody going to help out?

(Vicki): This is (Vicki). Can I come in?

(Gary Kaplan): Absolutely.

(Vicki): So we looked at this issue of stigma around epilepsy after the epilepsy IOM report, well, during and after the report was released on epilepsy. And, you know, so there were a couple of things that happened.

I think within the epilepsy IOM report it was recognized that it really falls to the advocacy groups in large part working together with professionals to try to dispel the stigma of the disease.

That's not to say that HHS doesn't have a role, and so please don't think that that's what I'm saying. HHS - or NIH had a (grant) mechanism specifically to address stigma and specific disease entities that was on the streets for many years and attracted very few applications across any disease entity.

So I think that there are ways to address this but it really, I think, takes a concerted thought process as to how to address it from multiple angles, not, you know, public awareness, physician awareness, potential research efforts. I think it really takes thinking through many different approaches to addressing stigma.

(Gary Kaplan): And, (Vicki), is there any mechanism within NIH at this point that's similar to what we used to do at the consensus conferences?

(Vicki): Unfortunately, no. They did away with support for consensus conferences. And again, sort of pushed it off to the relevant - whatever disease relevant advocacy group is to organize those.

I think they are sometimes organized within research conferences such that then the research conference can get support through - in R13 conference grants but it technically can't be called a consensus conference.

(Gary Kaplan): And I'm sorry, what's the number for their grant?

(Vicki): R13.

(Gary Kaplan): Oh, okay, yes.

(Donna): This is (Donna). I'm wondering if - our HRSA member talked about grants and I'm wondering if the challenge of the stigma might specifically be something that would be appropriate for a grant through HRSA.

Woman: (Donna), I was wondering as he was presenting - (Joel) was presenting on a number of facets that might provide some opportunity from HRSA, so that's another one. And I was going to follow up with him after this meeting. But that's a great idea to see what's possible there. And, (Joel), if you're still on the line, yes.

(Faith): Yes, that - this is (Faith). That's an excellent question, (Donna) and (Mary).

Woman: (Joel), are you on the line? We lost him. Okay, can we decide and reflect in the minutes that we feel that this is something we should follow up with him about? Or is this not (what the) (unintelligible) would do?

Woman: Yes.

Woman: Probably not, actually now that I think about it.

((Crosstalk))

(Gary Kaplan): (Donna), it is absolutely (unintelligible) the subcommittee will go.

(Donna): Oh, yes, that makes sense.

Woman: Right. Right.

Woman: Okay, so (Gary), you'll handle it as a subcommittee?

(Gary Kaplan): Yes, ma'am.

Woman: Okay, thank you. If anybody else...

((Crosstalk))

Woman: That was an excellent presentation.

(Ben Seborger): Sorry. Excuse me. this is (Ben Seborger) with ME Action. I just want to say, Dr. (Kaplan), though again, that was a very impressive presentation we received.

And I see - is that presentation available to send to the members of (SIFSAC)? I didn't see it when it was - the other presentations were circulated. So I was wondering if you could provide that to the other members.

(Gary Kaplan): (Unintelligible), (Gustavo), could you send that out?

(Gustavo): (Ben), the presentation will be on the (SIFSAC) Web site in probably about three weeks because they have to go through clearance by the Department, what we call 508 compliance, to make sure that the deaf and hard of hearing people can see it.

But if you need it right away, I can send it to you. But if you're asking if it's going to be available to the public, it will be in three weeks on the Web site.

Woman: (Gustavo), this is...

(Ben Seborger): Yes. No, I was asking if it could be circulated to the (SIFSAC) members.

(Donna): Yes, my understanding was that all the non-voting liaisons are supposed to get every single thing that the voting people get...

((Crosstalk))

(Gustavo): I know, (Donna), but Dr. (Kaplan) sent it to me a day before.

(Donna): Oh, oh, so you didn't - I saw it from him directly. All right.

(Gary Kaplan): My bad. We were editing this thing and going back and forth on it until (today).

(Gustavo): Not everybody meet the deadline because I tell them, you know, I need it by a certain time. So I send you what I get by the deadline that I set.

(Donna): My apologies.

(Gustavo): Okay. So do you guys want me to send it to all of you now?

((Crosstalk))

(Faith): Yes, could - this is (Faith). Yes, could you please send that out to all of us?

(Gustavo): Okay.

(Faith): Thank you, (Gustavo).

(Gustavo): You're welcome.

(Ben Seborger): And sorry, just one other question. Was the epilepsy report that was being referred to, is that the 2012 epilepsy across the spectrum promoting health and understanding? I just wanted to clarify that was what was being referred to.

(Vicki): Yes, that's what I was referring to. This is (Vicki).

(Ben Seborger): Thank you.

Woman: Does any - do any of the other ex-officials or (SIFSAC) members have any comments or questions for (Gary) and his group?

(Gary Kaplan): Or recommendations in terms of future directions. The HRSA thing is obviously one - excellent and one we have to follow up with, but any ideas you have in terms of where else we should be looking.

(Donna): Oh, so again, this is (Donna). I just want to remind everyone that at our - the meeting in January, we were attempting to submit a recommendation about asking HHS to

identify funding from the combination of agencies so that we could incorporate the new evidence to refine the diagnosis and then also to incorporate some clinical evaluation as well.

In other words, to hire, for example, an IOM type of committee to do this work. Dr. (Kaplan) said the strongest argument for reconvening a meeting is that a public health emergency exists.

And I remember Dr. (Matono) said that there was a great body of knowledge within a small group of clinicians who really know the disease from dealing with it directly.

And it would be a huge step forward if we could combine an updated diagnosis with some type of clinical management. So the way we ended up leaving that was we did not submit a recommendation.

Instead, (Beth) and (Gustavo) had agreed that they would work with the ex-officials on how to implement what we wanted to do and see if there was any way to fund that.

So that is some way that we need to be thinking about it because that's kind of part of this whole discussion about how we're going to come up with medical education and treatment guidelines. I don't know...

((Crosstalk))

(Mary): (Donna), this is (Mary). I just want to add onto that. We really have a sense of - a need for urgent action here because the number of our clinicians are reaching - not all of them - I just want to be clear, but a number of our clinicians are reaching retirement age or are leaving their practices. And so we need to capture the knowledge of - that's in their heads before that happens.

(Donna): Okay, we might be held up because I know that Dr. (Colin Sharp) said that they were going to mention it with the new permanent (ASH) and the HHS...

(Gustavo): Yes, and the (unintelligible), (Donna), that we still don't have an (ASH), like...

(Donna): Yes, that's what I thought, and the secretary is probably so busy doing other things that it's not even on their - I mean, we can't even get our members approved here, new members, so.

(Gustavo): Exactly.

(Donna): I understand the issue, but I'm hoping that somehow we can work through the channels with - maybe through the ex-officials just to see if there's any money available, you know, to pull together like with them before. That's it.

Woman: Anybody else have any other comments? (Gustavo), do we want to open it up to the public?

(Gustavo): Yes, we have 20 minutes before our break at 3:00.

Woman: Right.

(Gustavo): And actually, (Faith), also from 3:15 to 4:00, we have discussion of the recommendation for the (medicare occasional) workgroup but Dr. (Kaplan) does not have any. So we really - the only thing we have left to do from the agenda besides opening the line to the public as to discuss the SOP.

Woman: So do you want to take a break and just move everything forward or how do I do this?

(Gustavo): Whichever way the committee wants to. We can take...

Woman: What's the pleasure of the rest of the committee?

(Gary Kaplan): This is (Gary). I'm on a really tight schedule. If we could move forward and just finish up, if you need me for a quorum, otherwise, I'm going to have to sign off by (unintelligible).

Woman: I am fine with that. (Donna), are you okay with that?

(Donna): So we're just - yes, we're going to hear from the public, is what you're saying right now?

Woman: Hear from the public, (take a break) and just go right to SOP.

(Donna): Yes, let's finish up what (Gary) needs to be involved with.

Woman: Right. I would agree.

(Gustavo): So (Michelle)...

Woman: (Katherine).

(Gustavo): (Katherine), I'm sorry, can you instruct the public how to dial into the queue?

Coordinator: Certainly. Once again, if you would like to ask your question, please press Star 1, unmute your phone, and record your name. Your name is required to announce your question.

One moment, for the next question. Once again, if you do have a question, you may press Star 1 on your touchtone phone. We do have a question coming from (Charlotte) Flynt. Your line is open.

(Janet) Flynt: Yes, can you hear me? This is (Janet) Flynt.

((Crosstalk))

(Gustavo): We can hear you. Go ahead.

(Janet) Flynt: Okay, my first name is (Janet) and my last name is Flynt - F-L-Y-N-T. I first wanted to just take a quick moment and I hear a lot of pain and criticism sometimes from patients, as I listen to things.

So I wanted to just express personally my heartfelt gratitude for what's being discussed, and I can see the momentum forward. I know it's a difficult and you're managing multiple things and so I really appreciate it especially since I know energy is precious.

As I look and watch the news, you know, - and I am, you know, a Trump fan, so I'll get that out of the way right away - the current administration is emphasizing innovation to patient centered care and public-private (par) initiatives.

And what I've heard from, I think it's Dr. (Kaplan) and others, that you know, your funding is very, very tight, and also the attention of the DHS secretary is spent or directed elsewhere.

So coming from a high-tech industry, having worked in both the public and private sector and, I just (wanted) a (unintelligible) (down) approach to getting, you know, a big boost in funding can occur or coming both from the public government, you know, addressing Congress, and that also from the private sector.

A lot of high-tech billionaires are talking about, you know, dedicating - and non-high tech - dedicating their money to help, you know, even things in other countries, and so this is an issue, perhaps an emergency issue for public health in our country.

And I know that's the emphasis of our - the new administration, whether you agree with that or not. And so I just wondered, has anyone done, like, an elevator pitch for - and a



roadmap for Secretary Price, that he could present to Congress that would, you know, give him the presentation that he needs, you know, to get attention to this?

I don't know how this area works. As I said, my government - it was more high tech. I worked in defense, NASA and some medical devices and other things related to embedded electronics that controlled machines in the safety arena.

So I'm totally out of my element here. So I just, you know, don't mean any disrespect but I just think more needs to be done to kick-start this initiative and add to the momentum that you all are working so very hard on and I appreciate very much. Thank you.

(Gustavo): Thank you for your comment. I'll try to answer your question about bringing this issue to the attention of the Secretary Price. This would not - I mean, the recommendations put forward by this committee are sent by the secretary through our boss, the assistant secretary for health.

It would not be something that directly would come from the staff within HHS, directly to the secretary. It would have to come through the committee. So it's a large bureaucracy and unfortunately, things from your perspective, as the public, it might look easier.

But it's a little bit more complicated than that. But, like I said, the recommendations do go through the secretary, made by this committee.

(Janet): Okay, so - and I appreciate what you're saying. I sometimes think out-of-the-box as, what as a patient, I could do to - and maybe it's through some of the societies, you know, that are in place to complement what you're doing and get attention.

I also don't hear - and I hear a lot - some about clinical trials, and again, I come from the high-tech background. I understand, you know, some of the statistical data analysis.

I was involved early in my career. But it seems to me like capturing the aging physician's knowledge, you know, there's IBM Watson out there and there may be some other tools.

You know, the high-tech industry with the social media. You know, where is that in the solution space? And where - you know, are there other things that could be brought to bear here?

Can you give me an elevator pitch that one might make to, you know, some venture funding outside just the drug community because, in my view, it's really the patient.

You know, I gave up thinking about doctors as, you know, gods, because they're not. And I just as a patient would like have other patients, self-help, learning how to advocate, but I don't have the energy to produce these documents and so I would look to the government maybe to partner with you know, whomever. I can't manage government projects anymore.

So I guess that's my point. I'll leave it there. You can tell I'm tired and I'm getting a little bit emotional, but - and I do appreciate all your efforts and I understand the government bureaucracy in getting funding very well.

(Dr. Faith Newton): (Janet), this is (Faith Newton), co-chair of (SSEC). We have just added in the last two years advocacy groups, and some of those advocacy groups are doing a lot of visiting or work through the Internet and through social media. I am sure that they are - would be more than willing to reach out to you to participate in health.

And so you put your name out there and maybe somebody will give you a contact. If not you can always contact me and I can pass your name along that way and just see what we can do to give you some support.

(Janet Millwood): Yes, thank you very much, (Faith), for that. I do want to mention that I am like starting to link with (unintelligible) initiative, and I committed to doing a letter to our Senator (Burr) here in North Carolina, but I think I'll connect with some of the others, and I do appreciate that comment and your energy. Thank you.

((Crosstalk))

(Ben Tuborger): This is (Ben Toborger) with ME Action. I just want to say, (Janet), thanks for your comments. If you want to have some discussions about maybe non-traditional ways we can think outside the box and give some elevator pitches to some influential people, you can contact us at [info@meaction.net](mailto:info@meaction.net). I-N-F-O at MEaction.net, and I'll be happy to talk through it with you.

(Janet Millwood): (Unintelligible).

Woman: Thank you, (Janet). Are there any other speakers on the line willing to have comments?

Coordinator: We have no further questions in queue at this time.

Woman: We still have a – so (Jerry), do we need to do anything else to move forward with you?

(Jerry): Yes, hi. No, I think I've got some good ideas from here and I'm just going to (unintelligible) in the process of setting up the next meeting, so the idea of crowd funding and this outside the box stuff, we're – what we need to do is you know – secretary, but the idea of doing crowd funding, I don't know.

We're getting our white paper coffers together, maybe going through the (Arthur Teague) process, could we partner with one of the major medical bureaus such as (JENA) in terms of getting something published that they might be interested in. We have to discuss with the committee that you've given me some very good ideas, and I think we just need to follow up on it.

((Crosstalk))

Woman: I want to commend your work (unintelligible) very evident.

(Jerry): Well thank you, and I've got a hell of a committee, so you know, it's been truly the work of everybody on this committee, and we've got everybody's contributed a huge amount and I really want to thank everybody (unintelligible) we've got more to do.

Woman: Thank you.

Woman: We still have a – did you want to move on to your standard operating procedures?

Man: Can we start (unintelligible) honestly I have to take a bathroom break.

Man: Do you need me for quorum on anything?

Man: No, I don't but the SFE is not something that the committee needs to vote on. I just want to share with you and get your feedback. I mean, it's not a recommendation to the secretary, so I don't think we need a quorum or a vote.

Woman: We should be all set because we're going to continue your working group and my working group and I have some comments that I wanted to say about that being at the end, and that should wrap it up.

Man: Okay, so let's take a ten-minute break until three o'clock, we'll come back, go through the SOP and then you can take your – you can say your final comments, (Faith).

(Donna): Can I just ask a question? It's (Donna).

Woman: Yes, go ahead, (Donna).

(Donna): I kept trying to get in, but I couldn't. I was on mute. Really, I just wanted to make sure, we had briefly talked about resubmitting an outstanding recommendation that (unintelligible) had developed in accordance with the IOM standards for developing trustworthy clinical practice guidelines.

Man: I mean, that is a standing recommendation, but Secretary (Price) has certainly overseen it and it wasn't addressed when it was submitted about a year and a half ago. Is that something that we can just ask that it be resubmitted, or would you rather we not do that at this time?

Man: Evidently that's (Gustavo)'s call. I'm completely fine with resubmitting it, but I apologize, I did not prepare to do so. So (Gustavo), your call whether or not that needs to be resubmitted or simply needs – it's already been approved, so just needs to go under the secretary's attention.

(Gustavo): I mean, we can resubmit it in the memo. If you guys already submitted it when the – I think it was Secretary (Burr), no, this is before my time being a DFO but I would like to get a vote from the members to have the recommendations resubmitted, and then we can – I can include it in the memo with the one we got through yesterday when it goes to the secretary.

Man: Well I would easily vote to resubmit it, since we've already approved it to submit to begin with.

Woman: That's fine with me.

((Crosstalk))

Woman: Like a formal vote, (Gustavo)?

(Gustavo): Yes, just for the sake of the minutes and then...

Woman: Okay. (Jerry), can you word that vote?

(Jerry): (Donna), if you would word it, because you've got the particulars, I believe.

(Donna): Yes, I will just read what the recommendation said and then we're basically asking to resubmit it. It says (SSEC) recommends that these specific diagnostic tools be developed and validated in collaboration with these experts and also that comprehensive clinical practice guidelines be developed in accordance with the IOM standards for developing trustworthy clinical practice guidelines.

Woman: Okay, (Donna), will you be able to send that in writing to (Gustavo) when we get done here?

((Crosstalk))

Woman: It's in our (SSEC) record that's posted on the Web site.

(Gustavo): Yes, I can go and grab it from the Web site.

Woman: In 2015, it was submitted to the secretary. There was a two-paragraph rationale, a quote of the IOM report, at least maybe the PTP as well.

Woman: Okay, so moved.

Woman: On the IOM report, I mean the IOM report made it very clear that that should be considered something that should be done ASAP.

(Jerry): It's been moved and I will second.

Woman: Second by (Jerry). All in favor say aye.

((Crosstalk))

Woman: Any opposed? No opposed, so it passes unanimously (unintelligible).

Man: Okay, just have our minute-taker record it, so we'll submit it with the one you guys came up with yesterday about having a standard semi-CFS update on the agenda.

Woman: Correct. And (Jerry)?

(Jerry): Yes?

Woman: (Jerry), the rest of your afternoon, (Gustavo), what time do you want to come back?

(Gustavo): At three o'clock, in about eight minutes.

Woman: Okay, okay, we'll be back.

(Jerry): Thank you all, have a great weekend.

Woman: You too, thank you.

Coordinator: At this time we'll take a few moments break. Please continue to hold. There'll be music until the conference resumes. Thank you for standing by. The conference call has resumed.

Man: Okay. Okay?

Woman: Yes, are we all set?

Man: Yes.

Woman: You want to start the SOP?

Man: (Donna), are you on?

Coordinator: She may be dialing in right now. Give me just a moment to open up her line.

(Donna): I'm on. Can you hear me?

Man: Yes.

.(Donna): Okay.

Woman: Yes, (Donna), we can hear you.

(Donna): Great. (Courtney)'s here.

Woman: Welcome, (Courtney), welcome back.

(Gustavo): So this document came about – I'm sorry, let's send them in to our note taker because she just emailed me to send it to her. As you remember this document came about because you guys wanted some kind of structure as to – and structure and things that needed to get done at every meeting, you know, for the meeting to be successful. So I went about the other committee members, the other DFOs in August and asked them if they have an SOP.

Some told me they didn't. Others told me they did. So I took some of the work that one of the committees here with (unintelligible) did in terms of SOP and redrafted and made some changes and guarded some things specific to (unintelligible). So I'm not sure how to begin this

because it's the last document and there are a lot of people – a few people on the line but you might get a chance to read it and comment since I sent it.

I know (Donna), I sent it to you way ahead of time before anybody else because you seemed to be the most interested in this topic, but does anybody have any specific comments? Did you get a chance to read it, look at it?

(Dr. Faith Newton): I read it. This is (Faith), and I thought it overall looked good. I was really glad to see things spelled out. (Donna), do you want to comment? Did you put a lot of work into this?

(Donna): Yes, I just – the reason this was brought up, there was a couple of reasons that this was brought up. We've obviously been changing the DFO, and some of the information that we get communicated from one to the other, and at each meeting (unintelligible) that public comment has been a struggle to get the public comments in advance so that we can all look at them before we start making our decisions.

And that's really important, so we wanted that to be spelled out very clearly, but with an also – or also an issue with the January meeting where (Gustavo) did not know that the wording that was used to describe how the meeting should be held was not clear that the community is now accustomed to live streaming when we're all meeting in person.

We were all there in Washington, DC. We all assumed we were going to be live streamed. I think the community assumed we were going to be live streamed, but that didn't happen so we wanted to make sure that that was also clear in a document like this. And then there were some other things that have been you know, suggested through the last couple years since I've been involved at least that we thought would make for a better meeting.

(Gustavo): Okay, so some of those things were not included in the SOP because of funding in this office, lack of, believe it or not, not necessarily in this office but lack of more modern technology to be able to live stream, so we basically have to work with what we have and you know, I'm sorry about that but it's the reality.

So if you all turn to page one, there are four bullets. The second one then says stakeholder will be notified of meeting topic at least two weeks prior to the deadline for submission of public comments. Go up, Syreeta, first page you see four bullets, the second one. I make I think I have been doing that or trying to for the time that I have seen the DFO.

The second bullet, the public comment process in the in-person meeting shall be between three to five minutes. We just went to the DSA training and GSA we have two competing arguments from the – one lady say I think two minutes is too short and another person say I think five minutes is too long, so they really left it up to the DFO and the agenda as to how long each individual should speak.

I know when (Nathan) was here it was two minutes and then it went up to three minutes. I think three minutes is too short and I think five minutes is just about right. However I will not promise you that public comments will be five minutes every time, because I have to work with the agenda and how much time we have, and if we get an hour for public comment, five minutes each individual, that would be about 10 to 12 people.

And if we give three minutes it would be more people speaking, so that's – I just wanted to bring that up to you guys, so the time might change. It could be five, it could be three, depending on the agenda.

((Crosstalk))

(Leah Williams): This is (Leah Williams), can I...?

(Gustavo): Yes, go ahead.

(Dr. Faith Newton): Who's ever got – don't forget to turn your phone on mute if you're not speaking so we don't have any feedback. This is (Faith) commenting. I actually thought that it worked the best I've seen it work in years today. People weren't rushed. Five minutes I thought worked very well. I also liked the new procedures we put in place where the (SSEC) members commented and then we opened the lines up to the public for them to ask questions.

I thought that went exceptionally well. We had a lot of input from both our own members as well as the listening audience, so I thought it was a win-win for everybody.

(Gustavo): My fear, (Faith), is that in future meetings, when I send out an announcement in the research saying if you want public comments, send it, or if you want to speak, let me know, or the (SSEC) support staff, it worked like that, it worked well today because very few people asked to speak. But if we have on the agenda an hour of public comments and we get 50 people requesting to speak and only the ones that make the request first are put in the list, then we will not be able to open the lines and have the public speak at random.

(Dr. Faith Newton): That makes sense. And we will obviously go with your judgment. I liked what you wrote, exactly what you wrote is fine.

(Courtney Miller): This is (Courtney Miller) from Cimarron. I want to ask a question, and a comment, make a comment about today and signing up to the meeting to make public comment.

(Gustavo): Yes.

(Courtney Miller): This meeting people who requested to be signed up (unintelligible) happened with my husband, got a response saying which of these three things are you going to address. And the three things were not necessarily what he was going to address. And so he didn't know how to answer that. It wasn't very clear that he could comment on whatever...

((Crosstalk))

(Courtney Miller): And then he did get a slot for today and I'm sorry but he's just too ill to make that comment and talk to you, too ill to be on vacation with us. So what – one – I want to make sure that people know unless you're going to make a policy change that they can address the topic of the agenda, but they can also address whatever they need to.

Being that the meetings are only six months apart, it's – there are a lot of issues people want to bring forward and the committee ought to be considering, so I wanted to make sure that's clear in whatever communications are sent out by whoever is hired to do the sign up and that kind of stuff.

(Gustavo): (Courtney), the background to that is that when (Beth Coleman Sharp) who is also the alternative and my direct supervisor, when we sat down and brainstormed as to how we can make these meetings more powerful, more accommodating to the public, she said why don't we start by selecting a date in which if the date rolls ahead of time we'd know when the meeting will be and put it on the Web site.

And that's an – idea because now we have a date set for December. So when that happens, we publish the RFN, the federal register notice, that by FACA rules have to be out at least two weeks prior to the meeting. While we publish it in March for this meeting, and I send via the list serve a link to the RSA, the federal register notice says if you want to make comments for the meeting, email the (SSEC) inbox by June 1st.

And I didn't get any comments. When I put this issue – or any requests, I'm sorry. When I brought this issue to the committee chairs, the working groups, they said well, fine, let's just then ask for comments around the work that we are doing. But in the past the first opportunity that is given to the public is to provide general comments, and that is usually done via the federal register notice.

(Dr. Faith Newton): Okay, well in the past it hasn't been on – you filled out a federal register notice but you also send out an email list serve saying if you want to make comment on this date, please let us know by a certain date by emailing whatever that email is. So rarely does a patient read a four-page federal register notice.

I recognize you have to send it out and you have to post it that way, but a direct email to the same list serve saying if you want to make comments please respond by such and such date, you're going to get more than two people wanting to comment. I think that's probably why it was late today for this meeting.

(Donna): So this is (Donna). I think a simple solution would be just to add a fourth option and that would be other topics. One of the reasons that we had – we had suggested to ask for specific topics was so that if we had commenters on topic one, you could slot them before that work group was going to be talking so that work group would have heard those comments before the deliberation.

So you wanted to separate out comments that way. But there should be the fourth category, or however many – you know, there should always be an extra category for somebody who wants to just talk on some other general issue.

(Dr. Faith Newton): I agree with (Donna). That's an excellent point. This is (Faith).

(Leah Williams): This is (Leah Williams). Can you hear me?

(Gustavo): Yes.

((Crosstalk))

(Leah Williams): Hi. So I have made public comments in the past and it would be really helpful if we knew if it was three or five minutes specifically because that's a very different amount of time to prepare something, and I think the last time it was very confusing because it said different numbers in different places. So – and I personally think three minutes is enough time.

(Gustavo): Okay. So going forward, what does the committee think that's here, three minutes or five minutes for the general public? I found that at the last meeting that I did and my first meeting at DSO last January that three minutes was enough, but that most people really took between four and five before I had to tell them okay, your time is up.

(Donna): This is (Donna). I think you should say three minutes and then account for a little leeway, because I think patients end up getting – they're sick, they're tired, they're nervous, they don't speak as quickly as they might want to, and we hate to interrupt them, but I think

that we should – the goal should be three minutes and that leaves time in case somebody does run over a little bit. And it also gives us a little extra time if we want to ask questions after we add it here and hopefully we'll incorporate it as part of the finalized SOP. If everyone else agrees, I'm not sure.

(Courtney Miller): I agree with that, this is (Courtney).

(Donna): It's very difficult to make comments in three minutes and say something new.

(Gustavo): Okay, so we'll stick to three minutes but as the general public here is on, we'll give them a little bit extra time, but not more than five because then I have to you know, I have a hard time putting an agenda together when we have so many things to discuss and you know, the time is being taken by some of the comments and the committee's not conducting its business.

And stakeholders and attendees (unintelligible) to provide further information, okay, so moving onto 1A on the agenda development simply says that the agenda will be developed between myself, the chair, or any work group chair. Number two, and stop me if you have any comments, the agenda shall be posted on the (SSEC) Web site at least a week prior to the meeting. (Donna), I know you had an issue with this before, but I cannot do any earlier than a week. People drop.

(Donna): I'm okay with that. I'm okay with a week.

(Gustavo): Okay. Federal register notice...

(Donna): Can we wait though – I am – there is something that I had suggested that didn't get included. I'm not really sure why, but it's an issue that we keep bringing up. I think (Carol) had brought it up yesterday, and that was that we need – each agenda should have adequate time for a brief review regarding the status of recommendations made at the prior meeting.

You know, in the – again, I'm from the business world, but the first thing you do when you're getting ready for a meeting is you look at the minutes of the last meeting and see what was it we were supposed to accomplish, did we accomplish it, and can we report back? And if anything's unfinished, you discuss why is it unfinished? Should we do something about it?

And we just lose track of things because we don't do that, and I'm not sure why that recommendation did not get incorporated, (Gustavo). Perhaps you have a good you know, something that you should explain about why, the government that I don't understand.

(Gustavo): I just felt – I didn't include that in here. I'm looking at it, I mean I maybe – I put some of your comments almost five weeks ago, and I think that one was not included because the agency updates, the (unintelligible) provide update on the agency activities. And some of the recommendations usually are tied to an agency, though not usually. Most of the recommendations are tied to a HSS agency.

For example, I think that (Unintelligible) gets an update on their – on the work that they have been doing with the department of education which was one of the recommendations you gave last year. I mean, at the last meeting, so why build something into the agenda that it's already going to be addressed by the insufficiency?

(Donna): Well if you think that we shouldn't put it early in the agenda, perhaps it can be you know, after all of the reports have been given, we then can say okay, you know, we recommended this, we're thrilled, this is what (unintelligible). We recommended this other thing, like the thing I brought up with you about the – we made an, you know, an informal



recommendation last time which nothing's happened on that. We should be aware of that and figure out you know, what are we going to do about it? Do we need to...

(Gustavo): Well, nothing happened on that specific recommendation because you guys didn't vote on it.

(Donna): No.

(Gustavo): Remember, it was tabled.

(Donna): I suggested specifically that we don't need to do a recommendation for it, that it's something that you guys can work on that doesn't have to go to the secretaries. That was how we ended that whole situation.

(Gustavo): Yes, but that's also tied – remember, that's also tying in, my recollection is that let's say we will also bring this issue up to the (unintelligible), and that's also tying to the fact that we still don't have a permanent (unintelligible).

(Donna): Right, and all I'm saying to you is I brought that up, and I think that should be part of the agenda. I mean, if it's not, then I'm going to bring them up anyway. But other you know, members may not do that. I think it's important to follow up on what was supposed to happen and now we know why it didn't happen, but at least we just haven't ignored it completely.

((Crosstalk))

(Courtney Miller): This is (Courtney).

Woman: Go ahead, (Courtney).

(Courtney Miller): I just wanted to say I agree with (Donna) about her (unintelligible) recommendations and learn if something's happened on them. And if we don't have an assistant secretary's help (unintelligible) push for one because we can't stop doing what we need to do because the administration hasn't moved on it.

(Gustavo): So what you're asking is that you want at every meeting before starting, we go through the old recommendations, so you got – so we can get an update as to where we stand.

Woman: Well, I think, (Gustavo), you – I just want everyone to know that you've been doing an excellent job. I think you're fantastic, very responsive, right on top of things, so I'm not trying to criticize this in any way.

(Gustavo): No, no, no, but listen, this is not personal. This is not my life. My life is not work.

Woman: Okay. So this is just the way I am accustomed to doing things. If I was the DFO, you know, in the past I've been the manager. I would look at the last meetings and I would see oh, (Donna Pearson) said she was going to do this. So and so was supposed to do that. And I would get an update on those things. So at the last meeting, the minutes say (Dr. Collins-Sharp) said that she and CDRU actually will use the recommendation as an example for the new permanent (ash).

And it also says that you will work with the (unintelligible) on how to implement the proposed recommendations. So those are two things that can happen, and I understand why they didn't happen, but I don't just want them to get lost.

(Gustavo): Okay.

Woman: So knowing that that's why they didn't happen, they're still pending, and I also mentioned one other thing that (Nancy Lee) had done, but then it never got continued. (The SUSAC) had decided to create a list of all outstanding recommendations (unintelligible) and they created it, I think it was maybe in 2013 or something.

And then it was supposed to get updated each year and then that never happened. So this is just a simpler way of trying to just keep track of what's still outstanding.

(Gustavo): So in revisiting the recommendations, doesn't the response that the agency provides as to whether or not it can be implemented, isn't that enough?

Woman: Yes.

((Crosstalk))

Woman: Can't (Gustavo) just say these recommendations will be (unintelligible) and just leave it at that, this point here is the situation with this. Would that work?

(Gustavo): I mean, I'm thinking that (Donna), let me give you an example. When I first came onboard and (Nancy) was the DFO in May of 2016, one of the recommendations made by you guys was to create centers of excellence, and that was direct primarily at NIH. And I think (Vickie) at that meeting say and it was very unlikely because of funding that NIH was going to do that.

So if we get a recommendation like that in the future, what kind of update will you want to hear from NIH when the response was this will not be done because NIH doesn't have the money?

(Donna): I wouldn't want an update. I would want that answer, which we would have already gotten. That would not be a pending issue.

(Gustavo): But that answer is on the (SSEC) Web site on the recommendations, the agency which funds are always there.

(Donna): Right, and that is not – again, that is not something that would be a pending issue other than the fact that we did ask her if she could explain the difference between them at the last meeting, and she did that to everyone's satisfaction, so now that's a closed issue. But there were some recommendations made and there was no response to them. None of the agencies stepped forward and said yes I'll do it or no, I'll do it. They didn't say anything that responded.

(Gustavo): And this goes back to when?

(Donna): Well, I could go back through like, you know, the last several years and point a couple out to you.

(Gustavo): Because my understanding from (Nancy) was that she was the one who implemented an agency response because of that very same reason, recommendations will be made and you know, you will never hear from the committee members will never hear from the government as to what happened to those recommendations.

(Donna): Yes, I'm not asking – just I'm not being very clear. I'm not asking for – I'm asking for us internally among ourselves to bring up anything that we've noticed that is a pending issue so that we don't lose track of it, that's all I'm asking, that there be time for that, that's all.

(Gustavo): Okay, so I will put on the (unintelligible) meeting let's just say that we will revisit the recommendations from the last meeting and provide an update by the ex officio. Moving forward under the federal register notice, number one, we will announce the meeting is in

person or Webcast, going back to live streaming, we try to (unintelligible) might have to help me on this one.

We try to – we find out within the department if we could do live streaming and the capability that we have does not allow it. I know in the past it was done. It wasn't done in the past, I think it was filmed.

((Crosstalk))

(Donna): It was live at the in person meeting.

(Gustavo): And is it (unintelligible), didn't the people here in the building tell you they don't do that?

((Crosstalk))

(Gustavo): Yes. I mean, (unintelligible) homework here within the department, and she was told that they don't do that.

(Donna): If – Syreeta, if you go back and look in the (SSEC) records, you'll see many live streamed meetings in that room #800 which we're going to meet at in December, that's been on the first floor, that was live streamed. And it all came out of advocates getting together and fighting this and (Wanda Jones) ultimately saying yes, we agree this is something that we should do for this particular patient community so that (unintelligible) issues. And they are not able to attend, many of them certainly can't attend.

(Gustavo): (Wanda Jones) is (unintelligible) is back in OASH, she wants details on other office. I personally will go see her and find out how she managed to do it.

(Donna): Oh, cool. And (Nancy Lee) did it always, too.

(Gustavo): I cannot talk to (Nancy) by – for a year by federal law, we cannot talk for a year.

(Donna): Oh, okay.

(Gustavo): You see, we also have a bureaucratic system here that you guys don't know about, but we have to abide by certain rules. The federal – so number B2, the federal register shall include a request for public comments to be submitted to the (SSEC) mailbox by the given deadline. That's been done. On top of including a deadline or on the federal register notice, I will instruct the support team to send out an email saying we want your comments by this deadline, general comments, not necessarily comments related to any work group.

I think B3 is a given. C1 meeting logistics, that we are posing, and this is an idea that (unintelligible) which I think is wonderful, six months in advance we'll be selecting the date of the meeting. I have been sending you the public comments, B2 – C2 I mean. (Donna)?

(Donna): Absolutely, that's great. We have time to read them that way. That's been excellent because then we've been able to tie them specifically to the – we've been able to respond to the comments. I thought it was wonderful because I could change my comments based on what they said. It's been excellent.

(Gustavo): C3, we'll find out from (Wanda Jones) how we can do live stream (unintelligible). One thing that I want to implement here is C4, and this is – directive from another committee here within OASH, I'm a tree-hugger, and I hate to print so many papers and create more garbage. They give this specific committee, they give thumb drive with all the presentations and all the documents needed to the members when they have an in public meeting – an in person meeting. So that would require that you guys bring your computer.

(Donna): I'm fine with that. I already – I don't need the paper.

Woman: I'm okay too.

(Gustavo): Okay.

Syreeta Evans: This is Syreeta. That would also require that that deadline for presentations and any other materials be sent you know, prior or on that deadline so that the thumb drives could be – have all the proper material.

Woman: That's fine. I'll try as chair to see if I can push that.

Syreeta Evans: Thanks for that.

Woman: You're welcome, Syreeta.

(Gustavo): C5 is a given which is reminding people to say their names. C6 is belonging to discuss that (unintelligible) housekeeping. C8, I know you guys like having the meeting here in room 800. We kind of learned that in order to get that room we need to make reservation way in advance. I mean, we already have that room for December.

Syreeta make those – reserve the room one, but in January, so a year ahead. What happened at the last meeting was that I didn't think it was so difficult to get that room. You know, we ended up figuring out that it wasn't available. Moving onto page 3D1, basically says that a week prior to the meeting all the materials will be provided to the members and if it is an in-person meeting a drive will be provided when you guys arrive.

(Donna): (Gustavo), can I interject, I had a suggestion that it also include the draft recommendations that we will be discussing and that didn't get incorporated in there. Is there a specific reason?

(Gustavo): Probably because of the same reason I told you last time that the ex officio provides updates, but because a lot of this is going to be a standing agenda item to discuss the previous meeting recommendations and (unintelligible)...

(Donna): Oh, no, I'm not talking about that. I'm saying that it – you know, if (Jerry)'s group is going to bring a recommendation to this committee for voting, include that in our package one week prior so we have time to review it.

(Gustavo): Well, that's usually at the end of the – of each presentation, (Donna). They have recommendations at the end of our presentation.

(Donna): Right, and I'm – what I'm suggesting is if you're going to make a recommendation, shouldn't we know what they're going to be recommending so that if we had any research we needed to do in advance or whatever?

(Gustavo): Yes, and if I'm sending you the presentations a week before or say you receive them, those recommendations would be at the end of the presentations from each work group chair. Are we talking about the same thing?

(Donna): Yes, we are. I didn't know that it said – it says presentations outlined in C2, so let me go – if C2 includes work group chairs, we're all set. I don't know. So – I don't think it says it.

(Gustavo): So what's the – are you confused about D1?

(Donna): So I'm confused about D1, we're going to – maybe you're talking about slide decks, are the slide decks...

(Gustavo): Yes, that's why I'm saying all meeting materials, slide decks, ex officio, all the reports, background documents, public comments and presentations.

(Donna): All right, then that's fine. It wasn't clear to me, that's okay.

(Gustavo): Slide decks and presentations are the same thing. Okay, so let's get rid of slide deck because that's confusing and then just call it presentation. So you – what I'm talking about is sending to you guys a week prior to the meeting presentations from working groups.

(Donna): Right, that's what I wanted.

(Gustavo): And the work group usually at the end includes their recommendation. Now whether or not you guys change it when it comes to the discussion to the entire committee, that's another matter.

(Donna): Right.

(Gustavo): D2 has to do with people who don't provide presentations on time, which is that I have to add it to the USB drive. That might be a pain but there's no other way. (Unintelligible) whether the USB will be numbered (unintelligible). This is all internal. Public comments, E1 says I will make the determination whether or not public comments will be five or three minutes, but we agreed it should be three minutes.

For in person meetings, E3, public comments can be provided by in person attendees or both on the phone, attending conference meeting, public comments will be provided, blah blah blah. E5, what else – moving onto F work groups, we agreed last year – at the last meeting any work, that every work group will have an ex officio meeting, an ex officio member, and most likely a member of the agency which will most likely be affected by that recommendation, right?

(Donna): Right.

(Gustavo): And if we have any new work group, in order to receive volunteers from the community, might be on the list serve. I think we did that last – at the last meeting with the medical work group. Moving onto 2A, I think you guys can read all of these for yourself, these are very standard.

(Debbie Ebie): (Unintelligible)?

(Gustavo): I'm sorry?

(Debbie Ebie): This is (Debbie Ebie). The arrangement is that two weeks after the meeting, the minutes are forwarded.

(Gustavo): Okay, so we'll change that, a week to two for number B, (Debbie), right?

(Debbie Ebie): Right.

(Gustavo): Okay.

(Debbie Ebie): Thank you.

(Gustavo): And this is where I've incorporated the minutes being reviewed by the chair.

(Donna): I think the way it's worked in the past is the minutes are published after they've been reviewed by the DFO and the chair. However, they're not authorized by the committee until the next meeting. And that's a question for you to find out, you know, if that is required or not. It certainly is common with (Robert Schools), but I don't know if it is required de facto.

(Gustavo): I'll find out from our committee management officer and from other committees as to how they do it. I don't – I'm not – I know FACA rule says that the committee has to be up within a week, but I don't think it says it's clear or even says if they have to be approved by

entire committee. I think if I remember from the training that I took online I can go back to my notes, is that it has to be approved by the DFO and the chair.

But I will confirm that, and if that's the case then we'll change it to have the committees – the committee approve the minutes at the beginning – for the last meeting, at the beginning of each meeting.

(Donna): And if that's the case, you would want to remind the members to review those minutes before the meeting. That was done sometimes in the past but not always.

(Gustavo): Okay. These (unintelligible) E5 for the next (SSEC) meeting the DFO will provide committee members with a copy of the minutes from the last meeting for review. At the meeting the chair will request any additional comments or changes. If the committee is satisfied with the minutes, a vote for approval will be taken. Here's your vote.

(Donna): Yes, did you get this from another DFO?

(Gustavo): Yes, (unintelligible).

((Crosstalk))

(Gustavo): (Unintelligible) that the previous chair approved minutes. Okay, so we hit it.

(Donna): That's how it's been done in the past too, and I get it. I forgot it was in there too. It was already there.

(Gustavo): And then the rest is internal stuff that we have to do, sending the recommendations to the ASH, and having the agency respond to each of the recommendations.

(Donna): (Gustavo), can you clarify for this committee because it's changed, the change was two secretaries ago I think. It used to be that our recommendations went straight to the secretary, and then they got distributed out to the agencies for response. I think it was secretary (Burr), well, maybe, I'm not sure, who said I don't even want to see the recommendations until I already have the responses. So is it you that has to get these responses, or is it the ASH or who is it?

(Gustavo): I do. I mean, the ASH – really the ASH doesn't do much but probably read the memo and sign it or make changes and send it back for changes. But I'm the one who has the DFO (unintelligible) before we have to share the recommendations with the agencies, and get a response from them and include that in the memo we send forward to the ASH to send to the secretary.

(Donna): But do you think that's something the future DFO would just know, or do you think you should just be a little bit more clear about that here?

(Gustavo): Yes, I can include a language that says the DFO has to get the recommendations from the ex officio. I mean, the response.

((Crosstalk))

(Donna): Doesn't C say that?

(Gustavo): (Unintelligible) must include the initial response (unintelligible).

(Donna): Should say who does it though?

(Gustavo): They say – yes, but (Donna)'s right. It doesn't say who will do it. Okay, making myself a note.

(Donna): Can I ask one other request, when you're asking about the live streaming?

(Gustavo): Yes?

(Donna): Can you also find out if there's – and I know you – I think you've done some research on this, but I know a lot of people do not like not being able to hear the Webinar through their computer but rather having to use up hours on their cell phone or whatever. So in a lot of other Webinars they just have it through the computer. Is it because we – you have so many people that are talking that are not in the same room, or – I guess the question is, is there a way to do it so that it's all from the computer, not including those of us who are participating in the meeting, but for the benefit of those who are just listening in?

(Dr. Faith Newton): And this is (Faith). I want to echo that. What happened yesterday is I must have gotten kicked off at least 7 to 8 times, and every time I got kicked off on my phone, I had to redial back in and that was a nightmare because it took five, eight minutes, so I missed – that's why I ended up missing the whole discussion on my working group. So if there's a way to do it through the computer, that would be really nice.

(Gustavo): Well the issue with that also is that a lot of people you know, have old computers or they don't have speakers. So a suggestion that I sent out via the list serve was if you have a Google account, you can access the meeting through Google and then listen through your computer if you have a speaker built in.

(Dr. Faith Newton): Oh, that's a good idea.

Woman: (Unintelligible) that's with the HHS studio that may do the live streaming.

(Gustavo): Yes, but to do that we have to go (unintelligible).

((Crosstalk))

(Gustavo): We're not at studio here, Syreeta was telling me, in HHS. It's called HHS studio, and that – it appears that that's what they have used in the past.

Syreeta Evans: We're going to see if that's what they used in the past as opposed to just the meeting space IT group. There's an actual live studio here that they use for secretaries, so I'm going to contact them and see if we can start working on that avenue for December, and hopefully we can get the live stream going.

(Donna): That would be great, Syreeta. That would make life much easier.

(Gustavo): Well, when we have a Webinar I think we are somewhat limited to what we have, I mean, to what we used today. Unfortunately Syreeta and I, we – I should've said Syreeta and I, she tried to find out – she's more technological than I am, as to how we can do this better and she called Verizon and the contract that the department has with Verizon does not allow this – people to be able to hear and speak through the computer at the same time.

(Donna): Okay.

((Crosstalk))

(Gustavo): We're not ignoring your request. We are just limited by what the government has to offer.

(Donna): No, we appreciate you looking into it. That's really nice of you.

((Crosstalk))

(Gustavo): Yes, sir.

Man: No, I was just going to say echoing that I too have been on the other side of the table with this thing trying to put together public input sessions and meetings at the state government level, and I appreciate how difficult and challenging some of the technical aspects can be. I wonder if in addition to this you know, we can – and the action committee continue to

look how we can maybe continue to disseminate and pass out some of the information that you have to provide through very strict legal channels in some more plain language for people – for patients particularly in the patient community so they could access this more easily.

(Gustavo): Yes, well definitely feel free then, are you on the list serve for (SSEC)?

Man: Yes.

(Gustavo): I mean, feel free then. Anything that goes out on the list serve to send it out through your media channels, any action.

Man: Yes, we will do that, and I'm just saying I'll probably also follow up with you later just to clarify, make sure that we understand to the best possible extent all the things and when they will come out so that we can communicate them more effectively to their – to our community, so thank you for all your hard work.

(Gustavo): Thank you, and I appreciate your help. Anything else regarding the SOP?

(Donna): Thank you so much for doing that.

(Dr. Faith Newton): Yes, I agree, thank you, (Gustavo).

(Gustavo): I want to put these on the Web site, I don't know where yet but once they are finalized, we're going to put it up. We're also working with (unintelligible), but that's proving to be a little bit more challenging. I know I sent out an email months ago via the list serve asking for questions, and then none of the questions I received were not necessarily related to what we were asking.

We were asking about things about the committee and how it works, and the only response I received from the community was more medical and so...

(Donna): I will – this is (Donna). I will volunteer to help with that. I think I have an understanding of the many misunderstandings about the committee at this point, so I'll help you with that.

(Gustavo): Well, the Qs and A are final. I just have to – I collected all the questions, you know, disregard the ones that were not really addressing what we are asking which is you know, how is a chair elected? You know, how many members are on the committee? Those are the kind of things that I wanted to – I want to post on the Web site so people will know instead of emailing the (SSEC) inbox and then you know, and then having the support team reply to every single email.

So I thought – that's when I sat down and said let's do some Qs and A. So when I sent out that email, I'm not sure how many of you saw it, a lot of the questions I got back was why isn't my doctor diagnosing me or where can I find a doctor in Oregon, you know, those – that's not what we asked.

So the questions that we did receive, we answered them, but now we have to put in for clearance within this office before we put them up on the Web site. Well, if there are not any more comments regarding the SOP, (Beth) – (Beth), sorry. (Unintelligible) your...

((Crosstalk))

(Gustavo): ... on the Webinar.

Woman: Does anybody have any final comments before I go?

(Courtney Miller): Yes, so I wanted to comment – this is (Courtney Miller) from Cimarron – on a couple of things not directly related to the SOP. Do we have a moment to do that?



Woman: Yes, you do. Go ahead, (Courtney).

(Courtney Miller): Okay. It is sort of related to the functioning of (SSEC). I would like to see the federal agencies ask (SSEC) for review or input or recommendations on particular things they want to implement. I think NIH did that once, maybe it was six months ago, maybe a year ago, I don't remember, and they set up a working group on how to get public patients and community input into you know, a more systematic method for that.

And I think one, HHS has asked the committee to – maybe two years ago to provide some recommendations related to the IOM group forward. But to make this more of a two-way use of the expertise on this committee, I'm wondering if there's a way we can get different agencies to pose a particular you know, give us input on this. We want to find a way to do this, and have that be something this body participates in.

(Dr. Faith Newton): This is (Faith). That's a very interesting idea. That goes along with my idea of I don't want us to be making recommendations that they cannot possibly implement, so the same thing as you to make it more of a two-way street that we're working together to move the bar forward and get things accomplished. That's a really good question and I don't think that question's ever been asked.

((Crosstalk))

(Gustavo): I'm sorry to interrupt, but I think I was part of the agreement when we discussed at the last meeting that at every meeting the next official would be in the working group to advise the working group on whether or not the recommendations would be doable or not.

((Crosstalk))

(Donna): The recommendations that we – that the body, (SSEC) makes, so they're – if there's active programs happening in these agencies related to a disease, and there should be, they could be asking us for a formal (SSEC) forward, what is your recommendation about such and such? What should we do with this program? How can we make this work for NECFS? So right now there's mostly a one-way (SSEC) makes recommendations, the working groups are trying to make them work, and make the argument for them and have the ex officio in the working group. But only on occasion has an agency come to (SSEC) and said okay, we have this idea, we want your help in defining it or recommending it or making it work. So I'd like to see more of that.

(Gustavo): I don't know what to say and I will turn it over to the ex officios, if there are any on the line still.

(Beth): This is (Beth), I'm on the line, and I – that is the way advisory committees are supposed to work. They're supposed to respond in – to specific questions, and that is not the way the committee has been working, and so it's an interesting and important suggestion.

Man: You're saying that we're not doing it right, (Beth)?

(Beth): I'm – I don't mean that, but I just mean you know, for example the other advisory committee that I work with is the ACIP, which is the advisory committee on immunization practice, playing a very different kind of role, but they have – they are asked very, very specific questions, and they need to answer them, whereas as it's been pointed out, the committee, this committee has not been presented with very pointed, specific questions.

So we have – it does a different thing, and I think originally, I mean, this came out – I need to try to coordinate the government response to – I mean, there was I guess in the beginning of time a committee just of the ex officios, and then it kind of evolved into this committee.

And I think everybody has been trying to figure the way to make it most effective because I think that there has been some dissatisfaction both in the community you know, and just in general. So I don't mean to say that it's wrong, but you know, I just think it is a good idea to think of how to make it more effective.

Woman: So (Beth), say that a little bit – say that again. What does – how is it the other committees work?

(Beth): Well, they actually respond to you know, should this vaccine be approved or not and what – how should it be approved and they are charged with making specific recommendations or answering specific questions. And that is most advisory committees are constituted to answer questions, to provide specific advice. And that's exactly what (Courtney) has suggested, that the committee, you know, it – there should be questions that the committee's responding to.

Woman: Where do those questions come from?

(Beth): Well, she's right. It comes from the government. This is – or HHS. HHS, this is a committee to HHS, so HHS or the HHS agency should be the ones providing questions.

Woman: Yes, I (unintelligible). The DFO asks – does the DFO then approach each agency beforehand and I mean, I did (unintelligible) solicited questions somebody gave us for that meeting that (Courtney) brought up, so for questions that we were asked, and I know that (Vickie) just (Unintelligible) off the top of her head has made some – a suggestion at one time. But I'm certainly (unintelligible).

Woman: I was going to say, I would be fine with it.

(Gustavo): I'm sorry, I have to step away from my computer (unintelligible), I'm running out of battery, I have to go get my cable. So what were you guys saying?

Woman: Well, we'd like to see the agencies who are represented on (SSEC) either via you or HHS or directly the ex officio, come to (SSEC) with – not every agency every meeting, but we have this program or challenge or desire to do something related to NECFS. We want your recommendations on how to make that the most effective effort so that there's two-way recommendations and essentially...

((Crosstalk))

(Gustavo): I think I understand what you're saying now. But I cannot go to the agency. They have to come to me because I'm not – I don't know every single program in every of the agencies.

Woman: That's right. They should come to you or they should come...

(Gustavo): They should come – for example, I'm going to try (Unintelligible) because it's an agency that I know well because I used to work there. (Joel Nursin) from HRSA finds out that they're funding something around NECFS, some kind of project and he should come to me and say can we bring this up to the committee and provide recommendations for example?

Woman: Yes.

(Gustavo): I couldn't know what every single agency on the committee's doing for – I could ask them on my monthly meeting, do you guys have any program that is likely going to be funded you know, with NECFS? But otherwise they would have to come to me. I cannot go to them.

Woman: Well, it would help if you'd prompt it in those meetings. I do think it's got to be substantive, and it's going to – you know, there are more agencies who could be coming in with more proactive programs and that need our – could benefit from our input or recommendations.

(Gustavo): We also have a committee here in the office of women's health. It's called committee on women's working group. Anyway, it's...

Woman: Coordinating committee for women's health.

(Gustavo): Coordinating committee for women's health and it's basically all the HHS agencies including the VA and (unintelligible).

Woman: (Unintelligible).

(Gustavo): But I think the VA's the only non-HHS agency. Anyway, they come together every month and they provide a number of presentation and activity affecting women. I know this is a condition that not only affects women, but the chair of that committee, I could ask her to make an announcement and find out if they are doing anything around NECFS.

Woman: Yes, and how could they ask us what they could be doing around NECFS.

(Gustavo): So I will – but to be honest and to keep it real with you guys, if this was – if there was something being done at CDC around NECFS, I am sure that (Dr. Unger) would know outside her scope of what she already knows, same thing for HARQ. But like you say, (Courtney), it would be worth at least...

((Crosstalk))

(Courtney Miller): One more thing, like what NIH did, right, they were implementing a whole new renewal program and they came to (SSEC) and said give us a model for how to have patient and community engagement as we move forward. Right? And we spent a work group and a bunch of time coming up with recommendations.

(Gustavo): Okay, well, I have monthly meetings with the ex officios, so we can – I will ask them at the next meeting.

(Courtney Miller): Thank you.

Woman: Anybody else have any other comments?

(Gustavo): Now I think we can move on with your final closing remarks and until the next time, but I'm sure there's much work to do between now and December.

(Dr. Faith Newton): Sounds good, all right. Let me thank the – start by thanking the committee members that were here today and yesterday, too, my staff, (Shane), (Jerry), and (Donna). Everybody's put in a lot of work and I'm looking forward as well to (Unintelligible). The ex officios, (Beth Unger), (Janet Millwood), (Joan Ralston), (Michelle Staples), (Vickie), and you, we appreciate all the work that you've put in and the time that you've put in and what you've done the last six months since we've met.

These power points were very clear. The presentations were well done. I'd like to also welcome and thank the mid-line budding liaison members, (Leah), (Courtney), and (Ben). I think you added a lot to the last two days. And lastly, (Gustavo) and Syreeta for all of your work and

your time that you've put in, we very much appreciated it. And then I've got a final comment to (Dr. Levine).

I don't know if she's on, but I wanted to – and it should be up on the whiteboard – I wanted to take a moment and thank (Dr. Levine) not to (unintelligible) over her past year as (unintelligible) committee but also her lifelong commitment as a clinical researcher, a compassionate physician and a dedicated colleague and an awesome mom.

From my own personal perspective I'm quite aware that without (Sue Levine), my son (Michael) would not be a rising college senior next year. He got NECFS when we was in fourth grade. He had never been to school full time until he got to college. I can say with parents and children and other patients that you have helped, either directly through her office or indirectly by consulting with other physicians, she is just unbelievable with her time.

As (unintelligible) she's given her time, her wisdom, and her patience in ways that people hearing now may not have ever had the opportunity to witness. (Unintelligible) position is a positive advocate and a role model quite seriously. She's never failed in good humor, even when the demands associated with the position ate into her time for research or her time with her patients.

We've been exceptionally fortunate to have (Dr. Levine) as chair, and I can only hope to emulate her example, but it's going to be quite a challenge. Thank you again, (Sue), for everything. Syreeta, can you scroll down just a little bit more on that screen?

Syreeta Evans: I sure can. Do you – I'm sorry, (Faith), did you want your contact information there?

(Dr. Faith Newton): Yes, I did. That's exactly what I was hoping you'd put up there, the contact information and the summary information. A couple people asked for it and it was the easiest way to get it there. There is – I'm going to put up there my contact information, which is (Dr. Faith Newton), which is [fnewton@desu.edu](mailto:fnewton@desu.edu). There's also the primary link for the NECSF diagnosis and management in young people, a primer. Several of you asked about that.

That link you can either get from me or Syreeta will put it up. It's the journal in frontiers in pediatrics that just came out the 19th of June. That was done by an international working group. It has phenomenal information there for both parents and for clinicians and practitioners. Again thank you for your time. This meeting is adjourned and I thank all of you for the last two days and especially those of you in the government for your time.

(Gustavo): Thank you, (Faith). If you like we could put your public email on this (SSEC) Web site, but do realize that a number of people you will get probably lots of emails.

(Dr. Faith Newton): That's fine, I'm used to it. Just add it. If they want to contact me, I don't have a problem with it.

(Gustavo): Okay, I think you have to call a motion to end the meeting.

(Dr. Faith Newton): Oh, that's right. Can we have a motion to adjourn?

(Gustavo): Can somebody second?

(Dr. Faith Newton): (Donna), somebody?

(Dane): This is (Dane), second.

(Dr. Faith Newton): Oh good, thanks, (Dane). Everyone in favor say aye.

Man: Aye.

Woman: Aye.

(Dr. Faith Newton): Anyone opposed? All right, we are adjourned.

END