

**CDC 15th Stakeholder Education and Communications Call
Feb. 6, 2020**

Ermias Belay: Good afternoon, everyone. My name is Ermias Belay and I'm the Associate Director for Epidemiology Science in the Division of the Centers for Disease Control and Prevention where the ME/CFS Program is located.

On behalf of the program, I'm pleased to welcome you to today's ME/CFS Stakeholder Engagement and Communication conference call, also known as the SEC call.

Dr. Jennifer McQuiston, who was originally scheduled to moderate this call, is - has been deployed for CDC's Coronavirus Emergency Response unfortunately and she's unable to join us today. I'll be serving as your moderator for the call today. Our primary purpose is to share information on ME/CFS as part of our regular outreach communication series.

First, we'll hear from Dr. Elizabeth Unger, who is chief of the CDC's Chronic Viral Diseases Branch. She will provide some program updates. And then Dr. Dana Brimmer will provide updates for CME educational activities and Dr. Nanda Issa will describe the School-Based Active Surveillance Project.

After these, when they're done, we'll open the line for questions. The operator will provide information about how to ask a question after the introductory

remarks.

Before we start, I would like to read a disclaimer and the disclaimer is, these calls are open to the public. Please exercise discretion on sensitive content and material, as confidentiality during this call or items submitted via email cannot be guaranteed.

Today's call will be recorded, and transcripts will be available - at a later date on the CDC Web site. I would now like to ask Dr. Elizabeth Unger to provide her introductory remarks. Dr. Unger?

Elizabeth Unger: Thank you very much, Dr. Belay, and welcome all to our 15th Stakeholder Engagement and Communication call, CDC's forum for regular communication with the ME/CFS community.

In the room with me today are two additional members of the division leadership, Donovan Newton, Associate Director for Policy, and Christine Pearson, Associate Director for Communications. In addition, we have Dr. Sally Lin, Team Lead for the ME/CFS Program and two new staff members that I'd like to introduce.

First, is Dr. Jeanne Bertolli, who joined the Chronic Viral Diseases Branch in October as Deputy Chief of the branch. In this capacity, she's serving as senior advisor for all of the branch's programs including ME/CFS. Dr. Bertolli has a doctorate in epidemiology and has worked at CDC for over 20 years, most recently in the Division of Human Development and Disability as Associate Director for Science. Her broad public health experience and knowledge of CDC will greatly benefit our work in ME/CFS.

Next, I'd like to introduce Dr. Anindita "Nanda" Issa. Dr. Issa is a physician

who joined the ME/CFS program in June. Prior to joining our program, Dr. Issa served in the CDC Epidemic Intelligence Service and completed fellowships in preventive medicine and epidemiology.

We also have a guest joining us, Dr. Renee Calanan. Dr. Calanan is the health equity coordinator for the National Center for Emerging and Zoonotic Infectious Diseases, the center where the ME/CFS Program is held at CDC. Dr. Calanan began her service in the Commissioned Corps of the U.S. Public Health Service in 2007 and joined the center in July 2019. In her position as health equity coordinator, Dr. Calanan is a consultant for the ME/CFS Program on addressing the stigma and health disparities that affect ME/CFS patients.

Today's call will be different from our previous calls. On past calls, while we've provided an opportunity for questions from participants, these questions came through email.

We understand that many would prefer to have a chance to ask questions directly, so we worked with the CDC leadership to identify a method to allow callers to ask a question and hear an answer directly. To allow more time for this new feature, we will have brief updates on some of CDC's activities, but will not have an external expert speaking.

We look forward to bringing back guest speakers for future calls. As a reminder, if you have suggestions for speakers and/or topics for future calls, please send them to the SEC call email. That is MECFSSSEC@cdc.gov. This is also the address used if you'd like to be added to the listserv with the email notifications about upcoming calls.

I should mention here to not email questions to this mailbox during today's

call, but instead, follow the operator's instructions to ask a question when we get to that portion of the call.

Now, moving to updates on CDC's ME/CFS Program, I'll give a general overview followed by more focused information on our work with Medscape presented by Dr. Brimmer and the contract with the National Association of School Nurses given by Dr. Issa. I'd like to start by answering some frequent questions we received about the multi-site clinical assessment of ME/CFS study, also referred to as MCAM.

One is a basic question about why we did not specify a case definition and instead relied on study clinicians to enroll those who they considered to have ME/CFS. We took this approach because each clinical investigator is a recognized ME/CFS expert, whose clinical judgment is reliable.

Getting data about the ME/CFS population in seven experts clinics provides important information to refine the case definition health providers use to recognize ME/CFS in their patients. We shared preliminary baseline data with the Institute of Medicine committee and this data informed their ME/CFS clinical case definition.

We are extremely appreciative of the dedication of the clinical experts, their staff and their patients. While somewhat intangible, the collegial working relationship we established has been one of the most beneficial to our program. Our clinician collaborators continue to be a valued source for information and advice.

The next most frequently asked question is about the pediatric/adolescent component of MCAM. Enrollment of children and adolescents with ME/CFS and similarly aged healthy people was slow initially as the original

MCAM clinics primarily served adults. Therefore, we began working with additional clinics in 2019 to boost the pediatric enrollment.

We are now in full swing with current enrollment of 200 participants, 105 with ME/CFS and 125 healthy controls. Baseline information is completed for about - for 140, and 20 have completed a one-year follow-up. The study protocol includes data collection at enrollment and follow-up data to be collected for two more years.

The clinicians that have contributed to pediatric data collection are: Drs. Lucinda Bateman from the Bateman Horne Center, Utah, Nancy Klimas, Institute for Neuro-Immune Medicine, Florida, Andy Kogelnik, Open Medicine Clinic, California, Patricia DeLaMora, Weill Cornell Medicine, New York, and Amy Smith, Nurse Practitioner, Open Medicine Institute, California.

Contract for expanded pediatric enrollment was enrolled - was awarded to Eagle Global Scientific, which is partnering with Open Medicine Institute as a subcontractor. Eagle and Open Medicine have been working to increase study recruitment of both patients and clinicians and they reached out to Solve ME/CFS to announce this study. This promotion of study recruitment has led to numerous inquiries and will potentially increase the enrollment and completion rate.

Finally, the third most asked question is about when more MCAM publications will be coming. First, I'd like to update you on our most recent publication, just in case you missed it. In 2019, we published data on the validity of the PROMIS Fatigue short form to measure fatigue experienced by people with ME/CFS in the Journal Quality of Life Research. This publication titled, "Psychometric Properties of the PROMIS Fatigue Short Form 7A

Among Adults with ME/CFS" is an important step towards establishing PROMIS Fatigue as an acceptable outcome measure for ME/CFS treatment trials.

Our American Institute for Research colleagues are preparing to submit PROMIS Fatigue through FDA's Clinical Outcome Assessment Qualification Program. The FDA has said previously that a lack of validated tools like this one is a major factor that keeps drug developers from entering this field and wanting to try to develop a treatment.

So we're excited to be advancing the science in this area. We will also continue to collaborate with subject matter experts in PROMIS at AIR, at the American Institute for Research, to validate PROMIS sleep and pain measures used in the MCAM study. We started data collection for MCAM in 2012 and the study design allowed for enrollment of new patients through April 2019.

We are still finishing finalizing data entry and cleaning for many of the analyses. Specifically, we've been working with subject matter experts in exercise, neurocognition and neurology on developing manuscripts in those areas. We have planned three manuscripts based on analyses of exercise testing, cognition testing and NASA lean test data.

While we work on finalizing the manuscripts and getting CDC clearance for submission to peer-reviewed journals, we plan to share our preliminary results at the IACFS/ME (International Association for Chronic Fatigue Syndrome/Myalgic Encephalomyelitis) Conference in June at University in New York.

We have plans for additional publications that will examine illness heterogeneity, methods for assessing natural killer cell function and natural

language processing for automatic extraction of data such as medications that are entered as free text in our study instruments. We thank you for your patience and support during this data collection period.

Now, I'd like to ask Dr. Dana Brimmer to provide an update on our medical educational activities with Medscape. Dr. Brimmer will be familiar to many of you as she's been a contractor with our program for many years and has been the facilitator for our prior calls since these began in 2012. She's an experienced health educator and has been guiding our collaboration with Medscape. Dr. Brimmer?

Dana Brimmer: Thank you, Dr. Unger. The CDC ME/CFS Program has partnered with Medscape to provide Continuing Medical Education, known as CME, to physicians, nurses and other health care providers in the United States. Medscape is the largest provider of CME in the world and has the largest position in health care provider audience.

Practicing physicians and nurses turn to Medscape as a trusted source for current medical information and education. CME courses help to raise awareness, increase knowledge and Medscape research has shown that, when physicians participate in continuing the medical education, they're more likely to make evidence-based clinical choices.

We have three different types of continuing medical education courses that were developed in partnership with Medscape. All of the courses can be accessed by either a computer desktop or a mobile device.

The first one is a roundtable spotlight and features ME/CFS clinicians Lucinda Bateman, Natalie Azar, Nancy Klimas and Jose Montoya. The course is called "Diagnosing Myalgic Encephalomyelitis/Chronic Fatigue Syndrome

- The Experts Weigh In” and it was posted on February 25th, 2019. While it was originally accredited for one year, we're currently working with Medscape to recertify this course for another year.

As of December 31st, 2019, there has been 7,713 learners and over 2,700 test takers. Learners are people who take part in the activity, but may not complete the test for credit; whereas test takers take part in the activity and then complete the testing process to earn the CME certificate.

Of the learners, 44 percent were physicians, 37 percent were nurses and 19 percent were other types of health care providers. The numbers for the ME/CFS course are like other Medscape learners and test takers who complete CME courses offered by CDC on topics such as HIV, cancer and immunizations.

We have received some wonderful feedback from learners who took the course and I want to read a selection of comments. One nurse said, "Fabulous CME! Very useful to educate health care professionals in identifying and diagnosing patients with ME/CFS." A nurse practitioner remarked, "I will be more aware of thinking of this diagnosis in my patient group." And a physician commented, "One of the best 30-minute CMEs on Medscape. Very informative. I was ignorant of this topic."

The learners also suggested some topics they would like to learn more about, including medication management, comorbidity such as sleep disorders and depression, and POTS, Postural Orthostatic Tachycardia Syndrome.

The second course started on January 15th, 2020, and is accredited for one year. This CME is called a Clinical Practice Assessment, or CPA, and Dr. Nancy Klimas served as the expert author. The title of the CPA course is

"ME/CFS: Test Your Strengths and Gaps in Knowledge." This course is intended for primary care physicians, pediatricians and other clinicians who manage patients with ME/CFS. The Medscape team also worked with Dr. Klimas to incorporate suggested topic areas from the learners of the spotlight course.

In this educational activity, the learner takes a self-assessment test to establish baseline knowledge. Then the learner is taken through a 20-question case-based clinical learning module. It provides examples of clinical cases that practicing providers may encounter. Through this course -- skills, attitudes and knowledge are learned. In the two weeks since the course has launched, we have had 2,766 learners with 615 certificates issued and about 150 credits earned.

For our third Medscape CME, Dr. Steven Gluckman, in collaboration with the Medscape team, developed a course called, "ME/CFS: A Case-Based Learning Module." It is designed to increase clinicians' ability to diagnose and manage patients with ME/CFS.

This CME activity takes the form of a "test and teach" unit and is based on two ME/CFS patient case scenarios. A test and teach course challenges the learner to apply clinical data and evidence-based recommendations to test for knowledge. The CDC ME/CFS program is in the final stages of approval for this course and it will be posted on Medscape as soon as possible.

Now, I'd like to turn the call over to our next speaker, Dr. Nanda Issa, Medical Officer with the ME/CFS Program.

Nanda Issa: Thank you, Dr. Brimmer and welcome all. I want to start by pointing out how people generally tend to think of ME/CFS as an illness that affects adults, but

children – both adolescents and younger children – suffer from ME/CFS too. While each child with ME/CFS has a different experience, the illness has been known to impact children’s school attendance, relationships with peers, ability to participate in social activities and complete assignments and their overall quality of life.

Currently, there are only a handful of studies that estimate the number of children affected by ME/CFS and these estimates do vary. The assumption is that all children with ME/CFS have been diagnosed, which is not likely the case. In order to plan appropriately for children's health care needs, we need to know how many children are affected by the illness.

We recognize the importance of engaging parents and guardians, as well as health care and education professionals in providing care for a child with ME/CFS. Within the educational sector, school nurses play a vital role in student health, serving as a bridge between the educational and medical parts of a child's life, particularly for a child with a chronic illness like ME/CFS.

School nurses are encouraged to participate in continuing education courses throughout their careers. This can involve learning about a variety of topics, including management of certain common chronic diseases like asthma or diabetes; however, ME/CFS in children has not been a continuing education topic for school nurses at the national level.

Covering pediatric ME/CFS as an educational topic for school nurses could raise awareness of the illness and provide guidance on how to identify students with ME/CFS symptoms. Nurses can help students manage the illness and be successful in school. In many school districts, school nurses already monitor how many students have certain chronic conditions like asthma, diabetes and seizure disorders. Adding ME/CFS to the list of chronic

conditions that school nurses already track could provide a more accurate picture of how many children have ME/CFS and could, in the process, educate more school nursing professionals about ME/CFS.

Considering school nurses' roles, responsibilities and needs in September of 2018, the ME/CFS Program at CDC awarded the National Association of School Nurses a three-year contract. I may refer to the National Association of School Nurses as NASN throughout this update.

The project goals are, first, to support school nurses from six school districts in conducting active surveillance for ME/CFS by identifying, documenting, and following school children with ME/CFS symptoms and, second, to provide education and training to school nurses nationally on ME/CFS, chronic condition management and data collection and reporting.

As part of this contract, in-person trainings are available to school nurses in the six pilot districts and the school nurses in NASN's state affiliate chapters, while online training opportunities are open to school nurses across the nation and the general public.

NASN is known well for its role in leading school health initiatives and have been developing projects to track student health prior to this contract with CDC. We expect this active school surveillance pilot will tell us whether working with school nurses can help track ME/CFS in school children and whether such an effort would be feasible on a larger scale in the U.S.

School nurses involved in this pilot are from six different school districts across four states, namely Florida, Massachusetts, Michigan and Utah. NASN chose these sites because clinicians who are experienced in seeing patients with ME/CFS work in these states.

The school nurses will conduct surveillance by tracking students who are chronically absent or have withdrawn from school, document how many of those students are absent or withdrawn for health reasons and categorize the health reasons as a diagnosed illness or undiagnosed symptoms.

If the symptoms include those seen in ME/CFS, the school nurses will contact the student's parents or guardians and refer the student to a provider who is experienced in caring for patients with ME/CFS. The school nurses in this pilot so far have entered data from the first several months of the 2019/2020 school year.

As the active surveillance pilot continues, focus groups and interviews will be held with the school nurses to gain further insight into their experiences with the trainings and active surveillance process. Their evaluations will inform a manual and a multimedia toolkit that could, in the future, provide a foundation for expanding the project.

The training NASN is providing as part of the CDC contract will help prepare the way for expansion of the active surveillance process to additional school districts if indicated by evaluation results.

To date, NASN has provided training to school nurses across the U.S. at state, district and local levels through various methods including in-person presentations at national conferences, train the trainer, and online webinars on topics like chronic condition management and data collection.

One of the continuing education sessions titled, "Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, School Nurses Can Improve Outcomes" was presented at the National Association of School Nurses 2019 Annual

Conference in Denver, Colorado, by Dr. Kenneth Friedman, Dr. Faith Newton, Beth Matthey and Michael Newton.

It has since been launched on NASN's online learning center platform and promoted in their online listings. This session is available free of charge to all, regardless of membership status with the National Association of School Nurses. NASN has promoted the education session through their weekly digest, an electronic publication that goes to 50,000 subscribers and through a flyer for parent and advocacy groups to use to promote this session within their networks.

As of December 16th, 2019, 312 individuals had completed this course. This concludes my update. Thank you for your attention and participation. At this point, I would like to turn the call over to our Associate Director for Epidemiological Science, Dr. Belay, to moderate the call.

Ermias Belay: Thank you, Dr. Issa. We'll now move on to the question session. In the interest of time and to give others a fair chance, please try to keep your questions as brief as possible. Katrina, over to you.

Coordinator: Thank you. If you would like to ask a question or submit a comment, please press Star 1 on your phone, record your name and your line will be open. Thank you. So far, our first question we have Afton Hall. Your line is now open.

Afton Hall: Thank you. I have had ME/CFS since March 6th of 2016. I've spent four days comprising this question because it's so difficult to proceed, so I apologize for my slow speech.

I'm wondering if the CDC can help physicians and patients on the Web site by

somewhere prominently displaying the ICD-10-CM codes for ME, PVFS and ME/CFS. The ICD-10 code, G93.3, reads, "Post-viral fatigue syndrome, myalgic encephalomyelitis." When the physician uses this code, it results in a monthly benefit 60 percent higher than the ones that is used, the ICD code of R53.82, which reads "chronic fatigue unspecified."

Because of a lack of knowledge on my physician's part, I am given less than \$500 a month because of my compromised situation. I'm not able to advocate for myself very adequately. I think that, if these codes were made more commonly available, that patients who are in my situation where we are having to educate our doctors by giving them these resources that they don't have the time and - often not even the inclination - to research, it would ease part of our burden in trying to maintain an adequate lifestyle.

And I'm wondering if the Social Security Administration has a representative that is invited to this conference also? The other thing, the concern I have, is that it is not listed - this illness is not listed in the compassionate allowance list, which would take our struggle to be approved for help from anywhere from 11 months to 2 years, would take it down to being able to apply the month -- at the 6-month mark of our illness where the diagnosis can finally be confirmed. We would then be allowed to apply at 6 months rather than at 11 months.

Ermias Belay: Thank you, Mrs. Hall. So I will have Dr. Unger address some of your questions that you just raised.

Elizabeth Unger: Yes, thank you. And I'm very sorry that you are faced with so many difficulties. The Social Security Administration does have special processes in place for addressing disability in ME/CFS. We have a link on our Web site that could get you to their resources.

We do not have a Social Security representative on this call, but we are working with NIH and to rearrange a process where we could reconvene interagency communication because we agree with you that it's best for the agencies to speak together.

The issue of ICD coding is very complicated and the part of CDC that deals with coding is a different part from where we're located. It's the National Center for Health Statistics. And we had proposed language for our Web site that actually provided ICD codes and they said that it was not possible for us to give coding guidance, that coding was supposed to be entirely left to the physicians – that would be considered guiding too much.

So we're kind of left with where it's at and we are in dialogue with NCHS. They've explained that changes in coding really come from initiatives that are started in the professional medical organizations and that would be the way to probably get the best traction on this issue.

And the other comment that the coding group always says is that the ICD codes were not intended to be used for insurance or reimbursement or anything like that. So it's unfortunate that we're kind of misusing the codes. The codes were really only to track health and I'm sorry for the difficulty that this has made for you.

Ermias Belay: Katrina, next question.

Coordinator: Our next question comes from Denise Lopez. Your line is now open.

Denise Lopez: Thank you. Good afternoon. I'm sure you're aware that there was a recent article published by Lenny Jason and his group on pediatric epidemiology in

which they reported that only 5 percent of 5- to 17-year-olds had previously been diagnosed with ME/CFS by a doctor -- the rate similar to that in adults.

The question that I have is two-part, but let me preface it with CDC's current epidemiological efforts, however, only rely on either studies in tertiary clinics or a previous medical diagnosis of CFS. Both of these methods though are known to introduce bias and result in small epidemiological findings.

So now, my questions. How does CDC intend to address the bias and risk inherent in its current strategy and why hasn't CDC undertaken a proper epidemiological study in adults using the community-based random sample and medical confirmation of diagnosis with specific and well-defined criteria? Thank you.

Ermias Belay: Thank you, Ms. Lopez. Dr. Unger will address this question for you.

Elizabeth Unger: Yes, thank you very much. Yes, we are aware of Dr. Jason's publication and it's good that more people are looking at this illness.

Our epidemiologic approach uses a variety of methods and Dr. Issa just explained that the approach that we're taking to use school nurses and that should substantially reduce the bias because the school population is more diverse and we won't be filtering them through any pre-conceived case definition.

And we -- our reliance on the experts will give - in the tertiary care settings will give a different view of the illness, but we feel that it's still a valid starting place and with an - no study is perfect. So, the most important thing is that when we present our findings, we explain the context and how it can be interpreted and the limits of interpretation.

We will continue to plan more studies. It's important to keep in mind for that we are working with the health care community to improve diagnosis so that questions of counting patients will be easier and better managed through routine - more routine surveillance approaches.

Ermias Belay: Thank you, Dr. Unger. Katrina, the next question?

Coordinator: Sure. Our next question comes from Liz Burlingame. Your line is now open.

Liz Burlingame: Hello, Dr. Unger. It is well known that we have a serious clinical care crisis because of the rapidly shrinking pool of disease experts and the continued medical stigma and misinformation that harm patients every day. The CDC's current medical outreach efforts such as its CMEs, Web site and the single call you recently made to Mayo Clinic are not comprehensive or proactive enough to make a dent in this crisis.

I want you to please talk to us about the ways in which your outreach like your call to Mayo -- which we appreciate because we've been begging for that for years -- but a call like that isn't comprehensive enough. We need the CDC to take a proactive approach and reach out on a national level.

We also need the CDC to publicly disavow cognitive behavioral therapy and GET, which is Graded Exercise Therapy, which continues to harm patients. Can you please speak to the efforts you can - the way you can improve that crisis?

Elizabeth Unger: Okay. Thank you. We agree with you that there is a crisis and our NIH colleagues agree with you and we are all working to see how we can increase the pipeline of both researchers, young researchers, and clinicians that are

interested and knowledgeable about this illness.

Our current outreach efforts are a start and we feel that the best way to amplify these is through partnerships and we are hoping to increase outreach by our - convening our roundtables where we enlist the interest of stakeholders of all types.

Ermias Belay: Thank you, Dr. Unger. Katrina, the next question, please.

Coordinator: Our next question is from Ben HsuBorger. Your line is now open.

Ben HsuBorger: Thank you. So, Dr. Unger, I have a question. At the beginning of this call you listed out several names that were involved in the pediatric MCAM study, but my - specifically I would like to know what are the names of the specific additional pediatricians, not just doctors, who have been recruited to the Open Medicine Clinic initiative to participate in the expanded pediatric MCAM study. Could you tell us what their affiliations are and their expertise in ME/CFS? Thank you.

Elizabeth Unger: To date, these are the names of the clinicians that we have. Some of them have pediatric patients in their study – in their clinic population – and they are accredited by medical organizations. Most of them are not primary pediatric ME/CFS specialists.

As we indicated in our letter that you wrote asking about this, we have reached out to Dr. Peter Rowe, who's one of the most well-known clinicians, and he was unable to participate and we are - have been trying to reach out to other clinicians to get them involved.

And this is - we're doing - working with our contractor to get the very best

clinicians in - that we can.

Ermias Belay: Thank you, Dr. Unger. Katrina, the next question, please.

Coordinator: Our next question comes from (Therese Russo). Your line is now open.

Therese Russo: Hi. This is Therese. My understanding is that CDC's work with the Georgia AAP (Academy of Pediatrics) was a pilot program and that at the closeout of evaluation you would review options for potentially expanding it nationally or to other states. Has a decision been made on whether to expand this pilot?

Ermias Belay: Yes, thank you, Mrs. Russo, for that question.

Therese Russo: Okay.

Ermias Belay: And Dr. Unger will address it.

Elizabeth Unger: Right. You're correct that the pilot project that we had with the Georgia Chapter of the American Academy of Pediatrics was a pilot that ended in September. We were pleased with these initial results and we do hope that we will be able to take a similar approach with national organizations, as well as, perhaps starting with local chapters of other health care providers.

We do not have this in our specific plan at this time and we're continuing to look for other mechanisms or new contracts to partner with Georgia AAP again, and, as well as, other organizations. So it is definitely a worthwhile program and we are - we have it in our future plans.

Ermias Belay: Thank you. Katrina, the next question, please?

Coordinator: Next question is Arthur Mirin. Your line is now open.

Arthur Mirin: Yes. As you know, preregistering studies provides important information for stakeholders. Have you registered the pediatric MCAM study in clinicaltrials.gov or similar study registry? And if not, why not and what are your plans in that regard? Thank you.

Elizabeth Unger: Thank you, Dr. Mirin. As a surveillance project, we did not register it in clinicaltrials.gov. So we did not think that was an appropriate listing. I think that is an interesting suggestion though. We could see if some sort of registry would be helpful in increasing interest in the study. Thank you.

Ermias Belay: Katrina, next question, please.

Coordinator: Okay. Our next question comes from Michelle Lee. Your line is now open.

Michelle Lee: Thank you. I just want to raise an overarching problem that I guess that sort of watched the field for over a decade now. It seems to be at the root of virtually every single significant challenge it's facing. It's the point of view of the clinicians, the researchers, the government, the patients, insurance companies, and it really boils down very simply.

So there does not seem to be an effort, an organized effort, a systematic effort, to really get granularity. It is all well and good and certainly necessary that, over the years that, you know, various researchers and efforts of the patient groups and so forth have gotten sort of the bullet point concept of the illness and have tried to at least, you know, deal with the ME/CFS nonsense and all of that.

But, you know, there's a huge chicken or egg problem. If you're getting

enough detail, you know, details about, you know, with what the prodromal stage looks like versus, you know, years in, if you're not getting details about the, you know - obviously, again, basic demographics and so forth, but you're not getting details about this sort of interesting system clusters that pop up here and there in the literature, but aren't being comprehensively, you know, included in the elucidations either in studies or even in the basic stuff that goes out in material.

And it would seem to me that if you're looking at this as a very interesting multi-system, multi-symptom illness that getting that granularity is crucial. You're not - there's never going to be a real understanding of precisely what the mechanisms are or how they interact without getting that.

And I think - and it's something that, I think, could be done relatively inexpensively that it just started - starts getting put out there even in terms of clinician's level, you know, for what kinds of data clinicians and what kinds of questions clinicians ask their patients.

I hope that makes some sense. It was a little rambling, but it seems to me that that getting clarity could be really achieved by a greater effort by getting details, about things besides just fatigue and get that was it viral and that kind of thing, but really getting details. Thank you.

Ermias Belay: Thank you for your comments, Miss Lee.

Elizabeth Unger: Yes, your comments are absolutely correct and it's - I think we have taken a very important step forward in increasing the granularity and that's through the CDC/NINDS Common Data Elements Project. And in this project, we are - we have provided - not we. I mean, the field got together. Experts internationally got together and assembled the best information they could

about what instruments and approaches are - can be used to measure all facets of patients with ME/CFS.

And we are urging researchers to use this standardized data collection so that the data will be more comparable. And that goes a long way to addressing the heterogeneity of the illness, which is part of what I think you were commenting on, that it's not enough just to meet a case definition. You really need to have a much more refined accounting of all of the things that are going on.

As part of MCAM, we were hoping to end - we're going to be evaluating the instruments that we used in that study and providing - hopefully at the end be able to say this one or two are most helpful for clinicians to use in evaluating their patients.

I'd also point you to the IOM report at the very end. There's a resource for clinicians that one of the appendices provides - a list of suggested questions to probe patients about their illness. That should be very helpful in having - helping clinicians identify ME/CFS in their patients.

And then your next - your additional question about details, sort of hinted at the problem that the field has that most patients that are enrolled in studies have been ill five to seven years and, at that point, it's very difficult to make strong conclusions about what might have been the inciting cause and it's also difficult to go back and really dissect and determine what the characteristics of the illness were at the onset.

And so we have been discussing this in our program and have planned - have a plan that we hope will work out where we will start to identify patients earlier on in their illness course and because that's really what's needed in

order to get at some of these risk factors for illness - risk factors for recovery. Well, that's not a risk. That's a positive factor for recovery.

Ermias Belay: Right. Predictor.

Elizabeth Unger: But yes, predictor. Yes, thank you.

Ermias Belay: Thank you, Dr. Unger. Katrina, the next question, please?

Coordinator: Yes, Wilhelmina Jenkins, your line is now open.

Wilhelmina Jenkins: Thank you. Hello, Dr. Unger. I'd like to go back again to talk about the evidence we got from Dr. Jason's recent prevalence study. He found that only 5% of 5- to 17-year-olds with M.E. had been previously diagnosed by their own providers and also, as he found with the adult populations, he found that African-Americans and Latinx young people are represented at a higher rate than the general population.

What I wondered is what communities for the doctors participating in the pediatrics MCAM study serve? Do they serve racial and ethnic minority populations or is there any plan for CDC to reach out to the medical populations that treat Latinx, African-American young people so that they're able to be included in the study?

Using the same methods, we've used all along is not going to get a representative number of African-American and Latinx young people in the study.

Elizabeth Unger: Yes, thank you, Wilhelmina. It's a really important question and concern and we find it striking how many - how few minority patients were enrolled in the

- in the seven specialty clinics that participated in MCAM. It's likely that people in the minority communities that have ME/CFS face even larger barriers to health care than the general population with ME/CFS.

And so, we are directing our continuing education activities at health care providers to help reduce the barriers for all and working with the National Behavioral Risk Factor Surveillance Survey and the National Association of School Nurses will broaden ethnic representation in the data that we have.

We have this concern in mind as we plan our future studies. The pediatric MCAM study will face the same problem that the adult MCAM study faced in that these are basically tertiary kinds of clinics and will not be representative of the whole population. We recognize that as a limit of the data that we have. And so we interpret our data with caution. But thank you.

Ermias Belay: Katrina, the next question, please?

Coordinator: It's from (Sandy Martin). Your line is now open.

(Sandy Martin): Thank you very much. You noted when discussing the upcoming Medscape course that Dr. Stephen Gluckman is an author of, I believe, the third module you discussed. In just looking up his article on - I'm sorry. No, I blanked out. Merck Manual. He recommends in his article, CBT (cognitive behavioral therapy) and GET (graded exercise therapy).

So, I'm just wondering if the CDC is trying to hurt us or help us because if you invited Dr. Gluckman, who recommends CBT and GET for ME/CFS, I just I'm alarmed at CDC's judgment, number one. Number two, that second part, Liz Burlingame asked you - actually, Liz Burlingame reiterated that CDC must publicly disavow GET and CBT. We've been asking for this for

years and you've been denying that it needs to happen. You've ignored us. You've pretended that it's unnecessary. You've blamed people for misunderstanding.

This really must happen and you continue to harm us as long as you stonewall on this. So, it just terrifies me what you're doing, what you're refusing to do, hiring Dr. Gluckman. I just really - I think we deserve some answers. Thank you.

Elizabeth Unger: Thank you very much. Appreciate a chance to talk about some of these issues. Dr. Gluckman is representative of the mainstream medical community. He has authored the Up-to-Date section on ME/CFS and is very influential. We felt that the best way to reach the medical community at-large was to work with people like Dr. Gluckman.

We've had many conversations with him and his Up-to-Date module now reflects cautions about use of options such as CBT and GET. The module that Dr. Gluckman is addressing - is working on - does not address treatment. It just talks about the illness. And finally, CDC did not hire Dr. Gluckman. We are working with Medscape and Medscape suggested him as one potential expert and we accepted his credentials and his experience.

And the whole question about CBT and GET is very complicated and we have modified our Web page to reflect our position and that is that the - first of all, it's - those words are not understandable anymore. They've been used and abused too many times. Whatever you call these approaches, they are not cures or treatments. They could be management tools in the right setting and we do not refer to GET.

We are recommending pacing and that is a very careful approach to managing

activities that reflects the balance that's needed between maintaining an exercise regime as much as possible and avoiding overexertion that will illicit post-exertional malaise. Thank you.

Ermias Belay: Thank you. Katrina, the next question, please?

Coordinator: Comes from Cynthia Johnson. Your line is now open.

Cynthia Johnson: Yes. Thank you very much. I was wondering what the CDC and the international community is doing in terms of the coronavirus and also even the CDC in terms of flu season, in terms of following up to see if there's - you know, where the outbreaks of ME/CFS are because most people, I think, with it had - were post-viral. I know I was over a decade ago and I know there's not a lot of neglect that area.

So I just wanted to see with this - a lot of attention nationally, internationally on the coronavirus, but just what you're doing in general because I think that's where we're missing - the children and a lot of other people - is when the viruses happen that maybe no one following up would happen to the people that got sick. It's very sad when people die, but I have a feeling a lot of people are getting sick that we're maybe missing. So I just kind of wanted to throw that out and see what you guys were doing in that area.

Elizabeth Unger: Yes, thank you for that question and it actually has been a topic that has been discussed. To date, there's no evidence that flu outbreaks are associated with ME/CFS and the problem with trying to link in follow-up studies when people are dealing with an outbreak is that all resources are going to acute measures.

And CDC is actually discussing what other chronic sequelae there could be of some of these very acute severe illnesses. And so the means to study that are

very difficult to put in place and they don't exist yet, but it's definitely important to keep in mind. Thank you.

Ermias Belay: Thank you, Dr. Unger. We are getting close to the end of our call. This will be the final question that we'll be able to take because of the time. Katrina, the next question, please.

Coordinator: Thank you. And the next question will be from Michelle Carlisle. Your line is now open.

Michelle Carlisle: Yes. I wanted to just make a few statements. I'm really happy with the pediatric trial that you're doing in Utah and I'm sure that you're all aware the importance of early diagnosis. I could've been diagnosed way sooner. I wouldn't have gotten near as sick. And so, I'm really happy with this trial in Utah.

Also, I'm wondering does the CDC have any plans to get more information about the illness into the press? And if not, if that would be a possibility?

Elizabeth Unger: Thank you. Maybe I could ask Christine Pearson, our communications person, to address that.

Christine Pearson: Hi there. This is Christine. So we have made multiple efforts over the last couple of years to submit letters to the editor and other types of communications for the media. And, to be honest with you, with the state of the media and the large number of, you know, big outbreaks and things that have been happening, we've just not been able to, you know, with limited space, they've not been wanting to focus on that. But there are a number of sort of more targeted ways that we are looking into trying to get information out to sort of more targeted groups like - and we'll continue to do that.

Michelle Carlisle: Okay. Thank you.

Ermias Belay: Thank you. This brings us to the close of our call today. Thank you, everyone, for participating. Thank you for the presenters. Thank you, Katrina. We look forward to having you join us again at our next call. Thank you so much.

Coordinator: Thank you. This concludes our conference. You may all disconnect. Thank you for your participation.

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