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PEASE COMMUNITY ASSISTANCE PANEL (CAP) MEETING

September 29, 2022

The verbatim transcript of the Meeting of the Pease Community Assistance Panel held virtually on September 29, 2022.

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P R O C E E D I N G S

(6:00 p.m.)

WELCOME AND INTRODUCTIONS

MS. BARRETT: Okay. Hi everyone. On my clock it says 6:00, so I want to go ahead and get started. So good evening everyone. Thank you for joining the Pease CAP meeting. I want to go ahead and start with introductions. I want to first start with our CAP member. I know up front that Karen Anderson and Toni McLellan and Joe Ryan have told me they wouldn't be able to attend, but I will start down the list. Andrea Amico [phonetic]? Are you on the line? I thought I saw you on the line.

DR. REH: I thought I saw her too.

MS. BARRETT: Okay. Well, I'll circle back to her. Michelle Dalton. Alayna Davis. Rich DiPentima, sorry, DiPentima, Senator Martha Fuller Clark. Bill McQuillen. Jared Sheehan. Mark Sullivan. And Shelley Vetter.

MS. VETTER: I'm here.

MS. BARRETT: Hi Shelley. Hi, nice to see you. Thanks. And next, I want to go with our CAP technical advisors. Dr. Schaidler, are you on the line?

DR. SCHAIDER: Yep, I'm here.

MS. BARRETT: Okay. Awesome. Nice to see you. Okay. I see you Andrea Amico. Okay, I see you. So I see you're on the line. Okay.

MS. AMICO: HI.

MS. BARRETT: Nice to see you. And next, I want to go through our ATSDR folks that are here on the line. I'm just going to say your name and just let everyone know your position here. So, first, I want to start with Dr. Chris Reh.

DR. REH: Yep, I'm here. Associate director, ATSDR.

MS. BARRETT: Captain Tarah Somers. Hi.

CAPT SOMERS: Hi, do you want us to say our -

MS. BARRETT: Yes, just say your position.

CAPT SOMERS: Oh, I thought you were saying it. Sorry. I'm the regional director for ATSDR region 1.

MS. BARRETT: Awesome. Dr. Katie Egan.

DR. EGAN: Yes, Hello. I am the team lead for the community studies team and the health studies section.

MS. BARRETT: Awesome. Thank you. Dr. Marian Pavuk.

DR. PAVUK: Hello. Good evening.

MS. BARRETT: Hi. Dr. Frank Bove.

DR. BOVE: Good evening, everyone.

MS. BARRETT: Evening. I see Kim Dills is on the line.

MS. DILLS: Hi, good evening. Policy and Congressional Affairs.

MS. BARRETT: Awesome, nice to see you. And last but not least, I believe we have our Air Force folks, Colonel Holifield.

COL. HOLIFIELD: Hey, good evening. Colonel Holifield, Air Force Secretariat.

MS. BARRETT: Good evening. And Major Kirk -- I'm trying to see if it's all coming through.

MAJ. KIRK: I'm here.

MS. BARRETT: Hi. Nice to see you. Okay. So is there anyone that I forgot on the line? Okay.

PEASE STUDY UPDATE

MS. BARRETT: Hi. With that, I'm going to move forward with our Pease study update, the next item on our agenda. And I want to give it up to our subject matters. Let's see, Captain Somers or Dr. Pavuk or Dr. Bove.

DR. BOVE: Well, I think I'm supposed to give the update.

MS. BARRETT: Yeah, sorry. That is you.

DR. BOVE: Well, And first of all, the contract with ABT Associates has ended. They provided us with the -- all the data and also with a summary report that went over the study design and methods. So the contract is over. So we do have all the data except for those people who participated in New Hampshire Pease biomonitoring program who did not give us their results from that program. So we're mailing, doing a mailing next week to those people. I can't remember, they're about 300 or so, to try to get them to give us their information. They can either send it directly to us if they have it. If they don't have it, they have to fill out -- actually it's pretty much all filled out already, but an authorization form they need to sign, send that to the health department in a preaddressed envelop with a stamp

on it so you don't have to pay for postage, and then the New Hampshire Health Department will give us those results. So they're important for the study, so we're hoping people respond to the mailing. Also, the last of the clinical results were sent out, I think it was last week or the week before, so people should have gotten them. They were the immunoglobulins, IgA, E, G, and M, and Alc, glycosylated hemoglobin for those who know what that means. That all was sent out to participants. So that's it for the clinical results. So the participants have all the information now about their particular serum results. Let's see, is there anything else. Marian and Katie, do you want to add anything?

DR. EGAN: Not for me. I think you covered it.

DR. PAVUK: So is -- let me find where I am. As Frank mentioned, we do have this kind of first phase of building the data and data management that we worked on [inaudible] on complete. We do have the dataset aggregated. We have received PFAS data in July and got all the other clinical data then in August/September. So it's all very fresh. We have received the SUNY results, kind of just really last minute, but we did manage to work with them and get that accomplished by the deadline of end of September. Thank you.

DR. BOVE: So if are there any questions for us about the Pease study?

MS. BARRETT: Yeah, so if any CAP members have any questions or panelists, just unmute yourselves.

MS. AMICO: Yep, hi Frank, Marian. Thank you very much. I just -- yeah, I have a few questions. The first one is, can you just remind the CAP why you used SUNY, the State University of New York, and like why those lab results were done there?

DR. BOVE: Do you want to take that, Marian, or do you want me to take it?

DR. PAVUK: Sure. So very simple reason. The analytical plan as was proposed, especially the parts on immunoglobulins and some other annelids that went to SUNY, the lab corps simply uses their commercial technology require, for example, from children, to measure because we were interested in looking in immune function, right. So being able to measure just those four immunoglobulins, we would have to collect additional, about 8 to 10 milliliters of whole blood for each child just for that one analysis. So that was not possible for the age groups that we were doing the same thing for glycosylated hemoglobin as diabetes is an important thing to look at in adults and

children. So lab corps would require additional 4 to 5 mL of whole blood just for that one test. So we have to look at the noncommercial solutions that provided analysis in much smaller amount of blood, and that's why we needed to find a different source, and we have choose SUNY because we have had previous collaborations with them and had good experiences with them delivering the results.

MS. AMICO: Great. Thank you for that. That's a very helpful explanation. My other question is just around the timing of reports and like what can we expect next. So I think it's great that you have all the data from ABT, individuals have all their own results. So now what? Like what can we expect in terms of next steps and report back and, you know, how, and what you find and how we compare to others in the study, and then also like how will this be combined with multi-site study data, which I know is the data collections ongoing at those sites. So what can we expect for next steps in the timeline?

DR. REH: Marian? Frank?

DR. PAVUK: So, so yeah. So the next steps on this that we can start analysis of data for the Pease. So there are two major directions that we want to go first. That would be the evaluation of their exposure levels at Pease and compare it to their previous levels and to current, and hence, our efforts, you know, to kind of boost the number of people that reported those data since we can't get it directly from New Hampshire State Health Department by a monitoring program, right. Even though we specifically consented our participants to provide the data, state health department rejected that consent, their lawyers. So hence the extras step. Nevertheless, back to your question. So two major things that we want to do. So one is the exposure, doing, you know, presenting your results, you know, on age, sex mostly since you are racially one race, sample 96% white, right. So we'll present, you know, age groups, age categories for children and adults. So we are planning to have that paper as initial draft and manuscript to address that, how that changed from 2015-18 by monitoring and also how it compares to, and hence. So that's our one prong. So we're hoping that, you know, by the end of the year we will have some sort of draft that will start going through the agency review and start that process like we do for the, you know, manuscripts and developments of reports. So that's one part. The second part, of course, is to look at the health outcomes that they reported on questionnaires and that we verified through healthcare provider. So there's three sets of data there because, of course, they don't match, right. People report different things. The

physicians report different things. Also, we have a lot of outcomes, and we have a lot of [inaudible], right. So this is a little bit more complicated, and we need to do, so we'll do some preliminary analysis and screen, you know, how it looks. I'll be working on the exposure paper, and we'll have to make some decisions like how to structure this. Normally, as you see, I mean you've been in the area as a professional for some years now. So you see from the updates, you know, for PFAS and for other things that people like to publish, you know, paper on lipids and PFAS and heart disease and PFAS, diabetes and PFAS, right. So we don't have that luxury, I think, here to kind of do it piecemeal like that, so our strategy at this point is to do overview of health outcome with all PFAS kind of screening, look at the most prevalent ones. I mean the sample has a certain sample size, so there's only about seven to ten outcomes that have more than 30 count, right, for the adults, that has, that can be, you know, analyzed in some more details. The others would have, you know, small numbers that would be more appropriate to be analyzed together on the, you know, together with the multi-site study, right. So, so that's one, one way to do that initial assessment where we are and what we focus on. So we agreed that we would do an overview of health outcomes, right, first, and you know, and start developing, you know, based on those initial results next year, you know, we may start developing some collaborations, you know, that we would like to see for some individual, you know, health outcomes that either are promising or they show signals, right, those of high interest to you, and those that show signals in the preliminary analysis, right. So that we can focus on things that have the most interest or impact, you know, for your community based on, you know, having sufficient sample size. So we will not be looking at, you know, ulcerative colitis because there are seven people, right. So it will not be a separate paper in January, right. But so, without going into too much detail, right, so these are the two big prongs that we want to do. The question is then for, for the point of as this will be, this will be kind of, there's a lot of tables that we're going to generate in this way, and it's long, you know. We'll have to decide if we do it separately for children and for adults. So I think that will be made sometimes early next year or by the end of this year. So, and as I said, the third part is really to identifying, you know, future collaborators. We will work, you know, over the next month or two to try to find and maybe even get some funding to identify the person that would focus on neurobehavioral outcomes. Right. Because we don't have that expertise in house, so we would like to engage, you know, somebody who actually [inaudible] for the neurobehavioral assessment manuscript.

MS. AMICO: Okay. So, I just want to make sure I understand. So there'll be like two initial papers that we can expect? One is strictly looking at the exposure and the PFAS levels, and then one will be looking at an overview of the outcomes.

DR. PAVUK: Correct.

MS. AMICO: And those two papers will be coming out potentially the end of this year or early next year?

DR. PAVUK: Oh, they won't be coming out. There will be, there will be drafts that will start the review, you know, process at the agency.

MS. AMICO: Okay. So do we have a timeline as to when us as the community will be able to read these reports?

DR. PAVUK: Well, that depends not only on us but, you know, on others as well, on how, you know, this process plays out. We would hope that this would be sometimes in the first half of 2023.

MS. AMICO: Okay. And who are the others that it would depend on?

DR. PAVUK: Well, number of factors here, you know, figuring out if it will be one, two, or three papers right at the end of the day. You know, so it depends on the capacity that we have in house. It also depends on the comments, right, that we receive inside the agency. Then, as you well know, the agency has to do external peer review. So that takes just a month to send it out, then for us another, you know, month just to review, and if there's a request for reanalysis, that process takes another month, right. Then the actual process of publishing the paper may take anywhere from three to six months, right. So that's your timeline for seeing that. So that doesn't depend on us. You know, the journal may decide that they don't like it or that, you know, they want reanalysis of stuff or, you know, or splitting article in two or other things. So that process is not entirely under our control. So it's not like exposure, assessment, report. You know, we prepare a report, it goes through agency clearance, and you know, and you can project like when that will be on our website, right. So this is a different process.

MS. AMICO: Okay. Will the CAP get to see a draft? Will we get to comment on it?

DR. PAVUK: Sure.

MS. AMICO: Okay. Once the papers are published, does ATSDR anticipate hosting a community meeting or, you know, how are we going to release this information to the broader public?

DR. PAVUK: Yeah, we expect that, yes, that's part of the overall plan that, you know, once there's at least two or three of those papers published that we would have a community meeting. And as I'm saying, so, we would also, you know, like to broaden it up the spectrum of, you know, who is involved on this, right, and you know, we have a number of collaborators, you know, on the multi-site study, so depending on, you know, the things that we see here, you know, we'll broaden it up. And so, in the second half of '23, I think, was the original plan to see whether we can have such meeting.

MS. AMICO: Okay. Okay. And then, in terms of how this will fit in with the multi-site study efforts, what is, so I'm assuming ATSDR is going to be following the same process or their contractors will be following the same process at the other sites where the multi-site study is happening, meaning the different papers and what not, but then, can you speak a little bit to how, how will all the sites be analyzed together, and like, we probably don't know when, because I know those sites are still collecting their data and everything, but like at the end when all the studies are done, what is ATSDR's plan to analyze all those sites together, and could we, will we also expect a paper on all the sites?

DR. PAVUK: Oh, definitely. That's the plan. Chris, do you want to address overall plan or?

DR. REH: No, go ahead, I was going to add something to the question before, the question Andrea just asked. So go ahead and finishing answering this, and then I'll put my two cents worth at the end.

DR. PAVUK: All right, all right. So, so yeah, Andrea. So, yeah that's the ultimate plan, is to, you know, leverage our, you know, data management experience and the work that we have done all this year, which is really the difficult part, you know. We have developed, you know, data dictionary that has 40 sections, and we have 5,000 variables, right. So we will start a process of planning, you know, that kind of data management for multi-site, because it's even more complicated because we basically have certain [inaudible] trying to put them together. So there needs to be a coherent plan of how, you know, those variables. Because everybody wants to have the thing separate, but then also you're going to have everything aggregated as possible, right. So that creates a problem for you, how you're going to

handle, you know, the same variables, you know. Do you want to, on one hand do you want to know how many diabetes are in Pennsylvania and in California at the same time, then you want to aggregate the variable across all the sites, right. So that's a more complicated process than Pease, right. And it will take a longer time to do that. Nevertheless, the overarching plan, as Dr. Breyse envisioned, that's the strength of all of that, that we will ultimately combine all the exposure data and all the health outcome data into aggregated dataset. So every -- investigators from all sides will receive the aggregated dataset, right, that will put it together, but all the parts of the consortium will receive that, so all investigators will have access to that. And I assume that, you know, the same kind of, you know, approach as we do at Pease will appear, you know, kind of addressing the exposure across the sites and contrasting them, how they're different across the country, right, because that's your first step, right. And then, having the overall view, you know, of the cohort, right. So we are envisioning, and we have started kind of even putting together now kind of the methods paper for multi-site because the multi-site will need that, right. So we'll have something kind of describing how it came together, and then we'll have the description of the exposure and description of a cohort like, you know, how many diseases at each site and at all sites combined you have. So, C8 study [inaudible], you know, done something like that before. So that's what we envision as a first thing that will be, we are working already now on, right, to have once the, you know, everything gets collected and complete before the actual statistical analysis of data starts, right. And so for the overall cohort, I think that each side, you know, each set of investigators have their, you know, have their specific set of skills and expertise and focus on specific outcomes. So it really will be as part of consortium and in consultation with ATSDR, you know, decide who will be doing what so that, you know, we can start working, you know, on eight to ten papers at the same time from the multi-site study on different health outcomes of interest and importance. So that's the kind of overarching plan. Chris.

MS. AMICO: Thank you.

DR. REH: Yeah, the only thing I was going to add, which was kind of to your previous question, Andrea, is whenever we finalize a project like the Pease Study and the reports roll out, we're always going to have a roll-out plan, and we're going to come and meet with the community. It may include talking to physicians. It may include looking at using our PEHSUs, our pediatric environmental health specialty units to help get

education around the results of the study out. But, you know, there will be a roll-out plan that will develop as part of that finalizing the Pease study and the roll out of those reports that we'll definitely share with the CAP to make sure that we're hitting the right spots.

MS. AMICO: Okay. That's great. I just have two other questions. One, is just to go back to a previous thing. Regarding capturing people's health information, I know people signed a consent for you to review their medical records through their primary care office. So, like you said, there's problem discrepancies where maybe some people reported certain health outcomes, but then you couldn't verify that in a medical record. But I'm just wondering, what if someone didn't report a health outcome, but maybe they didn't know they had it or they forgot, would you still verify their health records like to see if they have that health outcome? Just thinking of like high cholesterol. If maybe someone said, no, I don't have high cholesterol, but then would you still check their medical record for that too or -

DR. PAVUK: So, so just to correct you a little bit on the process, right. So we have not physically verified or bent over their records. Right. We don't have their medical records, right. That's just not possible or feasible at this day and age, really on this type of studies. What we have done instead, they gave us, participants gave us content to check with their primary care provider or provider of their choice or several. They didn't have to put just one doctor. They could have put more, right. And we would give that provider the same, basically the same thing that people have on their questions, reporting, we would give the same thing to their doctor. So even if participants, so we went one better than C8, right. C8 only confirmed those that people reported. Instead, here at Pease and in multisite, we are giving the same set of diseases to the participant and to the provider. So if the participant didn't report high cholesterol, their physician got the question, and if they had the higher cholesterol, more likely than not they would report that.

MS. AMICO: Okay. I see. Okay.

DR. PAVUK: So that's, so I think we have more data than C8. It's a little more messy, but at the same time, we have more coverage than they had. So yes, if they didn't remember or they didn't report, we have a number of those that their physician reported and participant didn't report. And we'll look at that as combined, you know, because of, is in clinical trial intend to treat, so any information we get we will analyze, right.

MS. AMICO: And so, are you planning to, if you do see discrepancies one way or the other, whether the participant reported it and the physician didn't, or the physician reported it and the participant didn't, how are you treating that discrepancy? Are you then like calling participant to say, hey, we just want to double check. Or are you calling the physician -

DR. PAVUK: No, we [inaudible].

MS. AMICO: So how do you factor that into the study?

DR. PAVUK: Yeah, that's, you know, even, even just doing the, doing that process was the most time-consuming part for the staff and for the contract. So, no, we couldn't do back and double check. That just is just immensely time consuming and costly. So we'll account for that in statistical analysis, right. So as I'm saying, even in the report, we'll analyze it in all three ways, you know. We'll analyze the way participant-only reported, provider-only reported, and then reported by either participant or provider together. And then we'll see, we'll come up with a picture.

MS. AMICO: Okay.

DR. PAVUK: So that we can account for that. It's not the purpose of the study to necessarily 100% be sure whether the participant had it or didn't have it, right. Then we also have, I mean, that would be ideal, right, that would be ideal to get that.

MS. AMICO: I think so.

DR. PAVUK: But we're not in Denmark, right. We don't have participant ID, and we don't have one healthcare system where all the data are put in and verified, right. We have 125 insurance companies and countless providers, right. So, so we're not going to get that kind of data, but what we can do on both those things that participants reported or providers reported, we have additional information to verify or check, right. We have their medication information, right. So for example, if participant says I have hypertension, and his provider says he doesn't have hypertension, and he doesn't take any antihypertensive drugs, right, well, then, you know, it's kind of not very sure of it if participants have hypertension, right. But if participant says that he has hypertension, and for example, we didn't get his provider confirm it, but he is on antihypertensive medication, then we are almost 100% sure that participant is hypertensive, right. So we also have, you know, their measurements in the office, right. We also have the measurements for people that for example doesn't, do not report diabetes, we have their insulin levels and their glucose level,

right. So we are, we would be able to classify participants, you know, based not only on their report or a participant's report, but also on their clinical tests.

MS. AMICO: Okay. Thank you for clarifying that.

DR. PAVUK: Sure.

MS. BARRETT: Okay. Awesome. Thank you for those responses. Do we have any additional questions from our CAP members or technical advisors on the line.

DR. SCHAIDER: I had a couple of questions. One question, I was wondering is were you, like once you've been able to summarize the PFAs levels for the participants, and you know, looking for trends over time compared to the biomonitoring results from 2015, are you going to do some sort of an interim report for the Pease community in advance of having the peer reviewed paper published on it?

DR. PAVUK: I don't know. That could be considered. You know, I mean, we used to do that regularly, that preliminary data we reported, you know, at conferences, or you know, public meetings, with the scrutiny that the government gets these dates, it's not anymore the, you know, current pathway that we're taking. So that is not really for me to decide how that will go. But in the past, that was something that we would do. I don't know if we would be able to do that now.

DR. SCHAIDER: Yeah. I'm well familiar with how long it takes to get a peer-reviewed paper published, and I just think some of the interim findings, you know, would be of interest in the shorter term for the community [inaudible].

DR. PAVUK: Oh definitely. I mean, you know, so -

DR. SCHAIDER: For some of the easier analyses that don't require the complex statistics of [inaudible] have a [inaudible] like the, you know, the kind of short reports you created for exposure assessments.

DR. REH: Yeah. We could, we could look at something like that, Laurel.

DR. PAVUK: Yeah, yeah.

DR. SCHAIDER: Okay, great. And then just my other question for the people who took part in the state biomonitoring program that I understand you have to get them to reconsent to release the results, if you don't get those back in the mail, do you have a

plan to do follow-up phone calls or text messages to remind people, and would you do a second round of mailings?

DR. PAVUK: No, that is last ditch mailing.

DR. SCHAIDER: So like if someone moved or something and you didn't have their current address, and they didn't get it, would you check by e-mail or phone with them as a reminder?

DR. PAVUK: We don't have their e-mails or contact information.

DR. SCHAIDER: For your participants?

DR. PAVUK: Oh, for the participants, oh, the current ones.

DR. SCHAIDER: Your participants. You send out letters to your participants who took part in the biomonitoring program.

DR. PAVUK: Sorry, I was thinking about different thing. Yeah.

DR. SCHAIDER: So for your participants, for the people who don't -- I guess, do you know, do you know who was in the biomonitoring study, but you can't access their data unless they sign this extra form? So if they don't -

DR. PAVUK: That is not necessarily -- we only have people that, I mean, I don't remember on top of my head how exactly it is. We do have obviously we have their mailing addresses since they participated in, but I don't think we have a cross-section of that. I think we have that, that they indicated that they were part of biomonitoring. We know that. So that's why we're sending it to those people. But as we said, our contract has ended, so our capability of reaching out again and following up are limited at this point.

DR. SCHAIDER: So for the 300 or so people you sent the letters out to who reported to you that they took part in the biomonitoring study, if you don't get the letter back, you don't have a plan to follow up the second way?

DR. PAVUK: Well, as I said, we have already closed the contract, so we do not have the money to follow up on that.

DR. SCHAIDER: Okay. And there's no interim [inaudible]. I mean it just seems like it wouldn't necessarily be a heavy lift to send out --

DR. PAVUK: Oh it seems -

DR. SCHAIDER: A round of emails or phone calls.

DR. PAVUK: Oh, you know exactly how much time and effort it takes, so.

DR. SCHAIDER: I do, yeah.

DR. PAVUK: So, you know that that's not entirely true. So, you know, we were, we don't have, I don't have 10 staff, and we can't get the insurance easily to do that kind of thing. So I mean we can try a second thing. I mean if we, if we do not hear back, you know, it depends on what the response is, right. If we do not have the response, you know, then we will decide on the next steps, right. You know, so it all depends on what kind of thing is. We already have, you know, it's not like we don't have that information from anybody, right. We have it from a number of people, and from a couple hundred people, we do have it, right. So we are able to do the analysis, meaningful analysis, you know, on that part, right. There are also published data from the whole cohort, you know, previously. So, you know, it's not like we are operating in the dark here, right. We're trying to reach out to those people that didn't provide the information for one reason or another, and we have took, you know, we have spent six months trying to wriggle this out through New Hampshire State Health Department, right, to get to that spot and pressure their lawyers and figure out like how this could be done, right. So, you know, there's -- at some point, we'll reevaluate, you know, what is the, you know, cost-effective solution to continue this or not.

DR. REH: But, Laurel, the question is, if we do all these mailings, and some of them come back that wasn't the right address, and you're asking, are we going to try to at least somehow connect with them if we've got their e-mail on file or phone on file, if I'm understanding your question right?

DR. SCHAIDER: Yeah, I mean from the 300 people, some of them will, you'll get it back, and some you won't.

DR. REH: Right, right.

DR. SCHAIDER: So, I was just wondering, you know, if that's the end of the line or -- I know you won't get, you won't get everyone [inaudible].

DR. REH: And are we going to do an attempt, do another attempt at getting others. We'll look at that. I mean it's a fair push. We'll look at it. It just depends on how, you know, how it looks like and a lot of other factors, but I'm not going to close the door on a second follow-up.

MS. AMICO: I think that's a fair ask from Dr. Schaidler, you know, and I think let's see what we get with the mailing, but it won't be all of them, we know that. So -

DR. REH: Right.

MS. AMICO: We have their contact information, you know, let's, yeah, I appreciate you leaving the door open to revisit a second round of trying to rally that information because I certainly understand what Marian is saying, you know, it's not going to make or break the study completely, but it absolutely will contribute to the study in a very meaningful way. So doing everything we can to get that consent back would be really important, you know. And I think something beyond one round of mailings, depending on the number of people, you know, let's revisit that, for sure.

DR. REH: Yep.

MS. AMICO: Thank you.

DR. SCHAIDER: And just, I'm sure you already totally explored this, it has to be a paper copy. They won't accept an electronic consent, the [inaudible].

DR. EGAN: So I can jump in here. So we provided actually three different ways for them to respond with the information. So for participants who have their own results at home, they can send us a secure e-mail with those results. They can also mail us directly a copy of their own results. So the authorization form is only for participant who don't have their own results anymore and they want to authorize New Hampshire to send them to us. And then they're going to mail that authorization form directly to New Hampshire for them to give it to us securely.

DR. SCHAIDER: Okay, great. Well, thanks. It's just a -- it's too bad that you have to go through this whole process to get data that you already asked for in your consent form. So, I understand.

DR. BOVE: This is what happens when the lawyers get involved.

DR. PAVUK: You see, the participants are volunteering for the study, and they decide whether they want to provide this or not, you know. So that also needs to be respected, you know. So you can't, you know, endlessly call the same people over and over and over again. There's a limit by IRB and OMB on how much you can contact participants.

DR. SCHAIDER: And the people -- I'm just curious, the people mailed the letters out to, are they all people who had signed

that consent form initially to say they did consent to sharing the results? They're the only ones getting the letters, right.

DR. PAVUK: Yeah, obviously.

DR. SCHAIDER: Well, good luck. I hope you get a good turn around from it. It's frustrating because it's information that's out there and unobtainable, so.

DR. REH: Yeah, but we'll definitely look at that delta between what we got and who's remaining and see if there's another way. And we'll be happy to share that information with you guys.

MS. AMICO: Yeah, and if, if -- when the letters go out, is it possible, Tyra, or someone, to share it with the CAP just so like it'd be great for me to put something on social media like look for this letter. If you get it, please fill it out, or share your results. You know, like if we know, because you said it's going out next week I think I heard? So if there's a way to provide us a sample of the letter or something so we can help raise awareness so when people get it in the mail they're not like what is this? You know, like I already did this study.

DR. REH: Yeah, yeah, yeah, yeah. Yeah.

MS. BARRETT: Sure, I got you.

DR. REH: Because so often these days what you get in the mail is nothing. And so, that's a great idea. So I think we can circle back with you on that, Andrea, thank you.

MS. AMICO: Yep, thank you for that. Sure, thanks.

MS. BARRETT: No problem. I just want to make sure, do any other CAP members or technical advisors, do you guys have any other questions or any other panelists on the line?

QUESTIONS FROM THE AUDIENCE

MS. BARRETT: Okay. Hearing none, I will go next to audience questions. On the line, we have the awesome and gracious Ms. Pam Wyton to help us with our tech issues with Zoom. So I'll let her speak on the line to just update the audience how to ask questions.

MS. WYTON: Yes, thank you, Tyra. You guys can raise your hand if you have a question, and I will unmute you, and you can ask your question verbally. To raise your hand, you can click on the icon on your screen, or if you're only on your phone, you can press star nine, or you can use your keyboard and do ALT-Y.

MS. BARRETT: Awesome. Thank you, Pam. And I'll just pause to see if we get any questions, and I also want to say that at the end we can also circle back towards the end of the meeting if there are questions that arise at a later time. Okay. I'm not seeing any hand raises. Are you seeing anything on your end, Pam?

MS. WYTON: No, I don't.

MS. BARRETT: Okay. So with that being said, again, we can always circle back towards the end of the meeting.

MULTI-SITE STUDY UPDATE

MS. BARRETT So next I'm going to go the multi-site study update. Dr. Egan or Dr. Pavuk, if you guys have any updates.

DR. EGAN: Multi-site would go to Marian.

DR. PAVUK: Yeah, so on multi-site, we are in about, in about a year into from when majority of sites really started collecting. You may recall the first site opened last year in August, and the sites tried to open all their study offices and started recruitment and enrollment process through the Fall of 2021. As you may remember, that was not the best time. The procedures had to be put in place still for the COVID. It didn't want to go away. And then we had all sites open in January. California started last in December/January. We really started the year 2022 really with only about 400 people through that startup period. So August through December 2021. Then in first quarter of 2022, of course, Omicron came in, so that didn't help much either. But in the second quarter and throughout the summer, you know, we were able to make great progress at a number of the sites and have all sites collecting and went, you know, to about over 1,000 people in April; 2,000 people in July; and in August, at about the end of August, we had about 2,100 people. We are at 2,500 people now, and we are on track to be at around 3,000, 2,900/3,000 by Thanksgiving or so. So different sites have of course different communities and different setup. We have very large sites like Pennsylvania with great suburban population and California in the middle of [inaudible] basically. And then we have sites that are part of very small communities like New Jersey, Massachusetts, you know, small towns. And New York, slightly bigger towns, right. Michigan to a degree as well. So it's a combination of small and bigger communities. Colorado, about 70,000, the whole area, right, that is, you know, much bigger than New Jersey that is 5, 6,000. So that has been our primary focus because of pandemic, you know, we are about a year delayed from the point of where the, where the plan or overall plan was likely to be. And so we were, at this point reviewing

with the leadership our recruitment targets and where we are, how are the sites doing, and what they need for the continuation of the efforts in terms of time and potentially funding. So these are, you know, difficult questions. The original plan, original, original timeline for the end of data collection as allowed by OMB is May 2023, so that is about eight months out from now. So as I said, we are in the process of very detailed review side by side of what can be accomplished at each site, what the projections are, and what are our options in potentially extending the collection or not. So situation is different at different sites. Pennsylvania is the first site that is close, already collected, almost 1,000 adults. Other sites that are doing well are at about 350 or so, and on the way of, you know, projecting maybe six, 700 people through the original period. So, so we are spending a lot of time and effort to understand the site needs and the projections and provide, do the assessment and see where we are and what we can achieve through the original period, and if any additional time, you know, could be helpful or possible for a number of the sites to be added. So that's our major preoccupation right now.

MS. BARRETT: Okay, thank you Dr. Pavuk. Do we have any questions from our CAP members or tech advisors?

MS. AMICO: So the numbers that you were projecting, Marian, that's just for the seven other sites, or were those numbers combined with Pease?

DR. PAVUK: No, those were for other sites without Pease.

MS. AMICO: Okay. And then, in terms of the data collection that's supposed to be wrapping up by May of 2023, is there an opportunity or possibility to extend that? I know at Pease we had to pause for a while, we reopened. Is there any consideration, because you mentioned the Omicron variant and just different, you know, things that are probably making recruitment difficult or were at one point. Is there an opportunity to consider extending data collection?

DR. PAVUK: Yeah, yeah. There is. So, I mean, the short answer, yes, in a sense we have a mechanism how to be able to extend at least from our approval point of view that is possible. The issue is that a number of the sites, you know, the cost of inflation and the problems, the cost of, you know, random and issues with retaining and training the staff are really very difficult right now. So, you know, in some places, you know, it probably, they're -- in a couple of the sites they are not even considering it really because they simply ran out of the overall scheme and are planning to finish by the original time anyway.

But we have a number of other sites where this would make sense, and the investigators are eager, they feel that it's needed. So, well, clearly this is on the table, and we are considering it.

MS. AMICO: Okay. That's good to hear. Thank you.

DR. REH: Andrea, we've had a few internal meetings as to what we can do from our end to get more recruitment and to get closure to the target numbers from our statistical analysis. So it's a, it's going to be another no stone unturned type effort.

MS. AMICO: Great. Thank you.

MS. BARRETT: Thank you. Do we have any additional questions?

EXPOSURE ASSESSMENT UPDATE

MS. BARRETT: Not hearing any, I'm going to move on to our next point on the agenda, at the exposure assessment update. And I believe Dr. Reh, there's been a lot of, many of you may know the best updates for the -

DR. REH: Yeah, well, the exposure assessment is finished. The final report was published last week, September 22nd. It is up on our website. If you guys haven't seen it, Tyra can send it around to you, and now they're working on publications and peer reviewed publications and that type of work. So interesting information in the report, and you know, one thing to note is it covers ten sites, you may remember are test sites for exposure assessment where New York and Pennsylvania, and that was through our PEEP program, but it's the same protocol, the same approach, and so the EA final report includes the eight sites that were part of NDAA and then the two other sites that were part of the PEEP program. Have any questions?

MS. AMICO: Yep, I do. So, yeah. It would be super helpful if you guys could share that report with us.

DR. REH: Absolutely.

MS. AMICO: I'd love to see it. And then, I just didn't know, is there any like high-level findings that you can share with us or, you know, any key takeaways that, you know, you could share with us on the report?

DR. REH: So, let me think. I'm dredging my memory here, Andrea. One of the key takeaways is that we found PFAS levels in excess of the 95th percentile of NHANES in all of the communities that we study. So definitely communities that where the source of contamination has been thought to be a nearby current or former military base that those communities, where PFAS was used, that

the levels are higher than what you see in background levels that we see in NHANES. And there are some of the, the PFHXS, I'm pretty sure I got that wrong, but --

UNIDENTIFIED SPEAKER: No, that's right.

DR. REH: It's the PFAS most commonly found in firefighting foams. We found that quite a bit. There's also some interesting findings like the Delaware site is interesting, and we believe it's the result of not only the contamination from the nearby base but also they're upstream from the community is a Dupont facility. I think it's Dupont, or at least a chemical, a large chemical plant that used PFAS, similar to what you guys have seen in New Hampshire with [inaudible].

MS. AMICO: Great. And is there any spinoff work or any additional projects regarding the exposure assessment that ATSDR has planned now that you have gathered this data, analyzed it -

DR. REH: Yeah.

MS. AMICO: And been able to identify elevated levels in every single community.

DR. REH: Yep.

MS. AMICO: Are there any next steps or future action items or projects as a result of this.

DR. REH: Yeah. So there's a couple of things. Thanks for asking that. First, we have joint study, and I think we've reported out on this. We have a joint study with EPA looking at some of these communities and looking at other sources of PFAS. So looking at household dust, I forget everything that's part of the study, but it's looking at, you know, asking the question, do we still believe that the source of PFAS is drinking water, and what's the contributing factor of other sources. We're also looking at possibilities of doing other exposure assessments. If we can figure out the funding in communities where the source of exposure is not current or former military facility, but it's some of these other many uses that we see out there, you know, you raised the issue in one of the previous meetings around PFAS and synthetic turf fields, and of course, there's been quite a few sites in New England where PFAS exposure has been associated with biosolids that have been used to treat fields. So we're looking at that also, and then the third part to that, which really excites me, is we're starting a process with our -- internally, and by starting I mean we're just now starting, and looking at what does PFAS 2.0 look like. If you remember, we published a paper oh about six or eight months ago on how we at

ATSDR see a research agenda for PFAS. And so we want to build on that and determine and come up with a plan that we can start thinking about, seeing how we can fund it, and seeing how we can build on the work that we've already done.

MS. AMICO: That's great. Could you guys also share that paper with us too?

DR. REH: Yep, yep.

MS. AMICO: Okay. And then -

DR. REH: Have you met Rachel Rogers, Andrea? You have, haven't you?

MS. AMICO: Yeah, I've met Rachel, yep.

DR. REH: Yeah, so Rachel is the lead author and then she put myself and Pat Breyse on it, because she's a nice person.
[laughter]

MS. AMICO: Okay. Yeah, I'd love to read that. And then just going back to the exposure assessments, when you guys, I know you captured blood in urine for those assessments, correct?

DR. REH: Yeah.

MS. AMICO: But when you obtained information from participants, did you ask any information about like food sources, like were they eating fish in the area, you know, things like that, was that information also collected in terms of other pathways of exposure?

DR. REH: Yeah, there was a whole questionnaire that came with it, occupation, a lot of different things, I just can't remember off the top of my head, but when you see that final report, that'll all be laid out for you.

MS. AMICO: Okay. So it kind of, it addresses that part too. So not just -

DR. REH: Yeah, the final report is very detailed.

MS. AMICO: Okay.

DR. REH: So it's not just a summary report. It's, there's information on each site. There's cumulative summary information. It talks about all the different types of information they collected. It's got all the analyses in it.

MS. AMICO: Okay.

DR. REH: So it's the complete deal for that part of our PFAS work.

MS. AMICO: Great. Thanks so much. And exciting that that project has completed, you know --

DR. REH: Yeah, it really is, yeah.

MS. AMICO: Because you guys have been working on it for a long time --

DR. REH: Thank you, it is.

MS. AMICO: So that's great.

DR. REH: Yes.

MS. AMICO: Yeah.

MS. AMICO: Awesome. Thank you. Do we have any additional questions?

DR. SCHAIER: I guess just to piggyback or maybe elevate one of Andrea's questions, just looking at the data here, I just google the report and found it. The Washington site has such high levels - Much higher than all the other sites.

DR. REH: Right.

DR. SCHAIER: I was wondering if you were going to think about follow-up work, I guess. There should be a health study there. Those are really highly exposed people.

DR. REH: Yeah, that site outside of Spokane, some interesting results, and we -- I agree, we agree with you, Laurel. Yeah.

DR. SCHAIER: And I'm just curious, like what's the community response been. I think you have -- did you have a community meeting in each area?

DR. REH: Yeah, so we've had community meetings in, you know, as the individual site reports came out, we had community meetings, and then there was a rollout plan that came out with the final report. I don't know if we have any follow-up planned on the community meetings just because I don't remember.

DR. SCHAIER: Yeah, I mean I was -- yeah, I was curious. I feel like it's one thing to report to one community and compare them to NHANES, but for, by reliving that Washington community, you know, it's quite, it really stands out that it's so much higher than the other sites.

DR. REH: Right, that's exactly right, yep.

DR. SCHAIER: Okay -

DR. REH: And that was one of the sites that we did later in the process, and so it was kind of interesting. We were kind of seeing the same thing, and then all of a sudden that site.

MS. AMICO: Did they high level, higher levels in their water, or was there something -

DR. REH: Yeah, I don't remember.

MS. AMICO: Okay.

DR. REH: I -

DR. SCHAIER: Well, we'll read the report.

DR. REH: Yep.

MS. AMICO: Thanks.

NASEM REPORT UPDATE

MS. BARRETT: Thank you. Are there any additional questions? Okay, not hearing any, I'm going to move to our next agenda item, the NASEM report discussion. And Chris, Dr. Reh, take it away.

DR. REH: Yeah, I can take this one. So as you know the NASEM report came out 1st of August and some very interesting findings and interesting recommendations for ATSDR to consider for positioning guidelines going forward. We've got people working on it. We've started -- we've got the work somewhat done where we're looking at what NASEM, what we have in our physician guidelines and what NASEM says and what's that delta. It's not as far apart as we thought it could have been, and so, we're in the -- right now, we're working on a draft report that is going to have to go through quite a bit of review. We're using, in this first draft, we're using the shortened physician guidelines as the, as kind of the basis for where we're starting because there's, it's a lot easier to tackle, and we feel a sense of urgency to get information out and follow up to the report. It's going to, you know, there's a lot of parts of this that the review is going to be significant. It will have to go to external review, of course. It will have to go through OMB to federal family review. Also, since we're talking about population-based testing, it will need some input from the folks at CDC that do that, and our policy office is already working with us to get that in place. And that's where we are today. I can't provide any more update than that. I'm not in a position to provide details, further details, but we're definitely

pushing forward and wanting -- with a sense of urgency and wanting to get some form of guidelines out as quick as we can.

MS. BARRETT: I just want to open up two questions from our CAP members or technical advisors.

MS. AMICO: Yep. I have a few questions. So the NASEM report, I think, was significant to me in three ways. You know, number one, it was recommending PFAS blood testing for highly exposed communities. I don't think we've seen a government agency or a federal science agency recommend that. So that was a, you know, that was incredibly important and different. It was also important because it laid out screening level values within the blood for PFAS and kind of what you do if you're blood level falls within these ranges. And then it also, you know, listed out the medical monitoring guidance, right. So, I guess if we're starting with, you know, is ATSDR planning to adopt these guidelines or they're just reviewing the guidelines to determine if they're going to adopt them. Like I guess I'm just looking for a commitment, are you challenging any of these recommendations or do you agree with them?

DR. REH: So, it's an interesting document. You know, you're asking me to give predecisional information, and I just can't do that at this stage, Andrea. We are looking at the guidelines. We're looking at how we can implement what is in there, and then there's going to have to go through a lot of, it's going to have to go through some review in order for us to get to where you want to be.

MS. AMICO: Okay. But I just want to be clear. ATSDR funded this work through the National Academies, right. So like this was something you asked -

DR. REH: So, so whenever you, yeah, whenever you do work with NASEM, you always have to provide them with money, so we in NIEHS co-funded this.

MS. AMICO: Okay. And so, can you speak a little bit more to the review, internal review process that's going to happen? Like who is part of that team? Who is looking at that, and you know, you mentioned CDC being involved and OMB and like can you just like walk me through a little bit more about what happens? So ATSDR receives this report from NASEM -

DR. REH: Yeah. So we have our normal review process that -

MS. AMICO: Okay.

DR. REH: And our normal external review process, and then whenever we do work like this, it has to go to OMB, and they share it with the federal family. So we'll get input from NIEHS, from EPA, USDA, FDA, all the federal players in the federal space for PFAS. Just like we do with our tox profiles. And then we also will consult with CDC because some of the test, it's population-based testing, and they're the ones, you know, ATSDR is not an agency that typically recommends population-based testing. And so -

MS. AMICO: Can you just define population-based testing? What do you mean by that? Individuals getting their blood test?

DR. REH: Right. They're now, with the NASEM report, the recommendation is, you know, there's the two in 20, and what type of testing should be occurred, and that people who are concerned should talk to their doctor about getting tested.

MS. AMICO: Okay. So I'm sorry, ATSDR doesn't typically make recommendations like that?

DR. REH: So population-based testing, there's a whole preventative medicine group that U.S. Preventative Medicine Council, I can't remember, Marian and Frank, you may know it, but there's a -- they recommend that type of, the procedures for that type of testing. And so, we will have to get guidance from them through this process.

MS. AMICO: Okay.

DR. REH: I don't see it as, and Andrea, I don't see it as a, as a hindrance. We see it as a, as just part of the process.

MS. AMICO: Okay. And so, I know you said you're acting with a sense of urgency, and you want to get information out quickly. So do you have an estimated timeline? It sounds like there's lots of players that are going to be involved in this. So do you have an estimated timeline as to when ATSDR will have revised guidance that will be public to communities and local physicians and things like that?

DR. REH: It's hard for me to put a finger on that right now, and we've been working with our policy folks on that type of information. I will say this, that before we, when we talked to you a long time ago about this, it wasn't that long ago, but you know, and we didn't know anything about what was in the report, we were saying it could be up to a year. Well, we're not, we don't think that's, we're not in that ballpark anymore.

MS. AMICO: Okay.

DR. REH: We're talking months and not up to a year.

MS. AMICO: Okay. That's good to hear.

DR. REH: Yep.

MS. AMICO: Okay. And then, I guess my only other question would be once the report is revised, what does outreach look like for ATSDR because you've now done work in multiple communities, not just Pease, but exposure assessments, multi-site health study. You, you know, what is the plan to get this information or get your revised guidance out to communities as well as like local physicians so they're aware of this information, and they can order blood tests, and they can monitor their patients, and because this -- this is a big change, a big but much needed change. So I'm just curious what outreach looks like for you folks [inaudible].

DR. REH: Yeah, so we've already started thinking about that. It's definitely going to take our outreach in areas like this to a new level because we're going to have to go and talk to physicians and do more training and healthcare providers, and there's a lot of pieces into whatever we come out with is going to require that. You know, we would be remiss if we just put it out, put it up on our website and don't start going out very aggressively and talking to people about what's there.

MS. AMICO: Do you see opportunities to work with the state health departments too so they can also help, you know, help with the outreach and potentially revise some of their state guidance as well? I think some of them, I can't speak for all of them, but kind of defer to your current guidance, you know. So -

DR. REH: Yeah, our first step on that is always through our Appletree grant program, our state grant program, and so we'll start there. The NOFO for that just came out. We're expanding the program this year. I think we're targeting 30, 34 states and territories, whereas when, a few years ago we were just in the, you know, mid-20s. So we'll start there, because we already have that relationship in place, and they're used to working on us with that, and then we'll build off of that. But absolutely, yeah. The states are going to play an important role with whatever we do in this space.

MS. AMICO: Great, thanks. Those are, I guess, my initial questions. I don't know if other people have questions.

MS. BARRETT: Yes, if you have any additional members have questions, just please unmute yourself.

DR. SCHAIDER: So, just in terms of the deliverables, so you said that you're working on a report. So would there be a report and then sort of the guidance itself, and the report would explain the rationale behind it? I'm just wondering like what the final product [inaudible].

DR. REH: Well, if you go on our website, we've got that 20-page physician guidelines, and then we've got the shortened version. And so, we're starting with the shortened version because we feel like we can get that out quicker than going through the whole, long process. That whole 20-page thing took a long time to get out, and so, that's why we're starting with the shortened version. At some point in the future, we will make a decision whether we want to do another long version or not and what that will look like, but we feel LinkedIn building off of the shortened version that we have as kind of a format, so to speak, is the right way to go. We've got a new product at ATSDR called clinician briefs, and if you go on our website, you can find one for radon, and I think we just published one on ethylene oxide, and that's, again, getting more towards, instead of having 20 pages, which is hard to get a position to read, having something that's more concise and, you know, it's like physician guidelines developed by physicians to make sure physicians read them.

MS. AMICO: So do you anticipate using that same model for this too? Like will there be part of that?

DR. REH: So the briefs were developed for a different reason, but it will give you a flavor of how we're looking differently as to how we put out medical guidelines and brief clinicians on substances, environmental substances that are of concern to communities.

DR. SCHAIDER: Okay. So just so I'm understanding, so as a starting point you're starting with your shorter version of the clinician guidance -

DR. REH: Right.

DR. SCHAIDER: And when you talk about the report, is that updated one, or is there a report that would kind of accompany what that looks like? [inaudible] how much you have to write. Is it just the guidance itself, or do you have to write about the guidance?

DR. REH: Yeah, yeah. So the shortened version will probably be the first thing out of the gate, and that's because, again, getting the information to people as quickly as we can,

considering the processes that we have to go through to do things like this.

DR. SCHAUER: Okay. That's great. And are you working with getting input at all or part of your determination plan with the American Medical Association, like American Academy of Pediatrics, like all the medical associations?

DR. REH: Yeah, yeah, absolutely. And that's why I mentioned working with our policy folks. They're the ones that help us with those critical partners. You know, ASTHO helps us with, will help us some point in the future in this with our outreach to states, and of course, we're connected very closely with AAP through our PEHSUs, and they're actually meeting with the PEHSUs this week in Chicago, and the NASEM report is on the agenda. But, yeah, we'll be looking at all of those other related groups to get input from them.

DR. SCHAUER: Input from as you work on the report or just for the dissemination?

DR. REH: Depending on which group you're talking about, it could be one or the other or both.

MS. AMICO: So is it, is it going to be a team of people working on this for ATSDR, both within ATSDR as well as external? Like I don't mean just the reviewing of the federal family. Who is going to help with this? Is it just ATSDR folks and then you're going to let other people read it, or is there a team being compiled of different professionals who are going to all work on this together?

DR. REH: So, you know, I want to get a, kind of a draft that we can start sharing and kick around instead of getting together a bunch of people who may or may not be ATSDR in a room to create something.

MS. AMICO: Okay.

DR. REH: And so right now we have, we're working with the people in ATSDR who do this work.

MS. AMICO: Okay. Got you.

DR. REH: And then, once we have that draft, it makes it easier to have the, and quicker to have those discussions. They have something to react to versus us having, getting, you know, I don't know to get bogged down in these conceptual discussions about things.

MS. AMICO: Okay. No, that helps to understand. So ATSDR is going to draft a revised version first and then collaborate with other people external to ATSDR to give guidance or comments or however you, you know, okay.

DR. REH: That's right.

MS. AMICO: Okay. I know in the past our CAP was able to look at the physician guidance and give feedback. I would be happy to look at a draft as well and provide comments from the community perspective if you're open to that.

DR. REH: Absolutely.

MS. AMICO: Thanks. And I just want to say, I thought NASEM did a really nice job on this, not only because I think they listen to communities, and they looked at the science and made good recommendations, but I think they did a really good job in how they engage with the community. They created community liaison positions where they took in a lot of people in that role, and then they hosted the townhalls, three different townhalls all across the nation, and I felt like they did a really nice job of hearing from different people, getting different perspectives, and then really just listening, you know, and putting out guidance that was very much needed for communities. So I applaud NASEM for their efforts on this. I think they did a really nice job, and it was great to work with them as a community liaison on this project too.

DR. REH: Yeah. Yeah. I totally agree with you, Andrea. You know, one of the -- what I -- you know, we all take what we liked out of it. You know, what I liked is the way they synthesized the health information on PFAS, and you know, in those three buckets of this is what we know, this is what we think we know, and I'm overly simplifying, so excuse me, and these are the areas where we need more research or information. And I, I thought that was a huge benefit for how we look at PFAS.

MS. AMICO: I think recommending blood testing was huge, because if you talk to communities, that's what they want, you know. They want to be able to quantify how much is in their blood. They had no say in being contaminated, so they want a say in identifying how much and figuring out how to monitor their health, and so, that was a huge missing piece for a lot of communities, and this was incredibly validating and needed. So it's just a big, big step in the right direction.

DR. REH: Yep, yep.

DR. PAVUK: What I missed from the NASEM report is that it didn't address and left it open how the physicians are going to order those tests, who will be paying for those tests, and what labs will do to tests. So, as Chris correctly pointed out, the states will have to step in if this has to go anywhere, because at this point, the physicians, the recommendations that the people should go and ask their physician to order the test, the physicians can't order the tests, right. There's no ICD code for ordering the test, and no insurance will cover it. And even if you want to pay it by yourself, there's no labs generally available that will do that. So I find that a very glaring omission from that recommendation that it doesn't show any pathway in implementing that and leaves that to ATSDR or CDC or others to figure it out.

MS. AMICO: So a couple things, Marian. There actually are -- Quest Lab is a lab that folks are working with, and they partner with NMS. And there are CPT codes that can be given. I know PFAS Reach has published a document on how to obtain PFAS blood testing, and it lists the codes. And then in New Hampshire, our state legislature passed a law that New Hampshire insurance companies have to pay for PFAS blood testing. So in the state of New Hampshire it is covered by insurance [inaudible].

DR. REH: I did not know that.

MS. AMICO: Yeah.

DR. REH: That is interesting.

MS. AMICO: I can share that -

[Inaudible Comments]

MS. AMICO: Because to get the labs to be able to provide this, you know, this service, or get the physicians educated, we didn't have anyone recommending it. So it was like we couldn't get people to do that. So now that we have recommendations from NASEM, it's like we have another step to do for sure. You know, it doesn't end here, but having this guidance, I think, carries a lot of weight, and it allows for more advocacy and opportunities to create the pathways to have this done. But I just wanted to make sure you knew that Quest Lab does it through NMS. There are CPT codes, and New Hampshire insurers do pay for PFAS lab testing [inaudible].

DR. REH: And there are, and we've run across other labs in other parts of the country that will do it commercially. You know, when we got our brief from NASEM on the report, you know, they said just what you said, Andrea, you know, this is, this is, we

wrote this from the standpoint. They said that we wrote it from many different standpoints, but one of the standpoints was from the communities, and the other thing they said is that we realize there are some challenges with our current, how things are currently across the country, but this is a step in trying to build a different path going forward. So -

MS. AMICO: Correct.

DR. REH: Yep.

MS. AMICO: I agree.

MS. BARRETT: Thank you. This was a great discussion. Do we have any additional questions from our CAP members or from our technical advisors?

DR. SCHAIER: I'll put in the chat our two PFAS Reach documents with information. We have one that's a general guidance about how to order PFAS lab tests, and we do have the CPT codes for the Quest test there, and then another one that provides information about specific labs, which we're seeking to keep up to date. So, we're always happy for information about updates. It certainly has limitation. There's not a lot of labs that offer the testing, and it's not always easy to offer the testing, and you need a doctor who is willing to order the testing, but I'm hopeful that with this guidance out there that it will become an easier process, and maybe other states will follow New Hampshire's staff of requiring insurers to pay for this. It doesn't mean that every doctor will order it, but I think it will become easier. So I'll put those links in the chat.

DR. REH: Or if you could just, Laurel, if you could just e-mail them to Tyra -

MS. BARRETT: I think you have my e-mail. Yeah.

DR. SCHAIER: Okay. I'll do that. Yep.

MS. BARRETT: Yeah, yeah, yeah.

DR. REH: And then we can disseminate them through our PFAS community of practice here.

DR. SCHAIER: Okay. Sure thing. And then the other thing I'll add is that our PFAS Reach team in collaboration with some of our science advisors, and Andrea is part of our team, created a webinar for medical professionals that offers CME credits, got a whole bunch of presenters as part of the webinar, Linda Birnbaum, Alan Ducatman. We have community voices, our core PFAS

Reach team researchers including myself, and Phil Brown, and Courtney Kerrigan as well as community partners including Andrea created this webinar for medical professionals about PFAS. I talks about medical screening and PFAS blood tests and provides a pretty comprehensive overview of health effects linked with PFAS. We were pretty much done with it, and then the NASEM report came out, and so we made some updates to reflect the parts that needed to be updated, and that's now available. We just, I just googled it today. It's actually available online now, that course. So I'll also include that update. It just came out this week, so we're still working on a dissemination plan, but that's another resource that we'd recommend.

MS. BARRETT: Thank you. Thank you, Dr. Schaider, for that. Do we have any additional questions or comments? Okay. Not hearing any, I wanted to, again, open up questions from the audience. And so, I'm going to have Pam, again, just come on the line and explain how to ask your question.

MS. WYTON: Sure, Tyra. The audience can raise their hand, and then I can allow them to unmute themselves. You can click on the right-hand icon on your screen. Or if you're only on the phone, you can press star 9, and also on your keyboard you can press the ALT-Y keys.

MS. BARRETT: Thank you, Pam.

MS. WYTON: Sure.

MS. BARRETT: Again, I'll pause here just to see if anyone raises there hand. Okay. I just want to double check. Pam, am I missing anyone?

MS. WYTON: No, I don't think so. I don't see any hands raised.

MS. BARRETT: Okay. Awesome. Thank you, Pam.

MS. WYTON: Sure.

CAP CONCERNS

MS. BARRETT: Now, just before we wrap up, I want to open it up to our CAP members and technical advisors if there is any general questions or comments.

MS. AMICO: So I just have two questions. One is regarding how the NASEM guidance may impact health assessments that ATSDR has already done. This is a question that has come up through different communities that have had health assessments done already by ATSDR and the, kind of the conclusions that we're drawn because of them, and I'm just curious if there's

opportunity once ATSDR revises their physician guidance, and now that we have screening levels and PFAS blood testing is recommended. Is there an opportunity here to go back and do some additional work on some of these health assessments that maybe said if you're below 70 parts per trillion, that's, you know, and there was no risk, and we don't recommend you do anything different. Would there be any -- and also, I guess, that would play into the EPAs health advisories, which are obviously much lower than 70 now, and they're working towards an MCL. So now that like there has been some significant changes in PFAS, whether that's, you know, the NASEM guidance or the EPA health advisories, is there opportunity for the health assessments to be revised and different recommendations to be made or even just different conclusions to be drawn because in some communities the health assessments, that's the only thing they have with ATSDR. You know, they're not part of the exposure assessment. They're not part of the health studies. All they have is the health assessment. That really hasn't recommended a whole lot for them. And so, just wanted to put that out there and see if ATSDR is thinking about that and if there's opportunities for additional work there.

DR. REH: I don't, so I don't know the answer to that. Let's table it and get back to you on that, Andrea. I just don't know, and I suspect there is some precedence with how we dealt with lead over the years at ATSDR, you know, something that we've looked at quite a bit, and the exposure levels and the levels in water and the levels in your blood have gone down over the years, and I, I'd have to go back and ask our policy people what's the protocol we do on things like this. I certainly see the logic to it. I'm not arguing the logic. I just don't know what that answer is.

MS. AMICO: Okay, yeah, and I think finding out that answer but then also finding out like does it mean, if a community already has a health assessment done with ATSDR -

DR. REH: Right.

MS. AMICO: And it's based on the 70 parts per trillion from the EPA and, you know, it was -

DR. REH: Do an addendum or something.

MS. AMICO: Yeah, like would that community, would you automatically do that addendum, or would that community need to reengage with ATSDR and make a formal recommendation to have you come in and revise their health assessment? So, yeah, just understanding, like you said, if there's a precedent, and if

communities want to reengage on this, like what is the process for that? Or if there is even one needed or if you would just automatically do it.

DR. REH: Yeah, yeah. Okay.

MS. AMICO: Okay. And then just the second thing I wanted to bring up, and it's something I bring up at all of our meetings, but, you know, really just continuing to advocate for longitudinal studies. You know, here at Pease, I think, you know, it's important that we've had the health studies. We have two sets of, you know, PFAS blood tests now, but, you know, I think the concerning part is how PFAS will affect us over time, and so I appreciate the Pease study and the one-time snapshot that we're getting with that, the cross-sectional study, but I just want to continue to advocate strongly for longitudinal work here so we can follow people over time. I know we didn't hit our recruitment goals, but we still got a lot of people, you know, who came back for the study many years later after the contamination had been discovered, and we have people in our community who have been highly exposed, and you know, I can speak for people that I have heard from that have health defects or have abnormalities in their labs, in their kids labs, that they're concerned and really want to see how this is going to play out over time. And I know that we're analyzing the data and, you know, working on reports. I just, you know, I guess the more time that goes by, the less, you know, people pay attention, and I just want to say that if we're going to do something longitudinal, it's not something I want to wait years to come up with another plan, which will take another few years to, you know, develop and get funding. Like I'd like to proactively work on this now if we can, and so, I bring this up often at our meetings, because I think it's important, and I would just love to know kind of where ATSDR is at with this and if they're thinking about it or if there's steps being put in place or anything you need from the community to be able to make this a reality for us.

DR. REH: And so, is there a question or a statement -- I'm sorry.

MS. AMICO: Yeah, the question is, like, are you planning to do anything longitudinal at Pease?

DR. REH: Okay, okay, got you, got you, got you. Okay. I'm sorry. So as we've always said, you know, once we see the results from the multi-site, we think that may be a good place to start with that. And we're getting closer and closer to that. We'll, you know, longitudinal studies will require resources, and so we'll

have to figure that one out also, but it's not off the table. It's not something that we've decided we're not going to even think about or consider. We definitely are. It's a great push. It's just we, we've always said we want to see more of what we get out of the multi-site study.

MS. AMICO: But so, so for the Pease community, even though we'll have our data well before the multi-site study, you won't make any determinations on long-term studies until you have the multi-site data?

DR. REH: I don't think so but let me talk to Pat on that one.

MS. AMICO: Okay. And I mean I think in terms of funding we've been very fortunate, you know, that we have had congressional support who have been able to prioritize funding for these things, and so I'm not saying they're not a problem, but we have been very fortunate that there has been funding for these efforts, you know, exposure assessment, multi-site study, Pease study. So I'm grateful for that, and it makes me hopeful that funding potentially won't be a barrier for, you know, I think it's more getting the willingness from ATSDR first, you know, and so, I hope that you see the need just like we do here in our community and many other communities, that, you know, PFAS is something that's going to affect humans over time. It's not a one-time thing. I think the one-time thing is a very good start, but the reality is, like, this is going to affect people over their lifetime, and we should be wanting to learn more about the effects over time and not just a one-time snapshot. So -

DR. REH: Yeah.

MS. AMICO: Just want to keep pushing for that.

DR. REH: Yeah, and I'll tell you this, Andrea, that, you know, I talked about earlier the work we're doing on defining where do we go next with PFAS and building off our research agenda, you know, that's something that when we charge the group to do the work that they're going to be, you know, that's going to be one of the things they'll consider.

MS. AMICO: Okay. Thanks.

WRAP-UP/ADJOURN

MS. BARRETT: Thank you. Do we have any additional general questions from our CAP members or from our technical advisors? Okay. Hearing -- okay, hearing none, I'm going to push to wrap up this meeting. Again, I want to thank you for all the CAP members, CAP tech advisors, the Air Force members, our ATSDR

staff, and the community members, of course, for joining us this evening. Hopefully you guys can go and enjoy the rest of your evening, but again, thank you, thank you, thank you for joining us, and we hope to see you guys again soon.

DR. REH: Yep.

MS. AMICO: Thank you very much.

DR. REH: Yep, all right, thanks everyone.

UNIDENTIFIED SPEAKER: Thank you.

UNIDENTIFIED SPEAKER: Good night.