This is a test for captioning.

>> We're right at 10:00. David, should we get started?

>> Sounds great.

>> OK. Perfect. Good morning, everybody. I'm Deb Houry, the designated federal official for our A.C.D. Welcome to the meeting of the advisory committee to the director. The closed captioning link has been provided in the chat box for your convenience. And now I'll turn it to our chair, Dr. David Fleming.

>> Thanks very much. Good morning, everybody. Welcome to the February A.C.D. meeting.

This meeting is one day and will be entirely virtual. It's still good to see people's faces. Our next meeting will be in may and that is scheduled right now for Atlanta in-person for two days.

Today's first order of business, I would like to start with a quick roll call and declaration of conflict of interest to start off with. I'm here and I have no conflicts.

>> Hi. I'm here. I have consulted for Merck and Gilead but I have no conflicts related to this meeting

>> Thanks. Daniel?

>> Good morning, present and I have no conflicts of interest.

>> great. criasal?

>> Good morning. No conflicts.

>> Lynn?

>> I have no conflicts of interest for this meeting.

>> Good to see you. Rachel?

>> Good morning. I have no CLIKTS -- conflicts of interest to report.

>> Good morning. No conflicts of interest.

>> Good morning, Octavio.

Rhonda?

>> This is Rhonda. I have no conflicts of interest.

>> Hi, Rhonda. Julie? She's on her way so I know she's joining.

She said she might be a few minutes late. Her compatriot is also going to be joining the meeting late. Josh?

It's always wonderful to be with you all, especially as you begin another year. I'll start the way I often do with a big round of thank yous for all the hard work and productivity as part of A.C.D. as a whole and for being part of an born work groups on equity, data and surveillance and laboratories counsel and welcome I've relied on. You probably already noted that Dr. Deborah houry is the official for the A.C.D. and I'm personally grateful for John's service in that role and we wish him now -- wish him well as he opens a new chapter. Dr. Houry has been serving as our deputy director since the retirement of Dr. schuck18 months ago and she's been the chief medical officer of the agency. She'll continue to serve as acting principal deputy director until Dr. Shaw of Maine joins C.D.C.

as principal deputy director next month. Your agenda for today is packed with what has been discovered by the work groups, a deep dive in the laboratory work group. Speaking of the laboratory work group, I just want to extend my deep gratitude for the leadership of coat shares, Dr. Jill Taylor and Dr. Josh and all the time and effort of the members who have put their -- put into their proposed action steps. Given the strong interest in the reorganization process, I know you're going to be talking a lot about lab this afternoon but I thought I would give you a high level update on our reorganization process and progress. The organizational changes you've seen were developed by the C.D.C. senior leaders with extensive staff input through ten strike teams focused on public health data, global health, advancing equity, science, policy, laboratories and more. Taking their input into consideration, we have submitted a proposed organizational structure to H.H.S. and prior structure and the proposed new structure are in that printout that you have received. Ultimately the proposed changes for our processes are about eliminating reporting layers, breaking down silos within the agency, putting our foundational public health capabilities and facilitator bi directional communication and accountability. So the first change you may notice in our organizational structure will be the number of offices reporting directly into the immediate office of the director. The first three I will mention may be of particular interest to you. We are creating an office of public health data, surveillance and technology reporting to the director. As we continue to move forward, all the data modernization initiatives and bring the data infrastructure necessary to connect all levels of public health with the critical data needed for action. Data functions from csels will move into the next office and ncsh health statistics will report to the director of the new office.

We're also creating a new office of health equity reporting to the director to help us weave equity into all the work we do across cdc and improve accountability of our shared equity goals. And the office of science and the office of laboratory science and safety will now report directly into the needed office of the director.

The mmwr and the community guide will move into the office of science. Speaking about changes for the laboratories in particular, we are elevating the office of laboratory science to report to the director and that will immediately improve accountability for delivering timely information. The functions that support all cdc labs, quality management, regulatory oversight,

safety training as well as support to state and local labs across currently in olsc, deid and dls are all centralized into the office of laboratory sciences.

And after the new structures are in place, I'm empowering the C.I.O. leaders such as Jim ppurcell in laboratory to move forward on other organizational changes within their own cio's.

The office of the associate director of policy and strategy will be remained. This will now be the office of policy performance and evaluation, still reporting into the office of the director and that office will now include regulatory affairs. And the center for preparedness and response will be renamed the office of readiness and response and report to the office of the director, creating a centralized office to promote accountability and excellence for all readiness and response efforts. Our new center for forecasting and outbreak analytics will report to the director of this new office of readiness and response. We are doing some consolidation. We are consolidating the public health infrastructure and work force activities of csels and cstilt into a new national center for state, territorial and public health infrastructure and work force. New center will combine the critical if you thinks related to supporting state, tribal, local and territorial public health infrastructure and work force and as Deb mentioned, cdc awarded first of its kind $3 billion grant to provide the people, SCHLSs and systems needed to promote and protect health in U.S. communities. This new proposed center will centralize cdc's activities to further accelerate this work. We will have a new global health center and that will consolidate the work of the global health coordinating unit that included you're regional platforms as well as the center for global health. I'm pleased to say that Dr. Howard joined cdc in January in a new position as the agency's deputy director for global health with broad operating authority responsible for overall planning, direction and management of the cdc global strategy, both here in the United States and around the world. And this position will have data oversight of our global health center and will also work directly with our GAISH global health programs across the cdc. We have the director of external affairs in the office of the chief of staff to strengthen our relationships across government, academia and non profits as well as the business community and helping outside organizations navigate and partner with cdc. As you can see, we are doing far more than moving boxes. I call that necessary but not sufficient. We are addressing long standing agency wide challenges which will require change across all of cdc from structure to processes to operations. So in addition to the organizational changes, we are improving our systems and processes as cdcN.

January, we began and now in February, we are continuing our process improvement and implementation. Because we know reorganization moving boxes alone will not improve our processes, we also convened 21 priority action teams to offer process solutions. These teams include more than 160 staff from across the agency and provided input in five key areas. How do we share our science and data faster? How we translate that science into implementable practice, how do we prioritize our public health communications? Develop a cdc work force that is ready to respond to future public health threats and promote result based partnerships. So that is the action of the 21 priority action teams and a lot of work ahead in implementing the

advice of those priority action teams. I want to thank you for working with us as we make our agency stronger and better positioned to deliver our public health mission now and in the future. Before I turn the meeting back to David Fleming, let me thank him for his leadership of the A.C.D. and again, thank each of you for your extraordinary participation in the work groups and full meetings and for your ongoing support. I'm always grateful for your wide counsel and proposal to the C.D.C. on key topics and for any wisdom you're willing and able to share. I look forward to hearing from the committee and pass it back to you.

>> Thanks. You and C.D.C. have been busy. My goodness. Sounds like a lot of our great changes.

I'm going to open it up to the committee for comments and I see first Lynn. You're on.

>> Hi there. Great to see you, and thank you so much for all of the work that you're doing on behalf of the people of this country. It is really impressive. As you are walking through all of those changes, I felt like I was watching a ballgame that I don't understand. Cricket maybe. I don't know. But it would be really helpful at some point for us to see -- I mean, maybe in a diagram or something, you know, these changes that you have already made because I did think some of the work that we're doing does involve looking at the structure of the agency and it would be great to be able to catch up with exactly where we are. I tried to keep notes but I'm pretty sure I didn't follow all of that. It's obviously a lot of really good work and we appreciate it. Thank you.

>> Yeah. So let me just reflect and say I appreciate where you're coming from because coming into cdc from the outside, which is part of the reason it took me some time to really understand what we were working with and the pros and cons of the structure we had and really hear from the strike teams as to where we should be going. I think you may in your packet have a before and after flow chart but what I will just generally say is, in the before flow chart, there is this layer of offices called the communities of practice. We are generally moving away from that external layer. Part of that is because it didn't offer full visibility, full line of sight as well as accountability reporting into the needed office of the director and then also if you sort of look at how that is built, it created silos between our infectious side of the house and our non infectious side of the house and I felt like the silos were not productive because we really would like them working more closely together and if anything, Covid showed us that. So we are moving away from that structure of communities of practice. The other sort of big picture thing that I can say is that we have raised P our foundational public health key areas. Our laboratories, our equity, our work force, our data, so that those key foundational areas are really front and center in reporting into the immediate office of the director. They are an important office of science, office of equity. They are really important areas that I really wanted to highlight so those are kind of the -- if you sort of get stuck in acronyms and lands that you don't necessarily understand every center, you know, where the acronyms for each center, I will say that's the big picture areas we worked towards.

>> Thank you. And we did get the moving forward briefing so if it's all in there, then we're good. Thank you.

>> Thanks.

And one of the things as we move on we're going to have to do is with all the organizations, very quickly they will become acronyms with pronunciation associated with them so as that moves forward, please help us as cdc starts to use the new acronyms, getting us a little cheat sheet so we know what you're talking about.

>> Our website will be updated at the end of February with all of these changes.

>> Perfect. Perfect.

>> All right. Thank you so much.

And Dr. Walensky, thank you for the insightful update. I always look forward to hearing the exciting things you've been leading and of course, very grateful to you for your continued commitment and leadership on health equity. I was hoping that perhaps we could get some more insight, you know, on what power and resources will be given to the office of health equity moving forward.

>> Yeah. You know, what I can say here is this was one area that I hope you all recognize was one I did not wait for moving forward on. It was an announcement we made, I think weeks after I started. This was an area where we had done a lot of work already in developing our core equity infrastructure and getting, I think, 160 proposals on how we can make equity front and center. Part of the reorganization was to move that office of equity into a --

into reporting into the immediate office of the director but all of that hard work has been ongoing really since I started. There are areas where I want to strike a balance where I don't necessarily want to have all equity efforts only in the office of equity because I really actually think they need to be integrated into everything that we do. We can't have just an office of equity that feels responsible. Every piece of this agency needs to be focused on health equity. But in terms of best practices for nofo's and how we can prioritize the equity work that we are doing, how we can engage in the best practices, what's the latest science and that's, I think, really important in the office of health equity. We'll be posting a position, the lead of that office coming soon.

>> Great. Thank you. Monica?

>> Yes. Thanks, David.

And thank you, Dr. Walensky, for walking us through the updates about the plans around the reorg. I was wondering in the slide deck that was shared, there was a general time line in terms of the activities that you recapped for us. I'm wondering if you could say more about the different strike teams, the process improvement activities.

It said January February and then a reference to an executive committee or an enterprise-wide kickoff. Can you say a little more about the activities across those five areas just general process time line to give us a better sense of the dates or key kind of milestones in the calendar this year?

>> Yes. Maybe I'll start with the organizational pieces. Those organizational pieces are -- I anticipate by the end of this month we will be fully functioning in this new organizational structure. Now, what we have said, and I think is really important is under this new organizational structure, there may be further organizational things that need to happen at the center level and so we have asked individual centers to do that work now.

This was going to be the one sort of centralized piece but we wanted to -- we understand in sort of cdc moving forward that to accomplish those missions, people within those process and procedure missions, people within the centers may have other changes they would like to make. Those are currently ongoing right now within the centers they're doing that evaluated work right now. So that is really sort of what's happening at the structural level. The priority action teams, 21 priority action teams, developing science faster, developing implementation guidance, communications, partnerships, all of that, there have been lots of recommendations from each of the priority action teams. What we've had in the 21 teams is them talk about what are the most important things that we need to do? We can't do everything all at once but what are the most important -- even if there's hard, even if they're going to take time, what are the most important things that need to be done? Some of those we need to just do immediately and some of them are going to take some time and so each of them --

and some of them are going to be ongoing activities. These are some of the differences in how we have to work. What I will say is that, for example, in the communications area, one of the things that we really wanted to do was look at our website. Now, Americans are now coming to our website in ways they hadn't before and when I arrived, I believe we had about 200,000 webpages of content on the cdc website. We're doing a project called clean slate where we are looking at our website, all of our components of the website, seeing what needs to be archived, what can be archived, what is not in plain language and accessible and that work will probably take close to a year. It depends sort of on what the activity is in all of the priority action teams. Some partnership stuff we can do outreach quickly but other things will be truly heavy lifts.

>> thanks. Josh?

>> Thanks. Hi, Dr. Walensky.

Thank you so much for the presentation. Thank you for this hard work in rethinking the allege. It's really like a back to basics reorganization, really making sure that these, you know, foundational areas are strong across the agency. You know, really important move which is great to see and we'll talk more about that later today but I wanted to really appreciate your understanding of the fact that cdc is a lab agency. In addition to other things and it really has to do that well. It's really terrific.

I had a question. One of the things through the pandemic that's become obvious is that the cdc is challenged by the sea of misinformation out there in ways that your predecessors were not. You know, and the preceding VERGs of the cdc work chart were not. And it just continues to, you know, amaze the kinds of things that take off and people tend to believe and even DRM everything that the cdc releases gets distorted in some way and fed back into this situation that can be undermining people's ability to know what is right.

And that also impairs, I think, on the political side the ability of people to support cdc if their constituents are being fed a steady diet of falsehoods, frank many, in many cases. Not just about Covid but about vaccines and other kinds of activities. I wonder whether you think the organizational structure or the way you think about the changes like, you know, adapt to go that reality.

How do you see the ability of the cdc to understand, respond, build bridges, you know, to get over the river of misinformation? You know, how does that fit into the organizational restructuring?

>> Well, so first of all, this is something that is deeply concerning to me, obviously, for all the reasons that you comment on. We have a lot of work to do on our communications side. One of the real challenges, I think, and, you know, our office of communications always fed into the office of the director. We have a lot of work to do in bolstering that and reorganizing that office specifically and that work is underway not just on the website but in terms of do we have the right structure of divisions and branches that are happening within that office specifically. If you look at where we are in terms of the resources that we have and communications and our communications resources have not scaled with the resources that, you know, have been provided to the agency through this pandemic or otherwise and so -- and, you know, I don't necessarily think that we at cdc alone can -- we need to and we are addressing misinformation.

But if people are challenging government information to begin with, then we alone are not going to be able to tackle that.

So we are doing a lot of work to get at and working with other outside groups to get what are the sources of that information, can we cut it off as it's starting to blossom and what is our role in that misinformation?

So for example, there have been, and we've had discussions, when there is a tragedy of a public figure and the next thing is it's due to the vaccine, what is our role in that? And, you know, that may take off but I'm not certain that we have a role in being able to -- we don't necessarily know the cause of whatever the issue was. Likely not the vaccine but, you know, what is our role in response there? So we have had a lot of conversations. We have more conversations to be had. I think this is an agency-wide effort.

It has to be a whole of usg effort and I think it also has to be an academic and industry effort as well.

>> Thanks for raising that up. I do a little work with communications at the state and local level and I think the issue around misinformation when you talk with state and local communicators rises to the top of their list as well. As we're trying to devise a way forward, please work with them as well.

Julie? Good to see you. I mentioned to folks you were going to be a minute or two late so please ask your question but if you could just quickly declare any conflicts of interest first, that would be great.

>> Sure. I have no conflicts to disclose. Hi, Dr. Walensky.

Thank you for the work you're doing and the progress you've made. I have kind of a general organizational structure question and then a more specific question related to data. The organizational structure makes me nervous for you. I look at all of the spokes coming off your office and the responsibility that you have to them and one of the things I was wondering about as you talked about the siloing we see happening, it's in all organizations and larger scale for you, there's a silo we see happening. I wonder if you envision these offices that report to you will have authority over the centers, the institutes that report out to you as well because I feel like in order for it to help eliminate some of the siloing that occurs, if you look at equity or you look at laboratory, you look at how data and surveil gentleman technology, these are cross cutting functions. Do they have enough authority over the center SNZ unless there's an authority, I would think the siloing would continue to be a problem. That's question number one. The second question I have is related to office of public health data.

Just curious if you could elaborate what that means to the data modernization initiative.

There's a lot of -- we were all working toward that aware of what was happening and just wondering how the restructuring changes or doesn't change that effort.

>> So maybe I'll tackle the first one first -- or the second one first which I think is easy.

That is the data and modernization effort. All of that is centralized into one place. And that will then speak to the second issue which is it's not lost on me that there are a lot of spokes coming out of the office of the director so what we've been doing in the office to facilitate that is, you know, you may or may not be aware our current immediate office of the director, even the immediate office of the director of six months ago was a really tiny team. And so what I have done is bolstered that team so I have deputy director of program and science so that will be Dr. Houry, we have a global deputy director, a principal deputy director so we're bolstering that team, we're bolstering that team so I have a bigger, mightier team around me to help facilitate that. One of the questions I asked I think is an important one. How does the infrastructure weave into the centers? So it's really important to me from a dmi standpoint that all the centers are on board for the data modernization piece. If anything, I would like to say that infrastructure is more important. We need to have all of that -- and there's not more or less but we need to have it all together, similarly for our readiness and response program.

We need to have an infrastructure that allows people to be ready to respond and those responders may have to come from the centers, right? So that is part of the work of this government's board, this executive governance board which will overall take the agency's needs to say what is public health need, what does the cdc need in the moment. Let's check our own interest at the side to say, and that will be a rotating board, people from everywhere to say, you know, I recognize this data modernization effort may cause your data collection in the center until we get it up or may put you a little behind or you might not get that singular piece that you wanted. But for the purposes of streamlining data, standardizing data collection, making it easier on all of the stilts to provide daylight A at large, we need to do this. That's actually the work, a lot 6 work of our governance board is, too.

>> So director, much appreciation and no questions for you. Just a comment. Thank you very much for continuing to work through the difficultness and quietness at times but the challenge with so many that have so many opinion. I appreciate the element that you brought in closer to you, the intentionality behind it around why you do these things and the way you're approaching them and then the acknowledgement there's more to come. So just a deep thank you. You need to hear that every once in awhile.

>> thank you very, very much.

I'm grateful for that. Not everybody's comments are like that all the time. Thank you for that.

>> Thanks, Rhonda. Well said.

Lynn?

>> Yes. I just have -- for one, I really did want to second the point that Josh raised and I'm happy to hear that you are intent on bringing more sophistication into cdc's communication efforts. It's something that we all have to do in public health. Everybody has to do this. And -- because public health has become a target by many. And we're not going to fix that by just controlling the communication or, you know, in some ways it's a former government employee myself, you know, I worry about elevating the communications if you thinks because to some extent the trust, you know, in the government is fostered by people being able to hear from the experts and the government, the people who really know what they're talking about even if they sometimes don't understand all of the words. Sometimes it does come through, those folks know what they're doing and that very important for trust. The other thing I wanted to bring up, I agree the intentionality behind the changes you've been making in the structure is wonderful. At the same time, where we put people in the organization doesn't often fix problems in the organization.

The fact that sole of -- some of the issues in the cdc is siloing and there's too much siloing between communicable and non communicable diseases. And yet, the temptation is, well, let's create another silo and the problem with siloing isn't always the org chart. It's the way people

do or do not work well in teams across an organization and an organization like yours needs a lot of team work that's cross cutting and it's also what motivates people?

Am I successful only because I have more people in a bigger budget? Then I'm going to fight for that. And I won't care about the health and the well-being of the rest of the organization. I will future for bigger budget and more people. That's what people often do in any kind of organization. Corporate, government, whatever. If I'm a scientist, I'm not going to be recognized as a scientist. I'm only successful if I turn myself into a manager. I might not be a good manager. I'm trained to practice but if success is defined as I have to manage or I can't get, you know, that promotion, I don't get any recognition, then I will try to turn myself -- I see that again and again especially in the government. People abandon science, they can become an administrator and be recognized for that. And, you know, is success only identified as individuals' own accomplishments or is a team recognized for what they do? And because if I want to be recognized as an individual, I may not be a good team player. It's possible to foster that which means that it's not just the org chart but the part of your office HAs that to do with management, you know, really strengthening the -- just like with communications, the savvy and the capacity of those folks to help to realign the expectations, the motivations because you can reorganize and they just create new silos and you have the same problems with disfunction.

>> Lynn, I think you're spot on and it is why we needed to do the strike team work in parallel with the priority action team work where the strike team work is really speaking to what's the organizational structure that will allow us to operate in our maximum capacity and when we do that, what are all the other things that we need to do to operate at our maximum capacity?

So I always think that people come to work because they feel valued and if your science is feeling valued because you can get it into a peer review publication, then that's great.

But -- and if we at cdc are both a science based agency and a lab based agency as Josh noted, and a response based agency, how do we make sure that people are feeling valued in their response based work? Part of it is are they good at it? Have we trained them to do that work? Do they know what they need to do? That is everybody who books the overnight flights to the person who does the logistics to the person who is out in the field to the person who is doing the studies. How do people feel trained in what they do and how do they feel valued? How do we promote them for their response based work? That's a lot of the work of having a cdc work force ready to respond. It is how we are organizing our performance metrics where they're no longer going to be -- they will somewhat be based on the science we put forward but also be based on the work you're able, willing and wanting to do and trained to do in responses. So that's one example of some changes that we need to make that people need to be valued for many things. I call the people my unsung heroes and just call them and say thanks for the work you did. It didn't necessarily make the biline of a publication but I saw you in that work.

People routinely say, it's like super fulfilling. They didn't necessarily realize how fulfilling it would be to work in a response. That's some of the work we're working to do.

>> Thanks for your efforts.

cristal?

>> Yeah. Thank you. Hi, Dr. Walensky. Switching topics a little bit but I wanted to revisit something that we've talked about, a challenge we talked about at previous meetings which is the disconnect or the misunderstanding that many people have about the authorities that cdc has. So there's kind of an expectation of what cdc does or what people think cdc should do and then there's the lack of authority that you may have to actually do those things and I know you've had conversations on the hill in recent months and elsewhere about that, doing education about that advocacy around it. I wanted to see if you might be able to speak to that a little bit as how that educational process is going. The answer may not always be to have more authority but just advancing the understanding of, if you want cdc to do x, then this is what would be needed in order to accomplish that.

>> Thank you for that. So I have frequently said we're going to do everything that we can at cdc to bolster or public health infra STRUSHG at cdc and around the country and that's laboratory work force data and equity and we are going to do the work of cdc moving forward within the agency but there's a critically important pillar that you note and that is the things that we can't do that we need help and support to do and maybe I would put them in probably four buckets. There are probably more but four big buckets. One related to the data authorities.

We receive data currently in a non standardized fashion that is voluntarily reported. I still don't know who is vaccinated in hospitals. And that is with the public health emergency in place. We are not confident that we will get immunization data from every state at the end of the public health emergency.

We're working through that now.

That's with Covid. So when you get a sense of all the other data that it took us two to three months to work out data use agree manies on getting vaccination data for the genious vaccine. If you're in the precipitous of the public health meeting, you don't want to be working on health agreements. To be very clear, we want to have it privacy protected. We're looking to do this from a public health vantage point. Want just cdc. We want you to know the neighboring counties so you know what's happening around you as well. State to state standardize that data reporting and have it accessible so people know what's happening so data authoritied -- authorities is one. The capacity, if we're a response based agency, what does a response base like FEMA have?

What does that look like? I had some incredible team members who went in the thick of the Uganda ebola outbreak. They did not receive hazard pay. Our work did not receive overtime pay. So as we don't have tax deductions for loan repayments so as we think about those kinds

of human resource authorities that if we are intended to be a large scale response based agency, we need to have. The third is paperwork reduction act which we actively work under that does not allow us to get -- to do studies or collect data necessarily in real time. We've been exempt for some of that during Covid. But during the -- we quickly were able to funnel passengers to do screening during ebola for people who are coming from Uganda but we were not able to get the survey to receive the data from the states. That just gives you an example. If there were environmental hazard, a spill or an environmental toxin, it could take us months for us to be able to get an approved survey for the potential damage that was done. And that would be absolute at that time. The third would be paperwork reduction act. And then finally, and another one that is critically important, we don't have capacity in the country for vacsvaccine for adults. We have saved trillions of dollars since it started in 1994. We do not have a comparative program in adults. 50% to 60% vaccination for influenza every year, we're working towards what's going to happen with the Covid vaccination and working towards efforts there but about 20% of adults over the age of 19 have received every vaccine they should and we have under and uninsured adults who don't have access to vaccinations so those would be the four big buckets on my wish list.

>> Thanks for laying those out there. They're critically important. Our job is to advise you but please known talking with committee members, if there is work that we can help with in educating others about these needs, you know, we're on your side because you are absolutely correct. We have a few more minutes left. I'm going to ask my question while I wait to see if anybody has a final question.

It has to do with work that you're doing which is great to think about ways to break down the silos at cdc and many of the new units you have as director are designed to do that. My experience has been that the centers are working full steam, often underfunded on their priorities and working across centers on some of these issues like equity and data takes more work. It needs to happen but it does take more work. I'm wondering how you're thinking about advising your center directors for the increase in workload that they're about to inherit as a result of the reorganization and the need to begin to work in a more integrated way across the agency. That's going to take time and energy at the center level as well.

>> Yeah. What I'll say, certainly everybody in cdc is not like minded on this issue.

What I will say is there's active energy toment to improve.

There's TIFR energy to want to be better and people are motivated by some missions and goals in ways that -- I mean, I haven't been there for longer than two years but ways I'm hearing that haven't happened before. So certainly there's a diversity of opinions there.

What I can tell you is in areas where there have been -- there's a long menu of things of areas to improve. I would ask people to prioritize. I would have people to strategize. Maybe you don't need to own that one alone. Maybe you can own that with a center. It's a different center. It's also the case that I think people are energized by the cross cutting work. When we have had

people engage in work or across social determinants of health, there has been -- people are motivated. The equity work we did to create the core infrastructure, that was April of 2021 when we launched that and the agency was tired. This was knee deep in the middle of Covid responses and people were energized so I think that it was really -- it's really important -- when people are committed to it, they're willing to put time and energy in the place even if it's the extra time and energy they didn't otherwise have. They find value in importing that work. Maybe I will just -- I will say just in response to the prior comment that you had, David, if I might is from before my being here, the authorities that cristal allowed me to raise were not obvious to me. I do think that people do not recognize ways in which our hands are tied to deliver on things that they expect from us and so you're helping to send those messages to your academic circles, your political circles, to say, I would love to deliver and be very transparent in the data we have. We don't have authority to get it. And so I would really, real well come your outreach on those areas because even, you know, in the best of academic places, I don't necessarily think those are obvious to people sitting in those seats.

>> Go ahead point and we will do. Time for two last quick questions. octavio and Jill and then we'll move on.

>> Thank you, David. Good to see you and you've covered a lot of ground which is fantastic. I've been listening intently. One area that I'm interested in, because the cdc has for such a long time has been seen as the gold standard but on the international scene, how do you feel your relationships are and what are you sort of prioritizing as from outside of the U.S. in working with our other public health partners out there around the world?

>> I think our global mission is key and critical and it's MUN the reasons we had -- we have a new deputy director in place. I love travelling internationally because we are still perceived, we are perceived as the gold standard. When there is a new public health agency that is developed in a different country, they often come and look to cdc for what we're doing. I am hearing at our ministry meetings -- in our international meetings that meetings do not start without cdc at the table. I think when you look at some of the responses that have occurred, and there are a lot of responses happening across the world right now, our ability to do the field epidemiology training programs, to launch those programs and to create -- I mean, the whole goal, of course, is that we would love to put our public health self out of jobs in those countries because we've done the training necessary, the laboratory, the surveillance, all necessary so they can be sustained and I do think in those countries and what I do think we saw happen because of that I want integrative work we do, is trusting people on the ground, trained people who then -- I think all the fte graduates from Uganda were working in the ebola response. That's what you want to see. So I -- I personally think that our global work is probably the most unappreciated, incredible jewel we have in this agency. So I --

we're doing work in kyiv right now and reestablishing our office there. It's really, I think, underappreciated domestically.

>> Perhaps after the meeting we could have a session on global health. Many on that committee would be interested in that.

>> That would be great.

>> Jill, last question.

>> Dr. Walensky, good to see you last week. Thank you for all you're doing. So last thing the world needs at the moment is another pandemic but as I read every day and see isolation on detection of avian influenza, moving into the mink population in Spain, to put another pressure on the cdc, we need to be ready for that, particularly motivated to talk about the response network. It did not play a role during the pandemic.

It really needs to. So I apologize for raising one more problem but I think that it's essential in any response of that potential magnitude and I wanted to keep it on your radar, please.

>> High on my radar. We've already been in touch with our teams as to where we are with both surveillance and detection as well as our usda colleagues and the detection in the avian population as well. In fact, I know I have -- I have a hearing tomorrow and a briefing the next day on exactly that issue.

>> Thank you.

>> We've run a few minutes over time. Thank you very much for staying with us. And I hope you feel both the energy as you create it and the support of this committee and the work that you've done. We will be willing, ready and waiting to continue to provide advice because as you've said, this is the first big step forward but there are additional steps that are going to need to be taken so thanks very much.

>> Thank you all very much.

Thank you all, everyone.

>> Great. Wow. Julie, you're going to have a tough act to follow here but we're going to move on the agenda now to hear our report from our data and surveillance work group. You need no introduction. I'm going to ask you to go ahead and take the floor. nirav will join us later but I think you're doing this solo.

>> Yeah. Thanks so much, David.

You're right. It's a tough act to follow but everybody is clearly wide awake. That gives me an advantage so thank, everybody. So I have the honor of giving the data and surveillance work group update on behalf of nirav who has a conflict this morning but will be joining us later today and also the incredible working group members. I think some of them tuned in to listen to the meeting as well. So it's -- I'm glad to do this and look forward to sharing our progress and feedback as well. I wanted to update you on what happened to the acd recommendations we

all submitted to hhs. They were approved and accepted by hhs so that's exciting to hear. And I just -- this is a reminder so you all remember what it is that we all approved last time we met, there were three priority areas to improve essential data exchange between health care and public health systems. And the first was really focused on defining the minimal data necessary for core public health data sources. The second was to establish public health data systems, standards and certification and the third was really as it relates to -- as Dr. Walensky mentioned earlier, how there are limitations in terms of the authority that cdc has. We made a recommendation for establishing data use agree manies and frameworks even though there's not a whole lot of authority that cdc actually has. So just to get a little deeper into each of the recommendations, I thought I would just provide with you a little more detail about each one of them. And then I'll ask jenn to give a little update to what happens next. But first, in terms of defining the minimal data necessary for core public health data sources, our recommendation is for the cdc, in consultation with the state tribal local and territory YAL partners and with input from health care and federal agency partners that they should develop, publish and regularly update a list of data necessary for disclosure to cdc for public health activities and also there was a followup recommendation to work with stlt so develop a list of data elements that would be reportable to the stlts as well T. Went to the state, local and tribal territorial level as well. The second was really establishing public health data systems, standards and certification. The recommendation was for the cdc, in collaboration with the stlt partners and the office of the national coordinator for health information technology or onc, that they should develop and implement a coordinated phased approach to certification which to start with expanded guidance for public health criteria, move to require manies and ultimately advance to certification. As has been done for health care system, electronic health record systems, this is a certification process that would be done for public health data systems as well. And the their was to establish data use agree manies and frame bornings, recognizing that the cdc doesn't necessarily have the authority they need, the feeling was that cdc, in coordination with stlt partners could establish a proactive approach for data use agree manies and looking at umbrella approach that would standardize language, provide standardized language for core components of data use agree manies to address the common challenges and looking at ways to leverage sharing data, expectations through federal funds through some of the assistance mechanisms like grants and cooperative agreement. That's what the third recommendation did entail. So at this point I'll just open up for Jen to give us an update from the cdc and now that the recommendations have approved, what happens next.

>> Thanks. Really excited to see both the endorsement as well as the approval by hhs for these recommendations. I think these will help to be really strong and important steps we take to promote the sharing and exchange of data process of the public health eco system. Now that the approval is place, next steps are to lay out an implementation plan, I'm very excited to move forward with this. There is some ongoing work already that is occurring around minimal data sets, particularly for cake data, both as part of the surveillance system as well as the response standpoint. In doing this, we will need to work very close well our partners, state and

local partners, to develop some of the language and get to consensus on some of these critical aspects around dua's as well as data necessary and identify some of the challenges and barriers as we lay out an implementation plan for standards and certification.

A lot of work to do both within cdc to bring the team together for these three recommendations but also doing it carefully with our partners. Thanks.

>> Yeah. Thanks so much. Jen was asked to be the interim director lead for the office of public health data and surveillance that reports directly to the directors office. Thanks for your ongoing support, Jen.

>> Absolutely. Thanks.

>> Next slide, please. So now I want to switch toward talking about what we've done with the data surveillance work group recently since we last met. WUCH the areas in our terms of reference that was of great interest to the group itself was data science and information technology work force and the other was something that emerged kind of as an outcropping of the conversations that we're having related to sustained funding challenges. So what the working group did in the beginning was to get a presentation from Dr. Pattie Simone to understand some of the challenges they're experiencing in which she identified a couple of clear categories of challenges that were really significant including work force shortages which I think is not news to any of us and also in addition to the shortages that a problem with needing increased needs for our work force training that the current support and trainings available are not keeping up with the times and the technicalities the staff needs.

The second thing we did with the group was query members to get a sense behalf they're priorities were. It was interesting to see the priorities that arose from the group were focusing on state, territorial, local and tribal work force needs and then also really taking advantage of leveraging academics and private sectors so these are the areas that emerged from the working group members themselves. So as we talked about the work force itself, we'll recognize we have some needs that we really need to get -- to address from a work force perspective, in terms of work force shortages, we need to quantify the staffing needs. We have a sense there's enormous needs but we haven't KWAU quantified by category or need what it looks like. We also have a sense there's an opportunity to supplement workers through partnerships with private sector, academia and health care so there's opportunities there.

We need to understand them better and also in the context, better understand what the public sector's capabilities are versus what is best suited for academia, health care and private sector, recognizing if there's a role to play, then what is primarily the public sector's responsibility and capability and also what is best suited for the other partners?

In terms of work force training needs, we also have identified there's a need to define what competencies are necessary. So we say this work force is inadequately trained but we haven't FM detected what the competencies are and while they're existing, they need to be enhanced

and then acknowledging again that in addition to addressing work force shortages, partnerships with private sector academia and health care could actually help to address some of the work force training needs as well so there's opportunities there. In terms of next steps for the working group, we don't have areas of focus to bring to the acd today for consideration for voting but really, we will be delving into these priorities, these issues have arisen and identify which priorities we want to bring forward to you in the coming meeting. Just wanted to give you a sense of what we're thinking about and where we're heading at this point. And then what emerged from our conversations related to work force was a lot of concern about sustained funding challenges.

There's concern about the current levels of funding given the enormous needs that there are for really shoring up the data science and information technology work force. We need to really have -- they're not necessarily sufficient funds to meet the needs of states, locals or the federal level and then also in addition to that, some of what was hampering the ability to use the funds are the anticipated funding cliff that although there may AB lot of money out in the system right now, we know that it's very limited and there's concerns about how much you can really invest in a work force if you know that the funding isn't going to be sustainable for the long term. That's a topic we just started delving into. What we've done more than anything else is just identify what we need to better understand and so we need to better understand existing funding. We want to understand funding approaches for enter size services and resources, for example, cloud officerses and then also understand the challenges being experienced by the state, tribal, local and territorial partners and also understand what other federal agencies or other models have for sustainability and I think we heard Dr. Walensky mentioned how some of the other federal agencies have greater authorities or greaterables for lots of different things. cdc has some limitations so looking for other sectors for models and sustainability may be helpful.

In terms of next steps for the funding challenge we've identify San Diego we anticipate asking for an update on the infrastructure grant which I think we'll be hearing shortly in the next session from the centers for surveillance, epidemiology and laboratory services and then we also want a better understanding of the epidemiology and laboratory capacity grant to see how that fits in with the infrastructure funding as well. Last on our list for right now is really understanding the funding challenges by hearing from astho, cste, naccho, himss as well to know what the funding challenges are themselves. I will stop there and just pause so we can hear your thoughts or reeks to what I've shared with you today and really again, appreciate having the opportunity to share this update with you all today.

>> Great. Thanks so much for that great presentation. Thanks, Jen, also for updating us on recommendations and where you stand with moving those forward.

We'll open up to the committee for questions for Julie or Jen on the presentation path forward for cdc and the path forward for the data and surveillance work group. I'm able to participate in the work group and as Julie said, it is concerning look at the amount of financing, how long it's

available and then the gap. We're a long ways behind where we need to be and that the financing that's currently available will only get us partway there. I'm wondering whether or not there's any recommendations that might need to be made on prioritization on saying, OK. Given that we're in a place where we need to get some things done, but we're not able to do everything, how we might think about what needs to happen first.

>> Yeah. I think that makes --

I'll start but Jen, please jump from. I think that's a critical thing we need to be thinking about because you really do have to prioritize, one of the things we list Ford a next step as a recommendation to the cdc is to consider really quantifying what the need is. If you can quantify it and categorize it, then you can see in these categories, there's clearly a need and we need to prioritize it but it's difficult to do that. We don't at the work group level have insight into that itself and I don't know that that's our decision to make as much as a recommendation to really understand what is available, what the deficiencies are and then to prioritize based on what we see. Jen, feel free to jump in.

>> Yeah. Thanks for raising that, David, and yeah. There's been some really good himss on the cost of modernization and the costs projected are much higher than the funds that are available. There's continued effort to update those, to be consistent with the reality of the situation. We do hear, I would say quite often, from states and locals the concern of, you know, investing in something not knowing their ability to sustain that long term so it is a challenge we hear and recognize to be a real challenge for states and locals and the federal level. For the cdc, as we're standing up the data and technology, one effort that works in function of that office is to define a public health data strategy and doing so, one of the things we think is critical is to outline the priority work for the next couple of years. Recognizing that the fund as well as the bandwidth as far as personnel and resources and time don't enable us to do everything right at once. We have to articulate from a response readiness and the core mission, what do we want to prioritize for the next couple of years? As we're standing up the new office, our goal is to disseminate that and work very closely with our partners to support the less alignment on that, recognizing when we're talking about the core priority work and the core data system, the exchange of data occurs across the eco system. The more we can be aligned on that, the better.

There's effort there. To the sustained funding, you know, one of the things that we are --

need to start looking at is what that sustained funding model looks like as more and more jurisdictions are going to cause migration, the reality of the costs are high and how do we support that in a way that enables a sustained function and not specific effort to some of the progress that's been made across the jurisdiction.

>> thank you. Jill?

>> Thank you for the presentation, Julie. Just a short plea. When you reach out to the appropriate public health societies, could you include the aphl, please? We can SEFRNL give you information about specific needs and quantity -- quanquantificatin. That would be appreciated.

>> Thank you.

>> Congratulations again on getting these recommendations approved by hhs. I just had one question just a reminder, if you could just remind us on the minimal data sets and maybe this will come up in the development for their work on the work plans where the discussions landed in terms of equity or social determinants of health measures as part of those minimal data sets.

>> Yeah. We made -- thank you for pointing that out. I have to AK no, ma'amming it was kind of oh, my gosh. We need to make sure we need to include health equity and social determinants of health and we did include language in that. I pull it up right now. There was definitely an inclusion or recognition of the need to do that.

>> It's actually in our report and it was discussed by this committee when the committee approve the idea of sending the report guard to hhs. It was included.

>> I have the language in front of me. We were able to get that included.

>> Thank you.

>> It wasn't a complete after thought but it was definitely like -- it's like you have to keep health equity front of mind all things. We did make a point of getting that include sod thank you for lifting that up.

>> Yeah. Thank you. I know we discussed it in November and we had seen it in drafts but some time has passed and so just wanted to make sure that it wasn't, you know, on the cutting room floor and that it made it in the time approval. Then I guess one other question related on the work force. Maybe this is a question for Jen. With the two new Bobbings in your interim leadership role of the new office, can you say a little bit more about how the work then gets connected with -- this is in terms of I imagine business improvement strike team with the new structure for the state, territorial agencies.

>> Yeah. Absolutely. Just maybe close the loop on the minimal data necessary, the case data is the farthest along as some great work based on the partnerships with some of our public health partners in finding the minimal data has pulled in some of the data elements that has been identified to be consistent across different diseases. So they're starting -- race and ethnicity is there as well as other data elements around social determinants of health.

As far as the working with the infrastructure, that will be really important in close collaboration as we work on both commitment to resources that would go out to the infrastructure, how we align on guidance, how we align in partner with messaging and coordination around some of the work will continue to be strong and growing partnership. As far as work force goes, we recognize those within cdc as far as upscale training for already established present fte's as well

as bringing in new skills and expertise and working with hr on that but then there's also the partnership with our state and local jurisdictions to identify best practices and mechanisms.

>> Thanks. Thanks for those questions. Lynn?

>> yeah. Hi. I'm a member of the working group. I really appreciate the presentation that Julie gave and Jennifer, you know, I think one thing, I think we understand, I know cdc understands this, the kind of overhaul we want to see in how the data are identified, collected, managed, used, applied to the public in real time. We know that that is not cost free. We know that is not something that can be simply absorbed within your budget or the budget of state and local entities. But -- so we know that any way that we can do this that, you know, if there are ways that we can do our work to help to not only identify our recommendations but what are the -- you know, the words that need to be used to allow people at the policy levels and others to understand why this is critically important and why this investment is -- for society, for society has a good roi. You know, it's hard to say that within the little silos of our agencies and the cdc but societally I think this is extremely important and that message needs to come across.

The other thing I wanted to say is that, you know, a sustainable system that might come through at the end as a result of some of the visioning that we're trying to put in this as well as internally in the agency, you're putting into that is -- it's only going to happen with the injection of more resources in the intermediate time to turn the system around. In other words, I believe it's a considerable amount of activation energy that's needed in order to establish a better system that can be more workable but at the end of the day, it's not going to be that expensive.

This is a time when, you know, if we're not able to capture the fact that many people have recognized that this is the critical need for cdc to do this, this is the time to get those investments so I just wanted to say this. Not all of the shorter term investments are problematic. I think they're problematic where they are supporting core staff who are going to be meeting year after year after year after year to keep systems modernized and to keep them working but not when it comes to the investments that need to be made to transform the system. And I think we saw this as well at the electronic health records the amount of money that has to be injected at the beginning to transform how the hospital says it's doing. That doesn't go on year after year after year but, you know, even hospitals have to inject quite a bit into their processes right at the point of transformation and that's where you are, that's where the state and locals are and I think one way we could be, you know, possibly helpful is to identify, what are those costs and if there's short-term funding, put them there. What if the long term funding is going to be needed to sustain the system as well as something we talked about a lot. But the kind of expertise that needs to be available at all levels which is not in place. So thank you for that.

>> Thanks for those comments.

And thanks. I think we're going to move on but I really appreciate the presentation and thank, Jen, for taking time to be here and Julie and nariv.

We're looking forward to the work you're doing and potentially an update with a report in the coming meeting. So thank you very much.

>> thank you.

>> Julie mentioned and I think we did this well on the agenda planning that one of the issues that the GRUP is looking at is work force issues. And so we wanted to move forward now to our next presentation. Early in the acd career, maybe a year or so ago, we had a presentation about the upcoming cdc infrastructure grant. We're now going to hear how that's been and we're delighted today that the director of cdc's proposed national center for state, tribal, local and territorial public health infrastructure, I'll ask her what the acronym is going to be but she's a perfect person to be leading that center and as we move forward, she'll look at the management and improvement of the scientific infrastructure services. Her leadership goes without saying but it's also been instrumental in cdc's moving forward infrastructure prime minister.

You're on and thanks for being here.

>> thank you. And good morning.

Really delighted to be here to talk about -- well, two things.

I'll talk about the public health infrastructure program that you requested to hear about in which as Dr. Fleming mentioned, Dr. Simone talked about during a previous update and then I will talk about the cdc's national center for state, tribal, local and territorial health. David, to your question about the name, we are embracing those big name referring to it as the public health infrastructure but it is a big name because we think the new center has a really big mission which I'm delighted to talk to you a b a bit today. I think that Julie's presentation was a nice segue with the discussion about work force shortages and needs and I really appreciate the comment by Lynn about the topic around sustained funding so I'm hoping as part of our discussion, we can talk about that with regard to work force so thank you. We are excited about the next five years of work and its potential for strengthening public health infrastructure and if we could go to the next slide, I want to share the definition we're using. I think you heard Dr. Walensky mention this a bit but I want to be clear because we did a thoughtful approach in looking at some sort of many references to think about what we're really referring to here.

And when we refer to public health infra STRUSHG, we're referring to the people we think the public health work force is the most precious asset, we're referring to the services and then the systems that we need to promote and protect health in every U.S. community. And it's important when I refer to you as communities that I'm really clear that we are looking at, along with the 50 contiguous state, Alaska, Hawaii, U.S.

territories, freely associated states as well as our government to government relationships with tribes which is also indicated in the name of the center that I'll talk about. The other thing I want to highlight there is the thread through every U.S.

community is really us demonstrating our strong focus on health equity in every initiative I'm here to talk about today. Before I really get into the details of the grant program which you asked about, I thought it important to highlight some challenges we're really trying to face with the establishment of the new center and the development of the grant program so if we could go to the next slide, please. We all know that for decades, neglect and underinvestments in our public health infrastructure have really caused us challenges.

We've existed in the cycle where we have a crisis, then there's a highlight of the weakness in the nation's public health system with the short-term investments flooding our health department with no TAENed funding to maintain the system, particularly around the work force and then experts examine the public health system and highlight the need to strengthen it. We see this time and time again. I highlight the 1988 SH -- the hiv and aids epidemic.

Next slide, please. And then we saw it again, one example, 2002 following the 9/11 and anthrax, same thing. Crisis, influx of funding, examine the state of public health and the 21st century once again noting the neglect of public health infrastructure and vulnerabilities it presents for the nation's health and then more recently, next slide, in 2022, the senate committee to Homeland said unprepared with findings recognizing the need to support public health system.

These are just three examples where we've seen the cycle of underinvestments, flood of investment during a crisis and then identification of a need to really address the system. I did want to highlight also some others, more recently and specifically related to work force, in October of 2021, or far into the public center for innovation conducted a first of its kind analysis to estimate the number of state and local public health staff needs and highlighted that there's a minimum of 80,000 full time equivalent needed to be hired to provide the minimal public health services. 80,000 just for the minimum public health services. We saw, they highlighted that the public health work force has shrunk by nearly 56,000 positions primarily due to funding crisis so this issue around support infrastructure, making sure we have the resources to support the needs as well as the work force have been highlighted time and time again. So the question is, what is the cdc doing to address some of this? I want to highlight two major changes which you've heard about. Really geared towards supporting and strengthening our public health infrastructure. I'll start with the new national center which I mentioned, then I'll give an overview of the grant program.

These are just two approaches.

This is not really impacting the ongoing work we do in our funding categorical errors to address work force and infrastructure needs. Just for an overview of the new center, the goal of the new center, which I'm honored to say I've been asked to serve as director, will focus on strengthening public health infrastructure through effective and efficient delivery of public health infrastructure and workforce development services. The center will have three primary if you thinks which are highlighted here. Jurisdictional support and this includes our broad non

categorical grants and cooperative agreements that serve as mechanisms to provide funding service to jurisdictions and tribal communities. The second is partnership and technical assistance and this includes those mechanisms that we use to fund our partners to move our collective public health goals forward and then the third which I'll spend some time talking about is workforce development which is why I thought the first segment was really nice lead-in to this. We view the work force as the most precious asset. We can't do the work without a confident and prepared work force so a focus on public health work force is a key function in this center.

Next slide, please. I brieflied wanted to share, the center will be a science based organization focused on evidence based solutions to push our work forward. So we do have three cross cutting scientific if you thinks we'll focus on. The first is data management. This report refers to the data related to reporting for grants and cooperative agreements as well as our work force related initiatives and I should mention the work force related functions in the center focus internally in collaboration of cio's across the agency as well as working really closely with our human resources office or enterprise-wide approaches to strengthen our internal work force as well as our support to state and local through our fellowships and internships and training programs and doing investments we made at the state and local level. So managing that data is going to be a big part of one of our cross cutting if you think -- functions. The other is system and infrastructure. Is this is where our collaborative work on the data modernization initiative will be helpful and our collaboration with the new proposed office of public health data surveillance and technology. Then finally, evaluation, evaluation, evaluation. Evaluation and assessment will be critical. How are we looking at the impact of our work? Where are we adding value? What are the returns on investment? Are we serving communities well who are our primary customers? And how will we contribute to the evidence base? This will be a really big part of the cross cutting function. If we can go to the next slide, I'll give an overview of the grant program.

So it is named strengthening U.S. public health infra STRUSHG, work force and data systems grant. This is now one -- I want to highlight one because we have many grants and cooperative agreements across the agency that support work force through categorical funding but this is one tool that the cdc will be using for addressing the challenges I mentioned earlier. This is a first of its kind grant for advancing foundational infrastructure in the work force that is not tied to specific disease or condition. So this is disease agnostic, if you will.

It's a five-year programs that recipients we hope can work to lay a foundation for stronger public health infrastructure.

November of last year, we took the first major step with the rollout of the nofo to 107 jurisdictions and three national partners so the important thing here is that everyone in the U.S. lives in a jurisdiction that receives settlement funding from the program. So let's go to the next slide. In addition to the states, territories and associated states, the grant also funds 22 cities and 27 counties so if you're interested in really looking at details here, we have this published

on the website at cdc.gocdc.gov/infrastructure. Now to go through the GRNT. The grant is broken into two components, a and b. Component a to directly support the 107 jurisdictions that I referred to and strengthening public health capacity and systems and then component b to support the three national partners that were funded in providing technical assistance to the component a recipients. So component b refers to the resipents of a, thinking about evaluation and we're working very closely with them on the planning for that.

If we can look here, go to the next slide, look at some of the key strategies for this. I mentioned 107 jurisdictions. At the top you can see who was funded. I just wanted to walk through a few of the strategies here. So around work force, we are looking at how we recruit, train and support our public health work force. This is a critical component of the grant program. I did want to highlight once again that along with this, we are working with colleagues across the agency to see how these strategies for this grant program can complement strategies that are already underway through other grants and cooperative agreements that provide work force funding. This is not the only mechanism to look at funding our work force.

The other strategies around foundational capabilities. There is some flexibility here and utilizing funds to strengthen systems, processes and policies.

Then the third strategy is around data modernization and this is where our close collaboration with our colleagues and the office that Jen talked about, the proposed office of health data, surveillance and technology will be really helpful. This is a mechanism by which we can provide funding to support our data modernization initiatives.

So first we get the states. I wanted to highlight a few other things about the grate. They'll establish at least 40% to local health departments. This is important. Second is critical to highlight that recipients do not put additional administrative or burdens. Lastly, we wanted to highlight that recipients should identify other sources of cdc funding received to determine how they might best supported some of those foundational capabilities. So this is intended to serve to support other sources of funding and investments in the areas. We know these are huge investments but it's not enough. We're already thinking about how we will be moving towards evaluation and looking at how we can really show return on investment how these are supporting as a bridge for other investments and making the most out of these resources. But I wanted to highlight that there are at least two other -- two dozen other -- I think we found close to 40 grants and cooperative agreements that some component of work force associated with so working together on those other mechanisms to see how we can really show value is going to be important. OK. Let's go to the next slide so I can give an overview of component b. So component b does have a narrow focus. The three national partners who receive funding were the associates of state and territorial health officials, the national network of public health institutes and public health accreditation board and these partners are working together. They will be working with additional partners through several awards to provide funding to support those resip YENTs of component a. The key activities with technical assistance and capacity building support for assessing and improving work force policy and implementation, grant

program evaluation and then coordination and communication. I want to talk about sort of where we are.

So where are we now and what's ahead? This time line shows the progress thus far. We've been working on this since January of last year when we kicked off the process. As a part of that kickoff, we had numerous listening sessions and those conversations really have influenced our work every step of the way from the development of the nofo to engagement with partners to support on working with programs and a development of work plans and then now on how we're going to evaluate the progress of the program. The final recipients have turned in their work plans earlier this week so we are really seeing progress here and we will share work plans, performance measures and success stories from the jurisdictions as they are available. Let's go to the next slide so we can talk about some of the key outcomes that we're expecting. We've outlined the jurisdictions are -- they do have some reported requirements and some things that we expect to be achieved by the end of the five-year performance period.

However, this is a very flexible program and we're excited that this is flexible. One of the requirements for this GRNT program on the work force component is that every recipient was required to develop a work force director that will be responsible for working at their entire work force needs and helping to develop their work force plans and working both with cdc and those funded partners under the component b of this grant program to really think about using those resources around work force wisely. But otherwise, this is pretty broad and while that's great because we heard when we ENgaged at the state and local level that non categorical funding was important. We know that that also raises some risks. You know, there's a sort of balance and we can go back to the last slide. There's a balance of having flexible funding but also making sure that we have some help here. Some of those that we outlined for short-term around work force was increasing hiring of divorce public health workers. We highlighted this in the language of the guidance that was provided here. We're also looking at opportunities to improve organizational systems and processes. This is the foundational capabilities component and then utilizing the funding to really support and strengthen some of the ongoing data modernization work that was previously funded. And the intermediate outcomes, we highlighted increase size of public work force, though we realize this is only one mechanism to strengthen work force, stronger foundational public health capabilities and then celling the availability and use of public health data.

Component b, continuing to work with recipients on improving and sharing lessons learned so we use that to inform our processes moving forward. Let's go to the next slide now. Thank you. I did want to talk about evaluation because I mentioned that this was really foundational. We have to be sure that these investments really show a return on investment and that we're having some public health impact so the evaluation component is a critical work of the success of this grant program. We'll be tracking progress, documenting success and challenges, trying to drive improvements where we can and then build evidence for enter very long --

interventions. We want to use assessments to build on the work already done while continuing to reduce burden on data collection from our recipients. So the performance, measurable reporting will complement work plan and financial report. OK?

Let's go to the next slide. OK.

I did want to talk about performance measures. We are planning a is hes of limited performance measures that component b recipients will work on, on a regular basis. These measures which include both process and measures will be finalized by component b evaluation partners in the spring. While we're performing -- preparing for that, we're engaging in other organizations to get input on what should we be considering as evaluation measures? We are already thinking about five years from now. We know there's a lot of visibility on this program and the investments that we have thus far and there will be an expectation that we show some progress fairly soon so while this is a five-year grant program, we're thinking about that cliff and where we have opportunities to show our successes so that we can really, really push to get sustained funding to support the important work in our state and local health departments. We will look at measures to monitor and assess recipients, individual and collective progress to our intended outcome of the grant over time. This information paired with what other case studies and evaluations will be used for the overall public health impact. I think I mentioned in the beginning of my presentation that this new national center will have a focus on evaluation. We had established a small office that will solely be focused on evaluation looking at the data that comes in and how we really are able to assess the impact of our work, looking at measures such as return on investment, looking at customer satisfaction, engaging at the state and local level so we can also get success stories of where these investments really had an impact at the state and local level. All of that is going to be important for us to continue to push for sustained support in this area. Why don't we go to the next slide. As a part of our -- I didn't see it advance. Next slide, please. I keyed up some discussion questions. I'm sure you'll have many but as part of our engagement and learning about how we can utilize this mechanism to really show impact, reduce burden and strengthen our infrastructure, I thought this would open up discussion. I want to thank you for the opportunity to give an overview of the center and the program, look forward to your questions but would love to tee these off if I may. So I will stop there. Thank you.

>> Thank you for that incredibly good presentation and the work that's unbelievable. It's clearly not as much as needed but it's certainly a great start and so we're really thankful of the energy that you have put into this and the thought that you put into this. We'll open up the floor for questions. And let's see. Daniel.

>> All right. Thank you so much.

Thank you, Dr. dauphin. I was really delighted to hear about you say health equity is really being embedded throughout the program and you talked about increased hiring of public health staff. What I wanted to see if you wouldn't mind sharing with us, what is being done to ensure that

the resources provided by this grant are targeting disproportionately impacted and underrepresented groups in the public health work force? And also if you wouldn't mind sharing a little bit more on what is being done to embed health equity specifically.

>> Thank you. Great question, Daniel. Good to see you. I appreciate that.

>> You, too.

>> As I mentioned when I gave the overview, there's some very specific language on the -- in the guidance for the work force component, that's component a1 around considerations for diversity, equity and inclusion and the hiring so that's one aspect of it. Regarding thinking about the communities, this is where our work with those funded partner $ going to be really helpful. You may recall that I mentioned that these partners actually have -- will be sub awarded to other groups that have an opportunity to really make sure that as we are staffing up and thinking about those reflecting the communities that are being served by this --

by these investments so with regard to diversity and equity and inclusion, we do have some specific language there. Now with regard to health equity, this is really, really all about assets. So thinking about the component a2 where we think about the foundational capabilities, this is where there's a real opportunity to think about strengthening some of the practices, systems that are really credible to thinking about access to health in our communities. So we think that through the guidance and language around thinking about the work force component and hiring and as well as the foundational people we're considering both diversity, equity and inclusion as well as health equity as part of that program.

>> thank you.

>> thanks. Number of questions.

octavio?

>> Thanks, David. Great presentation. One thing that made me think of and especially reference to the number of tees that you have, are you creating a learning community among your grantees? It's a great model for not only accountability to each other but obviously sharing of challenges and successes. We've had great success with that in working and trying to change rural communities here in Texas.

You're shaking your head. Could you share some of that maybe conceptualization of how you'll have a learning community part of the process?

>> Yes. Thank you. I'm glad you raised that. That is actually something we've been thinking about for two parts of this. So the first is interestingly, I'm learning that through some of the work plans that have been submitted, some of the recipients are thinking about this. They're thinking about doing this which is fantastic.

Then through the component b where we're working through funded partners, this is a way they're providing technical assistance. Where can we look at those that have been successful and learning best practices and share with others? So through both the work plans being established by the recipients and our work through our funded partners, I'm certain that this notion of sharing through community practices or networks is really going to be a component of this program and we have to rely on that, right?

This is really how to make some progress in the very short time that we have to see results from this program so that's a big part of this.

>> That's great. And also segues very nicely with Daniel's point because you can use learning communities to keep themselves accountable when it comes to health equity and addressing diversity as well so wonderful to hear.

>> thanks. Julie?

>> I've been a beneficiary of these learning communities as a cdc grantee and really felt it was incredibly valuable to hear about errors that were made or lessons learned to actually improve the work we were doing in the grantees so I think that's a wonderful idea and I'm glad you're moving in that direction. So much. Good luck with the huge center. It's so needed and so appropriate and congratulations to you to lead that group. It's such important work. I have a couple of questions for you and one of them is kind of in response to your first question was how do you minimize the burden on the states and local grantees that are receiving this funding? I am -- in my role in Chicago, we went through the process both for accreditation and re-accreditation so I see the value and understand the purpose of it. What I would say is that it is incredibly -- it was an incredibly burdensome process to get through to become accredited and so I'm wondering if you all are working with FAB to actually see if there's ways to streamline the process because I think in the midst of trying to rebuild an infrastructure, rebuild a work force, just the thought of going to go through a burdensome accreditation process is really -- I think it would be demoralizing or I could see it being demoralizing to the states trying to get through the process. While I appreciate the value, I would just hope there's efforts being made to streamline the process. Second question was in the description of the funding and what's been made available, there was an area that was not funded yet. I think there's funding that's coming.

ICHLS just curious if you could elaborate on that. Thank you for all your work and the work that lies ahead of you. You have a huge challenge.

>> Thank you. Yes. Absolutely.

We are working with FAB. This is a lot of ongoing discussions about exactly what you raised, that sort of burden and the challenges. So I should clarify that in the language and guidance for the grant program, there's not a requirement to achieve accreditation. This is language that encourages moving towards accreditation and that could be one area where we could look at

measures for success of this program but it's not a requirement. It's really there's a lot of flexibility we're doing and how recipients choose to use the funding that is to support the foundational capability. The point that you raise continues to come up as a discussion topic and I should mention that a part of the functions and scope within the new national center is really around technical assistance for public health accreditation and how we work with FAB and other partners. So these are definitely discussions that are underway and we have heard that loud and clear TWLU some engagement that while we want to sympathize moving towards some measures that could show impact that it is extremely burden some and how do we work together to look at streamlining processes and where we can actually see moving the needle forward towards the transitional capabilities even if you don't achieve accreditation. So that's for your first question. The second question, yes. Regarding the component a2, data modernization did not list funding in the slide because the funding has not realed out yet.

We absolutely do have plans to send funding out. We had committed to utilizing so we can use base proportion. The nice thing about the grant is that we can use a variety of sources and there's a lot of flexibility there. I have plans to initially roll out, we committed to $40 million of fy23 for the data modernization initially and we're looking at where there are opportunities to leverage what's already gone out. And support that ongoing work through the funding that goes out through the component a2 as well. So it wasn't listed because it hasn't rolled out yet but we do have plans to roll out fy23 funding.

>> thanks. Really good to know.

Lynn?

>> Thank you so much and thank you very much, Leslie, for that presentation and it is truly wonderful to see the the beginning of a process where what I would call core support is going to the states and particularly that you are making sure that a lot of it is reaching a local level and even giving special support to cities and who obviously sometimes get short changed. You know, there's a lot I could say about all of that having, you know, at one time worked for a very large state, California, and we never felt that the amounts were c commensurate of the dollars. But I did think that there's probably further work that you guys could do and one of the things that -- you know, this is a good beginning to in terms of I see the care that's gone into minimizing the bureaucracy and the burdens and I think some of that Julie asked about kind of went to that but there's still a lot of support that is coming from cdc to state and local government that is in silos that each, you know, do create burdens and bureaucracy, much of which is not necessary. Some of it exists as if there's no other cdc program that people are involved with and it really is, I think, on all of us and where the act could once again get involved in, you know, just as we can, I think, streamline a lot of data collection processes, there are ways that grants are being implemented that could be streamlined that could make it less burden some for the states and I think what LEZly is doing is maybe starting to lead the way for that by creating paths, you know, for more general levels of relationships. So I appreciate it and I think we have a long ways to go. There's so many needs, you know, that the infrastructure

has and every time that people are doing unnecessary bureaucratic stuff instead of their jobs that is not necessarily, you know, benefitting the public's health.

Thank you.

>> Lynn, I so appreciate that you raised this. One of our priority areas in the new national centers, we are -- at our core, we have identified collaboration across the agency as a core value. So we are committed to working with our colleagues across the agency to address just the things you mentioned. If nothing more, we would like to convene a forum where we have opportunities to look across all of our agreements and say where are there are opportunities to streamline how we're doing reporting. Not just the processes but also the systems.

You know, this is why I mentioned earlier, our work, internal working on looking at our systems and working closely with the colleagues in the office of public health data and reporting on enterprise approaches. This is an area we're targeting. We're very much interested in, as a priority area, working with our colleagues across the agency on where we can reduce burdens and we welcome. That was one of the questions I had. We welcome any input from the acd and others on ways that we can do this. So thank you. I really appreciate you raising that.

>> Monica, last comment.

>> Thank you, David. And thank you, Dr. dauphin, for would you being us through the updates and congratulations to you on this new leadership role. Having been at the state and the city, I really appreciated the partnerships and support when it was ostlts and cstlts and emphasizing your commitment on working in an enterprise way and partner $ really reassuring.

Your slide on the questions, so the second question, the bullet about things that would be helpful to learn about, we know that during the pandemic that a community based work force really was able to emerge into the extensions to the work that our local public health and state public health partners were doing to respond to Covid and then the work force kind of waxed and waned and depending on the jurisdiction, some were able to become permanent hires. I think as you're going through the work plans and some of the themes are emerging about the different strategies and approaches, something that would be helpful to understand is where those jurisdictions have been successful in actually making sure that the communities are reflected in the work force moving forward so that was one comment on the questions that you shared. And then a question for you about clarification because I've heard about this 40% sub award to locals and so can you just please clarify, the 40%, is it to local health departments and/or community based organizations or is the 40% to local health departments who then might have that flexibility to then work with community partners?

>> It is the latter and thank you for asking that question.

The 40% to local health departments and they will have some flexibility in how they use that. And to your first question that I think is fantastic, yes.

I should highlight I was asked to talk about the new center and the grant program but there are other efforts we have related to work force to think about community based work and I wanted to mention just briefly, some of you may be familiar with our partnership with Americorps for public health Americorps.

This is the first and this is a program that is funded through the American rescue plan to really get at looking at pathways for workers in communities and we are really, really proud of this. This gets back to Daniel's question earlier about how we're thinking about health equity. This is a holistic approach. We're thinking about all the work force related programs, all the infrastructure related activities around grants. It's not only this. It's a multi pronged approach making sure how we're planning, implementing and evaluating all of our work with health equity principles in mind. So I just wanted to highlight that partnership because it wasn't for this preparation but it does get at the core of some of the questions you're asking about.

And I would love if you're interested in just take a look at the work that we've done with Americorps for public health.

It's really fantastic. We have 3,000 grantees so this is really a pathway to public health. We know that hiring alone is not enough. We have to have really a multi pronged approach to think about our work force from our training, to our fellowships and internships and group pathways.

Thanks for that question.

>> So unfortunately, we're at the end of the session. Thank you so much for your presentation, for your work, for your leadership. I feel like we're just at the beginning of this pathway with you so if you are willing, we would very much enjoy the opportunity at future acd meetings of reconnecting with you and continuing to be able to ask questions and perhaps provide something as well.

>> Absolutely. I very much appreciate that and look forward to it. Thank you so much for inviting me.

>> Thanks again. Now we have one more session before our break and so I'm delighted now to turn this over to our health equity work group co-shares, Daniel and Monica to lead us through discussion, a vote and some brainstorming. Over to you folks.

>> Fantastic. Thank you so much, David, and of course, on behalf of Monica, we are delighted to colead the health equity working group. Just want to thank you, Monica, David and the entire team. It's been just really a team effort here and in conjunction with our exceptional members, we are really excited to share with you some updates today. So next slide, please.

Thank you. To help Dr. Walensky and the cdc as a whole meet their objective of actualizing health equity, you know, we established a working group of 21 health equity members consisting of 11acd members and ten additional members with expertise in pop LALGS groups that are disproportionately impacted across the United States. Intentional about making sure

we focused in geographic representation, racial and ethnic, disability, LBGTQ, ageism and so forth. And to better manage our charge, we created three task areas. Task area one was to enable and assure the meaningful involvement of communities in agency decision making, the development of health equity policies, program implementation and of course, evaluation. That was the first task area. The second task area looked at aligning and restructuring, if anything, ycdc policies, resource allocations and program practices so as to maximize the ability for staff and partners to address health inequities in their day-to-day work and Task Force three was looking at taking immediate and decisive action to expand, embed and integrate approaches to measure and influence drivers of health equity across all public health programs so looking at the drivers of health as a whole.

I'm going to pivot to Monica now who is going to give us an update on our work thus far and how we're going to move forward.

>> Thanks, Daniel. I want to acknowledge that I think we have some work group members who are also watching this portion of the meeting so thank you for all of our members joining us remotely, too. So just to recap, as Daniel said, we all met in person last November and the advisory committee approved in concept the recommendations we shared in draft form under task areas one, two and three and since we met in person in November, Daniel, David and I have worked with the cdc colleagues in terms of streamlining the report and also hiking the pause button in some of the work that we are doing and wanted to share that with you as part of the next steps updates. What we have been talking about is the possibility of the hew providing some additional specificity and making more of the recommendations under task areas one and two specific and concrete to help with going ahead and implementing and operationalizing the operations as Daniel has said. We'll talk a little bit about what that means in terms of the work itself between now and our next meeting which will be in person in the spring. But it will create some opportunities for the hew to work with cdc's office of financial resources and services to make sure the recommendations are as specific as can be and implemented in the new structure that Dr. Walensky has walked us through at the top of the call.

This afternoon we'll have David go ahead and present task area three because it is approved and ready for implementation and I believe a vote to move forward by the advisory committee. So these task area three recommendations which David will wake us through are specific enough that our understanding is that our cdc colleagues will be able to move forward in implementing each of those so David is going to share high level recap and we can move towards a next step related to task area three specifically and then come back to Daniel and me to quickly walk us through some of the questions that we're working through with our cdc colleagues. So next slide, and I'll hand off to David, please.

>> Yes. So there were -- when we got down to the three task area and two co-chairs, so I got the lucky job of taking on the third task area which was more straight forward and we're bringing that forward today to you for a vote. That's been provided in your packet as well.

You've seen much of this as well.

There's been a little streamlining of the language and the specifics but it's basically very similar to what you approved at the last meeting and just to recap it in task area three, the basic concept is to urge cdc to adopt an agency-wide approach to working on equity and health equity. We decided it into two parts. First part is to encourage that agency-wide approach to identify and implement measures of the under lying drivers of equity and health equity to make it successful and useful to the communities and other public health programs. Sub parts, recommend that the cdc need a process to synthesize what is currently known about the issue, to initiate a process with the key partners and stake holders to assess the feasibility of developing and implementing field testing measures as consistently as possible, ensure a development of measures to include asset and solution-based measures of equity and health equity, focus attention on measures that can be assessed in a timely way and locally and granular as possible and to promote through public health program funding the incorporation of these measures into the evaluation of public health programs. That's the measurement. Please look at the next slide, please. Second, we said measure is only a value if you do something about it. So we're also encouraging simultaneous parallel agency-wide approach to developing and integrating strategies to influence the drivers of health equity across the entire range of public health programming at cdc.

There's more details in the packet that you got before the meeting but we specifically would recommend that cdc align, integrate the internal organization and leadership of health equity and social determinants and a big step forward in the moving ahead initiative. We're recommending that the cdc promote and enable program funding across all of the programs for assessment and mapping of the drivers and individual programs that are most important, that cdc should incorporate funding to develop and implement strategies to change the drivers as they're mapped out, including drivers that are most important in individual categorical programs and that these approaches that should be implemented at the program level again should routinely include asset based approaches that are directed not only at individuals but systems, policies and environments in which people and communities live, work and play. And that timely, in addition to measuring drivers, we're recommending that the cdc implement effectiveness of the strategies and programs to influence drivers as well. So again, you have seen that before. That's in a nutshell task area three. I would like to ask Daniel and Monica to introduce a motion for the adoption of these recommendations by the acd and then we can have some discussion before a vote. Daniel, can I ask for a motion for you?

>> We have a motion to adopt this.

>> Second.

>> Perfect. Thank you. Is there any discussion before moving to a vote to adopt these recommendations that would then move forward after this meeting to hhs and then to the cdc? If not, let me call for -- Josh?

>> You're muted, Josh.

>> Sorry about that. Trying to get through one day without that. So one of the challenges facing cdc in trying to do this is that a lot of these factors are not directly part of the cdc's orbit. In fact, may not even be directly part of hhs's orbit. Is there a way to get it that at all? How do you -- you know, how does cdc become really engaged in the work of other departments even and the federal government or the private sector in order to accomplish some of these goals that relate to the fundamental drivers of health?

>> Yeah. A great point and as you know, I would also say that that's an issue that the state and local level as well as public health programs are working on these issues. Fine print of the recommendation, we tried to address that a bit by pointing out that many of the interventions that are required fall in other domains, both within health and human service agencies but more broadly, in transportation or planning or et cetera. And ask that or recommend that cdc take a leadership role at the federal level in convening those appropriate groups and establishing the appropriate liaisons between cdc and the other parts of hhs and the federal system that are actually needed and that the program funding that's going down to states and local health departments, that that be a legitimate use of the local and state funding as well to create those partnerships to assure that as best as possible to assure that the public health perspective of -- is included in the work of those other agencies that are fundamentally working on the underlying determinants.

We tried to address that but by no reasons, believe that it's simple and will require additional work. And Rhonda, did I see your hand up or no?

>> I did but you said what I was going to say more eloquently. My point would have been and everybody has a responsibility of integrating and coordinating, even outside of their so-called silo and I think that's where we have a major misstep and until we actually all own that responsibility, it just doesn't get done. So you rolled it out beautifully, David. I'll be quiet now.

>> Thank you. Lynn?

>> I just wanted to say that I think Josh's point is a fair one. But I think that the only way to get started towards seeing more collaboration across all the various entities and some of them are not state and local, some of them are federal that have these data. It's not necessarily data where there's a state agency that matches each one but I think it's a great starting point for us to support this and for cdc to be taking this on but it is not something that can be accomplished by the cdc alone. I think that Josh's point is well taken that they do have processes for collaborating more broadly as do the state health departments and local agencies and that is going to have to follow any effort on their part to make this happen.

I'm thinking that Josh, what happened years ago when environmental public health surveillance started and most of the data were in the environmental agencies and some were only federal and over time gradually cdc has had more and more of that but it's not what it ought to be. So I

think it needs to be viewed as a process that needs to be kicked off and not something where, you know, we vote for this and then it's just going to happen.

>> Over to you, Josh.

>> Sorry. Yeah. I appreciate all these comments. I think the point isn't that because cdc is not in charge of all social policy that this isn't the right direction. I think it totally is the right direction. It's just that critical part of what cdc can do is to use those kinds of analyses that Lynn is talking about to kind of become relevant to some of the other conversations and pick up on whatever strand there is of interest and engagement in other areas for this and just really be excited to work with people because that's going to be, you know, really important to go beyond the measurement into the action particularly.

>> Right. Right. Good point.

Hopefully these other areas can be embedded in the thinking that goes into the measurement and actions that we're recommending here. Julie?

>> Yeah. I really appreciate these recommendations or these action steps. I think that they are necessary and building on what Josh and what Lynn said, I think that while we recognize at cdc alone can't address the issues and need to work with other federal agencies to do this work, I don't know that cdc has been asked to play this kind of a role explicitly by anyone.

I think these action steps make that clear that cdc has the role and could play that important role. When I think about it as a local level, we did this in Chicago, we engage with the other partners and it was really like Josh said, identifying that strand or whatever it is that would be of interest to these other agencies to work with us and see the value of our partnership and be able to move it forward. I think this is --

what you're outlining here really helps to make clear that cdc, we think the cdc could potentially play a major role in this way and not that it will be easy or that everybody will embrace it but that we have this expectation, desire for this to happen. I think that's really important and good to see it in writing like this. Thank you for your work.

>> thank, Julie. I'm about to call for a vote on this. Deb, would you like to make a comment on what we've just been talking about?

>> Yeah. Very much so. I think this is great. We've done a lot of this work in social determinants of health. I agree that not everybody thinks cdc and public health is the convener but in my mind, there's a great opportunity for public health and cdc could be a convene era cross the different disciplines. This is newer but it makes sense to me and I think it's something we're supportive of and delighted to really be able to look at how we can focus more on social determinants, drivers of health equity and thinking broader. So I really appreciate the committee's thoughtful time on this recommendation action steps.

>> Thanks. We're about to make the recommendation.

>> Yes.

>> So we have a motion to -- for the acd to make as official recommendations to the cdc, the action steps that are outlined in task area three. All those in favor, please signify by saying aye or raising your hand or some other way of affirming.

>> aye.

>> aye

>> Opposed? Are there any abstentions? Fantastic. Motion is adopted unanimously by the acd as recommendations to cdc.

Thank you very much, folks. Big step forward and we'll now hear about additional big steps forward from Daniel and Monica.

>> Thank you. Thank you so much, David. Next slide, please. So as you heard from David and Monica, we're working diligently to provide additional specificity for recommended actions for task areas one and two and what you see on your screens are areas that will be meeting with cdc to dig ailing bit deeper and provide more specificity on. So what we've tried to do was to bucket them in these general areas and develop some questions that we believe is going to help us to accomplish this objective.

So in -- I guess for task area one, we're really focusing right now on the current rules, policies and practices in community participation and I think this is a sensitive topic for those of us that I obviously just moved to Tennessee and we have an issue now with the Tennessee department of health deciding not to take cdc money for hiv/aids work. It's quite interesting to see how do we work then to ensure that the people who are really closest to the pain and the problems of many of these public health issues continue to get the resources they need? Some questions we'll be asking and we welcome your thoughts on additional questions include, if you look at the first bullet, options for community engagement and input, you know, one question is understanding that to address and ultimately achieve health equity changes to the cdc structures, processes, culture and policies are required. What needs to be changed in order to effect positive changes to allow for the advancement of health equity and the prioritization of community engagement as well as increased funding and resources to non governmental entities that are working to bolster health equity? When we think about ways for communitieses to participate in decision making, some questions that we'll be asking cdc is can cdc organize community based listening sessions to help inform developing nofo language? Or does the cdc have the ability to build approaches to still programs that help integrate communities in decision making and resource allocations through nofo requirements? And as another example of how much flexibility does cdc have in the application or nofo process to require community participation?

So we really want to get a concrete example, specificity in how communities can participate in the decision making process there. The third bullet, understanding and influencing authorizing

corporations, language limitations, some questions we developed was does Congressional language explicitly preclude or explicitly limit funding to certain entities, non governmental entities, how does the cdc liaison work with other Congressional staff? I think it will be interesting with the new position the director of external affairs that Dr. Walensky mentioned, it will be interesting to see how that person will be working and influencing and ensuring that appropriations and authorizing language include this.

I'm going to open for questions, comments, additional ideas that we may use to probe as we move forward with GEing more specificity for task area one.

Yes, Deb.

>> I will start the conversation. I think it's really helpful to give us guidance really on this. I know Monica had given an example at the state level. Understanding if there's a lever that the state level versus the federal level to really unpack where sole of these barriers are, that's really helpful because if it's an artificial barrier, we can address it. If it's a state level, we can work with state.

If it's federal or Congressional appropriation, that's harder for us to work with but understanding it and being able to drill down is really helpful so I think the more you all can help guide the questions that would be great for the cdc to pull that data and information.

>> Thank you for that. Josh? I see your hand next.

>> You know, first of all, I think this is a great topic.

Really a great topic to focus on. The processes are often kind of boiler plate used but they're an untapped opportunity. I wonder when you might think about asynchronous ways if they're not able to attend an advisory board or listening session and ways that people can weigh in, in writing or videos or things when they have time if they hear about it. The other thing, I don't know whether this is within scope but there may be certain policies, et cetera, that it would make sense for the cdc to propose and draft for comment. You know, typically what happens is -- this is not just the cdc, people go out and get input and here it is. Here is what they're doing. They might explain about how they took it in but they haven't really thought about a bunch of things and then people get upset afterwards because now that they actually see what the agency had in mind, it brings up a whole bunch of other thoughts. One way to do this that can keep things moving forward is for the agency to propose, even if it's not like a notice and comment rule making where proposal is required but you propose what you're thinking just for comment. This is how we're going to be doing a grant. But it's a proposalproposal. Does this make sense?

You're not dealing with it afterwards but you're able to get the information up front. So in general, I don't know whether that's considered in scope but I consider proposals a kind of back doorway to do community engagement. Media and everybody revs up when you see the agency is thinking so like the word --

if you just say we're having a listening session on the grant, OK, fine. The grant is proposed and it's going to work in this way. That really helps kind of energize the proposal and for cdc it could make clear a decision so they're making a final decision with the full knowledge of the landscape.

Thank you

>> Thank you, Josh.

>> If it's OK, maybe we can go to the second one. People with comments can continue.

>> Sure. So next slide, please.

I appreciate your suggestion, Josh. We used to do that all the time at the city and the state in the request for information and in terms of gathering feedback. I think that is the spirit of these two task areas is really to open up opportunities for resources to go to a more expensive group of grantees, even listening to Dr. dauphin talk about the 40%, the funding, majority of funding from my understanding is that it does flow to the states and local health departments and to directly to some big cities so for task area two, that is really the spirit in which I want to present some followup questions is really looking at exploring specific business practiced and different rules that can help guide resources and the ways in which funding is distributed to community based organizations. Let me pause and see, if OK if we come back or did you want to ask your question now?

>> It's fine to come back.

Actually, all I wanted to suggest, having been on the board for very small not for profits so for safe grants from cdc is bringing in some people with lived experience of what the processes really look like and the burdens they create which are considerable in proportion to the budget that these small organizations actually have. That's all I wanted to say.

>> that's a great suggestion.

And that actually came up when we met in person last summer with our Colorado colleagues and a specific issue around advanced payments, especially for non profits. Many times grants are set up on a cost reimbursement structure is not required. Is it necessary? I'm not sure. So I think your suggestion about lived experience and actual real people receiving GRANTSZ and leading non profits is important to form recommendations we're making. Like Daniel described, these are sort of the overarching categories of questions and so just a flavor of some things that we'll be asking our cdc colleagues to provide more clarity on is around the current status of funding that's provided directly to cbo's. Are they tracking that? How much funding is actually going to cbo's across the agency? Which programs are mandated because of authorizing language to go through governmental public health at different levels? The second bullet, understanding the ways in which funding is structured, stepping outside of authorizing language but within the centers, how does cdc and the different programs and divisions

determine whether funding will be distributed competitively or formula and getting a better handle on that. And whether there's any flexibility and influencing competitive criteria so could the cdc require certain demonstrated partnerships, for example, with community based organizations. Could that be a criteria beyond just some of the nofo's and grant opportunities provide a list of community partners but beyond providing a list, how can cdc gauge true, authentic, meaningful partnerships with community based organizations? And when we begin this process, learning about core, there were colleagues within the cdc from Dr. Hacker and others who were able to share exemplars that currently exist. We heard some examples last summer with the 2103 health equity grants and there's also sister communities in terms of those different pots of funding comes from hrsa Ryan white. So being able to lack at those and scale those across the agency.

The other categories around just identifying where there are barriers that limit their ability. Are there barriers?

What are the actual rules? Is it in statute? Is it an administrative policy or procedure? These are things that would be helpful for the huge explore with our cdc colleagues so we can understand where there are really truly barriers and where there are opportunities to get those funds out to community based organizations and then finally, understanding what mechanisms might exist for ta and capacity building to support cbo's. If there is any flexibility or ability to restrict or limit payment for different financial models, something we just started to talk about. The payment structures that go out in contracts and understanding the policies and procedures.

Understanding how cdc may be working or partnering directly with cbo's beyond what the state or local health departments might be doing to promote funding opportunities. That 40% example to locals in the public health work force infrastructure grant, I'm not sure if community based organizations understand yet or are aware of opportunities that they might have to partner with their local health departments in building that future work force at the health department. I'll stop there and it looks like we have some questions teed up and Rhonda, your hand is up.

>> Yes. I agree with everything that is laid out. I think it's well done. I have a question, though. How do we get in part when we get feedback from people receiving services? Do you get what I mean? We're talking the people receive the grant, provide the service and the solution and then the local public health department that's kind of being the planter, right? Organizing it. How do we get the actual feedback from the people in the community and the public? I think if we don't intentionally either build it in a requirement, I'm concerned, right? So some of the community groups ordinarily would get feedback from the people receiving their services. I think it needs to be particularly for equity work we're calling out the need to get specific information. It's not just about whether or not a grant should be given but the effectiveness of whatever is being provided. Does that make sense to you?

>> Yes. Very good point and much more -- I'm much more familiar with how we got community feedback at the state and the local public health department levels but certainly you're right in terms of the effectiveness with how the resources are flowing to actual communities. I picked up on doctor something Dr. dauphin said. The XHUPs are the customer, right? You raised the point how cdc can gauge the effectiveness of the dollars being implement sod we'll make a point of that. Julie?

>> Yeah. I think it's great. I love the way you're diving down deeper in terms of trying to understand, get more specific about what each of these task areas is focusing in on and I saw there's an opportunity for overlap between task area one and two. You identified looking at the exemplars. I feel like Ryan white is a great example of an exemplar for funding but also in terms of community engagement because of the expectations for engaging with people with lived experience as part of decision making or allocations of resources so there is that. I think as you're looking at exemplars, I feel like that example might also be a good example for how you do community engagement that forms decision making in addition to allocations of resources. It's both. It's a great example and I think there's a lot learned from that kind of approach. In terms of how the grants are affecting them and reaching them.

>> Thank, Julie. I would welcome other examples from acd members if you're aware of them, you can share them offline with me, Daniel and David. Ryan white was the one that came immediately to mind but there may be others.

Healthy start is one example. I know when I was at the city, we did have community coalition but that's different than the community advisory board which was written into the law, right?

Into the Ryan white statute. So any other examples we would welcome those so that we can put those in the discussion.

>> I'll add this because nobody else has their hand up. The community health needs assessment, public health agencies are doing throughout the country actually do -- many of them are using community engaged approaches to hear from community directly in terms of how the public health agencies are building health improvement plans, what needs to be prioritized, what is working well, what is not and so those are models existing and some are doing it better than others.

>> Thanks, Julie.

>> OK. Thanks, Monica and Daniel. I think we'll go ahead, we've got some great input.

First off, we have a fair number of acd on the health equity work groups. We can continue to tap them and we'll continue to work with folks offline as well for this important work. I'm sensing a lot of excitement and enthusiasm about the groups so thank you very much. And we now are going to take a break. We been a little over on this. What I would like to do is give us a 30 minute break rather than 35.

We'll start up at about five after the top of the hour. This is labeled lunch break that's application for those of you on the east coast. Where I am, it's more like a breakfast break and a brunch break for others. Take 30 minutes and come back at about five after the hour for our laboratory work report.

Thank you very much.

>> Let's go ahead and remove the slides so we can see the acd members and I would like to ask acd members that are back from lunch, if you could turn your camera on so that I can see who is here. We're getting a note from Josh saying he cannot turn his camera on. Is there something that the -- it's good to know he's here but it's important to have his camera working for this presentation.

We could temporarily remove the slides so it's a full view of the acd members. Maybe not.

There we go. Thank you. Josh is there now. So I think we're getting pretty close. Daniel, Julie, Lynn, cristal, Jill, octavio, Josh and ADA. I think that gives us a quorum. Yeah.

Good. Thank you. We'll get started. Now we're going to move into the laboratory work group report and that will comprise our entirety of the afternoon session. Let me turn this over to Deb for a few remarks.

>> Great. Thanks, David. I hope everybody had a good breakfast or lunch break. Fiscal year 2022, Congress directed the secretary of health and human services to establish a Task Force that includes participation from outside stake holders and subject matter experts to evaluate what contributed to the shortcomings of the first Covid 19 task and what qualities, programs and systems should be addressed for the future. Through an agreement with hhs and Congress, advisory committee through the laboratory work group has served as a Task Force requested by Congress. cdc welcomed the in-depth review of the work group conducted of the laboratory policies, practices and systems under the direction of Jill and Josh and we look forward to hearing the presentation of their work over the past six months. I truly to want thank them as well as the cdc staff that provided a lot of time and input and lab work group for what I believe will be a comprehensive review, action steps and discussion.

>> Thank, Deb. Yes. This has been a great working group and my thanks in advance both to Josh and Jill but also the entire working group. You have the floor.

>> Great. Thank you so much, David. Jill, how are you today?

>> Thank you, Josh. Take it away. I'm well.

>> Great. So we have decided what we're going to split up the presentation and the following way. The first part I'm going to do the play by play Jill is going to do the color commentary and then reverse when we get to the recommendations. So I'll go through kind of the facts and Jill will elaborate and then a little bit vice versa. We have periods of times to pause for discussion and questions and at the end we're hoping the advisory committee will accept the report.

>> Josh, just want to add that several members of the work group are listening in.

>> That's great. And it may be possible if there are questions that relate to their expertise that we could have their input.

I want to say two things to start. Then we'll get into the outline. First is that the cdc has been remarkably open through this process. You just heard the charge from Dr. Houry and we have had just a really productive sessions with cdc throughout this process. It's very much appreciated and really reflects the spirit of like figuring out what the issues are so they can be addressed. Second thing, and you heard a little bit of this from Dr. Walensky this morning is that the cdc has taken some steps and we had a number of cdc as the work group was doing its work and I think the cdc is unquestionably moving in the direction of the recommendations that you'll hear today and we'll be more specific as we get into it. We're going to talk a little bit about the background and then the findings and then the proposed action steps. So in general, this is the purpose of the lab work group to provide advice and work products for the advisory committee of the cdc, advisory committee to the director regarding the implementation of the laboratory quality improvements. This is the all star dream team of work group members we had and we have.

Fantastic group that really gelled when it came down to cdc for a two-day meeting. We had state laboratory leaders, academic lab leaders, public health experts of different kinds and it was really extremely productive to work with them, puzzle through some issues we'll talk about.

Anything you want to add about the group?

>> No. Just say thank you. They were marvelous.

>> next slide. So this is what Dr. Houry had mentioned, that Congress requested Task Force to evaluate factors contributing to the shortcomings of the cdc first Covid 19 test as well as POECHLs, practices and systems that should be established to mitigate future issues. That's what we'll be talking about today. Next slide. So in order to get at this, the work group met with experts within the cdc and then some cases outside of the cdc. We requested and received many documents that we reviewed from the agency and we developed a report with findings and action steps that's in draft form that I believe you have. So we're going to start by telling a little bit of the background still of what we know. Going into this, this is what we knew going into this. There were known failures in the first round of the sars Covid task. In particular, there

were three well described. One is the n1 probe was contaminated by the positive control because -- and we'll get into this, because there was no actual virus that the cdr had when it was making the test, it had to manufacture the positive control to demonstrate that the test worked and that contaminated one of the probes resulting in false positive results. The n3 probe, which was a different part of the virus was poorly designed, leaving to false positive results and we'll show you that in a second and finally, the quality control detect the failures before the test was sent to public health laboratories. Next slide? So this is a table from one of the cdc's published papers showing the fact that the n1 probe was contaminated and it was known to be contaminated by what the cdc itself manufactured as the positive control because that positive control had a certain genetic signature. Anything to add on that, Jill?

>> Yes. Thank you, Josh. This table in the plus one paper just shows if you look at column where the arrow is, there were three -- the cdc looked at three lots, if you like, of the eua, the actual eua kit that was sent out, the pre-eua lot which was used in internally for their own diagnostic testing and a commercial -- a commercial lot that was manufactured outside of cdc and you can see that -- what they did was they took the false positive amplification product and sequenced it and looked for template contamination and this where the arrow is shows that 30% of the pcr products showed contamination by the positive control but only in the eua kit.

It wasn't in the pre-eua kit that was used for diagnostic testing nor was it present in commercial lot manufactured outside. So this was evidence that the n1 probe was contaminated in the kit to be sent out. I think that's it, Josh.

>> great. Just to be clear, when we refer to the eua kit, we're referring to tests that were sent to states and localities that couldn't be used and created all the problem. And so this demonstrates that n1 problem. This -- the n3 probe had a different challenge, we believe, and based on the science that cdc has put forward and that was that the probe essentially could bind to itself and create or bind in a certain way, I'll just say, that actually created a false positive result so this was about the design of the probe itself and we'll go one more slide maybe and this shows with the arrows here, finding where it says percent reads involving the probe. What it's referring to and Jill can explain better than me, it's referring to the fact there was unexpected problem with the probe being positive even when it wasn't supposed to be, believing that it was a related to the way that the probe binds upon itself and other elements in the test.

>> And just to add to that, that false positives was in the testing. E.U.A. kit sent out and the commercial lot so it was an inherent problem in design. It was not a problem of contamination.

>> Next slide. And then the third issue, all of this is just background to what we were getting into.

This was all established before we started was that there was a failure in the quality control procedure so the test was deficient as we all know and their quality control procedures that are supposed to catch that.

But turned out, first of all, incorrect procedure was used to evaluate the test kits and it was still -- that test, the inadequate, incorrect one still found some issues but when the correct procedure was performed, one of three was positive which should have been negative and 33% failure results were accepted and the test kits were not recalled. So the problem, the test having contamination and design errors and when it was done correctly, and found the problem, it didn't lead to action. This is from the cdc's own recon analysis.

>> It's good. Go ahead.

>> You good? OK. Next slide. All right. So now our lab group comes into play. Our lab work group comes into play and the question was, what was behind the failure SNZ we looked at the science we went through, no, you know, major questions. It all was very compelling but what was behind that? This gets to the systems and prophecies that led to these problems. That was really where the lab work group focused. Next slide. We really focused on four major shortcomings. We'll talk about these and then we'll pause for questions after we're done with these. First is inadequate planning, the second, ineffective governance and the third, inadequate quality control, quality assurance and regulatory oversight and poor test design processes. So pretty significant issues led to these series of problems that caused the failure of the test. Next slide. So inadequate planning.

And what we found in our document request and interviews is that there was not a plan for how the cdc could develop and scale a test in this circumstance of a pandemic, you know, rapidly so it just --

there was no such plan. There was no in case of emergency, Greek glass inside of the plan.

Instead what cdc was really relying on was something called a graduated response framework which was a document that was supposed to support responses with -- that were too big for just one office to do but too small for agency-wide activation and for really the key weeks of test development, cdc was operating under a graduated response framework. The overall incident command had not been activated. It wasn't clear what was happening with Covid so it was a less than full agency activation and there was no clear plan for how to develop a test in that circumstance. The framework that we were given really wasn't relevant to test development as much as it was their ways to organize the agency when it's in between just the normal day-to-day and the full agency activation, did not have a clear governance structure particularly for labs and it didn't have a clear explanation for how you went from a graduated response to a full cdc activation and the agency management system would take over so it was really an inadequate plan. If you go to the next slide and then I'll pause for you, Jill. Here's an example of what it means to not have a plan. The same lab had to be relied upon for both the primers and probes as well as the positive control. So it's obviously a risk when you are manufacturing positive control in the same lab you're doing the actual probes in that created a risk of contamination but the cdc felt like it had no reasonable alternative approach.

I should be clear, it's not known actually. In fact, the cdc's conclusion was that it wasn't actually in the lab where it was manufactured that the contamination occurred but nonetheless, everybody saw it as sub optimal to have to manufacture the things in the same place but there was no plan when you didn't have the virus itself and you had to manufacture the positive control and so they wound up having to do it in the same lab. Jill, do you want to add on this issue of planning?

>> No. Well, yes. I do. I think that it's important in any emergency plan to have some redundancy, some backup. So things can go wrong at any point and so this was clearly a vulnerability point, manufacturing in the same lab and so the cdc -- it would have been good in the cdc said, OK.

What alternative is there to do it here and we feel there would have been alternatives that we realize that time was of the essence here and so that certainly was a governing factor. But just ringing in the importance of redundancy. Thank you.

>> Right. We're not saying it was a wrong decision under the circumstances to produce in the same lab but it was the absence of a plan anticipating that we wouldn't just be able to wait for the virus to come to make a test. We had to do it in advance. Without that plan, there was not an alternative that the cdc had readily available. So the second major issue was ineffective governance. There were three different labs at cdc that were involved in manufacturing the tests but they were not led by someone whose job it was to oversee that whole process. That did not happen. The labs were just engaging based on their job descriptions. There was no point of coordination responsibility across these labs so if you were to say who is responsible, who is empowered to make this test the right way across all these different labs that are participating, there wasn't someone in that role. There was no clear governance like that and that's prior to the emergency, it was also true during the graduated response and even true during the incident management mobilize because one of the labs was not included as part of the structure. It was really a big gap in governance that everybody was doing their job handing it to the next lab or just doing what the other lab asked for without somebody thinking, is this a good idea? And that created the potential for additional problems. Next slide.

There's an example of this P.

There are a few examples of the consequences of ineffective governance. It caused delays in understanding the scale and cause of the test issues. There wasn't anyone who was, you know, empowered and responsible for seeing these issues across the different labs. In addition to the fact that one lab made the positive control and the probes in the same place, there was another lab which restoring the positive control near where some of the tests were and it's thought that that could have been where the contamination occurred. In addition, once problems started happening, the incident management leadership, in a crisis is really responsible for the development of the test and for everything to happen was not even made aware of the performance issues.

The flow of information was not effective so even when you had somebody who was nominally in charge of the test, they were very frustrated that they couldn't get information about what was happening and were learning about it after the fact. They did not know, for example, the test had failed the quality control step so you --

you know, it's a big challenge if you don't have a clear person responsible and when they --

even when they got to that point for at least two of the three labs, that person was not able to get the information they needed and our sense was that early understanding of the problems could have led to different decisions on development, validation and distribution if they had realized these problems and quality control, that might have changed the way they reacted instead of continuing to do different kinds of investigations trying to figure out what went wrong. It would have influenced how the investigations happened and the steps that the cdc may have taken. Anything you want to add?

>> Just the importance of having both single point of authority and very good communication.

Just emphasizing the need.

Thank, Josh. So the third major area of the causes of the causes were inadequate quality control, quality assurance and regulatory oversight. One of the challenges that cdc has is that research and clinical lab space is intermingled and that creates different risks because there's not a clear quality management system for the clinical space.

clia is a law that we'll talk about on the next slide, I believe, but it's a law that's supposed to assure quality in labs but it is really for tests that are done at the lab so it does not apply for the test made for the state and locals and cdc did not rely on its clia office for oversight so you didn't have a clear quality system coming from clia. You might wonder, what about the fda which was reviewing the specs on the test?

Failed quality control came after the cdc application to the fda. fda looks at the design issues and not so much the quality control so that also was not able to catch the problem.

The biggest overall issue is that there was not a clear quality assurance system to oversee the test development.

And one thing that I learned in this process, not being a lab specialist myself, is we talked to people in the work group who do this for a living is that having a clear quality system for a lab is like the air they breathe and really understanding what each step, you know, what a test has to do with each step to proceed through the next step for the quality system is really important and that was missing for this test. The lab level of clarity. Jill, what do you want to add on that?

>> just want to add to the first bullet, the research and clinical space were intermingled. We were also told that a scientist in the lab might be doing clinical testing in the morning and then research in the afternoon. That's too us a vulnerability, especially in emergency situations

where time is of the essence. You're moving very quickly. You really need to know what system you are working under and we worry about that and we'll deal with that --

we'll bring that up again later.

>> What system we're working under, you mean what quality system.

>> Yes. Thank you.

>> Right. So there's a different quality system for research and a very specified system for clinical and it can be challenging if it's not really clear.

>> So for those of us who are not lab people, just wanted to remind you what clia oversight is. This is a set of -- it's essentially a prodigal, set standards for training and competency of the staff, the space, the instrumentation and the protocols that are used. It really applies to quality standards for lab testing that's performed on specimens from humans. So it's a rigid and rigorous system but this is the air we breathe that Josh mentioned earlier that really does not apply to research labs and so it's important to know that this is the oversight that all clinical, hospital, commercial and public health labs in the country work under for clinical testing. Thanks, Josh.

>> And it didn't quite apply to the test that was distributed to states and localities.

>> But it would have applied to the validation of the test.

>> Yep. So during that period of graduated response, we were not able to really hear that there was a clear quality system in place. In fact, what we heard was that there was a lack of clarity around manufacturing, that the clia rules were not used as I said before, they didn't technically apply to some of this but they weren't used and what was put into place was described as a hybrid system drawing from different kinds of quality systems and was not considered to be effective. This relates, of course, to governance which had there be more clear governance, it might be possible to say, here is the quality system that is going to be used across the design of the test. Next slide. And the fourth of four topics and then we'll break for questions and poor test design processes. So typically when a new test is developed, there's sort of a series of gates that the test goes through. There are people who will review the test, make sure that it's right, it's not all on one person to make all the decisions and then put the test out. And during that process, there may be certain steps you go through, including using computer models to predict design failure. When cdc went back and used a computer model on the n3 probe, it predicted design failure. It's unclear whether that was done in the control process. The other thing that the test design process would do is specify the criteria for releasing the test at the end so when the test was released even after a failure, it indicated that something was off in the design process. So that was another fundamental cause of the more proximate failures. Like we mentioned that the test design really reflects this last issue and it reflects several of them. The n3 issue for sure because it might have been picked up and a better test design process but it also reflected the quality control step, particularly, without prespecified clear criteria for what

passing means. Want test was distributed despite one in three kits not working. Jill, anything you want to add on this?

>> No. No.

>> Next slide. Breaking for questions.

>> Thank you so much. I mean, this committee has done a fabulous job here and I have to say that, you know, reading your report was like reading a mystery story. You did an investigation and I love the way you unfolded the things that went wrong. The one thing that I wanted to kind of explore with you guys, and maybe it's just reading between the lines and I'm reading too much into it, but it's sounding to me as if some of the organizations involved, once this moved from a soft emergency to a real emergency and cdc actually had an eoc, it appears that the labs didn't necessarily feel they were working under the eoc. It appears that they felt they were still working under their normal chain of command. And I don't care -- if that's true, I don't care how you rearrange the deck chairs. In an organization like cdc, every single person needs to be trained, you know, in command structure and function and needs to understand that in the case of a major emergency that they report through that chain of command. We are reassigned, period. And it seems to me that even though they had an incident command structure that training and maybe the protocols for that happening was lacking because after all, you can't possibly foresee every test kit you might need for any emergency, right? A lot of things are going to be developed in this fashion during a crisis but if you don't have coordination from incident command, I mean, I think that's part of what happened. I'm just wondering if you would be willing to consider that. I do think it's doable and I'm kind of shocked when I read what you wrote here about the behaviors.

I'm kind of shocked by it

>> Thanks. I teach a course on crisis response that goes into management and what can be done and it's extremely important when you switch to that, everything goes to it. In the government section, that did not happen here. First of all, they didn't put all the labs under incident management that we understand and even to the extent they had labs underneath, they were not reporting up. We don't know why that was the case, why the people who are empowered didn't get the information. We did hear that people may have been like calling other people inside the structure but not necessarily informing the people who were supposed to be responsible for the lab test. So that is very much related to the governance.

>> So Josh, I know you teach this so I know you know this.

None of this happens unless it's rehearsed and drilled and, you know, it just doesn't happen.

People continue to do what they do every day. You have to do drills. This is not a huge recommendation but I think they should do it.

>> I think it would be fine to add something. This relates to the planning issue. You have to be able to -- you know, you're planning for the kind of structure that you're going to have and it needs to be specific about, you know, what is happening and then you have to be familiar with it and, you know, be comfortable actually doing it and Jill certainly helped with that. This issue you're raising is at the juncture of planning and governance and I think that it is definitely important and I think it would be fine to find a spot in the recommendations, maybe in some of the underlying tech the around planning that we would say it's important to have governance in the plan and to practice.

>> I'll beat the dead horse but I haven't seen their plan but they usually, you need to create that office, that office. They need to create a lab office that reports to the commander, right?

They just do.

>> We haven't talked about the recommendations. That's coming next. We can see where -- if there's a little tweak that would just elevate that. I think it's in there but elevate that a little more. Sorry. Jill?

>> That's OK. I just want to make the note, Lynn, that the individual who designed and developed this test is a researcher. In most institutions it would be the clinical people who are in the ims structure, not necessarying the researcher.

So I think it's, again, looking at that structure to make sure that everybody that is involved is in the structure and knows the reporting chain. But we'll see -- you'll see what we have suggested in the recommendations.

>> We can talk more about that when we look at the recommendations.

>> OK. Julie?

>> I agree that that's an important point or concept as it -- how this relates to incident command and also the office of readiness and response. So it sounds like we'll get into that more. I just wanted to thank you both because I think you did a fantastic job with this reports and your presentation in terms of making something complicated very accessible and understandable. I felt like I could read the paper and listening to you talk, I can understand what the key issues were of concern and then anxiously waiting to hear what the recommendations are but I think you did a nice job in summarizing something. It was very complicated so thank you.

>> We'll pass that on to the whole group.

It was a big group activity there. Are we ready to proceed?

>> I'm sorry. I just wanted to recognize that nirav has joined.

I'm wondering if you would declare any conflict of interest.

>> Director at sterris.

>> I know you're going to be speaking to this issue as well but some of the problems that you've identified as you mentioned in the interim have been recognized by cdc and so we should remember that. For example, current incident command structure of governance may not reflect what you just reported because of the identification.

>> Correct. And that was definitely something that I applied at the beginning and as we go through, we'll mention some things we know that the cdc has done and I should say that just to be clear, while it may read like a mystery that we're unfolding, the cdc helped us unfold this, you know. So we were learning from people at cdc who spent a lot of time thinking what went wrong to put this assessment together. This is not sort of figured out around cdc.

This is figured out by the cdc.

>> And I just want to add to that, there is absolutely no gotcha aspect to this report.

And the cdc were incredibly forth coming and honest and so the whole turn of the group was very much how can we help.

>> why don't we proceed. Jill, you're going to do the play by play.

>> OK. So the second part of the Congressional task was policies, practices and systems that should be established to address the issues going forward in the future. Next slide, please. We have ten proposed action steps and as has been mentioned before by Josh, cdc is already addressing many of these as an urgent priority and so it's really nice for us to see our recommendations in many ways overlapping and complementing what the cdc is already doing as part of the moving forward process. So let's go to the actions steps. Next slide, please. So addressing the issue of who knew what in the ims system. We believe that there should be a senior leader from the laboratories reporting to the cdc director with major responsibility and really importantly, authority for laboratories at the agency. We have suggested that this position should be a deputy director or equivalent position within the cdc organization and we've said equivalent position because we are aware that there is a lot of change around the deputy director's positions. But we want to make sure that it's close to the director of the laboratory, it has responsibility and authority and there is not a sense that the --

let me address the clinical versus research later. Do you have anything to add, Josh?

>> Yes. Yes. I think that first of all, we heard from Dr. Walensky there will now be a senior laboratory leader reporting directly to the immediate office so that's a major step for the agency in this regard. The second thing I would say is that there are a lot of issues that we didn't, you know, focus on like, you know, the difficulty scaling the test, what was the problem with the gaps and the -- all the supply chain issues, you know, big issues in testing that happened that really weren't part of the cdc making the first test but the work group felt like it would be great for the person who is the lab leader at cdc to also be related to owl of those

problems out there that what cdc is part of a lab development system for the country, not just focused on this one task of creating the first test and it's really important for cdc to fit into the system and there needs to be leadership convening people when necessary to get to the bigger issues so having someone at a very, very high level, it's both to assure, you know, quality and other things we'll get into within the agency but also for this critically important role nationally, intersecting with the private sector, with the fda and with cms and others.

>> So that this position should be both internally facing and externally facing. We also believe that cdc should consolidate key laboratory support into a new center. The center should focus on clinical laboratory quality, safety, work force training, readiness and response and manufacturing. And here I want to address the research labs because the research labs are very important in the individual centers but that at times, the -- for an emergency response, the research leaders must have a really important role to play. For instance, in lab design for a particular pathogen in test design for a particular pathogen so this should be connectivity so the center and leader are very important in that. But in the center, it should be all about quality, safety and all the other lab based issues.

Josh?

>> Just to say that again, Dr. Walensky talked about the office of laboratory, olss, safety and system and that, I think -- and she talked about pulling in different functions from across the agency into that office and so this is definitely responsive to this idea that labs are fundamental aspect of what cdc does and it's really important for there to be an office that's empowered around the core issues to make sure that people have the right training, right quality in place, labs are safe and just having that be a distributed responsibility is not successful for the agency.

>> And really, I'm not saying this with sort of -- because I'm a lab person. The lab needs to be at the table in importance decision making and I think it hasn't been in the past. So leadership and management. cdc should create plans for developing tests for novel public health challenges that include the governance structure to be utilized in an emergency.

In many ways, as a public health national system, we need to be thinking ahead and creating tests for pathogens that have a good chance of a clinical ends commercial partners but when an emergency hits, you must have a much more defined and rigid protocol of the governance structure so everybody understands what needs to be done and who needs to be told and so the plan for the developing test should be part of that plan for an emergency.

Josh?

>> I would just say this reflects a little bit to create an exercise plan, something like that, would be a consistent with what's in the text of the recommendation. The interesting thing here is that it took awhile to activate the full incident management and a lot of problems that led to the three areas happened before like the origins were before the full agency activation. It's clear it goes from the moment the test starts being developed and not start at the point of the

full-on agency response. So this one, we talked before about the fact that there are clinical labs at cdc that do testing.

There are labs that do surveillance and there are labs that are basic research and those are all necessary but they have a different mission and a different oversight system. One would not want to put the rigid regulation of clinical testing which is incredibly necessary on a research lab where you want to support innovation and creativity and allow the research leader to change the protocol when it's necessary to get answers that they need. But we too feel that while there has to be cross center collaboration with epidemiologists and basic research scientists that there should be a strict separation of lab space and staff between clinical labs and basic research labs. This, I think, will present cdc with some logistic challenges but I think that they are addressable so we as a group feel that this is a very important action step. Josh?

>> Just to say that right now or prethe latest changes, I believe, that the cdc has announced, there are a lot of labs at the team level within the cdc and the way I thought about this was that if you took the highest person in the hierarchy for each lab who is a lab person, you said I want all the lab directors who don't report to somebody who knows as a lab specialist and put them all in a room because we're going to announce a new policy, there would well be over 100 people in the room which is a very difficult thing to manage if you're a lab organization, that lab is central to what the organization does. If you were to go to branch level, which I think is the direction that the cdc is moving, it's in the ballpark of 30 people in the room. If you were to go to division level, it would be a handful of people in the room but the idea is that the --

there should be a relatively small number, smaller number of people who can really implement changes that are necessary or policies that are necessary or be responsible for all the different things that labs are supposed to do, having it be so distributed and decentralized creates a weakness because you can have -- give 105 lab directors and 104 of them are doing well, you could have a big problem. It's just very helpful to have fewer people, you can hire more senior people to do the job, you can have whole systems behind them and you don't have to have an a in every single one of 100. You only have to do it right fewer times. This is the concept behind consolidating in a particular hierarchy. Other advantage that we heard from the discussion is that from an hr perspective, if you're in a lab that is at the team level, you can move around in that lab but if you want to be promoted, you have to find another lab. So people are jumping across the organizational chart there were more of a lab structure within different parts of cdc, then people could stay and just be promoted in the structure of the particular branch or division and that would create more continuity over time. Just a work force issue, too.

>> thank you. That was important to bring up about the promotion.

Action step number five, please.

Next slide, please. So work force. There's been a lot of discussion about work force on the ocd call and today and it's a huge issue in labs as well as in other parts of public health departments.

And we believe that cdc should take a much -- very much leadership course in creating and training a robust work force for clinical labs.

They are doing an amazing job in fellowships and internships but we also feel that they would be -- it would be very good if the cdc in association with the regional hospitals who develop a program for training of laboratory directors. And we think that this is a very important role that cdc should play.

>> I would just add that we may want to add like robust comment divorce work force. The discussion behind this recommendation also talked about the need for diversifying the work force in different ways, based -- and using different creative training programs to accomplish that goal.

>> Next slide, please. So this comes down to quality and it feels like to the team that cdc did not have a comprehensive, clinical laboratory quality management system across the whole agency. There are certainly clear regulated labs within cdc but it's not embedded in the culture. I know that Dr. perkel has done a tremendous amount of work towards this approach but we feel that it's something that really needs to be prioritized and valued. Josh?

>> I think the -- this is very much in line that the position that Dr. perkel has taken since he's been engaged. The idea in part is that there are clinical lab quality management systems that could be implemented across the clinical labs. cdc did not necessarily have to invent one for the cdc labs but needs to implement it. It's like that part of cdc that's doing clinical rise testing should rise to the standards of the clinical labs across the board.

There are a few ways to do that but if you're working in the lab, everyone should know that there's a very clear quality system that you're being held to and that will again -- generate a quality. It's a reason the group felt to separate the labs.

If you're in the same place not following the protocols and following the protocols, it's not the same.

>> It's all right. It's late at night. I can just use this instrument. It just creates a system where you can cut corners and that's just not something we need to encourage or tolerate.

Break. Any questions?

>> thank you so much for this great report and lots of really great recommendations. I did notice the word culture once and it's related to quality but are there other things that you noticed in your review, certainly there's incredible people doing great work across the cdc, but are there other cultural aspects that might warrant a light shined on them at this point? Beyond the structural changes, ultimately culture has to be defined differently. I'm wondering if you have thoughts.

>> Can I jump in first, Josh? I think the staff was demoralized and I can understand why.

They've been working incredibly hard for over two years and having bricks thrown at them.

And, you know, public health is really interesting. Public health works when nobody knows about it and then when something happens and something goes wrong, everybody knows about it.

So it's a bit -- it's an interesting culture to work in but I do think that whatever cdc does in pairing the scientists is really important because they are the best. Really, they are.

Josh?

>> I don't think I would add anything to that. I think the cultural quality part really came out that it's a really fundamental expectation and that was -- you know, when there's confusion about that or isn't really -- people don't feel like this is what you have to do, this is the way we do things, then you can wind up with different challenges you don't want. I think that the ability to get to that culture is really partly the reason for some of the structural recommend ages.

You know, having -- one of the issues that comes up is if you're a lab that you report to somebody who is not a lab scientist and just a team and, you know, that they have a lot of competing demands on them and don't really appreciate, you know, all the intricacies of what learn lab STRUSHGs are, it's difficult to maintain that culture so partly the structural reorganization that we're suggesting and that the agency is actually pursuing is to try to line up the organization with the more support for that kind of culture.

>> can I just add one other thing, too? I think it's important that the cdc staff understand or get the message from the cdc leaders that public health is as important as research. You know, at the moment the promotion system is built on papers and academics sort of aspects but there are leadership tracks in public health which I think should be evaluated as approaches to promotion and advancement and I don't think that that currently exists in cdc.

>> In the labs as much, right?

This is partly the issue of the fact when you have so many teams at a lower level, in the hierarchy it's harder for people to be promoted on the basis of running a great lab.

>> Lynn?

>> Yeah. I agreed with nirav. I think the culture is an issue.

When you have a culture and people working in SIEL OEZ just creating different silos doesn't necessarily fix that. And one thing that I found to be a bit dealt with, not only do we need to have people who are doing lab work, working together across silos, we need to have people doing lab work, working together with epidemiologists, program managers and others. You create new STRUSHGs in an organization that works in a siloed fashion.

You don't necessarily make the organization work better. This is a lived experience that I have with reorganizations, period. And I think to think that a reorganization will repair the culture is an illusion. It does not. It does not. You know, a couple of things that I would say to the recommendations, I think there's a lot of very strong shoulds in the recommendations that I'm questioning. I'm going to be frank. Should the leader report to the cdc director. Well, everybody wants whatever they care about, they want somebody who is a direct report to rrochelle. How many direct reports can she manage? Will that person actually have a strong voice if they're one of 20 people who directly report to her? I think what you're looking for is not the structure, the process. You're looking for an outcome which is the person that's placed, you know, in a high enough level and that that person can influence policy, the flow of resources, the work with the external community and allow the cdc a little more flexibility than you get with a should statement. Do we tell the secretary of health and human services that this is the only way that the cdc can do this?

Not with the outcome you're looking for but is this the only way to Ahieve that outcome?

That's the thing that everybody thinks. I would also say, and I think you already touched on some of this, that definitely the issues that you're raising about centralizing around some of the key support functions like laboratory quality, safety work force, you know, training or readiness response, manufacturing, that is really critical and whether it's a clia lab function or not, you want the labs to be safe and function well. It could be just as important, by the way, if it's a lab doing epidemiology, not clinical work but epidemiology if they're coming up with the wrong answer, say, about what's the prevalence of lead exposure or something, that could have profound implications as well so I think that is really an important recommendation and I would think about adding to that, and it kind of gets into the next area, you want the research to be somehow feeding into the -- either the clinical lab work or the work that supports the epidemiology and it's not clear to me they have a strong what I would call translational process for translating from the bench and what the researchers are developing to something that can become a clia test or that's validated for the use in epidemiology, you know, like who makes that determination. So I just wanted to kind of raise that because I think that's part of what happens here. The piece that -- so that whole issue of separation of the research from the clia function, I get that because, you know, that's also part of my experience. At the same time, though, there's a should statement here, separation of space and staff.

I'm not sure I can agree with that strong of a statement that in might be things that are extremely specialized that are going on in the clinical lab space and in the research space where you might not want all the staff to be separated. You know, where there's just a handful of BHEEM have the knowledge and skills to be able to do certain things and again, it's just --

it just gets back to the way that this is stated. I know what you're looking for is an outcome but I think it could be interpreted to mean you can't have a single person who, you know, both walks into a research space and walk INTUZ -- walks into a clinical space and when you're doing that transitional work of taking the work from the bench into the clia lab, you might need the

researcher in the lab to help make that happen, even though that's not where they generally work. I enthusiast think that the agency -- I'm worried about people who don't know science reading some of this and thinking, OK. That's a line you have to draw. You must not do x ever. I think the rest of this, I mean, certainly the work force issues, the lab quality issues, the culture around that. It's been a long term issue for the cdc and frankly, for some of the other agencies as well. The need to bring in the external experts definitely. The only other thing I wanted to say is that it feels to me that a lot of this is focused on the exclusively infectious disease laboratory processes and remember there are clinical labs and environmental health in other areas like lead testing that we could have huge national emergencies, heaven forbid, around radiation exposures, chemical weapons, things other than pathogens, things other than pandemic that might need to trigger similar kinds of lab responses and I take what you say about, you know, it would be good to have all the labs in one place and fluidity but actually, cdc has a lot of labs that are not co--located, in different places and they're not going to be able to collocate them. They need to manage around that, too.

Realistically there's only a certain amount of consolidation and only a certain amount of mobility. If you work on malaria and that's what you do, you're unlikely to become a radiation lab expert and be able to qualify for a job although a radiation lab. Maybe it's in the transmittal of this to hhs to make it clear that, you know, we're more interested in the outcome than that there's an exact process they have to do to get there. Thank you. Sorry.

>> Thank. Why don't we take Dr. Admora's question and then go back.

>> Thank you. First I wanted to say thank you. I thought this was a wonderful reported. It was fascinating to read. And I really appreciated seeing all those details. I have a -- my question, and this is probably not an born question but I'll ask it any way. I wonder how much of what happened was at least part due to what appeared to be the extraordinary chaos at the very top, not only the top of the cdc but at the highest levels of government which to me, I'm not a lab person but could only observe to further demoralize and confuse people. I like these recommendations because they seem -- you know, they seem to fix a lot of things that you and your careful assessment and the cdc itself felt went wrong but that chaos could easily happen again in the future. In fact, it probably will depending on the elections of the next few years. And is there a way to make the cdc response more bold? I wonder actually -- I actually agree with everything in the report but a question I have is, it is good for the person to report to the director but to the extent that the director comes under attack for whatever reason, what effect do you -- what effect do you think that will have on lab performance? And maybe I'm way off base in terms of this and my assessment of things may not be correct but I'm just curious about what your thoughts are. I really just have this sense that there appear to have been chaos and I can't imagine how that did not impact the performance and the systems.

>> Jill, did you want to jump in?

>> In terms of the reporting to the director, from my perspective, and being a director of a lab much less complex than cdc, it's important that the director know what's going on, what the challenges are, what the pitfalls are, what is working, what's not. The director must have that knowledge. Ultimately that's where the butt stops. Was there chaos outside? Absolutely.

Although I think that the chaos was much more obvious a little later. I guess I don't think that the White House probably was even aware of what the cdc was doing would be my judgment at that very early stage. I think at that very early stage, administration was saying -- was sort of downplaying the problem.

So I can't -- maybe I'm wrong but I feel that cdc was doing what it was supposed to do early on, not that much influenced by chaos. Having said that, being in public health emergencies in a public health lab, there's a lot of tension. You know, people are working long hours, they're tired but it's the communication that -- and the reporting structure that mitigates the chaos, controls the chaos.

>> So thank you. There was a report recently released by the science committee at the house of representatives in December that really talked about the relationship, for example, between the White House and the cdc in great detail. Tremendous detail.

And all the different things that happened with mmwr and different components. I think our sense is that these were failures at cdc. You know, not having a plan, did not have any governance structure. We focused by kind of the four corners of this report on cdc. That's not to say that there weren't major issues that were inhibiting the overall response. I think we really stuck to what can cdc do better. And --

>> I agree with that. Thank you for that. I was just curious about your opinion about how it could have affected -- but yeah.

Focusing on cdc given your task, quite appropriate. Thank you.

>> And I think also, ADA, working on the clear gives you a structure. You know how to do things. You know how to follow a protocol and so from the clinical side of things, that's -- almost like a shield. This is what you need to do. This is how to validate. This is the past/fail criteria and that's actually very helpful to the clinical labs.

>> Let me move back to Dr. Goldman's questions. I think we can bring in lab work members to address some things you're saying. Just to go through, the issue of how consolidated. We consider the recommendation to consider all the labs under one structure and decided not to do it. Now you have a very decentralized system. cdc is given flexibility. It says that, you know, ideally at the division level but maybe a different level depending on which one you think is the right one. There are geographic distributions of the labs and, you know, there should be more than one person M the room but the smallest number of people who allow you to effectively manage the lab is something for the cdc to figure out. I think it's worth talking about each of the things. There's some flexibility in the discussion of the senior laboratory leader because it

does say at the end of the recommendation, you know, whatever structure the cdc feels best to accomplish this. I would just point out that the cdc has done.

This they've created a lab position that reports to the office of the director and we think for very good reason. This is such a neglected area of the cdc's, you know, governance structure overall that it is really important. I'm sure 20 other groups would make that case. And cdc, I think, has heard that and agreed. The issue about laboratories beyond infectious disease laboratories, this does talk about multiple places laboratories beyond infectious disease and recognizes specifically that the next one could be different and for workplace safety is for all labs so I think we want this to read like it's about laboratories generally, clinical labs particularly. No matter whether it's an infectious disease or different kind of clinical lab because you don't want to have gone through a huge assessment and plan for one challenge and suddenly, it's another lab issue that has popped up because you haven't thought about that. I do think that it is clear enough but if there are other areas that you think need to be more clear, we should look at that. The issue about learning how to translate research better is not something that we really focused on in the report. We respect research but also see the function of the lab as a clinical lab and there may be a set of recommend AGSZ for how to better translate research over but I don't think it's so much -- it was not part of why we felt the fest failed. This was a clinical quality issue and governance issue. That's the reason why you don't see a whole section on that aspect of this.

It would probably require us to go all the way back and think about, you know, what research France -- translation could look like. The last one is the --

something that we should bring in a couple of other people into the conversation on has to do with the separation of clinical and research lab space and functions and the lab work group had a number of people who work in very high tech lab situations where there is research going on around them and thought about this particular recommendation quite a lot and it may be worthwhile to have a couple of people chime in. I don't know if Daniel is here.

>> Daniel, Angie?

>> Angie and Denise, if you all could turn on. Anything you want to add to that?

>> Sure. I could add commentary around the discussion. I work at Cleveland clinic and I'm a physician and I oversee the diagnostic laboratory here and I also work with the team that does research, clinical research and those two teams are mostly separate in their function here.

I think from our visit with the cdc, it seems to me with my limited interaction with the cdc that there's a strong priority, a strong culture around research and I think that's important and that's great. But at the time when Covid emerged, it seems to me that the clinical labs, the clinical testing was rolled up essentially inside the research laboratories and this is, in my opinion, if it remains that way, there's always going to be tension and different priorities and if research is a priority, then clinical diagnostic laboratory testing potentially is less of a priority. There's a lot of

-- as you know, there's a lot of clia regulations, proficiency testing and when scientists in the morning are doing research and in the afternoon working in the clinical environment, it's going to be hard to do that successfully and I feel like we saw an unsuccessful attempt with the emergence of sars cov2. I still feel that breaking out those focused on diagnostic testing into their own group where that is the only priority for that group and where they've put all their effort, I think it could lead to better outcomes in the future.

>> But Daniel, I thought you just said that you do that, that you work in the research setting and then you work in the clinical setting. So it would be straight separation of space and staff and at cdc, you would be called staff. I just want to want to be clear. You're saying they can't do what you do.

>> No. I was talking about -- I was thinking about, maybe I didn't say it clearly, the people doing the work on the bench day in and day out. The people doing the testing, manipulating the samples, you know, signing off that they're confident in doing the testing.

I think it's good that the people on the bench can focus either on research or on testing. Now, will it be like that 100% of the time every time? Probably not. And like you said, there's good -- a the of these eyeally translate from research to the clinical lab so there should be good handoff between those doing the early development to those who are VAP I haddating it and using it on clinical testing.

>> I want to see if Dr. caliendo wants to talk about this at all.

>> Yes. I'm currently vice chair of medicine at brown but prior to that I spent about 20 years in clinical laboratory and directing clinical labs and it's interesting the point, Lynn, you bring up because I initially had my research lab embedded in the clinical laboratory and it did not go well. And what I ended up doing is pulling and operating out my research lab and getting my research lab clia certified.

The reason that was done is you need a culture of quality even in research. I was doing testing for clinical trials and so we kind of came to this conclusion that the best cased scenario would be separation so that people that are doing clinical testing are focusing on the quality program around clinical testing. And then researchers need more flexibility. If there are, and you gave a scenario of something that's so specialized that you cannot separate the clinical from the research, then you're going to have to have your researchers live in a clia environment. And that is very different than what exists now at the cdc. What we saw was --

and I think it led us to say that the person overseeing all the laboratories reports directly to the director because it gets at the question someone raised earlier about culture and the culture at the cdc has a different hierarchy for research labs here and clinical labs are here. We need to elevate that culture of the clinical labs and that praises them and makes them different from research labs so there may be situations where you can't have full separation.

In that case you need to default to the higher level of quality oversight.

>> In a way you're saying the staff separation is intended to be the laboratory technicians basically more than the -- and second of all, that the separation has to be that if there is an overlap that the quality standard, like a significant overlap between research and clinical, the quality standard that should be adopted is a clinical standard.

SFWLA that goes not just for the technologist at that point but the director of the lab. If you're going to do clinical lab testing, then that person needs to be trained.

>> Where overlap is inevitable, it should be at the clinic. I want to say if Dr. Tonyments to jump in with anything.

>> I'm den ice Tony. I'm the DABT director for Virginia state public health laboratory and we are a clia accredited laboratory. I did want to make a couple of comments. The comment about when a test is moved into a clinical diagnostic lab there may be a need for input into the researcher. I feel as if a test is properly Valitiated and robust enough to move into the clinical diagnostic sector, that lab should be able to run that test without the need for input from that researcher because if you still need input, it's not ready for clinical management testing. It should be able to be quickly validated or verified and then be put into action, especially if we're dealing with an emergency. Then along the lines of clia and having this strong quality measurement system, we have research functions and then separate diagnostic functions and for those diagnostic if you thinks and for the laboratories to operate seamlessly, there needs to be structure and repetition and consistency and those are essential to maintaining all the compliance factors that you need for quality. And especially when the system is stressed, that's when that training and consistency is so important because if you are teetering back and forth between a research mindset and a quality diagnostic mindset and you're tired and stressed and there's lots of pressure, that's when you're going to make missakesmistakes.

That separation is really important and is the best practice if we want to ensure success and accuracy of the work that comes out of our laboratories.

>> thank you very much for the laboratory workers that have joined us. This has been a really productive discussion F.

You're willing, I would like to ask we move forward to complete the recommendations. I'm watching the clock a little bit here. We have a bit more discussion. I want to make sure we get through.

>> Great. I think we probably hit the most challenging parts of the recommendation but this is great and why don't we proceed.

>> Could we have the slides back up, please? So action step seven. So Josh put up before the fact that we need a national laboratory system and cdc, I think up to this point, has seen itself as free standing and connected but not part of the national system and I think that the pandemic has shown us that one entity can't do anything.

cdc and public health has a role, commercial and academic labs have a role, manufacturers have a role and we need a conversation national well a national lab system with cdc at its center. And that means that cdc needs to be much more outward facing and involved in external experts in the review and deployment for pathogens with pandemic potential. I think it changed in focus for this cdc to be much more outward looking and to involve external outlets.

Josh?

>> Keep going. That's good.

>> Next slide, please. One of the problems that we feel was very crucial for the failure of this test is that there was no redundancy. cdc was developing the test and the external labs, public health, academic, commercial were not taking a role and certainly in New York, we had delayed validating our own test because we knew the cdc was developing the test. This is the way it's been but I think going forward, we need much more redundancy and the initial stage of a pandemic not just public health but certainly academic and commercial labs should be involved in test development so that you've got multiple versions of the test available in the nation to -- if one institute goes down, one test fails that you have more redid you understand AEBS -- redid you understand -- redundancy.

There's a whole load on cdc and in many ways, it's sort of the reference lab of all reference labs in the country. But there are many -- a number of very competent, high complexity labs around the country who have the ability to test for rare agents.

cdc has recently funded centers of excellence that are a collaboration between public health labs and academia and the work group feels that using that model to develop centers of excellence in -- for diagnosis of other red pathogens would be of value. The next slide is the last action step. This talks about the data issue. I think everyone is totalalal -- totally aware that data transmission and data information, the system is incredibly complex and so the work group felt that it was not possible for us to do a huge analysis of where the country was. There's other entities doing that. One thing that we feel and that cdc certainly can take the leadership on with public health labs and other clinical and commercial labs is looking at standardization of health data collection and use of determining the data set and we think that the cdc should take the lead here but VOVRL --

but involve partners in there.

That's already happening with the cdc and csge and not only for the case to reports but for permission to perform a test. So that's something that we feel quite strongly. I think that's our last one and the next slide should say discussion. Any other additions there? Any other questions?

>> Let me add for the last one, we had a little engagement with the data work group, very consistent with what Julie was presenting earlier today.

>> Yes.

>> Julie?

>> Yeah. Thank you so much for the presentation. I just was flipping through the report that you shared with us and I was so pleased to see in your first recommendation that there is inclusion of -- that the director or that person reporting to the director has the responsibility and authority to require of laboratories these things and I think that's really important. That was the heart of my question with Dr. Walensky where the offices are centered.

They need to have the authority and responsibility to make sure the things happen so I was really pleased that you called that out explicitly so thank you for doing that.

>> And Julie, I read so the other Dr. shah, there's two Dr. Wonderful shahs and the one from Maine is joining as deputy director and I believe that Dr. Walensky has given him the task of taking the lead on lab issues and so I'm really excited by that.

>> Incredible presentation and great questions. I would like to move towards a vote to accept the report of the committee.

First off, we checked and it's very appropriate for the committee to approve the report and if there are a couple of issues around fine word Smithing or issues that could be added in the letter of transmittal, that could be after the fact. I want to give you a moment to reflect on the discussion we've had and if there are a couple of areas that you might want to add a few words, for example, to some of the flexibility, culture, et cetera. I did also want to give the floor to a moment for Deb to give a little cdc's perspective on this and the discussion that we've had. So over to you, Deb.

>> Great. Thanks so much and again, Josh, Jill, lab work group, really, really appreciate the depth and breadth of the report and the recommendations.

As I was listening, a few things that I was reflecting on. These issues happened three years ago and I think it was Jill or someone else that mentioned, these are long standing issues but we've not been waiting to address them since they've come to light and you've highlighted a lot of progress we've made.

Something that's been a top priority for Dr. Walensky. I did want to highlight we realize that moving boxes doesn't solve things and that's why we have the whole cdc moving forward.

That includes 21 priority action teams that also looks at the systems, processes, how do we change culture and we've EN changed that at all levels to empower our scientists, our practitioners to be engaged in this and another thing we've done is we have a response ready work force so that we are ready for the next response and all staff are poised and ready to join responses, only revisited things like the graduated framework as well for responses so that the programs, central agencies, we're prepared to stand things up and we're piloting it and looking to have it agency wide under the leadership of Dr. perkel and I did want to thank all our staff for

-- our lab staff and also the staff that worked tirelessly 24/7 during the response and have kept all the other programs at cdc going on. You mentioned morale. We have a resilient, amazing group of staff and scientists, practitioners that I'm so proud to be shoulder to shoulder with and I do just want to thank them as well. The one piece of house keeping I'll say while I have the floor is as you review the work group report and vote if approved, then the report will be transmitted to hhs and that takes about 30 days to review and respond from hhs.

That will then be published to the website so for folks that are tuning in or work group members that want to revisit it or share, it will be about six weeks before the report will be publicly available on our website. Thanks, David.

>> Thanks. That's great. Let's now begin the process of moving forward to a vote. Josh, I wonder if you could make a motion for adopting this report and translating the action steps to recommendations. If you see a couple of areas where you might want to do a little word Smithing. ocatvio, you have your hand raised.

>> Sorry. I want a clarification on some of the guidelines referring to Josh and Jill so I'm clear. It was such a robust discussion, in two themes that came out to me were -- one was really an organizational cultural laboratory behavior and the other one was -- and I appreciated Lynn's incite into the discussion followed, recommendations themselves. It would be nice if those two issues, even if a few sentences were addressed or WHAK you said, it could be after the fact. How is the discussion going to be incorporated? Maybe that's a Jill and Josh question.

>> So I have a little list that I would suggest that would be sort of for that -- those adjustments to the report based on this conversation and also based on a comment that you sent us beforehand which is just -- I should just mention also to point out -- so I've got, I think, six items on my list. I could go down them real fast.

>> Yes.

>> One, octavio, you made the point when we have a senior lab leader who is going to engage in other senior agencies that part of the remitt include the supply chain, at least cdc's engagement in the supply change. We would just add that to the text around there. That's number one. Number two was, when we discuss plans to talk about exercising the plans, number three was just to add a robust, diverse work force for the lab. Number four was to modify the language around the strict separation between research to be more clear about what we mean. That would be that we would discourage the use of technicians who would work in both -- in research space that is not being held to clinical standard and a clinical space that is held to a clinical SDPARND that the spaces should be different. If they are two different quality systems, it should be two different spaces.

And then the last one would be related which would be that when -- if there was an inevitable need to have a shared research and clinical space that it should be held to a clinical standard of quality protocols.

Those would be the changes to adjust with what I thought was a great discussion.

>> Absolutal GREE. Thank you, Josh. Let's go ahead if one of you would want to make the motion, we'll have an opportunity for final discussion just to get the motion on the table.

>> I'll move the report.

>> Any adoption of the action steps as recommendations?

>> And the adoption of the action steps as recommendations of the acd.

>> Is there a second? I see Julie seconded. Thank you. Any further discussion at this point?

>> Dr. Gold MON looks like she may have frozen mid point.

Reaching for the mouse perhaps.

>> I'm sure that she would understand. We can connect with her afterwards. Listening to her comments, which were great, I think that you've incorporated them and if we missed any, we could hear. Let's take a vote.

All those in favor of the motion of adopting the report and making the action steps proposed as official recommendations from the acd signify by raising your hand or saying aye.

>> aye.

>> Are there any opposed? Any abstentions? Fantastic. The report is adopted unanimously with the adjustments that will be made after the fact by Josh and Jill according to what we just talked B. Thanks very much to the acd and most importantly, my goodness, thank you to the laboratory working group and our fantastic co-chairs for taking this very, very difficult job and really creating a clear and succinct report that will make a big difference to public health in the future. Thank you very much for that. Virtual round of applause.

>> Thank you and thanks to you, David, for your guidance throughout the whole process and a special thanks to Dr. Houry for really organizing so much to make this all possible and really cdc for its critical work and unquestionable movement in the right direction on this critical issue.

>> I think what we learned helps us all as an organization. So thank you very much.

>> I have a profound sense every accomplishment not just for the session we've just had but all the sessions today. Really, really appreciate the work starting with Dr. Walensky and her update and the insights she's brought to cdc is quite remarkable and Dr. dauphin of her review of the incredible new center that's being created and the laboratory -- the public health work force initiative that's going to make a big difference. And then special thanks, really, to each of our working groups and our co-chairs. Julie and nirav and looking forward to the next couple of meetings when you have done some work on the issues today and Daniel and Monica, including the approval of the task area and the exciting work you're doing. And then Jill and Josh and the

work that you've presented today and the good news for the committee and for cdc is that that was only one terms of reference for the laboratory group.

>> We'll be back.

>> You will be back. So thanks to all of you. I'm going to in a moment give you, Deb, the last word for the meeting today but I do want to express my personal appreciation in addition to the acd members to the incredible staff that we have at cdc that have been working tirelessly behind-the-scenes who like to make all of what you've heard today happen as well as seamless mechanics of the meeting today and special thanks to Deb who has stepped in for John and just incredible way, a huge difference already and is just a real asset to the committee's work moving forward. So thank you very much and I'm seeing Lynn put a note in the chat that she did get bounced off but she votes emphatic yes on the report. We'll add that to the official vote total. Over to you, Deb, for any last words.

>> I want to echo what David said and really thank all the work groups. I personally am really excited for the action steps and recommendations that have come from today's really robust discussions and what I've seen the past year with the acd being constituted, it's been really great to have all these external experts with your opinions on -- and advice and expertise on health equity, data as well as certainly lab and really, when we presented our responses, talked about communications, hearing from you where we can continue to do better as well as also appreciate what we do and our staff really appreciates hearing from all of you but it's been an honor and pleasure to work with all of you and I'm excited to see you in person in may.

>> I think that date is February -- is may 9. We'll be getting back to you with specifics of that meeting. Thanks, Deb.

Thanks to everybody. And with that, we're officially adjourned.