- >>Thank you so much. It's an honor to be here. I'm Josh. Professor the practice and policy management John Hopkins school a public health O. I'm also vice dean for public health practice and community engagement. I worked fell, trait and local level in my career as health commissioner of Baltimore city. The health secretary for state of Maryland and print pal deputy commissioner U.S. food and drug administration. I'm also a pediatrician by training.
- >> Great. Thanks so much Josh wonderful, wonderful to have you here. So, our first order of business is to do roll call and conflict of interest disclosure. I will start I'm here today and I have no conflicts of interest. Next were you able to join yet in
- >> Yes. I'm. Do you see my zoom background I this see?
- >> We do. It's perfect.
- >> All right. I'm sorry my apologies for being late. My conflicts I received personal funds and research funds from both Gilead and Merck.
- >> Thanks so much. Dr. Albert I believe on clinical service this week so will be unable to attend today. Dr. Dawes
- >> Good morning. No conflicts to report. Good morning, Daniel. Ms. Gary.
- >> Good morning. Sorry about that getting off mute. Crystal Gary, I have no conflicts to report.
- >> Great. Thank you. Dr. Goldman.
- >> The good morning. I'm sorry that I'm not on camera. I have no conflicts to report. Thank you.
- >> Thanks. Dr. Hard man
- >> Dr. A Rachel hard man. I have no conflicts to report. Thank you.
- >> Good morning. Dr. Ing Martinez.
- >> The good morning, David and welcome to our new member Joshua. No conflicts to report.
- >> Thanks.
- >> Dr. Meadows.
- >> Good morning I'm Dr. Rhonda meadows, I have no conflicts.
- >> Good morning. And Dr. More Rita.
- >> Good morning I'm Julie more Rita I have no conflicts to report.
- >> Good to see you this morning Julie.
- >> Dr. Sack is this week so will be unable to attend the meeting. Dr. Shaw.
- >> Hi there Nirav Shah, I have conflicts to report as director of and I'm board of kin is a.
- >> Thanks Dr. Shaw. And Dr. Conflicts of interest P?
- >> I'm not sure whether these counts I will say it anyway ado some consultancy for sacks policy group based out of New York really with large health care systems on population health issues.
- >> Great. Thanks so much. Dr. Taylor.
- >> Jill Taylor, no conflicts to report.
- >> Good morning, Jill. Ms. Valdez
- >> No conflicts to report.
- >> Good morning, Monica. And thanks everyone. Good news is that were well over our quorum for the meeting, and we can proceed. All right.
- >> Excuse me David I should probably also report on the board of directors for the infectious disease society of America.
- >> Perfect
- >> I don't think that's a conflict but just letting you know.
- >> Thanks so much. Just a housekeeping reminder for members, during Q&A session if you wouldn't mind keep your video on so folks watching can see. Use your raise hand feature which will relet me know you want to make comment then I can call on you. So, we have a lot of important stuff on our agenda today. Including action on formation of three working groups. So, I'm going to just dive right into agenda. And speaking of important stuff, boy, our first agenda item as of last meeting we wanted to start off today with an update by director of CDC Dr. Walensky. Doctor Walensky thank you so much for spending time welcome and we really look forward to presentation ask discussion
- >> Thank you so much. Dr. Fleming. Good morning, everyone it great to be back with you today I'm really excited for another robust day of discussions. Your last meeting was full of insight and engagement I really can't see what this one brings. So, while we are once again as you mentioned David meeting virtually, I do look forward time we can meet in person and I'm quite hopeful as it sounds like

you are as well that might be for our next meeting. So, I will look forward to that. I know I've expressed my gratitude for all of you before, but I feel like I should do so again. I remain so appreciative that each of you in committed to sharing your collective expertise with us here at C dryment. Again, I extend my gratitude to our newest advisory committee member Dr. Josh. Really delighted to have Josh joining us for a group of advisors to me. As you all know, we reestablished advisory committee to be recognize how important it is to have a group of knowledgeable experts on a very broad range of topics. We want and need your input on our current activities and your feedback on how we can optimize or impact. As we thought about where we could most use u I don't your help we identified three critical areas for how we function at CDC. Equity, data, and laboratory quality. And understanding you've already established working group on equity and later today you will vote on whether to establish the work groups on data modernization and a. We know there are more questions and more areas to consider as we continue our work together and I'm grateful for you sharing these important priorities with us. I could not be more excited about the noteworthy group of people who have agreed to be part of the ACD health equity work group. First as an indication of collective commitment I find it truly remarkable actually that nine out of the 15 of ACD members chose to actually will do double duty to be part of this work group. So truly thank you. And many thanks to Monica and Daniel for taking on the role of co-chairs of this important work group. And then it was truly incredible that the notice of federal register brought a staunching number of applicants given the really quite short deadline. We received 109 applications and each of those applications and applicants would have been a stellar addition to our work group. Ten people selected for the work group do the work of health equity every single day. Work workgroup tribes' people with uncertain housing people with a disabilities working with a youth of our country and bringing health services to those underserved just to touch oh few examples of experience that being brought towards -- the list is impressive and testimony to the recognition of the need for this conversation. I believe that many of work groups are actually listening today and I'm A.R.aw,d what you already do bring to the table. So, thank you very much very much again tore a sharing I don't skills your commitment your expertise and your professional experience. And especially I want to thank you for bringing your passion to this work. I have heard great reports from your first meeting looking forward to what will happen in months to come. Also, to your vote later on whether to form the work groups on laboratories as well on data modernization. Of course, these are not only areas that receiving attention. The lessons learned from COVID-19 pandemic along watt feedback I've received inside and outside of the agency over the past year and made it very clear to time to take back and a take step back and strategically position CDC to support the future of public health. As we enter a different phase of the pandemic, with an eye towards future health threats we're looking for advice from inside the agency on how best to transition much of our Covid-19 program mattic and scientific response activities from the centralized incident management structure to the agencies to that end I've asked Dr. Barbara ma honor incident manager to work with senior leaders across the agency to develop a transition plan to align our Covid-19 activities with our agency functions. We except to make this transition in June when Dr. Ian Williams will take over the COVID-19 incident manager. I'm dliektd to know that Barbara will join later in this meeting to talk more about what is happening and to update you on the state of the pandemic. In fission to looking at the pandemic response specifically I have also asked Jim McCray a senior long-time leader from the health services resources and services administration and senior leaders robin Bailey and sherry Berger to hold confidential one-on-one interviews with an employee's other key stakeholder inside outside the agency to get a feedback on our agencies process processes systems and structure to solicit suggestions for are strategic change. You will hear more about the recommendation and our twaks at later meeting will where we will dote time to dive into questions that came up through this effort. This is at work that will position us strategically for our future and to advance our future goals. In addition to these efforts recently CDC updated its strategic plan to reflect where were in this moment of the pandemic and public health. And to emphasize our agency-wide commitment to health equity and workplace and workforce diversity and inclusion. In 2022 through 2027, CDC strategic plan advances science and health equity and affirms agency's commitment to one unified vision. Equitably protecting health, safety and security. The plan continues to leverage five core capabilities of the agency reflecting our commitment to equity and diversity and lifting up where we have invested three the Covid-19 pandemic. These core capabilities are building and maintaining a diverse public health workforce, developing and a deploying world class data and analytics, maintaining state of the art laboratories,

responding to domestic and international outbreaks at their source, and finally, strengthening our global capacity and cedar preparedness. To leverage capacity we built with criticalestments in support of at COVID-19 response and a position u for us in future. Those vest investments include developing COVID-19 vaccine implementation extra structure, expanding our lab capacity to support sequencing and enhance CDC Data Modernization Initiative and a workforce capacity within CDC and through response related funding to help the departments. And we've made I nor now strides in diversifying our leadership with the selection of robin Bailey as the agency's chief operating officer, less as the director of the center for surveillance epidemiology and laboratory service Leann as director for division of STD prevention and Jose are mer roto lead or national center for immunization efforts. In our last meeting I mentioned our new center for forecasting and outbreak analytics or CFA. I have I had opportunity to April 19th to White House for official launch of the center. Now CFA will bring together next generation public health data, expert disease modelers are hub healther respond and communication experts to help make sure we never again face a public health emergency unprepared. Creation of such a center along with creation of this advisory group has one of my top priorities since becoming CDC director in January 2021. CFA will be there analysis at every stage of health threat early on, the center will assess an outbreak and potential potential to reach epidemic status. Later the center will be able to compare the expected impact of different intervention and help jurisdictions decide whether and when to direct their their resources. And the center will provide data on epidemic and how we will know when an outbreak might be over. In this way, CFA will help reduce the potential for social and economic disruption from health threats. CFA has already been proving its value. During the prelaunch phase CFA helped us anticipate the timing and an impact of impending Omicron surge. Shortly after the variant's arrive in United States CFA partner HSS assistant secretary P and CDC already robust data analytics team. We were able to a letter public health leaders and their partners provide advance notice of timing and magnitude of the surge as well as the severity of the disease itself. Allowing them to plan. This just the beginning. Through CFA, CDC will develop a program to provide insights about disease events for the public, and work closely with a partners across the federal government to fortify preparedness activities. Sinner gistist with ongoing efforts with CDC this new center has the potential to improve and save even more lives in ways we can only imagine at this time. So I look forward to which wassing it grow along with our today Data Modernization Initiative that will strengthen the data sources available and make sure that, pipes are in place to feed those data to CFA working collaboratively. So it's an exciting time for CDC and I'm so grateful and so glad to be a part of it and to have you a part of it. Let me close by once again thank things you for each of willingness to participate on this committee, over next few years, we will come to know each other very well I very much look forward to that. So with that I will pass things back to do you Dr. Fleming and look forward to the conversation.

>> Thanks so much Dr. Walensky. I'm going an open floor questions from members I'm tempted to ask with all things what how do you decide what first thing to do each morning is but I'll let others more insightful questions. We're having a little bit internet connect problems during your presentation you were coming will you threw but occasionally stopped and caught up if you see people look odding they are waiting for voice to catch up. So hopefully that won't happen too much. And as I said, for members who would like to ask a question, please go ahead and raise your hand. Looks like we have a little bit of a shy group this morning.

>> So I have one question, Dr. Walensky, the CFA sounds fantastic and sounds like it has done great work. Do you see that it is, do you see the need for additional resources for it? Especially in they are where there's sort of fund funding for COVID sort of questionable.

>> DR. WALENSKY: Yeah. Thank you. So yes we have early start up funding from the American rescue plan. I think resources both for out DMI efforts as well for longitudinal plan for CFA are going to be an essential. First of all the data are going to have to fluently and flow to it. Because the efforts here will only good as data and surveillance data that we have. So it's going to be a data issue as well as working towards longitudinally available personnel to be able to staff it. To be able to work collaboratively innovate within it. So I am very interested in main maintaining not only fund thing we have but in growing it. The team that we have right now is as they frequently tell me small and mighty. And we are working towards expanding that team and it's actively ongoing right now. Like so many engines public health funding it tends to not have the durability that it needs so I think the durability will be essential

for us to be able to as the predict, prepare, innovate. And inform. So that sustainability of that funding will be essential.

- >> Yeah that durability is what I was referring to thank you.
- >> Thanks. That has been the problem in the past obviously with we've experienced finance has become available but oftentimes one time and hopefully working with you we can make that not be the case this time. Julie.
- >> Good morning Dr. Walensky. Congratulations on all that you've gotten done even in the midst of the pandemic. I think what you out lined is lot of progress. It is impressive so thank you for all you're doing and progress that you've made. I'm equally excited about this CFA as well I ink that just wonderful work amazing what you've were actually able to accomplish again. My question relates to just authorities. I want for today it. I'm wonder if you hurdles to overcome as you're trying to do this forecasting for Omicron. Because I think some of the challenges have been experienced by governmental public health in passage related to the authorities of public health to access today it I don't know if new authorities that CFA has granted or you have been granted to allow atto overcome some of those issues? >> DR. WALENSKY: I'm so grateful that you asked this question. I think this one of the key alcohol which enthat is certainly I have seen in 15 months, is that things are expected of CDC that are data that people have expected us to see from us a that we don't have authority to report on or collect. Does and so one of the things that I know you with regard to our data modernization efforts, and I think we will be able to connect the pipes where all the data could flow. But, if we don't have a standardization of that data all of those data forthcoming even pipes connect if righting things arp flowing through we will not capacity to look for what we need. Even yesterday I was in conversation as to whether after the public health emergency ends whether we will have the capacity to report all of the data that people are expecting of us. And certainly, I've heard from some jurisdictions that you know, people are interested in (inaudible) but some jurisdictions are not sfwhd reporting it to us. I think this authorities are going to be one the very key issues that are going to be among our item knowledge blocks as we try and report what through our data modernization efforts and again through CFA. I think that's key in something we're actively working on.
- >> Maybe something that working group on data and surveillance modernization can provide some advice on as well, yes. Important issue
- >> DR. WALENSKY: That would incredibly helpful yeah. Josh.
- >> Great. I wanted to ask another question about a CFA this time from state and local angle. I remember when I was health commissioner of Baltimore and there was a researcher who had figured out some equation to predict heat related deaths. He told us in the city every morning he would send me predicting hey related deaths and that day if was going really hot we would open okay willing? And issue press Reese's leases. It became something that we really were known for at the local level and based on getting you know good forecasting information about heat related deaths I wonder if you think about it great resource we're
- >> Ed to contribute the great faculty to at CDC, what how envision working with states low cattle and a to be give them something to pivot and translate it for their population how do you see that interaction going?
- >> DR. WALENSKY: Thattist a great question. Actually it dovetails with two things. First I love the question because, I want us sort articulate that while this was stood up in has the time of a pandemic, this resources is intended to be for infectious and noninfectious forecasting just as you said heat related. Weather want to do it for both. I want to be very clear about that. Second is that it is intended to be innovative both with work with industry and partners a well as how we work academic partners CDC have done less of in forecasting. So that something we want to do more of. And then third, to do this we do this a lot of models over this pandemic, if they are at the national level, but it's sort of like you know one area of country is in trouble but other area of country is fine. Average doesn't really help the local public health partner. What we really want to do the where I think communication is to say, and also to make sure that the models maybe applicable if we have a user inner face where you public health department could input your in a user interface and have those potentially be applied to your local situation. All of those goals are on table for what CFA is working to stand up.

>> Thanks, Josh. That's correct Dr. Walensky. I was going to ask that same question about a noninfectious perspective. I was just delighted to hear that's on agenda. We really welcome states and locale tease as well.

>> Dr. Walensky, congratulations as well on CFA. Really exciting. It makes me me think of an opportunity especially when you stand up a new center to be thinking about really effective communication. So I'm wondering what your thoughts are on that especially as it relates to recently because of the pandemic over the course of the last two and a half years, how trust is also become an important component. And obviously CDC needs to be trusted and to continue that. I was just wondering what your thoughtser especially now standing up new center of how that plays into the overall image of the CDC.
>> DR. WALENSKY: Yeah. I think that communication has really been one of those area throughout this pandemic that people have now really been talking, who our audiences who do we need to sort of communication communicate with. Communication is part of the center is actually one the key goals is to make is to with communications team to be able to articulate for proper audience who is audience here? Is this public health departments? Because I think people communications are going to differ depending on who we're talking to. And I think that's true of our day to today a work as well. Is this guidance intended for school systems? Is this guidance intend intended for parents and how do we communicate differently with each of those is this so we're working hard on understanding the audiences and communication strategies.

>> Dr. Walensky thank you for your passion and all you do. I just really need to make a comment. Really about communication and getting CDC back to being trusted voice. I think that the CFA as a source of data directed to multiple it targeted audiences could have a great deal to do with that to restore the trust in good science and get people to understand that science is a part of our lives. So thank you very much. That was it.

>> Thanks, Jill. I was hesitating to call on Dr. Walensky's internet came back up. But you were faster than I owes enthat. So thanks.

>> Dr. Walensky I want to thank you prioritizing health equity as one of your three important issues moving forward. It really dovetails into CFA as well. I'm curious because from my standpoint we've worked with groups across the country when it comes to data literacy. And we've seen how it hasn't been prioritized and without a working knowledge of data to drive decision making, I believe that the movement for health equity is hindered. So we've come up against issues dealing with a data sovereignty, with native American communities the lack of community community engagement early on for xunts disproportionately impacted by COVID and other co-morbidities. I am curious if >> First of all Daniel. Thank you for your leadership in our health equity subcommittee. I'm grateful for that. So this has to be a key part of it. We have said from our workforce standpoint our workforce has to be diverse as communities they serve. So if we have public health workforce from and working in those communities they will understand their data and their data nfblth I do want to lead to data sovereignty. I think that is key. There is no intention here to have anyone lose data sovereignty. The whole point is that we work together collecting data sinner gistcally so we can feedback to you and say this is how you're faring compared to local communities versus versus not. So the whole intention is to be sinner gistic not for anybody to singularly own it. But it come comes to sequentially it just a further delay. We really noticed that being a challenge. So we want to work collaboratively with local health departments to understand their data with them to collect them standardly so we can cross compare other health departments to define how they are doing. In order to forecast at the local level. Because if doing it at a sort of national level is just not going to help the local communities. The sort of weight average is no the locally relevant in terms of their policies as Josh said, you know, you have problem in some community that doesn't help a different community. They don't know what to do.

>> Thank you.

>> I'm wondering you mentioned that I'll get to you Monica, just quickly ask a question. I was intrigued you to hear he mentioned after couple of years now, CDC tran off full agency wide globalization for COVID to more measured response. And doctor ma hon will be a providing guidance she will be here later. I was wondering from your perspective if you could give snapshot what that looks like for the agency I can't imagine people having doing this full speed for two years and now maybe have a little bit of a light at the end of the tunnel for some return to normalcy. How you and agency thinking about what

the next stage in the COVID response will look like and will this give you chance to do a little bit of rest and relaxation and get back to all of the other things that agency has to be working on as well? >> DR. WALENSKY: Well so maybe I'll just start, first I know Barb will give you lot of details when she comes. But let me start by saying first the work of agency continues even though many people are hearing about COVID we haven't slowed down. In fact I will just note over last question 8363 foodborne out breaks we've been involved on. So that is still going on the also the case that we have had over 2,000 people in our response at any given time throughout pandemic. 2,000. What we're working to do is the activities of this will be more streamlined. And they will be brought to program and science and programs. Where things will be both in program and working on COVID or if we have a vaccine task force that will be working on vaccines for other vaccines a well for COVID. So what we really need to do is have fewer people sort of solely focused on detail on COVID, 2000 of them right now and a have that back to program but some of these activitieser in really were in program but they need to find a natural home because activities do need to continue. So that's it, we will still have an incident management structure. We still need to have an incident management structure. And I'm I'm really grateful -- we're trying to bring many of the activities into the program that will then roll up to incident management when we, when there's a communication or new guidance or what not. So that we don't have, 20 percent of agency on detail for the response. So that's actually -- a lot of a work has happened a lot stream lining has happened already Barbara can give you more details on that. But I think two and a half years into this we need -- and in fact really working the country working towards a more closer towards the steady state in where we are, that we need to do this at CDC well

- >> Thank you. Welcome that. I appreciate your response. Monica
- >> Yes, thank you, David and thank you Dr. Was Walensky for sharing those updates and for emphasizing the importance I think I heard in terms of building equity into the way in which you approach implementing your strategic plan and the services that related to health and safety and security. And I had a question about the organizational review that you included in your updates to us that our colleague Jim will be doing over the next month or so. Was just curious how that might be different in terms of previous assessments that have been done and action steps you imagine will follow vis-à-vis the core capabilities that you outlined and sort of this future of the CDC and kind of shifting into this more steady state. Because I think a lot of state and local health departments are taking stock at the last couple years and revisiting organizational capacity and capabilities. So I was just wondering if you could say a little bit more about this organizational review and how that might be different and also inform inform the work ahead.

>> DR. WALENSKY: Great. Thank you for that question. So we're partaking in three really activities at the same time. The first is what I just outlined for Dr. Fleming with regard to how can we bring the response activities to program or at least many of the response activities to program. The second is many of theses listening sessions that Jim is doing I'm very grateful to him. That is what did we learn through this pandemic with regard to how we implement new guidance. We have had to work, I mean CDC has never been in a pandemic the way we've had to actionable so swiftly with such evolving science. And are there lesson that is we have learned, things that went really well? Things that could have done better? And that we could have done better. And truly, on ways that we could stream line our other guidance and processes that we learned from this pandemic that we should take back to other ways that we operate. And you know, so what are lessons we learned in the last year and a half? We want to formulate those and understand those. Either for next waves, I hope there aren't too many of those. But also to see what we can and should learn from and bring back to our standard operations. And then, it's really not lost on me, that we haven't had a review of the agency in a while in terms of our systems and structures and processes. We've hired about 10 percent new people, FTD during this pandemic. We have new center for CFA that that needs to find a home. So while we're doing those two activities we're really doing some listening sessions in this review to understand, you know, what it is, where some of these things should live, how we integrate some of these structures back into our I should say into our CIOs. Is there anything more we should be learning? And I have really open mind. We haven't had over last 15 months time to digest some of these activities that one might have wanted to do when, I started. So this is really the moment that we have taken to all of those activities, those listening session at once. I don't necessarily -- we're not through them so I do want to keep an open mind as to where we go. But I do

think we've had enough critique certainly everybody there has 95 magnifying glasses and enough discussion that he should do an internally facing one as well.

>> Thanks so much. Any last questions for Dr. Walensky? Is wow. Thank you so much for spending time with us this morning. This is very incredibly thankful and just give us a great benefit and luxury to us to make yourself here during this time. We look forward to our next meeting when we can do this again. Happy to

>> In person. Yes that what we're trying to. And maybe even a dinner or something before so we can bond as a committee and bond with the CDC leadership which is something I know we're all looking forward to. So thanks again Rochelle we really appreciate you we have busy agenda time for us to move on to the next item.

- >> DR. WALENSKY: Thank you so much, everyone.
- >> Okay. Thank you.
- >> So with that let's move on to our next topic which today modernization and surveillance. As you remember had an initial presentation on this at our last meeting today we wanted to move forward including officially forming an ACD working group on this good news in this a regard. As we've already shared with committee ACD members have agreed to serve as co-chairs for this group which fantastic news. Thank you so much you two. And we really do appreciate you making this contribution. So start us off today my pleasure to once again introduce lead CDC official on the Data Modernization Initiative Dan Jernigan. Dan is going to to get us up to speed and talk a bit about the specific terms of reference for this work group. Over to to you, Dan

>> Great thanks very much if you could go to the next slide. Want to start off saying thanks to number of folks at CDC that helped put this material together Agnes warner Taylor Manny. Want to the our new perm associate deputy director, Dr. Jennifer Layton. She comes us to us with lot of experience state epidemiology's and chief medical officer for department and health and city offic which. So the task we have at hand is a big one. And it's one that touches on multiple parts of public health. So I look forward to hearing from all of you about how CDC can have the greatest impact and improving our surveillance and data systems to have faster, better data for actionable intelligence for decision making at all levels of public health. If you could go to the next slide. Just to two quick refresher on DMI priorities that presented previously I spent time last time I won't go into too which detail again they will underpin the rest of today's conversations. Questions that we have will actually mirror along these areas these priority areas. So as you may know in 2021 CDC published its first Data Modernization Initiative strategic implementation plan that is available a website that is list there had. This comprehensive new approach is framed around five critical priorities for work across CDC and across our state territory, local and tribal partners. Those five areas are building the right foundation you can see under each of these are outcomes we want to see happen. Building around foundations essentially getting those pipes like Dr. Walensky mentioned from healthcare sources of data and other sources of data into in a place where it can land. For that we are implementing a cloud-based infrastructure at CDC and supporting our stating through cooperative agreements and other funding to do that cloud-based initiative as well. Once that data is there we look to see using shareable approaches to data analysis and visualization tools that can reused across different programs so we can move toward actually busting those pro oh gram mattic silos that are out there. For second dolly mentioned an all activities. And really look to that group to help push the innovation for predictive analytics for scenario modeling and for other efforts for forecasting. It's in that space also that we're supporting a lot of standard standards development, working with our office of national coordinator, folks and HHS so we can get public health into the electronic health record environment so that public health is part of that healthcare ecosystem. Those standards development activities will take some time. They have to get started now. The third is to develop a state of the art work worse. To support and an extend partnerships to address policy issues. Really looking at what are all of those nontechnological lever that is we can pull that will help us to use that technology best and get us to that better faster actionable intelligence. And finally, managing change in governments because we all recognize we're trying to do a CDC what's need state, territory local tribal health departments to think about surveillance differently think how we receive and share data differently and understand this a change management issue that requires a lot of understanding, where people are and where we all need to go and helping people to get there. So our commitment to Data Modernization Initiative is an in the limited to these investments this include data systems, they include

strategy and capabilities as policy like I mentioned clearly multi sector partnerships that in place now through our DMI con so are shim and other mechanisms we're using as well. Do DMI strategy is changing collaboration innovation across CDC and hoping that we are driving that change also and our state and territory local partners. And includes agency-wide commitment to setting and then achieving specific objectives and key results. If we could go to the the next slide. So maybe the biggest difference in today's DMI efforts is the community we have around the this effort toward shared success. Many of you have been a part of the dialogue and talked with lot of folks and multiple listening session and there have been multiple recommendation provided to us or published. Those support DMI valuable recommendations and it does provide a shared vision for what public health can be. We're listening and incorporating though is recommendation as we complement DMI. You can see here just a snapshot of just some of the papers that have been part of this thoughtful input. Listening to our partners, wider conversation will ensure DMI is responsive, flexible, and attune to the needs of public health and our nation. Next slide. So we'll have an opportunity to the go more in depth on this later in the presentation but I feel like it's important for for us to touch on how CDC is funding and structure have impacted our modernization efforts so ever. So when it comes to implementing the DMI one of the CDC's biggest strengths has shown it elf self to be one of our biggest challenges P CDC is made up many different centers. Each with different areas of expertise and that is the plural, the S is in the centers for disease control and prevention. This way of working has allowed us to go deep in our science. Which is a benefit. The good thing about this is science and surveillance are engrained in every part of our agency. A survey done a few years ago found about 1 quarter of CDC staff conduct surveillance related activities and nearly half CDC's health scientist, about 45 percent in medical 50 percent of them work in surveillancerelated units. Underscoring importance of CDC's scientist to irrelevant is available lens enterprise. However, the challenge comes from the fact each center often has it's own disease specific funding streams which overtime tracking thousands of disease and conditions. This type of categorical funding can result will in what we call data silos and lack of connection across different parts of the agency. That then translates into heavy burdens for our data providers at the state ask local levels that often must report to the multiple systems in multiple different ways. So further this way of working has become the status quo across all of public health. These siloed systems exist at every level from the state, local all way to the national level. Next slide. So CDC is known for and marketing our expertise tlur surveillance items and sharing today it discoveries to informed decision making. Statement, CDC maintains more than 100 surveillance systems for different uses creates a reporting burden, duplication and it can create discrepancies among data elements and need to use multiple information technology systems. When we avault surveillance estimates as part of CDC surveillance strategy we identify CDC active cover broad ranges topics falling into 4 category things infectious diseases systems about 60 percent pf noninfectious health conditions about 23 percent. Rick factors of 17 percent. Example provided there the example may not exactly in right place but they are there in order to show breadth of different kinds of information that we are collecting. If you could go to the next slide.

>> Creating an additional challenge is that world data continues to proliferate and change rapidly. We're middle data revolution. This creates opportunities to advance public health in ways that hard to imagine a generation ago. But also brings increase complexity to our work. For example, data informed COVID response originally from traditional and nontraditional healthcare settings community and municipal organizations private sector and many different electronic health record systems. Big system and small both electronic and paper, the central challenge for CDC and for public health at large is to take vast data and deliver delivered at different times different channels and different squall tafb and turn them into useful will actionable information. And enter pry view of can offer insights that make information more timely accessible, content rich and cost effective. The big question we're addressing through DMI is this how can we harness or strength, this deep expertise build up over decades while overcoming these challenge so that we can truly operate as one CDC and as one public health community along with our partners at state, territory and local and tribal. If you go to next slide. That brings me to main reason that here, data and surveillance work group DSW is been established to a provide work groups to advisory community and director regard agency-wide activities related to scope and mren mentation a data modernization strategy. There's document with terms Terms of Reference that you will have already received or will be receiving. Through this work group we will will Abe to look logistic challenges. Go to the next slide. The work groups efforts will assist the advisory committee in, innovative and

promise modernization practices and approaches and line with principle pillars of DMI. It will also seek opportunities to advance modern harmonized policy and practices and support of public health activities. And work groups primary charge input to advisory committee regard potential solutions to issues and questions. So keeping equity as our focus the work group will convene balanced group subject matter experts in public health science and practice. Policy development things and analysis mren mentation and surveillance and infomatics. We'll have members from jurisdiction government agency from nongovernment organizations academia and the private sector. These experts will work with the advisory to CDC to support effective execution of CDC data modernization strategy across the agency ultimately playing a key role in the agency's work with public health, healthcare, academic and private sector partners. Next slide. I want to use this time to walk through a set of slides through main issues that are listed here. We will walk through and related question that work group will be asked to consider. Next slide. The first issue we want to look has already be raised in preliminary questions to Dr. Walensky. That is CDC does not have at direct authority to require jurisdictions or other entities to report data. CDC, statement and tribal and are still depend on and are bound by laws regulations and policies which determine the content, form and manner data they collect today it. Variation in laws regulations and these policies across jurisdictions levels public health may create impedestrian incidents to data sharing exchange and limit efforts to gather data at the regional or national level on critical elements such as social often depending upon their interpretation. Next slide. We are in a very different place now than we were before the pandemic. There are lots of data I won't go through all of these here. Electronic lab report thing electronic case reporting ED, and immunization records, healthcare data. Hospitalization capacity data. Much of this data gives an incredible national picture what going on but lot of made possible through emergency orders that made when the pandemic public health emergency has ended. Those authorities may end as well. Next slide. So a question for us how can CDC support common approaches to data sharing and access for public health data particularly through supporting policy and system approaches consistent with applicable laws and regulations to build trusted networks for data exchange and addressville nationalities created by variation across sectors ask levels of public health. That is question for our issue number one. The next slide. For issue number 2 on data exchange, this is data exchange has been a very burden burdensome and time consuming process. The burden and the friction of exchanging data forces staff across the public health enterprise to folk us a significant amount of time, effort and resources on data management rather than conducting public health surveillance and response activities. Much of the time the state local health department staff is getting just, just getting the today it at that in so that they can work on it rather than letting the data work for them. We need to be able to change things so some jurisdictions aren't spending 80 percent of their time just getting the data in shape in order analyze it. CDC is working with partners to explore the design and implementation of a modern public health information ecosystem that can 11ed to reduce the cost and complex tee of stilt operations. One component of that information could include a centrally hosted infrastructure and services which are provided to jurisdictions by CDC. Next slide. This is a picture of a graph framework in development. This discussion that been ongoing with the CDC, with our STLT partners and under active discussion with DMI consortium which include multiple public health partners plus other partners in this public health ecosystem space. This north star ecosystem model often referred to north star back tech choir describes who, what and how of a future state of ecosystem where data flow and information systems are coordinated, correct across healthcare and public health at all levels of the government. Out I'm not going oh go into details model maximizes benefit is of cloud compute thing open arc tech choir and industry standards for data collection, exchange, management and and a propose a spectrum of options for STLT participation that protectives their control of their today and their decision making autonomy. This work is being done jointly between us and office of national coordinator along with our consortium in order that we capture the needs of entire ecosystem and we come up with decisions or directions CDC can help support through the building or the development of unnecessary components as we have funding available. This is founded on lessons learned from the Covid-19 pandemic. And draws inspiration from and goods on success for COVID ELR, a dramatic thing acceleration of lab reporting efforts to modernize surveillance program which provides most of the emergency department encounters in the U.S. right now. And increased scalability of national disease surveillance is it which receives ten times usual case volume due to Covid-19 among others. We want to offer a range of support through the data modernization efforts to our state

territory and local partners to realize that most of the activities in those departments of health are supported with federal dollar. We want to be able to have solutions that address at least three kinds of models of how data can shared local host environment where state is responsible for their own systems, but in the quite cloud enabled yet. Hybrid approach where they maintain their own cloud but able to have services that they can use to help them increase the work that they can do and decrease the amount of burden that they have getting data together. And then finally like I mentioned before, a locally, a central hosting which would be the cloud-based platform enable states and local that do not want to do their own hosting that would have cape ability to use all the services available and those case management tools that are being developed. So we will working on this over the next two years. It's going to take time and planning. But we look forward to your input on this. Go to the next slide. The question that we have in that context is what role should centrally hosted infrastructure and service play in a Momo Dern public health informations he could system? Everybody is and everyone familiar how using cloud when ever you use Amazon or when ever you do Expedia or travelocity, those are hosted infrastructures. Is there a role for that for public health? And how can the structure and use modern public health information ecosystem support and ensure partners receive added value through participation for example through sharing harmonized data to jurisdiction CDC. So how can we have a good national picture of what's happening at the same time our state and local partners getting all the data that they need in order to do the important public health work that actually happens at the local and state government. Next slide. So in terms of issue 3 forecasting analytics policy makers, individuals and citizens often rely on CDC for did I Gans and information P that fends on use of models, forecasts, analytic and so clear applications of these tools for situational awareness early warning and emergency response continue to be explored. We have ad fair amount of discussion rd already about new center for forecast ask outbreak analytics so this particular issue 3 an opportunity where some of those concerns or some of those opportunities can be voiced. Next slide. So the new CFA stood up in August of 2021 and it really starts taking capabilities to the next level. The work of DMI underpin this is work and will be necessary for its suggestion success. Slide hear just provides proposed value of this center during outbreak of a novel pathogen with those three areas that are listed a priorities for center for forecasting outbreak analytics that predict, in which and innovate. Those include parameter estimates, scenario models forecasts targeted studies, response analytics et cetera. We look forward to hearing from you. Next slide A question we posed how should CDC prioritize advancement of forecasting and analytic efforts to integrate public health activities and address health equity? Next slide. Our fourth issue is with workforce. A CDC supporting modernization public health workforce a major activity to ensure sufficient capacities and capabilities across the STLTs and a CDC. If you can go to next slide. So in line with our DMI priorities we've taking a variety of innovative approach to build a state of art workforce. We're recruiting and building through fellowships, infrastructure grant that has \$3 billion and will be available over three to five years where those are not specifically just for data scientist and DMI related activities but for whole of public health workforce. But clearly those data scientist and related needs are a strong component for that workforce. Also the public health which will be provided over \$65 million and awards to 82 grantees across 32 states. We're offering training a CDC through data science upscaly and teams and applied public fellowship infomatic data science and laboratory capacity at state and local health departments. And forecasting our future needs through the public health workforce research center which will in which health workforce enindicators planner policy makers and audiences interested in public health workforce. And working closely with national center for health workforce analysis. Next slide. The question we have here how can CDC work with partners to support the public health enterprise by increasing access to data science and information technology skill sets and staff from academia and private sector and addressing barriers to hiring and retaining experts in these fields. The next slide is issue number 5. Breaking down silos. As a touched on either they are complicated and disconnected web of public health data systems which create data management reporting burdens on public health staff a large part a result of siloed programatic opportunities propagated over time by categorical approaches to funding. Next slide. So when you hear about different DMI projects you may notice they are led by or funded through a specific center. Because way we have traditional been funded in past each centers holds long standing expertise in for specific systems and we need to recognize and tap into that knowledge. At the same time we need to build bridge. For example in our first property to build right foundation we have our office of achievement information officer at CDC leading

development of our cloud base based enterprise data analytic and visualization platform. And we have our center for surveillance and laboratory fs information and leading much of the work around our core surveillance systems. So at the same time our national center for immunization respiratory disease leading way on immunization system modernization. So as we recognize the expertise we also need to recognize the old way of working no longer serves us an an agency. That at an enterprise level. Our data modernization approach is applying mechanism that will bring us out of our silos. We have begun forming cross agency teams that will allow us to find shared solutions to shared problems. We've set up a structure that guided by our DMI priorities and objectives and does not dictated or limited by center or even who is funding and who is not. We this is a greaterer needs of agency and our investments are available and reusable across enterprise. We want to unlock answers to large public health challenges by using all data we can across program areas. This is a big shift from how we've done things before that will have really meaningful implications for what we're able to do in the future. Next slide. So the question here is for next phase of DMI what agency-wide activities would most benefit from a coordinated all CDC approach. What efforts could ensure long-term sustainability and success in achieving modernization and supporting advantagesment of agency priorities like climate change and health equity? P next slide. I believe is last of the issues there are a lot of them. But, they are all important. The last is an assuring sustainability. Implementing and maintaining a modern public health data ecosystem will require all levels of public health to rething the Biggs policies practices, and procedures of public health agencies to support more nimble approaches to information technology ask sustainability of infrastructure. Next slide. This is a -- next slide. Yeah, this is a bit of a busy slide. Sustainability is critical and jurisdictions repeatedly caution us that their hands are often tied when support is limited to annual funding and to address this we kwlu component in infrastructure grant thing managed services that could fund data modernization activities for five-year period. If fund thing were to become available to the program, our still partners would have more time over which plan and implement modernization activities. They would have more flexibility and how to use those funds compared to the current cooperative agreement mechanisms. And current mechanism we're using lab capacity grant program cooperative agreement which delivered \$200 million in direct DMI funding for are jurisdictions in F Y 21. That 200 million was focused on supporting foundation data modernization activities on accelerating modernization of national violations statistics system. And in leveraging the incredible progress made over the last two years by scaling up electronic case reporting to include all notifiable conditions. The big task of for one we're prioritizing through the funding. Through ELC we also increase access to technical experts and consultants. We've also provided funding for a variety of mechanisms to natural partners. To strengthen learning communities, communities of practice and targeted workshops. By putting the new extra structure grant mechanism in place now we've opened door for more flexibility and sustainability as our state and local partners build on this progress. So next slide. Final question how can CDC work with partners to addresses barriers related to finding mechanisms, procurement, and program delivery? What mechanism for assuring sustainability of modernization systems need to be developed and implemented? The final slide is the data surveillance work group has specific activities participating in sessions to consider and address the guiding questions. Drafting a report of finding observations and outcomes. Receive ad hoc presentations those could CDC DMI leadership team or other CDC to review aims, content, and underlying assumption which DMI strat industry. They could come from CDC programs on evidence based approaches tools and what's driving successful implementation of Data Modernization Initiative activities and an initiative on internal and an internal that will impact DMI outcomes. So review CDC's DMI outcome progress and metrics is another important to go provide feedback to the ACD and providing updates also to ad have I other committee at each meeting. With that I believe I'm going to hand back over to Dave Fleming.

>> Wow. Thanks Dan. That was incredible. If rest group like me I kind of feel like I need a break. We'll do that after the end of this session. Thanks so much for your leadership. And clearly, many, many issues here important ones and work group clearly has its job cut out. I would like to open floor for questions. And yeah questions and then comments on Terry. Dan the committee was sent Terms of Reference. First off I see Rhonda.

>> Good morning. That was probably the one the most comprehensive presentations I have ever had. That was a four coffee cup presentation. I know that what you presented requires a lot of work. Just want to make sure that we were including nontraditional public health partners during H1N1 and this

current the pandemic we've learned a lot about how to use nontraditional public health data to kind which identify whether hot spots developing whether there maybe a problem emerging but we also discovered new ways of actually using the information coming from the public health side to the healthcare side. So I really hope that on this committee on this sub group that we're going to have you're including a lot of people who had the work of Erika on the ground. Right and not just in the hospital setting that's important. Hospital. But also the people who are in primary care who saw things and local communities, people who have pharmacy data real time. Right? Because sometimes people can proscribe a lot antivirals without a test. Sometimes that's first clue in some local rural communities I'm just say nontraditional partners please make sure we include them. I liked your questions oop I think I'm still in the mode and I'm talking I don't want to take lot time. I'm still in mode one questions need to be how do we lefrnl all of these diverse information sets and data to be faster, better, stronger before the next wave or the next pandemic occurs.

>> Great, appreciate that. I think that focus on the what we call nontraditional data is really important. It may not have come out in the slides. But I do think that is an important thing for are us to recognize. There is so much that we need to do with the existing traditional public health data. But there are other data sources clearly that have been used through the pandemic. That really provide additional information. They also can provide significant sources of social determinants of health information health equity data. Those are that things we absolutely need to consider. I think we here at CDC is considering those a part of data sources. But identifying how to call that out here I think would be very helpful.

>> Great. Josh, you're up.

>> Thank you so much. Ask I really appreciate the presentation and the scale of the challenge. I ink there are comments about how dense your presentation was necessarily because of the different data topics. Led me to thing about my time on the HIT policy advisory committee for ONC where I spent a couple years where you could sit in meeting sometimes just hear about you know metrics galore for what DHR going to exchange. But not really understand why. Like what the purpose was. And I wonder my experience with data there's always people who are like dragging their feet at whatever level, just very abstract concept until it really matters for health. And there's a real explanation for what you can do with data. I wonder along side your sort of you know technical goals do you have a set of goals for what the health pib health systems can do people should get immunization records where ever they show up. Or you know, out breaks asthma should be able to identified within a week. I mean what are the things that motivating this that could be functionality that inspires people to do all of this you know work underneath the surface?

>> Yeah. You're getting some of the presented in an original presentation that get some of that. You are getting at identification objectives. Ask and key results to make sure we have measurable outcomes. So some of those are listed in these strategic implementation plan I really appreciate comments we're going through and further defining a lot of those objective and key results. As we update the dmre mentation strategy that will be your point is can we have clear objectives that could presented rather than dense presentation I think for this discussion here on this specific questions I did we erred on the side density but happen to get back with you on the higher level objectives and key results.

>> Thanks, Dan. We need high level results are important.

>> Yeah, great work going through lot of material. I know you thought of it but you mentioned the words all of CDC approach. And I know you thought of what about beyond CDC to CMS, FDA, and others actually even outside of HHS in government as well? And what work has done around those approaches for public health?

>> Yeah as part of the Data Modernization Initiative most of our efforts have been within HHS working closely now with CMS on some of capabilities that they have that might be leveraged in order to improve reporting and data gathering. We've working very closely with the office of national coordinator and using their capabilities to help electronic health records and certification of systems. Has discussions. Actually activities with them through the and an and utilizing some. We have not tried to have a whole of government approach here. I think focused mostly on addresses that are within the CDC and still partner ecosystem because of the near term need to focus on those. There are a lot of possibilities of utilizing other data sources and data systems. And we would love to have your input on exactly how to best utilize those.

>> Great.

>> Yeah Dan great presentation. I'm going stand up to what I already mentioned to Dr. Walensky, which is, recommendation to consider a work group us a stand up something really their skill set and expertise about communication. I think good communication, effective communication, evidence-based communication is truly a skill. We all think we can communicate; we can all talk we're not necessarily communicating. And reason I bring it up is because the work you're doing when is so key and a lot of I think having someone who has had skill set and understand the difference between just regular communications health communication, public health communication, they all nuances can always really breakdown silos I know you're going to have to also deal with especially when it comes to data. Just wanted to put that out there for you to and your work group to consider.

>> This sishs there are change management, many. So I appreciated that. So part of that communication is also identifying those key priority activities that we're focused on and communicating and what happening on those focused activity

>> Let me take opportunity to mention some here, and we're also going to talk about it briefly when we talk about laboratory working group. As you know, the working groups are constituted ACD members but supplemented with nonACD members as well. We've, woulding hard to, CDC has working hard on this. We use federal registered notice pro roses to solicit outside applications for folks folks to join work group that that notice for both work groups going out on fourth. In a couple of days ten-day turn around time. Maybe John someone can put into the chat the link just so that people can see what those notices look like. But would really encourage first off all members of the ACD to extent that you know of people who provide value to either this work group and data surveillance and we'll get to in laboratory work group as well to encourage those individuals to apply. And I might I want to put either Julie or I know she's done a little bit of thinking already on the nature of expertise that would be important to have in order for work group to be functional. I'm wondering if one or other of you would want to briefly mention some of the criteria that we might be looking for in these outside mriktsz.

>> Let me start with maybe Julie can pick it up from there. Certainly the expertise in state and local active experience in state and local data and issues is highest on the list. In terms of urgent and important needs. But there are many other issues. We need folks who are lawyers who know about data privacy. We need subject matter experts who know about cyber security. And many others. I think that Dan has done a nice job showing some things we some skill sets we need. Already, we're starting to draw a wide umbrella full of people who we might reach out to actively. Because it is a very quick turn around time for I believe ten days we need to have all nominations in. So stay tuned. Julie.

>> Yeah agree with what he said already. And also, add I think we're looking at healthcare systems as well as electronic health record systems we do recognize the value of those, those systems and the data that they have in terms of informing public health and really coordinating with them carefully. I think, other thing we want to make sure we keeping an eye on equity. Looking for people who have expertise in data as, data health systems as public health data systems as relets to equity as well. So we have a list already of spreadsheet and nir Raffy and I adding more names we welcome your suggestion your solicitations of people to apply then also look for ACD members that are willing to joining group as well.

>> Thanks so much. Back to questions.

>> That. Thank you for that great presentation. I have two sort of questions that are related to each other. One is, concerning concernings use of electronic medical records, which have been kind of really driving force in medicine and a great source of data, and it sounds like that was your intention was to try to loop things in. Which is a great idea. I was just wondering how to do that. Probably not even appropriate question for this stage. But you know these systems really appear to have been developed more as billing tools than as actually medical communication tools or even or certainly surveillance systems. And the systems themselves seem to sort of work against this. And in is there all laws and issues related to privacy. But they would be a great source of data and so I really, I really support your trying to loop them in. And one suggestion I have in for people on this committee, if you look at the members, are is someone representative from some of the major electronic medical records companies, especially epic perhaps Cerner. To really try to help with this. The next question is related. And that is, I was trying to understand the central hosting versus local versus hybrid. Does the central hosting you may have said but I just missed it, would that mean that the data could go simultaneously to state and state local and to CDC at the same time? If it's centrally hosted? If so that's sounded like a good idea to

me. Because it would much faster and actually my while with the state and local systems you know would get the data it sounds as if they also could potentially have legs work. Is my understanding correct?

>> Correct. So there are currently in place solutions that we have for electronic case case reporting where those reports from an electronic health record go to one place and they are made then available to state territorial partners. So that model could be expand and through that mechanism that, way we would do that would through data use gra ements and other approaches. So the technological model is already being used for electronic case reporting. And then there's also the model that is used for reporting where 71 percent of all emergency departments in United States are currently able to oh be represented in a, in that information is captured in a place where state health departments have access to their data and there are capabilities where by we can at federal level certainly for COVID be able to see what happening at the different emergency departments. Those technologies are in place. A matter of policies and other things that have to be figured out P so what we would like to be input from group on how best to enter into that activity for broader part of the public health system and not just those two examples. With your electron health record first question. There a different claims today and a data capture used for medical encounters. Case reporting data that we're getting currently is coming directly from the electronic health records because it does include information about the patients the demographics, s encounter information, the medical therapeutics listing vaccines et cetera. That data is collected as a part of that encounter for a reportable event is what's been captured in and sent to state health department. So again, the capability to use the electronic health record which not just hospitals it anywhere where health record is used, in fact most of facilities reporting now or not hospital, they are actually doctors offices and other settings. So the capability is there. The DMI is allowing for that to increase in its use. Worry work workgroup CMS to make sure there are incentives or conditions that make it used more. So we're in a good place of knowing how to capture that data. We just need to know how to do that for multiple different public health data requirements. So that's where I think task of us figuring out that will be occurring. Over next few years. But also, we Elbe working continuing to increase the amount of case reporting the that's already under way.

- >> Kudos to you because many researcher have been brought to ground trying to deal with that epic and getting to do research. Thank you.
- >> Also in communication with them as well a part of our public and private partnership through krts foundation.
- >> Thanks.
- >> The great, thanks, Dan. I see four more questions.
- >> Thank you. So I've got a great presentation I just wanted to say how much I appreciate how thoroughly the agency is mapping out this effort. I think that along same lines of prior discussion, there are a lot of data outside of CDC that, that CDC will need to consider. And I think the EHRs are among those. The EHRs there collect social soerm soerm determinants of health that could collect and make that system better from standpoint of addressing public health. I think if you're working with a vendors, that's very helpful because certainly a lot of. But there are other data environmental data and other data that are not CDC system but CDC uses that I'm sure will be as well. I think that even during COVID, you know the data about travel and the amount of time that people were spending this their cars every day was important. Right? And so it's not all going to be in the healthcare system I hope that the group can think broadly about that.
- >> Agree. Totally would an issue of other data sources.
- >> Daniel.
- >> All right. Sure, thank you so much. So I understand from your presentation that you are looking innovative and equitable approach and practices. And you you've identified six main areas that you all will be focusing on. But I'm cure us as to whether the inequities in digital health and related technology design and application as well as the digital and technological conditions that influence health inequities something you all will be specifically looking at within those six priority areas.
- >> These six questions are the ones that we would pose to the group the issue you're getting at I think is the problems within equity's that maybe introduced that you technologies themselves. So a part of forecast outbreak analytics there funding provided to academic partners to actually look at inherent bias in algorithms in and other tools that are used and many have heard about the means by which you can

teach these systems and prediction and due forecast. And a may not be equitable may not be describe. And so, those kinds of CFA work with their academic partners. I think the agency are looking a ways to improve health equity through collection of information development of standards noed to get that health equity data and to earlier questions about different sources of data. Looking to see how we can connect with different data sources to the program so that they can link data and understand the context around a case so that they can infer social determinants of health and other factors that may be available in other data sources to that case. So those kinds of tools we're looking at to help local and states with work they do to try and get at that. To your point inherent biases and equity, digital equity issues, we're not we don't have specific focus within DMI right now on digital equity. That is availability of internet capability to have deck technology available. But that's something that we love to hear from you about if that's an important thing for us to report on

>> Fantastic. Thank you.

>> Josh.

>> I just have one quick questions a we were thinking about other sources of data have you given how much data and is part of this sort of helping other agencies kind of put package their data and make it more available to for state and local health or CDC? I mean that's not exactly building pipes new system but they have so which information which often is you know, hard for are state and local the health departments to access. In other words do you see this enagained in building or this be con conduit for other data to

>> I totally agree we have to push against the one sh day data flow we're we're really not trying to speed it up I known it really is decreasing friction of data to getting to those that need to do the work state and locals for those national view of things. Through, a number of process we've learned through COVID there as real came ability to a back to local that aggregated that can very meaningful information. Get data back is critical. To your point, are there data source not capture tlud any kind of traditional public health route like CMMS data. It could be a made available to partners. The answer is yes. But I think indicateds, interest of him look an authority for sharing thing is there ways to take that data. And access in and targeted to and ready access to the very helpful for them to hypertension and other interventions. We would love to think through those things as well as part of the not just data but really, a flow of bye directional flow.

>> So in a moment we would need to move on terms of reference. Talk about. But Jill, last question before that.

>> Very quickly thank you, Dan. So, Nirav brought up the need for attorneys lawyers on the work group to deal with patient issue privacy. Only an issue we struggle many years what Meta data needs to go with say lab data. Personal data goes with sequence. One an issue that is coming up the rapid tests over the counter rapid tests and what data is useful for those screen scene screening and surveillance examples what is what you've done what mechanism view a used to figure that out?

>> There is a lot there. Historically laboratory data critical component of what public health establishment needs in order to come a case. That makes molecule for the case. So that laboratory data from our standpoint in public health, you know that's where we moved forward the most in collection of data often comes from laboratory information management systems reference laboratories places that are performing the test that are not providing care to patients. We have a situation where there's a lot of lab data that we get which does not have a demographic data. So there may be ways coming from those that report it from reference laboratory tow could augmented through other means to provide some of that data that can give more information about the demographics race, ethnicity, et cetera. There are possibilities that now being explored in developing standards development space where by a laboratory that is reporting may be able to done an at Mac makt query of that reporter, that that ordered test. And gather them and number of different possibilities there. It's not an easy thing to try and address as low hanging fruit but it is important that we definitely recognize the laboratory data is probably one the most critical components of information that we need. So as part of our DMI consortium we have identified laboratory test order and results as one of our primary use cases to Troy to identify ways to fix it.

>> Thank you.

>> Thanks, Dan. Rhonda I see you raised your hand

- >> No question I just wanted to say thank you, Dan. I can't imagine all work team put together for you to do this incredible presentation. You can hear passion passion our voices and our questions we're going to good friends I can tell already. Lots to do. Lots of things to connect and thank you.
- >> Thank you. Well said. Well said. So we do, for terms of reference need to take official vote of the committee to approve them. So so far I've not heard anything but general agreement. I'm going toive good Nirav and Julie just a brief opportunity to say, express their comfort level or not with the terms of reference. And then presumably we will proceed with vote which will amotion and the second and then the a vote by all the members. So Julie and Nirav, you're comfort level with the TORs
- >> I'm very comfortable with it I had a chance to review it several times and lucky to speak with Dan in detail as in advance of this meeting. So I ink we thoughtful selection of the right additional members to the group we Elbe able to do a lot.
- >> Thank you.
- >> Yes. I agree with Nirav I also had Hans chans to review terms of reference a couple times and had conversations with Dan and with John as well previously and fill feel very comfortable with it. I am impressed with the way it approached in terms cover quality data coming ins an as well how infrastructure necessary to use the data in meaningful ways. So I'm excited to see about the way we can engage and support this group moving forward. I also appreciate the focus on standard difficult uzation and yet also flekt flexibility built into very ours elements of plan. And feel strongly appropriate roles for us to play and would be comfortable moving forward.
- >> Thanks Julie. With that I will accept a motion for accepting the terms of reference for the data and surveillance work group. Doif such a motion?
- >> So moved
- >> Is there a second P
- >> Second.
- >> Any furs discussion? If not could all members crystal are you –
- >> No I was raising my hand to vote.
- >> Please raise your hand either on screen or you can just perfect. I'm also in favor of this. Are there any opposed? Abstentions? Great. The terms of reference pass. Congratulations. Thanks so much to the cochair and special thanks to Dan Jernigan for leading us through that discussion. And we're off oh and running on this one. With that we enough earned or break. So we will take a break until John just correct me we want to go until 15 past the hour, right?
- >> If possible we we might go only for half an hour so that would ten minutes after the hour.
- >> Okay we will do that. We're on a break until 10 minutes after the hour. That's 10:10 pacific. 1:ten eastern daylight time. See you back then.
- >> May I ask the ACDed memberses to come on camera. We want to the do a visual roll call to make sure we have a quorum. And I see –
- >> Okay. We currently have eight members of the ACD on camera. David, so we have a quorum and feel free to begin when ever you like
- >> Great, thanks action John welcome back everybody. Good it oh have that break and good to get started. We have a busy rest of the meeting. So let's go ahead and get started. I believe Barbara Mahon is on. Hi Barbara.
- >> Hi. My pleasure to once again introduce you to the committee. You're the current incident command era CDC for Covid-19. We really appreciate your update to us last meeting and thanks for coming back. Emergency away also delight to a hear from Dr. Walensky in up coming role in assisting CDC in transitioning back in to centers institute and offices. We're glad you will be staying busy doing that. And look forward to your presentation today. The floor is yours.
- >> Great. Thank you so much. And hello everybody everyone. Good to be back again. It's, always enjoyable to give an update on Covid-19. So if we can go ahead and start the slides.
- >> And just like last pren days I gave to you I will start on update on the panned. And then I'll tell you a little bit specifically about some of our current CDC response priorities. So since I spoke to you in beginning of February, the world has passed 500 million mark for cases. And the 6 million mark for deaths two rather somber mail tones. And of course both of them are under estimates and more so some areas of the world than in others. Next slide, please.

>> I'm going to focus here the situation here in the U.S. And as I think most of you all know, and the recall, back in February, CDC rolled out a new metric which is called the Covid-19 community levels. And this is a measure of the impact Covid-19 is having on communities. And is intended to be the link to mitigation recommendations. So I wanted to spend a minute on that. The COVID community levels are based on hospitalization rates and the proportion of staffed hospital beds that are filled with COVID patients. As well as on case incidents. They they reflect the that at this point in the pandemic, it is pretty clear that SARS cove 2 is going to continue to circulate. So our metrics that link to action really need to be focused and to reflect the goals of preventing medically significant illness, protecting the most vulnerable, and minimizing stress on our healthcare system. Before I get into actually data I wanted to make few other points. The first COVID community levels have not changed our surveillance system. We've continued to collect and report daily reports of cases, hospitalizations deaths, et cetera, variants, none of that has changed. Secondly, the COVID community levels are built on hospitalizations. We selected hospitalizations as the foundation because hospitalization data are available for every county or health service area which includes every county in the nation. And because hospitalizations correlate with the outcomes of public health significance. So not just hospitalizations but also deaths, ICU in additions, medically attended outpatient illnesses, loss of work and school time, even post COVID conditions which are strongly correlated with severity of illness. So it's not that hospitalization are all that matter, it's that they are universally available measure that correlates with all of the outcome of public health significance. Also, I wanted to mention that the framework in fetch we encourage jurisdictions to think about their COVID communities levels also includes their vaccination coverage, critically important. And other local information that may be available. Some local cattle have access to information about waste water surveillance or emergency department surveillance to a mention a couple. And localities that do have that information. COVID community level can add but certainly not intended to replace. We also continue to new suings I'll show you some of those leading indicators in a minute. So on this map we see the Covid-19 community levels as actually from April 21st, a little bit more than a week low green, medium yell Le high is orange. As ache see, we were in low for most of the country. On the 28th last week this was bit more yellow and orange. But still last week, more than 98 percent of population was low or medium level. As you're all aware, cases have been steadily increasing in recent weeks. With some localized increases earn I'll go into that a bit more on the next slide. So could we go to the next slide please? So this graph shows the transitions between low, medium and high levels for the whole country over the past five weeks. So each of vertical bars is the state that country was in during one week. Then you seat changes in those ribbons that move over the top from one week to the next. In some what you see here most the country has low level for this 5-week period. But in recent weeks we're sewing so far relative small increases in number of countries that a high or medium level. And we we can continue to follow these transitions closely and a work with jurisdictions both on data, these are a new metric. So have there been some questions that have come out that we're working closely with jurisdictions to try to answer. And on implementation questions. Next slide, please. >> So in next few slides, I'll go deeper into our current epidemiology. And here you see the cases shown in purple. You see currently over the entire pandemic. So currently cases at quite a low level although you do see some recent increase in the last few weeks. Again this is graph from April 24th. The updated graph continues with steady but not steep increases. The bottom figure in orange shows hospital admissions. So new admissions not prevalent admissions. And we are at some lowest hospitalization rates that wee seen since the beginning of the pandemic. Again slow increase in recent weeks that we're following closely. Next slide, please. In terms of deaths they have thankfully decreasing for several months. We were a daily average of 314 when the slide was made, we're now down to 308. As of last night we're continuing to Doe crease. Next slide please. Waste water surveillance has been in the news quite a Lott recently. This is a really promising approach. But it is a new approach. And we're still learning how to best take advantage of it for Covid-19. At the same time, that across the agency we're thinking about how else, for P what other pathogens it could be or conditions it could useful. This the map from April 24th, with dots that are color coded to match the percentage of increase or decrease. These are very local measures. Just in single sewer shed for each dot. And you can see that there's a lot of variation across the country. And one of the things we're learning about is this have variation can due to things that have nothing to do with disease rates but things like rainfall and whether rainfall goes into the material had sue wablg treatment plan. Canless due to how close a case lives to the sewage

treatment facility. Waste water surveillance leading inindicater we've increasing four to six days before increases in cases. And wastes water also has potential to identify a variant a known variant. You can't discover a new variant with waste water. But they can identify a known variant before case surveillance does. I will point we are seeing decreases in New York State and are hoping this is a leading indicator of decreasing cases in New York State whiches really been the state that has had the great it's increases in highest community levels over the last month or so. Also I'll point out that if some other states you see very mixed pictures with areas of increase and areas of decrease. Next slide, please. In terms of variants that are circulating we're currently seeing all Omicron in the United States. This is the now cast figure that we're each vertical bar shows the strain distribution for one week. So this goes back to mid January and up to last week or the week before last. We are seeing the sub variant of Omicron B2 comprising an increasing percentage of what was across most of the this time a decreasing number of cases. BO two sort light lavender pink color you can see it an increasing percentage. Now just in recent weeks we're seeing a sub sub variant, sub variant BA2 this BA2.12.1 making up an increasing pro proportion of cases. First seen around New York. And shown in this figure in sort of the Sal salmon red color at the bottom. Is now present in all regions of United States. Not shown on this graph are BA.4 and BA.5 which you see in the press causing some cases in South Africa in India. We have seen a handful BA do 4BA.5 in U.S. But just a handful starting for each of them first at the end of March. So they've not been increasing rapidly here. We continue to monitor this carefully. Next slide please. In terms of vaccination, last week we passed 500 million doses administered milestone here in the U.S. Which is not everything we would like to achieve but I do think it worth pausing to celebrate. 500 million doses is lot of doses of vaccine. And represents represents a huge amount of really good work to get those doses out. Even while it's not -it's not the end goal and there are still a lot of work to be done. There's as you see in map here, a lot of geographic variability in vaccine uptake. That is no the news to any of you. Most of doses that being administered now are second boosters. On next slide I'll go deeper on boosters. And then subsequently on second boosters. So this first graph on the left with the side way histogram shows receipt of boosters by racial and ethnic category among people who are eligible for booster. And so you can see, in the third row down, that the highest rate of booster receipt in people who are eligible for booster is in the Asian non-Hispanic group. And then in the top row you see lowest is in the Hispanic Latino group. The figure on the right shows booster receipt by age group overtime. A remarkable range here from over 70 percent in the 75 and older group with 65 to 74 right behind them. Those are the purple and pink dashed line at the top. To under 30 percent in the 12 to 17-year-old group. Next slide please. I wanted to say a word about second boosters. At the end of March FDA authorized a second booster dose of either Pfizer oh are Moderna COVID vaccine for people over 50 or for those over 12 with moderate or severe immuno compromised who received their first booster at least four months ago. The CDC director and AC UP both endorsed option for these groups. And also for people who perceived two doses of Johnson and Johnson vaccine at least four months ago. Last week, we posted some considerations that people would who are eligible for second booster can use to decide whether to get that second booster now or whether to wait for later in the summer or potential booster campaign in the fall. Next slide, please. So that's a brief update on the pandemic and now I'll just quickly turn to some current priorities and recent chaeftsz of the sponges. Next slide please. We continue to prioritize health equity. We have in the last couple of months had an increase emphasis on persons with disabilities and established a disability officer position within the response unit of chief health equity officer which John is currently leading. And some of the work here has related to strengthening ties and addressing concerns of people with disabilities and people with immuno compromising conditions. And ensuring involvement from these communities in planning and responding to new developments such as issues around travel mask mandates. We're also working with other governmental departments that are in the lead on therapeutics to promote accessibility of therapeutics to marginalized communities. And whether disabled or immuno compromised or not. We're also reviewing the impact of and lessons from the grants we made earlier in the pandemic that focus on communities of color. And planning to ensure that equity remains, remains a priority and remained inactive priority both inside the Covid-19 response and in CDC centers and as activities are moved to their program mattic homes. This is an area that you on commit committee might be able to offer us to as we move forward into the next phase of COVID. Next slide, please. Related, we we are working on recently launched some tools and materials to help communicate with the public about their kavdz risk. Launching materials to help people especially those

who are out at higher risk to better understand their risk of get seriously ill and actions that they can take to protect themselves. So there's a planned know your risk tool. And communications that are available ebl and also in you know, in development for in communication around treatment availability. And we're working in collaboration with other governmental departments. Next slide please. We continue to work to sustain the use of Covid-19 vaccines which are just the critical foundation to protect the health of individuals and communities and the recommendations are still rapidly changing. So this still a great deal of work. We're supporting up the update of second booster. Working to improve equitably access both domestically and globally supporting efforts for all eligible individuals to be up to date on their vaccines. And importantly preparing for vaccines for are children under five years old. And here too very interested in your perspective on any aspects of vaccination. Vaccination program, both domestically and globally. Final my last slide, We're working on the response activity transition planning that you've already heard about. And at this point, CDC and really all of the public health needs to incorporate Covid-19 into routine public health practice and planning for the long-term sustainment of key public health activities. So we're working to transition the majority of program mattic and scientific response activities to long-term homes within the agency. And but, we important that we will be continuing with an incident management structure that reports directly to CDC director. It will be a streamlined but it will remain activated. And overall our goal this is transition should seamless from the point of the view of the public, CDC public health partners, jurisdictions, et cetera. So with that, that is what I wanted to tell you about. And I'm glad to hear your thoughts and advice and to take any questions that you might have.

>> Great thanks so much Barbara. Excellent presentation. Learned a lot. I will open it to the floor to ACD members for questions or comments on the issue that you raised. I know you have hard stop 45 minutes past hour we will make you are get out by this in. First over to Julie.

>> Barbara thank you so much for your service and for planning this role for so long you've done a great job. I wanted to just talk about a couple things I'm worried about. And I think it relates to this therapeutic and also vaccine work. Because we're headed looking forward I was excited to see that the distribution or path for and that at the same time I was worried about how we're going to get this information into hands of communities that have so disproportionately impacted throughout impact. Because I think that for people who have access to the information they know it really good option but you have to get initial period of time after diagnosis. I'll just concerned some of these communities of color low income communities might not have that information. So really wanting to encourage CDC to really ramp up and build support to really get that information into communities. And at the same time, thinking about leveraging that same kind of community based effort to support the childhood vaccine when childhood vaccines are available. Pause weather know we're on brink of having some under 5 vaccines available and that's very exciting opportunity and yet what I don't want to see is the disparities that we've seen in past with childhood vaccine and adult vaccines play out again with this effort. I am hoping CDC will put effort and resources into the supported community organization really able to get the information out into the communities as related to adult vaccines to do same for both therapeutic and childhood vaccines. I think those efforts would really had beneficial and really beneficial in these situations a well.

>> S yeah thanks for the comment. And very much agree with both points that you made. We are working with the ask for options for first of all expanding access to the test to treat program which is a great idea, that to have the ability to just go into a pharmacy with you know your home test or to get tested there and just get a prescription right away. But we also know that the pharmacies that have prescribers tend to be in wealthier lower SVI communities. So we've actively working with the assistant secretary preparedness response to work, you know to evaluate equitably the distribution of an at this virals has been been so ever. And to explore ways of expanding access. So that's just simply access. You also were talking about communication. And very much agree with you there as well. We're working with the surgeon general on communications around oral anti virals. I think you're right. There's lot more than needs to be done. And we share the sense urgency to get that information out there. In terms of the vaccines, we u the under 5 anal group is a little different than others like where they will vaccinated, right? So ink ayou're a pediatrician, kids under 2 aren't going vaccinated in pharmacy very much if at all we expect. And so, it's even more than for older children going to be very important for providers of primary care for children to be, to have all of information they need and all the operational

support they need to be able to administer these vaccines. And the number of will organizations American academy family practice American academy of pediatrics and other we're working with them to plan Dr. Doer Lavigne, the assistant secretary for health is very concerned about that pediatric issues as well. So I am hopeful that we will have an equitable roll out. I also see a lot of barriers awe as you do. And anticipating lots questions from parents.

- >> Thanks Barbara. You know one thing I'll just add a pediatrics I'm completely appreciative role Hale care provider as to young children yet I also have a firm believer that need needs company meant educational efforts through community as well to make sure that people are getting messages from other trusted sources and information as well. So feel like that would important to support. And also, I'll add this on tangentially, you're thinking about integration of COVID vaccine back into rest of CDC efforts when I look childhood vaccine cover as what went result of COVID feeling like those efforts should coordinate a you're folk's on COVID vaccine children less than five also addressing the other routinely recommend vaccines covers. So thank you for all you're doing.
- >> Really good point. Thank you.
- >> Thanks for raising that Julie. Over to you crystal.
- >> Yes. Thank you so much, Barbara and I appreciate doctor raising though is this top mind for me I had two other quick questions. One, when you talked about the university increasing percentage of 12.1 variant, is that are we seeing that in hospitalizations as well as growing percentage of hospitalizations or right now we only seeing in the community? And then my second question is about vaccines vaccination. And one of things I'm lettering a lot of confusion out there about what is the difference between eligible recommended. So if you know, once CDC says a group is eligible for a booster does that mean the same thing as it's recommended that they get a booster?
- >> The yeah those are two very good questions. And the in terms of B a 212.1. I think the there's two answers, two components of answer to that question. Our variant surveillance is based on strains received a laboratories. That isn't necessarily linked to clinical information. We do know we've seen a somewhat of increase m hospitalizations less an increase in cases recent weeks. And we're following that closely. We separately we and others are working on studies to try to look at the severity of B A actually in populations that their ability to gather the data to and to really look in a robust way at severity. To date there is no information suggesting that BA12.1 is more severe than the disease caused by other variants. It may be a little about it more transmissible, but there's no indication of a this incident positive of an increase in severity. In terms of an I'm sorry I should have made a note you were talk oh
- >> Eligibility verse.
- >> Yeah this is this has been confusing we know even before COVID, that vaccine recommendations that are not like clear cut, you know you should are always difficult for providers and for and for the public. So the first booster recommendation is a should. Right? If you have had a complete primary series and the relevant amount time has passed four months. And then you are eligible for a booster and you should get a booster. That's recommendation. The second booster is a May. So if four months has passed since your first booster and you are over 50 or over 12 and moderately or sphere severely immuno compromised or had two Johnson and Johnson shots you are eligible and May get a second booster those considerations I mentioned an attempt to help people work through like well I may, but what am i a going to decide to do. And sort of outline, you know if the person or if the people they are in contact with are at higher risk of getting seriously ill, then that might be a reason to go ahead and get it now. On the other hand, if they recently recovered from Omicron, or if they thinking if I've got booster now I wouldn't want to get one again in fall. Then maybe it better for them to wait. So that kind of information to help people you know make that decision where we don't have a clear cut should statement. Hope that helps.
- >> It does u thank you. I think rolling out that tool consequent just continuing communication to clear up that confusion will really help. Evening in my conversations aink that one reasons we're not seeing more people get first booster is this a lot of confusion about is that May a should, and how they make that decision.
- >> Yes four more minutes and three questions, so if we can try do them quickly.
- >> Thank you so much for sharing those updates. Progress and continuing priorities. This is a sort of building upon what Julie was asking in terms of under five. So I know that we've been hearing from lot of

our community based organizations partners, local health departments that parents and families have been waiting so patiently. And now we're heading into a new school for schools in some going into summer and masks are off. People are traveling. I weapons wondering I was reassured that you said there are partnership collaboration with Dr. Lavigne at the secretary level could could you say a little bit more in terms specific details I might be able to offer in terms of planning collaboration and the preparation that you're doing going into June and summer and the maybe the tailored perhaps out reach you might be doing in BIPOC communist we know they are amazing in numbers vaccinated across country there still persistent inequities that we're seeing in specific cities, regions of the country. >> Yeah. So I think lic just sort of in interest of time, probably the best summary I could give you is that we are working with -- we have really pretty extensive network of partners, provider organizations, community based organization since the start of vaccination campaign. We have very detailed operational planning to roll out the vaccines and to support their their being available at and to support providers with information to support for parents, you know previously it was just people who would get vaccinated. And, we are our team have been really thinking for a number of months and working quite intensively on preparing, sort of adjusting that for the under five scenario where we expect vaccination and pharmacies will be less important. I would happy to tell you more but I know we don't have very much time. Maybe I could follow-up with you afterwards.

- >> Thanks Barbara p we do need to be respectful your time make one more company.
- >> Thank you for a that Barbara great presentation maybe there won't enough time for this, but, seeing that there's an'in equity when it comes to Hispanic Latino in information you shared with there concert effort in equity is no the beaquality where do resources need to go when we see inequity there strategic fan plan to increase that racks rate
- >> Yeah there quite an it about of work I do have to jump to another call I should, so I don't know if fair to John, but John is currently leading our response unit of chief health equity officer he may be able to tell you more. But I can also share some information with him and with David to share with you. Thanks so much.
- >> Appreciate Barbara.
- >> Thanks for your time we know you need to 62 account.
- >> Yes. All right
- >> No apology necessary.
- >> Bye everyone.
- >> John any follow-up on that one?
- >> I think our the best situation might be to get that package that information for send it directly to you share with other members as well. I'll work with Barbara to do that.
- >> Great, thanks, John. I was just wondering about what is process for reaching out to trust voices in community and engaging procedures and skill sets. Because I know how challenging it is. And other one is, how many materials and what different languages we using the different modalities. That would be really helpful. Thanks.
- >> Thank you. We'll make sure to get you that information.
- >> Thanks. It's time to move on to our next topic. I was thinking on NPR when they move from one story to the next story there's a little bit of musical interlude to allow you to do mod shift. We don't have that. Maybe we can put on agenda for next meeting imagine a short musical interlude now. It time talk now about formation laboratory work group. And unlike data modernization surveillance working group this is our first presentation on this subject ub. And so we'll get to that in a minute but I did want to the let folks know I told ACD already good news for this committee as well, ACD ebbs m Jill Taylor and Josh have agreed to serve a co-chairs for are this group. So thanks very much you two. This is a huge task and we really appreciate the commitment of your time and energy. And to lead off the discussion today is really my pleasure to introduce a person live no long time kurp lead CDC official on lab science and safety. He will give background on this issue and then, with Jill and Josh, help lead us through a discussion of draft in terms of reference. Just wanted to make quick note we talk more detail but a slight speed bump in clearance process of the terms of reference. So we weak have a full discussion today and you can express ideas if any for revision but we will defer the vote on terms of reference to our that vote include formation of work of group but, it will result in a vote in our next meeting in on terms of reference. Having that that, Jim over to you.

>> Great thank you very much. It's a pleasure to be here. I have the next slide, please. I'm going to organize my presentation today into several parts. First will be just a background a little bit on CDC laboratories and what goes on in CDC lap Torres and I was asked to kind of give a provider how we got the materials in advance I sent about nine slides that would give some context on what CDC labs do. So I'm going to try to do that actually rather quickly P then I'm going to get to the laboratory quality plan and then the third pardon would be the discussion of terms of references. So in terms of CDC laboratories this is your overall chart. If you know this chart you would considered a CDC expert. We have a 6 CDC and NIOSH. And spread all throughout CDC. There some 2500 laboratory radars. There are over 20 different laboratories. So this is a major group of CDC, I think u you're all familiar with laboratories in general. So I'm just pointing this out to show where this affects CDC and where these things are locations, where locations within the structure. Next slide. So I don't ever all the public health role of CDC laboratory is to a provide an effectively supports detection, diagnosis and treatment and reprevention of disease and harmful exposures in populations. This is essentially to effectively support the mission of CDC. Next slide. I have two slides here that go over what are common laboratory activities. What are the things that laboratories are doing day-to-day. And so at CDC a common and important thing we do we analyze samples to find unknown pathogen or toxic agent in an outbreak. Those things you're familiar with. We work on developing better diagnostic methods for diseases and harmful exposures. We work to support detection and diagnosis of infectious diseases including extremely dangerous pathogens ask is those require high containment library there moon soot pictures you seeing people in very, very dangerous. And of course if you are ever interested we can probably take you to see one of though is laboratories if you haven't them before. And just to know the kind of work that goes on there. But high containment laboratory specialty a CDC. Some other labs have them for sure, but CDC we work with some very dangerous things that require these labs. We support surveillance of disease incidence and prevalence. A lot of of these things depend on diagnosis from laboratory. And gives us it instance and prevalence information. The laboratory results identify vulnerable population groups. That at higher risk of disease or harmful exposures this of course very important so we can target preventive activities towards people highest risk. We also help define risk factors that cause people to higher risk of disease or harmful exposures. Next slide. And we we have really just six more things to say. But first three on this slide deal with outward facing things that CDC does in collaboration with partners. We serve as a reference laboratory that provides it quality testing to other labs. So there are some tests that are not really well available in many classes. CDC has some tests that only CDC does. And we try to strive to be a reference quality laboratory. So that we can provide quality testing to other labs that need reference center to say what should the result look like if I compare my result to yours, I can confident this CDC labs did it right and I'm going to use that at reference measurement. We a conduct quality assurance programs to assist state and local other laboratories. And we have lot of these that actually take things that we do at CDC and we work with other labs to inensure quality analyses on these same tests. This is many, many laboratories are involved you know certainly well over 3,000 laboratories are involved in this. We provide technical assistance on performance and interpretation and diagnostic tests and then we help treatment challenges such as an bottic resistance, big effort is in supporting research studies to better understand disease transmission resulting in better health prey ventive action and we also work to help evaluate effectiveness of treatments or preventive actions. This is kind of the cast of things that common. Next slide alight overview to say we have lots of infectious disease things. Lots of chronic disease themes a lot of stwiernIsal things things that deal many nonstwek sis we will do through some of these you've had these slides you can look at these in more depth. Most these labs are doing common laboratory activities that I just mentioned so I'm not going to go into in great deal of depth in these labs. This also will help you C CDC acronym pegs walk through this at the end and you know what NC E I A DNCHHSTP is we give ten bonus points. After career those bonus points ad up these ponder thing to know in terms of structure. The. Largely bacteria viral pathogens in several centers. But it is the largest center that we of that deals with bacterial viral pathogens they also have a heavy emphasis on in looking at identifying things that other laboratories cannot. And also look very heavily in anti microbial resistance. Next slide. Then NCIRD is the center for immunization and respiratory diseases. And so they are big place that flu works out that big place that we'd deal with Coronavirus. So the COVID outbreak had a major support here. They also deal with a global Polio eradication. Next slide. And so the national center for HIV viral hepatitis, STD

and TB prevention. NCHHSTP. I don't think I know five leaders rat CDC that can say that fast thee times. So it is a, this is essentially aids. Viral hepatitis sexally transmitted disease and tuberculosis. They do exactly what you think they would do in that area. And we have a special national reference laboratory that north worthy. The center for global health is got vision out for world. They help more 50 countries and outbreak response building laboratory systems and pathogen discovery. Big programs and parasitic diseases ask malaria and large laboratories in both of those areas. Next slide. Then we have a small laboratory in national center for birth defects and developmental disabilities. That looks in persons with bleeding disorders. Monitors for selective infectious agents. And other abnormal factors. Next slide. Then there's a large laboratory in stwiernl for environment health looks lots of things in the noninfectious disease area monitoring people for exposure to environmentalal chemicals assessing exposure to chemical threat agents, tock in and rad ledgic threats providing quality assurance proficiency testing technical assistance for newborn screening in every state for early detection of treatable diseases assessing nutritional status of nation in cooperation with the national health nutrition examination survey. Working on addictive toxic substance tobacco products including vaping products improving quality of measurements in many state clinical and research partners laboratories addressing chronic diseases nutrition and environmental exposures. Next slide. Then you have NIOSH. Interester this particularly interesting to me hi like to hear about NIOSH laboratories they are working to test and certify respirator and make sure protective equipment is working the way it should. They develop med methods tore sampling analyzing contaminants in air and blood and Europe. They do other interesting work engineering controls as well. So a really a variety of stuff in NIOSH. Next slide. And so that finishes just a brief overview of kinds of things going on at CDC. And this presentation though is largely to focus on CDC laboratory quality plan. Next slide. Now Dr. Walensky asked me to take this position because we had had some problems, you're very familiar with problems we had in February 2020 with can with our initial COVID tests. And review inside of CDC that came from that identified other problems that we really needed to address. She asked me if I would come in and work on this and to make sure that CDC labs operated a gold standard quality level. And that our labs are at the forefront of advances in laboratory science that benefit public health. So so I came into this position November 1st of last year. With that goal. So that is our vision. What we're presenting is a plan here is a strategicic plan. This is the vision for that plan. Next slide. So we have really six be specific goals underneath that. And some of these are very large goals. So three of them on this slide three on the next slide. And the things that we're talking about here do have a focus in infectious disease laboratory area. We are looking at other laboratories, but the thrust of what I'm going to present today is really working on assuring high quality and infectious disease laboratory. So the goals that we have to make sure that we have excellent quality infectious disease lab methods with review that documents that excellent quality. The second one is to make sure we have excellent quality infectious disease lab results that leads CDC that all pass appropriate the quality control criteria. And thirdly we want the clinical, infectious disease did clinical labs to pass external reviews with only an occasional minor deficiencies. Next slide. The fourth one actually very important in pandemic response. And that is that we need to have a demonstrated effective capability to rapidly develop high quality diagnostic tests for new high risk pathogens under emergency conditions in collaboration with private and public health partners. So that's pretty easy to read. But that is extremely difficult to do. So this says when under very tight timeline of emergency conditions we have to come out with a very high quality product, that's got to be able to diagnose a high risk pathogen get out such a it can applied quickly and do that collaboration with private P and public health partners. Fifth thing we want to have a single excellent quality manual for micro biological laboratory that is covers all micro biological laboratories. And the sixth one we need scientists and sustained funding to be available to labs can ensure high quality be and forefront of advances laboratory across ins that benefit public health. These six goals P we've undertaken as a result of that review. Next slide. I've got slide here on constraints. That several things that make that task difficult. The first one at CDC we have clinical surveillance and research labs commonly together. And this is a very tough constraint. It is very common that somebody will work in a diagnostic laboratory in the morning that a clinical lab and this the afternoon they will spend three or four hours working in at research lab working ensay developing new did I nossic assay. That's same individual. Also possible that people could be working in a research lab developing new things or doing studies and then, in that afternoon, they are running samples that used for surveil available lens that aren't used for strict clinical test thing but

sample that is give surveillance information that don't have patient information attached to them. And so it's very important for us that if we we have a quality plan that that individual that's working in one lab in the morning and another lab in the afternoon is not schizophrenic about what they are responsible for but we have integrated quality system so we have common quality standards that go across clinical surveillance in research labs. This is a huge, huge challenge. And so this is something weed to spend a lot of time addressing. And the second I've already mentioned we've got to make sure we have quality ensured for emergency rapid test development for test that is have high consequences for quality failure. I'm sure you're all familiar with this. What I generally say is that there are three conditions that fight each other. They are quality, time and resources. And if you're been in management you've had to deal with all the time. Trying to figure out how you will balance those things. And of course everybody that above you in management wants everything in high quality and very fast time and use very little resources. But those things fight each other. Well at CDC we basically say there's isn't a, there isn't any kind of option available in terms of quality. We're locking quality at high. So there is no chance to say we Ed to develop it fast so it doesn't have to be of high quality. That's not acceptable. So that is locked at high. That means only two things we really have to adjust are resources and time. And emergency locks time at fast which means all we have to do adjust is resources and make sure that resources are trained ahead of time systems are in place and everything can work as smooth as possible. But this is a big issue the very fast development work that has done to high quality and we have adequate resources to make sure that happens. And then we have more than 1700 people in stwek infectious disease laboratories that that spread in 200 lapse across multiple states and territory ps you can't just walk around CDC campus and see all the labs. They are in Alaska, fort Collins they are in Puerto Rico. They are all over the place in NIOSH lapse are in multiple states as well. Next slide. We came up with laboratory quality plan. It really has 5 these 5 elements and rest my presentation really going through these elements in a little more depth. Infectious disease test review board. Second to three separate quality management systems one for infectious disease labs, one for noninfectious disease labs and one nor NIOSH labs. Third to have quality manual for micro biological labs laboratory woes call QMML. Fourth is we need flexible and use friendly quality management software. And the last one is to have biennial that once every two years external review of every laboratory which would clinical laboratory surveillance laboratories and research. Laboratories. I will talk about these in turn. Next slide. So infectious disease test review board. Next slide. The infectious test review board is board that we have already pulled together and its function is to review test method developed a CDC before they are shared with external laboratories. In this review to ensure the quality of test and transfer ability of test suitable for intended use was. So the concept here that is if a person develops the test then has to put it up for review by this board before it can shared from CDC. So who performs. We have a panel of but at least three scientists who expertise in the method science. Oh if are. It PCR we have people that are experts in R. Enzyme immuno assay people very familiar with assay. But they cannot involved in the test development ask they must recommend approval of the method to test review board who then votes and provides final approval. Next slide. So when they review it, when these people 3 people review what are they looking at for those that familiar with lab what we call method validation review. We look at the test performance specifications and performance of the method and see if suitable for the intended use. Those of you more kind especially deem logically bents you definitely will recognize the value of diagnostic sensitivity and did I nose specificity. A careful relimit detection sample collection and stability, quality control pry criteria through quality control criteria evaluate all of the parameter that is influence the quality of measurement and then can we successful electric ever the test to another laboratory so that it all really works not only on paper but it actually works in reality as transferred to another lab. Next slide. Most of you have seen a some point. Not really diagnostic sensitivity bp but did I nose specificity thattal Milt goal but predictive value of the test. So this is that same table showing how sensitivity true positive rate calculated. House specificity or true negative rate is calculated. And of course, both of these are much better if you have low false positive and fall negative raets. I generally like to talk about low low false positive and low false negative rates from communication point of view people clearly understand that. Some people have difficulty just grasping the that that sensitivity is true positive rate or specificity is true negative rate. If you this deal with often sometimes it just slips through your mind. We want to post predictive value and those thoen and we better positive predictive value when we have these low false positives and low false negative rates. So kind of short summary here is

always benefits you to get your false positive rate and false negative rates as low as possible. It helps high highly in predictive value. If being away Geoff to take into conversation predictive values function of prevalence of disease. So it does have to do with the population that you're sampling. Next slide. So this infectious disease test review board then is actually one of the very big things that we wanted to put in place. Had we had this board in place in February 2020 then that test would not have been shared and problem with test would have been identified. And so any test now that goes outside of CDC has got to in front board board began meeting in early March of 2022. And so anything from here on that CDC puts out has got to through approval of this board. So this is actually a very major check of quality check at the end to make sure in all of the processes that went on is the product that we're going to send out an excellent the quality product suitable for the intended purpose and this board is what verifies that. Next slide. Thee separate quality management systems. Okay. So let's go to the next slide. One of early things I had to address was there of course have been many quality meeting at CDC over years. Lot of quality system running around CDC. There have been concerted efforts to try to bring things together. But one of the difficulties has been CDC has got such a diverse set laboratories you talk a quality management system that fits everybody, it really can't get down to the detail that it needs to get to. So one first things that we did is to say we're going to have three separate quality management systems. We're going to have one that deals with an infectious disease labs one that diesel noninfectious disease labs and one that deals with NIOSH labs. Again this allows us to get down to the depth, to ask really specific questions and this is kind of analogous if you are familiar with hospital laboratory set ups there micro biology laboratory in one place. And there's a clinical chemistry laboratory in another place. And the quality control systems and quality management systems those two laboratories use districtly different and we're in one way doing that a CDC. Saying we're going to focus heavily on micro biology laboratories with one quality management system for them and we're going to go deep so we specify quality standards that really make difference in quality output and do same thing for clim which em industry labs and same thing for NIOSH. NIOSH has to more custom related things because of specialty of their labs. NIOSH actually has a lab that literally an underground mine. Literally a mine underground. So it has got to have a specialized quality management system. Known of these other would fit. Actually a big step because it allows us again to get to the depth of looking a utility request standards that are most relevant to quality output from these different labs. Next slide. Now I'm going to talk now on quality manual for micro biological labs. QMML I have about 5 slides on this us bah huge Ang or of all efforts we're doing. Next slide. So the concept for this manual is it will be one stop resource for comments micro biology laboratory quality practices. Now for those of you that have been in lab you may be familiar with the bio safety and micro boj we call BMBL. You can just walk out this meeting and you're not a lab person walk lab person we heard about the BMBL you will they will think you're very knowledgeable. Bus this go to safety things in laboratory how you're going deal with very virulent pathogen BMBL will tell you how to do. We want to have U.S. just like that go to manual for safety. We want to go to manual for quality. The mantra a CDC would safety first and quality second. We want to make sure that we set standards and they are high standards for CDC. Now the standards set in quality manual will exceed the standards that are required by for clinical laboratory and will also exceed the standards that are required by FDA when they review methods or have to approved meth methods for are use. We'll in this quality manual separate the sections that handle clinical laboratories and athe section that handles surveillance lab and another section that research labs. So that's what purpose is and what is inside of it. Next slide. I'm going to spend a minute or two on this you don't have to read everything that inside theers bah. Is important why your eyes you can tale from salmon orange from the purple blue. And so you got to El it the bottom from the top here. So this is what we eventually did to address this problem that we mentioned under the constraints that we had people working in different kinds of laboratories and we need to make sure that that our quality requirements integrated and made sense. So if you look at the field the clinical laboratories have regulation that CMO oversatisfies called CLIA they which and requirements requirements that every clinical lab has to meet. You go hospital are you get a test though laboratories have certified by CLIA, that they are all kwaut standards that they should. That's what we would call a clinical or CLIA lab. You went to the research lab and said well what quality system is there, there is no quality system that set up U.S. that says this what research labs should do. There are if you attempts to that have been made in literature and none of them have generally be successful. So what we're trying to do a CDC is to say that there are some components in a

research lab and surveillance lab and a CLIAA lab that are common. When we common elements in laboratories we want to make sure that they have at same quality standards for elements. When alook research lab on far right, research lab should make sure it good test documentation. Including method validation like we just talked about since sensitivity spes activity, it needs to have quality control samples rejection criteria, proper calculation, it has got to have right kind of quality criteria all four tests. You're research laboratory you you're using a test you need all of those things. It needs to have ability to address noncon femur forming incidents NCE and come up with corrective and permitive action smmdz called kappas if an instrument is no the working radio the O ring leaking and not performing at the way it should you've got to say that's a nonconforming event. We have to figure out root cause and implement a corrective action and prey ventive action if necessary. All of that has got to be documented. Next researcher that comes along with know that. We won't have that problem again. So a research laboratory has got to do that surveillance lab has got to do that CLIA lab has got to do that. For personal document duties training competencies qualifications of your people, make sure that they are adequately traineded to perform the test that they are doing. You have to do that in research lab, and surveillance, also in a CLIA lab. You have equipment maptd nens and function checks. The things in tale or common elements that we find in research labs surveillance labs and CLIA lab. We're setting up in this quality manual to say they are standards for research labs and for the common elements that we're research labs overlap surveillance lap and overlap CLIA labs going to about 95 to 100 percent the same quality standards. There's an a little wiggle in there. But almost all of them will have the same quality standards. So the person that walks out of the CLIA lab in morning having worked in that lab in morning will walk into at same quality standards in the afternoon when they are working working in the research lab. Now moving from a research lab to surveillance lab what do you add? Now you're getting specimens in from field that surveillance specimens you have to deal with sample collection, shipping and storage and handling and stability studies. And so we've got some of those things lessed in that kind of orangutan section there I did guess salmon color. And those are also things you have to deal with in the CLIA lab. So our quality standards for things that in surveillance and CLIA lab are shown in salmon we want them to be same. Now when you move CLIA lab you new things enough you samples coming in that relates to specific people and results are going to sent back to get to someone managing patient care. You have to an other things test requisition, test records, test reports you have to a complaint system. You have to special security, personal data you have to have a system to handle sample referrals. So it isn't meant that everybody box here exhaustive, but this but this concept of stair stepping up starting with research and going to surveillance and going though CLI A and common elements have common quality is novel thing we're doing. Next slide, please. Now a second thing that is really big in the quality manual is that weer convening med supper groups and by that I mean thee CDC lab scientists per group. And each of those groups develop an excellent test method quality standards for each method type. Now a method type, you will familiar with this from COVID a lot laboratory stuff come out with COVID. PCR test are RTPCR test is method type. And an antigen based test like you get the very rapid test for COVID, well that's a method type. Enzyme assays is method type serology is method type. So each one of these an expert group that comes together is sets up what an excellent set of quality standards for that method type. And then, every CDC method that is in that method type must meet those standards. Right now we have an RTPCR group working that first group we're trying this out on. They are coming up with excellent standards for RTPCR. When we finish that then every RT P CR assay at CDC will have to meet those quality standards. If they are missing some data they will have to generate data. And they will be written up according to really some excellent test documentation standards as well. And so they will be on such a quality that somebody will on outside could pick it up and really know all things they need to know about executing that test. Would be able to so all the method validation and would able to see all of the work that shows et cetera high quality suitable for intended use. So these method expert groups another brand new thing so we can set what is the excellent quality standard and then make sure that everybody that CDC working in that method meets that quality standard. We will do that for each method type. Next slide. I'm not going to go through these kind of things they deal quality standards are shown here. It's a long list of things and these are very important things in method validation. I do want to mention at the bottom there tran parent listing of all td data if be some you can developing for Sikh did you it you test other viruses to make it didn't cross react with your assay. You can check we did and here's the results for everything that we tested to validate our

method and you can see everything about it and somebody else well did you have in the inn outliers here is the raw data you can look and see if there are any in there any no we didn't but we're publish thing raw data not just calculated values. So everything that goes into calculated did I nogsic sensitivity and spes activity ever piece of raw data that goes into in a calculation will also be shared in raw data form. So the provides is completely transparent. Next slide. Now I just want to mention when they work test documentation for these methods we are two special sex put into method emergency single method at CDC will have a first section that is safety pointers. And this will be about 5 to ten pointer to pay terrible attention to when you're running this assay in laboratory. First two comments that are always going to be on every assay are shown here. If you're not certain about the safety of every step in this procedure, then stop and consult your supervisor. And the second is do not hurry. Work a steady, controlled pace. The reason we're putting these in these are things that cause problems with safety. People don't want to share because they are afraid people will think they are really not competent enough or know enough so they don't ask questions. We need to know people very important to ask questions on safety in any time you have a safety question. And also, don't hurry. Problems are so often related to people that are in a hurry. Now they can justify why they are in hurry but theyer in a hurry. That causes safety problems. And then list other things that maybe specific to this method like all steps required double gloving. That's not true in every assay but it is true in this assay this lets people get right in the beginning method and say is though are the special safety things for these methods. Again up to around 10. Next slide. Now that safety pointer followed by quality pointers. And we have same thing. If you're not certain you can perform every step this this procedure at the quality level needed, then stop and consult your supervisor. Same principle as with safety. And then, when we, this common in the laboratory, they will say something like heat something in water bath for 30 minutes and at 56 degrees. We we've got write things 30 muss or minus one minute temperature must be 56 plus or minus 1 degree. So people don't eat it for 45 minutes saying well I surely for 30. Disastrous in lab. Some of this might seem kind of simple to you, but this is really based on what is it that additional caused problems we want to make sure we in advance we keep problems from happening. This would be about five or ten quality pointer specific for this assay things you want to make sure you uld attend to that you don't to will come back bite you I know. Is seems very common sense this not done but we're going we will be having this for every CDC method. Okay next slide. That's quality manual a lot on quality manual but it why I Gancally important when it freely shared and available to states available internationally, it will be sitting on our website where anybody can use it we would encourage them to use it. The next one we're almost done here is the use of flexible and user friendly quality management software. So in laboratory next slide. In a laboratory you will hear people talk about quality management systems or you will hear them tall. I want to clear on this, a limbs is a laboratory information management system that tracks the sample from cradle to grave. From time it was first collected until final report is sent out. That's the limbs. It keeps track of it all the way make sure that it was sent in analyzed correctly the report was generated correctly, very, very valuable. But totally independent of a laboratory information management system is another kind of software which a quality management system software. We call eQMS. These things go in and handle things like document management try to get the documents make sure you've got test method and SOPs and everything done in a, you know in a manner this you're look latest version and all of the important things are being done with it that you track nonconforming Eliot Spitzer kappa training records competencies testing, it's largely administrative but really helps manage all of the documents and all of things that go into equal laboratory operations. So we're trying to get a very good package that is user friendly as much we're trying to make like apple app user friendly as possible so people can really benefit from it. We can make sure these things are up and operational uniformly in our labs. Other advantage is if we have it in all of our labs a higher levels we can look across the CDC labs and make sure that they are taking care of all of these things like they are nonconform incidents whether what do their corrective action look like something we're pushing very hard. And I know I'm short on time I'm going to go to next slide. And that is all laboratory have review for every two years. For CLIA labs, next slide. The next slide is for CLIA labs this has got to be done ever year review by CMS or a couple of surrogates for CMS, American association for laboratory accreditation or college of American pathology. They both can perform CLIA reviews. We've worked out special arrangements with American association laboratory accreditation so we will have special reviews for our surveillance and research laboratories they are very interested in making sure that this research thing can get off the

ground because general quality management systems for research labs antiavailable. If our thing works out well A2LA is very interested parole um gaiting Tut oh large research in community a federal and sedate governments and private sector. So I ink me with this, am going to stop or want me to run through terms of reference

>> Thanks Jeff what I agreed was given the amount of material here, we would let committee come up for air a little bit.

>> Okay.

>> And the purpose of this background was to number one as you've done so well, outlined the scope and scale of laboratory operations at CDC. And then second, we wanted to the committee to know about the huge amount of work that you've already done. In approaching this issue a laboratory quality. We will go to the terms of reference which Waugh aspecifically asking of committee. But did want to give folks an opportunity the at this point if they have any questions about scope ask scale or about the work that we've already done to be able to ask. And to you, Josh.

>> Thank you so much. Thanks for is such a great presentation. I think it would helpful, and everybody has read about the COVID test problem in has early 2020. But there are obviously some other things on your mind you're trying to accomplish P with this laboratory plan. What are those things? And either by way of reference and I don't mean just generally so to have excellent labs I mean, you don't want employees exposed, has that been a problem? You uniwhat are the challenges at CDC have had that you're really hoping to resolve beyond challenges with the one test?

>> Yeah. Right. So they are largely reflected in the goals. So kind of every goal is really addressing a problem that we've had. When we say we don't want the a test result shared that isn't of quality standard that we want, that's what what happened in COVID that was shared before. That was a problem. We've had some problems with some test results not going through as thorough review they need that's one other goals. We've had some difficulties that we've HAN external review they found deficiencies in some laboratories that weren't just just few casual deficiencies but things we felt were more casual deficiencies we didn't want to have that. Another big thing there wasn't an overall set of quality standards that was uniformly accepted. We had lots of pockets of people who had worked on quality and had their own idea. But this set of quality standards was different than this. And if you said whats the CDC standard this person would say something different than that. And we really needed to get those people together and agree what is the excellent standard that we're going to adhere to. We can't have all of different things across different centers. And so those are the big things. And we also have to give the director the assurance that when something comes out CDC she can stand on it it's going to absolutely right. He has got to makes decision that lot implication and you can't second guessing wonder thing well I wonder if lab really got that exactly right. She's got to be high will confident the lab got that exactly right. She can stand on it.

>> Thanks, Jim. Really helpful. Jill.

>> Hi Jim. Thank you for all the work you have done so far. It's just really great and reassuring. Can you talk talk a little bit about the partnerships with a public health partners in relation to the development of a test for high risk pathogen, you know lab failures can happen in any lab for all sorts of reasons not just a quality issue. So we have to boil it down. Can you talk about that?

>> Yeah. That's very excellent point. So that is something that we're moving. The plan right now is that if we end up in the situation where we have a rapid test that needs to be developed and there's significance consequences for failure, then at CDC we do not want to the only lab that working on it. We're going to give it our best shot, pull best people together to do it we want to have at least two other laboratories working independently and a parallel on this the same task. And we want to fund them in advance. So that we're giving them some some funding to help them out to be prepared so they can work rapidly on that. And so I'm, my preference is that that be towards state laboratories and I think that there definitely a couple of, a bunch of excellent the state laboratories we work together with them, then if we have something really difficult and risky on our plate we have three independent shots. If the state laboratory comes out with best method we will go with that we will go with what every the best method is you're exactly right we're trying to say in future redundancy is requirement not an option.

>> So, I total support that. I am nervous that this happen sooner rather than later. We don't know when pathogen not just pathogenic tests pathogen tests it could be chemical tests, whatever. But we don't

know when the next event will hit us. I just urge CDC by I know you have a heck of lot of new things but I urge CDC to keep that high on the list, please.

- >> Thank you. Yes.
- >> Thanks Gillette members know we have fair amount of slack later on in the agenda this afternoon. So let's go ahead and get these three questions. Josh.
- >> Thank you. So quality being such a critical goal in focus and so much effort a good quality plan is one component of quality. But obviously it's not all of quality. Among other things, is performance management for example. Are the quality is plan being followed at different levels? How much thought have you given to that? Is that something that that would be useful for the work to be assisting on? Like you have the quality plan but how, you know, what's the right level of transparency? What's right level of oversight? How do you manage to a quality plan? And how do you think about that?
- >> The right. So I didn't P that's I mean exactly right. I didn't go into detail on that because of time. But what we have done is in the past there has been a program called CLIA compliance program P infectious disease centers. What we've done is we have changed that, made it much bigger, and a put off office director deputy director for infectious disease laboratory quality office. They are assigned for infectious disease labs for that very purpose. Their job is to have oversight to make sure that when are enimagine gooding in these things all of this checked. It's done. Now the couple of checks that happen, we have review at least once a year an internal review. Then every two years, according to plan we have an an external review. So we have a review literally every year that are looking to monitor to see how well these performance requirements are being met. And then if people don't meet performance requirements there pretty straightforward path of citing a deficiency they have a come through with plan and you check in person periods time that that fix has sustained. So we have a lot of effort going into that. In addition to that, the office of laboratory science and safety which I head is another layer of above that that takes a look and says we want to make sure that that review being done by that body in DDID is done well and is up to snuff. And doing all of the things that they do we have are couple layers an ernl external review form swernl internal review literally coming into laboratory and so we feel pretty good that we're going to be able to track where their problems and people will be held to make sure that they come through and make quality changes.
- >> Just a super quick update. Is there any layer tracking not on annual basis? Are there
- >> Sure.
- >> Yeah.
- >> Set up a system that would give an early warning of problem?
- >> Yeah more than that, yeah. I may have to off-line it conversation so we don't go too far. There are lots of things one big thing we're talking about in quality management software if we get this into every laboratory, then a center director could sit in their office and take look all nonconforming erpts in laboratory in the last year without talking to anybody. Not doing a data call or anything. Just direct query. We will have ability to record oh quality metrics then when people are feeling cruelty control criteria that interest a nonconform thing ept. That will direct access to reviewed on a regular basis. But in addition to that we have things that cascade down down in structure where people going visiting labs and ument today's what's going on we're actually tret thorough on that in terms of what plan will be. But I can give you if we talk off-line. It's a little more detail.
- >> We'll go to the discussion terms.
- >> Great presentation really learned a lot. I really like the in a quality check I D test concept. You F. You said this I missed I apologize, what are you also sharing export exporting that concept to other labs not only national labs nationally but even internationally? Because I think it's a really important quality check you guys have identified and have created.
- >> Yes. So answer simple answer is yes. So when this quality manual that we're talking about describing it will be in the quality manual. So it says this how this works. And so it may not be that everybody has got same trur that we have at CDC. But the concept test review board independent people who develop test will be well written up in that. Again I've made this presentation several times when you Kahn send it we want first chapter. Because ernd wants a piece of this we're not handing it out chapter by chapter, but this is something that when we do finish will be a living document we'll keep improving it. But it will be an available lots of labs and it will have thing in you're suggesting.
- >> Thanks Jim.

>> Great presentation. Seems like focus working group is on the quality work this that you're doing so important my question my alleges tangential I hope you will address it. When I thing about the pandemic and early mid pandemic this was lot concern U.S. ability to detect variants. COVID variants. I was wondering if the genomic surveillance that Barbara mentioned earlier if really helping to build capacity where your folks primarily on the quality. I just would love to hear a little bit more about that. There was so much concern expressed about our ability to check and wondering what CDC is actually doing to address that issue.

>> Right. Yes my focus really is on the quality. I just happen to know the answer to that question so I can tell you that there's a huge emphasis in CDC to make sure that we have capacity to be able to do a reasonable sampling to spot variance when they are coming on. No they were no the set up for that beginning. So many things change in last two and a half years a CDC. I mean Dan's talk this morning a lots of things change in surveillance just night and day some of them are great burst because we are into authorities we never had and wanted. But this is one of in J J nettic sequencing keeps getting faster but you're still going to need ten or more labs out there CDC is work workgroup that are processing through the state. No way we can handle that at CDC. We have some things like that net in response we have things coming through. Question is what is it going to look like after the response when we don't have an emergency going on when funding streams are different, then how is that going to be? But a minimum, we're going to have to have at capability and have relationships built up with number of labs that if something else happens we can rapidly build up this stream of genetic sequencing and get it to a fast pace. Now where are we going to interim how lowest valley going to go on number tests I can't answer that pew we're for sure going to relationships built up so something like this happens again we can engage at this high level very fast.

>> Great. Thanks. Great question let's now movp oh move on to presentation of Terms of Reference >> Okay. I'll if I can have the next slide. Next slide after this. And so the next slide after this. There we go. So the primary charge of course is to provide work products to assist ACD in two recommendations on the scope and comble men traegs of improvements to stremthd enquality of work within CDC labs. We've mentioned these things already. This is the gold standard quality and maintaining the forefront status in laboratory science benefits public health to build a rapid high quality diagnostic tests for new high risk pathogen and recruiting ask Erie contain thing high equal fight scientist these are big areas for us. Next slide. But specific charge that we want to deal with is that we have a question sometimes comes into CDC, CDC sometimes the laboratory of last resort. So we get test spes specimens less than acceptable or. But regulatory requirements that say in advance you have to test for stability of your an light and specimens if something sitting out for three days on the counter, you only let it set out for one day on counter, you can't make measurement on that. But CDC often is laboratory of last resort. We'll get specimens that less than spentable. We would like to do what every analysis we could do. But it flies in face what if we have to regulatory rumors if it doesn't meet our criteria we have to reject the sample. We're conundrum on this we would like to get advice how we can report results with appropriate limitation to interpretation. So top might say not CLIA test result. Must be interpreted only with within the context of the description given here or something like this. But it's valuable because it's very difficult to come up say with a false positive for an infectious disease. And if we get a positive in any kind questionable sample it could really influence us to think that person really did have the disease. But if we get a negative there are lots of ways that that could come from not handling a specimen right or sample several der days. It would Hart to interpret negative result but we would have pretty good confident in a positive result. We've got to navigate this so we can still run these specimens we would like to and like some advice on how to do that. The second one K of MLL will be a primary for, and we would value the Sri review of this laboratory working group for that manual to provide us comments and edits that they request. We thing that would improve the quality of the manual. Again that will be coming out somewhat in pieces. It could be done but it will take a little white for all of that to get out. Next slide. And then the third one, the third one is same thing that Dan brought up that excellent laboratory scientist are certainly essential for high quality advanced laboratory testing. How can we better recruit and retain outstanding lab scientists to ensure this high quality advanced laboratory testing at CDC? It's extremely common at CDC for people to get thee years training really understand some advance tech knees and then go to the private sector and make 50 percent more money. And there's very little weak do about that. We have got to come up with something that allows us to recruit

and retain outstanding laboratory people. Because we're not competing with the private sector. And this is crucial for public health. This absolutely crucial I don't know how to put more emphasis on that. Finally the thing that David Fleming mentioned in federal budget agreement they asked there an external review to take a look at the shortcomings of the Covid-19 tests as well as policies practices and systems mitigate future issues. This laboratory quality plan that we were have developed and rear implementing right now we believe addresses that. But we would like an external review on that to have a group look and say, does the quality plan address the previous deficiency and a mitigate future challenge and diagnostic test development for public health out breaks. Instead I don't know how many Dan has it seemed like Dan had six or seven really, really tough one. We limited it to four. But they are tough things to do. So those are the places that we're specifically asking for input. But we would always take input from group if they felt they had something that would beneficial to krts. These would be would be our folk will points. And that's it.

>> Thanks, Jim. So we'll open it up for comment here just to reinforce that the speed bump the last item there in current terms and draft terms of reference that was sent out to you. My understanding CDC is still waiting for official word from HHS working u group construct is appropriate to address this issue that was raised a part of the budget document. And so, we El wait in will we hear definitively from HHS on whether or not they want and would agree and to take an actual vote on the terms of reference. So we'll further vote until August meeting, welcome an especially welcome comments on the content of terms of reference because we do have now a little bit of leeway in being able to redraft it if there are significant issues that committee members would like to raise about existing terms of reference. So opening it up for that discussion now. Nirav.

>> Thank you for this presentation. Seems like there is a lot going on as you said earlier in terms of quality. And kind of building off Josh's question request, I wonder, there's a lot of text around the QMML. I wonder if focusing on manual is not going give space to all other things you want to do. Maybe it doesn't belong in the or maybe it does how do we improve? How do away put systems in place? What are the I think Josh mentioned performance management opportunities there. There's things like expectation of labs. We did that in New York State. But we knew we didn't necessarily need to inspect every lab every year. There were labs we wanted to inspect much more others we could probably get by every three, four years. So starting to think beyond and outside in emergency rooms it of quality with the big Q obviously what you've described is foundational. Without the standards you're not going to get anywhere.

>> Yeah. But I feel like we need more in this tour to really get to the full scope of quality. I don't know how you're thinking about that whether it needs to be here or not.

>> So, yeah. I mean I understand what you're alggy is a. I think that the probably in part I may not have explained this agency well. Quality manual certainly includes the standards. Bowled read the manual as laboratory operation us manual. It includes all of the quality standards but it includes all the things that you're mentioning right there. I mean we are going to do a review of every of lab every year. That is going to happen. That's in the quality manual. That will happen. There things in quality manual that talk about you know I mean, perform answer management you would have to say we're on overkill on in a so many checks people doing and they will required trainings when people come in. So if somebody comes in CDC they have to take certain safety trainings to make sure they don't hurt themselves in lab they will have to take certainly quantity training to make sure they understand quality, how CDC does quality and how they do quality in the laboratory. So all of these things are in that quality manual and probably better to think of its way beyond just having the standard, but operational of how and a laboratory work I believe all this stuff not going to sitting on paper and quality manual but the big difference is these will not be guidelines, these will not be recommendations. These will be requirements. So you can can consider them a CDC policy, not we recommend you do this, but you must do this. And that's a very big change. There hasn't been really something like that coming out of CDC in this arena of laboratory operations in all years I've been here. So, which is 40 years. So that's long time. So there's just really a tremendous amount of here that it deals exactly what with what you're saying. Just hard to put one word on it. We're calling it the quality manual. It could have been quality the quality laboratory operations manual. But then, that's too long. So we called if quality manual. I think once you see it, those you're talking about will be mainstreamed in it.

>> Thanks, Jim. We will go ahead give Josh and Jill the last word before you two speak I do want to make a commit come committee aware as data surveillance working group we're moving ahead to fill out the member membership of this working group with outside members beyond the ACD. And that includes the same federal register notice that will go out on fourth with a ten-day turn around time. So be thinking if you know of folks that might be good for are this working group please encourage them to my. I would ask Josh and Jill and their final comments to also like we did with data surveillance talk a little bit about the nature of expertise in your discussions with CDC that you're seeing with the important for this group. First Josh.

>> I'm actually going to refer to Jill is that okay then I'll go next.

>> So first of all it's expertise work group we're looking at people with clinical experience, public health experience, state health offices with oversight of labs. So multiple levels there. If you've got any suggestions of names if you would let Josh and I know that would be great. But going back to the terms of reference, I don't see anything wrong with terms of reference in anyway. My gut feeling those though is that they should be broader. I'm folk focusing on something Jim said how labs have change sense pandemic. Nasty not just CDC. That's lever lab in country look impact genetic sequencing that was brought pick up. Just a change in every area. And I think that I know changes in lab I used to run in New York, I think that Gwen that we've got time for a vote before the August meeting, if it is appropriate for us to have alleges more discussion with Jim and John and David about how we may define somewhat broader scope in the terms of reference to other address other we know no where yit call of CDC but 15 ef diagnostic labs generally across the country. Just a thought I think would be helpful.

>> Thanks Jill.

>> Yeah I mean, I'm always open to your ideas. I value your assessment and your expertise. When we were trying to do term of rens we were actually trying to prior size some things so we didn't give the work group too much and too wide. But is balance. And can be some things, so for instance, we could talk about the difficulty of developing something in very short order and could we have a more input. That's something that we're certainly working on. We think we have a good ideas on that. So we kind of put ourselves together and said where are places where we really need some good ideas on some things that are difficult that we're having very hard time moving forward on. And where is some things that we say that otherwise review would highly beneficial. Things we're doing in terms of quality manual a complete culture change. Things very, very important and we will lots. If youerered out. Also share thing quality manual with if. DA. FDA agreed to review it. We're going to lots of back and forth on this. But this really going to gigantic thing. If I just gave term of rerns and like you that could take year. Just that would take you year because laws because there are lots of issues. I don't want to go over in this group. But just dealing with what are quality parameter that is say you're genetic sequencing has given you right result. You don't have something presents or absent you're looking sequence. Quality parameter do you use to assure you have adequately looked for and not missed anything and you're not saying something is there and, andth something that we're sorting out as we're trying to write the panel. We have and that's something that forward to you guys and say, and whole new way of doing something very specific very important. But we're trying to cover N CDC. And a send it to you kind as part quality manual for your comments. But I'm very open.

>> So to add more things you're very willing to do that. I consider four things we put down here to a lot of work. And sensitive to yot overload and we can't do any more. But answer to your question strict I'll love and specific to add. And this an opportunity, a we let it go. And that's what pushing me. Josh. >> I was going to suggest thing for future conversation, very, very small change would be about the quality manual and implementation. You nengs send to FD amount I would being FDA being they will see written document as just 1 piece of the quality puzzle. Hard to interpret outside of the context of implementation. And so, you know, understanding your focus on the quality manual it can hard to say how useful it entirely without understand how it will be put into practice what oversight will be. Those sort of things. There may things to limit some of the scope. While keeping it focused on a quality manual. But not have it just sort text rul analysis. So anyway. That kind of my thought for further discussion.

>> Josh we may, I'm a little concerned that the name has thrown things too far. In the first chapter the quality manual it lays out the responsibility of CDC director, deputy director for infectious disease HC UO director and all of their responsibilities on implementing what is written in the manual. So is very very

much an operational instruction rather than just setting up some quality standards. So if you read through it, it tells you how laboratories operate and what are the checks and balance to make sure they are operate willing correctly in addition any to saying when they operate they should meet these certain standards. It really does have both of those things in there. I'm feeling after this discussion, I should rename it the quality management laboratory operations manual just to make sure everybody gets it. But I think you read first chapter where we talk about personnel responsibilities and who responsible for what, it becomes clear that this is no no the document on the shelf but this an operating things and it has responsibilities laid out what everyone will do, and how performance evaluated in these things are checked overtime. So I, I might say let us get some text to you and let you see it. And then say, you know, we might be better you think we need companion document or something we're very open to discuss that. But we're trying to put it all within one document. Some people have something called a policy and procedures manual. You know, they have a big policy and procedures manual. Inside of that they have a quality section. That has fine. And we we could do that. But we're trying to call a quality manual to really help in the field so people in micro biology laboratories would say like, you know that safety manual is one place you go. We really want them to come in and see what the standards are and operational standards for laboratories are like. So I don't, I may have messed up the words in title a bit but the concepts that you're mentioning I think you're going to find are in there. If they are not we can discuss having more put to it. I've already made presentation to FDA on this. And guy you know Tim tensill I've already talked to Tim about this he's very excited. And, he made arrangements review my crow biological labs an FDA they are very exited it limit appear if there are limitations we certainly want to do it but I think we will try to put in word thing well enough you will be happy with it >> Okay. Thank you.

- >> Thanks Jim I'm going oh close out this session in moment. Give John some last words. But just want to the as we did last time for health equity working group weelt no going to take official vote want wanted to get an incidence is from a need to move forward with this work and if there is, objections speak now otherwise we will proceed for lace la laboratory working group and official terms of reference next time. So we will move in that direction. Over to you to you John
- >> I would just say given the nature of the discussion, what we can in abscess of voting on terms in reference I ink what we can say to the working group is do form a focus on those three questions that were the first three that Jim laid out. We will gather more information about the feasibility of that fourth question. And in the meeting of work group there can be the other questions that are have been raised in this discussion including one that is you raise, Jill. But that the nature of forming a work group is a collaborative process that involve CDC review suggestioning as well as suggestions coming from the ACD. Before there can a final vote on the terms of reference beyond those three questions we'd need to take any recommendation that came from the work group and Bo through our own review ask clearance process a CDC. So allows us to get started with notion that we'll gather more input and have an additional discussions clear. Both clearance and by the August meeting, this terms of reference should available for a final vote including by then we will know about that fourth question and whether or not it is included or not.
- >> I of a question. May I go ahead?
- >> Sure.
- >> Just a question of protocol. So as we reach out to and an ask them to join work group are we able to share the terms of reference with them? Just so they know what they are going to discussing? How does that work? Or do we just send them the register we can do do this off-line
- >> It's a good question. Jill. What we can share and will make public is information that was in Jim's presentation. And that includes those three questions that I was just mentioning. The specifics beyond that I ink we want to hold off on until we finish the review and vote. But as we did with the health equity work group, it was often sufficient just to have the summary questions the ones that really focussed on where the activities would begin. And we've shared that in a public meeting today. And again that will be available as a part of the public record as we make Jim's slides available on our website in just a few days.
- >> Thank you.
- >> Great, thanks John and Jim. Thank you thank you so much for spending this time with us. It was really pep helpful to get this. This to be continued for certain. But we're off to a good start. We owe that to

you. Thank you. Okay. We're now moving to our last topic for the day. And play that music mentally in your mind as we switch gears. This is really important update we will getting from health equity work group. And also we do need to officially at this meeting vote on that work group Terms of Reference. Daniel and Monica have been working hard some shins our lat meeting great to watch this take off. And so I'm going pass Baton over to you give us bit update on work you've doing and set up the terms of reference

>>S thank you so much David and good afternoon everyone. You heard Monica I are delight to co-chair the health equity working group. And we we are happy to be joined by 7 of our fellow ACD members who as we heard earlier are going to not only doing double duty but even triple duty it seems from the conversation we're having today. So I wanted to next slide please. I wanted Otto share with you less of the seven ACD members who joining us. We have Dr. ADA, million Ralph better. David Fleming Rachel hard man, Rhonda meadows and Julie is as part of oh seven we want to thank you all so much for privilege of your time and talent on this working group. Next slide, please. So as we heard earlier from the director the health equity working group was really spawned owing to the CDC strategic plan on advancing science and health equity. And in October of last year during our ACD orientation, we began the official health equity discussions to think about how we wanted to proceed with this. Who was we wanted to invite. Where were gaps and challenges yerl they are year in March of 2022, we published. Slitting nominations from people with health equity public health science and practice. Public health policy development analysis and sple mentation expertise. We received quite an incredible number of nominations those with front front line and field experience a local state, tribal and territorial levels we were exited about. After we receive those nominations we conducted three review rounds from March to April 2022. Right before we had our first official meeting on April 14th. And this the CDC team provided that technical review of all nomination to ensure that we were eligible for further review and ranking. The CDC panel also you know helped us in terms of reviewing and ranking all nominations. Based on those areas that we were looking for. Then made recommendation to ACD leadership. So, who are these ACD folks? Of course co-chairs our ACD chair David, and team who helped us review and rank the recommendations. Then afterwards, we chose ten experts, there were so many incredibly talented people with cream itly difficult we to push NFL and beg CDC to allow us at least ten to join this group. And these are the individuals who represent various groups issues, population homelessness, lpts plus issues, corrections, and an El with local and state pick up health and population experts. Next slide, please. So these are the ten individuals that were chosen. We have you can see on your screen their names. So those are our ten individuals who have accepted. We're really excited to move forward with them along with our 7 ACD or 9 ACD members including myself and Monica. Monica I will turn it over to you now.

>> Thank you, Daniel. I think we can move to the next peg slide. And while okay. Its up. Thank you Daniel for those updates. Just wanted to recognize that some of our HEW members were not ACD members I saw them on participant list earlier. So thank you to all of the members who are able to join us this afternoon. As Daniel said, you know we had a good first meeting last montd. In terms of next steps that we agreed upon, just wanted to recap for the ACD members members that the HEW agreed that between now and the end of this year we will meeting monthly. And so our next convening has already scheduled for later this month. As Daniel highlighted we were able to introduce CDC staff who will be joining us on the HEW. And those include Dr. La bird, Dr. Thing August, John, David, sorry David you're on ACD and then Carrie Caldwell. So those are the core team members from the CDC who will be joining the HEW in our monthly meetings. And then, as Daniel said, and the director point out, at the beginning of our meeting this afternoon we received over 100 applications. And so we talked about figuring out ways to include or invite some of those applicants who clearly bring at although of expertise and experience in the work of health equity to join us in has potentially some of our monthly meetings. In between, those month meetings, the HEW also agreed to bring together sub groups to help advance and to work onasteps between those monthly meetings all of this with goal of present draft report to all of you our November meeting at the end of the year. So the 1 piece that we do have to do is as David pointed out to approve the terms of reference. We approved the constitution or the convening of working group in February this 1 piece we have to do on this call this afternoon. Next slide, please. You can go on to the next one. So before we go to the vote, just wanted to point out a couple of things. First is that there original terms of reference which we all received no thing has changed in terms of the

content of terms of reference. What did change and what we have to vote on is specific language that allow us to increase the number of members. In original terms of reference, we I believe 15 seats that include current ACD members we want to increase that to 19. So that is the only change in terms of reference. And then just to walk through fairly quickly I hope the purpose. Just to remind ourselves of the purpose of HEW and really first to first and foremost to provide input to the ACD on implementation of the CDC's core strategy which Dr. Thing la bird did an Encore four us at the HEW to walk through this really comprehensive framework and approach that the agency is using to addressing Ecuador. The second is for HEW to prepare reports with top level findings, reflections and outcomes that can further enhance the implementation of the CDC's efforts around core. Because we have a pretty diverse group of HEW members. That will be able to bring into the conversations their experiences and in their perspective organizations and work workgroup different stakeholder groups on equity. Really providing that innovative expertise and insights in terms of best practices and promising health equity practices from the field. And then final to bring ways to the ACD and to agency around how to embed anti racist policies. And practices in public health programs across different types of organizations by the way. Next slide, please. Because there were many different steps that were included in the original terms of reference, the HEW has agreed on emphasizing and sort of focusing on the first three which you see on this slide. Again, to better understand what CDC will feed need to be successful in its core implementation, exploring perhaps what are the three top line cross cutting core goals that could adopted across the agency. And across the different krichlt IOs and what are most critical changes to advance these efforts. The second is to create opportunities for understanding what might be barriers to implementation and how we might work to support the CDC in minimizing or reducing those barriers or at least addressing those. And additional resources that might be required to overcome them. And finally, given work that start internally a CDC how might those efforts advance and accelerate work we know is going on in field across multiple levels of governmental public health. So I think at this point, I turn back to David for voting to approve the terms of reference and discussion.

>> Thanks Monica. Just reverse order of that. But first open it up to the committee for any questions or comments or suggestion you might have from the presentation that we got our on the terms of reference themselves before actually proceeding to a vote. Monica and Daniel you're doing incredible work I would suspect that there i maybe phone calls from the other working groups to you given how you're leading the way here to sort of figure out how the best way to do business. So I think that may may be another duty, double or Quinn it up El duty that you will be serving a he we move forward.
>> Thanks David. The question might be for you maybe for John. But, just think beg health equity and we haved 109 I think I heard applications and only chose ten in all of them we are really just outstanding. I though that we have you know the placement we're going to openings for the other two work groups, are they able to take look at this pool as well as they are thinking about especially since health equity is in all enterprise or do they have to reply? I'm just wondering if there's any folks that maybe on the line thinking about the other two work groups. I'm not sure about the process.

>> That's an interesting and good question. I'm going to pass it over to John maybe. But at minimum if we were to do that I think we would need to get back to the applicants. Because they would be solicited to work group activity out another group. So John what are you I don't your thoughts on that? >> You know, what I think we could do is notify them of the opportunity to apply to the two new work groups. We have the language that is in the federal register does say very clearly there are certain procedures that must be followed in order to apply to either one of other groups. So fact that we know who they are, we have ways to reach them I think is suggested we can contact them directly and a see if there is an interest and if there is encourage them to apply. So appreciate your thoughts on that. But I would also say, for some of the members is, there are other internal CDC groups where we looked for external members and we have shared their krment V's with those groups. And they have reached out to some the applicants to see about their interest in being considered for some other activity. And the final thing I would say Monica mentioned this as well in terms of possibility that there be guest speakers brought in to the health equity work group, some of the people who applied I think are would be considered for an invitation to be an expert guest Spear who could present to the HEW. So I think there are certainly are a number of different ways we might be able to follow-up on those excellent candidates.

- >> Thanks, John. Before calling for vote I wanted to give Monica and Daniel an opportunity to speak to the terms of reference. You've working with them for while I'm think you're comfortable with the way they are laid out now but just wanted to aaffirm that with you nor pot
- >> Absolutely David I'm highly satisfied with them I think they are flexible enough. But they are specific E. Specifically focused I'm quite pleased with what we laid out in TOR I'm happy to move forward. I have no concern.
- >> Agreed. I think we he had good discussion with the HEW members about the terms of reference and sort of unpacking and prioritizing these first three. So I don't have any concerns or issues to share.
- >> Great. Thank you so with that I would entertain a motion for an adoption of the draft TORs that were sent to committee as final TORs that committee will work under
- >> So moved.
- >> Second.
- >> That thank you. On that. Any further discuss on this issue? If not would ACD members in favor of the approving TOR signify by raising your hand or saying aye?
- >> Aye.
- >> Aye. Any on opposed? Any be abstentions? Is the TORs pass unanimously congratulations we now have working group with working TORs as well. Thank you very much Daniel Monica for leading this discussionless and a for your leadership on this work group. Very exciting.
- >> You're welcome, David, thank you. Okay.
- >> Okay approaching end I'm going going to turn this over to John for a moment to talk about public comment.
- >> Thank you, David as everyone on the advisory committee knows I believe we always allow time time in our meeting for public comment. And we advertise that ale ability in the federal register. We request people indicate to us ahead of time their interest in public comment. And you may remember if in our February meeting we had a number of different Fox have commented. We've not had any request for public comment this, during this meeting. We will encourage I think all of those who are listening to this equal to consider whether in future meeting in our August meeting or November meeting you wish to make comment, please follow the instructions that are on website how to indicate that interest. And we will make sure we have time for public comments again in the August meeting. But at this point, we didn't receive any requests. So we don't have any people requested speaking during public comment period.
- >> Great. Thanks John. While obviously we encourage public comment and would like to hear it, we do have a little bit of gift of time today for this meeting. So we're going to move on now to the closing. I'm going to start off and get last words to John. First off any comments from any of the committee members about meeting suggestions advice, on what we covered today or how we might do things differently and/or better in the future? We're happy to receive that now. As you think about comments off-line as well. Seeing none. Boy, we got a lot accomplished today. I wanted to give my thanks first of oh obvious toll Dr. Walensky for her clarity i and specificity and talking about the importance policies and progress that CDC is making. It was a great, great session. Thanks also to Dr. Van not only presentation today but for her past work COVID and future work she's about to doing doing for agency we're blessed in community to have opportunity to hear about different aspects of CDC or beyond just working groups. Really appreciate that. Speaking working groups. My goodness. Surveillance with Dan as CDC lead and jewel and Nirav thanks all so much for leading us forward on that getting terms of reference approved and we look forward to filling out that working group. And hearing about the progress thing at the next meeting. Similar to laboratory working group thanks to Jim for that unbelievable presentation and for work he's doing on CDC laboratory quality work and Josh and Jill for taking this on. And leading us forward. We look forward to vote on terms of reference at the next meeting. But in interim the formation of working group and beginning move forward on issues that have already been identified. And then on health equity, Daniel, Monica, certainly don't want to leave out CDC team as well. But you're leading the way and helping us and CDC do better on health equity but also helping this committee in figuring out how to make the working groups as successful as possible. And so thank you for your continued leadership there. And thanks I I would remiss if I didn't not not express my appreciation to all of those people at CDC who help make this meeting happen today. And more broadly my goodness for all of the work going on across the this agency to keep my and my family and my

community and you ask your family and your communities safe and healthy. Thank you for that. And special thanks to our DFO John who is expertly and tirelessly guiding the work of this committee. All while having to out P up with me. So over to you, John for final announce mgs.

>> Thanks. David I really want to echo your comments about how much has been accomplished already. This is only the second meeting of the ad advisory committee we've now got three working groups that will be diving into critically important issues. And issues where the CDC really needs to be advised and informed. Initially by the work groups and those work groups will come back full ACD for your review. And then, your advice to us on those areas. So we greatly appreciate that. Special thank you to the those of you who have agreed to co-chair those work groups that there is significant amount of work that goes into overseeing a work group. We really appreciate you're stepping up to be able to do that. You know ebbs I have to return the thanks David, David and I do you may not know that we practically talk every week more than once as in between meetings because there is a good deal of planning that goes in between meetings in terms of the work groups, terms of reference, and other matters. So David really appreciate the endless hours you put in. I also I would like to thank the CDC staff and just mention some of the key people who are supports to you Tiffany brown Kerry Caldwell Bridget ripped hearth Heather Lauren Agnes warner those are some of the key folks who have done really valuable work. I would like to say at the August meeting we do anticipate happily that meeting will be in person. We expect that be that will be the case as you've heard David say, we would like to have the ACD members come in early so that we can have on August 8th a dinner. Meeting is planned for August 9th. So if you each of you could look at your schedules now and begin to think about the travel arrangements that would necessary for you to arrive in time for dinner. There are also is at least some discussion that we're open to entertaining about whether there could be certainly sub groups that meet on that 8th perhaps with at co-chairs of the work groups. It may be that each of work groups may have over the course of the year one in person meeting. So perhaps the HEW work group will be considering that. So look, let's have some follow-up discussions about whether or not it would make sense to consider that on August 8th. But August 8th travel arrangements in time for dinner and then full meeting on the ninth and then travel arrangements back. For number of you that will take be you know that will mean a few days you have to block out. We anticipate that the August meeting we will hear updates on the three work groups. But we may also have time in the agenda for a more open discussion. And we've talked about that with David and with a number of you that you in addition to your support for the creation of the three work groups you also would like some time to be able to talk some other issues, some issues that are of interest to you. And so we'll try to allow some time for that that is less structured and more of an open opportunity. So again, just in closing I want to thank you all. I think this has very productive meeting and CDC is imum mensually grateful for the work of the ACD members aink away we will see over the course of the year the benefit of your input and expertise. So much thanks back over to you, David. >> Thank you, John. And last words my great appreciation for all members of ACD that investing time

and making this work. And with that we are adjourned. See you next time.