National Biodefense Science Board (NBSB) Public Teleconference Meeting

May 13, 2020

1:00 PM – 2:00 PM EST

Meeting Summary

The purpose of this meeting was to vote on two white papers submitted by NBSB Working Groups. Due to CDC COVID-19 guidelines and state travel restrictions the public meeting was conducted via WebEx only.

As the chair for the Disaster Medicine Working Group, Dr. Dele Davies presented the white paper *Integrating Clinical Disaster Response Training with Community and State-based Emergency Planning* to the NBSB board for voting purposes. The paper passed the committee with a unanimous vote.

As the chair of the All Hazards Science Response Working Group, Dr. Elizabeth Leffel presented the recommendations for the white paper *Medical Countermeasure Research and Development Goals to Prevent Infectious.* Following the presentation, Dr. Leffel provided all attendees an opportunity to review and respond to the track changes currently on the white paper. After making several corrections to the wording and some deletions, the paper passed the committee with a unanimous vote.

Attendees:

Voting Members

Dr. Prabhavathi Fernandes - NBSB Chair

Dr. Elizabeth Leffel - All Hazards Working Group Chair

Dr. H. Dele Davies-Disaster Medicine Chair

Dr. Carl Baum

Dr. Virginia Caine

Dr. Mark Cicero

Dr. Donald "Gray" Heppner

Dr. David Schonfeld

Dr. Joelle Simpson

Dr. Tammy Spain

Ex Officio Members:

Dr. Chris Hassell, Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response (ASPR)

Dr. Joanne Andreadis, Department of Health and Human Services Centers for Disease Control

Mr. Eric Carlton, Department of State

Ms. Rosemary Hart, Department of Justice

Dr. Randall Levings, United States Department of Agriculture

Dr. Marc Shepanek, National Aeronautics and Space Administration

Mr. Ian Watson, Department of Health and Human Services, Office of the ASPR

HHS/ASPR Staff:

CAPT Christopher Perdue

CAPT Theresa Lawrence

Dr. Maxine Kellman

Mr. Darrin Donato

Lt Commander Cliffon Smith

Mr. Jose Velasco

Ms. Mariam Haris

Transcript:

Meeting started at 1:00PM EST

Dr. Maxine Kellman: Good afternoon, I am calling this meeting to order. Welcome everyone today to our May 13th, 2020 National Biodefense Board Public Teleconference. I would like to welcome the NBSB members, ex-officio members, also the ASPR staff, and members of the public. I am Dr. Maxine Kellman, the alternate Designated Federal Official of the National Biodefense Science Board. This public teleconference is dedicated to the discussion and recommendations on the white paper "Medical Countermeasure Research and Development Goals to Prevent Infectious Disease Epidemic and the report Integrating Clinical Disaster Response Training with Community and State-based Emergency Planning".

Due to the COVID-19 response, there was an administrative delay in posting the Federal Register Notice. We apologize to the public for any inconvenience. We thank retiring members, Dr. Virginia Caine, Dr. Noreen Hynes, Dr. Cathy Slemp and Dr. Tammy Spain who volunteered to stay on the Board until May.

Before we move on with the meeting, I would like to read the FACA Overview and Conflict of Interest Rules. The National Biodefense Science Board is an advisory board that is governed by the Federal Advisory Committee Act. The FACA is a statue that controls the circumstances by which agencies or officers of the federal government can establish or control committees or groups to obtain advice or recommendations where one or more members of the group are not federal employees. The majority of the work of the NBSB including information gathering, drafting of reports, and the development of recommendations is being performed not only by the full board, but by the working groups or the subcommittee, who is in turn, report directly to the board.

Viewing conflict of interest rules. Regarding the conflict of interests rules the standards of ethical conduct for employees of the executive branch document has been received by all board members who, as special government employees, are subject to conflict of interest laws and regulations therein. Board members provide information about their personal, professional, and financial interests. This information is used to assess real, potential, or apparent conflicts of interests that would compromise member's ability to be objective in giving advice during board meetings. Board members must be attentive during meetings to the possibility that the issue may arise that could affect or appear to affect their interests in a specific way. Should this happen, it would be asked that the affected member be recuse him or herself from the discussion by refraining from making comments and leaving the meeting.

Public Announcement. Procedures for providing public input. Members of the public may attend the public teleconference toll free call in phone number which is available on the NBSB website at www.phe.gov/NBSB. And, we encourage members of the public to provide written comments that reference to the May 13th 2020 Public Teleconference. Send written comments to the email NBSB@hhs.gov with NBSB public comment in the Subject line. The NBSB chair will respond to comments received by today May13th, by 1PM EST, during the public teleconference. As a reminder, the meeting summary and any public comments will be made available on our public website. During the call, when you speak, please first provide your name and when you are not

speaking please mute your phone to prevent feedback on the call. This meeting is being recorded. Before we begin today's meeting let's take roll call. First, I will call the names of the NBSB voting members. Prabha Fernandes?

Dr. Prabha Fernandes: I'm here.

Dr. Kellman: Carl Baum?

Dr. Carl Baum: Present.

Dr. Kellman: John Benitez? Virginia Caine? Mark Cicero?

Dr. Mark Cicero: Here, yes.

Dr. Kellman: Dele Davies?

Dr. H. Dele Davies: Present, sorry I was muted.

Dr. Kellman: Thank you. Gray Heppner?

Dr. Gray Heppner: Present. Here.

Dr. Kellman: Noreen Hynes? Noreen Hynes? Elizabeth Leffel? Leffel? David Schonfeld?

Dr. Fernandes: Those who are not speaking, please mute your phones so Maxine can hear.

Dr. Kellman: Joelle Simpson?

Dr. Joelle Simpson: Present.

Dr. Kellman: Cathy Slemp? Tammy Spain?

Dr. Tammy Spain: Present.

Dr. Kellman: Beth Leffel? Ok we have a quorum. Prabha, I have not heard Beth Leffel so you may to start with Dr. Davies presentation, Prabha.

Dr. Fernandes: Ok we can do that. If someone could send an email to Beth that would be good.

CAPT Christopher Perdue: This is Chris, one thing before we get started, if we could.

Dr. Fernandes: Yes, Chris.

CAPT Perdue: I am joined by Ian Watson today. Ian just recently joined ASPR, he now is the Director for SPPR and he in a sense, he has taken Sally Philips' position.

Dr. Fernandes: Very good.

CAPT Perdue: So, I didn't. He just recently joined us form the White House, I didn't know, if just maybe 20, 30 seconds Ian you want to introduce yourself and anything you have to say.

Dr. Fernandes: Welcome aboard (background noise).

Mr. Ian Watson: No, thank you it's a pleasure. Welcome on behalf of Dr. Kadlec for all the National Biodefense Science Board members and also the public. I'm looking very forward to working with all of you. Like Chris said, I just arrived within the last two weeks to ASPR and I am looking very forward to all of this. So, with that I will turn it back over to Prabha and look forward to the meeting. Over.

Dr. Fernandes: Thank you very much, again please mute yourself if you are not talking. Please mute yourself its very noise. Thank you.

Dr. Elizabeth Leffel: Prabha can you and Maxine hear. This is Beth, can you all hear me now?

Dr. Fernandes: Yes, Beth we can hear you. Thank you very much.

Dr. Kellman: Any other ex officio on the phone?

Mr. Eric Carlton: Yes, this is Eric Carlton calling from the State Department. I would like to inform the group that the former PDAS, Deputy Secretary of State is gone. Our new PDAS is Mr. Jonathan Moore. He will be the new ex officio member here at the State Department. Again, I am representing him today. I will get Maxine and others information about the transition. Over.

Dr. Kellman: Thank you.

Dr. Randall Levings: Randall Levings USDA.

Ms. Rosemary Hart: This is Rosemary Hart for the Department of Justice.

Dr. Davies: Maxine, Maxine. Are you able to mute everybody?

Dr. Joanne Andreadis: This is Joanne Andreadis from the CDC.

Dr. Davies: Do you have control of just muting everybody that's not speaking, or not?

Dr. Kellman: Please, monitor the call please.

Ms. Faulconer: Maxine, I muted everybody. Except for the ones that are going to be speaking.

Dr. Kellman: Thank you so much.

Ms. Faulconer: You're welcome.

CAPT Perdue: Hi everybody, this is Captain Perdue. Long time no see no hear. I'm sorry for that, I will be listening in, but Maxine has the gavel.

Dr. Davies: Welcome Chris.

CAPT Perdue: Thank you.

Dr. Kellman: Is Captain Lawrence on the call as well? (Pause) Maybe her phone is muted.

Ms. Faulconer: She, she, she is on. I just unmuted her. I knew which call in she was. A whole bunch of people called in at one time. So, she's good.

Dr. Kellman: Thank you.

Ms. Faulconer: You're welcome.

Dr. Kellman: Thank you. We are kind of behind. Prabha can you proceed?

Dr. Fernandes: Ok, thank you. Thank you, Maxine and this is Prabha Fernandes. I would like to welcome all of you to our NBSB meeting, our e-meeting. We had hope to have it in person but because that is not to be. I hope your families are all staying well through this COVID-19 crisis. Today we are here to talk about two documents that the two working groups of the NBSB have been working on since late last year. They have been more or less ready in March, but because of

the emergency and availability of board members it has taken a bit longer to have this meeting. At this meeting the board will discuss and vote on the approval of these documents. The first working group, the Disaster Medicine Working Group led by Dr. Dele Davies will present today on integrating clinical disaster response training with community and state-based emergency planning. This is an extension on the paper approved in November which focused on disaster training in the hospital setting. The second working group, the All Hazards Science Response, is led by Dr. Elizabeth Leffel and she will present the white paper on Medical Countermeasure Research and Development Goals to Prevent Infectious Disease Epidemics. The NBSB started these discussions midyear in 2019. Although much is happened since this document was ready in March, we decided not to delay this presentation because much of what is in this document is still pertinent and could be useful in preparing for the current and future epidemics if any. I invite the two chairs to present the papers, each followed by discussion and vote. I note that this meeting is open to the public. Thank you. Beth you're on.

Dr. Davies: This is Dele.

Dr. Fernandes: Ok Dele. Whoever is ready, go.

Dr. Davies: Well thank you very much Prabha. Thank you Dr. Fernandes for that introduction. And as Dr. Fernandes mentioned we have been working on a document as a follow-up to the document that was approved in September that was looking at integrating clinical disaster training with community and state-based emergency planning. That is the topic of the current paper we are going to be discussing, but we had initially focused on health care, delivery systems and people primarily associated with direct patient care. So, this particular statement is sort of an extension of the original we released in September. Next slide please.

Should I just, should I just keep talking. Ok. So, do you want me to just go through it or are you going to go slide by slide? Ok. So, the recommendations that are in the report focuses on the urgent need for practitioners to receive better training, basically to be integrated into the state-based emergency planning. Next slide please. So here are the recommendations. We're recommending to the HHS that:

- Public health professionals, medical practitioners and emergency management representatives should be included in the training of clinicians. Especially in the, particularly in the area of disaster response.
- And we also recommended there should be encouragement, guidance, and facilitation of sharing of resources in all the various regions. Next slide please.

- The next recommendation is there should be formalization of incentives and grant programs that ensure coalitions have the flexibility needed to adapt resource utilization and response practices.

- There should be strengthening of engagements with health system leaders, communication of return on investments from emergency preparedness programs at the facility level, and establishment of incentives. Next slide please.

- There should be addressing of ongoing gaps identified through joint exercises and provision of reimbursements for joint simulations of disaster events and provision of "just in time" training, as needed, during emergencies. Next slide please.
- There needs to be an addressing of the need for special contingencies to provide medical care in shelters or designated alternate care sites.
- And evaluation of outcomes from exercises and real-world events that allows to assess the effectiveness of clinical preparedness on patient care. Next slide please.
- We need to address the needs of vulnerable populations during disasters.
- And then formalize, organize, and promote disaster medicine as a specialty. Next slide please.

Dr. Davies: So, before I take questions I just want to acknowledge the members of the committee and also the advisory staff members who helped with this and those will be Carl Baum, Virginia Caine, Mark Cicero, Joelle Simpson, Marc Shepanek, David Schonfeld were all actively engaged and involved in developing the proposal as well as the staff members included Maxine Kellman, Captain Perdue, Darrin Donato, Lt Commander Cliffon Smith, Jose Velasco and Mariam Haris. So, thank you very much for the opportunity to present this on behalf of the group and I will be more than happy to take questions.

Dr. Fernandes: So, you may want to unmute who wants to speak. Maybe they can unmute themselves. Maxine, would you like to vote one at a time or vote both at the end?

Dr. Kellman: We can take votes right now for this paper.

Dr. Fernandes: Any discussions from the board members? From the ex officio members? You have to unmute yourself if you want to say something.

Male Voice: Yes, this is

Ms. Faulconer: Hey everyone if you don't have a question, please mute your phones. Everyone is muted again.

Dr. Davies: Ok, should we proceed with a vote? Probably no comments or questions.

Dr. Fernandes: I just don't know. I don't know if you can hear them because they are muted Dele.

Dr. Davies: Oh, ok.

Dr. Kellman: Does anyone have any questions?

Dr. Davies: Should we use the comment box, maybe?

Dr. Leffel: Maxine, can we do it by roll call maybe? Like just mute everybody, then unmute them one at a time see if there is a comment and then they vote at the same time.

Dr. Davies: Good idea.

Dr. Fernandes: If anyone has a comment just put it on the chat box. No comments, ok well maybe we should, Maxine are you there? I don't even hear Maxine. Wow. Maxine are you there?

Dr. Leffel: Is it possible to do this by chat, for members to record their vote.

Dr. Fernandes: Oh, there is no one to know who is on the phone. If anyone has a comment please type into the chat box. I'm not sure how they are going to do it on the phone though that is the problem.

Dr. Davies: How about, how about going through the roll call one by one and having people comment?

Dr. Fernandes: Yeah, I thought that was is a very good suggestion. Maxine can you do that? Is she on the phone? Maxine can you hear us? I think we have been disconnected.

CAPT Perdue: This is Christopher. Can you all hear me still?

Dr. Fernandes: We can hear you (echo sounds). Someone who has the roll call should be able to do that.

Ms. Faulconer: Maxine or Prabha?

Dr. Fernandes: Yeah, I don't have the full list of people who are on. See if I can pull that up.

Ms. Faulconer: So Prabha, Prabha.

Dr. Fernandes: Yes.

Ms. Faulconer: I am going to unmute everyone but if I do that they have to be responsible enough to mute themselves by the phone.

Dr. Fernandes: Ok.

Ms. Faulconer: Or you're going to get all the feedback back. So, if I go and unmute everyone on their phones, please, mute yourself.

Dr. Fernandes: Alright guys you heard.

Ms. Faulconer: And unmute themselves if they are about to talk, when they call in, they have to unmute themselves.

Dr. Fernandes: When you get unmuted now, please, unless you're going to speak, please put yourself on mute. Thank you. Go ahead. We have to use the chat box, if you can chat box or email Maxine any questions.

Dr. Kellman: Go ahead.

Dr. Faulconer: Everyone is good now, it seems.

Dr. Kellman: Can anyone hear me? This is Maxine, can anyone hear me?

Ms. Faulconer: I can hear Maxine.

Dr. Davies: We hear you Maxine. (Lots of talking in the background)

Dr. Kellman: There is someone whose phone is talking.

Dr. Davies: So, before I start, I might make the recommendation that we drop off the call and try to get back on. Sometimes that is a corrective measure.

Dr. Cicero: I am in favor of that.

Dr. Fernandes: Can we try that?

CAPT Perdue: So, let's get out and call back in.

Dr. Fernandes: Ok, you want to try that Maxine? Can we try that? Ok let's try it. (Feedback)

Dr. Davies: Are we signing out? What are we doing?

Dr. Kellman: I think we are waiting for some to reconnect so we can determine whose line maybe.

Dr. Davies: Do we all do that?

CAPT Perdue: Be sure to mute your computer as well as your phone. Be sure to mute your computer as well as your phone. Ok, I'm hanging up and calling back in.

Dr. Virginia Caine: Does everybody get off the call and call back in?

Dr. Joelle Simpson: This is Joelle. I think one of the issues that has been happening is you can mute on the WebEx; you can mute on your computer and you can mute on the phone. If those three things are not muted, then there will be feedback. So, I think people think maybe there's two things that need to be muted, there's actually three.

Dr. Caine: Gotcha.

CAPT Perdue: Apparently whoever was causing the challenges earlier has left because this is very clear now.

Dr. Fernandes: Yes.

Dr. Caine: Yes, it's perfect now.

Dr. Fernandes: Perfect. Ok, now is there any discussion on the presentation?

Dr. Kellman: Hello. Hello, can I do the roll call so we can try and vote for this first document?

Dr. Fernandes: Yes.

Dr. Kellman: To make sure we have a quorum for vote. I don't know who fell off, so I just want to make sure we have a quorum so the vote on the Disaster Medicine's Working Group. Prabha Fernandes?

Dr. Fernandes: I'm here.

Dr. Kellman: Carl Baum? We lost him. John Benitez? Virginia Caine?

Dr. Caine: I'm here.

Dr. Kellman: Who just said "here?" Was it John or Carl who said "hi"?

Dr. Carl Baum: Carl Baum is present.

Dr. Shepanek: Marc Shepanek just joined.

Dr. Kellman: Thank you. Mark Shapiro? I'm sorry Cicero.

Dr. Shepanek: Mark Shepanek, I'm sorry. That's the guy.

Dr. Cicero: Both Marks are here.

Dr. Kellman: Ok, thank you. Dele Davies?

Dr. Davies: I'm here.

Dr. Kellman: Gray Heppner?

Dr. Gray Heppner: I'm here. I vote in favor and I don't have any comments for the group.

Dr. Kellman: We are just doing roll call fright now. Noreen Hynes?

Dr. Heppner: Oh.

Dr. Kellman: We had lost people, so we make sure we have a quorum before we vote. Beth Leffel?

Dr. Leffel: Here.

Dr. Kellman: David Schonfeld?

Dr. Schonfeld: Present.

Dr. Kellman: Joelle Simpson?

Dr. Simpson: Here.

Dr. Kellman: Cathy Slemp? Tammy Spain?

Dr. Spain: Here.

Dr. Kellman: Great. Now we can vote we have a quorum. So, for, so if you are in favor of this paper that was discussed by the Disaster Medicine Working Group, you can say "yes" when I call your name. Prabha Fernandes?

Dr. Fernandes: Yes.

Dr. Kellman: Carl Baum?

Dr. Baum: Yes.

Dr. Kellman: Virginia Caine?

Dr. Caine: Yes. Can you hear me?

Dr. Kellman: Mark Cicero? Yes.

Dr. Caine: Ok good I wasn't sure. Thank you.

Dr. Kellman: Thank you. Mark Cicero?

Dr. Cicero: Yes.

Dr. Kellman: Dele Davies?

Dr. Davies: Yes.

Dr. Kellman: Gray Heppner?

Dr. Heppner: Yes.

Dr. Kellman: Elizabeth Leffel?

Dr. Leffel: Yes.

Dr. Kellman: David Schonfeld?

Dr. Schonfeld: Yes.

Dr. Kellman: Joelle Simpson?

Dr. Simpson: Yes.

Dr. Kellman: Tammy Spain?

Dr. Spain: Yes.

Dr. Kellman: The paper has passed and is being accepted by the board. Thank you. Now on to Dr. Beth Leffel. Thank you.

Dr. Leffel: Thank you Maxine. Thanks for everybody for hanging in there with us through whatever that just was. I will be reviewing the white paper on quote on quote Disease X that the All Hazard Working Group has been preparing. As Prabha said in our introduction, we have been working on this for quite some time. In the midst of trying to finalize it and bring it to the board for a vote, COVID-19 happened. So, we recognize that there have been some advances and some changes as this pandemic has happened. But we appreciate you reviewing this paper in short order and putting up with us when we have some rather recent and quick changes, although they be minor. And go ahead and get this paper for a vote and hopefully get it out from the board. We had nine recommendations that start on the next slide, I believe. And did we need to put up the paper with track changes Maxine, or shall I just try to talk through it?

Dr. Kellman: You'll. After you do the presentation, we will put over to the white paper with the track changes. Thank you.

Dr. Leffel: Ok. Perfect, perfect. Thanks, so, in order to accelerate R&D goals to prevent infectious disease disasters, we have the following recommendations in this white paper.

- First one is to continue to strengthen the HHS capacity to identify potential Disease X event anywhere in the world.
- The second one is to increase resources for enhanced health diplomacy and other mechanisms. Next slide.
- Recommendation number three, which is to support the development of mechanisms and systems which share pathogen genetic sequence information and also allow the transport of specimens containing active specimen.
- Next recommendation is to establish pre-approved clinical trial protocols and train an appropriate number of staff to support implementation of protocol and emergency.
- Recommendation number five is on the next slide. Formalize plans to activate operations centers and R&D facilities, and also establish an appropriate chain of command to support those ops centers.
- Fund and conduct emergency diagnostic development tabletop exercises.

- Formulate and coordinate an infrastructure plan with the US biomedical and healthcare sectors that would ensure the needed facilities are ready to go in an emergency. Next slide.
- Is to establish mechanisms for rapid access to an emergency response fund.
- And finally, establish a task force to develop a national strategy to reduce vaccine hesitancy.

So, we can read, now review the changes, we used some track changes in the word document. Maxine and some of her little fairies. There, there it is, up on the screen for us. So, to orient everybody this white paper version that we would like to vote on today is precisely what we gave you to review last week and it was on the website with the calendar invite. Yesterday, we received some real good comments some potential changes that would improve the understanding of the paper. And we would like to walk through those now, we left track changes so everybody can understand what the language change would be.

The first one is under recommendation two and you may need to scroll down some on the screen. Not sure if Mariam, or who has control of the white paper, but we scroll down into recommendation number two. A little bit more, it's at the bottom of the page really. Perfect thank you. So, can everyone see the highlighted text with the track change that, in the first bullet point under an example benchmark we would like to add the words "and identification of a specific pathogen." And in the third bullet at the end of that sentence, we would like to change that language to include "to ensure this is done in concert with stakeholders that are directly engaged in MCM development and use." At the risk of causing chaos, I would just like to open it for a moment and see if anybody has specific concerns, changes, or comments regarding that edit.

Male Voice: Spell out MCM [in the document].

Dr. Leffel: It's spelled out, ok.

Mr. Carlton: Hi this is Eric Carlton in the State Department calling and I just want to make a quick notation I like the language but just want to let people know that the international framework for sample sharing, that is something we are working on very heavily here with HHS and others. Uh, we do support that, I like the language. I just thought that, want people to know ongoing efforts have been taking place for quite a while, uh, one of the challenges of which I highlighted in the email back in April is this "access and benefits sharing" issue. There is the Nagoya protocol. It's a complicated event, there has been plenty of effort, we need to push forward, but it's not easy and there's lots of obstacles. That is what I wanted to flag.

Dr. Leffel: Thank you for that comment and for the person right before that MCM is spelled out in bullet number two.

Dr. Simpson: This is Joelle Simpson, due to that last comment should we, it sounds like it if it is already existing, not necessarily "create support," but just "support the international framework for sample sharing."

Dr. Fernandes: So could I make a comment there Beth, please? For many of the things we're recommending.

Dr. Leffel: Yes, please.

Dr. Fernandes: For many of the things we're recommending, uh, there is ongoing activities. It's not that the government or any of the divisions or departments are standstill right now. Everyone is working, everyone is trying to do something. We are just trying to say that if there is work going on that it has to be enhanced in these areas because of the need in each of those areas which we have remarked. In every one of these areas there is ongoing work, it's just that it has to be enhanced even further. And that is what this committee is recommending.

Dr. Simpson: I think that's consistent with my recommendation that it's not just the creation but just overall the support for an international framework.

Dr. Fernandes: Right, thank you.

Dr. Leffel: If it's appropriate.

Dr. Schonfeld: This is David, I just put a minor edit in to the chat box. It's not clear what you meant by "done in concert and with stakeholders." Do you mean "done in concert with stakeholders?" Or are you meaning something else?

Ms. Andreadis: This is Joanne. I'm guessing the intent is to say that it is done in coordination with stakeholders, uh stakeholders. Is that correct?

Dr. Schonfeld: Well then it should just be "done in concert with stakeholders." I just didn't know whether you wanted in concert, what the "and" means.

Dr. Fernandes: I think you should just take out the "and." That is a mistake during the edits.

Dr. Leffel: Yes.

Dr. Fernandes: Thank you David.

Dr. Leffel: Is it possible Maxine for someone to delete that "and" in real time so everyone can see it, or how would we handle it that?

Dr. Kellman: G2 is it possible for you to make the changes, because I would have to control that, of the webpage?

Ms. Faulconer, a G2 staff member, deleted the "and."

Ms. Metheny: We are doing that right now.

Dr. Leffel: Perfect thank you. Ok, so we will leave that bullet as it is now with that "and" deleted. Simply because as Prabha explained we recognized that a lot of these activities could be ongoing. People are trying to do it but the working group did acknowledge that as we build on this paper, and felt like even though something may have been ongoing for fifteen or twenty years, which some of this has been, there is an opportunity to improve it. And perhaps this creating this support that's more in concert then it has already been is what, the point we are trying to get across there.

Moving down to page two. Please G2, in the middle of the page, recommendation number five, throw it out the next change. And David before you send me a grammatical correction. I already see that there is an "A" that needs to be fixed in management because it's capitalized and G2 can fix that for us.

So what we have added here is to formalize plans to activate operation centers. New text, "other incident management structures criticality of linking." Now that doesn't sound right does it David? The "other incident management structures criticality of linking it with other incident management structures and subject matter experts that will be needed across HHS and interagency partners to ensure an effective federal response. In other words, CDC, EOC, et cetera."

Dr. Fernandes: Just, just take out the other incident management structures, it's just repeating that. Sorry guys, but these things came in just this morning, so it's not easy. Or last night.

Dr. Heppner: This is Gray. I feel this is a turgent and wordy appendix that operational concept was a functional operation center that would establish an appropriate chain of command. This language is a distraction, it weakens it and I think the time for these types of vetting have long passed. I think we had agreed it's not fair to people that has had the luxury of debate to now take who ever can get the last bid in make a change. So, there is a new concept presented here that CDC or someone felt left out, I just think we are missing the point here. We need an active operation center with appropriate chain of command that can rapidly launch MCM development. It's not ours to prescribe the particular entities that feel left out. Over.

Ms. Andreadis: This is Joanne. The intent was not that anyone felt out, but to ensure that it was clear that it was inclusive. To, uh, ensure that we had coordination, that's all. If that is understood with the, original language that's fine but that was the only intent. It was not to specifically advocate for any one entity. Over.

Dr. Heppner: I don't malign anyone's intent, what I'm saying is the clear and concise language we were asked to do a one-page paper initially and the proliferation of verbosity is not conducive to a clear understanding. If you want to add CDC, I would suggest other entities to be added as well. I would like to move on and say the HHS is the leader and under that is NIH, ASPR, CDC and others. I suggest no change, I suggest we reject the changes as presented.

Dr. Fernandes: Joanne, if she accepted that I am ok with taking it out. We can take it out.

Dr. Leffel: Maxine the procedures. (Interrupted by Schonfeld)

Dr. Schonfeld: This is David. I just put one small change in we can delete an entire addendum, and just after, just change, you will see in the chat box, say "establish an appropriate and inclusive chain of command task force structure." We are not specifying what the plan should be which is saying you have to formulate a plan so we can indicate a desire to make it inclusive.

Dr. Leffel: But Maxine, procedurally do we need to make Gray's comment a motion, vote to approve or whatever this comment and then if it's rejected, we can add in David's language. I don't know how far into the weeds we have to do this procedurally.

Dr. Kellman: By a voice, voice vote if you want to keep it as is or make the changes with David Schonfeld's.

Dr. Fernandes: Take out, take out the yellow highlight because that was what is suggested because, yeah, so.

Dr. Kellman: Is the rest of the voting member ok with it?

Dr. Heppner: I'm not ok with it. I'm not ok with it. It's an ad hoc, it adds nothing to the understanding. If you want a functional outcome say "an appropriate and effective change of command." But inclusive it, it begs the question "what's the new concept here?" The language has been vetted for seven, for six months. I don't understand why we are accepting these last-minute minor changes. They're bigger concepts here. It's more like political correctness at this point.

Male Voice: I, I disagree. What this is reflecting is what we saw in this current crisis. There was a lack of coordination among the operation centers. So, you know you can take all that out and leave it out. I mean you could maybe put a note in the benchmarks, but that was a key issue that is why it came from the CDC and that's why I'm from ASPR advocating that somewhere that needs to be captured that the different operation centers need to be coordinated. They were not inclusive and was not coordinated. That's the real-world experience we just went through.

Dr. Heppner: Effective, we are overarching.

Dr. Leffel: Gray I think you have a good point, we could be here six hours if we argue about words. So, I would like to do one thing at a time. The first thing, my first recommendation would be that we have a quick roll call of agreement about the change you see currently on your screen. Which is all the yellow highlights deleted but the words "and inclusive" have been added. The second recommendation to then discuss the second bullet benchmark and see if that can be improved to get to the point that people are making about coordination.

Dr. Kellman: Ready for the roll call?

Dr. Leffel: So. Yes please.

Dr. Kellman: Okay. For the first mentioned change, Prabha Fernandes?

Dr. Fernandes: Approved.

Dr. Kellman: Approved?

Dr. Fernandes: Yes.

Dr. Kellman: Carl Baum?

Dr. Baum: Carl Baum votes approved.

Dr. Kellman: Gray Heppner?

Dr. Heppner: Approved.

Dr. Kellman: Dele Davies?

Dr. Davies: Approve.

Dr. Kellman: Mark Cicero?

Dr. Cicero: Approved.

Dr. Kellman: Tammy Spain?

Dr. Spain: Approved and I have a question. I have to have a hard stop at 1:55 so, will you still have a quorum once I leave?

Dr. Kellman: We will.

Dr. Spain: Great, thank you.

Dr. Kellman: Joelle Simpson?

Dr. Simpson: Approve.

Dr. Kellman: Virginia Caine?

Dr. Caine: Approve.

Dr. Kellman: Beth Leffel?

Dr. Leffel: Approve.

Dr. Kellman: All board members on the call accounted for.

Dr. Leffel: Thank you.

Dr. Kellman: Next.

Dr. Leffel: So I'm sorry if I'm going to get voices messed up but I think it would be Joanne and Chris that really have this comment, and idea and concept we need to strengthen. In that second bullet under benchmark is there, do you have an idea how we can improve that to get to the point that you all are trying to make that there should be better coordination? Because I think that is what the working group wanted to get across and maybe it's just not coming across strongly, uh, appropriately enough.

Dr. Fernandes: So maybe just say "for the needed coordination for all teams within 48 hours." All teams that was the point.

Dr. Leffel: Any discussion on that before we do a roll call approval?

Dr. Schonfeld: I would just like to ask someone from ASPR if this is what they are looking for. I support the concept I just want to make sure that it is stated the way they would like.

CAPT Perdue: This is Chris. I would say team is a little ambiguous, cause there is lots of teams. All relevant or associated operation centers, I mean many other departments have them.

Dr. Davies: Yeah, I was wondering about that too. I think teams is pretty broad.

Dr. Leffel: Should we change teams to operation centers?

Dr. Caine: That sounds better.

Dr. Schonfeld: Should, should it be "needed coordination among all federal operation centers or all federal relevant, relevant federal operations? Is that the point?

CAPT Perdue: In some cases, we do have to deal with State operation centers.

Dr. Schonfeld: Or say all federal, state, and other operational centers?

Dr. Leffel: I think operation centers kind of implies that, right?

Dr. Fernandes: All operation centers includes federal, state, everybody.

Ms. Faulconer made the recommended change of "all operations centers."

Dr. Leffel: Thank you Shannon, and can you make operation centers, capital "O" capital "C?"

Dr. Simpson: And can you put the "of" in front of all?

Ms. Faulconer made the two recommended changes.

Dr. Leffel: Thanks Joelle. Now, does that help address what we were trying to make sure comes across clear?

Female Voice: I believe operation is singular, centers is plural. So, remove the "s."

Ms. Faulconer made the change.

Dr. Davies: So, the only confusing part here is, you know, "Hold stakeholder meetings for the needed coordination of all operation centers within 48 hours of activation of the HHS Secretary's Operation Center." So, we need to distinguish between the first operation center and the HHS Secretary's Operation Center.

Dr. Fernandes: And I think that is why we had teams there because there was to many operation centers.

Dr. Davies: What is the difference between the two? Maybe if somebody described it, we will find the right verbiage to use.

Male Voice: Emergency medical teams, there are a lot of things that are not operation centers. Teams is a very common word for many different things were operation centers is more specific.

Dr. Leffel: Well, originally the working group wanted it to be that open. So, it could be that inclusive because we were trying not to be prescriptive on, that's why we had the word teams there, so.

Female Voice: So if we just actually remove the text we just added, and it just says "hold stakeholder meetings for needed coordination within 48 hours" it may its broad enough that its stakeholders that are relevant to the HHS SOC.

Dr. Davies: I like that idea.

Dr. Leffel: I agree with that.

Dr. Leffel: I think we have consensus on that sense now. That has improved. Thanks everybody. I'm sorry does somebody need to mute their phone or is that for me. I think somebody needs to mute their phone. Recommendation number six we would like to add, based on recommendations we got yesterday, the highlighted text which just include the words "after identification of the pathogen." To better clarify what the fourteen days was referring to. Is there any angst over that language?

Dr. Heppner: I move to accept.

Dr. Leffel: Thank you.

Dr. Caine: Sounds good.

Dr. Fernandes: It's a substitution, that's fine.

Dr. Caine: Sounds good.

Dr. Leffel: Okay. Alright, now we can get down to recommendation number five, I mean number nine.

CAPT Perdue: If I can ask, this is Chris. So, I can understand when we are trying to review this later with the boss. Uh, the timelines there, the 14 and 28 days. I don't see how that can be anywhere realistic the way it's stated. I realize this is aspirational but 28 days for an experimental therapeutic after identification of a pathogen.

Dr. Caine: I think that's so unrealistic and so far off that I think it takes away from the credibility, credibility of this document. This is Ginny.

CAPT Perdue: That's exactly my concern.

Dr. Fernandes: You should take out deploy because it's develop diagnostics in 14 days or less after identifying. So, it's exactly an experimental diagnostic you're going to start developing at that time or somewhere on the way to developing one. It won't be ready, but the diagnostic should get started as soon as possible.

CAPT Perdue: Of course, so initiation of development and deployment that would make sense on all three of them.

Dr. Fernandes: No, no, no. The idea is not to initiate.

Dr. Leffel: I would say this is a very, this is key point of the whole paper that the working group spent like a year talking about. Which was to push the envelope and accept these days. Like we spent too many hours talking about the number of days finally coming to compromises and agreements and realistic.

Dr. Fernandes: Please mute. Thank you.

Dr. Leffel: So, I think it would be reasonable to delete the word "deploy" perhaps from each of these three bullets. But if we go any deeper than that to make changes, (background noise) I think it needs to go back to the working group unfortunately.

Dr. Fernandes: Beth, we had changed the therapeutics to experimental therapeutics in 28 days. We put the word "experimental" because you want to have something you can start testing in 28 days. So, the same thing for diagnostics you want to have something which you can start testing. So, you want to develop and deploy an experimental diagnostic in 14 days.

Dr. Leffel: Yes, thanks Prabha. That's a good, that's a good idea.

Dr. Caine: This is Ginny, I don't have a problem with the diagnostics in 14 days or less. And I don't even have a problem with, I don't know what you mean "deploy an experimental therapeutic in 28 days." Are you talking about human beings or you talking about models like rat models or something like that?

Dr. Fernandes: No, no. Diagnostics is for humans so, we can say develop and…

Dr. Caine: I just don't like the word "deploy." Development is not a problem. But you get a therapeutic and deploy in 28 days or less.

Dr. Fernandes: Develop and use an experimental diagnostic in 14 days.

Dr. Davies: She's not talking about the diagnostics, she's talking about the therapeutics.

Dr. Fernandes: So, again it's to be able to use, instead of "deploy" you can say "use." To use in patients and were its needed.

Dr. Caine: I want to keep the 28 days for the experimental therapeutics but to deploy a vaccine in 28 days. That's just to me a miracle.

Dr. Fernandes: No. (Interrupted by Leffel)

Dr. Leffel: That's exactly. (Interrupted by Heppner)

Dr. Heppner: Let's talk one at one time. People in the last four comments have commented on all three topics and I think we need to have some regular order.

Dr. Caine: Sounds good.

Dr. Fernandes: So, let me make one comment here. We have again, as Beth has said, discussed this a lot. And what was acceptable to the working group, of which I am a member of, was that we can have an experimental diagnostic for testing in 14 days, we can have an experimental therapeutic for testing in 28 days, we can have an experimental vaccine for testing in 28 days. It doesn't mean the vaccine is ready to be deployed in mass but will be ready for testing. As long, that was our real goal of this whole exercise.

Dr. Heppner: With respect Madam Chairman, would you please bring regular order and in sequence agree on diagnostics, therapeutics, and vaccines. I feel this has become if we are going to finish on time or a little bit over. I think we ought to have regular order.

Dr. Fernandes: So Alright. Thank you. So, for each of these was not meant for diagnostics, therapeutics, or vaccines the days and time was not meant to be deployed as an approved product. It was meant to be to begin testing in those time limits for each of those diagnostics, therapeutics, and vaccines as an experimental testing in either clinical trials or any of those experimental situations. So, may be "deploy" is the wrong word. If you can replace "develop experimental diagnostics in 14 days" that will be fine. "Develop an experimental therapeutic" as well as "develop an experimental vaccine" is fine. The word "deploy" I think a lot of people will misunderstand and expect it to be, you know, given out to a lot of people. That was I think the problem.

Dr. Caine: Prabha, I think he was trying to say can we do it one at a time. We may not have a problem with the diagnostic, and we may not have a problem with the therapeutics. If we could just go down each one and say "do we have a problem at all" of these three bullets.

Dr. Leffel: So, we have the first bullet to be changed as "develop an experimental diagnostic" I would suggest to keep with the point the working group was trying to make that under bullet number one we also add "develop and experimental diagnostics for testing in 14 days."

Dr. Fernandes: Sound good.

Dr. Caine: Sounds good.

Dr. Leffel: Ok. And I think that is a very good point about deployment, Shannon has already deleted that, those two words from the second bullet, the therapeutics bullet. But I think it would

be a good idea now to make that more clear by also adding "for testing." "Develop an experimental therapeutic for testing in 28 days."

Dr. Caine: Sounds good to me.

Dr. Leffel: Ok. Then do the same thing for vaccine if that is also ok with everybody.

Dr. Fernandes: It's good.

Dr. Caine: Sounds good.

Dr. Leffel: Ok.

Dr. Heppner: I move to accept all these changes.

Dr. Caine: I second it.

Dr. Leffel: Thank you all. Thank Ginny for that comment, I understand now that the point was confusing. So, that actually walks us through all of our changes, and we would be ready to vote on the final paper. Turn it back over to Maxine.

Dr. Kellman: Great, thanks everyone. If you are in favor of the changes made to the current document, to final, finalize, in the final report it will be given for public viewing please say "yes" if you are in approval.

Dr. Simpson: Maxine, hi. Carl Simpson the State Department. I'm sorry I have one more comment I wanted to wait until the end. But back in April I sent an email to everybody reminding them there is a Global Health Security Strategy. In fact, my office was a primary drafter. I sent a copy of this strategy to everybody, but, uh, I saw the final recommendation number one still has a bullet at the end, and CDC also pointed this out in their comment. The way it says now "written comprehensive Global Health Security Strategy that complements the National Health Security Strategy." And I think the way it's there it ignores the fact that there is a Global Health Security Strategy and that's not accurate because it implies it doesn't exist. So, I still have concerns about that.

Dr. Leffel: I would just like to point out it does say example benchmarks we are not prescribing that this is what would have to be done. But I do also, you know, hear you and perhaps what would be appropriate is at the end of that bullet put a parenthetic statement, you know "e.g., for example the global health," whatever. You give the proper title, but we could put that in as an example to acknowledge that there is a document.

Dr. Heppner: If we do acknowledge documents why not acknowledge the biosecurity, uh, policy from the White House which we reviewed last summer. Why not make that the e.g. it covers the Disease X and biodefense. That's more specific is it not, and it's national. We're not speaking for the world we're speaking for the United States.

Mr. Darrin Donato: Well again, yes. And there is a United States official United States government uh, Global Health Security Strategy. That is the title of the document, so when you use the exact same phrase "Global Health Security Strategy" of an existing document that's where I think you may cause confusion.

Female Voice: Perhaps change the word to "implementation of the Global Health Security Strategy, National Health Security Strategy, and National Biodefense Strategy."

Dr. Davies: Let me interrupt for a moment. I need to leave. Will you still have quorum if I step off? I need to get on another call.

Dr. Kellman: Uh, cutting it close but uh, it will be close. (Interrupted by Schonfeld)

Dr. Schonfeld: This is David I just recommend a change to that I think is simple. It's really not "create," it's "ensure any comprehensive global health security strategy used complements the National Health Security Strategy."

Dr. Davies: I am just going to say again I need to leave. Can I just interject, I miss the part of approving. I mean if there is ah, of everything that I heard there is not going to be a substantive change, I vote in favor. But I just have to run off now to another meeting.

Dr. Fernandes: Okay, your vote has been approved, yes. And we will accept that you have accepted this paper.

Dr. Davies: Thank you.

Dr. Fernandes: Thank you Dele.

Male Voice: That works.

Dr. Kellman: Are we good? So let me quickly capture Dele, vote for quorum? Prabha Fernandes?

Dr. Fernandes: Yes, vote.

Dr. Kellman: Dele Davies?

Dr. Fernandes: He has voted yes.

Dr. Kellman: Ok, Beth Leffel?

Dr. Leffel: Yes.

Dr. Kellman: Carl Baum?

Dr. Baum: Yes.

Dr. Kellman: Virginia Caine?

Dr. Caine: Yes.

Dr. Kellman: Mark Cicero? Gray Heppner?

Dr. Heppner: I vote yes.

Dr. Kellman: David Schonfeld?

Dr. Schonfeld: Yes.

Dr. Kellman: Joelle Simpson?

Dr. Simpson: Yes.

Dr. Kellman: Tammy Spain? May have dropped off as well.

Dr. Fernandes: Do we have a quorum?

Dr. Kellman: Prabha, Beth, Gray, Dele, Mark, Carl, we do, we have seven.

Dr. Fernandes: Perfect.

Dr. Kellman: The paper has passed. The report has passed.

Dr. Fernandes: Thank you. Congratulations to the working group.

Dr. Leffel: Thank you everybody we appreciate your input and participation. We really do.

Dr. Fernandes: So, since it is right on the hour shall we just conclude I want to thank everyone for participating and for the extra work and edits especially on this latter document, it was not an easy one. I especially want to thank each member of the working group and the NBSB members and all of ASPR staff who helped us a whole lot for your work and also for your help right through the last few months. A special thank you to our retiring NBSB members Noreen, Virginia, Tammy, and Cathy for the years of service on the NBSB. And with that please take care and stay well and thank you and have a good afternoon.

Dr. Kellman: Thank you everyone. The meeting is adjourned at 2:04 PM eastern standard time.