Tick-Borne Disease Working Group
2:34 PM to 3:53 PM

> John Aucott:
Well, let me just clarify. I mean one of the things the subcommittees will be doing is asking the NIH for a report on what they're doing, and other agencies. So, each subcommittee -- this is a later topic -- but they'll be getting data on, from these relevant groups.

> Richard Wolitski:
John, so I put the immunotherapy with the treatment, and I put vaccine with prevention is that working [unintelligible] --

> John Aucott:
I'm feeling for you, Ben. That's a lot, [laughs]. That's a lot for -- I know it is.

> Richard Wolitski:
Or do you want to -- or we can put them as separate, pull them out. I wasn't quite -- it sort of sounded like it was towards combining, was --

> John Aucott:
Yeah.z

> Patricia Smith:
I think that in, you know, in listening to everything, and thinking about it, I -- you know, I respectfully disagree with what you said, only from the perspective of that we have to think about what kinds of people are we going to put on a subcommittee, that's going to look at that issue.

So, obviously, the immunotherapy and the vaccine would seem to be, you know, similar, and I don't know about the new drug development. But those would seem to be maybe the same type of people that might be on that kind of committee; where if we stick it in prevention, it's unlikely. There's so many other types of prevention that don't involve the human organism, shall we say?

So, I think we should put it in a separate -- for our purposes. It doesn't mean NIH -- you know, I don't think it means much difference to you, but I think from our perspective it does.

>> John Aucott:
So can you review for us, Rich?

>> Richard Wolitski:
So, I think, so if we're going to pull things out, then basically we'll move this group up, and we're getting past the point of capacity, unfortunately, to manage the group. So, I think just kind of -- said this to a couple of people individually, but our assessment is basically the max that we can support is six, to be able to do the things that need to be done, to document the process, to support the literature reviews, et cetera, et cetera.

> Estella Jones:
So, for the vaccine and immunotherapy would it be, maybe, better to call it vaccine and therapeutics, to make it more broad?

> Female Speaker:
Yes.

> Richard Wolitski:
Okay, so then would treatment --

Male Speaker:
You got [inaudible].

>> Richard Wolitski:
So, I kind of -- so basically what -- this is a crosswalk between -- let me explain what it is. And I'll number these, so it's a little clearer. So, the first group that folks had talked about was vectors, and prevention, and surveillance. And so, that covers both the surveillance and prevention ask in the Act, and in the charter. So, it covers those areas that have to be covered.

Then, if we go to "pathogenesis," that's number two, then that is our second category, and -- two, and that fits -- seems to fit within "duration of illness." That covers that piece of it.

And then if we go down, our next group was "testing and diagnoses," which seems to fit under this heading of "interventions for people with tick borne disease," which includes treatment and those sorts of things. So this is the third group; then "pathogenesis" is already there, so it's number two again; and "access to care services," and "support to patients" would be group number four." And then group number five would be -- so these are categories that didn't -- "other tick borne disease and co-infections" didn't map quite on to the charter information. So, I'm going to call that one number five, and it goes in its own bucket.

And then here, "vaccine and therapeutics," once I write it up, would fit under "intervention for people with tick borne disease and prevention," presumably, because it covers a couple of categories.

Male Speaker:
In what subcommittee [inaudible]?

>> Richard Wolitski:
So, the "vaccine and therapeutics" -- okay, I knew I was not going to spell that right. Okay, so this I believe, then -- I'll number this before I move it, but it goes under "intervention for people with tick borne disease," certainly, right?

Male Speaker:
[inaudible]

>> Richard Wolitski:

Yeah, yeah, that's the -- wait, no -- oh, it does, six, okay, good.

> John Aucott:
We can manage six?

> Richard Wolitski:
Six is the max.

> John Aucott:
Okay. So, let's take some last comments, and then maybe somebody will make a motion.

> Dennis Dixon:
We typically group product development into the three categories of drugs, vaccines, and diagnostics. And so, I think diagnostics is likely to be kind of a rich area, but there's no reason why you couldn't have them grouped that way, and not have an additional committee.

> Vanila Singh:
I just wanted to also mention surveillance will also include epidemiological services; kind of scan, right, in a formal way, because that is statute. So, maybe we make a note of that.

> Richard Wolitski:
Include what, [inaudible]?

> Vanila Singh:
Epidemiologic services.

> Richard Wolitski:
What does that mean?Vanila Singh:
It comes under -- surveillance is the assumption. But I just want us to be clear, since that it is in the statute, that's all, I mean to cover our bases. We're naturally going to get into that, butI think that's probably the sub area where that would most likely come up.

> John Aucott:
Okay; any other comments? Epidemiological activities.

> Patricia Smith:
I move that the categories that we have up on the screen.

> John Aucott:
[affirmative] So, you're moving the categories out there, the specific number and types that we've outlined?

> Patricia Smith:
Correct.

>> John Aucott:
Do I hear seconds? We can discuss after the second.

>> Karen Vanderhoof-Forschner:
Can we just wait until he finishes typing?

>> Richard Wolitski:
Yeah, I'm done, so --

[laughter]

> Karen Vanderhoof-Forschner:
We've got numbers wrong, and always fix some of -- yeah, he's got numbers wrong.

> Richard Wolitski:
Okay, so just put number six as this one. I think they're right. They change, it's sorted to do an automatic, like, list, and it renumbered them. So, I think --so we've got "vectors and prevention surveillance," and that's number one, and it's not any place else. So, that's good; "vaccine and therapeutics" is number -- oops, number five, my bad. And so, what I did is the ones that get repeated, I just moved them up to the front, so they don't get renumbered automatically; "pathogenesis, transmission, and treatment," group number two; "testing and diagnostics," including laboratory and clinical, number three, "pathogenesis" fits under this area as well; "access to care services, and support for patients," group number four, "vaccine and therapeutics" is group number five, and then group number six is tock borne -- "other tick borne diseases and co-infections."

> John Aucott:
All right, so we have a motion on the floor. Is there a second?

> Karen Vanderhoof-Forschner:
I second it.

> John Aucott:
All right, any final discussion? All right, let's vote. All in favor say, "aye."

> Multiple Speakers:
Aye.

> John Aucott:
Opposed? All right, passes unanimously. So, we have subcommittees. It's an important first step because that's going to be the backbone. Remember, I'll just remind everybody, that the subcommittees don't make decisions. They don't report directly to anybody outside of the total working group. They are transparent in the sense that anything they recommend is recommended at the total working group committee.

So, this is the working body of the group, but is not the, you know, final arbiter of decision making. It's the working core of the group. All right, good work.

>> Scott Cooper:
Excuse me, John?

>> John Aucott:
Yeah.

>> Scott Cooper:
Before we move forward I just -- this is kind of a point of clarification I hope you can straighten out. It's kind of for you, for Nila, and Rich with the Department. I'm reading the statutory language, and as it relates to the charter. I'm seeing a lot of language around the Department, HHS and activities related to it. Particularly we've got the language about NIH reporting on their activities, who the core members are, federal members.

I just want to make sure as we go forward, we're going to be able draw information from all sectors of American life and, you know, the medical community. Are we -- is that how you understand it, or are we limited to --

>> John Aucott:
So, I'll give my understanding, then Rich will correct me.

>> Scott Cooper:
Okay.

>> John Aucott:
So, my understanding is that we are expected to ask for reports from HHS members, like the CDC and the NIH, and groups -- and maybe not all the groups under HHS, but obviously the core ones, and maybe some of the, you know, smaller ones, depending on what the activity is.

It may not be appropriate to ask every group to do every subcommittee if it's not relevant. But that's the core. Something that's actually up for discussion is whether we would also ask other non-HHS governmental groups for input, and then certainly the experts that we ask to be on the subcommittees would have their own expertise. So, that's my understanding.

>> Richard Wolitski:
So, the language in the Act is a little bit unclear because it talks about HHS very specifically in a number of places, but then it also talks about all federal activities in another place. And so, that's just kind of what it is. But it doesn't ever go into the task being to assess what private industry is doing, or other components of society.

And so, it seems that the charges relate to look at what's the federal government doing with taxpayers' dollars, and are those resources being used well, and with an emphasis on HHS. And then I think that's an issue for the working group to kind of discuss and decide, you know, how deep to go with non-HHS agencies, and how to kind of put out the requests for information for

the inventory. It seems like there's some flexibility there for the working group to define it.

But it's not a -- our job's not to assess what, you know, private drug manufacturers are doing, or other entities that are non-federal.

>> John Aucott:
Okay, thank you.

>> Karen Vanderhoof-Forschner:
Can we move it along by saying that it might be a good time to have -- decide who sends out that letter, and authorize them to send it out to gather the information? Because it's going to take a while for someone to get the information together.

>> Richard Wolitski:
So, I think there just would be normal channels that that would go through. So, certainly, like, for HHS agencies it would probably come from the Secretary, or one of the -- [unintelligible] Secretary for Health, and that would be probably the signatory on the request that would go to other departments as well, I would expect.

>> Karen Vanderhoof-Forschner:
So, that means that you'll seek that information for the group?

>> Richard Wolitski:
So, we will seek clarification from our exec sec, as per the process to do it.

>> Karen Vanderhoof-Forschner:
Okay.

>> Richard Wolitski:
But that's -- in general when we've done information requests that's where it would go. And then the information would come back to the office originally, and then we would take it, and we would process it, and put it together, and chunk it out in the right pieces, so that the subcommittees could use it appropriately.

>> Karen Vanderhoof-Forschner:
Thank you.

>> John Aucott:
Pat?

>> Patricia Smith:
Yes; I think this is the opportunity to bring up the issue I mentioned yesterday, and we agreed we would hear today, and this we're talking about other entities from which to gather information, and the other entity which I believe needs to provide information is the other government all federal, working group on tick borne diseases.

And I need -- I think we need to find out first of all what they're charter is, who charters them, and what kinds of information, what do they have, and get perhaps what they have been discussing, because otherwise we have two separate groups that are dealing with tick borne disease information, at the federal level, if you will, at least looking, and collecting, and so and so forth. And we won't have any idea what has been done, or what is being done.

>> Ben Beard:
Can I comment on that? Because I -- you're talking -- there are two of those that I'm aware of. There is sort of an all federal -- and both of these are informal working groups. But there's one that's an all federal tick borne disease integrated pest management working group that's been kind of in operation, you know, probably for five or six years. Candy Brousard [spelled phonetically] I, when she was at the EPA, we actually sort of got that group started.

We drafted a white paper that was published about two -- I think in 2014 or '15, and that paper actually is a good summary or review of all the different federal agencies that are working in prevention of tick borne diseases up to when the tick bites, you know, so -- which really covers EPA. And of course USDA has those partners.

So, that's for the record. That's published, it's posted online, but that's a good sort of starting point to kind of get an understanding of what he different -- there were 10 federal agencies that were involved in that effort. Dan Strickman [spelled phonetically] and myself edited it when Dan was at USDA. So, that's available as a good starting point.

The other group I think you're referring to is the informal HHS tick borne disease working group. And that was a group that -- actually CDC and NIH informally started just so that we could begin to coordinate our activities. There's been a lot of talk about duplication and overlap of government.

And so, this was a group restarted, so we would be aware of what each other's doing, so we could coordinate our work together. A great example is something that came out of that, was that with the reservoir targeted vaccine NIH Funded development of that, but they wouldn't fund field trials for that. So we actually funded CDC field trials that gave rise to one of the reservoir targeted vaccines that's being studied right now.

So, another thing that came out of that was referred to earlier today. It's a serum panel that's used for development of new diagnostic tests, and it's a 450 some off panel, and it's used so that companies who have a diagnostic test ready to go, or even researchers, can evaluate their tests with very well characterized serum.

And so, that was a combined effort of CDC, NIH, and FDA, because CDC and NIH co funded it, and then FDA works together with new tests producers to be able to get those tests adequately validated.

So, these -- and then of courses we did the webinar series that, you know, has been referred to. So, all those things -- just to say that working group is informal. I'm not sure if it was a charter or not. It was just several of us that got together. We should know what we're all doing, is we

should talk about it, share notes, and work together, rather than work in parallel, separate universes.

It's not a formally recognized HHS group, but that's all open, and I, you know, can provide that information. I'm part of this group. I'm glad to provide that, for either of those.

>> Karen Vanderhoof-Forschner:
Pat, I have HHS working group Lyme and other tick borne diseases -- webinar and Lyme disease, and Borellia persistence.

>> Patricia Smith:
Yeah, I --

>> Karen Vanderhoof-Forschner:
Yeah, and it's CDC and FDA, NIH, under HHS.
And it's a very thorough discussion of a little bit of pathogenesis that they can't figure out exactly how it's happening, a little bit of on using ticks for culture, that -- and how they are finding Borellian ticks. So, there is this particular group. And it's apparently informal. But it has some good information that this committee would benefit from having.

>> Patricia Smith:
Yes. I was privy to that, and on that webinar. And I understand all that. But I think that because they are existent, and they do carry clout, when patients or even myself as an advocate and physicians saw that, they took that to heart, there is a working group.

And whether you're totally, official, or you're not official, it's a group, and I would certainly -- I appreciate, you know, you're little summary there, but I think -- I would like either to get some kind of report out of that, and if it is indeed going to continue, now that this working group is, you know, in existence, I think we need to know that, and -- you know, so that can become part of what we base our things on.

> Estella Jones:
Well, and I know we're going to talk about the population of the subgroups we just voted on, but potentially that might be a way to integrate the efforts of those groups. Because clearly the folks who are on those groups are subject matter experts in the various aspects. So, possibly if we could include some of those experts on our subgroups it might be a way to roll in what they're doing into the -- in an informal capacity into the official capacity.

> John Aucott:
Okay. I want to keep our momentum up here because we're doing great.

> Patricia Smith:
Do we agree with that? I mean is this -- are we agreed?

> Richard Wolitski:
I guess the question I would ask is sort of what would be most useful to the committee? So, it

seems like there are a number of -- and this is going to be an issue you could be saying this about any agency, or any, you know, other entity within the federal government.

How do you want to get this information? As a report, what you would like to -- kind of a summary, what's been done, and what's come out of it in products, or to have somebody come and present on it, have a dialog with them, and kind of think, like -- just think about what your information request is, and what form you want to put it in is probably the thing to do.

>> Patricia Smith:
Okay. Well, I certainly like the idea that you had, about possibly bringing over, you know, a few of the -- I don't know who those people are that come to you in that particular tick borne -- that's a good idea. But also again if -- I guess it's always better to have something in person, but you know, if it's going to be something that's going to take, you know, three meetings to do, obviously that would not be, you know, vital.

>> Ben Beard:
Any request to CDC for activities that we're doing as a request from the Department will include a summary of those efforts, and you know, so -- and we've reported that up in all of our sorts of -- report outs that are pretty regular. So -

>> Patricia Smith:
So, that would be included?

>> Ben Beard:
Yeah, [affirmative]

>> Patricia Smith:
Under your -- is Lyme core included under that?

>> Ben Beard:
Lyme core -- yeah, sure. I mean not under that. Lyme core is just simply a CDC funded program for health care provider education. And I know that it's also been highly criticized, but for the record the slides for those are available, you know; all of that information is part of the provider education work that's done at CDC.

>> Patricia Smith:
Well, yes, and I'm certainly aware of that, but again I feel it's important that everyone here understands the breadth of these things, like, the, you know, Karen [spelled phonetically] pulling out the paperwork with that. You know, she and I obviously know about it. But other people don't, and I think it's imperative that we do know. That's also part of the education that we talk about. And I think we need to see well, what kinds of educational things are being put out there, and are they effective, and are they, you know -- do we have any problems with those, and if we do let's put them into our report. If we don't, well fine.

Richard Wolitski:
So process questions seems to be with this; one way of approaching it would be to say that the

inventory needs to explicitly include and identify which activities are considered a part of the working group, and include any other activities that are non-funded activities the working group's doing. So, those get captured, and they just get done as part of the inventory, as I think Ben was proposing.

Or you treat it as a separate activity, and you pull it out, and you hear separately about it, which you know -- I don't personally know the scope of it and all that, but I think we could pick any one activity, and pull it out, and say this is what we want to hear about. But timing wise I think the subcommittees are going to be formed before any of that information would come. And so, whether somebody's a member on a working group or not, that's just going to kind of happen as it's happens with the regular process

>> Karen Vanderhoof-Forschner:
I found the Division of Vector Borne Infectious Disease National Center for Infectious Diseases report -- you're familiar with this -- was the most useful, because it would say their entire budget for the year, for the future years, what they're working on, what they're looking forward to -- well, I don't know if you call it looking forward --

Male Speaker:
[unintelligible] historical archive.

>> Karen Vanderhoof-Forschner:
Hey, hey, hey -- don't say how old it is, please. You're dating me. But there is a lot of information I'm hoping that they present. Thank you.

>> John Aucott:
Okay.

>> Richard Wolitski:
And just to say, like, with the inventory, that'll be a job that the group decides what to ask for from the agencies. And so, certainly looking at that report, other reports, for figure out what's the reporting form, you know; and so budget, and duration, is it part of the cross agency working group or not, you know. You can think about all the categories of things you want to collect information on.

>> Patricia Smith:
I like that idea, and the inventory, and then down the line, like you said, we could always look and say, "Is this of more interest to us? Do we want someone to come to report rather than wasting, you know, someone's time?" And I like that, thank you.

>> John Aucott:
Okay. All right, we're going to keep our momentum up here, so we're going to move now to the process of identification of the subcommittee members, and we're not going to necessarily decide -- we're not going to decide the subcommittee members today. But we're going to talk about the process for what the subcommittees will look like, what the membership looks like, and the process and principles for how to establish the membership of the subcommittees, but we're not

actually naming names or soliciting names today. That's was in Rich's timeline.

So, starting with basic principles that flow from our charter: again inclusiveness, diversity of opinions, expertise; and so the membership should be broad to include not only content experts, but other members. And so, I'd like to open that up now for discussion, about what types of people are important to be on the subcommittees, and peoples' thoughts on that.

>> Kristen Honey:
One idea we had before was to make sure that every subcommittee has at least one patient perspective on it.

>> John Aucott:
And could that be a patient or a patient advocate, or --

>> Kristen Honey:
My gut feeling is yes, a patient or a patient advocate, since many times the patients themselves are too sick, but people can speak on their behalf.

>> John Aucott:
[affirmative]

>> Wendy Adams:
Do people who are presenting to the subcommittee have to be on the subcommittee?

>> John Aucott:
I don't believe so. I mean I think the subcommittee can invite content speakers that aren't on the subcommittee to speak to a subcommittee, right?

>> Richard Wolitski:
That's correct. So, I think it's kind of -- you know, think about, like -- this is my shorthand way of thinking about the subcommittee. This is really where, like, a lot of the busy work is going to happen. People are going to be getting documents, reviewing documents, talking about evidence, coming up with reviewing the inventories, and kind of really working with the documents, and then trying to pull out from that what are the things to bring back to the working group about the gaps, the duplication, and potential solutions?

So, it's the busy work, and to inform that there could be presentations made, and we'd probably want to coordinate them in some way. There may be some things that all the groups want to hear about, or most of the groups want to hear about, and that could be done as a -- something that the working group pulls together then.

So, it's shared by multiple committees, because it would be bad to have, like, the same people asked six different times to come and present. So we'll have to figure out some sort of mechanism for that.

>> John Aucott:

Ben?

>> Ben Beard:
Well, just one comment that's been mentioned to me several times has been just someone to give an overview of surveillance and burden of disease for all of these across the country. And any of us in our program at CDC would be glad to do that. It would probably crosscut all of the different groups.

>> Dennis Dixon:
If I could share experiences on the Presidential Advisory Committee for combatting antibiotic resistance -- I'm glad we have a shorter name for this group. We broke up into subcommittees, and there were standing subcommittee members, but we invited outsiders as guests on a topic specific basis, and they would come in, and give a 15 minute slide presentation, virtually. We would have telephone conference call.

We'd thank them, they would go on, and if we wanted to keep the material we'd ask for them to submit something, and we could consider that when we were preparing our reports by the various subcommittees. So, it didn't have to be an ongoing burden of a large carrying capacity to schedule in each call, it was a lean and mean subcommittee that invited one-off type guests for topics of interest. So, if you wanted to have the other trans-federal committee on tick borne diseases present, that would be one way to do it. They could come in and give you a however long summary of their activities, or document if that committee wanted to hear that activity.

>> John Aucott:
Obviously the members of the working group would be on the subcommittees, and just as -- starting place we were thinking that each subcommittee would have at least two members of the working group. The math kind of works out, because how many groups did we end up with? With six, six times two is 12, there's 12 non chair, non-vice chair members. So, that math kind of generally gestalt works out, is two working group members, although that's not fixed. I mean if the -- you know, if people had, you know, certain, you know overlapping interests it's not in stone, but that the math generally works out for two working group members on each subcommittee.

You already mentioned patient advocate, and then we thought that there would be content experts, and that Rich has already hinted at a process for soliciting, you know, people that want to be working group members, that would join as content and those could be clinical content members, or scientific content members, or patient -- you know, that the content's defined pretty broadly there. It's not just science, basic science. It could be clinical, you know, it can be anything, and there -- and we'll talk later about the process for how that selection of the non-working group members would occur.

So, that kind of gets us up to around eight to 10 members, on a subcommittee. Sounds like a little bigger than what you were working with, or --

>> Dennis Dixon:
Similar.

>> John Aucott:
Similar? Okay.

So, that's a process. We don't -- again, we're not picking the members today, but we'll entertain a motion soon about accepting that as a process for selecting the members.

>> Richard Wolitski:
And I can run up again -- I can run up again and put the summary up on the screens that people can follow it. One question would be: so if we're talking about following the direction provided in the Act, and reflected in the charter about the composition of the working group, will there be consideration given to federal versus nonfederal as a category to look at, or not? And so, I think that's one question.

>> John Aucott:
From the working group?

>> Richard Wolitski:
From -- for the subcommittees.

>> John Aucott:
Yes.

>> Richard Wolitski:
Yeah, because that's one of the principles that this group was established on. And I think everything else has been talked about, but that was the one that thing that I didn't hear raised yet.

>> John Aucott:
Thoughts? So, your point is should there be one federal and one nonfederal as a rule, or could there be two --

>> Richard Wolitski:
So, it's just really the question of balance.

>> John Aucott:
Yeah.

>> Richard Wolitski:
And if we're kind of just making sure that, as we're talking about bringing the kind of criteria --

>> John Aucott:
[affirmative]

>> Richard Wolitski:
That were used for forming the working group, just asking the question, is that explicitly going to be considered or not?

>> John Aucott:
[affirmative] What do people think about that?

>> Dennis Dixon:
[unintelligible] it seems reasonable.

>> John Aucott:
Yeah.

>> Female Speaker:
Well, and however you want to do it, you know, it has to be equal federal and nonfederal, but it seems in keeping with the kind of spirit of this overarching group, that the subcommittees would also have federal and nonfederal members.

>> John Aucott:
Yeah, yeah.

>> Kristen Honey:
Yeah, I think it would be nice to have as, like, you know, a guiding principle or balance, but not rigid numbers. So, not, like, four and four, dividing people up; because I think one of the values is that we're bending fed and non-fed, and if we can remove those hats, and have people just seen as members, that would be good.

>> John Aucott:
Once they're on the group, [unintelligible] --

>> Kristen Honey:
Yeah, and like -- so, it would be good if there's balance, and as part of balance we, you know, say, "are you part of, you know, public or government," and recommend in addition to having a patient on everyone at least there's one fed. But I don't think we should do four and four, or some, like strict criteria, or strict numbers, that --

>> John Aucott:
Well, I want to clarify. Are we talking about the working group members, or the --

>> Kristen Honey:
The subcommittees.

>> John Aucott:
The working group members on the subcommittees.

>> Kristen Honey:
Yes.

>> John Aucott:

So, it would be one and one, on each subcommittee?

>> Kristen Honey:
But then allow maximum flexibility for the other six to eight, or whatever.

>> Female Speaker:
Right; so more in the spirit of diversity and balance.

>> Kristen Honey:
Exactly, spirit, diversity, rather than quotas, is what I'm trying to get ate.

>> John Aucott:
[affirmative] And the other six to eight are not working group -- this working group members, they're outside members, right? Okay.

>> Ben Beard:
Just for clarification, I thought I understood this. Now I'm not so sure. So, you're -- were talking about, was -- Rich's original suggestion was that the subcommittees roughly reflect the fed and public compositions that are seen in the working group, that's what I thought. But are we also saying that -- is that the fed members? Are they from this group, or can we pull from other -- you know.

>> John Aucott:
No, I think --

>> Ben Beard:
And I we do on each committee it just -- it could be a heavy lift for some of the -- I mean CDC and NIH, FDA; I mean are program people working in tick borne diseases, you know, to put, three, you know, one from each organization, on each of those subcommittee [sic]; that's a big ask, but I mean -- but the flip side of that is that our people are all very engaged in the issue, and very eager to give input, and -- but you know, from our perspective we're going to be providing summaries of all the things we're doing, and you know, I also have to think about what work we're going to get done, you know, in addition to the tasking. So, it's just -- I just throw that as a lot of thoughts, but --

>> John Aucott:
Can I clarify that, Kris? I mean were you talking about -- there's two working group members on each subcommittee, and then there's the other content experts. Were you talking about the two people from here being one public, one non-public, or are you talking about the whole group showing that composition?

>> Kristen Honey:
I was talking about the two from here. It would be good if there's a balance, but not having that be a rigid thing.

>> John Aucott:

Among the two from here?

>> Kristen Honey:
Among the two from here.

>> John Aucott:
Right.

>> Kristen Honey:
So, that there could be, you know, two feds who are on o working group, because that makes the most sense in where the expertise lies, and then the patient perspective comes from, from people who aren't on the working group. That was sort of my leaning, but if we can have the balance with federal and non-fed in this working group, okay.

>> John Aucott:
Among the two.

>> Kristen Honey:
Yeah.

>> John Aucott:
The other five people that will join eventually, I wasn't thinking that was going to be [unintelligible]. They could be, right? Could they be?

>> Richard Wolitski:
That's for the group to decide. In my comments I wasn't intending to communicate that the permanently assigned seats that are named by the agency in the Act would all be asked to kind of have that same representation on the subcommittees. I was really just kind of thinking about the federal/nonfederal dimension.

>> Karen Vanderhoof-Forschner:
But only the working members have the voting rights, if there is a vote on that subcommittee.

>> Richard Wolitski:
I mean everyone on the subcommittee would be able to vote. But there really are not --

>> Karen Vanderhoof-Forschner:
So, if there are five federal people, and one working group person they would all be --

>> Richard Wolitski:
No, I think we're getting things mixed up.

>> Karen Vanderhoof-Forschner:
Okay.

>> Richard Wolitski:

So, from the working group there would be two members on each subcommittee. So, basically, you all would divide yourselves up, and be on one committee, so that we have connection with the working group, and that the group doesn't go off in its own direction to say no, way, that's not what we talked about, and have that kind of continuity. And then that's its own thing. It could be decided that it's one fed, and one non-fed from the working group that goes. But then there's all the rest of the committee.

And so in the rest of the committee just consideration to the issue of balance, and how you want to manage that, so like having one or more -- at least one patient or patient advocates in each group. It's a principal that's been proposed. If that's adopted, then you would kind of look at each group and you say, "Do we have that representation?" That might come from somebody who's on the working group, instead of somebody who's brought in a subcommittee member.

The subcommittees, remember, do not make decisions that go beyond kind of the work of the subcommittee. They draft materials basically, is one way of thinking about it, that then come to the working group.

So, the subcommittee may have discussions among themselves, they may vote on some issues, but that's just relevant to the work of the subcommittee. And that has to then all go forward to the working group. And if something happens where there's a really contentious vote, and people feel like something was misrepresented, or done in not a right way, the members can come to the chairs of the working group, or that can come in the discussion, when it's brought to the working group.

So, that's kind of the -- they function on their own, and they can vote about things, but just those things related to the work assignment that they're doing. Does that make sense, Karen?

>> Karen Vanderhoof-Forschner:
No.

>> Richard Wolitski:
Okay, what would you -- what would make --

>> Karen Vanderhoof-Forschner:
When we talked the other day, and I asked you about voting, you had mentioned that subgroup, non-working group members wouldn't be voting.

>> Richard Wolitski:
They don't vote for the full working group. So, only the working group members have a vote, so just the people at the table and --

>> Karen Vanderhoof-Forschner:
But by the time the report gets here, that report will be voted in by some people not on the group? Okay, clarify.

>> Richard Wolitski:

So, the subcommittee will do a draft of its own summary of the work it's did, that goes to the working group, and then from that the working group will decide what goes into the report. They're completely separate things.

> Kristen Honey:
So, I think of them as, like, nested scales, and we have this scale of the tick borne disease working group, with 14 members, and then subcommittees under it, and each one of those can have people who vote in their own rules that the subcommittee decides that will roll up to this larger working group. So, there's kind of two level that we're talking about.

> Richard Wolitski:
[affirmative] And the decision as to what rolls up and what doesn't roll up rests with the working group. So, there may be things that are discussed and proposed to you, by a subcommittee, and then you will consider them, weight the evidence, and decide what you think is the right thing to be included or not included in the report.

> Female Speaker:
So, I mean to that extent, sort of vetting what's going to go in, come up to this group from the subcommittees, do you envision the subcommittees having chairs or co-chairs?

> John Aucott:
We do, yeah.

> Kristen Honey:
And we were thinking that maybe we have co-chairs rather than a chair and a vice chair, so it can be, like, dually run, yeah.

> Female Speaker:
That would hopefully help with some of that.

> John Aucott:
And we're thinking one of either the chair or one of the co-chairs would be for this working group, one but not both, again providing that continuity, and connection to the main working group here.

All right, so do we have everything up? Do we need --

>> Richard Wolitski:
I got everything that I think I heard, but I'm not sure I got it right. So, let me bring it up just a little higher.

John Aucott:
While people are looking at what Rich has, so we'll take a comment from Pat.

>> Patricia Smith:
Well, yeah, I didn't see what he had written up there but -- and I think this is the summary of

what everybody said, and I'm not quite sure. But I -- this is what I was thinking.

The working group shall include one seat for a patient/family member, or an advocate, two members shall be from the working group, one federal, one non-federal, the remainder shall be divided in a balanced manner when available, between federal and public, I'll call them. I don't know what else to call them. Is that what we're kind of saying?

>> John Aucott:
I think mostly I still think we're not done talking about -- I mean to have a balanced federal/non-federal for the rest of the group, may put a pretty big burden on federal --

>> Patricia Smith:
I said if available, when available, is what I --

>> John Aucott:
Yeah.

>> Richard Wolitski:
And keep in -- I mean -- and we've talked about the process, the draft proposal is that people have to be nominated to come into the process, and so that could be something that's considered as well for the feds this time around.

>> John Aucott:
Yeah, okay. So, people are looking at that. Any other comments before we need to approve these guidelines at some point?

>> Richard Wolitski:
The one thing that [unintelligible] what Pat said, and I may have just kind of didn't quite get it right when we were talking, there are two different kinds of perspectives on the, how the members from this group would be going to the subcommittees for that activity. And one point -- heard exactly what Pat said, that it be one fed, one non-fed, so we kind of break the group up into two groups, and then that's how you decide who goes where.

But I also heard that we'd have -- someone proposed having some flexibility in that process. And so maybe it's two feds that want to go to one group, and two public members who want to go another group, and that people could have a discussion and make those choices. But -- I just wasn't sure what the group sense was to put on here for the vote.

> Kristen Honey:
Yeah, my inclination is still for flexibility, and so we encourage, you know, one federal member on each group. But it doesn't have to be, and so that way it's a filter, or desire, but we're not having these quotas that will maybe leave some great people off just because they're employed by the federal government, or vice-versa.

> Karen Vanderhoof-Forschner:
I like the way you're typing's going; that's clarifying it for me.

>> Richard Wolitski:
Okay, good. I guess [unintelligible], not public, not fed.

>> Dennis Dixon:
I'm trying to think about the best coverage, and picking best committees for, if you're sitting on the cross cutting area of research, which [unintelligible] across all of them, and so on the plus side if we were on all of them we'd be using a lot of people and stretching people thinking

On the minus side if we just picked one then there might be benefit in an ongoing discussion. We'd lose in the alternative.

On the other example I gave you we used ad hoc staff members to fill in on particular calls when we knew what the topic was going to be, sort of an ex-officio member that was there to provide information. So, maybe we can solidify which is better as we move forward, and see how these materialize.

>> Kristen Honey:
I think that's an excellent recommendation, and then also part of the reason John and I did not want to assign ourselves to any one committee is so we could float and help with some of the cross cut, and also the HHS staff here, I think they'll also have that eye on the big picture, where you know, groups might want to have synergies and talk to each other.

>> Dennis Dixon:
And it might depend on how the subcommittee functions as to whether you want a report or, whether you want a dialog.

>> Karen Vanderhoof-Forschner:
And so, people are nominated to the subcommittees; the selection is how?

>> Richard Wolitski:
See, that's a whole process that's on the agenda for discussion.

>> Karen Vanderhoof-Forschner:
Another time?

>> Richard Wolitski:
No, today, after this, so --

>> Karen Vanderhoof-Forschner:
Oh, okay.

>> Kristen Honey:
We were thinking that the selection for this committee seemed to go pretty well. I mean I didn't -- I was not part of it, didn't have an inside look, but we have 14 -- 13 members, soon to be a fourteenth. And it was done a rigorous, merit based process, and reflects a lot of the values and

qualities that we put up there.

So, we had discussed possibly replicating that, and people who put their name in the hat, we either nominated or self-nominated, but are not on the working group now; would automatically be in for consideration, and then we could open it up again for more submissions, and people could follow the same process to submit now folks, now that the know what the subcommittees will be; have a window, and then when that closes we could review the applicants.

And our thoughts on that was that people from this working group, and again this is just ideas to stimulate discussion, if you know which working group you want to lead or co-lead, or help with, that you might roll up your sleeves, take responsibility for vetting all those awesome CV's, and cover letters that come in, and picking your subject matter experts in your diverse group of eight or 10 that will get these deliverables across the line.

So, we kind of would divvy up from all of the pool of people that have already come in, and will come in the future, and then organize ourselves into subcommittees, and have each subcommittee for there do a merit based review to figure out, you know, who should be voting members on the subcommittees.

>> Wendy Adams:
Does that include federal members as well? How do we get the federal members on from, you know, CDC, or do they self-nominate, or --

>> Kristen Honey:
I was thinking that it would include federal members. They could self-nominate, or be nominated otherwise as well as what we have now with the feds, where you can -- when you have to be missing a meeting, or something, have your replacement stand in. And it may be because they're subject matter experts, or scheduling conflicts. But a similar idea to what we did with this working group, but do others have thoughts on that process?

Rich, you were at the heart of selecting this group. How did that go from the inside perspective, and replicating it at subcommittee? Is that recommend, or do you have changes you'd make?

>> Richard Wolitski:
So, I was not at the heart of the selection for these members. I was at a distance, and had a supervisory role in that. Jim Berger [spelled phonetically] was actually in the heart of it. And Jim could probably better describe it than I could.

>> Kristen Honey:
And if there's anything you'd change?

>> James Berger:
We started off by writing a procedure, so that we could be standardized, and we identified according to the 21st Century Cures Act identified four agencies that were listed, CDC, NIH, FDA, and OASH [spelled phonetically].

And so, we asked for each one of the organizations to identify who they would have on their selection panel. And that's -- after receiving the nominations we went through the process of looking at the candidates and deciding who would be sent forward for nomination, through the Assistant Secretary of Health, all the way up through the Secretary for approval process.

And it seemed to work well. It was the consensus of the group, looking at the CV's, looking at the bios, and we submitted the packages, and we have the committee at this time.

>> Richard Wolitski:
So, maybe kind of building on that, Kristin, and this is just, you know, a proposal; so if we have the two members of the working group being in charge of kind of doing the merit based criteria review, they kind of make their selections of who they think would be the right mix of people, taking into account the balance in all of the issues we've talked about.

And then those come forward to -- either the full working group, or to the chair and co-chair for review, and kind of discussion, just so that there's kind of, like, not any sort of thinking that, "Oh, two people got together, and just picked all the people themselves," and that there's a little broader process for examining it. And then it goes forward from there.

I don't -- and I'll have to check and see. I don't think that we would want to say that we need to get the members approved through HHS. It's not going to be the same kind of process as it was for the members here. But we might want to have an opportunity just to kind of look at the list and also say, "Okay, yes, HHS supports this list."

>> Kristen Honey:
So, does anyone have any major objections to this general process we've very nebulously outlined?

>> Richard Wolitski:
And I've tried to capture it up here on the screen.

>> Kristen Honey:
All right. So, as a motion -- as a motion I want to read off everything on the screen, but it's hard to talk into the microphone and see what's behind me.

>> Richard Wolitski:
Yeah; and so we've got -- there basically are two separate categories of things that I've captured from the discussion. And I'm going to go back up to the top one, because this is really the -- what were the principles in establishing a working group.

And so, you don't have to kind of strain your neck. I'll read them to everybody. So, on, that you know, these are topically oriented groups. And so, you want to make sure you have subject matter experts that know these issues; have at least two members from the working group. It's not mandatory, but they're encouraged having one federal non-federal member from the working group on the group; there'd be at least one patient, family member, or patient advocate; and that the goal in this is to ensure diversity of points of view, and expertise among federal and non-

federal members of the subcommittee.

And I think we had -- maybe one thing that would help is to kind of put a -- we talked about approximate number of people. That would be -- what was the group size we said, like about eight?

> Kristen Honey:
Eight to 10.

> Richard Wolitski:
Eight to 10, okay, and so --

> Kristen Honey:
And then -- one other thing that's not yet on there, but we've talked about, is allowing minority opinions, so that if there are dissenting or different groups we could have the subcommittees capture that, and maybe we want that to be a principle across all the different subcommittees.

> Richard Wolitski:
And I'm going to start another category of principles for doing the work.

> Kristen Honey:
Okay.

> Richard Wolitski:
Because there probably are, like, a bunch of those --

> Kristen Honey:
Okay.

> Richard Wolitski:
That we want to talk about as well.

> Kristen Honey:
So, for establishing the subcommittee with those that we just read, I propose a motion that we --

> Tracy MacGill:
Can I -- can I make an addition or suggestion for an addition?

> Kristen Honey:
Sure.

> Tracy MacGill:
Add the ability to add to add the ad hoc ex-officio members. I like that idea a lot, because we use it on other working groups.

> Kristen Honey:

[affirmative]

> Richard Wolitski:
So, say a little bit more about that.

> Tracy MacGill:
So, Dr. Dixon made what I think is an excellent suggestion, for allowing ad hoc ex-officio members based on topic. So, these are folks that wouldn't always be -- they wouldn't be a standing member.

> Richard Wolitski:
But, as I heard it they were kind of people coming in, making a presentation, and is the role more than just someone invited to do a presentation? Do they deliberate with people, or discuss with people, or --

> Dennis Dixon:
We did both. We did a staff extension, because there were more subcommittees than there was representative on the PATCARB [spelled phonetically], and so I had four other people sit in the four other subcommittees, and on occasion they couldn't be there. We had other people in, or sometimes we would have the more relevant subject matter expert come in. So, they were sort of standing ad hoc -- standing ex-officio representatives for committees, and in others there were a case by case basis.

We had more subcommittees to cover than we had seats on the panel.

>> Richard Wolitski:
And for everyone let's define ex-officio. What do we really mean when we say ex-officio members?

>> Dennis Dixon:
That's a federal person, meeting literally "from the office," so someone from the office of the NIH, to cover the NIH topics, on the subcommittee of relevance to the NIH.

>> Richard Wolitski:
And so, it would be standing ex-officio members for --

>> Dennis Dixon:
Yes.

>> Richard Wolitski:
Agencies represented here, or what's the group of people?

>> Dennis Dixon:
Some faculty committees have an ex-officio who's a designated ex-officio, who does not vote. They're representing the office of the agency.

>> Richard Wolitski:
Yeah. And so -- turn this into something. See what I've got here, tell me how to word it so it captures the idea. So, if there be eight to 10 members, other people can always be invited to present to the group, and share information with them.

Standing ex-officios -- I don't think I've got that right, but [unintelligible] members --

>> Dennis Dixon:
It could be either a permanent member, or an invited guest member to represent the relevant agency if the topic suggests that.

>> Richard Wolitski:
And that would be decided at the, like, the co-chairs of the subcommittee would decide this? I'm kind of, like, trying to make it so that people could vote on it, and they know what they're voting on, that these will be allowable, or --

>> Kristen Honey:
I was thinking that each individual subcommittee member would decide who was most appropriate to go to that meeting. So, if they think it's best to send in someone else from their office, they could send that person. So, it would be at that individual membership level, not needing co-chair approval, or vice, you know, chair approval.

>> Richard Wolitski:
I think we might be talking about --

>> Kristen Honey:
Okay.

>> Richard Wolitski:
Another issue, too; sort of, like, what if on a committee FDA needs -- there's an issue that people think FDA really needs to talk about and weigh in on, and there's no FDA member on that committee?

So, they could be invited to come make a presentation, if it's an information request, or if there really were, I guess wanting more engagement, that then you would establish an ex-officio member position in the group, that then you'd have FDA representation every time the subcommittee met, so that you could be assured that the FDA point of view was present. Is that -- that's kind of the distinction between somebody being invited to come and do a presentation, versus somebody who's an ex-officio member.

And then for the -- our federal people who are working on a group, then that [sic] same kind of rules would apply, that apply to the working group, I would say. So, that's --

>> Ben Beard:
I guess what I'm struggling to understand a little bit is if these subcommittees are not formal members of the working group, and if they operate in a fairly informal manner anyway in the

sense that they're not voting in a vote that goes through the working group, I mean whatever they decide is really just at that level. I'm not really sure what an ex-officio designation means, I mean other than if someone's just going to come and go as they will, or they --

> Dennis Dixon:
Well, you can drop the term "ex-officio." Do you want a representative from the agency on a permanent basis, or on a case by case basis? That's the principal.

> Ben Beard:
Well, I think we provide for that, saying that we would have both federal and non-federal members, and so we have that option, and then we also have the option of inviting someone to come in to give a presentation. So, it seems like that -- I may not be understanding it, but seems like --

> Estella Jones:
Well, the distinction is someone coming in just to give a presentation, the request for information, versus someone that is not one of those eight to 10, in this case probably federal members, coming in and engaging in the dialog just as a the normal federal member would, you know, either from agency perspective or subject matter expert perspective.

I think it's just -- you know, it's codifying that flexibility, and if we don't need to be so specific, then maybe putting a bullet, you know, basically allowing that flexibility, since some of the other things are very specific, such as the number of members; because there's the potential, I think to say okay, this is what it's going to look like, and then a situation comes up where you would like to have someone else from your agency, or an agency that's not represented to come in, and it could cause some heartburn because well, that's not on the list. That wasn't what we agreed to.

> John Aucott:
I think if it allows flexibility but isn't required, then it probably can't hurt, and could provide that option.

> Richard Wolitski:
So, for clarification -- so talking about including something that allows for -- and the points made for standing ex-officio members, and it was specifically labeled with regard to federal representation; and so I'm going to kind of put little caveats on it.

> Tracy MacGill:
And I didn't mean to suggest that it couldn't be used for the non-federal. I think it's just in the context of this discussion, the understandable concern was raised that -- in the federal agencies, because that's what we can speak to, those of us who work for the federal government about over taking our resources, potentially.

> Richard Wolitski:
Yeah, so we're a little bit at odds, because we talked about federal people not being nominated, and going through the regular process, and [unintelligible] the ex-officio.

So, those two things can co-exist. It's not -- they're not in [unintelligible] with each other, but we have two processes, then, for considering federal participation.

>> Ben Beard:
Maybe I can confuse it further. The working group, federal members, are as it was explained, and I understand it, is we represent our agencies, and so that if one of us or -- I mean we're not in --

>> Richard Wolitski:
In agency seat.

>> Ben Beard:
Agency seat, exactly.

>> Richard Wolitski:
Yeah.

>> Ben Beard:
So, why would that principle not carry down to subcommittees as well? If you did that then it covers that option.

>> Richard Wolitski:
I think we're mixing up the issue of can a federal member who's on a subcommittee have somebody replace him or her, when they're not going to be there?

>> Ben Beard:
Yeah.

>> Richard Wolitski:
So, that's one thing, and I think everybody said yes, that sort of -- that seems to be a principle. This other principle, though, is basically adding additional seats to the committee, so that certain agencies are represented in those discussions over time, as I understand the proposal.

>> Kristen Honey:
And I don't think it has to be just federal agencies, right?

>> Richard Wolitski:
Right.

>> Kristen Honey:
Can we drop the federal, and allow for standing ex-officio members? And then that way if there's a future unknown thing that comes up, and say we need the best, I don't know, Amazon web cloud services, because we're going to do a lot of this through digital platforms -- we can bring in someone from the tech sector.

>> Female Speaker:

Yeah, I mean I agree with that because it seems like it's more covering the relevant subject matter expertise, as the discussion is coming up, versus that idea of a particular member or agency.

>> Ben Beard:
Yeah, so that you don't have to do a formal nomination process, to add to the group. Perhaps, maybe; is that the benefit?

>> Kristen Honey:
Yeah, my inclination is to have maximum flexibility at the subcommittee level, because we are pretty rigid and formal at this level. So, if we can go and have flexibility to address all the science, the complexities, every, you know, opportunity and gap ahead of us, at that subcommittee, it will roll up into this more formal process. So, plus one vote for flexibility on this end.

>> Richard Wolitski:
And I'm going to put the point about the federal member being able to have an alternate in a process point. That's not really a criteria for selection. Okay. So, actually -- I'm sorry, I keep on moving on to the next thing, and it's driving you crazy, I'm sure.

So, you want to see this? So this is what I got down, as the principles: roughly eight to 10 members per group, there can be experts and others invited to come in, present information to the subcommittee, allows for standing ex-officio members, federal and non-federal, to come in and provide specific expertise that's needed.

Because these are technical issues, and they're oriented around that, that there'd be a desire to have subject matter experts, would the primary group that we'd be looking, people who know the stuff that is going to be talked about.

There'd be at least two members from the working group here; encourage a division between the public and the federal members, but that's not required. There'd be at least one patient, family member, or patient advocate serving on each subcommittee, and that goal would be to achieve a diversity of points of views, expertise, and balance in accord with the 21st Century Cures Act.

>> Kristen Honey:
I make a motion that we vote on that.

>> John Aucott:
Second? All in favor say, "aye."

>> Multiple Speakers:
Aye.

>> John Aucott:
Opposed? Passed.

>> Richard Wolitski:

Okay, and I'm going to stop typing. So, now that's passed. So -- and there is the second set of issues which was the process.

Female speaker:
[inaudible]

>> Richard Wolitski:
I can, yeah. So, that is in the same document, and -- wait, it's not in the same document.

>> Kristen Honey:
So, we're just going to call up the timeline, and in the meantime we can think through do we want to automatically include everyone who submitted their name, either self-nominated, or was nominated to this working group, as potential candidates for the subcommittees, and then open up a window where we can put out a call for additional names, and then think through the voting process, which it sounds like -- one of the suggestions was to have the working group members who are leading, or who are on that subcommittee, lead that process?

>> Richard Wolitski:
And to help people there are hard copies of the timeline right at my desk, my seat.

>> Kristen Honey:
Oh, perfect.

>> Richard Wolitski:
They can be passed around to the members. See, the timeline's in one of these documents, and I'm just not finding it. There it is, okay.

>> Kristen Honey:
So, according to this draft for those in the audience, we will put out a formal call to the subcommittee members for new names, either people could self-nominate, or be nominated by a third party, opening around December 18th, so next week. And then it would close around January 1st.

>> Richard Wolitski:
And the thing that's not clearly specified on the sheet or on the screen here, the January 17th to 26th timeline was kind of basically when we had targeted the next meeting, potentially. So, then it would mean that after January 1st we would probably need a day or so within the office to get everything put together, so we could send it out to the individuals doing the reviews. People would probably have, like, a week or so to do the reviews, and then a quick time for discussion and review by either the chair and vice-chair, or the total committee. And then let the people know.

Unfortunately it's a virtual meeting, so it's not going to be something where travel will be involved, and it's hard to imagine that being an all-day meeting. It will probably be a part of a day, so it would be probably, reasonably okay for people to be able to find the time to attend with a week or so's notice. But hard for some people.

>> Lise Nigrovic:
Do you want to consider the closing date to be after the federal holiday?

>> Kristen Honey:
Probably the second would be smart, yes.

>> Lise Nigrovic:
Or third, or, you know --

>> Kristen Honey:
That's true.

>> Lise Nigrovic:
Either before the holiday, or a few days after.

>> Richard Wolitski:
But, the reason for proposing it this way was that that would be when things would close, and then it's -- it would be a submission over the Internet. So, people could, I they wanted to, on the 1st send things in from home, and then we come in on the 2nd, and we'd do our work on the 2nd.

So, if you move it out we're --

>> Kristen Honey:
[inaudible] on the 1st, have a fun new year.

>> Richard Wolitski:
Yeah, and it just takes that time from the review process, so it's kind of --

>> Wendy Adams:
Do they become SGE's, or -- no, they're just representatives, right? Okay.

>> Karen Vanderhoof-Forschner:
And the meetings are web based, right? This is not travel?

>> Richard Wolitski:
All of the subcommittee meetings are budgeted as virtual meetings, so we have no travel resources to travel people.

>> Patricia Smith:
I have a question. Did we definitely establish that we're going to use the people who submitted, you know, and didn't get selected for this, and then additionally ask for other people, or did --

>> Kristen Honey:
We have not yet. That's what we're talking about right now --

>> Patricia Smith:
Yeah, okay.

>> Kristen Honey:
-- is the process for that.

>> Patricia Smith:
Right.

>> Kristen Honey:
So, one thing to consider is do we want to have all those people who were nominated, or self-nominated, but not at this table --

>> Patricia Smith:
Right.

>> Kristen Honey:
Automatically be considered, or should we ask people to resubmit?

>> Patricia Smith:
Well, that's what I thought, but I -- when I saw the timeline I said, "Did I miss something?" So, I guess the reason I'm asking is my only thoughts were that okay, when you submit for this perhaps you're submitting, like, an all-around CV or whatever you want to call it. Okay, because you know, you're looking at a broad overview. When you're submitting for a subcommittee these would be in many cases very specific. So are we going to get the specificity out of group A, who already applied, that we need -- you know what I'm saying, for a subcommittee application?

>> Kristen Honey:
Yeah; that's an excellent point, and I think that we could easily open up the new nomination process to everyone who's already been submitted. And maybe we have the forms or something on there, saying did you -- or is your name in the hat from before, and if yes, this is an updated one.

So, they would have the opportunity to show all that expertise in the niche area where they'd like to be on a subcommittee, but not necessarily have to.

> Patricia Smith:
Right; not have to -- and not have to resubmit, yeah. Maybe it could say something like, "If you've already submitted, you know, provide your expertise in these --" you know, "with one of these particular areas that you feel you would be valuable," something like that

> Tracy MacGill:
And that would also allow them to express a preference, if they are particular subcommittees that they're most interested in.

> Richard Wolitski:
And just kind of as a point of record, we have told everyone who applied that they would have the opportunity to be considered for other opportunities, and they would not have to reapply. So, I think the solution that's been presented here would be one that would be consistent with that statement on the part of myself and the office.

So, if people are already in the pool they can indicated whether they'd be interested in doing this at all, and if they are whether they want -- they'd have the opportunity to provide information that's tailored to what they're being considered for, so that we don't evaluate them poorly, because they didn't send in the right information.

And then -- so I think that kind of accommodates everything, and doesn't create a bad situation for us.

>> John Aucott:
[inaudible]

>> Richard Wolitski:
Okay. I think I can, we'll see. That's in -- I think it's -- I'm trying to remember which document -- I'm trying to figure out which document I was typing in; not this one. So, I'm going to get rid

of this, because it's been saved, and moving on; [unintelligible] either.

It's probably at the end of this one. No; okay, I can find it, I swear. Let's see, document --

>> Karen Vanderhoof-Forschner:
Our new draft timeline --

>> Richard Wolitski:
Yes?

>> Karen Vanderhoof-Forschner:
You mentioned, "inventory requests sent, 30 days SOT provide." What is SOT?

>> Richard Wolitski:
That's a typo.

>> Karen Vanderhoof-Forschner:
Oh.

>> Richard Wolitski:
So the idea of it's, you know, kind of I think the minimum that we'd be allowed to make a request to the agencies would be 30 days, and quite frankly [unintelligible] will weigh in on that a little bit, and kind of advise as to whether 30 days is appropriate or not.

But that would be kind of the minimum level that I think we'd be able to give agencies to respond.

You want to go down more. This is the process stuff, then.

>> Kristen Honey:
All right, so I propose a motion that we put out a call for nominations, opening December 18th, with the caveat that those who are already in the pool can resubmit. We'll put up what the subcommittees are if they want to give a more custom CV to show their expertise in a specific area; and that if people don't want customize it, use their old stuff, that's fine too. And then we will close this on midnight, January, 1st.

So, on the 2nd when we all come back in the office, we're ready to go. And each of the committee tick borne disease working group members who will be leading the subcommittees will be the ones responsible on the other side of this, of selecting their folks.

And I imagine we're going to have to do a little bit of coordination across to make sure we don't assign the same person to four different subcommittees.

>> John Aucott:
Do I hear a second?

>> Patricia Smith:
Second.

>> Patricia Smith:
Seconded.

>> John Aucott:
And we'll open it up for discussion before voting, okay.

>> Patricia Smith:
Yeah, I just wanted to make sure we were going to -- I thought we agreed we were going to say to the people if they wanted to express which subcommittee, is that correct?

>> John Aucott:
Yes.

>> Patricia Smith:
So, do we want to -- I didn't know if I heard that.

>> Richard Wolitski:
I'll add that as a general point, because it seems like in the -- for any of the people, the newly nominated, or the previously nominated folks, that would be helpful, and help us deal with duplication, too.

>> John Aucott:
Any other discussion?

>> Richard Horowitz:
Will we have a chance to -- we have experts in our field that we know, or you may know people.

>> John Aucott:
[affirmative]

>> Richard Horowitz:
Can we make recommendations to these different subcommittees that the people can then decide on, or get a literature search, for example, so that we identify experts, maybe in those 64 people, whoever applied there may be experts that are out there, that didn't apply, that if we do a literature search we're going to find out, like, wow, Peter Krauss [spelled phonetically] needs to come in on Babesia [spelled phonetically]. Like we can identify people specifically in each of these six different categories?

I would just suggest we do some type of search of diverse opinions on that that we can at least --

>> John Aucott:
Well, think that might fall under the working group co-chairs for that subcommittee --

>> Richard Horowitz:
Yeah.

>> John Aucott:
To do for -- specific to their subcommittee, yeah, [affirmative].

>> Richard Horowitz:
Okay, right.

>> Kristen Honey:
And Jim just made the good point that we should probably clarify how we're going to put out the call, so a suggestion was we put out this call around December 18th through the HHS website, so the tick borne disease working group web page, and then that would be our point of communicating with folks for new opportunities like this, rather than the federal registrar, and that slower process.

>> John Aucott:
Other discussion? All right, let's vote. All in favor accepting this plan say, "aye."

>> Multiple Speakers:
Aye.

>> John Aucott:
All opposed? Passed, all right. Great job. All right, so obviously people need to think about what subcommittees they want to be on. So, we're not going to discuss that today, but that's your homework, is to think about what subcommittees, and we envision people being on, you know, one or at the most, two, but probably not more than two, okay?

So, think about that, and that's your homework.

>> Lise Nigrovic:
Could you send out, or show us again the list of the final subcommittees?

>> John Aucott:
So, we'll need to get you the final subcommittees, yep; thanks.

So, we were going to -- in the agenda it said re-review the timeline. Do we need to do that?

>> Richard Wolitski:
Well, I guess we didn't really have any discussion on the timeline at all. So people may -- there are a couple of things that were messy. I did this rather quickly.

>> John Aucott:
[affirmative]

>> Richard Wolitski:
So, there may be, in addition to cleaning up some of those errors, like the one Karen found, was there any discussion people wanted to have about it?

>> John Aucott:
So, discussion and the timeline? You can see it's pretty tight, so we've got some work to do. Part of the process is we have a team that'll help with generating the report, so even though it looks pretty tight there's actually a professional team that helps with the report preparation. And so, there's support for the process. It's not just us writing the report.

>> Lise Nigrovic:
Will there be more than what we've discussed today -- guidelines for what the subcommittees need to address, I mean in terms of -- are we just doing --

>> John Aucott:
[affirmative]

>> Lise Nigrovic:
Inventory of current work, and listing gaps, or is it more comprehensive than that?

>> John Aucott:
So, it's doing in inventory, and getting reports from the responsible agencies about their work. It's doing an actual -- and we have resources to actually perform literature searches, and then it's bringing in those experts to provide content as well, to identify gaps and areas of need.

So, it's all of the above with the overriding theme of what's in the charter, which is to identify gaps and areas that need work, as brought out form the comments from the public, as well as -- and they'll be public, you know, patient members on the group, so it's really putting it all

together to identify what we think the important gaps are.

>> Richard Wolitski:
I think what we've talked about thus far, what's been proposed, thus far, is that -- so that next, the third meeting, when all of the members of this group and the subcommittees come together, that would be the time when we can discuss the charge, and we imagined we'd send out one inventory request to the agencies.

So, we're not asking each of the subgroups to develop their own inventory. There'd be some discussion about inventory, and then the subgroups would review it to make sure that in includes what needs to be included for them. And folks would approve that as an inventory from the working group, and then it would be sent out. Because I think if we send six separate requests out to some agencies that will not work very well. So --

>> Kristen Honey:
And in addition to giving guidance on what each of the subcommittees can do, we can also compile some resources that are available to all the subcommittees. So, there are a lot of interagency working groups. I know the Interagency Working Group on Open Science was critical in the Ebola and Zika response, so maybe teams would want to hear from them, as well as all the different groups we've talked about, that may be cross cutting.

So, I can work with HHS to make sure we got those interagency resources, and if folks from the outside have resources that may be of interest we'll pull some of those out as well, because I know we've received a lot of suggestions there.

> Tracy MacGill:
Just a quick clarification question. With this timeline where would the agency's time to review be?

> Richard Wolitski:
It's the public comment, and the agency review --

> Tracy MacGill:
I see.

> Richard Wolitski:
Are concurrent with each other.

> Tracy MacGill:
Okay, thank you.

> Wendy Adams:
So -- and just vis a vis, that they -- public agencies comment and give suggestions, but don't have an obligation or a duty, or there's not a -- it's not incumbent open us to incorporate, or how does that work?

>> Richard Wolitski:
So, I'll have to kind of get a little additional guidance on that. I mean my understanding is it's not a clearance review, and so it's not -- it's a little different. But it is -- I was going to bring it up on the screen.

But like, for example, with PATCARB, they publish with the report. There's a statement in it that says the information included in this report represents the opinions of the members of the working group, and not HHS.

And so, it's not seen as an HHS report, it's the working group's report to HHS Secretary, and to Congress. So, it's different than an HHS publication.

>> Scott Cooper:
And Rich, will it be publish in the Federal Register, the final report, or no, or just on the website, and --

>> Richard Wolitski:
So, we are not aware of a rule that requires that a notice be put in the Federal Register that the report's available. And the reports don't get publish in the Federal Register. They're standalone documents that are just separate, so --

>> John Aucott:
All right, any other comments on the timeline? So, then, our last order of business is kind of getting a general consensus, then on the next full working group meeting, okay. So, there was a Doodle poll that went around for that, so every should have gotten that. So, that's on the plan, is to have the next meeting. It'll be a virtual meeting, not in present -- in person meeting. And that Doodle poll has gone out. And then subcommittee meetings will occur after that. And then additional stake holder input, or meeting -- is that on the timeline?

>> Richard Wolitski:
So, I think with the additional stake holder input other presentations kind of -- that folds into what I think Kristen was saying, about coming up with a plan of figuring out who the subcommittees want to hear from, who the full working group wants to hear from during this interim, so that would be something that -- if you want to set up a process we'd be happy to receive suggestions, or they could go directly to Kristen, if you want to -- however you want to do that.

So, we'd be happy to be the keepers of the information, and the passers on of the information, so that you can decide.

>> Kristen Honey:
Yeah, my recommendation now is that we have HHS be the keeper, and receive it all, and we take some time to see what's come in, to just be able to gauge what is the public response, and how much information's out there, because the quantity of everything is going to affect how -- you know, our process forward.

So, I think we need to do a little more homework and see what's come in, and for those who have comments, and maybe weren't able to speak, or whatever, the address to send it to is on the website, and we will be reviewing everything. So, send your information and your requests, your recommendations in, and we'll make sure we include that in a rigorous way, and everything does get incorporated after we wrap our heads around how much reading there is.

>> John Aucott:
So, we did it. I'm incredibly impressed. I mean this is just an amazing group.

[applause]

Yeah; you know, this is -- a sign of success is we work together. Not everyone got everything they wanted, but we got a lot, and we got some really important things started here. So, two thumbs up. Thanks, guys; fantastic.

We're adjourned. I'll take a motion for adjournment.

>> Patricia Smith:
Oh, before -- I'm sorry. I just wanted to -- now wait.

>> John Aucott:
Oh Pat, you're killing --

>> Patricia Smith:
This is important. I want to thank John, and Kristen, and Jim, and Dr. Wolitski for what they did, because it's very difficult to pull something together.

But John, I just want to tell you, there was no homework in the charter, so you better reread that.

[laughter]

>> John Aucott:
You were on the school board, so you know that's part of the job.

>> Patricia Smith:
Oh yeah, well, I gave that up, yeah.

>> John Aucott:
I'll accept a motion for adjournment. Second? All in favor say, "aye."

>> Multiple Speakers:
Aye.

>> John Aucott:
Opposed? Thank you, we're adjourned.

[end of transcript]