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IECRN Findings: Management and Governance

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MR. DURAKO: So to start with management and governance, first, to help orient you to what is in this presentation, I am going to give you a mini-roadmap. This is certainly not as ambitious as the NIH roadmap, but it will help you get through the next 15 or 20 minutes of the talk.

First, I will give a semblance of a definition of what we mean by management and governance. Then I will present a few general findings that we think are important in considering management and governance of clinical research networks and how they operate now.

Then I will spend most of my time on several major themes and these themes come from the eight areas of accomplishment that I showed on the slide this morning that were related to our best practices study.

So we focused on themes that we felt were most relevant to management and governance and where management and governance can have the most impact, and, within each of those themes, there will be some additional findings particularly related to that theme.

There will be a summary of some of the barriers and facilitators relevant to that theme, a description of some best practices or at least concepts that we think are important in good management and governance, and then I do have a couple of examples in some of the themes about groups that have actually had some accomplishments.

So, first, a definition. I have to say this isn't quite a definition, as you might find in Webster's. It is really more of a list of some of the areas that we felt were encompassed by management and governance and that we asked questions about in terms of practices.

So, certainly, organization of the network, whether it has bylaws, policies and procedures for how it works; who participates in the leadership and the operational management of the network; how do networks determine membership; and, importantly, are the clinical research networks open to expansion of networks, inclusion of new networks.

And I think that this is a particularly important point when we talk about one of the -- when the question was asked this morning about what are some of the outcomes we might expect.

As I suggested, one of the outcomes may be whether other investigators who are seeking grant funding actually are

able to come into a network and work with a network and, also, whether new, young investigators are able to join the network and work productively within it.

Also, the management of a network is important in setting its research agenda. Staffing and how much staffing there is and how staffing is supported by funding, and then some things that are particularly critical, dissemination and publication of results and along with that, actually, implementation into practice of the results that a network has found.

And then something that is really key, I think, to the effort to expand the use of clinical research networks, the network's ability and current practices in internal collaboration, that is, among investigators within the network, and external collaboration, that is, either cross-activity with other networks or with other clinical research investigators.

So here are just a couple of important general findings, and you may wonder, when I start talking about leadership, why I don't talk about the investigators who are actually the leaders of the networks.

I think you can find that information in our report, but I just want to highlight a couple of things that I think are food for thought in our discussion sections.

The first is that in two-thirds of the clinical research networks, we were told that the primary funder is highly or somewhat involved in overseeing the governance of that network. And this may not, on the face of it, seem very important, but when I get into barriers and facilitators, I am going to spend a fair amount of time talking about the importance of sponsor involvement in moving a network's agenda forward.

Another finding related to this is that NIH-funded networks actually, for the most part, do have sponsor involvement in setting their scientific agenda, and this is, again, related to the first point, and I will talk about it a bit later.

Finally, we found that clinical trials networks generally have a stronger, I guess, at least a more complete staffing arrangement for their networks in terms of leadership, with more project directors and managers, other health professionals participating, and, in particular, more information technology staff available to support the network.

Another general finding about clinical research networks relates to committees and I think this slide probably implies that committees are a good thing. I am sure that there would be considerable debate about that and I am certainly one

of the people who often is reluctant to participate in committee work.

But I think that it is an indication, in my mind, of how much attention management is paying to a particular activity, that they have actually seen fit, in some way, to establish a group that focuses on a particular issue.

And, again, the NIH-funded networks are more committee intensive and those of you who are funded by NIH probably realize that NIH networks are more likely to have an executive committee, which I think is certainly important in setting and expanding the research agenda; publications committees, which that is actually a committee that I find has been very useful; information technology, data management, training, and unit performance committees to evaluate the work.

Interestingly, clinical trials are more likely to have budget and finance committees, and you will hear through all the presentations today I think that money is a big issue and I am actually surprised that not every network has a budget or finance committee. But certainly I think everybody needs to pay a lot of attention to the use of their resources.

And, finally, more than half of the clinical research networks did say that they have some sort of scientific planning committee and I think, in my mind, that certainly is a plus.

That brings in all the strengths of the members of the network in establishing a broad and cohesive research agenda for the networks.

So those are just a few general findings. Now, I am actually going to move into the major themes related to management and governance, and this is a repeat of the slide that I showed this morning, but with four of the accomplishment areas deleted.

So the ones that I am focusing on for management and governance are internal interactivity, external interactivity, expanding or broadening the research scope, and the effectiveness for the clinical research network in changing clinical practice.

So, first, to internal activity. Here are some of the findings from our quantitative research. As I said earlier, I think that an executive or a steering committee is certainly useful in setting a networks research agenda.

I think that it also can be very useful in bringing the network together, bringing investigators together, establishing rules for interaction and collaboration among investigators, and, importantly, mediating differences or disagreements among investigators who are tasked to work together, and NIH, again, is a leader in this field.

We did find that the vast majority of networks do have some information sharing going on across network partners, within their own network. Eight-six percent said they have information sharing. This is not necessarily total data sharing across the network, but sharing of opportunities, particularly in the funding area, and in presentation and publications.

There seems to be a considerable amount of interactivity within the networks in the development of publications from their research.

And, again, NIH-funded networks are more likely to actually have policies, formal policies on the sharing of research data within the network.

And I think that those of you who have applied for NIH grants know that there is a requirement now for data sharing policies not just within your network, but with the community at-large, and I think that that is something that NIH has strongly supported and is certainly a positive development in terms of maximizing the benefit of research that is done in clinical research networks.

So what are some of the barriers? I think as Dr. Zerhouni said, we didn't really find anything surprising. Those of you who have worked in clinical research networks and in academic research for years and years probably have heard, at

one time or another, almost all of the things that we found.

But as Dr. Zerhouni said, we are integrating them here in one place with a group of people who can really discuss these and see if we can make recommendations for how to actually remove some of these barriers.

I think the key barriers in terms of internal activity are really related to the career needs of the investigators who participate in the research.

So many respondents from the clinical research networks felt that there really wasn't sufficient investigator commitment to full collaboration and a sense that they are willing to contribute to the greater good rather than being sure that they have total recognition for the contributions that they are making.

And that is certainly difficult when you get into things like protocol development and publications, where you might not even be listed in those documents if you are a collaborator.

And then, in particular, academic barriers and these is actually something that I had wanted to ask Dr. Zerhouni about, but the microphones up here in front weren't working this morning. So I didn't have time to ask the questions.

But we heard very loud and clear, particularly from

young investigators or more junior investigators, that if you are in an academic environment, the pathway to promotion is really a barrier for collaboration.

Whether you are going to be promoted or not usually depends on whether you have been a PI on your own grants and, also, on how many first authored scientific publications you have.

If you are truly working in a collaborative environment, you don't necessarily get the same opportunities that you would if you are working on your own. And, particularly, junior investigators usually are not the PIs on large network grants and they are usually not the first authors on publications.

So I think the one thing we see is that if we are going to encourage collaboration and we are going to encourage new blood in the networks, the academic community and I hope NIH, working with them, needs to address this and needs to provide greater recognition of the value of participating in collaborative projects.

A few best practices. As I mentioned to someone during the break, many of the things that we are calling best practices are not sort of formulaic "here is how you do it" kind of thing.

They are really a distillation of philosophies, approaches, concepts to making this thing happen.

So in the internal activity area, the number one thing is you have to establish some sense of collegiality among the people who are in that network. That should be very obvious to everybody, but it is the one thing that you really have to work on and you have to find ways that you are going to bridge any divisions across investigators within the networks.

You really have to trust each other. You've got to have ways of acknowledging everybody's contributions and, certainly, it is important that you have a common focus on what you are trying to accomplish through this network.

And establishing that collegiality, I have listed here a number of points of things that need to happen and I think probably the most important one is the first one.

It is an intense effort. You really have to spend time. You have to interact. And the second part of that first one, you really need the sponsor to be supporting that, working with you, telling you that they want collaboration.

And as we will see in some of the later slides in these presentations, that the sponsor also needs to provide the kind of financial support that is going to allow you to collaborate.

So this is where, when I put up that slide about how much are sponsors involved, even though sometimes you may feel that sponsor involvement is getting in your way, if you don't have sponsor involvement, strong sponsor involvement supporting your mission and supporting collaboration, it is going to be hard to get there.

Another point is being open to new members, which I mentioned earlier.

Also, providing opportunities, especially in the area of governance of the network. New people coming in, junior investigators need to have a chance to actually be heard. They need to sit on some of the important committees that are determining what the network is going to do, and they need to feel that they actually are welcomed to the network.

Here is an example of one response that we had from a network that felt that it had successfully achieved internal interactivity. And I have to say, in presenting this example, as you will see from the very first arrow on here, the starting point was that the sponsor actually emphasized collaboration and bi-directionality in the funding announcement and that is where it started; that there was something there that said, "We want this kind of collaboration."

And that sponsor support continued through all levels

of the project and was consistent in insisting on that collaboration.

So it really laid the groundwork for making people work together, strengthening their interactions, especially through face-to-face interactions.

And what this network found was even though it takes a lot of work to emphasize collaboration, it really paid off. They were able to actually get off the ground much more rapidly. They had very clear short-term benefits in productivity of their research network.

So, next, I am going to move on to external interactivity. As I said earlier, external interactivity means working with other people outside your network.

We were primarily focused on working with other clinical research networks, but, of course, you might also work with other clinical investigators, basic science investigators, other people who are doing research in your field.

Here are a few findings from our quantitative research. I think we were pleased to see that, at least in NIH-funded networks, 72 percent of the sponsors encourage cross-network collaboration.

We found probably the reverse of the second arrow, that it appeared at least 73 percent of networks did indicate

that they do have some current connection with another clinical research network.

To me, that was a little bit surprising. We didn't probe in-depth as to how strong those connections are, but at least there is a sense out there that people are willing to talk to other clinical research networks.

We also found, on the negative side, that 29 percent said they had had a failed collaboration, and I am sure a number of you here in the room have had failed collaborations. I know I have been involved in networks with failed collaborations. They can be very frustrating and sometimes it takes a couple of years before you finally give up and say that it has failed.

But despite that, it appears people are still coming back to the table. Nearly half of the networks said they are working on establishing new collaborations.

So I think it is important for people not to give up. You do have to change the mind set. You do have to figure out what you need to do to work together, but people are still coming back and I would like to strongly encourage that.

So what are some of the barriers to external interactivity? Well, I think the ones that I showed with respect internal activity clearly are there. The common good, recognition for your work, academic advancement certainly are

important, as important in external relationships as they are in internal relationships.

But others that we saw, funding, this is the first time, I think, that funding has explicitly come up in our presentations. It will come up many more times.

Generally, there isn't money set aside for external collaboration. So, often, networks get hung up on who is actually going to pay for this, because it takes time. It is not easy to do and you have got to figure out whose budget is going to support this and most people don't think they have enough money to do it.

Lack of time is also important and this is going to come up many times in our presentations. The investigators just aren't funded for enough time. They have many, many other things to do.

As Dr. Zerhouni said this morning, 50 years ago, perhaps, people could spend 80 percent of their time really promoting this field. Now, there is so much to do just in the clinical care environment and administrative environment that there is not much time available, and, also, there is not necessarily enough funding available for that time.

The flip-side of active sponsor support is lack of active sponsor support, of course. Then, obviously, when you

are trying to work with people outside of your network, lack of common standards and procedures can be a real high hurdle to overcome.

So what are some of the facilitators? Many of them are the reverse of the barriers. Funding that is actually explicitly dedicated and committed to collaborative efforts, and that may include putting those requirements in funding announcements.

I have certainly worked within a network in the HIV arena where the primary focus of the network has been trying to work with other networks and I think that that makes a difference.

I know in the cancer cooperative groups, there has been a big push to interact across networks and I think that that has been very successful in terms of cross-sponsorship of studies and enrollment of patients in each other's studies.

Of course, sponsor support. Setting up some sort of organizational vehicles that can actually manage the collaboration. And then, probably most importantly, recognizing that there is actually some value being added by the collaboration, that this is something you couldn't accomplish on your own.

Neither network is actually going to be able to do this on its own in the time frame that is necessary and that you do have a common research focus and you are going to conduct mutually beneficial work.

So best practices, again, collegiality, I think that that is no surprise, very importantly, with external collaboration, probably even more so than internal collaboration is the networks have to believe that they have common goals in mind and that they are going to be attacking them in similar ways. So there is a compatibility of interests.

And, then, that there are structures set up in some way through management of both networks, as well as sponsor collaboration, to be able to actually address the differences that come up and resolve them, that they don't fester, that they are not just left there and people come back to them six months later with no resolution.

You have to have active processes in place and it definitely helps to have formal written agreements, so you know what each of you committed to doing. You can pull that out when you are straying afield from that.

And here is an example and I think we talked a lot about practice-based research networks this morning already. But the practice-based research networks have definitely seen

the value of external interactivity and they have created a federation of practice-based research networks to establish alliances, as well as to provide support to all of their research networks.

It has helped them broaden their research base, gain additional support. They are able to share lessons that they have learned in trying to conduct research.

They have been able to build networks of networks and, in particular, with a common voice that represents more than 50 research networks, they have been able to educate their funding organizations. They have been able to lobby for their positions and they have been able to gain representation on national committees.

So, clearly, here, the sum in this external collaboration is more than what each of the individual networks could do on their own.

So, next, turning to expanding research scope, a couple of interesting findings.

Networks are already doing a lot of studies. The average in our survey was 5.8 studies going on in non-clinical trial networks and over 20 in clinical trial networks.

Now, I think that Dr. Zerhouni alluded to this, as well, this morning. Clinical trial networks often have studies

that go on for long, long periods of time. So there is considerable overlap. You know, some are starting, some are being developed, some are ending, some are in follow-up.

But it does raise an interesting question of how much more can clinical research networks do without additional resources.

I am going to skip through some of these, because I know I am going to be running out of time shortly.

But another interesting finding that I will touch on is that clinical research networks don't really apply for very many grants each year. The average number ranges between two and four. So this could be, also, food for thought in terms of expanding resources available.

Barriers, I think, are, again, fairly obvious, lack of time, not having protected time, which is an important thing for investigators to work on new ideas, and, also, in many instances, not having enough research structure to actually support the expansion of the research agenda.

I think I will skip over facilitators and just quickly go to a slide on changing clinical practices, the last area here.

As you can see from this, I hope you can see from this, we separated this by older networks versus newer networks.

Older networks, clearly, feel they have had a greater impact on changing clinical practice. I think that it is not at all surprising and the numbers get up into the 50 to 60 percent range in terms of having had impact, which I think is actually probably not too bad.

And another important feature in changing clinical practice is being able to get the information out.

I won't read over this slide, but it is important to have processes for getting your data into the literature, as well as getting it out into the clinical community.

So in conclusion, these are some of the high points. I think academic reward is a very important issue to address; sponsor involvement and encouraging collaboration; having enough funds and having enough time.

Can networks take on more? I hope you all think that you can. And an important point here is the tension between research and practice and, as several people said this morning, you can do the research, you can test it out in the academic bedside environment, but how do you really know that it actually is going to be effective, the difference between efficacy and effectiveness when you get out into the clinical community.

And observational studies are certainly very, very important, very relevant to this point.