

IECRN National Leadership Forum
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Report of Breakout Sessions: Management and Governance

Presenter:

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DR. SACHS: We're going to lead off the section with management and governance. I'd like to introduce you to the content experts and moderators of that session, which is Pat Dolan Mullen, Ira Shoulson, and Andrew Nierenberg.

Thank you.

DR. MULLEN: I'll tell you a little bit about who was part of the management and governance breakout group and also introduce you to some our global ratings and then we'll give more successive, concrete information by our two content experts.

The first slide was part of our presentation and, also, part of the discussion, which is to remind us of why we're here, why we have these networks, something that was really front and center for our group.

We were primarily academic and government-based people, with clinical research and organizational networks

represented, also. Notably, we don't have the private sector represented here and someone who described the affiliation of being with a company, at least not to a very great degree.

That's number four, two percent, one person.

We had the right people in the room. There was lost of leadership both on the sponsor side and on the network side and it led to a really very exciting conversation and lots of experience and perspectives on leadership and on management and governance.

Here is our ranking of the facilitators. These are kind of global facilitators to management and governance.

You can see that the scientific agenda, funding, communication, and collegiality were really highly rate. And what you will notice when you see the other side, the barriers, they aren't just the flip-side of the facilitators.

Our ranking showed that funding was elevated to the top of the list of barriers and communication, presumably, poor communication, second.

But tied on the second tier were collegiality, we've seen that before, but two factors that were not highly rated as facilitators, sponsor direction and lack of protected time. I think we've heard some of the speakers describe barriers and facilitators as kind of flip-sides of one another and I don't

think that is exactly what we showed here.

In terms of the factors that were taken into consideration in setting a CRN scientific agenda, I think we see the strong emphasis on met needs.

I think feasibility points then follow, method feasibility, funding, uncertainty of the interventions, effectiveness. Science rationale I think is going to cover the ones above and, therefore, looks like it ranks low, but I think not.

And public policy really does trail and that is something that is an interesting consideration in where the agendas are set.

Our discussion really took off when we got down to the specific kinds of suggestions and that is where Ira will take over to describe exactly what that shape looked like.

DR. SHOULSON: Thank you, Pat. Just by way of admission, when I got agreed to do this, I thought this was the "content" expert, not the content expert. So I'll do my best.

There was a lot of discussion. As Pat mentioned, there was an over-sampling of individuals from academia and NIH and a great under-sampling of the business world of the world of industry, which we know plays such an important part in clinical research and in clinical research networks.

But given that recognition, it was felt that a lot could be learned and gleaned from the business world, including dimensions of strategic planning, milestone-based engineering types of models, end-driven mission versus enhancement of an academic career, some of the tensions that may exist within even academic clinical research networks.

And a great deal of discussion on performance metrics, which I think are gradually evolving and I think are taking shape and in some comments I'll make in a bit, the question is how to maximize the informativeness of this evolving information.

Now, what I want to concentrate on is the concept that came put of our session of a toolkit; that is, a common resource not just for clinical research networks, but also for especially a big sponsor, like NIH. And I think there was a recognition that there is an opportunity for sharing of information, certainly, between and among the clinical research networks.

But, also, there was a sense that NIH itself, there are many project officers from NIH who are represented there and one heard a great deal of very interesting information that was new to many of us who are heavily involved in our own NIH-sponsored clinical research networks or in some way contributed by NIH and the sense that many of the project officers could

learn a lot from each other in terms of the sharing.

So we asked the question to the group, and this was done in a prioritization and using our electronic data, we asked if we would have a toolkit, what would be the toolkit items that would be of greatest interest to you and this is how it came out.

There was a great interest in the clinical research networks in terms of how networks are organized, how they have committees, what committees they have, what is really the structure of it.

And then specific issues, like constitution and bylaws, publication policies, conflicts of interest policies. And I'll also mention in a bit performance policies, which we didn't survey, and, also, training issues turned out to be also very important and at least came out of the discussion.

Common NIH resources refers to the fact that there's a lot of resources that exist now within particular institutes, perhaps either the disease-oriented or the infrastructure types of institutes that could be shared and we tried to summarize this in terms of the toolkit concept and, hopefully, if this is a recommendation that's accepted, that there will be some flesh put on this in terms of its implementation.

But the idea is there needs to share information and

knowledge about information and governance; one, most importantly, among the clinical research networks, but also within sponsors themselves, such a formidable sponsor like NIH.

In fact, one of the project officers said if a new project officer came on, wouldn't it be great to go to one resource at NIH to see what is going on between the institutes, even within a single institute that is heavily involved in clinical research networks.

Also, a sense that there are sister agencies besides NIH, such as CDC, FDA, and AHRQ that are important in terms of sharing information and resources.

Then the idea was how could this be done and I think there was a consensus, of course, that this would be a public access tool for management and governance, and here are some of the items that might be part of that public asset: constitution and bylaws of the clinical research networks; organizational structures, including committees; publication policies, we spent a good deal of time on that, don't want to go into detail; same thing with performance standards.

More and more clinical research networks are developing report cards and wouldn't it be nice to see what's going on at other networks. Also, interest in conflict of interest policies and, also, training requirements.

That, in essence, was a tangible recommendation that I think coalesced during our management and governance meeting in terms of a toolkit concept, something at least to share.

Already, of course, IECRN has developed at least a sharing of who the clinical research networks are, those 265 or 300 or 700, depending on how one counts, and I think the next step is now that the networks are identified or will continued to be identified, wouldn't it be great to be able to share this information between the networks.

DR. NIERENBERG: The other thing that we touched on briefly and there was great interest in is the whole issue of leadership.

In a sense, you heard before that communication and collegiality were some of the main points that people discussed, but it's a little bit like Strunk and White. In Strunk and White, they say write clearly, but they don't tell you how.

So it's lead well, but how do you do it? And there is no leadership training that is currently available centrally through NIH or the other organizations.

And we showed this very briefly, this was from Hackman's "Leading Teams," which is an interesting resource. And if you're leading a team of professionals, there are actually a set of skills that are very helpful and a set of

principles to follow.

And just very briefly, if you specify the ends, but you don't really tell people exactly how to do it, then you can use the resources of people who are expertise and if you do otherwise, if you veer from that, you could cause all sorts of problems.

So in a sense, what we do need and what we don't have is leadership training and, also, a sharing of leadership lessons. So what have people learned from trying to do this? What has worked well and what mistakes have been made that you can learn from?

So we were trying to really discuss, in a sense, the sociology of the CRNs, how were they put together, what works in terms of the structure, the management and governance, what doesn't work, that we have a lot to learn from business models, which many of us have never even been exposed to at all and especially not trained in.

That there is an opportunity to share between the CRNs and among the sponsors in terms of what works and what doesn't work; again, leadership training; research and development and practice can also be shared between them; and, that the ultimate goal is what we said in the beginning, that the purpose of this whole enterprise is to address unmet needs of those affected by

or at risk of the condition.

And the fundamental outcome of all of the research networks is do they improve patient outcomes and that's the ultimate test of whether or not they work.

Comments from the group?

DR. SACHS: The format that we're going to use is that we'll have the presentation of the reports, questions, and then the next group.

So we have a few minutes, like five minutes, questions. Feel free to add comments.

MS. BERKOWITZ: I'm Susan Berkowitz, from Westat.

I wanted to say that in the discussion that occurred yesterday, there were a lot of very specific examples that different networks gave about how they handle their publication policies and I would hope that that would somehow be captured in the writeup, because I think people were very interested in the specifics of how different networks have actually dealt with those issues.

DR. NIERENBERG: That also was a hot topic that people have struggled with to make sure that, I think, everybody felt good about what they participated in and there have been, I think, both problems and opportunities with different approaches.

So thanks for bringing that up.

QUESTION FROM THE AUDIENCE: I was shuffling among the three sessions yesterday. So I wasn't always there, but I have one question about the research agenda setting.

What I've seen in your bar chart, number one is unmet need. I assume that's public health need.

There wasn't any mention about innovations. So I was wondering whether that was part of the discussion, because I know in our network, our PIs have conceded early on that our product will probably never win a Nobel prize, but they are comfortable with that because the purpose of the network is different.

So I'm just wondering whether the panel or the group have discussed on that, which is one of the reviewing criteria for NIH, is the innovation of the signs.

DR. SHOULSON: I don't think there was much discussion in the group about that. Of course, innovation as a review criteria, as applied to clinical research, has been modified, as we know, by NIH in the past year or two to really kind of accommodate the nature of clinical research and there are certainly many innovating aspects of clinical research, but not in the traditional way in which innovation is applied to science in general.

So I think the point is well taken.

QUESTION FROM THE AUDIENCE: I hope that point can be discussed in a more full fashion, because that is often one of the criticisms about clinical research by people who are in discovery or whatever.

So I think that is a notable point. Thanks.

DR. MORRIS: Alan Morris, University of Utah. That was quite interesting.

I saw in your list of items for NIH project officers a number of interesting things. As someone just mentioned, I didn't see publications and I wonder if linked to the publications there might not be some consideration of what one does to assure proper ends and not academic career development, because for someone like me, it's quite easy to choose to do the proper ends, but for a new investigator who is just beginning her career and is 33 years old and is working on a big project, it becomes quite crucial how she will fit into the study, the contributions, and particularly the publications, and that is not a trivial issue.

The other thing I want to ask about is did you discuss, among those tasks for the new NIH project officer, the consent document?

That's another very important issue that might benefit

quite well from a more standard and uniform approach.

DR. SHOULSON: I would just say, on the latter, I agree. I think consent documents would be a great toolkit issue and, in fact, those of us, of course, involved in clinical research know if you really want to get at the nitty-gritty of what somebody is talking about, read the model consent form or the consent form or the consent document, absolutely.

It's nothing that we really, I think, discussed at great length.

We did discuss at great length, though, publication policy, perhaps too much. I think one of the concerns, several individuals -- one individual in the audience made a concern that, of course, publication policy is very interesting, but it is a little bit self-serving in the sense, but, of course, recognizing self-serving issues, such as authorship, is an important part of clinical research networks.

So it's nothing that we want to dodge, but I think it's certainly an important issue to get into and every time we discuss it, there's a lot of interest and activity in terms of doing it.

It would be nice to be able to pull it off the shelf and see what other people are doing.

DR. SACHS: We have time for one more question.

Please introduce yourselves.

DR. TOBIN: Jonathan Tobin, Clinical Directors
Network, New York.

The strategies for disseminating research results were an area that I think has been under addressed both in the conference, as well as in the session yesterday, and I think we create the new knowledge, the innovations. We kind of fall short at the point at which we disseminate and translate them.

So I wonder if there's a strategy or an opportunity to really build that into the requirements, build that into evaluation of the adequacy and the effectiveness of the performance and really make that part and parcel of demonstrating whether or not something works.

DR. SACHS: That's a great point. Thank you.