

**IECRN National Leadership Forum
May 31, 2006
Discussion**

MR. DURAKO: Thank you, Jim. I think we will count Jim's laser pointer and his mouse as part of information technology, since he was able to disseminate and manipulate information with those things.

We do have some time for questions and I think I will triage the questions. Since we had seven presentations, you are free to ask questions on any of them. Then near the end, Jody Sachs is going to give us a little bit of a wrap-up and a charge for our afternoon sessions.

MS. HAGER: I'm Elisabeth Hager with Balan Biomedical Analytics. I take from your presentation the definition of data management did not include data analysis, and, presumably, that is because first order analysis will be focusing on the research questions.

But I wonder if there is an initiative to look at second order analysis of the data sets being created, because it is a valuable resource that is being under-utilized and without actually thinking about it, we are not going to be able to tap that potential.

MR. DURAKO: Yes, you are correct. We did not include

the statistical analysis of data in what we consider data management. That is really sort of preparing the data for analysis.

But on the point of secondary analysis of data, this is actually something that, probably because I was running a little bit behind earlier, I didn't highlight enough and a very important problem that a number of people told us is there really is no resource available, generally, to actually use the data after you have done your primary publication for the study.

And so one of the recommendations from a lot of people is there needs to be funding, specific funding set aside for secondary data analysis that will both lead to better use of the data in terms of answering more questions; so that if you look at a data set, you can answer not just one question, but you can answer multiple questions; and, second, that it will inform the development of research agendas.

And I think I could say one thing that I have noticed in a few NIH announcements recently. There have been announcements from various institutes for people to do secondary analysis of existing data sets.

So I think there is a recognition that this is important and valuable. I believe, at one point, as I was developing my presentation, I said that secondary analysis

through a competitive environment is good, but that is also time consuming and I think it is important to add resources into the clinical research networks themselves to be able to analyze, to continue to analyze their own data.

MS. HAGER: I have a question about the financial side, also. Given the statistics, is there a best practice for the financial business model, the business plan itself?

Because most companies would never exist, given the numbers you gave. Well, no company would exist.

MR. DURAKO: I don't think there is as financial best practice. It will be interesting, in the breakout session this afternoon, to hear what the participants and the content experts say about that, but I don't have one in mind.

There are lots of questions. So we will go to this microphone, that microphone, that microphone, and we will keep coming back. So if you are at the end of the line on one, you might want to get at a different one and you will get a chance.

DR. MILLER: Doug Miller, from St. Louis University.

It is interesting that this important survey is taking place contemporaneously with the release and response to the CTSA RFA, and, obviously, the question that begs, because I expect that more than 95 percent of those responses including something to do with bio informatics, data management and IT, is

there anything about this survey that will inform the evaluation of the CTSA proposals when they are evaluated.

That is perhaps a question for Dr. Sachs.

MR. DURAKO: I think that is probably an NIH question. I won't be part of that process.

DR. MILLER: You would think there would be some thought along those lines.

MR. DURAKO: Let's see if the microphone works.

DR. SACHS: It is a good question and I would like to address it. I think we need to see where we are and that is what we are here today looking at, where we are in IT.

And the CTSA's and the future awards will have to look at a lot of issues that we are dealing with through the breakout sessions, especially in the informatics area and interoperability.

So I think the timing is right, as you said, and I acknowledge that; that looking at a snapshot of where we are and then seeing how we can utilize the information to go forward with the CTSA's and actually applying it is really of great value.

MR. DURAKO: Okay. I think I see Alan Morris down there.

DR. MORRIS: Alan Morris, University of Utah. I have

three quick questions, but I will limit myself to one.

I would like a clarification, Steve, if you would, of what you meant by internal interaction and open membership, because, in fact, contracts and grants are not open unless you are talking about the joining of a young investigator to an institution that already is a contractee.

So can you help me understand what you meant by open membership? Because Dr. Smith pointed out that Web site access, for example, is limited to the investigator. So even that is not open.

MR. DURAKO: Yes. I think, Alan, that that is a very important question. I think that in concept, the ability, the willingness to bring in new membership, new blood, new enthusiasm, with new ideas, and especially younger people who can be sort of filling in the stream for clinical research networks is very important to promote interaction and the discussion of fresh ideas.

But I think you have recognized a barrier that is something that does need to be addressed in some way. That is, if you have your grant and it is fixed, how do you make it possible for new people to come in.

One of the thoughts that I have had, and this is me speaking, not NIH speaking, but I mentioned it earlier this

morning, that is there a way for sponsors to encourage new investigators with new ideas to partner with research networks in their applications, where the network can bring a lot of the infrastructure and the force behind this, but the new partner is able to generate the scientific idea and to basically bring funding for both him or herself and the network to conduct that research.

To me, when we are looking at ways to promote greater use of research networks, that, to me, is something that seems like it would be an obvious thing to happen.

I can't speak for NIH, but I hope that that is something we will consider.

Jody says shorten up on the replies and that means no questions for you, Alan. We will get to them later.

Let's see. I have to go all the way back to this microphone.

QUESTION FROM THE AUDIENCE: It is talking about external interactivity. I think the way this was structured did not necessarily recognize a lot of the reasons the best practices became best practices and I want to say two things.

One is AHRQ. AHRQ has done really yeoman's effort to create infrastructure for networks, to have methods conferences for networks, to have annual conferences for networks. That

greatly has promoted external interactivity and I am concerned that there not be a bright wall or a line or a border wall between ARC and NIH in terms of promoting interactivity.

The other is the specialty societies. The Federation of Practice-Based Research Networks is basically funded by secretariat support by the American Academy of Family Practice, and PROS, which is one of the best practice networks, is supported by the American Academy of Pediatrics.

So there are partners out there beyond the research community that we need to look at.

My concern is and my question is how do we make sure that these collaborations are honored and brought in.

MR. DURAKO: Yes. Thank you for that. Jody, do you want me to speak first?

DR. SACHS: Well, I just want to acknowledge that you brought up some really good issues and really good points, and I think the future looks toward collaboration with HHS, with other agencies, as well as with societies.

And I think we see that as very crucial and evolving in the future, because we have to form these partnerships and collaborations.

So I am glad you brought that up. Thank you.

MR. DURAKO: Yes. And I would just add to that I hope

everybody knows what AHRQ is, the Agency for Healthcare Quality and Research. They are the main sponsor of a lot of the practice-based research networks.

And I will say that AHRQ was at the table with us on this. We talked to them. We encouraged them to encourage their networks to participate and the AHRQ networks are in the inventory.

The other point I would say about this, this is something I didn't have time to say earlier, is I think it is very important for different sponsors to try to figure out ways to pool their resources or to at least judiciously combine resources in certain areas to make things happen, because it isn't just NIH versus AHRQ or NIH versus CDC or others.

All the agencies are here. All of them struggle to find enough money to do everything we want and combining of those initiatives I think is important, and even with sponsors outside of the United States, not just the U.S., but other governments, as well.

So I hope to see that that would happen.

DR. SACHS: Wait, I just want to address -- there were about three meetings in May that were joint with AHRQ and one was the network meeting that talked about network activities.

One was a meeting to talk about practice-based, and

another one was an NHIN meeting, and these were both co-sponsored through AHRQ and NIH, as well as others.

Thank you.

MR. DURAKO: Next question.

MS. HOLBROOK: Janet Holbrook, from the Johns Hopkins Center for Clinical Trials.

I thought there was a lot of interesting information presented this morning, but one thing that I thought was missing was a table one. Who was in your study?

Because the reason it raises concern for me is that we have three networks running in our center and only one of them is in your database, and I am in a position to know that came across our desks.

MR. DURAKO: I don't know how we missed them, but if we did miss them, we want them. It may be that they didn't meet our definition for some reason.

MS. HOLBROOK: I am sure they would have met it.

MR. DURAKO: Yes. We tried every method we could. We went to everybody we could.

The list of networks we did not show, but you can see it on the Web site, the full list, is there and, actually, during the process, we asked everybody that we knew, please, look at the list, see if we are missing anybody, tell us about

whether there are any other networks.

We want them all. So if you have some that we missed, it is not too late to get them in.

MS. HOLBROOK: Well, how have you gone after this, who you have missed, and looked at it? I mean, that is really important.

MR. DURAKO: I can't tell you how we are going to after who we missed. I can tell you how we went after who we got.

DR. SACHS: I would just like to add to what Steve said. Collection of networks is ongoing and, certainly, on our Web site, we have an opportunity, if you think your network complies with our definition of a network or you know of other networks, please submit that. It is ongoing.

But I didn't know if your question was also related to the networks that were in the descriptive survey, which was the more in-depth assessment of the seven domains.

MS. HOLBROOK: No. We checked the database. But I guess what I am concerned about, if these results are going to be built upon by NIH, if they aren't representative and they miss particular types of networks and maybe focus on larger networks rather than maybe less well funded networks, that it could be problematic when you are trying to extrapolate them and

make decisions.

MR. DURAKO: I think I actually had a slide previously on limitations and one of the limitations we have is we don't know whether we got every network.

We used every available means we could think of, as I said, to find things that looked like networks, sounded like networks.

We went through all sorts of personal contacts. We went through literature searches. We went through Google searches. We tried to find everything.

It is possible that you may have a network that doesn't come up in any of those, I don't know, but we certainly want them. It is an ongoing, living, breathing inventory.

Unfortunately, we have the data we have. If you think that there is something that is not represented, it is certainly appropriate to bring that up in the breakout sessions.

DR. SACHS: There were over 800 that were actually reviewed. So I just want to make the point that there were a lot looked at.

If you feel yours applies, it is an ongoing collection of information. It will be a database that is ongoing.

So it is not too late. Please submit. Go to the Web, submit your information, and we won't overlook you.

MR. DURAKO: And this is not the end. I am hoping that this forum is the beginning. We have collected data. We are now putting that out there for you, but the next two days are input, feedback from you, what do you think of this, what do we need to do next, what should we recommend, and then we hope we will be able to go forward as a group to work with NIH to actually try to implement and, I hope, fund some of those things.

Next question.

DR. BRUBAKER: Linda Brubaker, Chicago. I think this is probably for Mr. Smith.

Are there any plans for looking at the finances at the practice or institutional level for the unique aspect of clinical trials, where you have clinical costs and research costs and variable third party payers?

And without being able to have the practice or institution identify those as research costs and bill the grant or the Medicare for research, when it is appropriate, or the appropriate third-party payer, the finances may not get cleaned up, which impacts so many of the other aspects of the best practices.

MR. DURAKO: Right. I think that is actually not Jim's area. He was doing information technology.

DR. BRUBAKER: But I think it is an information technology that needs to be able to identify the costs.

MR. DURAKO: Oh, I see. That you could use information technology.

DR. BRUBAKER: Cognitively, we know what it is on paper, but to be able to identify it efficiently as opposed to pieces of paper going back and forth.

And if that is not the scope, just if there are any plans to look at that.

MR. DURAKO: It was not our scope, although I think tomorrow morning we are going to have a plenary session from a representative of the Office of the National Coordinator on Health Information Technology, which is clearly oriented to sort of the universal health record, which I think we all hope will include research components.

I think that is an area where there is certainly great potential for being able to delineate clinical tests that are part of the research enterprise and actually be able to take advantage of what clinical tests and visits are covered by third-party payers.

So we don't have that yet. That is actually the financial practices session. I think that is a great question that we should take up as to how can we do that, are people

trying to do it right now.

Next question.

DR. HARRINGTON: Steve, Bob Harrington, from Duke University. A question in the data management domain.

Did you question the networks about ownership of data? And I am specifically interested in two components to that.

For the NIH-sponsored networks or projects, did you talk about when data becomes publicly available and available to other researchers?

And on the industry-sponsored side, what percent of these networks actually have true independent ownership of the data that allows all the other things, including secondary analyses, building of careers for junior investigators, et cetera?

MR. DURAKO: Thanks for the question, Bob. Sorry I didn't recognize you in the dark here. Your profile isn't quite as distinctive as Alan's profile.

DR. HARRINGTON: I guess that is good.

MR. DURAKO: I think I have a little trouble remembering if we actually asked it explicitly that way.

We certainly asked -- and this came in more in the management and governance piece -- about publication policies, data sharing policies.

We all know that that is a big issue of who owns the data and you are well aware, as most of us are, about NIH's push to have plans in every application for how you are going to share the data.

But I don't think we actually have any data on ownership by network at this point, but it certainly is important to external interactivity, as well as secondary data analysis.

DR. SACHS: My suggestion is to mention it in the breakouts and maybe bring it up for discussion.

MS. CALABRESE: Barbara Calabrese, the American Medical Directors Association Foundation. First, let me commend you on all the work that you have done and all the information you have provided.

But I was wondering if there are any opportunities to begin to look at those organizations that are more society-based rather than academic and then to compare and contrast them with the academics to see what differences and similarities they may have.

MR. DURAKO: Yes. I think that is an excellent question and suggestion.

Because this project moved along very quickly and had lots of information, we made our first very broad-brush cuts at

just presenting some fairly simple and straightforward findings.

We clearly want to dig deeper into that. I think that sort of society-based networks, as well as the practice-based networks, specifically, and, obviously, there is some overlap there, are very important for us to look at.

All we have done now is clinical trials versus non and NIH versus non, but there are many other ways to look at it and we should.

Other people have asked me this morning specifically about the practice-based research networks. So thank you. We hope to continue with the analysis and provide more data after the meeting.

QUESTION FROM THE AUDIENCE: [Unintelligible] from NYU. I have a question, that you had mentioned that these CRNs have been around for over 50 years.

What was the initiative that had the greatest impact that you had and was this a randomized control trial and what is the percentage of these CRNs that can handle a true RCT versus other forms of clinical research?

MR. DURAKO: Well, as a politician, I won't answer the first question. I think there are probably many CRNs who have had impact.

I would note that I think my friend Dr. Comis is in

the audience, or was in the audience, and he has been involved in the cancer cooperative groups for many, many years. Some of the oldest networks come in the cancer field.

For example, I think perhaps the National Surgical Adjuvant Breast and Bowel Project may be the oldest network in our inventory at the 50-year period and many of the cancer networks have been around for a long time.

So I would say if you looked at longevity, the cancer field has probably had a great impact, and those are all true clinical trials.

And as we said on our slide, about 40 percent of networks are doing true randomized clinical trials.

One more and last one.

DR. NIERENBERG: Andy Nierenberg, Massachusetts General Hospital and NIMH-sponsored bipolar trials network.

I wonder, for all of you, if you have given thoughts to the minimal requirements that a network must have in order to function and, related to that, have you thought about coming up with metrics to assess network?

MR. DURAKO: Metrics is a good idea. It was not part of our work, but, certainly, if you wanted to look at effectiveness and efficiency, metrics would be necessary.

That may be maybe a follow-up project. I don't know.

What is the minimum to have a network function? I'm not sure I can answer that question and perhaps someone else would like to hazard a guess.

I think, obviously, you need some kind of scientific or medical leadership, because you need some kind of agenda. Clearly, you need to have access to some sites.

Whether you need sites that are dedicated sites or whether you get sites on a study-by-study basis is something, I think, at a minimum, you can get them on a study-by-study basis.

My own personal belief is you need funding for infrastructure. How much infrastructure is debatable, but if you don't have some core that is there that can maintain the network and, in particular, can continue to generate ideas and obtain funding, you just can't do the work.

We interviewed a few networks, as I said earlier, who are dormant, they don't have core funding. So once one study ends, if they didn't get another one funded, they basically are out of business for the time being. They are technically still a network, but nobody is doing anything, because nobody has any time.

Anybody else want to comment on that? Anybody from the audience want to comment on that? We will take one last question and then we have two minutes, if somebody wants to

comment as a follow-up to that, and then Jody will wrap up for us.

QUESTION FROM THE AUDIENCE: We have heard repeatedly the importance of community involvement in various medical research networks and we heard something about family involvement.

Were you able to identify best practices in terms of involving the community of patients, participants? Not the clinicians, but the patients involved.

MR. DURAKO: Well, there are a number of networks, I think this started in the HIV field, but has certainly moved into the cancer field, as well, that have what they call community advisory groups and in the HIV field, this started with, basically, advocates from the affected population groups.

That has extended into advice from organizations, advice from actual real geographic communities. I am working on an HIV network where part of what we are trying to do in order to pave the way for HIV vaccine studies is to go out and engage the community and all the community groups and help them understand what we are trying to do and what it is about and that it is not just experimentation.

That is one of the issues that is involved. The cancer community has certainly developed many, many patient advocacy

groups, as well as associations that advise the agenda, and I would say that is an important thing to do. If the patients don't want to participate, if they don't think it is relevant to them, if they are afraid they are being experimented on, then you are going to have trouble with recruitment and retention.

DR. SACHS: I would like to also add that the HIV community and the HIV networks is a good example of doing something a little bit different and doing care based on their doing it in developing countries, family care.

So it is women who can come in pre-pregnancy, post-pregnancy, prenatal care, postnatal care, and, also, their family can come in and get care.

So it is a network based on total care, age span across the board, rather than delineating different network groups, like pediatric care or maternal care of the elderly.

It is across-the-board family care community and it is based on a community type care system and it works well, I think, in the developing countries, where they usually come in and they come in collectively as a group.

So I think it is an example that works well.

MR. DURAKO: I think that is a very important example that Jody mentioned. It is something that is usually called PMTCT Plus. Prevention of Mother-to-Child Transmission is the

PMTCT. The Plus is you are not just trying to prevent transmission to the child, but you are trying to deal with all of the healthcare issues of the mother, the baby, and the extended family.

That adds value and it makes people understand or appreciate you are not just coming in to experiment on them, you are trying to take care of them.

So I think that is important. Also, in those programs, they engage community members, people who are actually living with HIV/AIDS, to educate the community, as well as identify people who are eligible for the studies.

DR. SACHS: I would just like to add one other thing about that, that that also happens in the research world of TB, as well as with pediatrics.

MR. DURAKO: I think, Eric, you get no question, but you are going to respond to the other.

QUESTION FROM THE AUDIENCE: I am going to respond, but also ask a question.

I want to endorse your notion of core funding as key to success and ask the question about whether you observed anything between whether that core funding was internal or external and if that makes any kind of difference.

MR. DURAKO: We did not address that. There are

different models for that and, certainly, we are working on one now, called the cancer trial support unit, where NCI has attempted to take some administrative functions and total centralize them within one contractor as opposed to putting them in every single cancer cooperative group.

Now, I am biased in thinking that that is a good model because I am working on it, but I can't tell you whether everybody would think that that is a good model, but it is a potential for, if you have many networks doing the same kind of thing or needing the same kind of core infrastructure, like regulatory support and other kinds of things that are not really specific to the network's scientific agenda, you could centralize them outside the network and let the network tap into them.

I think that may be the end of questions. Jody is going to make a few wrap-up remarks and give us a charge for the afternoon, and then we will break for lunch.

[Applause.]