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Report of Breakout Sessions: Network Operations

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DR. SACHS: I'm going to move now to the next breakout session, which is network operations.

I'd like to introduce Kevin Peterson and David Schoenfeld. Would you like to come up? It's up to you.

DR. SCHOENFELD: Two people are speaking, myself and Kevin Peterson, about the breakout session on network operations.

The roadmap of the readout is I'm going to briefly discuss who attended the session and then we broke up the session in terms of barriers and solutions and best practices and then priorities for the future.

I'm going to report on barriers and solutions and Kevin is going to report on best practices and on priorities.

Barriers and solutions were broken down into protocol development, implementation, regulatory procedures and communication.

So who was there in our breakout? And 78 percent of the people had participated in the descriptive survey. We asked

people what was their level of research experience. We didn't actually define what these levels were, but people mostly self-identified as advanced, with a few people, also, experts, and people who talked to themselves as intermediates. Nobody self-identified as a beginner.

Most people were involved with NIH-funded trials, with a few people doing other things.

So, first, protocol development. The first point that was raised was that funded grant proposals are not protocols. That is, in their network, they do trials which are funded by grants. People send in grant proposals and then the investigators sometimes think that they've done their work, the grant proposal is the protocol, and this is something we also see in clinical research centers, as well, and this is a problem, how to change a funded grant proposal into something that really is a research protocol that can actually be used in a multi-center trial.

One suggestion was to use protocol templates. Apparently, people develop their own templates. So something that could go into a toolbox, I guess, would be a protocol template of what should be in a research protocol.

Then people should use consent form templates and, again, I think that was also suggested as something that could

go into a toolbox, what should be in a consent form template.

We actually developed, in our network, a consent form template for helping people develop consent forms locally.

Then, finally, in terms of protocol development, I like this carpentry saying that you should measure twice and cut once, the idea being, in carpentry, that if you measure the board twice, you don't cut it short, which can't be fixed.

I think that the time it takes, and other people agreed in the session, the time it takes for protocol development is time well spent and shouldn't be shortcut.

Protocol implementation. One of the participants actually has a patient recruitment survey before the study starts and this survey is done proximal to the start of the protocol and is not simply something that was done two years ago in order to get the grant, but something where they actually do it right before the study starts, to get a good idea of what their recruitment will be like, and this seemed like a very good idea.

The other suggestion was that to maintain a database of all past and concurrent studies, the past studies could be used to tell whether recruitment was adequate and the current studies could be used to tell whether recruitment will be impacted by competing studies.

Regulatory procedures. This had a lot of discussion as a major barrier and that IRB approval for a multi-site study is a crucial barrier.

It was interesting. I'm kind of a content expert, but I think I'm naive about IRB approval, since my network has 12 sites, all at major universities, and not 50 sites spread among universities, practices and so on.

So the agreement was that the current system is confusing and difficult to navigate and there are local IRBs, I guess, central IRBs, there are outsourced IRBs, then there are university IRBs, and they all are somewhat different.

Reviews are inconsistent. They have different forms. And it seemed that the real patient protection issues are somewhat unclear and so that IRB reform would be a major advance, but we didn't actually discuss how to do that reform, because I think we all realized that this would be a difficult and delicate issue that would need a lot of deep thought.

Communication. One person said that they actually have two shifts in their coordinating center so that they could communicate with -- that is, their employees came in on two different shifts so that they could easily communicate with the west and the east coast.

One of our discussion points was regular meetings and

I asked whether sites did have regular meetings scheduled years in advance and about half the sites had regular meetings. The other half, the sites probably scheduled their meetings in a more ad hoc way.

Everybody agreed that a central Web site, people agreed that a central Web site is important. It can be an information hub. The information is always there.

And I think all of us are in the process of trying to replace the voluminous e-mail discussions with the central Web site.

Our network is doing it and I got the impression that other networks are doing it and it's a culture change and I think it's still an evolving -- I got the impression at least that it was kind of an evolving issue that I think will change over the next couple of years.

It's interesting. When the ARDS network first started about ten years ago, we did not assume that e-mail would be the central method of communication. That was sort of a hope that it would be. There were some investigators that still expected to get a fax, but e-mail took over and now e-mail hopefully will be supplanted by Web sites.

DR. PETERSON: It's like a jungle up here. Thanks.

What we did next was to look at the best practices and

the best practices in many ways reflected the barriers that we looked at earlier in this session, but there were a few differences.

In the report that came out with the best practices, the report emphasized that staff and investigator qualifications were among the most important aspects of site recruitment.

Then site recruitment was broken down into two other pieces that sites either recruited with competition or sites were recruited based on what they termed in the report recommendations.

As we began to explore that more fully really in the session, we really found that site selection did -- that we had about half the group that looked at site selection based on performance-based criteria.

That is, they selected their sites according to who did well in the previous study. But the other group really wasn't using recommendation as much as it seemed to be using an idea of bringing people in and nurturing them along and training.

So that they would really take sites that had less experience and then train them.

Our next best practice was really looking at protocol development. Now, we had looked at protocol development earlier

as a barrier.

The reported findings in the protocol development had been to standardize and to simplify and to replicate and to trim the fat.

As the group began to look at that, there were some additional items that were raised. That selection of the appropriate protocol was important.

Several of the groups polled their membership and said what are the members interested in doing in order to determine overall interest and buy-in from the providers.

There was quite a bit of discussion on how to trim the data or trim the data collection, that protocol development seemed to be a very important part of the initiation of a protocol.

There were a variety of issues that were identified.

The group talked about balancing the cost and the value of having collected too much data or trying to collect too much data. Everybody talked about collecting less data. Nobody talked about collecting more data.

A variety of the groups had made it part of the governance system. In fact, some had created a mechanism that if you were collecting too much data, then you could go back and report back to that governance system.

There was a variety of suggestions looking at who to involve in that protocol development in order to help trim the data or trim the data collection.

That included involving study coordinators, interviewing of the protocol, involving monitors whose duty it was to address too much data collection, involving patient groups to identify what are really the essential elements of the study, and involving practitioners.

The group really looked at a two-part review then of most of these protocols. Some of the group was looking at a peer review, kind of a scientific review, followed by a community or affiliate review in order to make sure there's not too much data being collected.

Another section that we looked at was infrastructure support. The reported results from the IECRN suggested that infrastructure support kind of had two different modalities; that there was that group with robust information technology and there was a group that had less resources and had to pick the right technology.

Other issues were raised here and I think that the group decided that really part of network operations infrastructure should include that training issue and that staff training seems to be an important part of the infrastructure;

that training and good clinical practice, training and programs, having specified training programs for all new sites.

One group had one class a year at a national forum. Other groups actually took what were called practice enhancement assistance, or PEAs. I think that that was a concept developed out of Oklahoma that began to look at someone from a central group go out to the clinics and kind of act as a research assistant.

Another part that was described was how to monitor sites. That seemed to be part of the network operations, that we ought to be able to monitor our sites.

The reported findings from the IECRN suggested that monitoring sites, you wanted to have a local relationship with the site, to develop that local relationship; that the best practice was to help align the incentives of the sites with the incentives of the central organization; and, to go about and adopt existing models rather than reinventing the models.

The practices, as we talked about them in the group, began to break down a little bit in terms of these two types of networks, again; that some of the sites did specified data qualify exams and that, for example, they would stop after the first ten enrollees and do a data quality exam and monitor the site in order to determine specifically what the data quality

was.

Other groups leaned more toward the idea of continuing that training; that is, many of them involved some kind of mentoring program or partnership program with a more experienced site.

They all stressed developing the relationship and some actually used a data set to keep incentives aligned and match interests.

One of our questions was to ask for surprising or insightful things that were found in the report and determine enhancements. There were a few things that were surprising that came up.

One of the suggestions was that some of the recommendations for what a network ought to do weren't really very clear. It was unclear about which conditions would need to apply at a network, perhaps depending on how the network was formed.

There was some thinking that it was a bit surprising, that it was a description of what actually exists and not a prescription for what was the best.

Some of the insightful pieces, suggestions for additional things that could be done. I think there was a desire to see more drill down, that is, drilling down on the

networks specifically in terms of infrastructure funding, how they differed in infrastructure funding, how they differed in their sights or characteristics of the network or in the purpose of the network.

And, finally, we looked at possible enhancements to the report and there were a couple of really good suggestions. One of them was emphasize that the real question that was being brought out is kind of what is the metric for health improvement rather than the metric for the network itself.

Another group suggested that it would be a valuable resource to add to identify kind of the best practices people that were listed, to put them in as an additional resource so that other networks could call on those people and learn a little bit more.

When we tried to prioritize some of these, we asked which of the following practices were most likely to be adopted. Really we looked at -- actually, this was our second question. Can I go to our first question?

DR. SCHOENFELD: Just go forward, yes.

DR. PETERSON: Right. This was not the answer to the

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DR. SCHOENFELD: What happened is that somehow -- do you have your numbers?

DR. PETERSON: All right. Let's go this way. The first question is going to be this one, the first question was which of the following was the most important thing to be adopted.

That is, we looked at our resources, at IRBs, protocol development, site characteristics issues or community involvement issues.

People really began to say that the most important were going to be resources and mentoring, although IRB issues were also really quite important.

When we looked at which was the most likely to be adopted, then, again, resources and mentoring were the most likely to be adopted.

Protocol study characteristics were important and it was just thought a bit less likely that IRB changes were going to be adopted. Surprising.

We asked if you could select one thing that you would like to change or if you selected one of those things that you would like to address, we really found that IRB and regulatory reform -- that wasn't correct.

DR. SCHOENFELD: This is correct, yes. This is correct. I don't understand what happened, but it did. It was 40-40-40, wasn't it?

DR. PETERSON: And the correct answer really is. If you could select one thing to do, which one would you do. Resources and mentoring came in first at 40 percent; protocol development issues came in a tie at 40 percent; IRB and regulatory reform dropped to 12 percent; community involvement dropped to seven percent.

DR. SCHOENFELD: Something happened to the slide.

DR. PETERSON: The slide is correct.

DR. SCHOENFELD: I believe the slide is correct, that's right. This slide is correct.

DR. PETERSON: Great. I love these ARS systems. Actually they're a lot of fun, once you get the hang of them.

Right. So those are answers, and we're out of time.

DR. SCHOENFELD: They edited my slides. So some of them are correct and some of them are not.

[Applause.]

DR. SACHS: Thank you. We have time for questions. A reminder, please identify yourself.

MS. HOLBROOK: Janet Holbrook, Johns Hopkins. This may be a question specific to clinical trials networks, but I think even in epidemiological studies, there's more of this.

Did you discuss at all data and safety monitoring boards? One of the issues that we're facing in our asthma

network is we have funding from different places and sometimes the funders want different DSMBs and that gets to be quite onerous to be reporting to more than one DSMB.

Then they aren't able to integrate really all of the research we do and you get very mixed messages.

DR. PETERSON: Well, it only took the group about three minutes to get into IRB issues, even though we really hadn't intended to focus on IRB issues.

The group was really meant to be looking directly at network operations and I believe that there was another group that was actually looking more closely at IRB issues.

DSMB issues didn't come up specifically, although I have to say that we could tell from the group that IRB issues are a hot topic and felt to be a real barrier, not necessarily having any easy solution. We really didn't get into specific DSMBs.

DR. MORRIS: Alan Morris, University of Utah.

You guys represent very different network organizations and goals. I mean, David Schoenfeld runs a critical care network coordinating center and yours has quite a different focus.

Did you discuss the attributes of networks with regard to some of these important issues or did you just lump them all

together?

DR. PETERSON: Well, our job was to get the ideas of the audience and so the group thought that it would be valuable to look at the IECRN report and drill down on those characteristics.

DR. MORRIS: So they didn't focus then on what the networks were specifically intended to accomplish.

DR. PETERSON: That was one of the things that they thought ought to happen. They asked the same question you just did.

DR. MORRIS: Okay.

DR. PIHLSTROM: Bruce Pihlstrom, dental and cranial facial research, NIH.

Kevin, I'm wondering if you could or if someone could expand a little bit on the discussion regarding a metric of health information or health improvement rather than specific operations of the network.

Could you give us a little more information on that discussion?

DR. PETERSON: The question was really or one of the comments -- we are running -- quickly, one of the comments that was brought up was that we are looking at network operations, but we really also need to look at the overall effect on health

improvement; that the purpose of the research is really to influence healthcare and one of the best practices really hasn't been reflecting -- we haven't been measuring our practices in our ability to change practice.