

**IECRN National Leadership Forum  
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IECRN Findings: Network Operations**

**Presenter:**

**Nancy L. Dianis, RN, MS**  
Associate Director, Westat

MS. DIANIS: Good morning to all of you here and good morning to those of you in Web cast land. I'm told, at last count, we have about 200 people joining us by Web cast. So there's modern technology at its best.

For those of you who have come in late, perhaps, I am Nancy Dianis and I am the project director for the IECRN.

I have extensive experience working with research networks and working in the research setting. Previously, I was the director of nursing at the NIH Clinical Center and Johns Hopkins Bayview. So I have firsthand knowledge of working with operations and procedures and practices and I have a good appreciation for the need to have infrastructure.

As you know, a solid infrastructure is a cornerstone to a successful clinical research network.

I am going to talk you through the practice domains of network operations, recruitment and retention, and training and professional development.

As Steve has alluded to, this is a sample of the findings in our report. Believe it or not, just in the

quantitative part of our survey, we collected over 2,000 data elements. So as you can appreciate, it's not going to be possible to review every single one. I don't think you would have the tolerance for that today.

But I've tried to highlight some general themes that have come forward and I would encourage you, if you haven't had an opportunity to look at our report, to please do so and pick out the points that are of particular interest to you.

Also, I would mention that the breakout sessions later on this afternoon will go into greater detail about the findings and you will have an opportunity to give your opinions and thoughts about them, as well.

So as the magic oval indicates, we are now going to talk about network operations.

We operationally define network operations for our project and it is really the business of the network, and that includes managing the selection of sites, managing the study protocol development, taking a look at the regulatory issues and managing them, as well as network communications.

Here are some general findings. The first one deals with time lines. Almost half of the CRNs use standard time lines for protocol development and they indicated that they were able to meet those time lines almost all the time.

Again, I'd like to be affiliated with those networks, because it's very challenging. But, again, having a target and having a roadmap, if you will, in the form of a time line is very helpful.

Training was another issue that we talked about and fewer than half of the CRNs provide training on study design and development to support the process. Also, fewer than half of the CRNs use tracking tools, and these are tracking tools for the regulatory process, as well, when protocols need to be renewed.

Those who did use tracking tools found that they were able to stay on top of the renewal process and it made it a little simpler for them.

I'd like to now talk about some of the themes of network operations. In the yellow boxes throughout our presentation are quotes that we've actually collected from our participants.

We had the unique opportunity in that we did collect paper-and-pencil and Web information in the form of quantitative data, but then we also interviewed and had an opportunity to talk with people.

So I've tried to capture some quotes that I think are relevant and bring home the themes that were identified by the

majority of the networks.

As you see, I had mentioned briefly about protocol development. The issue here is protracted protocol development process and this quote by one respondent says, "There are a lot of review processes along the way and that can add quite a bit of time to the development of protocols."

Has anybody in this room ever experienced that?

And this next graph actually shows you the types of reviews that are available. There are quite a few, as you can see. I counted them up this morning and I think there are about eight.

The NIH-funded networks topped the list in terms of having the most opportunity to be reviewed. How shall we say that? They are reviewed by scientific committees, they are reviewed by regulatory groups, they have statistical reviews.

So it is not surprising that you really need a time line and probably a roadmap and a compass to keep you on track.

However, there are some innovative and creative people out there who told us some stories about how they have managed to deal with the issue of protocol development and how to stay on track.

The network that I'm going to speak with you now about is a network that is global, has global representation of sites,

and they realized that it took two or three years to develop a concept to implementation and there are a 120 steps in the process.

I give them credit for just being able to count the number of steps and identify them.

As I said, they had a very diverse group, not only culturally, geographically, as well as their knowledge of the scientific process. And as you may guess, the way they primarily dealt with the developing protocols was by telephone.

So consider time zones, et cetera, it was very, very difficult, as they understood. It took two or three years. So they thought, all right, if we start writing the protocol sooner, we've got to finish sooner.

That didn't prove to be successful either. So what they did was turned to business and there is a concept called "lean thinking."

Are any of you familiar with that concept? Just kind of raise your hand if you are. Okay. That's exciting, that's good.

So what this network did was to bring in a consultant to interview the stakeholders, to identify the problems with their current protocol process and to introduce this concept of lean thinking, whereby you look at the steps of a process and

the people and the activities involved in that and you begin to eliminate those that are redundant or unnecessary.

So that as you distill down, you end up with the remaining steps that are really critical and add value to the entire process.

So there was more support for this effort, because the lean thinking process, facilitated by someone outside of the network, so they couldn't have any, you know, hidden agenda, talked to them and found out what those particular -- what everyone actually did along the way and could document the 120 steps.

So they then began to look at what could be eliminated and one way they identified was to wait to start writing the protocol after certain milestones had been developed and attained, because if the milestones weren't reached, they kept going back and forth, back and forth and, as we saw, it created a lot more time.

So with that in mind, they reduced the unnecessary steps and now they have identified certain milestones that need to be achieved before they can start the protocol development. They identify stakeholders who have a particular interest. So they start with the small group first rather than starting with the big group and they have been able to accomplish the

finalization of the protocol in a one-and-a-half-day face-to-face meeting.

Now, they don't write the whole thing in one-and-a-half days, but what they have done is to reduce the protocol development process to 44 steps and they are able to accomplish this in about six months time.

Communication is another theme that runs really throughout all of networks, in general, and particularly in network operations. This respondent summarized the communication issue as a critical factor in the success of research.

We try to make it as simple as possible for them to get their hands on the information they need to do the research. That makes sense, doesn't it?

And here are some findings related to communication. Many CRNs have wide geographical dispersion and so it's not surprising that they have extranets, such as e-rooms, to communicate with. Most CRNs hold meetings, I'm sure some of them are committee meetings, but they also have business meetings.

One finding that was surprising was that the least common meeting method was the Web, at 22 percent. Now, again, this may be because we had a wide variety of experience of networks with electronic technology and some actually preferred

paper and pencil.

This is a bar graph that describes the various methods and, again, you will see, at the very, very top, what is number one but the good old conference call and at the bottom is Web meetings and the extra net.

So I would wager that if we conducted this evaluation in six months that we would find that the Web meetings and the external net would be increased.

So what were the strategies? I chose not to tell you all the barriers, because I think you probably know what they are, but what I think is interesting is what are some of the strategies that people came up with.

Those are listed on this slide. People use new or alternative modes of communication to increase efficiency and to reduce costs. They try to streamline communication by eliminating unnecessary communications.

How many e-mails do you get that you just automatically delete? You don't have to answer that, especially if they're from me.

And it is really important to develop a feedback method that you can get from stakeholders. I mean, you have invested in these individuals in the network, so you want to know what they think. They want to tell you what they think. So

you've got to find a way to do this in an effective and efficient manner.

Also, along those lines is being responsive to the method of choice of communication for people. You have audio learners, you have visual learners, you have people who like e-mail, you have people who are intimidated by it. So it is really important that you talk with the people of your network and find out what they think would be most effective. And not one size fits all for every type of communication, as I'm sure you are aware.

So what conclusions can we draw from network operations? Well, I touched a little bit on the regulatory process in terms of the protracted protocol development.

What usually hangs people up here is the protocol reviews and the regulatory issues. So if you can identify someone in your network or even at your site who likes this kind of work, there are people who do enjoy this, and to identify them as a resource and ask them to manage this for you, they can then help the individual PIs put together a packet in much less time.

You can also streamline the packet by creating a standard format. If you are developing protocols, you can develop a standardized format for your protocols.

Another is collaboration. I didn't talk a whole lot about that in examples, but it is really critical and you will hear more and more about this, that we have to collaborate with basic scientists and the clinical investigators.

We have talked about that quite a bit, so I don't think I need to elaborate on it. But I do want to talk a little bit about consensus, because that is the end way you are supposed to make decisions; which I think everyone wants to consensus, but it is also very time consuming and it sometimes can be a real roadblock, pardon the pun, if you don't have agreement and you can't reach consensus.

And believe it or not, it really is okay if you, as a network, decide up front how you are going to manage these impasses. So what when you come in contact with one for maybe the first or second time, it doesn't totally stop all of the progress that you are making; that you can then go to a policy or procedure that will direct you how to manage that and it won't be a surprise to the other members of the network, because they should have read the policy or the procedure.