

**IECRN National Leadership Forum**  
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**Report of Breakout Sessions: Training and Professional  
Development**

**Presenters:**

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MS. DIANIS: Now we will hear from the training and  
professional development breakout session group.

DR. HICKNER: Gee, last, but not least. Here we are,  
Jim and Mike, this is our chance.

We had a very active discussion group for training and  
professional development. We ended up with about four pages of  
notes, about 50 items, and Jim and Mike and I tried to distill  
those down to jut a few slides.

So apologies to those ideas that didn't make the  
slides, but I hope some of you might be in the audience and if  
we don't bring forward your ideas, please step up to the  
microphone and remind us what it was that you had.

But we've preserved all of that data. We will be  
expected to do a narrative summary of the session and we will  
try to incorporate all the ideas into that narrative.

First, I'll present a few comments about the survey  
itself.

In the survey instrument, the definitions of network staff and site staff may not have been clear to everyone and differently structured CRNs may have put the same type of people into different categories.

So we were a little bit unsure of some of the results in that regard.

Also, there was omission of community educators, data management folks, statisticians and economists, as far as we could tell, and we thought those were also important people on the research team.

Finally, although not in the slide, one of the participants mentioned that we should look on the communities in which the research is being done, also, as a group that needs some kind of ongoing education about the research effort.

There are currently varying definitions of and targets for professional development; again, some definitional problems. And there seemed to be insufficient information about what needs to be done or is being done in this area, especially for site staff.

It seemed fairly clear that professional development had to do with faculty, but there was less in the survey that had to do with professional development for site staff or perhaps staff themselves.

Thinking about further analysis of the data, another subgroup analysis that hasn't yet been done that might be informative regarding training and professional development is to look at the clinical research networks affiliated with academic centers versus those not, because obviously the academic centers have much more training and professional development opportunities than those that are not in academic centers, or at least so we would assume.

Some CRNs, in fact, are affiliated with academic medical centers that have more rich resources, like GCRCs, and some don't and we're interested in analysis of those two types, as well.

This came up several times. Survey questions appeared to be overly focused on the NIH-sponsored networks, a weakness, we felt, of the survey.

This was a bit cryptic here. Some of the results, one of the particular results seemed to show that succession planning, that is, training of future staff in the older networks was less common compared to the young networks.

So we weren't sure exactly what that meant and thought that needed to be looked at. Maybe it's that training needs weren't as great because these networks were more well established and knew what they were doing, but that's just

something that someone needs to think about.

Somebody asked who are the clinical trials networks that aren't NIH funded, because as the data was cut, it was clear that the results were different when you divided into NIH versus non-NIH sponsored and clinical trials networks and what were they, were they cystic fibrosis foundation sponsors the networks, arthritis foundation, CDC sponsors some networks, some other government agencies sponsor clinical trials networks, and I'm sure there are a number of others and we would like a further exposition of what other organizations sponsor the clinical trials networks.

Now, we're moving on to the implications and suggestions that arose from the discussion. A number of these suggestions had to do with ideas about standardization. That seemed to come up a number of times and there was very spirited discussion about standardization.

First, standardizing role definitions. What is a CRA, what is a clinical research associate, a site coordinator, a project director, a study coordinator?

We believe that those were interpreted, those terms could be interpreted differently by different networks and those terms are used fairly loosely.

So it might be very helpful to do standardized core

competencies for specific roles and then develop perhaps some kind of a role certification, perhaps a matrix of role versus type of certification might be helpful. Standardizing training definitions for these various roles might assist then in planning educational efforts and training.

Likewise, the training itself perhaps should be standardized.

Is there some standardized required GCP training, human subjects protection training, so site staff don't have to take multiple courses? That was a concern, that there was a redundancy in training requirements because staff had to go through the same training from, say, different sponsors and there was just a lot of redundancy.

And if we could standardize that, especially at least across the NIH institutes, that would be very helpful to the networks.

Perhaps having one Web-based human subjects protection training with different levels for different types of research and different research roles, because does a receptionist who is passing out invitations to a trial need the same kind of training as one who is getting informed consent and need the same kind of training as the investigator?

Many universities don't distinguish amongst those

different levels of participation. They require the same level of training regardless of what you do in a study.

Standardized training modules with an eye toward cross-institutional portability of the training between sites, CRNs, universities, this is all on the same theme of standardization.

Perhaps NIH could develop recommendations for CRNs on basic training competencies and techniques, to include such issues like timing of the training, the relevance of the training to the participants, dissemination over distance.

So many ideas and here we came back, of course, to the toolkit idea, which I think somebody carried forward from the morning sessions. So it reared its head again, this idea of the toolkit.

One participant mentioned that to include a chapter on negotiation and conflict management would be quite important, because networks have many different ideas and there are many different participants.

It was Jonathan Tobin who said that a four-day course that he took on conflict management and negotiation was one of the best trainings he ever had.

Training material should be based on a needs assessment, so training would become relevant to site staff and

clinician researchers, as well. Perhaps one could offer CME credit or reimbursement to community practitioners who participate in research training to get them more involved.

The timing, of course, is very important, because information doesn't sink in until you need to apply it.

So we need to determine what type of training could be provided at any time, sort of basic human subjects protection training, for example, and what ought to be provided just in time, just before a study, so it's fresh in people's mind and they know what they need to do.

There is great need to evaluate the effectiveness of training programs, as well, and perhaps some kind of a trans-network evaluation process could be very helpful for training programs. Before we begin to improve them, we need to know where we are with them.

A couple of miscellaneous suggestions here that didn't quite fit in with any other topic.

Stress protocol development that addresses the reach, effectiveness, adoption, implementation, sustainability and spread, as well as dissemination of research findings.

This is a model that has been developed called the REAIM model, and there is a REAIM Web site that talks about designing studies in ways that we can measure the effectiveness

of a clinical trial or any kind of study across the different elements of dissemination, reach and effectiveness applying to what patients you reach.

The effectiveness is the usual term of effectiveness or efficacy. But then adoption means does this new practice get picked up by medical practices and if they pick up a new idea, do they implement properly; and, if they implement properly initially, do they sustain that for the long run.

So if it's a new protocol, for example, for managing diabetes mellitus, do practices institute it and do they actually do it with patients and are they able to sustain that protocol over time.

On the other hand, there was a suggestion that we don't overburden all the CRNs with these translational requirements or efforts, because the top bullet has a lot to do with translation, because that does require a certain behavioral research effort that's maybe very independent of the skills of CRN scientific questions.

So it's this idea of balancing the effectiveness research, does the treatment really work versus can you implement it into practice and should we really require all of the CRNs to get into dissemination and adoption in great ways.

There was some questioning of whether that concept

really made sense for all CRNs.

Funding. Sponsors should fund curriculum development, staff development, training and evaluation of training effectiveness. Funding has come up in every talk.

I thought this was a great idea and I think this is happening in many medical schools and health profession schools. Incorporate research training into the basic curriculum of medical and other health profession schools.

Why not? If our professional students have some basic understanding of research methods and selection bias and other things that might be important to a clinician out in practice who is not going to be the PI, but who understands that when we're selecting and recruiting patients for a study, we have to be careful about the issue of selection bias.

What if we had clinicians out in practice who understood those concepts, so that when studies were being done in their site, they can oversee these kinds of elements of research effectively.

Certainly, at the medical schools, I circulate, and there seems to be some kind of basic epidemiology and research training.

Back at Michigan State University, we started training all of our medical students back in 1989 in basic research

methods and they were all required to develop a research project. They didn't have to do it necessarily, but they had to go through the basic steps.

And not that I have any interest in it, Steven Cummings' book on "Designing Clinical Research" is just outstanding. It's sort of a do-it-yourself book that I think ought to be required reading for all medical students at least and perhaps pharmacy, dentist and nursing students, as well.

Well, how might CRN mentorship be facilitated? Perhaps a national online K-30 training, that could be developed and disseminated, instead of everybody doing their own K-30 training. Why not? Everybody is learning to do online.

Right now, my daughter and son-in-law are both teaching online courses this summer. They teach at Michigan State University in education and the nursing school, all online.

So why not? It could be done.

Develop specific professional development activities for junior faculty and others, such as community clinicians, to participate in clinical research in a network; that is, some specific development for them about doing research in clinical networks.

Those ideas could be included in the CTSA's and, in

fact, I hope they are. The idea certainly was there in the one we put in from our school.

Case Western Reserve has just been funded to receive an R-25 to train PBRN, practice-based research networks. Those are the primary care research networks specifically.

So some of this is starting up.

A final thought. Should clinical research networks be a vehicle for improving practice? And if we believe that's true, how can we shorten the feedback loop so that the data, the results of the trials get back to the clinicians who contributed to it.

For example, should we train control group clinicians and staff on intervention protocols, if it's effective, of course, after the study is over. That would be sort of a benefit from participating in the study.

Could we look at CRNs as a learning community, the idea of we're all in this together and trying to bring in the practitioners and link them more tightly with the clinical research networks.

Well, I've gone through the slides pretty quickly. I need to give Jim and Mike a chance to comment on the findings, as well, although the timing is up, according to the red sign. Fifteen seconds for each.

DR. MOLD: No comment. Thank you.

DR. HICKNER: But I'm sure we missed some of the items. So I'd be very interested. I think we have time for discussion, a couple questions.

Very interested in what we missed, because I know we didn't include everything here and may have missed something important.

DR. DEAN: Mike Dean, from the University of Utah. It was a very interesting catalogue of suggestions.

I just dispute the item about the K-30 a little bit in that I think there is teaching trainees to attach to mentors and there's face-to-face interaction and seminars that are weekly or biweekly in many of them, and I'm not sure how you replace that.

DR. HICKNER: Good point. I wouldn't want to replace that. The question is how do we incorporate both, how can we capitalize on distance learning and do both.

MS. ZAFONTE: I'm Stephanie Zafonte from NHLBI.

One of the points that I think is of value to bring out a little stronger is that industry and academia are really looking to NIH to set some standards for what is the minimum or acceptable training for PI staff, for study coordinators.

I thought it was very interesting that this came out at this meeting. I was at an OHRP-sponsored meeting two years

ago at a training session and there was a very strong industry voice that was really looking to NIH to be able to set that standard, so that sites who are doing multiple-funded studies could have more of an, okay, I've done this training, they don't have to do it multiple times for multiple funders.

DR. SACHS: Thank you for that comment. I think once the report is posted, I think this will be helpful toward that. Thank you.

DR. MORRIS: Alan Morris, University of Utah. I also enjoyed your presentation.

I want to ask you about the feedback, the thing that is on the screen right now.

Should research be a vehicle for improving practice? I'm not sure there is much argument there. But how?

Education has been studied quite extensively. It's not a particularly effective way to change human behavior, unless it's continual and so forth and very resource intensive.

So have you considered developing and utilizing tools that would be able to be then transferred to the clinical community in order to extend the application of protocols?

The dependence upon human decision-making, given any information overload and short-term memory limitations, is going to be a constant weak link for us in transferring in a

consistent manner to the community the information we want to have implemented.

DR. HICKNER: Instead of answering that, I'll make a couple very closely related comments.

One is that the CCOPS, the clinical oncology group, I think has demonstrated pretty effectively that involving community oncologists in studies raised the boat, raised the level of adherence to cancer protocols as those are being spread around the country, which illustrates that involvement in the study seems to raise awareness of what's new out there.

The second issue is that at least in primary care practices, a lot of the issues tend to be systems issues and improving systems so that intelligent practitioners have a good system that supports their practice and has the necessary information technology and wedding that with research I think is a very interesting issue.

DR. MOLD: I would say that I run a network and I try to keep the practices interested in participating and it seems like there are three ways at least to try to keep people in a network.

One is to pay them and you can do that for a while and you can do it with certain people, but it's not very satisfying as a way to sort of build what I consider a network.

You can appeal to their altruistic tendencies. You say, "Well, you know, you're going to help advance the field. We're going to learn things that are going to be helpful to everybody."

There are some people that will stick with it for a while and they will do some work with regard to that, but it's not a terribly powerful incentive.

The real powerful incentive is if they get something out of it, if it's a win-win situation, if they actually learn something through the process of doing the work or if they actually feel like it improves their practice directly.

I realize that applies more to PBRNs, perhaps, than some of the clinical trials networks, but I think that concept is pretty important and I think the people in the PBRN world are pretty concerned about NIH getting into this business, because we kind of have this notion that what you're going to do is want to use our practices to find patients to put into clinical trials and it's going to sort of -- it's not going to preserve the relationship-based networks that we have tried so hard to develop that are based upon the notion that everybody gains from participation.

So I just wanted to raise that issue. Maybe I haven't explained it well enough, but it is a concern.

DR. PERL: I'm Harold Perl, from the National Center on Drug Abuse. I just want to follow up on the point that Jim just made.

I think that perhaps the most powerful incentive is giving people answers to questions they really need the answers to and they really want the answers to, as opposed to the research community coming down and saying, "You know, you'll be better off if you do it this way."

Answering a question that the researchers think is important, but that the on-the-ground clinicians and practitioners may have little or no interest in or not find it useful at all.

DR. SACHS: Thank you. I just want to wrap up this session and I want to thank all the content experts and all the participants, and I want to give a big hand to all the people, the folks up here, as well as the other group that we didn't clap for yet, the recruitment and retention, as well as the training.

Thank you.

[Applause.]