

**IECRN National Leadership Forum**  
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**Report of Breakout Sessions: Financial Practices**

**Presenters:**

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DR. SACHS: Okay. The format of this is we're going to begin with the financial practice breakout session report and then we will go on with recruitment and retention, training and professional development.

We will have 20 minutes. We will have questions and answers to follow each session and then we will have a discussion at the end of the three.

Thank you.

MS. ROTH: Good afternoon, everyone. Thank you so much for being here. Having to present on the afternoon of the last day after lunch is always a little unnerving and you wonder how many people are actually going to be here. So you get the official designation as the diehards to stay here for the presentation of financial practices. So thank you, thank you, thank you for being here, so we're not talking to an empty room.

So I'm going to start by giving you just a brief flavor for the nature of the discussion that we had at our breakout session yesterday afternoon.

We had about 40 participants. We had a very engaged group of individuals participating, with a very lively discussion. I was absolutely thrilled that so many people have such a shared sense of passion about the topic of financial practices for clinical research networks.

So we got a tremendous amount of input. So thank you very much to all of those who participated and for your comments and suggestions.

One of the things that was, I think, most reassuring to me and most satisfying about the session was the extent to which people had a very strong desire to share their own experiences and we got a very strong sense of people's shared commitment and sense of engagement to improve the system across all networks, and there was a very strong sense of commitment, which was certainly viewed as a very positive thing.

I would like to remind you that the financial practices session started in a slightly different place than the other sessions, because the financial practices component of the survey included the written descriptive survey, but not the more in-depth qualitative components of the survey and did not actually include the formal nomination of best practices.

So we started at a slightly different point than the other groups. So the focus of our session was, number one, to

provide a brief summary of the findings to get the reaction of the participants and get their assistance in interpreting the data and then to start the process, based on their input of attempting to identify some best practices.

So what we are going to bring forward to you this afternoon is some initial recommendations regarding potential strategies for the future and I think you will hear some evidence of the emergence of common themes in follow-up to the discussion this morning.

One of the themes we heard this morning from several of the groups was the concept of toolkits, of specific tools or resources, as well as the concept of sharing infrastructure and resources across networks, and those two key themes also came out in the financial practices session.

So I'm going to start with just a brief summary for you of the responses that we got from the participants when we asked them what of the findings were surprising to them, what information did they feel was most relevant to the types of networks that they participate in, as well as what additional information they would find helpful in the future.

So I think the bottom line summary was that there were not very many surprises; that, overall, people could relate to the data. They thought it was reflective of their own

experience, but there were several pieces of data that were a source of concern to people.

You may remember from Steve Durako's presentation yesterday morning one of the findings that was presented was that 40 percent of the networks responding to the financial practices survey, and we had a total sample size of 59 respondent networks, 40 percent of those indicated that they had experienced cost overruns either all of the time or almost all of the time and an additional 27 percent indicated that they experienced cost overruns 20 percent of the time. Only seven percent of the network respondents indicated that they never experienced cost overruns.

So this is clearly a significant issue that we are all dealing with and all struggling with and this was a topic that we discussed in more detail throughout the presentation, but is clearly an area that we need to focus on and Donna is going to tell you a little bit more about that discussion in just a few moments.

One of the other interesting findings was that only one-fifth of the networks responding to this portion of the survey reported that they bill third-party payers and it's not entirely clear to us, based on the responses from the survey, whether that's simply a function of the types of activities that

these networks who responded are involved in and whether or not such practice would be appropriate, given the nature of their activities, or if this is something that is not yet sufficiently a common practice or there is still a significant amount of confusion about those billing procedures, and that's certainly something that we felt needed to be delved into further.

Finally, one other point that actually was surprising to the group was the overall youth of the networks.

You may remember hearing yesterday that the range of the age of all of the networks, all of the networks involved in the entire survey, not just the financial practices component, ranged from six months to 50 years.

And I apologize for one piece of incorrect data on the slide. The average age of the networks was actually 9.6 years. The median was six.

One of the pieces of information we got from the financial practices survey was that the average duration of funding from the networks' primary funding source was 5.2 years.

So given the average age of many of these networks and the average duration of funding, there was a concern about the extent of the challenges that face many of these networks in terms of getting their initial funding, getting organized, building their infrastructure, putting their process in place

for developing protocols, implementing the protocols, completing the protocols, getting data, having demonstrated output from their process, and then needing to go into the very next grant cycle of attempting to secure a renewal, and that that was a very challenging process and was relevant to many people participating in the discussion.

So now I'm going to shift to the discussion of potential suggested strategies.

So one comment from the discussion yesterday is that there was a recognition that there are really a variety of different funding models that are used among existing networks.

And what I mean by funding models is the extent to which certain networks are funded on a study-by-study basis, the extent to which some networks have funding for core infrastructure, and a recognition that there really are a variety of different configurations of how the basic funding is structured.

So there was a desire on the part of the participants to drill down into the data, to the extent we could, to identify all of the various models that currently exist with regard to the configuration and the various permutations of the funding, and then to really explore further the pros and cons, the challenges and the advantages of those different models, with

the hope of bringing forth a recommendation regarding the most optimal configuration and structure for funding.

One thing that was definitely noted by the participants was the extent to which networks that are primarily funded on a study-by-study basis have a very challenging task. And you may remember from the information that Steve had presented yesterday morning that 45 percent of the networks responding indicated that they are, in fact, funded on a study-by-study basis and of those, only 56 percent indicate that they felt that the funding was sufficient to carry out their mission.

So I think there was a general consensus that the lack of ongoing core infrastructure support for many networks is a very challenging and formidable task and that the absence of that ongoing funding is a significant barrier to the overall success of the networks that are part of our nation's clinical research infrastructure and that determining a better approach for providing that core information funding is going to be very vital for the success of networks in the future.

One of the other things Steve had commented on yesterday, given the extent to which many networks face significant limitations in the available funding, is the importance in pursuing secondary funding sources.

And you may remember from the data that 73 percent of

the networks indicated that they have one or more sources of secondary funding.

Our recommendation was that networks aggressively pursue opportunities from a variety of sources for secondary funding. There are some very good examples of this.

The cooperative groups, as an example, have a long and well established history of securing secondary funding for a number of different types of activities, such as site or capitation payments or for mechanistic sub-studies.

So this was an area where even though many networks are already involved in these efforts to get secondary funding, that this was something that we really needed to focus on in the future.

One of the other findings from the survey is that older networks actually have a greater proportion of secondary funding than newer networks and that those networks appear to dedicate a significant amount of effort compared with newer networks, particularly on the part of the network leadership and network financial development committees to secure secondary funding.

So we felt that there were certainly opportunities to identify some lessons learned from these older networks and to pass those strategies along to the younger networks.

We also decided that it would be very helpful to develop and describe and characterize the various models that have been used for both securing secondary funding and combining and leveraging various funding sources, identifying the types of activities for which secondary funding has been used and providing more information and lessons learned and assistance to various networks in understanding how to manage a combination of funding sources.

The final suggested strategy I'm going to cover is the issue of shared infrastructure. So this gets back to one of the emerging themes that appears to be developing from our discussion so far this morning and from the other breakout groups.

The group felt that there were significant opportunities to identify sharing of infrastructure and core resources across networks. It was certainly noted that the vast majority of networks focus on a particular disease state or patient population.

So there was really a question in everybody's mind about whether or not it would be possible to effectively share resources and core infrastructure across networks that are focusing on different areas, but there was certainly a very strong sense of interest and commitment to explore that

possibility.

One example that was mentioned, in particular, about the development of shared infrastructure was the CTSU that works with the cooperative groups and that has been a very successful endeavor.

Finally, there was a remaining lingering question in everybody's minds about the extent to which efficiencies and economies of scale actually could be realized by the utilization of centralized infrastructure and a desire not to make assumptions about whether or not that was a good strategy, but to understand the underlying economics better.

I'm going to now turn things over to Donna to wrap up with the remaining suggested strategies and recommendations.

MS. MARINUCCI: Thank you, Deborah. I also appreciate the opportunity to be here, as well, and talk to you a little bit more about the suggested strategies to build best practices.

I think when Deborah mentioned that our group had a lively discussion, it might have been a slight understatement. I have never really seen the enthusiasm for financial modeling potential quite like that.

So one of the, I think, most important aspects of what was discussed was getting involved early and that was described as first cut feasibility.

Once the protocol concept is developed, it would be important to have a first pass at the feasibility aspect of it to make sure that it meets the test that could be set up as standards.

There is also a desire to have a second pass at that same feasibility activity to be sure that those tests were met once the full protocol was developed.

One of our group participants suggested that they had, from their own experience, set up a committee where representatives from both scientific aspect and operations aspect could perform a detailed review together and once the scientific concept is approved, I think it is important to keep those communications open between the two facets, because that protocol is dynamic and constantly changing with the development of amendments and sub-studies.

So I think it is important to make sure that that communication is ongoing.

There is also a very strong recommendation for development of a toolkit, as Deborah mentioned, and I think that this is probably one of the most important things we could do for ourselves and our sites.

There are virtually no tools available at the sites on a continuing basis to know how many patients need to be accrued

to a study for a site to break even. I think that, also, at the central level, even though the overwhelming majority of participants stated that they do cost analysis of protocols at the central level, it was a very uncertain aspect as to whether or not the sites also made those same cost analyses, as well.

I think that it is astounding to me to know that many states activate protocols without ever accruing a single patient and that is probably one of the most wastes of time and money and effort on everyone's part.

So I think that would be an important aspect to maintain.

The group was very strong in their opinion about the involvement of leadership and the role and responsibility of leadership in making sure that prioritization and decision-making were always afoot and that especially in the arena of controlling scope creep was the most, I think, pervasive discussion.

Scope creep is one of the major reported culprits in cost overrun, which I will talk about in a minute, but I think, to our advantage, that would be something that the leadership would be on constant watch.

We had a very interesting discussion about cost overrun and as Deb mentioned, cost overrun was a tremendous --

46 percent of our participants have experienced cost overrun at one time or another and I think that not only does this happen, but the frame of cost overrun was of particular concern to the group because we felt that the connotation of that term was probably not exactly accurate and it might be well worthwhile to consider other terms, such as under-funding, because it really is something that we want to be able to be reflected as not a management issue, but a terminology issue from that perspective.

I think that most places and at the central level and at the site level do try to manage their scope and keep accurate budget information, but cost overruns remains a huge problem.

Thank you.

DR. SACHS: Thank you. You did a great job of that summary. I appreciate it and I want to give a hand to all of you. Thank you.

[Applause.]

DR. SACHS: It's a hard job. Thank you.

I want to leave the floor open for questions. Please identify yourself.

MR. REARDON: Steve Reardon, from Westat. I didn't mention this in the meeting yesterday, but as far as toolkits goes, there is one that is worth looking at.

As part of the caBIG program, there is a finance and

billing special interest group that is developing use cases for doing financial modeling.

Now, there work is not very advanced at this point, but the information is publicly available through the Web site and there really is nothing that is cancer-specific about it.

So it could be applicable to a lot of other disease areas.

DR. SACHS: Thank you.

DR. BROWN: Martin Brown, National Cancer Institute.

I just wanted to make a comment about the issue of shared resources across the sites.

The cancer research network started as a cancer-specific enterprise, but it is across the network of HMOs who have very similar characteristics. So it's gradually been expanding.

So now the same sort of core data resources, informatics, et cetera, are shared across the cancer research network and the CERT project, which is our AHRQ sponsored project on pharmacology research.

And we also have interest from other institutes, Heart, Lung and Blood, genome, et cetera. So I think there is no -- I don't think there is anything intrinsic about disease categories as a barrier to sharing core resources, especially if

the network has other features that it shares in common in regard to the nature of its institutional structure and its data structures.

DR. SACHS: Thank you. I think everybody would agree that sharing resources is really essential. Thank you.

Dr. Comis: I'm Bob Comis, president of the Coalition of Cancer Cooperative Groups and chairman of ECOG.

I made this point at the meeting yesterday and I'll make it here before everyone. This is a grossly under-funded enterprise by the federal government and I think we can't shirk away from that.

Although it probably represents a greater level of funding than any country in the world, it is grossly under-funded. Dr. Zerhouni is in a position to go to Congress and say how under-funded this system is, but when you are talking about almost 70 percent of what all of us do being under-funded in some way or being unable to cover its expenses, none would run a business like that.

So this entire enterprise is at risk and I think we, as investigators, and the public need to somehow point that out to Congress and get funding for this research infrastructure.

It is the best infrastructure in the world, but it is probably the most at risk in the world.

DR. SACHS: Thank you for your comment.

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

I was hoping that Donna would explain the concept of scope creep.

MS. MARINUCCI: I can explain it, from my perspective, and others can certainly join in.

A lot of times, when a contract is long-term, for example, maybe over the course of five years or so, you are doing a good job and you have feedback from your clients or your stakeholders about that and they ask for improvements or enhancements in the system that may or may not have been discussed up front and were not covered in the budget when you originally proposed it.

For example, if you had a survey and the survey said that more education and training was needed in a particular area and the project officer suggested that that was a good idea, they may want you to implement that, but funding would not necessarily be available for that particular task.

MS. ZAFONTE: Thank you.

DR. SACHS: Two more questions, over here.

DR. FROMELL: Gregg Fromell, University of Pennsylvania.

I can't really tell whether the enterprise is grossly

under-funded, right funded, or over-funded at this stage, because I think going back to the CTSA concept, I'm not sure we've created the right home to do research in a clinical care setting.

I think there are a lot of inefficiencies in the system that, quote-unquote, are costly, but we can't control. If you take a look at the approval delays and there's an article published in the Journal of Clinical Oncology by Dilts from Vanderbilt just recently, it just came out, that wasn't so much focused on cost, but the number of non-value-added steps that exist in most academic centers and networks in getting research done and they estimated it was clearly -- some process had a 120 steps that could be reduced, in their mind, down to 20.

And when you think about that, that has to squeeze out some costs. So I would be nervous about throwing money at something we haven't fully assessed on best operational practices.

So maybe part of best financial practices might be that we do a better job of assessing the operations and how it can be more efficient.

MS. MARINUCCI: May I make a comment?

DR. SACHS: Please.

MS. MARINUCCI: I think your comment about assessment

is absolutely warranted. However, I think the trick will be to maintain the system as it exists while we do the assessments.

If we run out of money while we're doing the assessment, we're all in trouble. So I think there has to be some sort of balance here and I further agree that there needs to be assessment, but someone has to come forward and perhaps suggest ways of doing this in the interim.

I think we need a short-term plan and a long-term plan for its continued success, because we are successful.

DR. SACHS: Thank you.

DR. FOX: Chet Fox, from Buffalo. I am going to express a gripe here, but it is not directed at anyone here, so I should be okay, but it might get me fired.

Most of this money is done at the university level and we're talking about infrastructure is under-funded. Yet, when someone receives a grant, whether it be AHRQ at 24 percent or NIH anywhere from 50 to 99 percent, none of that, quote, infrastructure funding, which the NIH is giving to the university to provide infrastructure so that we can have core infrastructure to do future development, ever comes back to us.

Some of us, I think best case scenario I heard of was like nine percent, but most principal investigators do not get a penny of this money.

We have no idea where it goes, but it is a definite black hole. I wonder if NIH could do something to force the universities to be more fair in the sharing of the funds that they get from them for us.

[Applause.]

DR. SACHS: Comment duly noted. Thank you.

Thank you, again. I want to give a hand to our experts.