

IECRN National Leadership Forum
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Report of Breakout Sessions: Information Technology

Presenter:

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DR. SACHS: Thank you. We're going to ask the next group to come up, please. If this group wants to stay, that might be less disruptive. Thank you.

I'd like to introduce the experts in the next session, which is information technology. It is Charles Jaffe, Becky Kush, and Wayne Kubick.

Thank you.

MR. KUBICK: Good morning. Chuck Jaffe couldn't be with us this morning. So we'll do our best to express his comments here.

I'm Wayne Kubick. I was facilitator. Ms. Rebecca Kush is president of CDISC, who was our other content expert.

A lot of the comments and questions raised in the prior session were relevant to ours, as well. So it's just the difference between informatics and information technology and I think actually I take a broader stance that informatics and technology being merged together.

So I think we have done that in some of our reports.

We did an audience breakdown and within the group,

there were probably about 60 people in the total group. About 27 percent said they were IT, about five people only saw themselves as principally clinical, and about ten were data management and ten statisticians.

There were a few others hanging around who refused to identify themselves, for reasons unknown.

The purpose of our -- we followed pretty much the rules that were assigned by the Westat coordinating group and what we looked at really is let's take a look at what were the key findings in the reports and criticized them, both positive and negative.

We encouraged people to get up and talk and tried to get the audience to do more of the talking. We asked them to look for things, like consider the current state and look for common themes and gaps so we could report them back. We tried to capture a few of those.

We looked to get more to key recommendations, but we didn't quite get far enough to do that.

We did want to collect audience feedback, as well. Our process was just to go through the findings and just get people to talk about them.

In doing that, since we're all technology professionals and we have a native mistrust of technology, we

chose not to use the audience responses. Instead, we used the statistically proven technique of hand-raising and counting and you'll find that we don't have as many nice graphs as some of our predecessor talks, but I think we got more of a sense of what the audience really thought.

And we did put up slides like this, which sort of summarized. Becky put nice graphs together for us summarizing key findings, not to actually go through all of them, but, in this particular case, we pointed out out-sourcing and immediately fell into the same trap as everyone else of saying, "Well, what do you mean about out-sourcing? We can't get into out-sourcing." So then we went into the definition discussion for a long time before reaching some sort of conclusion.

What we tried to do was capture these conclusions and tried to capture some of the thoughts. We removed attributions, for the most part, so that those of you will remain anonymous.

But some of the key points we found was it seemed like out-sourcing was desirable and commonly practiced, although people, again, weren't sure what you meant by out-sourcing. Are we talking about basic technology information? Are we talking about data management services?

We tried to separate a little bit the concept between infrastructure and application. Some of the general comments we

received were, again, about the nature of the survey, by its nature, really started at the high level, but it seemed like the results came out through some sort of a low granular level, with a high level filter.

I'm not quite sure what that meant, but it may well have made sense at the time, I remember.

And there was a genuine concern that any results reported both in the survey and in this might misinterpret the NIH. So we had to be very careful what actually gets directed into recommendations.

But a strong comment that came through many times was a fear that there really is a need to get more commonality across networks, because it's both inefficient and ridiculous for 250 networks to start all over again and reinvent the wheel.

And this led to a partial discussion about how good it would be if there was sort of a common level of proficiency that could extend over all networks, which might be in the form of a toolkit or provided or funded somewhat by NIH.

We had a number of people said they'd love to get out of the IT business if they could. We had an example from one of the exhibitors in the technology halls talking about how they had already tried to implement, had already been working on an out-sourced solution; that it is really difficult, but actually

quite effective and that people tend to gravitate toward a solution when it will meet their needs. So that probably is a good opportunity.

caBIG also came up prominently, probably the most prominent example of trying to provide shared infrastructure for a federation of networks.

But it doesn't cover everything. It doesn't address a lot of the other non-oncology related areas or pharmaceutical research, for example.

Some said that we're a little immature to be going into out-sourcing, that there are fundamental problems and that was actually the next major thing, which turned out to be the communication gap between the general technology world and the general research world.

Again, part of the consequence of that is that we need more people who know how to bridge that gap, informaticians, business analysts. People can really work between them and that's probably the critical need across the board.

Here is a propeller-head comment. I think more experts to do the work, but build the frameworks for them to work within. There was also often a lack of alignment. These are kind of repeated thoughts, but we wanted to capture them.

The data is relevant, one said, only if you're looking

at electronic clinical trials. It really doesn't make much sense if you're doing paper trials.

We didn't really feel we had a representative sample in order to detect who is doing EDC versus paper in this particular audience. We didn't do that survey.

There was some talk about reexamining the return on investment of information technology, how to use the government. Again, these are repeated thoughts.

I've already done the most verbose of the presentations. We took a hyperbole view of capturing thoughts, so I'll be skipping through a lot of these to try to cover the key points and not keep you here away from lunch.

We talked a little bit about applications. Everyone had a Web site. Beyond that, it was kind of hard to say which applications were most important, but these are the ones that came out of the survey.

We asked people in the audience what was missing. There was a lot of discussion about clinical data management being closely associated with IT. And so that was, again, to how do people count for the survey.

There were some observations that specimen tracking systems, for example, were not included in the surveys, probably something some people may take for granted, but they're probably

out there pretty pervasively.

Adverse event tracking was noted as a gap. People felt that was probably under CDM. I think Jody told us that was probably covered, so we didn't get too far on the application side.

What we did find out, though, is that different networks focus on different applications, which is another prevailing theme, because each network has distinctive needs, which is what they're going to focus their attention on, which comes out later in our discussion.

Data standards didn't come out too well on the survey, either. We had three people on the panel who were data standard zealots, if not experts.

We tried hypothesize that maybe people didn't know maybe why they didn't specify them. But it was still kind of important that the need for standards in order to enable interoperability may not be high on the radar screen right now, but as you'll see later through this discussion, it gets a little more important.

Talked a little bit about the standard vocabularies and I think the NCI CDEs are probably the most prevalent that were used.

We talked a little bit about the difference between

NIH-funded CRNs versus non-NIH-funded. The survey indicated that NIH networks had better IT, as a rule. This was somewhat speculative, as it might be, because NIH tends to fund networks who have better IT infrastructures rather than those who are funded to build better infrastructures.

We're not quite sure about that and, again, we didn't have any definitive data, but it was an interesting hypothesis.

Pharmaceuticals were not as well advanced as NIH-funded. This was a surprise to us in the pharmaceutical industry, but the report speculates this might be partially due to regulatory concerns.

There's always still the biggest hurdle with IT investment is cost and how to balance that cost with other needs.

In terms of discussing the qualitative results, we thought that it's very difficult for CRNs to know what to buy and, again, that is something that could help by building the sort of shared toolkit.

It's very difficult to go out there and decide where do you start. Using the out-source facility, like a CRO, was easy and fewer concerns, but it also has to deal with that communication gap problem we've already identified.

Web-based tools, probably the biggest change in

technology in the last ten years. People tend to make Web-based tools very easy, which really makes it possible for technology to be adopted, as long as you build around that framework and the key is to play to the lowest common denominator, because some technology is out of reach for some users.

There was some discussion about IT tending to blame the users for not using technology and the users tending to blame IT for not understanding the business problems and that was fun. We do that a lot.

We had a question about whether -- this was Chuck's comment about he did a survey at one point of clinicians of what is the most important technology you need to learn, and the winner was PowerPoint.

So this wasn't an issue of intelligence in terms of technology, but in terms of what do you really need to use.

A lot of discussion, again, about things working together, infrastructure working with clinical. Interestingly enough, there was no -- there didn't appear to be a relative correlation between groups that had internal IT staffs and those who did not, with their ability to communicate.

Sometimes you can't communicate with the person sitting next to you any better than you could with someone located a couple of states away or something supporting you.

So I think that's a fundamental issue that, again, we have to wrestle with and we have to make progress on.

We talked about best practice. We tried to reserve a big portion of the session to try to drill down into the best practices. I think to many of us, that was probably the most interesting part of the reports, but we didn't feel that the details had been covered quite a bit.

And when we talked about best practices, we wanted to know about what were the value-added to IT. We talked about can you do things top-down and bottom-up at the same time and what types of examples might have shown ways to improve communication.

What we actually did was did a survey of how many of the best practice nominees were in the room. We had six or seven, which was pretty good. So we asked them to actually share their results, which I think was very helpful.

Within the report, there were things about the best practices, about breaking down barriers. Again, that's the concept of talking, of being able to get the two groups to talk together.

We talked a lot about the Oklahoma PEAs approach, which I think is a wonderful approach for solving this very problem, about getting the practice enhancement assistance to

work directly with the researchers, to help to get them close to that, and that really is -- it seems to be a great approach; time-consuming, but I think the time needs to be spent and it is worth it.

You need to get network buy-in, and you've read this stuff in the report.

In terms of what we got feedback from the various groups, both Buffalo and Oklahoma have practiced the PEAs approach and have really found that that has helped so much to get people warmed up to technology, as well as improving processes in general and really does look like a best practice that should be strongly emphasized within this environment.

There is always a challenge when you need to do -- there was some talk about the value of IT versus saving time. On the one hand, at one point, I think we said later that you can't look at only saving time, you really have to look at value, because the researchers will invest the time if they get more value out of it.

But I think there was also the concept of that it takes time to implement technology. There is always an investment before you get the value.

Some discussion of how much funding should go into IT versus other needs. There were a lot of topics discussed in

this particular research study.

And there is a lot of recognition that you need to spend time training, preparing. There was one particular case when training was done months before the technology was introduced.

When it actually appeared, it was a non-event. It was just like here it is and now we use it. It was a very, very time-consuming approach, but the fact is it was just sort of slipped into the environment and really had no resistance at all as a result.

These were some of the best practice networks that were in our group. Well, I seem to have some more details and maybe -- Jody, how much time do we have? Should I go through these? I can go through these. Is it worth going through? Do you want to go through them?

So some of the other specific examples. ARDSnet had an interesting concept of using IT for quality control. We think the very nature of using IT to measure and identify performance and provide feedback is really critical, and they seem to have a very systematic approach for doing this.

Again, it would be nice to be able to publish these details because I think these are lessons that can be learned and applied by multiple networks.

We may have gotten some of the affiliations wrong. I think there was a group affiliated with NERI. They were talked about, the system that they had developed, which was primarily a data management and protocol tracking system and it did some of the basic things you expect from that, which is reducing time and doing data, real time data management.

But one of the things was making sure they did hands-on training for everyone and they did a lot of reporting, too, as well, that seems to have got edited out of here by one of us.

CaReNet has done a lot in the area of pairing both physician collected information with patient reporting systems and putting them into a central aggregate repository, which is very interesting, very, very standards-based, I would imagine.

The George Washington University network on high risk pregnancy, they actually had been putting in systems. I think they talked about putting in systems since 1975, which was -- technology was not new, but one of the newest things they did was involving with the implementation of PDA for nursing assistants.

It was basically a very simple application that just helped them manage their time and do a lot of basic activities, very well accepted. You know, neat technology, but not terribly advanced, but what it was was picking the right tool for the

right environment to meet the need they needed, and probably not the place where many other areas would work, but a really good example of fitting the technology for the particular business needs.

MAFPRN used technology to help bring sites into the network, making it possible to improve recruitment. There was another topic that came up later, which was -- I think it was one of Steve Woody's points about the concept of virtual networks might really be happening more in the future, that the sort of ad hoc networks will be created around specific research projects or initiatives, and, again, focuses the need on having a common technology basis and the ability of standards for having things to slip together.

SWOG had a very nice approach. They started out with the concept of building the system that would be as easy to use as Amazon.com, one click research. But it was kind of a nice thing, very well accepted by the users, takes longer to change the system, because they develop themselves.

They're getting into the ongoing maintenance problem of buying versus building. But the benefit is that it's something fully accepted that is very closely tailored to the business, and that is a topic that we wish we could have drilled down more research.

The Buffalo primary care research network do a mock trial instead of using real data. That's interesting. I think their biggest point was that they had done vast video conferencing was their biggest advantage. It's not something you might think of as not being critical on the IT path, but what it did was improve internal collaboration and communication much more effectively.

It's something that everyone gravitated to and they get some use of the computer. So interesting points.

We asked what was surprising in this study. These were the three standard questions. I hadn't seen those from the other groups, but we did ask one.

And there was some talk about, well, the study overlooked some of the more advanced IT architectures for bioinformatics and micro array data, et cetera.

This topic of standards came up, that CHI has already identified standards. caBIG really has done a lot that needs to be -- that could be shared, but they really need to outreach more.

I think the last one was kind of interesting. There wasn't a lot of talk about cultural competency at the survey or in this discussion until this was brought up and I think that's an important point.

Let's see. What else? We ended up with a series of questions and these were open-ended questions, so we couldn't use DRS to get surveys and rank them or anything like that. It would have been nice. But we really wanted to get people's feedback. So the first question was, well, how important is interoperability to your network.

And I think a lot of people, it probably wasn't the most important thing initially, but others are very committed to it. So it's interesting to see how that's split.

By having interoperability, it really enhances the ability to work on -- to basically expand the number of trials that could be done and to do multiple trials with one computer.

Here is the concept of the ad hoc networks that came up. There needs to be a common basis to provide technology services to all the networks.

Interoperability led to the issue of quality of data. Even if data is interoperable, what is really important is making sure that it's useful, being that of sufficient quality and that has to be balanced with this entire interoperability issue.

There was some talk about the clinical care data. This comes within the pharmaceutical industry, that pharmaceutical data is so much better than clinical data, because they spend so

much time analyzing and correcting it over and over again and that was somewhat debated and disputed, quite rightfully so, I think.

We asked what would the impact of the electronic healthcare record be. Interesting, based on this morning's keynote talk.

I think there were some comments in that we think this will help, but it's probably still far away to affect us directly.

There have been use cases created. Again, potential to collect once and use often. This is the concept of having one system support both internal primary care needs, as well as research needs together. That's kind of the goal of it.

There are concerns about the issue of identity management, some of the challenges involved with EHR implementations, and I'm not sure what that last statement meant.

And I think the last one we covered is should all CRNs be brought up to a basic level of IT. There was talk about the NIH-FDA interagency task force that should be working together to try to incent groups both to get a basic level of proficiency, as well as to share data.

Sharing data is really the critical issue that I think

is going to be most helpful to public health.

NIH should be supportive, but not take over IT. There were comments about this, that this industry is still rather young in a technological sense. It is going through a period of rapid change.

This I will attribute to Steve for this, too, the need to look at IT differently to capture the process. We had several people bringing up the issue of how important it was to have these analysts and informaticians to capture the process adequately, to develop a participatory architecture that people can use to work together, and really to look at -- rather than looking at IT within this industry, look at IT in general across the industry and types of trends that are happening, such as spreading work across the globe, doing development constantly.

There are things like that we should be looking at, as well, using the lessons of IT within this particular application.

CRNs should really develop patients and hope that NIH continues to provide funding through this process.

So in terms of the key points and the conclusions, taking site investigator patient needs into considerations is high priority. This is really probably the most important thing to do in this particular space.

Out-sourcing may make sense for some networks who benefit from the service centers, particularly those who don't have the capability, some of the more advanced networks.

It's important to bridge, this is word play on the CDISC bridge model, to bridge clinical and IT gaps with informatics and business analysts.

Some of the thoughts of moving from EDC to electronic health records, you need to basically ensure that research needs are captured and that the industry architecture is in place.

And global standards are a big part, but it will take time.

I think, to my mind, the most important lesson came from the talks of the individual best practice nominees; that is, that you really have the most to learn from talking to each other.

So the collegiality and the collaboration is really the most critical thing and things that could be done through this mechanism to facilitate that would be extremely helpful.

That's another good source, reason for getting this basic level of technology out there to sort of get this common platform in place, because that's really what is going to be the most important impact.

NIH should support the transition, but be patient.

That's it.

[Applause.]

DR. SACHS: Thank you. Wayne, you did a great job. I would like to open it up for discussion, but in general.

First, I want to direct discussion to this particular topic in IT for about five minutes, if anyone has any comments or suggestions for this session, IT.

MS. NILAND: Very good summary. Thank you very much, Wayne. One thing you did state, though -- I'm Joyce Niland, from City of Hope -- was that caBIG would be a good initiative to kind of follow or facilitate this whole process, but that it doesn't involve pharma and it's only oncology oriented.

However, caBIG really has joined forces in this whole bridge modeling process. It has taken a year or two, as Becky knows. But now it's a joint modeling effort, the biomedical research integrated domain group model, between caBIG, CDISC and HL7, all of which were ongoing initiatives already, which do span FDA, pharma, all types of diseases, not just oncology.

So it has become a joint effort, and so I think there is that impetus to move everything forward. And everything that we do in caBIG, we are trying to keep an ostensible framework that could move to other diseases and other constituents.

So along those lines, the second comment would be there are so many initiatives already ongoing out there, I'd really like to encourage NIH to participate, collaborate, leverage initiatives that are already ongoing rather than starting a whole other swirl of activity, because so much momentum is already there and so much has already been started; that to join forces with that I think would be the optimal way to make progress.

Thanks.

DR. SACHS: Well said. Thank you. I want to ask all of you to give a hand to the content experts. They did a wonderful job yesterday.

[Applause.]

DR. SACHS: They're not all up here. Some of them in the first two sections are in the audience.

But I want to open the discussion up to all these areas we just covered today.

I just want to really thank you for your participation, because I know really the key is how we make improvements and we'd all do a better job and we all want to improve. It's just how do we improve.

And your participation is helpful, because we need to identify what to improve and then how to.

So I just want to ask anyone for discussion, comments, please come up to the mike and identify yourself.

QUESTION FROM THE AUDIENCE: May I make one comment?

DR. SACHS: Please.

QUESTION FROM THE AUDIENCE: Earlier, the observation of the people who returned the comment cards and I think you said that one-third of us did not respond.

I think that's incorrect. I think you should congratulate us for a 100 percent response, because if you look at the room since this morning, about one-third of the people are not occupying.

Another one, if you look at the table out there under pre-registration, one-third of these cards were never picked up. That means we 100 percent responded.

[Applause.]

DR. SACHS: Thank you. Any other comments or discussion?

MS. PEMBERTON: I'm Victoria Pemberton, from the National Heart, Lung and Blood Institute.

Currently, we are working on an initiative that I think was brought up in the management and governance committee, looking at a clinical trial Web site or a Web site that we could

encompass a lot of clinical trial information, clinical research networks, those individual investigators who may be conducting clinical research.

And the idea of a toolkit is an excellent one and we hope to vet this in the NHLBI community and I would like to get some feedback from those of you who are here as to specifics that would be included in the toolkit. I think you have given us some really good information about templates, protocol templates, consent form templates.

But we would like then to put it into the community to do some testing, as well, and those who may be interested in doing that.

So some suggestions for specifics that can be included in the Web site, as well as those of you who may be interested in doing some testing of the site itself.

DR. SACHS: Would you like to suggest having a subcommittee from anyone join and help you with this? What would you like to suggest?

MS. PEMBERTON: I think that that would be an excellent idea, to form a group who has a vested interest, obviously, in seeing something like this be provided to the public.

DR. SACHS: So maybe we can post that on the web and

ask for participants or volunteers to work on this effort.

Would you like that, yes?

MS. PEMBERTON: Perfect. Thank you.

QUESTION FROM THE AUDIENCE: I would also like to echo some of Joyce's comments about not starting over, but joining in with efforts that are going on.

One example I might have is that we tended to have a lot of discussions in the breakout groups about what certain words meant and what certain questions we're really asking, and I think there's still a number of words that we ought to be defining.

But CDISC started an effort, when it first was initiated in 1997, to do a glossary around clinical trials and clinical research and we combined that glossary with the applied clinical trials glossary that is published every December in their research issue, and that is published on the CDISC Web site, as well as in that applied clinical trials, and it has definitions for electronic data capture, for e-source, which means no paper is being used, and for a number of the words that we have been using, but not all of them. And every year we update that.

So anybody who wants to provide suggestions or comments on the words that are defined or new definitions, we

would like to have that collaborative effort. We've made a plea to caBIG to combine their glossary with ours and to provide that as a service to the community.

So it can be found on the CDISC Web site at CDISC.org and there's a number of other resources we can add to help collaborate on that.

DR. SACHS: Thank you. I have a question for you. Would you agree to have that glossary put on the forum Web site, in addition?

QUESTION FROM THE AUDIENCE: That glossary can certainly be there or you can put a link to it and every time we update it, you could have the updated version.

DR. SACHS: Thank you. I appreciate that.

QUESTION FROM THE AUDIENCE: So it is open to anyone and I would like to just get your input on it. What is up there doesn't mean it is in stone. We can modify it, as well.

DR. SACHS: Thank you. That would be wonderful. Kevin?

DR. PETERSON: I'm Kevin Peterson, from the University of Minnesota. I'm really big on community involvement and getting networks into the community and getting them into providers' offices.

I just thought I would mention just a word of caution

with Dr. Pemberton's announcement. NHLBI is a great group. They have some great networks already. NIDDK has some great groups and some great networks and the NCI has some great groups and some great networks, and the asthma group has some great networks.

Sometimes with networking it's really nice to get some of these groups to work together. I think that I would be a little cautious about having each of the institutes now kind of reinvent the whole networking solution.

We have a really great and new initiative here in the roadmap and it's being concentrated here under NCCR.

I would encourage the institutes to maybe work a little bit more closely with NCCR in creating maybe a single forum or network, so that people don't have to join lots of them.

DR. SACHS: Good comment. Thank you.

[Applause.]

DR. SACHS: I think we really need to work together and collaborate instead of working isolated. So I appreciate that. Thank you.

Any other comments?

Again, I want to thank all our experts who ran the panels. Thank you very much.

[Applause.]

DR. SACHS: Not only did you do a great job yesterday, you did a great job presenting today. It was difficult under a short time limit and I appreciate it.

Thank you. We're going to break for lunch and we're going to come back at 1:00.

Thank you.