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IECRN Findings: Information Technology

Presenter:

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DR. SMITH: Can you hear me? I usually don't have any problem being seen. I'm Jim Smith, spelled the usual way. I have been involved with computer software and systems in academic and private organizations now for about three decades.

At Westat, as Steve Durako mentioned, we have about 500 staff engaged in the full gamut of information technology functions supporting research in the organization, multi-project, of course. And, you know, IT stuff last night, so a tree falls somewhere and the community power goes out in Gaithersburg to 10,000 customers.

Included in that is several of our buildings and included in one of those buildings is our data center that services a bunch of remote sites that operate after hours, in different time zones and whatever.

So I get a call and the backup generator is running and the redundant Internet connection flipped in and other systems, continuity measures, or shall we call them investments, are working just fine and there is no interruption to service to these remote sites around the country.

So that's kind of a systems guy's dream come true. I'm pretty happy today. As long as it doesn't happen very often and for very long, that is fine. Knock on wood.

I am really pleased to be here today in a forum like this, to be associated with the kind of effort that involves prospects for IT contributing to something as important as biomedical clinical research.

I hope that our shared backgrounds and interests in research and in the application of IT to serve these research endeavors helps in our assimilation and communication of some of the results.

That's queued. I didn't know that was animated. So as Steve Durako mentioned, information technology is one of the practice domains. Proponents are encouraged by the idea that IT can create efficiencies in the research process, new capabilities, and various kinds of interoperability and communication collaboration.

This is kind of how I will proceed, a little bit of definition and some general findings, hit a couple of themes and go into them a little bit.

IT means here the pretty obvious thing of computer and electronic means for collecting, storing, processing, using, communicating information. No surprises in that.

In terms of management and governance of IT, the world is pretty complex and there is not necessarily a single formula, but one simple indicator that might be useful concerning one of the issues that Dr. Zerhouni raised, which is the persistence, I would call it, is what kind of governance structure is there.

And what we find is that about two-thirds of the responding clinical networks do not have any sort of standing IT committee or borrowing of seats on another committee.

So that leaves about a third without much committee structure, anyway, but we did find that about two-thirds of the CRNs have some form of centralized management of their IT and about half have some kind of dedicated IT director.

It is interesting to note here that, as we have heard in other places, that clinical trial networks and NIH-funded networks, there is overlap in that category, are most likely to have dedicated IT directors and this is certainly consistent with the other things that we have shown on the levels of support that those organizations often have.

Of course, clinical trial networks face regulatory requirements and NIH is often promoting, if not requiring an emphasis on IT with corresponding funding. So that helps to explain that.

How do these clinical networks get IT support? Well,

about half seem to do this through -- oh, this is a good time for my other technology here. Let me see if I can figure out how to aim this thing.

About half, I don't know if the Web people can see that or not, but anyway, I won't use this very much. It's not very substantive. It's just fun.

About half of them do this through a mix of in-house and outside services, and that leaves about a quarter that rely on outside services very heavily or only, and the remaining quarter tend to do almost everything in-house or everything significant in-house.

Now, without kind of getting into a lot of detail about what is the best model for doing this with IT, I think it could be said that the most general model kind of out there in organizations, generally, in the world is some mix of in-house, with some significant use of, in some areas, outside resources.

So I found it an interesting observation that we have that model operating in about half of the CRNs, with variation around that model.

There is a wide variation on the number of IT staff or staff that are identified as IT in the research networks. As you see there, the mean is four. This distribution is kind of one of those funny distributions. Most have less than two. And

the mode, as you will see in the last bullet there, is zero.

We think, number one, there is some question about how that question was interpreted. Number two, in smaller networks, it may very well be the case that there are zero for a while and then grab one when things get busy. And there might have been some misinterpretation of whether this meant dedicated or not.

But I do think the point is clear that there is a relatively small number. Now, of course, a very big network is likely to have a more established staff and about 35 percent, I believe it was, of the total IT staff represented in the survey group were in just a few organizations.

So there is one of these wide distributions of numbers there.

These are three of the IT themes. They correspond to other themes that you have seen that I would like to just focus on out of the eight accomplishments categories.

Let's look at internal interactivity. IT should be a facilitator and supporter of that, one would think, and it turns out that the way that it does that in two-thirds of the cases is through some kind of Web-based infrastructure. I can try to circle the ones that apply to that. I think it is those, but you might see -- that is a hard one to read. But it is on the handouts and it will be in the report.

But about two-thirds have some sort of Web-based infrastructure as their kind of major architecture.

This leaves about a third using client server architecture and about another third or, rather, within that, there is quite a few that have what they would consider to be mostly just desktop.

That doesn't mean they are not networked. They might be using a network with file servers and stuff like that, but in terms of the major applications, they would see it and report that to be mostly at a desktop level.

Now, IT architectures themselves aren't easily summarized in such simple terms, but this might be an indication that for the third that are really outside the Web domain in terms of what they declare as their main architecture, that there is some room to move in that direction.

The interesting thing about Web architecture nowadays is it can be introduced incrementally. It doesn't have to be a major, one-time, very large investment. And so there may be some room for movement there.

Now, although the architectures themselves, the prevalent architectures in networks may not always be Web-based, most networks have Web sites and a good share of those have some kind of a member portion, which means only network people can

get into it. There's some kind of log-in security around it.

And what do they do with that member portion? Sharing material, protocols, organizational directories and scientific information are the main things going on in those member-only areas on their Web sites.

What kinds of identified barriers might there be to internal interactivity in the networks? Well, there are many. There is hardware/software upgrade, compatibility factors, willingness, knowledge, things that aren't really surprising that are reported.

There are also some facilitators of internal interactivity and among those are the use of Web-based system and tools seems to -- obviously, one would expect would encourage that kind of interactivity, facilitate it.

Gradually adopting standards seems to facilitate the internal interactivity. Recognizing the clear value of what the software is. And I guess the flip-side of that is only getting software and installing it that has clear value encourages interactivity.

And knowing and responding directly to what the users are trying to accomplish, that is what that little quote is about. I won't read through it. And that is a perennial issue in IT, of course, is lining up with the business and research

practice and those that are most successful are able to do that, are doing that.

In terms of internal interactivity best practices, again, understanding what the users want, taking that perspective, and then I think maybe the focus here is on this idea of high tech and right tech.

Now, I don't want to suggest that high tech is bad and right tech is good. That is not what I mean by that. But high tech I am using here to refer to technology initiatives that involve the kind of investments and expertise and resources that can be fairly substantial and that is appropriate in certain places.

And then there's the rest of us. And right tech might be mean high tech in some cases, might be the right tech, but often it means lower tech, more selective, some criteria of doability, affordability, readiness, demonstrable value. And we found a number of CRNs that really had taken that right tech focus and had been in this best practice category.

Another thing that is indicated here is that studying the barriers, actually, explicitly recognizing that there are barriers and then addressing them was another best practice finding.

And this is a little more detail about those. I won't

dwell on those. Obviously, for high tech, it usually involves more dedicated staff, more dedicated support, and better finances to move into the higher tech types of technologies.

External interactivity between networks, let's consider a little bit of that. A lot of what we considered under internal interactivity in terms of IT infrastructure applies here, obviously, Web things and stuff like that.

But let's take a look here at kind of standards, which is another aspect of external interactivity. It's kind of like that old cartoon that has been around forever of the two railroads coming together from east and west and they are all standing there and then the two tracks are of different gauge, and that is the perennial issue with inter-organization, inter-network interactivity.

So standards become extremely important in that world. I guess the old IT question about standards is always, well, which standard are you using and that is important, too.

So there is a long list of standards, but I don't know if it is a lot or not. It is a minority in percentage terms are using common data elements, 40 percent, ontologies and vocabularies, six percent using LOINC, 11 percent SNOMED. You know, we can go through lists of these. Sixty percent using no data interchange standards. That is one kind of standard, I

guess. And 16 percent with HL7, 10 percent with CDISC. And I will comment on the XML in a second.

But I guess the list is interesting for some diversity, interesting for the levels of those percentages and people in a much better position than me in the subject matters and process world would know just what to make of that.

But it does seem like there is still a lot of work to do to get the kinds of standard adoptions that would bring about easy external interactivity.

And then 38 percent say that they are using XML for data transfer and storage. That is actually a technology rather than a standard. It is a technical standard and it is content-free, more or less, but it is a productive technology for a lot of standards work and it is just kind of an interesting thing to note the use of that.

Barriers reported are lack of time and funding. Obviously, limited use of standards is a barrier and lack of active sponsor support, which I think is correlated with the lack of funding.

Sometimes there are some hardware/software issues in there, too.

Facilitators of external interactivity, investigators being involved in it, not just pushing it over to the IT shop

and say "make is interactive." It requires a lot more substantive involvement than that.

Recognizing the value add in collaboration comes up in a number of places. I guess it is the issue that the capability is going to follow the goal which is set by the business. If the research entity doesn't want to collaborate, there is not going to be a whole lot happen on the interactivity front in IT and vice versa.

So the motivating factors here seem to be not technology, per se, but other factors that bring us into best practices.

Commitment to core principles of open development, open access, open source, one can see in a lot of areas these kinds of open keywords being used in systems nowadays, very productively. The caBIG initiative is one with National Cancer Institute that is leveraging this as far as they can to build software systems and interoperability.

Let's see. The last major IT theme is efficiencies. Some findings are that the adoption of standards and Web-based distribution and communication is not real high. It is diverse, but there is movement there.

The most prevalent things that IT seems to be contributing in efficiency and in the CRNs, as we see it in the results so far, is in online training, saving travel costs, et cetera, et cetera; in participant randomization happening; and, in clinical trials data management.

A number of other areas are lower percentage adoption and not seeing the same kind of efficiencies as a result.

In the efficiency world, lack of funding is, of course, a barrier to building IT everywhere. A small average number of IT staff may be related to that. It may be not always related to that, and so on.

Facilitators to efficiency, again, are just the flip-side of that. Again comes up the idea that the software processes need to show they have value to get by on.

IT has a lot to offer CRNs. We are a long way from state-of-the-art. I don't mean by that to be the coolest stuff around, but I think we mean that there are a number of areas where we can benefit by some more investments.

The proponents of IT need to understand what is going on in the research process, get the appropriate solutions and then, of course, sponsors and resources and skills are needed to be applied.