

IECRN National Leadership Forum
June 1, 2006
Report of Breakout Sessions: Recruitment and Retention

Presenters:

Jennifer Backhouse

Manager, Mid Anglia Cancer Research Network

Ken Getz, MBA

Chairman, CISCRP and Senior Research Fellow, Tufts Center for the Study of Drug Development

DR. SACHS: I'd like the breakout session experts from the next session, recruitment and retention, to come up, please. Ken Getz, Jennifer Backhouse, and Frances Heilig.

MS. BACKHOUSE: Thanks again for everybody staying behind so long. Obviously, the second day afternoon, it's brilliant to see so many faces.

My name is Jennifer Backhouse and I manage one of the cancer research networks that make up the national cancer research network in the U.K. There are 41 of those networks.

So, obviously, we are very interested in the different models that exist this side of the pond.

For recruitment and retention, we didn't have any of the voting technology in our group. So there won't be any results of any sort of questions that we gave out to the group, but these were the key survey themes that we discussed.

We talked about the importance of careful and up-front planning and that's in everything through from protocol design to selecting the centers to participate in a given study,

ensuring that the population is available.

One of the things that was talked about was the fact that a lot of centers tend to over-estimate how many participants they are likely to be able to put into a study.

There was a call for a model for that to see whether or not we could see how much people normally do over-estimate study entrants, but I think that probably varies too much across different disease sites and different patient groups.

I think one of the things that really kind of struck us was that the problems with recruitment and retention issues were consistent both within and across networks and that seemed to have no regard at all for what type of network it was, what type of study was being done, what disease was being studied or what population was being studied, which is, in some ways, reassuring, but it also means that we should be able to work together much better to find solutions for these issues.

We also talked about tailoring recruitment strategies to communities, including those for reaching families in cases of genetic diseases, special communities, maybe those of no fixed abode, ethnic groups, and we talked about lots of -- there were lots of different sorts of strategies we talked through about how you may engage a particular group through from contact, putting adverts for recruitment into new studies in

places where the mothers of some ethnic groups may see them rather than the study participants themselves, particularly maybe with African-American groups and things like that.

We also talked about the fact that it was essential to build and sustain strong relationships with stakeholders. Now, we split that down into separate issues for recruitment and for retention and for the recruitment issue, it was about researchers in the individual sites maybe having -- or, rather, the study organizers building relationships with researchers at the individual sites and all the clinicians or the nurses or whoever may be recruiting patients, to make sure that the understanding level was there.

And in terms of retention, we talked about the key relationship there was between the individual researchers and the volunteers themselves.

Some of the issues of best practice that were raised in the group were looking at maintaining those relationships after the point where active participation in studies was continuing, maybe feeding back results of studies a couple of years down the line even.

There were cases of researchers keeping in touch with patients or volunteers by means of a card in the holidays to say sort of happy new year, this is how the study is progressing,

and just regular feedback to just individual participants, hopefully, then, that word of mouth would mean that the next study, people actually had that relationship maintained and it would be slightly easier to recruit.

I think the only sort of issue on the downside of that is to make sure that there is no sort of coercion into involving participants making them feel obliged to enter another study.

Also, depending on the disease being studied, it may well be that the patients that were enrolled in a study before the study completes have passed away. So there are sensitivity issues in those cases.

The next couple of slides I've got actually show some of the main questions that were raised from the floor following our initial presentation. We didn't have all the answers and the floor didn't have all the answers necessarily, but we did have a really lively discussion around these areas.

Most of the questions raised were around recruitment rather than retention. We started off talking about how to engage referring physicians and health providers.

We talked about where we can find practical tips on the use of media, whether that's for adverts in magazines, whether it's appropriate to use advertisements on the side of buses, which groups are more likely to respond to Internet-based

advertises, or whether or not really the best thing you can do is to go out into communities and just talk to people direct.

We also talked about it may be that there is not very much money available for this sort of thing, so involving things like media study students to make the ad for you and actually getting some really good tips discussed, really.

The third question, what strategies and approaches work best among hard to reach populations. I have touched on that already, things like, say, getting in touch with mothers rather than the prospective subjects themselves.

The fourth question, how to determine whether or not recruitment in a small disease population has reached saturation point, and this was particularly raised in relation to cystic fibrosis, but applies to lots of sort of genetic conditions where the population is actually relatively small, that you can study for any of these disease sites, and more and more, in the case of cancer, that I'm more familiar with personally, we do find that studies are available for first line and then there is a study available for second line and maybe one for third line and how many times can you approach the same patient to ask them whether or not they want to participate.

We talked about how we standardize recruitment and retention effectiveness, the comparisons between sites, and,

also, comparisons between networks.

One of the things we talked a lot about was the fact that much of the study that was done was anecdotal and qualitative and it is very difficult to actually measure the quantitative side of the issues regarding recruitment and retention.

Maybe things like a screening log, that sort of thing, standardization, if it was possible across the way that screening lots are kept.

And we talked about the best metrics to gather effectively, manage and recruit retention strategies. One thing that did come up in this survey was that I believe it was around about 50 percent of the networks interviewed had any sort of formal way of managing recruitment and retention strategies.

This slide is just really giving a few details from the best practice study. There were five common techniques identified by networks for ensuring that participants were enrolled in clinical studies.

The first one, establishing a partnership with the affected community. This was highlighted by the Huntington study group and they actually involve families in the writing protocols to ensure that the studies are relevant to that population.

The second one, to ensure that research offers a win-win scenario. The research unit for psych, oncology and autism network, they prefer to use short studies so that the time from finding the results -- the time to find the results of the study are very short. The time to implement change to general practice is very short.

So that the subjects involved can have access to new treatments very quickly.

The third one, to work with local experts in developing recruitment strategies, this was the clinical directors network that was cited. They are talking about the importance of working with nurses, as they are the ones that are going to recruit patients and make sure that they are fully on board with the study, to maximize recruitment.

The fourth, to adapt the recruitment strategy to the local context. This was cited for the emergency medicine network and they were talking about the nature of emergency medicine being such that the patient is only available for recruitment for a couple of hours while they're in the system. So that's a very specific dilemma.

The last one, taking advantage of economies of scale, that is the NCRN, who I work for in the U.K. We have research teams in pretty much every hospital in the U.K., which means

that we can make the most of the size of the patient population that we deal with.

We've just got a couple of discussion take-aways. Overall, we decided that there were no surprises. The report was very general, anecdotal. It limited discussion of challenges, but it's a good beginning. We do need more quantitative metrics.

We do need guidelines and standardized proven strategies and approaches to export across networks and we need more opportunities like this to share successful strategies in practice.

And then just a few key things for the next steps. We talked about establishing a working group ongoing from this forum to share successful practices and valuable resources. We talked about spending time reviewing the IECRN online profiles, basically, the inventory.

People said that they wanted to go back now and have a look and just see whether or not there are other networks in their geographical area or in their disease area that they can then contact to work closely with in terms of reviewing issues on recruitment and retention.

And then it might be useful to go back and learn some lessons from private sector networks and investigative sites and

just to see what the differences are and what they're doing right and we're not.

This is the last slide, you'll be pleased to know.

We talked about developing a clearinghouse for recruitment and retention resources and templates, really, again, another way of sharing best practice.

There were a few, actually, the box incentives talked about, to attract volunteers, maybe the provision of a tax credit for those people who are volunteering and for the length of time that they're on studies. So that retention becomes an incentive, too.

And enhancement of convenience, talked about drive-through for dropping off sample and, also, for collecting of trial meds so that there was less inconvenience to general life in these studies.

And that's all I've got.

[Applause.]

MS. DIANIS: Thank you very much. We'll entertain questions now from the floor about recruitment and retention.

MR. DURAKO: This is Steve Durako. Jennifer, I think it was very interesting. I have one comment and two questions.

I think when you said take advantage of what the private sector does and see how they're successful, I've worked

on a number of private sector studies and they also tend to have recruitment problems.

So what they do is they increase the price from \$5,000 a patient to \$7,000 a patient and all of a sudden they get more recruitment.

So that's one technique they use, which I think is not available, in general, to us.

But the question I wanted to ask is in your situation, with the National Health Service, you said you have a research physician in almost every hospital, are those people paid by the National Health Service? What is the source of funding to have people available in every hospital?

Again, I'm not sure if we could do that in the U.S. or not, but it is certainly a nice idea.

MS. BACKHOUSE: All of the physicians are NHS employees. Most of their responsibility is clinical.

The NCRN itself, which is Department of Health funded, we do employ research nurses, research pharmacists, research radiographers within each network and we basically had free reign when the NCRN was set up as to how each network wanted to spend that funding.

So it does vary quite a lot, but basically they do it as an add-on to their general practice.

MS. DIANIS: There's a question over here.

MS. CALABRESE: I'm Barbara Calabrese, with the American Medical Directors Association Foundation, but I'd really like to highlight a situation that happened when I worked at Johns Hopkins.

We were working with Head Starts in Baltimore City and one of the things that we found, that after a four-year study, we had really ingrained ourselves in that community.

They knew us, they respected us, they felt comfortable with us, and then there was a funding lag between one study and the next study and you kind of drop out of sight because there is no funding to continue that association and that partnership.

I think that NIH really needs to look at continuing some of those partnerships between studies so that you're not rebuilding and, also, not reinforcing the community feeling like you're in there doing a study to them rather than with them.

So I really think that that's an issue that really needs to be addressed.

MR. GETZ: And it's also an issue that came through in the report, extensive discussion about continuity, that it can't be a focus on filling an individual project, per se, but nurturing that relationship long term. We really don't do a good job of that today.

MS. BACKHOUSE: We don't.

MS. DIANIS: Question over there.

DR. MORRIS: Alan Morris, University of Utah. I have a question about the recruitment efficiency, which I think is a very important issue, but, first a comment.

I was really intrigued by your description of the autism study and the win-win strategy.

Doing clinical trials in critical care, we don't have the opportunity for a win-win. We don't off the participants any benefit from the particular study, although they benefit from previous studies.

But I wonder if that's a common way to deal with more long-term trials. It sounds to me rather interesting.

But I want to ask you about the efficiency and the reason is the question about efficiency, that is, enrollment randomization of subjects taken from a pool of screened potential subjects, is tightly linked to the issue of generalizability, of how well the sample studied is linked to the population of interest, an issue that is very difficult to resolve.

We have, even in the controlled setting of critical care trials in hospitals, have had a great deal of difficulty identifying efficiency.

For example, in the ARDS network, in the first round of the network, the original sites were paid \$90 a patient to screen. The additional sites were paid nothing to screen.

It won't surprise you that the original sites screen more patients than the additional sites and, therefore, any estimate of efficiency would be clearly confounded by the payment.

But even beyond that, every hospital screening program had a different technique for identifying patients, which meant the general pool that was initially examined was very different from hospital to hospital.

So does anyone have any insight into how we could better identify the screened enrolled ratio and, also, thereby get a better sense, perhaps, of how the screened patients actually reflect the population of interest?

I think it's a fundamental question.

MR. GETZ: It's a great question and, to some extent, efficiency is tied to the center itself and the community it serves, the disease condition.

In the private sector, we've seen many examples, and I will give you a few of them. There are some centers that, for years, were directing inquiries from a promotion, newspaper ad, to a switchboard operator who had not been informed about how to

handle those calls and where to direct them.

So there was a high dropout rate of those inquiring until they were able to reduce that intermediary step.

Many sites now also look at the effectiveness of a recruitment strategy in the interim. Instead of waiting for a period of time, they look at it continuously, so that they can cancel or drop a program quickly and then reallocate those resources to a successful strategy.

So they're able to make their dollars more efficient by allocating them to a more targeted set of approaches or strategies.

So there are examples like that that many sites have found to be a great way to improve the efficiency of every dollar spent.

MS. BACKHOUSE: Also, though, to some extent, it depends on how you define screening a patient. I mean, we found enormous inconsistencies in the U.K., whether that screening -- some people may record that as having a half-hour chat with a patient to inform them about everything and then them deciding that they don't want to be in a study.

Somebody else may say screening because they've been through the notes of every patient coming in to clinic that day and decided already which patients are suitable to be

approached.

Other times, it may be a multi-disciplinary meeting and they are just discussing every patient and somebody is sitting there ticking whether or they're eligible for a trial or not.

It's how we define screening and how we then identify the reasons for patients not enrolling once they have been screened as being suitable.

So there are lots of definition issues.

MS. DIANIS: Thank you. Again, we're back to the definitions and consistency.

We'll take two more questions.

MS. HOLBROOK: Janet Holbrook, Johns Hopkins. I would just make a comment.

One of the things that we have instituted is to have kind of part of our training meeting as a consensus on what screening is, so we get a little more uniformity, but there is still going to be a lot of heterogeneity.

But my question was with regard to the best practices in the survey, were they based on empirical data about meeting milestones and retention rates?

MS. DIANIS: I can answer that. They were self-nominated based on solutions that they had encountered in

successful recruitment and retention of patients. So we didn't measure their performance against a standard scale.

MS. HOLBROOK: But you had in the self-nomination process that they met their recruitment target.

MS. DIANIS: Yes.

MR. FRIEDMAN: Mark Friedman, Westat. I actually had a question.

If you could expand a little bit about the slide that mentioned expanding the profile of the networks in terms of information available and what kinds of ideas come up in that discussion.

MR. GETZ: A lot of that is really tied to the last question that was raised. A discussion of adding more quantitative information to the profiles that would provide metrics on recruitment success or process improvements that are related to recruitment and retention strategies.

So expanding the profiles. There were not a lot of questions about recruitment and retention specifically in this early survey. So the profiles could really be enriched by a broader profile along those lines.

MS. DIANIS: Okay. Thank you all.

[Applause.]