

## Podcast Interview Transcript

Sarena D. Seifer, Margo Michaels, and Amanda Tanner

In each volume of *Progress in Community Health Partnerships: Research, Education, and Action*, PCHP editors select one article for our Beyond the Manuscript podcast interview with the authors. Beyond the Manuscript provides authors with the opportunity to tell listeners what they would want to know about the project beyond what went into the final manuscript. Beyond the Manuscript podcasts are available for download on the journal's web site ([www.press.jhu.edu/journals/progress\\_in\\_community\\_health\\_partnerships/multimedia.html](http://www.press.jhu.edu/journals/progress_in_community_health_partnerships/multimedia.html)). The following Beyond the Manuscript podcast features Sarena Seifer, the founding executive director of Community-Campus Partnerships for Health (CCPH), and Margo Michaels, the executive director and founder of Education Network to Advance Cancer Clinical Trials (ENACCT). Seifer and Michaels are the coauthors of "Applying Community-Based Participatory Research Principles and Approaches in Clinical Trials: Forging a New Model for Cancer Clinical Research." Associate editor Amanda Tanner conducted the interview. The following is an edited transcript of the Beyond the Manuscript podcast.

*Amanda Tanner:* Thank you both for being here with us today. Can you please take a moment to introduce yourself and describe the national project?

*Margo Michaels:* My name is Margo Michaels. I am the executive director and founder of ENACCT, the Education Network to Advance Cancer Clinical Trials.

*Sarena Seifer:* I am the founding executive director of Community-Campus Partnerships for Health (CCPH). ENACCT and CCPH are partners in this initiative. It was funded by the Agency for Healthcare Quality and Research and the National Cancer Institute, which are the core funders.

Our roles in the study really were two co-principal investigators in the design and implementation of the entire project. We were equal partners in the project, and I think it really effectively tapped our respective networks and areas of expertise.

I can speak for CCPH and Margo can speak to ENACCT, but CCPH is a national organization. We actually have members primarily in the United States and Canada, so it is actually international in that sense. And our whole focus is on building health and promoting health through partnerships between communities and higher educational institutions.

So we have a real interest and expertise in community-based research [CBPR], service learning, and other community-academic partnerships. Our network includes community groups and academics that are working in these areas.

*Margo Michaels:* Our organization is the only national organization that focuses on community-based approaches to enhance access to cancer clinical trials with a strong focus on enhancing access for minority populations. We work with researchers to help us better understand communities and work with communities to help us better understand research focusing on cancer clinical research.

*Amanda Tanner:*

What was the impetus for the creation of the national recommendations for improving cancer clinical trials?

*Sarena Seifer:*

What brought us together, was our concern and interest in having all people be able to participate and benefit from their involvement in research.

There are persistent disparities in cancer clinical trial participation and in the outcomes of the participation and research in terms of health outcomes. Particularly between racial and ethnic minorities and the medically underserved and the rest of the population.

From our read of the literature and numerous reports, some of them very high-profile reports, often cited, often quoted, but unfortunately not implemented. A lot has been written and said about the need for more community engagement, more community participation in studies, and in particular reaching racial and ethnic minorities and the medically underserved.

So what brought us together, is that each of our organizations have some very unique areas of expertise around cancer education and outreach in the community and with community-based participatory research. We thought that coming together and taking a more significant look at this issue and elevating the attention to it would really be a helpful step at this point.

We turned to the [Agency for Healthcare Research and Quality] AHRQ and [National Cancer Institute] NCI to support us in this effort. But I think the impetus was our concern about these consistent disparities and the need for action and the frustration that reports have come out, recommendations have been made, but they have not really engaged the constituencies that need to implement them.

*Margo Michaels:*

I would also add that even though those high-profile reports made those recommendations about the importance and the potential of involving communities in both the development and the implementation of clinical research, very little has been said about how and why.

We thought in developing these recommendations to set out some guidelines about how these activities could actually be implemented both at the local and national level rather than speaking in grandiose terms about the importance alone. We also got very specific about what that would look like and how we would know that participation was authentic. So that was another impetus that brought us together.

*Amanda Tanner:*

Before we get to the specifics of the recommendations, one of the really unique components of this process was bringing together different key stakeholders. Could you talk a little bit about the process that you went through in terms of identifying them and what their contributions were for the creation of the recommendations?

*Margo Michaels:*

Our core constituencies included communities that were affected by cancer, cancer researchers, government officials including officials from the NCI, [National Institutes of Health] NIH and cooperative groups, which are the largest sponsor of cancer clinical trials in the United States that are supported by the NCI.

We had researchers that worked in community-based participatory research and researchers that worked in cancer health disparities and cancer clinical trials, education, and outreach.

*Margo Michaels:*

And cancer patients, I am sorry. Patients that actually were cancer patient advocates. Since we both run in these communities, we drew from our respective networks to develop a national advisory board that was going to help us plan the conference, but also plan the participants.

We wanted to make sure we had relatively equal numbers of people from each of those groups in the planning and also in the implementation of the conference to develop the recommendation. These individuals met with us monthly and were quite involved in helping us develop the attendee list and really using a snowball approach to find appropriate people who were not only interested in attending, but interested in working over a year-and-a-half process to develop these recommendations.

It was not just someone coming to a conference and having a nice day, but really working with us on an ongoing basis. It took a great deal of perseverance to find those specific audiences that would represent those groups effectively and appropriately at these national meetings.

*Sarena Seifer:*

I would add that was important how we picked the people and who we picked, and then also the deliberate design of the meetings themselves. I think this is important for any effort that is trying to bridge multiple perspectives and have people learn from each other.

I recall at our first meeting, our facilitator, Monty Rulier, had a slide about the difference between dialogue and debate and that we were aiming for dialogue happening between these two very different worlds in many ways. The cancer trial clinical people and the community-based participatory research people coming together, learning from each other, really understanding how they each approach research and how they approach concepts of community and community participation.

Because we were seeking dialogue, not some sort of debate between the two. So the meetings were designed very thoughtfully. For example, before the first meeting we had a telephone orientation for the CBPR folks to learn more about the cancer clinical trial world, which has a huge number of acronyms and a lot of jargon—some very specific groups that are involved but are not so well known outside of that world.

And we also had an orientation and briefing on CBPR for the cancer clinical trial researchers and patient advocates involved in that world. At the actual meeting, we had a face-to-face discussion about these issues before the real meat of the meeting began. Although we could have probably done even more of it, I think that served us well in the long run because it allowed for people to come in with some basic understanding of each other's perspectives and definitions and concepts so we could have more of a discussion.

Throughout the meetings we deliberately structured the agenda in a way to allow for that discussion for small groups, for coming up with real concrete and meaty recommendations—not wordsmithing every word, but coming to concepts and consensus around the direction this project should take.

*Amanda Tanner:*

What were the recommendations this group put together,

*Margo Michaels:*

We had 58 recommendations that fell into seven broadcast categories, concerning everything from dissemination of clinical research results all the way to development of clinical trial protocol on the national level and everything in between.

*Margo Michaels:*

One of the greatest recommendations in terms of its potential is the idea of requiring community representatives or patient advocates, which I abbreviated CRPA, would be involved in and be required to be involved at the national and local level and called on the NCI, the National Cooperative Group, to collectively enforce that and create opportunities for those individuals to start sitting at the table in a more concrete way.

*Sarena Seifer:*

How we emphasize community representatives and patient advocates was a very important recommendation within this report because it makes the distinction, even though there is overlap between these two categories.

But historically in cancer clinical trials, the patient advocates have had a seat at the table. These are individuals that have experienced as a patient with cancer, a caregiver, a family member or someone who is affiliated with a cancer advocacy organization or group.

But we also wanted to broaden that participation to include community representatives who have experience with the healthy population at risk. So for example, knowing that there are great disparities between people of color and whites in terms of cancer outcomes, that the organizations and the community leaders that represent those communities of color need to be at the table also as a voice for ways to engage individuals from their communities, how to make studies more culturally relevant and appropriate and so forth.

I think that is an important recommendation to make that distinction again. It is not an either/or, but we are trying to broaden the community participation and input in cancer clinical trials at all levels.

The other thing, in terms of recommendations, is that at the local level many researchers are concerned about the lack of particularly minority participation in trials in terms of the outcomes and benefits from the research that is being done.

They are looking for ways to engage communities more in the work that they do. So this report, it does not just recommend that you must have a community advisory board. You must have ways of involving community every step of the way. It also provides a lot of resources and ideas for how to make that happen, how to actually implement the recommendations.

Through the appendices that we list a lot of other reports, helpful strategies, links to potential ideas for how to implement the recommendations, that sort of thing. And we have been doing a lot—both CCPH and ENACCT together working with groups that are interested in implementing the recommendations to be helpful in guiding them to implement them.

It is important. It is not just the recommendations, but the guidance for implementing them is the hallmark of this report.

*Amanda Tanner:*

What have you have been doing to support other people since the report has come out? Margo Michaels: One thing that we were able to do with the funding was to put in a call for proposal to organizations that wished to implement one or more of our recommendations with the idea that we provide some small seed funding for them and that we would provide technical assistance and training for a year period of time.

*Amanda Tanner:*

And to our surprise we got over forty applicants from all over the country and from all walks of life. Community-based organizations, cancer centers to CTSA's to local community hospitals. We were really pleased to see the number of applications that came forward.

We ended up choosing four after a review process, and they are listed in our article. We have been working with them since January of [2009] in implementing the recommendations locally, which has been both challenging and exciting. And we have also done training onsite with two of those partners to help them think through more about what it would take to implement this recommendation throughout their institution.

*Sarena Seifer:*

One thing I want to add is we have definitely been in this project all about moving to action and demonstrating that these recommendations can be implemented in practice. It is not just a report to sit on a shelf and refer to occasionally when you are writing a grant proposal.

These four implementation partners, they are attempting to do that on the ground. We are actually scheduling right now. We should be announcing shortly, a December and January webinar. Basically web conferences that feature the four implementation partners describing the work that they are doing and what they have learned so far in providing guidance to others that might want to pursue a similar strategy.

These will be archived on our web site, so I am not exactly sure when the podcast is posted, but if it is after they have taken place they will still be accessible to listen to and watch with handouts and so forth.

We are very much focused on demonstrating the recommendations. It may be the rare institution or organization that can implement most or all of them, but even taking specific ones and demonstrating that they can be applied is going to be very helpful.

And they are working in very different areas—in informed consent, in community outreach and engagement, public awareness about cancer clinical trials, engaging the public and providers. Across the board there will be a nice range of examples that others can learn from.

We are more interested in working with anyone who wants to implement the recommendations, whether they are part of this officially-funded program or not.

*Margo Michaels:*

We have also gone on the road since the release of the report in September 2008 to talk to a number of institutions and organizations about the report and to encourage the adoption and implementation of the recommendations.

We visited cooperative groups, the National Cancer Institute, several cancer centers to talk about the report and we have been approached by a number of organizations to help them think through grant applications, to perhaps help on new projects that relate to our recommendations. So we have been excited about that determination as well.

*Sarena Seifer:*

I think you asked in the question for us about the kind of landscape at the federal level or changes that are potentially supportive of the work that we have been doing. One thing I would say, obviously, change can be a very slow process.

*Sarena Seifer:*

It is only been about a year since the recommendations have been released. It is not realistic to think that they would all be implemented in that period of time. But there is some movement, both with the implementation partners we are working with, with the organizations Margo's referring to that have been contacting us, and I think part of what is driving it is, particularly at the National Institutes of Health, there is a greater emphasis on community engagement and community-engaged research.

There is no doubt about it, it is still a small part of the overall portfolio of funding at NIH, but it is growing. And Margo mentioned the CTSA's, the Clinical Translational Science Awards. They all have a core community engagement component.

There are a number of other program announcements that have come out of NIH in the last year that have a community engagement focus to them. And so researchers around the country, whether they are cancer clinical trials or other areas of clinical research, are looking at these announcements seriously and realizing that they need to build their own capacity and engage community and really fulfill the spirit of what these announcements are asking for.

That overall picture is really helping our report gain more traction. It is more relevant, and it is allowing us to play more of a role early on in the design of a project, which is really the ideal time to be involving community—not after you have got the grant, started the research, and you are trying to sort of back fill it at that point.

*Margo Michaels:*

NCI has, certainly concurrent to our report, but we think also has a huge impact on the implementation of our recommendations. The NCI is actually now mandating that advocates are on national committees approving new cancer clinical trials, and we are particularly excited on a new sort of emphasis on the national level [inaudible] and NCI.

And the second is that the new accreditation standards by the . . .

*Sarena Seifer:*

It is the accrediting body for the institutional review boards.

*Margo Michaels:*

One of its newest accreditation standards states explicitly the importance of institutions involving communities in the development and implementation of clinical research. And we believe that in March 2010 those standards are going to be put into place for new institutions that wish to receive accreditation.

That is a pretty exciting development that boosts the recommendations in our report as well.

*Amanda Tanner:*

Before we conclude, is there was anything that you wanted to add or any final thoughts that you had or wanted to share about the project or about where you would like to see the recommendations going?

*Margo Michaels:*

I think Sarena and I, when we started this adventure, and I do think it was an adventure, we did not realize some of the challenges and the barriers that were going to come up—not only in developing the recommendations, but in disseminating and trying to get them implemented.

I think we have learned a lot from this process and about the difficulty in changing organizational cultures and even institutional cultures like the institution I am talking about is the [inaudible] Institution on Cancer Research. How do we think—what are ways that we can really encourage change and help people think differently about a problem that has been persistent for many, many years.

We have been challenged by what Sarena was saying earlier, slowness of change and also the reluctance to adopt new ideas and new approaches to things that also are not easy. They are not slow fixes. Most of the things in our report suggest that doing something within a 5-minute period of time is going to make a difference in clinical research recruitment and retention.

These things are not easy. They require dedication and intention to continue with community engagement. So we have come to understand that we have got to continue to push this and continue to advocate for their implementation no matter where. That is a huge incentive for us.

*Sarena Seifer:*

The only thing I would add is knowing that the journal's readership is largely a community-based participatory research readership, I think more on the CBPR end than cancer clinical trial researchers—although we hope that this article being published in the journal may expand it to that larger audience to take a look at the journal and the work that you publish.

But knowing that it is CBPR readers primarily and community organizations, I just hope they take a serious look at this article and consider ways on the ground that they can help advance these recommendations. I think one of our challenges was that the individuals who are really leaders in CBPR, you can look at what we have been doing with a little bit of a skeptical eye and say, "Well, it is not really, truly community-based participatory research to design a cancer clinical trial because the studies are really emanating from investigators and are not community-driven studies."

I think that criticism is fair. In many ways, we really looked at community engagement and research more than the CBPR model in a very kind of classic, narrow sense. But when you take a look at this paper and also the larger report that it draws from, there are so many ways that community members can be involved in research, in clinical research, and really affect what questions get asked, how they get conducted, who participates and who benefits from the result.

I hope that readers will consider the work that they are doing, how they can make connections with cancer clinical trial researchers locally, with cancer clinical advocates, patients advocates and so forth and help build the bridges. I think these two worlds really do need to come more closely together to make change. There is a lot of potential now as we discussed with the changes in the environment at NIH and so forth that can really support doing this in a very authentic way.