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IN THIS ISSUE

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CT sites could learn a lot about community rapport from HIV trials

Community outreach best practices are renowned

Few diseases have anywhere near the clout, exposure, and clinical trial support of HIV/AIDS. Dedicated foundations, advocacy groups, and international organizations have spent more than two decades working to ensure HIV prevention and medication trials are a top priority for governments and private industry.

As a result, many HIV trials have best practices, including in working with local communities that could be a model for the rest of the clinical research.

"The work I'm engaged in sits at the interface between clinical research and the local community and, increasingly, the global community as well," says **Kathleen MacQueen**, PhD, MPH, a senior social scientist and coordinator of interdisciplinary research ethics at Family Health International in Research Triangle Park, NC.

HIV investigators and research sponsors have developed complicated and novel ways of educating communities about their studies. Their methods of laying the groundwork for clinical trials provide a template that researchers studying other diseases might emulate.

For example, the AIDS Vaccine Advocacy Coalition (AVAC) of New York, NY, and the Joint United Nations Program on HIV/AIDS (UNAIDS) have developed a set of guidelines called Good Participatory Practice (GPP) guidelines for biomedical HIV prevention trials that provide a framework for how HIV investigators should work with communities during HIV biomedical prevention trials, including vaccine trials and microbicide trials.

"The reason for the development of the guidelines came from when pre-exposure prophylaxis (PrEP) trials were being launched and proposed," says **Lori Miller**, MHS, a senior program manager of AVAC. "There were many controversies around community engagement with researchers, including controversies around the PrEP trials in Cambodia, Cameroon, and Thailand."

The GPP guidelines establish base principles between researchers and communities and include suggestions for how investigators should work with communities from the inception of a trial to the close-out of

the trial, Miller says. **(See description of the core principles of GPP, p. 65.)**

AVAC and UNAIDS brought stakeholders and experts from around the globe together to develop the guidelines. Once they were created they were published in draft form on the UNAIDS and AVAC Web sites to invite input and comments. The guidelines were updated and released in November, 2007.

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"They were created as a living document and will be revised on a regular basis to reflect the real needs of the field," Miller says. "We want clinical trials conducted in an ethical fashion and to have everyone feel like it's a positive relationship, and the guidelines are one means to that end."

HIV researchers are particularly sensitive to a community's perception of clinical trials because of the complexity of studying this disease.

"It's a challenge explaining this highly complicated disease," MacQueen says.

Community education is an important part of a vaccine trial's recruitment process, as well.

In a phase IIb HIV vaccine trial in the U.S., investigators used a broad marketing approach, relying on community education and a variety of methods, to reach the target minority audience.

"It did return a substantial amount of phone calls and interest from our minority community about the study," says **Paula Frew**, PhD, MPH, an assistant professor of medicine in infectious disease and in behavioral sciences and health education at Emory University School of Medicine in Atlanta, GA.

"We were satisfied with our recruitment approach because it was community informed," Frew says. "It gave us that necessary volume of interest we needed to far exceed our enrollment goals." **(See story about community involvement and enrollment, p. 67.)**

Complex issues explained

Before investigators can engage a community they have to be prepared to explain complex issues of randomization and what it means in an HIV prevention or treatment trial, she says. Remember, this is a community of people who live with the stigma and behavioral issues associated with the epidemic, she adds.

"HIV as a disease is clearly life-threatening, and it's something that's of great concern to people to find out whether they have HIV or to find out if people in their community have the disease," MacQueen says.

"You need to understand the social context within which this disease happens and do the clinical research in a way that would not worsen the social context of the disease," she adds.

About 15 years ago, MacQueen was a project officer at the Centers of Disease Control and Prevention (CDC) in Atlanta, GA, and led one of the first cohort studies to prepare for HIV vaccine trials in the United States.

"We worked with men who have sex with men (MSM) in several cities to try to get a handle on HIV incidence, as well as other issues," she recalls. "And we discovered that the social and ethical challenges would be very big."

In the early 1990s, there were far fewer treatment options for HIV patients, and people thought the only way the world would ever conquer the epidemic would be through a vaccine.

"The AIDS activists wanted a vaccine and wanted us as researchers to do a good job of explaining the vaccine and explaining the trials," MacQueen says.

"They wanted community representatives at the trial for all the discussions," she adds. "So right from the beginning we were engaged in active conversations with advocates in this country, and as we moved into the international arena, we worked the same way."

MacQueen learned from this and subsequent experience how important it is to educate the community in a way that's beneficial to the community, and she learned that it's important for the education to be in both directions so that researchers can learn from the community about how to improve their trial.

"At every single site that has been involved with HIV prevention research now you have something that looks like a community advisory board," MacQueen says.

"In general, you find there are key opinion leaders, gatekeepers, people who are working in their communities on HIV-related issues, and people who want to make it part of their life work to listen to what's going on in their local community," she explains. "These people bring this experience to the table for researchers, and they listen to researchers, and then bring what they've learned back to the community."

Good community advisory boards share that key characteristic of having members who take the role seriously and who listen to all sides, serving as an important bridge between investigators and the community, MacQueen adds. **(See a story about how a CAB has helped prevent enrollment problems in studies, p. 67.)**

"Basically, the more people can understand what you're doing and why you're doing it and the precautions you take to protect them, then the more trust you build," she says.

Broadening access

The GPP guidelines are one tool for building community trust.

Although they were written for researchers, community groups have expressed so much interest in these that there might one day be a version written specifically for lay people, Miller says.

"That's an important next step to make these more accessible to everybody," Miller says.

"The nice thing about these guidelines is they talk specifically about how researchers should work with communities, so community advocacy groups can read these guidelines and offer specific suggestions on elements of community engagement," she adds. "An important next step is to make these guidelines, which were written for researchers, more accessible to communities."

For example, the guidelines talk about how communities should be involved in the protocol development process and how a representative from the community should be provided with summaries of the protocol, Miller says.

The summary should be translated into a language community representatives understand, she adds.

"So community representatives can participate in the discussion about how it's done and make recommendations," Miller says.

"A community representative might say, 'We asked investigators to see the protocol, but they're not giving it to us,'" she says.

The community member can then advocate for greater community engagement by referring to the GPP guidelines which indicate that investigators should share protocols or summaries with the community and give specific examples of the way they monitor trial outcomes.

AVAC has a strategic plan around the guidelines and is looking at continuing relationships with people and organizations that want to work with the guidelines, Miller adds.

"We work with community members, and we build relationships on the ground to support biomedical HIV research stakeholders," Miller says. ■

H1N1 outbreak should spur CT sites to prepare

Disaster plans need pandemic specifics

As often happens with epidemics, the influenza A (H1N1) virus infection that began in

Mexico in April started small, but jumped across the North American continent with breathtaking speed.

The number of confirmed cases of the new and sometimes lethal strain of virus more than doubled from one day to the next. Hospitals quickly sent alerts to staff, and emergency preparedness plans were activated in readiness.

For clinical trial professionals and investigators, determining how seriously to take the burgeoning pandemic was difficult, given its arrival at the end of the usual flu season and its inconsistent virulence.

Even if this particular virus eventually proves to be a false alarm, it serves as a valuable lesson to CT sites. And it could be a harbinger of an even worse flu pandemic this fall and winter when flu season is fully underway.

"Our hope is this will die out over the summer, and the flu season comes to an end," says Ramesh Gunawardena, MBA, director of clinical trial operations for Beth Israel Deaconess Medical Center in Boston, MA.

"But the problem with these types of viruses is they take place elsewhere too, so there are international issues," he adds. "So there is a chance it can resurface."

Or another new, virulent virus could emerge.

"One lesson it does teach us is that it's possible we could have an outbreak of some infection similar to this that would cause a much bigger problem," says **Edwin V. Gaffney**, PhD, a clinical research consultant in Birmingham, AL.

"So it's a good exercise we're going through," Gaffney says.

For clinical trial sites, the lesson is to be prepared with policies and procedures that are specific to the site and not dependent entirely on the larger research institution or medical center.

"Absolutely, you should have your own epidemic protocol," Gaffney says. "It doesn't require a lot more than what the hospital already plans to do, but you do need a policy and procedure in place that is outside of the hospital's policies and procedures."

Key considerations

The CT site's P&Ps should be written within the context of research studies and perhaps address these questions:

- How should the CT site handle patients showing signs and symptoms of influenza infection during a regional or national influenza pandemic?
- Should CT participants exhibiting flu symptoms during a pandemic be tested for the pandemic virus, and how should positive findings be reported and characterized to the IRB and regulatory officials?
- If a CT participant develops a pandemic flu virus, how should flu treatment be handled (i.e., should the CT participant be taken off of the protocol if there's a possibility of drug-drug interaction or if trial participation could negatively impact the course of the person's newly-acquired viral infection)?
- What kind of extra airborne illness safety precautions, if any, should CT staff employ?
- If a CT site is located within an academic institution that is closed during a pandemic, should the site continue to operate, and, if so, where?
- If a CT site is located within a medical center that is flooded with patients during a pandemic, where should the site continue to operate?
- Should CT participants be given prophylactic treatment, particularly if they have an existing disease that makes them particularly vulnerable to viral infection or if they have been exposed to pandemic influenza?
- Should CT staff request prophylactic influenza treatment if they are not already on the county health department's list of qualified personnel to receive this?

The P&Ps might leave answers to some of these questions up to investigators to make on a case-by-case basis.

For instance, it would depend on the trial and the investigator's discretion whether or not to keep a participant who is being treated with oseltamivir (Tamiflu®) or zanamivir (Relenza®) on the study protocol.

"I think that would be at the discretion of the investigator about whether to use Tamiflu and whether to take the patient off the study or leave him on the study," Gaffney notes. "They shouldn't make a knee-jerk reaction because it might be valuable for the study to get data on the interaction of a medication for flu or infection and the drug that's being tested."

Also, principal investigators will have to base decisions about how to handle sick patients according to their trial's inclusion/exclusion criteria, Gunawardena says.

"It could be that if certain drugs are given to the patient, and drug interactions are part of the exclusion criteria that was predefined in the protocol, then the patient would have to come off of

the trial," he says.

"It's a health care decision, as well," he adds. "If the patient's health is deteriorating, and the patient cannot meet the timelines of the protocol, then you'll have to weigh the pros and cons of keeping the patient on the trial."

CT sites need to have a contingency plan if their investigators and nursing staff are called to work in emergency care during a pandemic response at a medical center, Gunawardena notes.

"We might not have the capacity to continue on the clinical trials we're working on if they pull all of our staff to handle the emergency," he says.

Or if the clinical trial space is impacted by a pandemic emergency, then the CT site might need to find alternative space for meeting with study participants, he adds. ■

GPP core principles would work for any clinical trial

Building health literacy is top priority

Clinical trial professionals who would like guidelines for working with communities during study enrollment might look no further than the 10 fundamental principles created for HIV biomedical prevention research.

The 10 principles of Good Participatory Practice (GPP), were developed by the AIDS Vaccine Advocacy Coalition (AVAC) of New York, NY, and the Joint United Nations Program on HIV/AIDS (UNAIDS). But they could apply to any clinical trial, especially as sponsors and researchers increasingly are seeing the importance of building rapport with communities in order to improve trial participation.

"These guidelines have very specific suggestions on minimum elements of community engagement," says **Lori Miller**, MHS, a senior program manager of AVAC.

Here is a list of the 10 principles and explanations about these GPP guidelines:

1. Scientific and ethical integrity: The guidelines ask researchers to adhere to universal ethical principles of respect for persons, beneficence, and justice while working toward a study's scientific goals.[1]

2. Respect: "The GPP document talks about respect and transparency being the foundation of a relationship between researchers and the community," Miller says. "There is an inherent power imbalance between communities where phase III clinical trials for biomedical HIV prevention research are conducted and the researchers who conduct them."

These trials often are conducted in places where there is a high incidence of HIV and higher levels of poverty, she notes.

"In countries where trials are conducted, groups such as sex workers and men who have sex with men (MSM) are often stigmatized or marginalized," Miller explains. "So there's often an inherent power imbalance between those being researched and the researchers."

Without first building mutual respect in a community, misunderstandings can escalate into crises for research projects.

For example, when HIV researchers were planning a pre-exposure prophylaxis (PrEP) trial in Cameroon and Cambodia a few years ago, a controversy erupted between researchers and activists and the local communities being targeted for the study.[2]

The U.S. National Institutes of Health (NIH) funded a grant for researchers at the University of California at San Francisco to conduct a trial of oral tenofovir as PrEP among sex workers in Cambodia in 2002. Similar PrEP trials were planned for Cameroon, Ghana, and Nigeria. Several years later, PrEP trials were organized for Thailand and Botswana by the Centers of Disease Control (CDC) in Atlanta, GA.

AIDS activists protested the trials in West Africa in 2004 as enrollment was scheduled to begin. A union of sex workers protested the trial in Cambodia. Activists cited ethical concerns and continued access to HIV care and antiretroviral treatment in the event of HIV infection during the prevention trial. They specifically objected to the prevention package being offered to female participants because it did not include female condoms.[2]

"There was a sense of miscommunication and misunderstanding about respect and objectives on both sides," Miller says.

The controversy eventually resulted in the Cameroon trial being closed and the Cambodian trial never starting.[2]

"It was a very unfortunate miscommunication even though the intentions on both sides were good," Miller says.

Call for clarity

3. Clarity in roles and responsibilities: This

guideline expresses the need for better communication about expectations and greater shared responsibility in clinical trials.

"Previously, researchers came in and did research on 'research subjects,'" Miller explains. "Now there needs to be a more collaborative approach."

Researchers, participants, and their communities have roles and responsibilities and should share responsibility of research, she adds.

4. Towards shared responsibility: Researchers should work jointly with sponsors, research site staff, local authorities, and the community that is impacted by the clinical trial.[1]

"Researchers can't just think it's their game and exclude the community and, likewise, communities — if they're interested in research being done there — should take responsibility too," Miller says.

And if a community doesn't want research being done, then it shouldn't be done there, she adds.

5. Participatory management: The community should play an active and informed role in the trial.

This means communities should make certain the people who best represent the community's values and concerns serves on the community advisory board. In addition, these representatives need to help inform the community about the research process, share the community's concerns with investigators, share investigators' explanations with the community, and help to find solutions to unexpected problems.

6. Autonomy: Community advisory boards should be independent without individual conflicts of interest. Their goal should be to provide critical input to the clinical trial process as it intersects with the community's interest and well-being.[1]

7. More transparency: Transparency increasingly is an important issue among research participants/communities and researchers/sponsors.

"The idea with these guidelines is that researchers have a responsibility for more transparency to the whole community," Miller says.

"There have been a lot of controversies, more in HIV trials because of the power dynamic in which phase III trials are being done in areas where people are poorer," Miller says.

Communities often don't receive information about the research in a timely way, so researchers need to work toward that more and have open and honest communication that is so important to good practices," she adds. "Researchers have an obligation to inform communities about what they're planning to do and to be transparent about it."

Risk reduction counseling

8. Standard of prevention: Risk-reduction counseling and access to HIV prevention methods should be provided to all biomedical HIV prevention trial participants throughout the duration of a trial, according to the guidelines.

9. Access to care: Trial participants have the right to access medical care for trial-related injuries and harm and to the experimental product if it proves to be effective, according to the guidelines.[1]

This principle also promotes the standard of providing HIV antiretroviral treatment, according to negotiations before the trial begins, to participants who become infected during the study.1

10. Building research literacy: "This is an issue that came up consistently in our consultations," Miller notes. "It should be one of the most important principles because you can't expect to work with communities and have conversations with them if you haven't educated them enough so that they can understand how research is done."

Investigators enter a community with complicated protocols, science, and epidemiology, so it would be difficult to have a conversation about these issues until the community's level of understanding is raised, she says.

"It's the responsibility of researchers, sponsors, and communities to do this," Miller adds. "And this is one of the hardest things to achieve because it costs money to do it."

It requires clinical trial teams to meet with community members to discuss how the science is done, why randomization is necessary, why a blinded study is needed, what the procedures are, and why these procedures have to be done, Miller says.

"It's basic information for researchers, but for communities this is a complicated topic," she adds. "But it's necessary that you do this basic education before you start recruitment for the trial."

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Community boards help build local awareness

CABs are experts on local attitudes

For many clinical trials developing a community advisory board (CAB) is the right thing to do for the local community and for eventual participants. But it's also the right strategy for investigators, who otherwise might miss cues about problems with their protocol design and participant education.

CABs are particularly indispensable in foreign cultures and countries where U.S.-based investigators might be unaware of beliefs that make biospecimen collection more complicated than it is in the United States.

Community boards work best when they serve as an advisory body that informs researchers, as well as assists in educating the community about clinical trials, says **Kathleen MacQueen**, PhD, MPH, a senior social scientist and coordinator of interdisciplinary research ethics at Family Health International in Research Triangle Park, NC.

Without a CAB or similar mechanism, researchers might not learn of major obstacles to biospecimen collection and storage until a trial is underway. But if a CAB has been informing investigators of local culture and beliefs, these obstacles could be handled before misunderstandings arise.

For example, some cultures believe that every part of a person's body must be buried after death, so even biospecimens from the person must be retrieved and buried or the person's soul will be restless.[1]

So if a CAB has alerted investigators to this belief, then issues related to the long-term storage of biospecimens can be addressed up front and resolved at the time of trial enrollment.

HIV biomedical prevention researchers have learned the importance of being fully informed by a local community board through trial and error.

"Several years ago, we'd heard anecdotal reports about concerns [participants] had about blood draws and tissue samples and what happens to them," MacQueen says.

"People had some interesting ideas about why we would want to collect blood and what would be done with it," she adds. "We heard about rumors of witchcraft and vampirism or using samples to do genetic engineering that would make people in the United States rich, but leave people in the developing world poor."

All of this was anecdotal, so at an HIV prevention trial network meeting, HIV researchers and experts held a special session to discuss these reports.

"We had about 80 researchers and community educators and CAB members from Asia, Latin America, Africa, and the U.S. there to discuss this," MacQueen says. "We broke into roundtable discussions."

Prior to the meeting, attendees were asked to answer a list of questions about their local communities' concerns and experience with biospecimen issues, and many people had conducted a little research in their own localities, she notes.

"So when they came to the meeting, they said, 'Here's what I am being told,'" MacQueen says. "We learned a lot and published the results of our tabletop discussion in IRB: Ethics & Human Research."

The big take-home message was that if researchers don't fully explain what they're doing and why they're doing it in a way that participants can fully understand, then participants will jump to their own conclusions based on their own life and culture experiences, she explains.

"If they don't understand what a laboratory is and how you would use blood to understand the disease, and if they only understand the use of blood in the context of witchcraft, then that's the model they'll use," MacQueen says.

In another example of cultural misunderstanding, clinical trial professionals would tell participants that they will collect two vials of blood, which is a couple of tablespoons of blood. The CT staff thought they were describing how small the blood amount would be by using a local term for "vial," MacQueen says.

But participants in one culture didn't have a good translation for the word "vial," so it was translated as "bottle." To these participants the world bottle evoked an image of a Coca Cola bottle, and to them it appeared that researchers wanted to take two Coke bottles worth of their

blood, she adds.

"So if you don't really talk to people and listen to them and understand what they think, then all of your best intentions can go haywire," MacQueen says.

After learning of this misunderstanding, clinical trial staff found a very simple solution: they showed participants a liter jug and explained that the blood in the human body could fill four or five of these jugs, MacQueen explains.

"Then they showed them a vial and said, 'We use this to collect a small amount of your blood,'" she adds. "Then they also explain that their bodies are constantly making more blood."

CAB members can help to anticipate and clear up these communication issues.

"I'm an anthropologist and I have a PhD that helps me figure out how to understand a new community," MacQueen says. "But every time I go into a new community, I start at ground zero, and I'm there to learn from the experts -- the community members."

Researchers should approach communication during the informed consent process the same way.

"You don't want people signing up if they don't understand what's required in the clinical trial," MacQueen says.

"Our informed consent process can take a half day or more since some HIV trials are so complex with screening, informed consent, and behavioral interviews," she adds. "We accept that as the way it is."

So HIV biomedical prevention investigators will give participants very detailed information booklets and sheets before they enroll and have them take these home to discuss with their families.

The point is to let them think about how difficult it might be for them to take pills each day or use a microbicide gel each time they have sexual intercourse and to come back to the clinic every month for an HIV test, for example.

"If someone feels this is too much for them then you don't want them in the trial because it's not about enrollment numbers, but about retention numbers, taking time to talk with the person and building a relationship," MacQueen says.

"Laying the groundwork in the community can be very important to that process," she adds. "If there's a buzz in the community that this is an important study then even if a person is not in the trial, he'll be supportive of people who are enrolled."

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HIV vaccine recruitment was aided by community outreach program

High-risk minorities were targeted

A clinical trial site enrolling for an HIV vaccine trial was successful in its strategies to engage and recruit from a local minority community, a new study shows.

"Our chief findings were our recruitment strategy works very well in generating interest and attention of a minority community," says **Paula Frew**, PhD, MPH, assistant professor of medicine in infectious disease and in behavioral sciences and health education at the School of Medicine and Rollins School of Public Health of Emory University in Atlanta, GA.

Part of the clinical trial site's strategy involved using a diverse community advocacy board (CAB) that participated in continuous dialogue with CT staff and investigators, Frew says.

"We had face-to-face meetings in the preparatory phase of the study," she says. "And we had lots of small group sessions and one-on-one discussions with CAB members, who were different experts in the community."

For instance, among the 15 CAB members, there was an expert on African American women in the urban context of Atlanta, and there was another person who worked with young men who have sex with men (MSM) populations, and yet another person who worked with young African American MSM, she adds. **(See story on how CT recruited minorities for study, right.)**

"Having that variety of expertise on the board really helped us to understand the different segments, what their values are, and what typical behavioral correlates we see with respect to HIV risk," Frew explains. "We also learned an awful lot about how to communicate with those groups."

HIV vaccine researchers have worked hard to

enroll African Americans and other minorities in their studies because of the need to find out whether the vaccine is effective for those racial and ethnic groups, Frew says.

Since African Americans have a disproportionate share of the HIV-infected population, their participation in vaccine trials is important, and the recent study shows that a targeted minority study enrollment program can be successful.

"Thirty-seven% of the people we pre-screened as eligible were from minority communities," Frew says.

The actual enrollment rate was lower among minorities than the pre-screening rate, however.[1]

"When we tracked their participation and actual enrollment rates, we found that number dropped to 25% of the total," Frew says. "We tracked it at different points in the process, and the majority of people that we lost were from the pre-screen to the clinical screen phase."

Minority individuals sometimes would contact clinical trial staff but then dropped out before the hand-off to clinical screening stage.[1]

"With white people we began with 62% eligible, and we ended up with their having 75% of the share," Frew adds. "The majority of people in the minority cohort were African American by ethnicity with a small group of non-white Hispanic/Latino/Asian Pacific Islanders in there."

The study's protocol did not address why participants dropped out of the study, she notes.

"That's another study we want to do with future populations," Frew says.

The current vaccine study's enrollment of minorities could have long-term implications, Frew notes.

"The thread we're looking at is how does this have an impact on health disparities in the long run and in our priority populations that could benefit from an HIV vaccine," she explains. "How does it impact this group's decision-making to take a vaccine in the future?"

By enrolling minorities in the clinical trial stage, sponsors build trust in the product because when consumers are presented with treatment and prevention options, they'll want to know that others in their community were involved in studies of these new treatments and prevention options, Frew adds.

Engaging a community through education and marketing during a clinical trial is a brand-building strategy, Frew says.

"Theoretically you should find that you've built a lot of interest in the study," she says. "It will get you attention and awareness of the study."

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CT site successfully recruited minorities for HIV vaccine study

Community recruiters, bus ads helped

When a phase IIb clinical trial site needed to ensure minority enrollment in an HIV vaccine trial, CT staff and investigators tried a variety of successful methods to engage and educate the targeted community.

"We enrolled for two years between March, 2005 and March, 2007, and were one of the top-enrolling sites," says **Paula Frew**, PhD, MPH, assistant professor of medicine in infectious disease and in behavioral sciences and health education at the School of Medicine and Rollins School of Public Health of Emory University in Atlanta, GA.

It's a priority in many HIV clinical trials to enroll minority participants, especially African Americans, because the African Americans are disproportionately impacted by the HIV/AIDS epidemic in the United States.

So investigators first formed a community advisory board (CAB) that included representatives from all of the targeted communities, and then devised strategies for community outreach. Here are their strategies:

• Recruiting black women: CT staff and investigators learned that a good way to reach African American women was to provide face-to-face activities, Frew says.

"We hired a woman from the community who had done clinical trial recruitment with high-risk populations in the past," she explains. "We went into parts of town where they had higher HIV prevalence and had this woman out on the street, meeting people."

The site also hired another woman to help

have discussions with women who might be interested in being part of an HIV prevention study," Frew adds.

Dázon Dixon Diallo, MPH, of SisterLove Inc. of Atlanta, a group focused on HIV/AIDS education for women, was an expert consultant to the vaccine study, Frew says.

"She's an expert on African American women issues related to HIV risk and on communication with the group we were trying to meet," Frew adds.

The site invited African American women to various activities and events an also bought advertising in newspapers and magazines popular in that community, she says.

"It's helpful to extend our reach," Frew explains. "We ran ads on Marta buses, and people thought that was very novel."

The key was having trusted members of the target community help the CT site with designing and doing outreach events that resonated with the target group, she adds.

"We knew where to find women, and that's where we went," Frew says.

• Reaching men who have sex with men (MSM): The CT site used the Internet to reach MSM.

When the study began several years ago, Facebook and some of the other most popular social networking sites didn't exist, but there were other online venues that were frequented by MSM, Frew notes.

"We identified various online sites that we could advertise on, and we placed banner ads on those Web sites," she says. "We also had one of our recruiters go into chat rooms and host discussions with members who were in those chat rooms."

The recruiters were part of the MSM community, who they hired because of their expertise on where the site could find its target population.

"We put about a 40% weight on the recruiters and a 30 to 40% weight on Internet recruiting," Frew says. "We also had a heavy volume of mass media advertising and advertising in local Southern gay newspapers."

A significant proportion of the recruitment budget went toward print and online advertising, and a smaller percentage went toward participation in community events, such as PRIDE, the annual gay festival in Atlanta, Frew adds.

"We had recruiters at the events and often CAB members with us," she says. "Many of the CAB members who are from the community are recognized and trusted in the community, so when people see them, it conveys a certain amount of trust in what we're doing."

• Targeting black MSM: The same strategies employed to reach MSM in general were also aimed at reaching African American men who have sex with men, Frew says.

There were some specific outreach attempts aimed at African American MSM, including having CT recruiters at Atlanta's annual black gay pride event called In The Life Atlanta (ITLA), and ads placed in black gay publications, she notes.

"We made sure we were working with our partners very closely and online, and we reached out through appropriate mechanisms," Frew says.

The efforts resulted in successful minority recruitment and enrollment in the vaccine trial, she says.

"We were very pleased our strategies and behavioral research done in advance of the study paid off for us," Frew says. "All of that investment did yield some reasonable percent of minority participation, and hopefully that will carry over into other studies."

In fact, there already has been a carry-over effect seen in Atlanta, she notes.

"We just finished a phase I microbicide study in Atlanta and 44% of participants were African American women," Frew says.

"It's all about building trust and a relationship with the community and having an informed recruitment approach," she adds. "We did a lot to help us understand the women we were going to try to focus on to enroll in the study, and understanding a lot of factors in advance helped us get to that point." ■

Compliance Corner

Tight ship: CAPTN enlists IRB oversight

Early and frequent collaboration key

When they set out to create a research network to conduct clinical trials in the psychiatric care of children and adolescents, researchers at Duke University's Clinical Research Institute

(DCRI) knew IRB issues would play a major role.

Many of the solo-practice psychiatrists recruited to be investigators in the network would have no IRB affiliation. And because of the funding level, working with a large central IRB wasn't possible, says **Mark Shapiro**, MA, a management consultant specializing in clinical research and drug development who served on the DCRI research team.

"Ultimately, it boiled down to just being cost-prohibitive for the research network," Shapiro says. "The budget for them to review the network probably would have been equal to the entire budget for the network."

So Duke University Health System's IRB agreed to serve as the IRB of record for investigators who needed one, through the use of unaffiliated investigator agreements. Thanks to the IRB's willingness to take on the project, Shapiro says the Child and Adolescent Psychiatry Trials Network (CAPTN) has successfully undertaken multicenter studies of antidepressant safety in pediatric patients, a comparison study of ADHD treatments and other projects.[1]

Shapiro says one key to the success of the venture was the ability of those creating the network to have multiple face-to-face meetings with IRB officials to work out details. Shapiro says his team probably had about 10 meetings with those officials in the nine months before they got final approval.

The structure of the network created some complexities. Duke determined that the individual practice sites would not be added to Duke's Federalwide Assurance (FWA), so the CAPTN project team helped each site file its own FWA. In addition to serving as the IRB of record for the sites, Duke's IRB also was the IRB for the researchers at the CAPTN coordinating center.

Research ethics training (including human subjects protection training) modules created by Duke's Trent Center for Bioethics, Humanities and the History of Medicine was made freely available to investigators, many of whom had no previous experience with clinical trials. This was provided in addition to NCI training or to training offered by local IRBs, if an investigator was affiliated with an institution that had one. ■

CNE/CME Objectives / Instructions

The CNE/CME objectives for *Clinical Trials Administrator* are to help physicians and nurses be able to:

- **review** pertinent regulatory mandates;
- **develop** practical clinical trial oversight strategies;
- **review** best practices shared by facilities that successfully conduct clinical trials.

Physicians and nurses participate in this medical education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue.

Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material.

After completing this activity at the end of each semester, you must complete the evaluation form provided and return it in the reply envelope provided to receive a letter of credit. When your evaluation is received, a letter of credit will be mailed to you. ■

COMING IN FUTURE MONTHS

- ■ Research offers strategy for determining trial risk
- ■ Improve education about writing best corrective action plans
- ■ Update risk analyses for biologics trials
- ■ Update on emergency preparedness

CNE/CME*questions*

21. Good Participatory Practice (GPP) guidelines for biomedical prevention trials were created for work in which field?
    A. Congestive heart failure
    B. HIV
    C. Type 2 diabetes
    D. Avian influenza

22. Which of the following is not part of the Good Participatory Practice guidelines for biomedical prevention trials?
    A. Participatory management
    B. Autonomy
    C. More transparency
    D. All of the above are part of the GPP guidelines

23. When an HIV vaccine phase clinical trial IIB recruited minorities for enrollment, which of the following marketing/outreach tactics helped them achieve a successful 25% enrollment rate?
    A. Forming a community advisory board with leaders and representatives of the target populations
    B. Advertising on buses and in magazines read by target populations
    C. Advertising and outreach on Internet sites and at festivals attended by target populations
    D. All of the above

24. When they set out to create a research network to conduct clinical trials in the psychiatric care of children and adolescents, researchers at Duke University's Clinical Research Institute knew that because of the funding level working with a large central institutional review board was not possible.
    A. True
    B. False

Answers: 21. B; 22. D; 23. D; 24. A.