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# Enrolling Study Led by Nurse Researchers\*

## DASH Trial Explores Best Practices for Adherence

Adherence sounds simple in theory. Yet in reality, many factors influence a consistent ART regimen. To ensure HIV positive treatment naive patients (those having never taken any antiretroviral drugs) start a routine they will follow for life, Tari Gilbert is leading the Durability of Adherence in Self-Management of HIV (DASH) Trial, AIDS Clinical Trials Group study A5250.

“Phase 1 of the study completed in 2011 with patients who had begun HAART within the past year telling us what barriers to adherence they experienced,” says Gilbert, a nurse practitioner at the University of California at San Diego Antiretroviral Research Center. “In Phase 2, treatment naive patients will receive either standard adherence counseling at their site or individualized adherence self-management training.”

The two sites currently participating in the study are the San Diego site and the Barranco Clinical Research Site 11301 in Lima, Peru. In order to be eligible for the study, participants must live near either city and be at least 18 years old. If accepted into the trial, Gilbert says participants will be randomly assigned either standard adherence counseling or individualized adherence self-management. If they receive the individualized plan, they will answer a questionnaire with their answers leading to the creation of their plan. Both groups will check in at weeks four and 12 and, then every 12 weeks for a period of 72 weeks.

“This study is long. I know of another adherence study that ran 24 weeks, but not 72,” Gilbert says. “Adherence is so important. If you can cement good adherence, that behavior will be there forever.”

For more information about the DASH study, contact Tari Gilbert:

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**“If you can cement good adherence, that behavior will be there forever.”**  
- Tari Gilbert, NP, UCSD

Gilbert hypothesizes that the targeted, individualized intervention will increase adherence, help manage medication side effects and lead to a higher quality of life. The targeted interventions were created based on the input from Phase 1 of the study and from clinical providers. The intervention is also modified as the patient reports barriers to adherence.

Having an international site involved has brought to light issues stateside clinicians had not thought about when creating the study.

“The structural context in Peru is different from U.S. sites,” Gilbert says. “They do a great job giving patients medication, but sometimes their supply is not available. That is not a problem we face in the US and not a barrier to adherence that we had considered. Medication regimens in the Peru also differ from the US because they are still using older medications with more side effects. We do have some barriers in common though. Stigma is still a big issue in both countries.”

In addition to hoping the study yields the best practices for ensuring adherence, Gilbert is looking forward to more nurse-led research studies. “With the position we are in, we are afforded nice relationships with our patients,” she says. “It has been so rewarding to collaborate with our international colleagues and I am excited to have a working relationship that extends outside of the United States. I am honored to be a part of the ACTG and hope to work on future projects with other nurses.”

\* Photo on the cover from left to right: Tari Gilbert, NP, UCSD; Patricia Segura, RN, M. Ph., Head of Community Education and Involvement for Impacta; and Fanny Rosas, RN, Impacta's ACTG Study Coordinator

# Education Dispels Myths in Africa

When a state-of-the-art infectious diseases research laboratory opened its doors in Kalingalinga, Lusaka, Zambia, instead of being thrilled, residents felt threatened. Lab staff quickly learned that a lack of educating the community about the purpose of the site spawned inaccurate rumors and even violence.

Harry Tembo, Community Advisory Board (CAB) member of the Center for Infectious Diseases Research in Zambia (CIDRZ), presented about the miscommunication during the recent International AIDS Conference and the AIDS Clinical Trials Group (ACTG) Annual Network meeting, both held in Washington, DC.

A member of the ACTG Network, the ultra-modern laboratory supports HIV/AIDS research as well as studies about co-infections. But residents thought the lab was a place foreigners went to for blood samples used to support satanic activities. Other myths about the lab included claims that it was a storage facility for dead bodies.

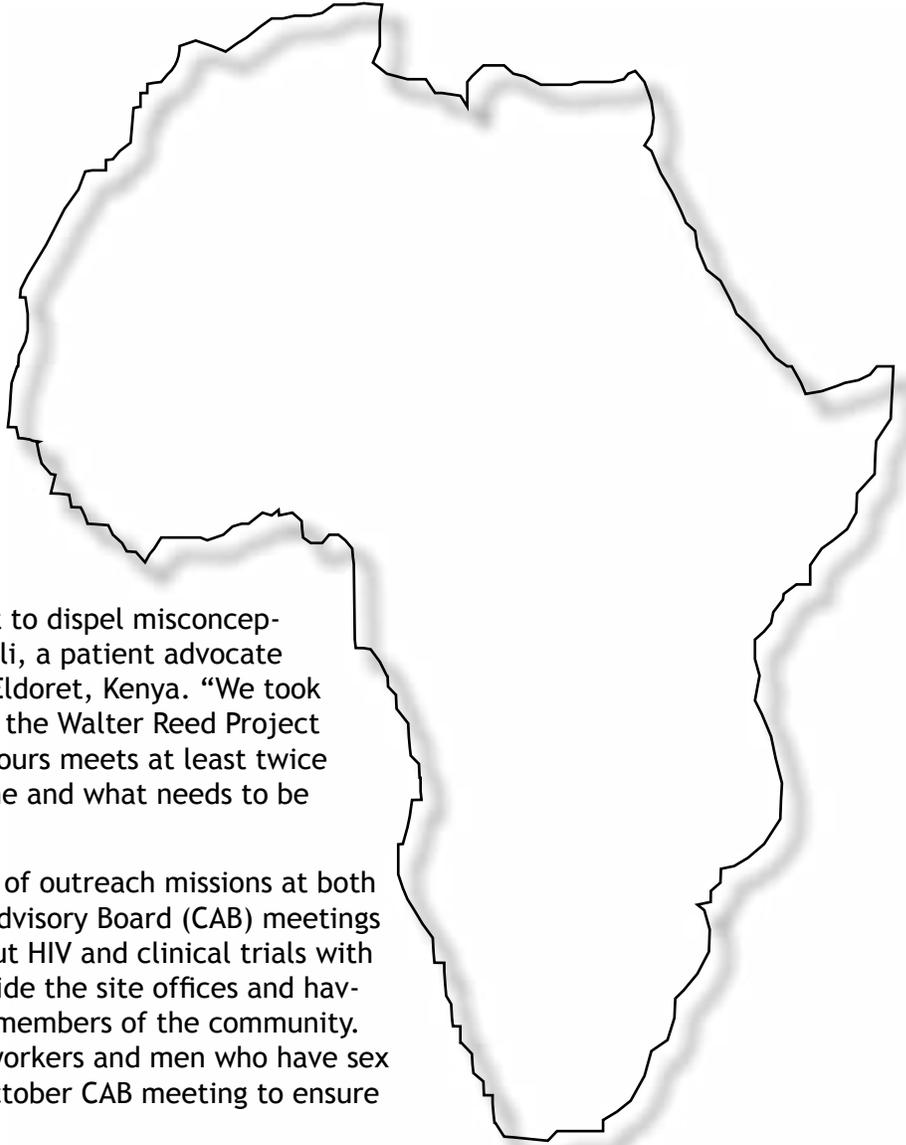
A similar situation happened at an ACTG site in Kericho, Kenya in 2011. Police stormed the Walter Reed Project Kenya Medical Research Institute after reports that a minor died from donating blood. The claims were false, but the rumors startled the community.

“Educating the community is important to dispel misconceptions and create trust,” says Amina Shali, a patient advocate at MOI University Teaching Hospital in Eldoret, Kenya. “We took the steps to remedy the situation after the Walter Reed Project misconception, and now their site and ours meets at least twice a year to gauge how much we have done and what needs to be done.”

Shali said the incidence led to creation of outreach missions at both sites. Three times a year, Community Advisory Board (CAB) meetings focus on educating the community about HIV and clinical trials with CAB members travelling to venues outside the site offices and having face to face meetings with various members of the community. Youth living with HIV, commercial sex workers and men who have sex with men (MSM) are invited to every October CAB meeting to ensure there are ambassadors from all groups.

“We work closely with the Walter Reed Project - Kericho CAB and the Partners in Prevention Study (PIPS) CAB. PIPS are in charge of the PrEP study and former clinical trials participants share their own personal experiences, which has promoted confidence and integrity” Shali says.

Back in Zambia, CIDRZ research staff and CAB members decided to act quickly and brainstormed ways to dispel the myths about the work being done at the site. CAB members like Tembo contacted influential community members including: church and civic leaders, men and women’s groups, youth sports teams and HIV/AIDS support groups. During these meetings, the process and importance of clinical trial research were outlined. Tours of the CIDRZ were provided to residents, offering them a chance to see exactly what was going on behind the doors of the new facility.



# International Study Yields Daily Safe, Effective ART Dosing

Researchers from the AIDS Clinical Trials Group have identified a safe and effective once daily combination of antiretroviral drugs well-suited for initial treatment in diverse populations.



*Thomas Campbell, MD, second from right, is pictured along with the other PEARLS Study Co-Chairs.*

Since most research on initial treatment was based in high income countries, The Prospective Evaluation of Antiretrovirals in Resource Limited Settings (PEARLS) or the A5175 study launched with a goal of testing the safety and efficacy of initial treatment in a culturally diverse population. Another aim of the study was to ensure women were well represented. Sites in nine countries enrolled in PEARLS and 47 percent of study's 1,571 participants were women.

The study compared three combinations of protease inhibitors and non-nucleoside reverse transcriptase inhibitors. The results showed that the antiretroviral drug efavirenz given in combination with emtricitabine-tenofovir-disoproxil-fumarate (EFV + FTC - TDF) was safe and effective in a once daily dose, espe-

cially for women. Thomas Campbell, MD, Principal Investigator at the Colorado AIDS Clinical Trials Unit, was the study's co-chair.

"What is significant about our findings is that EFV + FTC-TDF was safer, especially in women with HIV," Campbell says. "This is important because the regimen more commonly used now for initial treatment is not this combination. We hope our research provides countries with further evidence to adapt to using FTC-TDF-based regimens instead."

Campbell says the drug combinations more commonly prescribed for initial treatment in low-income countries include co-formulated lamivudine-zidovudine (3TC-ZDV). Although this is as effective as FTC-TDF, it is not as safe, especially in women. He credits these findings to the diligent work of site staff and study volunteers.

"The study team is grateful to all the participants and the site staff who worked on this study for close to a decade," Campbell says. "Without their hard work and dedication, these results would not be possible."

The study's results are in line with UNAIDS Treatment 2.0 plan that recommends simplified dosing, fewer side effects and lower long-term toxicity for antiretroviral therapy. The study also showed a difference in response between men and women opening the field for further research into sex-specific ART recommendations. The findings appeared in the [journal PLOS Medicine](#).



*Investigators from nine countries led the PEARLS study.*

# Education Dispels Myths in Africa

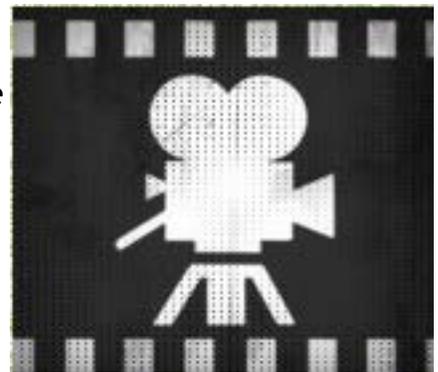
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“Success of any HIV/AIDS clinical trial or research is to a great extent dependent on effective community sensitization, education, involvement and participation,” Tembo says. “Without these, there will be negative speculation, myths, misconceptions and community apathy in HIV/AIDS trials. This may also lead to non-adherence to HIV/AIDS and TB treatment.”

Study volunteers now inform others of the importance of HIV/AIDS research and community participation. Site staff and community relations have become sound and clinical trial participation has equally improved. Thanks to these educational efforts and tours, myths and misconceptions about the research and clinical trials being conducted at the CIDRZ were corrected.

## Videos: Don't Reinvent the Wheel

Several ACTG sites are exploring the possibility of adding a video component to their upcoming studies to help educate potential study volunteers about what participation entails. These videos can be used to show and explain a procedure that would be necessary for study volunteers during the trial.



Since these efforts are ongoing, please feel free to contact Morag MacLachlan, ACTG Communications Specialist, at [mamachlan@partners.org](mailto:mamachlan@partners.org). She can help you figure out what resources you will need and if another site has already produced a video you might be able to use. Don't go it alone as you might be making more work for yourself!

Please remember that the ACTG has three videos on its YouTube channel explaining study involvement from minority participants' perspectives. All videos include subtitles and one is completely in Spanish. Told by actual past study volunteers, these are great tools for you to use. You can access the videos by logging onto <http://www.youtube.com/actgnetwork> and clicking on the Inside/Out videos.

## Questions, Comments and Story Ideas

This is the inaugural edition of the ACTG Update. If you would like your enrolling study featured or results from your completed trial highlighted, please contact Morag MacLachlan at [mamaclachlan@partners.org](mailto:mamaclachlan@partners.org). Any questions, comments and story ideas are also welcomed.

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