



SPOTLIGHT

FOCUS: Training the Next Generation of AIDS Experts

Dr. Mame Awa Touré was determined to unlock the mystery of AIDS by investigating the virus itself. Her resolve led her to seek specialized research training in the Fogarty AIDS Training and Research Program (AITRP) at the Harvard School of Public Health AIDS Initiative (HAI).

For almost 17 years, AITRP at HAI has trained scientists and biomedical researchers in AIDS research. Candidates come from countries that generally lack the infrastructure or resources to conduct advanced training in AIDS research. Participants take courses in the field of epidemiology, biostatistics, immunology, molecular biology, behavioral sciences or other sciences related to epidemiology. Trainees then return home to disseminate the skills-based education they received, and often become clinical researchers, lab researchers, faculty members, and principal investigators of their own AIDS research studies.

The participating program countries at HAI include Botswana, Senegal, Tanzania, and Thailand, with more recent additions of China and Nigeria. Each country hosts ongoing AIDS research projects, usually supported by the National Institutes of Health. Trainees are given the unique opportunity to work first-hand with Harvard collaborators and local investigators on research that examines the disease from various approaches.

The Botswana program has a large research base with three major research programs that support designated treatment, vaccine trials, and studies on the prevention of mother to child transmission. The program site also hosts the most comprehensive HIV reference laboratory and research facility in southern Africa.

The Tanzania program hosts two sites. The Muhimbili Medical Center, located in Dar es Salaam, focuses on nutritional studies and viral epidemiology in mother and infant populations. The Kilimanjaro Christian Medical Centre, located in Moshi, concentrates on a large cohort of hotel and bar workers. In this group, researchers examine the epidemiology of the sexual transmission of HIV, particularly for the role of cofactors such as Herpes Simplex in transmission, and for the evaluation of microbicides.



Students learn from renowned AIDS researchers and scientists.

Bangkok and Chiang Mai are the city centers of the Thailand program. Research focuses on mother and infant chemoprophylaxis. The Bangkok site examines the viral epidemiology and the characterization of the HIV-1 subtype E, the subtype that is endemic to the country.

Senegal was the first major collaborator for HIV studies at Harvard. The partnership began in the late 1980's, and together with investigators at HSPH, made the research discovery of HIV-2 and showed that it transmits much less efficiently than HIV-1 and causes AIDS less often. AITRP trained staff in Senegal have also been in-

strumental for training in epidemiological and laboratory skills in Nigeria. Each year several of the Senegal staff work jointly with Harvard staff to offer short course training in Nigeria and laboratory-based training for Nigerians in Senegal.

The collaboration with the China program developed from interrelated goals in HIV vaccine studies. Similar types of the HIV virus appear in both countries – China with a B/C recombinant which is mostly HIV-1 subtype C, and Botswana with the predominant HIV-1 subtype C virus. The collaboration has resulted in two major vaccine designs that will be tested soon.

After Dr. Mame Awa Touré earned her MS degree in epidemiology as an AITRP fellow at Harvard, she returned to work in the Ministry of Health in Dakar, Senegal. She continues to work with the national ARV program in Senegal, which is now in its fourth year of operation. The program has successfully started HAART therapy in approximately 1,000 HIV-infected individuals and conducted three separate pilot clinical trials since 1998.

Dr. Touré is also helping to implement the ARV program in the registered female sex workers cohort in both HIV-1 and HIV-2 infected women.

Dr. Touré is one of 63 researchers who has graduated from the AITRP at HAI. All are future AIDS experts who continue to make their indelible mark on the epidemic. ●

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Dr. Tonya Villafana
AIDS Researcher

A native of Trinidad and Tobago, Dr. Tonya Villafana is the site director of the HIV Vaccine Initiative (HVTN 048) at the Botswana Harvard School of Public Health AIDS Initiative Partnership for HIV Research and Education.

Dr. Villafana's extensive responsibilities include establishing and overseeing sites in Botswana for HIV vaccine trials and HIV vaccine-related research. She provides training and technical support to the vaccine initiative staff and supervises the implementation and coordination of vaccine initiative activities. She is also the primary liaison for national stakeholders in vaccine research, including the Botswana Ministry of Health, and the National HIV Vaccine Committee; and international collaborators such as the US NIH Division of AIDS, and the US HIV Vaccine Trials Network.

Dr. Villafana has been honored with awards for her accomplishments, including the 2004 International Award, HVTN Site Director of the Year, HIV Vaccine Trials Network;

and the 2003 Fellowship Award, Fourth Advanced Vaccinology Course, Fondation Merieux, Veyrier du Lac, France. She was the recipient of the Jack and Susan Rudin Scholarship, Cornell University Graduate School of Medical Sciences, New York, NY 1992-1998.

Spotlight: How is the HVTN 048 vaccine produced, and is there any likelihood of participants becoming infected with HIV or AIDS by receiving this vaccine?

TV: The experimental vaccine being tested in the HVTN 048 trial is the Epimmune EP HIV-1090 DNA plasmid vaccine. The vector, or carrying device for the vaccine candidate is a DNA plasmid, a small molecule of DNA that can easily be made to carry the working part of the vaccine. The working part of the vaccine is made from small, harmless pieces of HIV known as epitopes. These pieces cannot cause HIV infection and so participants cannot become infected with HIV from the vaccine.

The hope is that they will teach cells in the immune system how to recognize and fight HIV if it is exposed to the real virus. There is an additional epitope included in the vaccine which can help the immune system have a stronger and longer-lasting response. The vaccine is mixed with an enhancer called an adjuvant, which helps the body absorb the vaccine into skin and muscle cells.

Spotlight: Considering the huge cultural differences between countries such as Botswana and the United States, have those differences caused any major challenges for the HVTN 048 vaccine trial efforts?

TV: There were challenges with regards to the conduct of the 048 HIV vaccine trial, which were overcome by ongoing

community education efforts. One of the first things we did in preparing to conduct trials was to establish a Community Advisory Board to guide the research team on how to address community issues and concerns. We also have a community education team who pays attention to issues raised by the community.

In our consent form, we explain all potential risks to participants. There are times when issues, myths and misconceptions about the research process in general and HIV vaccine research in particular are raised. We address these issues with each participant and through ongoing education and recruitment efforts.

Spotlight: In most cases researchers hope to be able to stop early infection in its tracks and, eventually, prevent the disease before it begins. What do you hope to accomplish in the HVTN 048 Vaccine trial?

TV: The HVTN 048 trial is a phase I safety trial meaning that the experimental vaccine candidate is being evaluated for the first time in human beings. The primary objective of the trial is to look at the safety or side-effects of the experimental vaccine in HIV negative adult volunteers. The secondary objective is to determine if the vaccine can generate an immune response in volunteers. Ultimately the goal is to move a particular vaccine candidate through different phases of the HIV vaccine trial process which will take seven to ten years. It is only after large scale efficacy trials that it can be determined if a particular vaccine candidate can prevent HIV infection. Early phase-I trials such as HVTN 048 will not be able to answer questions about protective efficacy. ●

NEWS & EVENTS

First Annual PEPFAR Tri-Country Conference

The Harvard School of Public Health's AIDS Treatment, Care and Prevention Initiative in Africa, funded as a part of President Bush's Emergency Plan for AIDS

Relief (PEPFAR), held their first annual Tri-Country Conference, January 29-February 4 in Botswana. The conference was designed to allow investigators in the partner countries to share progress and lessons learned, and promote best practices across

the program. The conference provided a forum for discussing protocols and issues, and developing plans to meet training needs and collaborate on new multi-country research studies.

(continued on last page)

Partnership to Develop HIV Training Program for China

Henan province in China was an unlikely center for the AIDS epidemic in China, but this rural community made international headlines when it experienced a major HIV outbreak in the late 1990s. The outbreak was caused by a blood buying program that infected tens of thousands of people. In response to the epidemic, the Chinese government launched China CARES (Comprehensive AIDS Response) offering testing, counseling and free ARV treatment to infected former plasma donors in Henan and four other provinces.

In operating the program, however, it soon became apparent that more doctors and health workers needed to be trained to administer the new ARV medications. HAI's China Project began working with officials in China in 2002 to set up AIDS care training programs for local physicians.

Last Fall, Dr. Yichen Lu and other HAI research scientists welcomed a delegation of physicians and government officials from the Henan province to Harvard to learn more about HAI's ARV treatment programs in Botswana, Nigeria, and Thailand. While in Boston, the delegation visited area hospitals and AIDS treatment centers to learn how these organizations address the wide range of



AIDS treatment and care issues including ARV monitoring and human rights.

The group also worked with HAI faculty and research scientists to develop a practical training manual for HIV/AIDS Care. Based on the KITSO AIDS Training Program developed by HAI for use in Botswana, the manual was translated into Chinese and modified to meet the requirements to train both village doctors in Henan and neighboring provinces.

High-ranking Heilongjiang health officials, who previously attended an introductory HIV/AIDS medical training course presented by HAI at Fudan University, requested that HAI instructors hold a similar AIDS training workshops to enhance local

expertise. In January, HAI and the Heilongjiang provincial CDC offered a workshop in the city of Harbin, Heilongjiang province, using the newly tailored manual. A team of American professors including Dr. Sandy Burchett and Dr. Marcus Altfeld of Harvard Medical School and Dr. Yichen Lu and Dr. Roger Shapiro of HAI, traveled to China, where they were joined with many distinguished Chinese experts including Dr. Shen Jie, director of National Center for AIDS (NCAIDS), Beijing, Dr. Zhang Fujie, director of the National AIDS Treatment Program in NCAIDS, Beijing, Dr. Gui Xian, from the Wuhan University Medical School, and Dr. Cheng Xiaoduan, chief of the Wenhou clinics at Shangcai county, Henan province.

The professors taught "AIDS in China: Training and Research Workshop" to a group of trainees which included regional CDC chiefs and key infectious disease clinicians and researchers in the province, and several public health officials from Jiangxi, Henan, Jiangsu, Neimeng and Hainan provinces. The trip to Harvard and the workshop were supported by the United States National Institutes of Health Office of AIDS Research and the Heilongjiang CDC. ●

RESEARCH & INTERVENTION PROGRAMS

New HIV Vaccine Trials Network Vaccine Trial

The Botswana-Harvard School of Public Health AIDS Initiative Partnership for HIV Research and Education facility in Gaborone, Botswana has been chosen as a study site for an upcoming Phase I vaccine trial of the HIV Vaccine Trials Network. The trial will test an alphavirus replicon HIV subtype C gag vaccine, and determine the safety and tolerability of escalating doses of the vaccine in healthy HIV-1 uninfected participants. The study will enroll ninety-six participants. Other study sites for the year-long study include South Africa and the United States. The study is funded by Division of AIDS, National Institute of Allergy & Infectious Disease, and the National Institutes of Health, Department of Health and Human Services.

"Netefatso" HSV2-HIV Transmission Study

The Netefatso ("Netefatso" means "to verify" in Setswana) Study aims to determine the efficacy of using Acyclovir, a commonly used drug to treat Herpes Simplex 2, in reducing HIV transmission among discordant couples (one person is HIV-infected and the other is not). Since the study officially began in January 2005, study staff have seen over 150 discordant couples referred to them from other facilities and have about 50 couples eligible for screening once the study clinic is opened.

Netefatso study nurse counselors have been instrumental in the study's progress and began preparing for the study in the previous year. Nurse counselors attended a capacity building workshop on Couples' HIV Counseling and Testing (CHCT) organized by the United States Centers for

Disease Control and Prevention in Johannesburg, South Africa in April 2004. They successfully lobbied the CDC to hold their first Africa regional CHCT curriculum pre-test training workshop in Gaborone, Botswana this past July. They have since been very active in working with the community to increase the number of couples coming in for voluntary HIV counseling and testing.

The Netefatso team is also currently involved in conducting community awareness talks on the necessity for couples HIV counseling and testing under the theme: "Your partner's HIV status is not necessarily always yours." The study is being funded by the Bill and Melinda Gates Foundation through the University of Washington.

To learn more about these programs, visit <http://aids.harvard.edu/programs>. ●

Upcoming HAI-related Events

Wednesday, February 23, 2005

AIDS in Africa: Actionable Solutions

Lecture by Dr. Debrework Zewdie, The World Bank Group
Harvard School of Public Health, Boston, MA
(Africa Health Forum)

Thursday & Friday, April 14-15, 2005

Critical Research Ethics Issues in the Era of HIV in Tanzania
The Courtyard Hotel, Dar es Salaam, Tanzania

Monday & Tuesday, April 18-19, 2005

Critical Research Ethics Issues in the Era of HIV in Tanzania
Kilimanjaro Crane Hotel, Moshi, Tanzania

Friday, April 29, 2005

The 1st Congress for Health Care Professionals
AIDS/HIV Continuing Education
Hotel Cielo Mar, Aguadilla, Puerto Rico (ECI Puerto Rico and
Florida Caribbean AIDS Education Training Center)

For more information on these events visit: http://aids.harvard.edu/conferences_events

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Clinical Research Ethics Issues in the Era of HIV in Tanzania

Researchers at the Harvard School of Public Health are working to solve some of the most pressing public health concerns in the world from malnutrition to HIV. A number of the research studies reviewed by the Harvard School of Public Health's Human Subjects Committee now take place in developing countries. One of the major challenges in working in these countries is ensuring that despite differences in language and culture, participants fully understand the risks and benefits of enrolling in a study.

To help healthcare professionals, administrators and HIV researchers in Tanzania (the country that has the largest share of studies at HSPH) learn more about the ethical standards for research with human subjects, a two-day ethics course will be offered

April 14-15 in Dar es Salaam and April 18-19 in Moshi.

The course entitled, "Critical Research Ethics Issues in the Era of HIV in Tanzania," is being jointly offered by the AIDS International Research and Training Programs (AITRP) at Dartmouth, Boston University, Duke University and the Harvard School of Public Health in collaboration with the Kilimanjaro Christian Medical Centre and Muhimbili University College of Health Sciences.

Sarah Putney, the director of the Human Subjects Committee for the Harvard School of Public Health, and a course co-director said, "We aim to share the spotlight evenly between Western speakers and African speakers, and to include up to 140 participants from the Moshi/Arusha and Dar es Salaam regions who might otherwise not be able to get to such a conference because of

the high cost of travel. We hope to have lively debates, free discussions, and practical problem solving." Registration for the course is free. For more information, visit: www.hsph.harvard.edu/hsc. ●

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