

TREAT ASIA REPORT

The Promise of Antiretrovirals: When Treatment and Prevention Converge

The *TREAT Asia Report* Interview: Quarraisha Abdool Karim, Ph.D.



(Photo: CAPRISA)

Quarraisha Abdool Karim, Ph.D., is associate scientific director of CAPRISA (the Centre for the AIDS Program of Research in South Africa), which tested the first vaginal microbicide to successfully help protect women from HIV infection. She is also adjunct professor at the Nelson R. Mandela School of Medicine, University of KwaZulu-Natal, South Africa, associate professor at the Mailman School of Public Health at Columbia University in New York, and co-chair of the HIV Prevention Trials Network.

TREAT Asia Report. Almost a year ago, you and your colleagues announced the results of the CAPRISA microbicide trial, which found that a tenofovir-based vaginal gel cut a woman's risk of HIV infection by roughly half—the first good news about HIV prevention for women in a long time. Hopes were expressed that a product would be available to women within three years. Can you tell us where that process stands now?

Dr. Quarraisha Abdool Karim: The results of the CAPRISA 004 trial have injected much more energy and hope into the fields of microbicides

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TREAT Asia and Partners Move Treatment to Center Stage

The Imperative of Treatment in Asia

Even before recent research confirmed the powerful preventive effect of antiretroviral therapy (ART) on HIV transmission, demand for improved and expanded HIV treatment had been escalating around the world. Late last year, the World Health Organization (WHO) released treatment guidelines encouraging physicians to initiate ART far earlier than previously recommended, a target that stands to further intensify demand for anti-AIDS drugs.

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A pharmacist in Malaysia explains treatment issues to an HIV-positive child's caregiver.

The Temptation to Sacrifice Quality for Quantity



In the push to scale-up antiretroviral therapy (ART), we cannot forget our commitment to quality—the quality of drugs and drug regimens, patient support, provider education, and laboratory monitoring. At this point in the history of HIV/AIDS, we know a great deal about what works well and what doesn't on many fronts. Yet suboptimal

drugs are still being employed and effective prevention strategies remain underutilized. Why are we not phasing out stavudine (d4T) in both adults *and* children? Why is the Asia-Pacific region behind Africa in coverage of interventions to prevent mother-to-child HIV transmission?

In this issue of the *TREAT Asia Report*, Dr. Quarraisha Abdool Karim shares her insights into sustainable ways to introduce high quality ART in resource-limited countries—and fills us in on when women might have access to the microbicide she helped test through CAPRISA. We also examine the expansion of treatment through the lens of the new Asia Treatment Working Group, and look at a program that focuses on strategies for delivering pediatric treatment in the face of

drug resistance. Finally, we include a research update on lipodystrophy and its association with d4T in the TREAT Asia HIV Observational Database—results that mirror earlier findings in children by pediatric network partners in Thailand.

We cannot sacrifice long-term success to the urgency of short-term treatment numbers.

The past year's advances in HIV research have been "game changers," as UNAIDS' Michel Sidibé has said, showing us that the epidemic could be slowed or even halted if the goal of universal treatment could be realized. Putting people on ART is a critical step, but we need supportive health systems and broader access to antiretroviral medicines to ensure that they can stay on treatment over a lifetime. We cannot sacrifice long-term success to the urgency of short-term treatment numbers. As we set out to reach the United Nations' ambitious new treatment targets to get 15 million HIV-infected people on ART and eliminate mother-to-child transmission by 2015, quality must be a priority.

Annette Sohn, M.D.

Major TREAT Asia Grant Extended Another Five Years

A major research grant to support TREAT Asia's work in the Asia-Pacific has recently been renewed for a second five-year period by the US National Institutes of Health. As the regional representative of the International Epidemiology Databases to Evaluate AIDS (IeDEA) since 2006, TREAT Asia has been contributing data from its adult and pediatric observational cohorts to a global database that allows researchers to address key questions about antiretroviral therapy (ART) outcomes and how best to optimize treatment approaches. Funding for this grant is provided by the National

Institute of Allergy and Infectious Diseases (NIAID), the Eunice Kennedy Shriver National Institute of Child Health and Human Development, and the National Cancer Institute.

"The TREAT Asia research funded by NIAID five years ago is one of very few studies providing information on the treatment and treatment outcomes of HIV-infected patients in an area that includes nearly two-thirds of the world's population," said Gerald B. Sharp, Dr.P.H., of NIAID's Division of AIDS. "These studies have shed light on the outcomes of HIV infection and ART, including lipodystrophy, anemia,

viral suppression and treatment failure, HIV progression, and liver disease for patients with both HIV and hepatitis, which are highly prevalent infections in this region.

"TREAT Asia also has developed one of the most comprehensive cohorts for studying HIV-infected children and adolescents in Asia, providing information on treatment failure and second-line regimens as well as survival and disclosure of HIV status to pediatric patients," Dr. Sharp added. "We're particularly pleased that TREAT Asia plans to support new studies using large HIV databases in China in the renewal grant." ■

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The information in the *TREAT Asia Report* is compiled from a variety of sources and may contain controversial views and opinions not endorsed by amfAR. Material in the *Report* should not be used as the basis for medical diagnosis or treatment.

This newsletter is also online at www.treatasia.org.

TREAT Asia Report

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AIDS RESEARCH

When Children Face Treatment Failure Mastering the Art of Pediatric HIV Treatment

At only 18 months of age, a child with HIV was brought into a Bangkok clinic already experiencing first-line antiretroviral therapy (ART) failure. Given her age and local drug availability, her doctor had limited choices for constructing a second-line regimen. If the child developed treatment failure again, there would be few options to which the doctor could turn.

Such stories can be troublingly familiar to physicians caring for children with HIV in Asia. Early treatment failure presents a serious threat to almost 40,000 children estimated to be on ART in the region. When failure occurs and patients are no longer responding to ART, clinicians need to determine how to construct a new regimen to avoid the use of less effective medicines that can make drug resistance worse. Since few countries in the region provide free access to routine viral load monitoring, pediatricians often have to rely on treatment failure criteria that may not be sensitive enough to identify children who need immediate intervention.

To help pediatricians across the region better understand the art of managing HIV treatment for children, TREAT Asia is offering a series of specialized workshops as part of a pediatric initiative launched last year through ViiV Healthcare. “Doctors have to weigh the potential consequences of changing drugs too soon or too late,” said TREAT Asia Director Annette Sohn, M.D., who is also a pediatric HIV clinician. “Switching too soon carries risks because second-line is the last line of treatment for many HIV patients in the region. But doing it too late can be worse because of increasing drug resistance.”

The workshops build on the clinical experience of TREAT Asia network pediatricians by enlisting them to help train colleagues in their own countries. The core curriculum was first presented in August 2010 and the training is now being implemented across the region, led by TREAT Asia clinicians and other local experts.

“With so many of us facing the dilemma of treating HIV-positive children who are failing their regimens, pediatric workshops specially focused on the needs of clinicians in this region are absolutely needed,” said Nik Khairulddin Nik Yusoff, M.D., of Malaysia’s Hospital Raja Perempuan Zainab II. “Each country is unique in the burden of disease, health systems, and resources, and we certainly learned novel and innovative ways of addressing certain challenges.”

After attending the workshop himself in Bangkok, Dr. Nik, a TREAT Asia pediatric network investigator, helped teach a subsequent workshop in Kuala Lumpur, which was attended by more than 40 physicians and nursing staff, and he will do so again in Jakarta for Indonesian pediatricians in July. Organized as one-day programs to reduce the time that clinicians need to be away from their patients, workshops will also be held in Hanoi and Ho Chi Minh City, Viet Nam, in August.

Dr. Sohn is optimistic that the program will help improve treatment and care for Asia’s youngest HIV patients. “This initiative gives us a new opportunity to explore this model of education and training, and to utilize our network to spread knowledge about evidence-based treatment,” she said. ■



TREAT Asia investigator Dr. Nik Khairulddin Nik Yusoff is helping train pediatricians on treatment failure.

Lipodystrophy in Asia: Why Haven't We Phased Out d4T?

Lipodystrophy—a condition in which fat on some areas of the body shrinks or increases—is one of the most potentially disfiguring side effects of antiretroviral therapy (ART). In severe cases, lipoatrophy, which involves fat reductions in the face and arms, and lipohypertrophy, which involves increases in fat on the abdomen or back of the neck, can lead to stigma and discrimination, and the fear of developing it can lead people with HIV to avoid starting treatment.

A recent study from the TREAT Asia HIV Observational Database (TAHOD) examined how common lipodystrophy is in Asia among people on ART, and what factors increased the risk for having it.¹ A total of 2,072 patients from 12 clinics in 12 Asian countries were included in the analysis. The researchers focused on patients who were reported by their doctors to have severe lipodystrophy, defined as disfiguring or obvious body shape changes.

Lipodystrophy was diagnosed in 217, or 10.5 percent, of those in the study at a median age of 36 years. The study found that there was an increased risk of lipodystrophy for those on ART for the longest periods of time (16 percent of those on treatment for longer than the median of 3.8 years; 5 percent of those on treatment for less than that period), or who were on the antiretroviral stavudine (d4T). Up to 19 percent of patients who ever took d4T had lipodystrophy, compared to 1 percent of those who never took the drug. Taking zidovudine or a protease inhibitor was associated with a lower risk of lipodystrophy compared to never taking those drugs.

These findings confirm those of other researchers that the use of d4T is a strong risk factor for the development of lipodystrophy in Asia. Although the World Health Organization recommended in 2010 that countries begin phasing out d4T, its low cost means that it continues to be one of the most

HIV Linked to Lower Scores on Children's Intelligence Tests

Children who were infected with HIV at birth have been shown to have a higher risk of delays in various aspects of their development due to the damage HIV can cause to the brain. A study conducted in Chiang Mai, Thailand, focused on evaluating the cognitive functioning of children with HIV by

looking at their performance on an intelligence test.¹

The study assessed three groups of Thai children 6-12 years of age: 39 with HIV, 40 who were exposed to HIV (their mothers were HIV-positive but they were not), and 42 neither infected nor exposed to HIV. Of the children

with HIV, 87 percent had already been started on antiretroviral therapy.

The Thai researchers gave the children in this study an intelligence test that was modified and translated for use in Thailand, based on the Full Scale Intelligence Quotient (of the Wechsler Intelligence Scale for

Children Version III). An average score of 90-109 on this test is considered to reflect an "average intelligence" level. Intelligence test scores are not designed to determine how bright children are or to assess their potential for learning, but they are an indicator of how children may perform in school settings.

In the first assessment, administered six months after enrollment in the study, the Thai children with HIV had lower test scores (average score of 79) than HIV-exposed but uninfected children (average score of 88) and unexposed children (average score of 96). Although 76 percent of children who were not exposed to HIV scored at the level of "average intelligence," only 21 percent of children with HIV scored at that level. In a second assessment, administered 30 months later, all children scored lower on



(Photo: Louis V. Galdieri)

commonly used drugs to treat HIV in resource-limited settings. The potential negative impact of lipodystrophy on long-term treatment success and program retention should play a greater role in the policies of national HIV programs, and outweigh the short-term benefits of a cheaper drug. ■

1. Han SH, Zhou J, Saghayam S, Vanar S, Phanuphak N, Chen YM, Sirisanthana T, Sungkanuparph S, Lee CK, Pujari S, Li PC, Oka S, Saphonn V, Zhang F, Merati TP, Law MG, Choi JY, for TREAT Asia HIV Observational Database. Prevalence of and risk factors for lipodystrophy among HIV-infected patients receiving combined antiretroviral treatment in the Asia-Pacific region: Results from the TREAT Asia HIV Observational Database (TAHOD). *Japan Endocrine Society*. 2011 Apr 27. [Epub ahead of print]

Risk Behavior and HIV Among MSM in Malaysia

Sex between men is illegal in Malaysia and homosexuality is highly stigmatized. HIV organizations are consequently faced with the challenge of advocating for safe sex in an environment in which anal sex is prohibited and spaces where men meet are subject to police raids. In addition, clinical anecdotes suggest that HIV incidence may be increasing among men who have sex with men (MSM) in Malaysia.

To assess HIV prevalence and understand risk behaviors and knowledge about HIV transmission among MSM in Kuala Lumpur, a study—funded by a grant to the Malaysian AIDS Council from amfAR, with additional support from the World Bank—was conducted among men from Malaysia’s three main ethnic groups attending local entertainment venues. A total of 517 Malay, Chinese, and Indian men completed a survey on their risk behaviors and received an oral, rapid HIV test.¹

Among the participants, 3.9 percent tested HIV-positive, compared to 0.5 percent among the general Malaysian adult population. In addition, 59 percent of all participants reported that they had never previously been tested for HIV.

Knowledge of HIV transmission was relatively high, with 80 percent understanding that HIV can be transmitted via anal sex. Almost half, however, reported having unprotected anal sex with a casual partner in the past six months. Within the three population groups in the study, the only significant difference observed was that Malay men were more likely to report unprotected anal sex with a casual partner than Chinese men.



Surveys and HIV testing were conducted among MSM at a cruising park to determine levels of risk behavior. (Photo: CeRIA, University of Malaya Medical Center, Malaysia)

The high-risk behavior and lack of easily accessible HIV testing for MSM observed in this study raise concerns about the potential for further growth in the HIV epidemic among MSM in Malaysia. The study authors acknowledge the current restrictive legal and social environment, which makes prevention work and behavioral interventions difficult, but stress the urgency of providing effective HIV education to Malaysian MSM. ■

1. Kanter J, Koh C, Razali K, Tai R, Izenberg J, Rajan L, Van Griensven F, Kamarulzaman A. Risk behavior and HIV prevalence among men who have sex with men in a multiethnic society: A venue-based study in Kuala Lumpur, in Malaysia. *International Journal of STD & AIDS*. 2011;22: 30–37.

their speaking and reading questions. It is important to note that family income was lower among those with or exposed to HIV, as were parents’ and caregivers’ age and education levels.

The researchers noted that the poor test scores among children with HIV could be the result of multiple factors, including the effect of HIV infection on brain development during the first few years of life, the socioeconomic status of the family, and the lack of parental care for orphans. By receiving the HIV diagnosis and starting treatment in infancy, children with HIV have a better chance of avoiding the risks of developmental delay. ■

1. Puthanakit T, Aурpibul L, Louthrenoo O, Tapanya P, Nadsasarn R, Insee-ard S, Sirisanthana V. Poor cognitive functioning of school-aged children in Thailand with perinatally acquired HIV infection taking antiretroviral therapy. *AIDS Patient Care STDS*. 2010 Mar;24(3):141–6.

and HIV prevention. The process of moving from proof of concept—demonstrating that a product or intervention works—to public access is long and complicated. There are three broad streams of activity. The first is licensure; the second relates to access and encompasses normative guidance, manufacture, and marketing; and the third concerns implementation, i.e., how do you make it available to those who need it?

Within a month of the CAPRISA results, UNAIDS and WHO hosted a meeting with scientists, donors, advocacy groups, and regulatory bodies to review the results and map out systematically what we need to do to get this product into women’s hands. Based on progress being made on confirmatory studies, we anticipate that by late 2013 we could have a licensed product. A public-private partnership has been developed to establish manufacturing capabilities in South Africa based on a royalty-free agreement.

A key challenge to implementation is understanding the consequences for those women who acquire HIV while being exposed prophylactically to ARVs. We need to monitor drug resistance patterns and disease progression, and understand the implications for treatment options, particularly in regard to tenofovir-containing antiretroviral treatment (ART).

All of these efforts require funding, but this remains a challenge. At this point USAID, the US National Institutes of Health, and the South African Ministry of Science and Technology remain the key sponsors of tenofovir gel research. For the first time we have an intervention for women, one that empowers young women who have had no strategy to protect themselves from infection when condoms and monogamy are not feasible. You would think smart investors would be rushing in to advance its development, but shockingly we are not seeing this.



(Photo: CAPRISA)

Dr. Abdool Karim and colleagues in the CAPRISA lab.

“ For the first time we have an intervention for women. You would think investors would be rushing in to advance its development, but shockingly we are not seeing this. ”

TA Report: What do you see as the most promising directions for HIV prevention?

Dr. Abdool Karim: The future of HIV/AIDS prevention is very bright. In the past year, with the advances in using ART for prevention, our options have expanded substantially. For many years we relied on a variety of prevention strategies—the abstinence message, monogamy, behavior change, partner change, circumcision, treatment of sexually transmitted infections, and others—but HIV infection has continued to spread. Last year our microbicide study showed a 39 percent reduction in HIV infections among women who used a tenofovir gel, and 54 percent among high adherers. That was followed by the iPrEx trials, which demonstrated that a combination of two antiretrovirals could significantly reduce the likelihood of HIV infection, by 44 percent, among men who have sex with men. More recently the HPTN 052 trial demonstrated that treating an infected person in a discordant couple can reduce transmission by 96 percent. So overall the news around the prophylactic and preventive use of ART—either in gel or oral formulations or as treatment—is very encouraging.

TA Report: These new prevention methods involve the use of antiretrovirals in some way—at a time when global donors are increasingly unwilling to expand their distribution. How can we shift the momentum back toward investing in these potentially game-changing medicines?

Dr. Abdool Karim: The question really comes down to how we can reconcile using ART for prevention while we are unable to meet the treatment demand. We need to look at the cost of the continuing spread of HIV and also the cost of treating those who are already infected and need treatment. Plus, we now have evidence that early initiation of treatment can significantly lower transmission. While this makes expanded treatment desirable and moral, even a human-rights obligation, the question is at what additional cost? How much earlier should we start and what are the trade-offs?



(Photo: CAPRISA)

Dr. Abdool Karim explains how to use an applicator for the tenofovir gel.

I don't think the dialectic is between having to choose drugs for prevention on the one hand, or treatment on the other. Our goal has to be stopping the HIV epidemic globally and deciding how to do this. We certainly have the tools to achieve this goal, it's a question of how we choose to utilize our resources. I think it's important that we contextualize HIV as part of a broader development agenda, and recognize that HIV is single-handedly undermining our efforts to reach our goals.

TA Report: In addition to your microbicide research, you have studied sustainable ways to introduce anti-HIV treatment in resource-limited countries. What insights have you gleaned from this research that could be meaningful in Asia?

Dr. Abdool Karim: I can share my understanding of HIV care in South Africa and the centrality of nurses for healthcare delivery. The provision of ART has brought attention to longstanding issues in healthcare delivery, including weak infrastructure, understaffing, inadequate information systems for monitoring progress, and problematic procurement and supply chain systems. If we are going to depend on a clinician-managed system, we are going to shortchange a lot of people who need treatment. There are now several nurse-treatment-driven programs that demonstrate that nurses are as effective in treatment as doctors.

We have also learned that treatment can be reliably provided in rural, primary-care settings. Engagement with the community enhances adherence rates. Significantly, we are reaching substantially higher rates of therapeutic success with first-line drug regimens than are many industrialized countries. This is quite phenomenal!

Achieving treatment coverage rates beyond 30–40 percent remains a challenge. One option for increasing coverage and maximizing the survival benefits of ART is to identify and prioritize key groups. In Africa this includes pregnant women and HIV-TB co-infected patients. We know that HIV-positive pregnant women in Africa have high mortality rates in the first 42 days post-partum, as well as in the first two years post-partum. By prioritizing pregnant women for treatment initiation and using the opportunity of antenatal visits for HIV care, programs to prevent mother-to-child transmission and post-partum visits can make a substantial impact on survival outcomes in mothers and infants.

Tuberculosis is one of the most common opportunistic infections associated with advancing HIV in resource-constrained settings. You can reduce mortality substantially by initiating ART and TB treatment simultaneously. Investments in infrastructure, human resource development, supply chains and systems, and good partnerships with communities are important, but actively addressing TB is a key to maximizing the benefit of ART.

“ We have reached a defining moment in our response to the pandemic. Stopping the epidemic is a real possibility, but the false dichotomy between treatment and prevention has to be broken. ”

We have reached a defining moment in our response to the pandemic. Stopping the epidemic is a real possibility, but the false dichotomy between treatment and prevention has to be broken. And there is a great deal to do. We need to overcome stigma, discrimination, and fear so that people are willing to learn their HIV status, which is the most important gateway to prevention and treatment. We must understand how to optimize the available treatment and prevention options to meet the needs of different epidemic settings. We need investments by governments, philanthropic organizations, and multilateral agencies, and partnerships between communities, service providers, and public and private sectors. Finally, if we are to realize an AIDS-free world, we must continue our efforts to develop new prevention modalities, including vaccines. ■

TREATMENT WORKING GROUP

CONTINUED FROM PAGE 1

In Asia, the goal of expanding HIV treatment runs head-on into reality. The gap in this region between those who need ART and those who are getting it is among the widest in the world—only 29 percent of the 1.5 million in need are being reached, a figure well below the global average of 37 percent. Drugs to prevent mother-to-child transmission reach just 26 percent of those in need compared with a global average of 45 percent. Complicating the picture are increases in treatment failure and the emergence of resistance to first-line ART drugs.

Acting on the imperative of treatment expansion despite its steep challenges, TREAT Asia and other groups in the region have banded together to form the Asia Treatment Working Group with the aim of promoting treatment access and higher quality HIV healthcare. The Asia-Pacific Network of People Living with HIV/AIDS (APN+), the International Treatment Preparedness Coalition (ITPC), Médecins Sans Frontières—Access Campaign (MSF), and TREAT Asia have launched a series of projects with support from key UN agencies including UNAIDS and UNICEF.

Each organization involved in the Working Group brings its own expertise to the joint endeavor—from TREAT Asia's proficiency with research and APN+'s skill with community mobilization, to ITPC's policy experience and MSF's knowledge of access issues.

The gap in Asia between those who need treatment and those who are getting it is among the widest in the world.

One main objective of the partnership is to help implement the new WHO guidelines, which recommend a lower threshold for ART and the use of more potent and effective drugs such as tenofovir for first-line treatment. Currently stavudine (d4T) is the first-line drug of choice in most resource-limited countries because of its low cost, but it presents a host of long-term problems. TREAT Asia has helped make the new WHO guidelines clearer for community groups and activists by developing, translating, and producing community-friendly fact sheets on the revised guidelines that have been translated into seven regional languages with more to come.



TREAT Asia developed the content for a forum on HIV prevention and treatment among women and children in April.

“Shifting to tenofovir will be a giant step for the region,” said Jennifer Ho, TREAT Asia’s manager of community programs. “The push is to stop using sub-optimal drug regimens so you don’t have to go to second-line. Instead, you invest more up front so you don’t have to take the second step. This is what optimizing treatment is—improving the regimen.”

Drug access is another important concern for the Working Group, particularly in reference to ongoing global trade negotiations that threaten access to generic antiretroviral drugs. But the availability of medicines can be a local issue as well when it comes to maintaining supply chains to ensure that drugs are in stock when and where patients need them. To analyze treatment access at the community level, the Working Group is creating a database that will track how far people have to travel to get their medicines and whether they are consistently available.

With the aim of expanding interventions to prevent mother-to-child transmission of HIV (PMTCT), the Working Group hosted a regional community forum in Bangkok in April. “This information is highly complex and technical,” said Ho, “so it made sense for TREAT Asia to develop the content. We did the same for a previous forum on drug resistance.”

The Treatment Working Group is also providing technical support for a six-country survey of maternal and child health, including PMTCT, led by Women of APN+. Preliminary analysis has indicated multiple violations of HIV-positive women’s sexual and reproductive health rights and has raised serious concerns regarding the quality of PMTCT across all surveyed countries.

Summarizing the aspirations of the coalition, Ho declared: “It’s time to bring the quality of treatment in Asia up to what the Western world has had for 15 years.” ■