Therapeutics Research • Education • AIDS Training

TREAT ASIA REPORT

Pushing for Better Coordination on Cure Research

The *TREAT Asia Report* Interview: Françoise Barré-Sinoussi, Ph.D.

Photo: Laurent Perrigault (Froggies)

Françoise Barré-Sinoussi, Ph.D., is a renowned virologist and director of the Regulation of Retroviral Infections Unit at the Institut Pasteur in Paris, France. Dr. Barré-Sinoussi has been at the forefront of AIDS research since the beginning of the epidemic and in 2008 she was awarded the Nobel Prize in Physiology or Medicine, with Luc Montagnier, for their discovery of HIV in 1983. In July 2012 she was named president of the International AIDS Society.

TREAT Asia Report: The International AIDS Society launched its Global Scientific Strategy, "Towards an HIV Cure," last July. What do you think we can do to accelerate the pace of cure research? Is it just a matter of increasing resources?

Dr. Françoise Barré-Sinoussi: No, in my opinion that's not sufficient. Of course we need more funding but we also need to work better together. We need to improve coordination between the different HIV cure programs. We need to have more ongoing multidisciplinary research to better integrate basic science with clinical research and social science.

TA Report: Do you think these things are beginning to happen now? For example, the NIH has its cure collaboratory and amfAR has its ARCHE program (amfAR Research Consortium on HIV Eradication).

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TREAT Asia Launches Hepatitis C Co-Infection Study

Innovative project will address challenges in hepatitis C treatment

"If everyone has the right to health, why are many of our friends dying from HCV?" asked Hidangmayum Umesh Sharma, treasurer of the Asian Network of People who Use Drugs. Asia is home to 38 percent of the estimated 130–170 million people worldwide chronically infected with hepatitis C virus (HCV).[1,2] Mr. Sharma is one of approximately five million people (15 percent of all those living with HIV/AIDS) who are co-infected with HIV and HCV.[3]

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One of the study sites, the National Hospital of Tropical Diseases in Hanoi, Vietnam

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TREAT Asia is a network of clinics, hospitals, and research institutions working with civil society to ensure the safe and effective delivery of HIV/AIDS treatments throughout Asia and the Pacific.

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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Crossing the Aisle

From its beginnings, the TREAT Asia program has tried to find ways to link different areas of the HIV world together. We not only conduct research—we also teach clinicians how to be researchers. We not only train medical professionals—we also provide educational opportunities to the broader HIV community. We not only gather data—we also seek out ways to turn information into action. This issue of the *TREAT Asia Report* exemplifies this core principle and shows why we are committed to a multidisciplinary approach.

We profile two new studies looking at hepatitis C co-infection (page 1) and human papillomavirus in adolescents (page 5), both of which have policy implications for improving the quality of adult and pediatric HIV care in the region. We are launching a new section called "Insight," which will provide policy updates on issues related to HIV treatment access and human rights (page 8). In our interview with Nobel Laureate and International AIDS Society President Dr. Françoise Barré-Sinoussi, the co-discoverer of HIV explains why we need to find more ways to bring together scientists from multiple disciplines and the private sector in order to find a cure for HIV. "Crossing the aisle"—whether between prevention and treatment or science and community—is essential to achieving our common goals.

Annette H. Sohn, M.D.

Good News, Bad News in UNAIDS Report

For Asia and the Pacific, the 2012 UNAIDS World AIDS Day Report was a patchwork quilt of solid progress in some countries and regression in others. While new infections in South and Southeast Asia fell from 370,000 in 2001 to 280,000 in 2011, in East Asia they were up over the same period from 75,000 to 89,000.

At the country level, the swings were more dramatic. Decreases in HIV incidence of more than 25 percent between 2001 and 2011 in Cambodia, India, Malaysia, Myanmar, Nepal, Papua New Guinea, and Thailand were offset by increases of more than 25 percent in Bangladesh, Indonesia, the Philippines, and Sri Lanka.

In 2011, only one country in the region—Cambodia—reached more than 80 percent coverage of antiretroviral therapy. Compared to the global average of 54 percent coverage, South and Southeast Asia reached just 47 percent and East Asia was worse at 18 percent. Similarly, provision of optimal antiretroviral regimens for prevention of mother-to-child HIV transmission was a dismal 18 percent in South and Southeast Asia compared to the global average of 57 percent.

Local epidemics in the region remain largely concentrated among high-risk populations, including men who have sex with men, injecting drug users, and sex workers. However, HIV prevention services for these groups are generally inconsistent and frequently poor.

Laws and policies in some countries have improved since 2010, with China, Fiji, and the Republic of Korea lifting travel restrictions for people with HIV. The report should send a clear signal to policy makers in the region that current levels of commitment need to improve in order to reach those most at-risk and achieve our common goal of ending AIDS. ■

HEPATITIS C CO-INFECTION STUDY

CONTINUED FROM PAGE 1

HCV is a serious health threat and is particularly dangerous for people who are HIV positive. Around 75 percent of infected individuals develop chronic HCV, which can lead to cirrhosis—a potentially fatal condition that can result in liver failure and is a risk factor for liver cancer. HIV-positive patients who have progressed to AIDS and are co-infected with HCV have a 50 percent greater risk of mortality than HCV-uninfected patients.

HCV is curable with therapy in 50–90 percent of cases, depending on the virus genotype (strain) and patient characteristics, including ethnicity. Asian patients tend to have higher treatment response rates than Caucasian patients, for example.

> **"Research on the burden of chronic HCV infection, disease severity, and the treatment needs of HIV co-infected patients in Asia is badly needed."**

However, treatment is costly and not routinely offered in resource-limited settings. "An outreach worker, who is the front-line service provider for HCV and HIV education, earns US$100 per month and would need to save all of his income for approximately 180 months just to buy medicine to treat his HCV," said Mr. Sharma. Research on the burden of chronic HCV infection, disease severity, and the treatment needs of HIV co-infected patients in Asia is badly needed.

TREAT Asia Director of Research Dr. Nicolas Durier will lead the first regional HCV screening study and treatment demonstration project for HIV-positive patients.

In 2013, TREAT Asia will initiate the first regional HCV screening study and treatment demonstration project for HIV-positive patients in Asia. Led by TREAT Asia Director of Research Dr. Nicolas Durier, and with scientific and biostatistics support from the Kirby Institute, Sydney, Australia, this innovative project will study the tolerability and effectiveness of HCV treatment in HIV co-infected patients within HIV clinics in Asia. The ultimate goal is to develop a pilot model of care for HCV treatment in resource-limited settings that can be replicated within the region. In addition, the project could generate data to bolster advocacy efforts aimed at securing commitments from governments and donor organizations to expand HCV treatment programs.

The screening study is being funded by the U.S. National Institutes of Health, and the treatment project will be supported by a donation of 200 courses of HCV treatment from Merck and Co. and preferentially priced HCV blood tests from Abbot Molecular. It will be implemented in Bangkok, Thailand, at the Thai Red Cross AIDS Research Centre; Hanoi, Vietnam, at the National Hospital of Tropical Diseases; Jakarta, Indonesia, at Cipto Mangunkusumo Hospital; and Kuala Lumpur, Malaysia, at the University of Malaya Medical Centre.

> **"Medicines have been prohibitively expensive, technical guidance is lacking, and political commitment and international funding are almost nonexistent."**

"With hepatitis C, we are facing a massive epidemic," said Dr. Durier. "Most people with this infection live in developing countries, and, while we know very effective therapy exists, only a handful of them can access treatment. Medicines have been prohibitively expensive, technical guidance is lacking, and political commitment and international funding are almost nonexistent. All of this needs to be urgently addressed before we are faced with a new epidemic of liver failure." ■

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Lopinavir/Ritonavir Should Not Be Used Alone as Second-Line Therapy in Adults

Lopinavir (LPV) is an anti-HIV drug in the protease inhibitor (PI) class. LPV boosted by low-dose ritonavir—referred to together as LPV/rtv—is the PI most commonly used in resource-limited settings to construct second-line regimens in patients who have failed first-line therapy that included nevirapine or efavirenz. In a second-line regimen, the World Health Organization recommends that LPV/rtv be given in combination with two other anti-HIV drugs from another class known as nucleoside reverse transcriptase inhibitors (NRTIs). However, as HIV resistance testing is not widely available in resource-limited settings, it is often not possible to confirm which drugs in the combination remain active. This raises concerns over the potential unnecessary costs and side effects of drugs in a therapy regimen that are not confirmed to be effective.

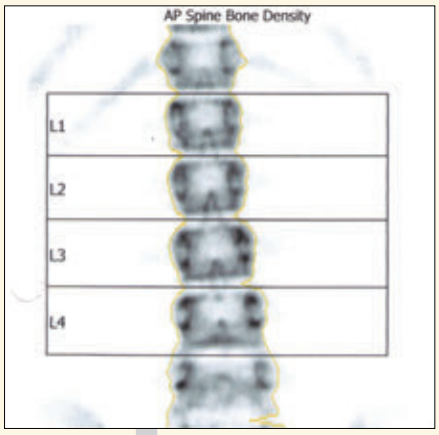
In this context, researchers in Thailand compared the outcomes of using a standard second-line regimen consisting of LPV/rtv and two NRTIs to using LPV/rtv alone. One hundred ninety-five patients who had failed first-line therapy were enrolled in the study in nine HIV treatment centers across Thailand. Half were randomly assigned to receive treatment with LPV/rtv alone, and the other half received LPV/rtv in combination with the NRTIs tenofovir and lamivudine. Resistance testing done for the purpose of this study showed that almost all patients had resistance to lamivudine and around 25 percent had resistance to tenofovir at the time of starting second-line therapy.

The study showed that after one year of treatment, fewer patients taking LPV/rtv alone had achieved full control of their HIV infections. Sixty-one percent had a

Photo: Kevin Tachman

Early Bone Damage in Adolescents

Both HIV and antiretroviral therapy (ART) can cause damage to bones, leading to reductions in mineral content. When these reductions are severe, they can lead to bone weakness and increased fracture risk. A special x-ray machine called a DEXA scanner can measure bone mineral density (BMD) and compare it to standard values obtained from healthy people, resulting in something called a "Z-score," which reflects how well or how poorly the BMD result compares to the average value. When the BMD Z-score is < -2, the patient is considered to have low bone density, a condition known as osteopenia. Thai investigators supported by TREAT Asia have conducted the first study of bone health among adolescents with HIV in Asia.[1]



A bone scan result as the doctor sees it

A total of 101 HIV-positive adolescents (with a median age of 14 years) who had been on ART for an average of seven years underwent DEXA scans. Their median CD4 cell count was 646 cells/mm^3, and 90 percent had undetectable HIV viral loads (at <50 copies/mL). When compared to DEXA standards developed from a separate survey of healthy Thai adolescents, 24 percent of those with HIV were found to have BMD Z-scores of < -2. In addition, 25 percent of adolescents with HIV had low levels of vitamin D, a key nutrient for promoting bone health. Factors associated with a greater likelihood of having a low BMD Z-score included low height for age (relative to other Thai adolescents; 6.2 times higher odds) and having had advanced HIV disease before

viral load of less than 50 copies of virus/mL compared to 83 percent of patients taking the three-drug regimen. The difference was even larger in patients who had a very high HIV viral load of more than 100,000 copies of virus/mL when they started their second-line regimen. The patients who took LPV/rtv alone were 12 times less likely to fully control their HIV infection than those on the three-drug regimen.

These findings provide evidence that LPV/rtv alone is less effective than a standard three-drug second-line regimen in adults, even in patients with resistance to tenofovir and lamivudine, and should not be recommended. ■

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starting ART (i.e., World Health Organization Stage 4; 3.7 times higher odds).

Studies such as this one point to the consequences that older children and adolescents are now facing because of delays in starting treatment for their HIV infection. Earlier treatment can prevent growth delays and protect against the direct effects of long-term HIV infection on bones and other organs of the body. By prioritizing earlier diagnosis and referrals to care, we can help ensure that infants and children with HIV will benefit from the lessons of the past. ■

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HPV–Another Challenge for Adolescent Girls Growing Up with HIV

Photo: Kevin Tachman

Adolescent girls cross a street in Bangkok, Thailand.

The introduction of highly active antiretroviral therapy (HAART) has transformed HIV from a progressive fatal disease into a chronic condition. As a result, perinatally infected children in Asia are now reaching adolescence. A period frequently associated with the search for independence and risk-taking behaviors, adolescence is accompanied by elevated risk for sexually transmitted infections such as human papillomavirus (HPV), which is the primary cause of cervical and anal cancer.

Adolescents with HIV may be at greater risk for HPV infection, disease persistence, and for developing HPV-related complications because of the impact of the virus on their immune systems. Pilot data from a small TREAT Asia-funded study of 16 sexually active, perinatally HIV-infected adolescent females (at a median age of 16 years) in Bangkok, Thailand, showed that half were already infected with HPV. Unfortunately, there are no available data on HPV in perinatally HIV-infected males in Asia.

With a new five-year research grant from the Eunice Kennedy Shriver National Institute of Child Health and Human Development at the U.S. National Institutes of Health (NIH/NICHD), TREAT Asia network researchers will begin studying the natural history of HPV infection among female and male adolescents in Thailand and Vietnam, with the goal of identifying opportunities to reduce the risk of early HPV infection and informing future HPV vaccination strategies in Asia.

In partnership with the Thai Red Cross AIDS Research Centre, TREAT Asia will collaborate with HIV-NAT and Siriraj Hospital, Mahidol University, in Bangkok; Chiangrai Prachanukroh Hospital in northern Thailand; and Children's Hospital 1 and Hung Vuong Obstetrics and Gynecology Hospital in Ho Chi Minh City, Vietnam. The study seeks to enroll perinatally HIV-infected and uninfected adolescents, and monitor their health and risk factors for HPV infection and pre-cancers of the cervix over the course of three years.

"The fact that perinatally HIV-infected children are now surviving into adolescence and young adulthood is a great achievement, but it raises new questions about what is necessary to allow these youth to live full and productive lives," said Dr. Rohan Hazra, of the Maternal and Pediatric Infectious Disease Branch of NIH/NICHD. "We are very excited about work such as this that is starting to address some of the challenges these youth now face."

By building on TREAT Asia's existing regional pediatric HIV research network and utilizing expertise gained through previous studies of HPV infection in adults, this study will enhance the region's scientific capacity for assessing the long-term impact of HIV infection on adolescents in Asia. ■

FRANÇOISE BARRÉ-SINOUSSI, Ph.D.

CONTINUED FROM PAGE 1

Dr. Barré-Sinoussi: I think it's a real start, with the different consortiums that have been launched since we started the international working group on cure. But we need more interaction between scientists and to integrate all the components that are required. We need to have more collaboration with the private sector as well. And collaboration between pharmaceutical companies is a complex issue, as you know.

We already started a working group with representatives of different pharmaceuticals. Recent data indicate that reactivating latently infected cells alone will not be sufficient. We may need to stimulate the immune system as well, in order to eliminate the cells that are reactivated. That means only a combination of different approaches will effectively cure HIV. It is thus important to be engaged very early in a dialogue with pharma to envisage how to develop that kind of combination.

TA Report: What do think are the most promising cure-focused research projects under way right now?

Dr. Barré-Sinoussi: It's difficult to say, because we don't know the results! Of course, there are the HDAC inhibitors, or a similar drug that reactivates latently infected cells, but, as I said, that will not be sufficient and we certainly need other strategies. It's too early to say because we need to test drugs—or some other strategy—separately and then to combine the best strategies. And that will take quite a long time.

TA Report: Can you tell us a little bit about your own current research?

Dr. Barré-Sinoussi: My lab is working on HIV pathogenesis and how to control HIV disease progression. We are involved in a cohort in France called "the VISCONTI patients." These patients were treated very early after infection, and after three years they stopped their treatment and they are now able to control their viral load by themselves. They have undetectable viral loads without any treatment and they're doing perfectly well. We are trying to understand the mechanisms behind this. We know they are different from elite controllers. They don't have the strong CD8 [immune] response or HLA B57 or B27 [genetic profiles associated with ability to control the virus] related to control in the elite controllers. Interestingly, these patients have a very low level of [HIV] reservoir in relation to their ability to control the virus. We are now trying to better characterize the mechanisms that led to this control. In addition, these data reinforce the idea that treating very early is certainly a good solution—but a challenging one on a large scale.

We are also working on African green monkeys that are natural hosts of SIV [Simian Immunodeficiency Virus]. We are trying to understand how they can control the development of disease and the relationship with a low level of [immune] activation, which is a characteristic of these primates. A group in my team is also involved in studying innate immunity and the interaction between NK [natural killer] cells and dendritic cells, looking at the impact of these interactions on the control of HIV infection in the blood and at the mucosal level. These are the main topics.

TA Report: Are you optimistic about the future of cure research?

Dr. Barré-Sinoussi: Yes, I'm optimistic because I can see things are moving forward…and I assume in the coming year there will be more collaboration between the different groups. Of course we still have a long, long way to go.

TA Report: What about the prospects for vaccine development?

Dr. Barré-Sinoussi: I don't think we should pit vaccine research against cure research because we need to have interaction between researchers working on HIV cure and researchers working on vaccines. Antibodies are traditionally viewed in the context of vaccines, but they may also be important for cure research. So I think new developments are coming in the field of vaccines.

Dr. Barré-Sinoussi co-chaired a symposium titled "Towards an HIV Cure" preceding the 2012 International AIDS Conference. Among the panelists (second from left) was Dr. Rowena Johnston, vice president and director of research at amfAR.

TA Report: You started going to Asia in the late 1980s and have collaborated on projects in the region since then. Are there challenges that are specific to Asia in confronting HIV, both in the research arena and at the community level?

Dr. Barré-Sinoussi: Indeed, the French National Agency for Research on AIDS and Viral Hepatitis (ANRS) has quite a long history of collaboration with Southeast Asia. If you consider a country I know quite well, Vietnam, one characteristic is HIV infection in drug users. We are discussing a collaboration with NIDA [U.S. National Institute on Drug Abuse] to develop studies of drug users in Vietnam. Additionally we have already done some work on co-infection with TB and HIV both in Vietnam and Cambodia. We were involved in the CAMELIA trial, sponsored by the ANRS and the NIH, that clearly showed that starting HAART earlier after TB treatment improves the survival of people with HIV/TB coinfection. The trial is finished but there are still other projects under way in Cambodia and Vietnam on how to improve the treatment of co-infection with TB and HIV. Another challenge that we are seeing in the region is co-infection with HIV and HCV.

amfAR and TREAT Asia are of course very much involved in the region, and I think we can improve collaboration between amfAR-TREAT Asia and other organizations that operate in the region.

TA Report: You've been involved with the International AIDS Society for some time now and you became its president last year. What inspired you to get more involved in the IAS and what do you hope to accomplish as president?

Dr. Barré-Sinoussi: First of all, I wanted to try and stimulate research on an HIV cure. One role of the IAS is to be an advocate for science and one of our priorities is to promote and accelerate research on a cure, and we will continue with that. We have several working groups on social science, cost-effectiveness, ethics and, as I mentioned previously, one industry collaborative group. We are trying to better coordinate cure research at the international level.

The IAS also has other priority areas including key affected populations, treatment as prevention, social and political research, human rights, and effectiveness and efficiency. Our objective in each of these areas is to promote and advocate for the implementation of scientific evidence-based responses.

As I mentioned in Washington, we also want to promote women in science and we're looking at the enrollment of women in clinical trials. The proportion of women enrolled in clinical trials is much lower than men. Earlier I mentioned injecting drug users, but we also have to consider men who have sex with men and all the key affected populations. This certainly has specific implications for Asia.

Photo: Institut Pasteur

Dr. Barré-Sinoussi is based at the renowned Institut Pasteur in Paris.

TA Report: Infection rates among MSM are on the rise in many parts of the world. What can we do to turn that around?

Dr. Barré-Sinoussi: It's a complex issue related to many practical, but mostly political and societal challenges that are truly impeding access to health services. Many countries still have repressive laws regarding men having sex with other men. We really need to advocate for the abolition of those laws that flout human rights, and we really need to start educating the new generation as well.

TA Report: You have been at the forefront of AIDS research for many years now. What is your current perspective on whether we can really get this epidemic under control?

Dr. Barré-Sinoussi: If we can improve access [to treatment]—and universal access to antiretroviral therapy is still a long way off—we know that we can slow down the epidemic everywhere in the world. We know that we can be successful in reaching an AIDS-free generation because we have the tools for that, but on the other hand we know that for economic reasons it would be very difficult to accomplish.

We have already seen some progress in Africa and other parts of the world regarding improvements in public health infrastructure. We know that there are not enough health professionals so we have to help communities improve access to HIV testing. In some countries, rapid testing is already available through communities, and then people can be linked with health services. But we have to continue the research because, of course, if we can develop new therapeutic agents and a vaccine, these will be additional tools for prevention and treatment. So we need to have both action and research. ■

A Step Towards Hepatitis C Treatment Access in Thailand

In August 2012, Thailand added two medicines used for the treatment of hepatitis C virus (HCV), pegylated interferon alpha 2a and 2b, to its national list of essential medicines, making the drugs eligible for coverage by government health insurance schemes. This is the first time that the national public health system has committed to providing HCV treatment for the general public. However, the guidelines for using pegylated interferon are limited to patients with certain types of HCV (genotypes 2 and 3). This excludes the harder to treat genotypes and also people living with HIV. Physician and patient groups are advocating for policies that allow for expanded access to treatment.

Indonesia Issues Compulsory Licenses for Seven HIV Medicines

In September 2012, the President of Indonesia, Susilo Bambang Yudhoyono, issued a decree allowing the government to produce seven HIV antiretrovirals outside of their patent protections. The list includes medicines that can be used to prevent HIV infection as well as those shown to have fewer side effects than the drugs currently used in Indonesia. Although this could mean wider availability of newer and safer medicines for people living with HIV in Indonesia, it remains unclear whether local Indonesian pharmaceutical companies will be capable of making these medicines and getting them to patients in the near future. TREAT Asia is working with civil society organizations in Indonesia to provide patient groups with treatment education on the newer regimens that may be used in the future.

Photo: Agência Brasil

The President of Indonesia, Susilo Bambang Yudhoyono

India Revokes Patent for Hepatitis C Medicine

The Intellectual Property Appellate Board in India revoked the patent on Pegasys® (pegylated interferon alpha 2a) in November 2012. The current price of the commercial version of this HCV medicine has been cited as a major barrier to accessing treatment. This patent was the first to be approved in India after the country became compliant with the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement in 2005, and this is the first decision on an application challenging the patent after it was granted. Indian community organizations are hoping that revocation of the patent will prompt local drug manufacturers to start producing and distributing high-quality versions of this medicine at lower prices.

Photo: Lawyers Collective

Anand Grover, Director of the Lawyers Collective HIV/AIDS Unit, appeared as legal counsel in the case overturning the hepatitis C product patent in India.

Does the Trans-Pacific Partnership Threaten Access to HIV Treatment in Thailand?

In November 2012, Thailand expressed its interest in the possibility of joining the Trans-Pacific Partnership (TPP) negotiations, a free-trade agreement involving 11 countries and promoted by the U.S. government. Thai HIV advocates fear that this will hold the Thai national HIV/AIDS program back from expanding treatment coverage, as the TPP includes intellectual property protections that they believe will block availability of low-cost generic antiretroviral medicines. At the request of Thai civil society organizations, TREAT Asia and its regional partners ITPC, APN+, and MSF Access Campaign wrote a letter to the Prime Minister of Thailand expressing concerns over the TPP and reminding her of Thailand's ability to use existing trade flexibilities to continue accessing affordable antiretroviral medicines in Asia. ■

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