

# TREAT ASIA REPORT

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ON THE INSIDE

## In Pursuit of an AIDS-Free Generation

The *TREAT Asia Report* Interview: Hillary Rodham Clinton



Photo: State Department

*Hillary Rodham Clinton was sworn in as U.S. Secretary of State in January 2009. Since then, she has traveled more than 800,000 miles on diplomatic visits to 100 countries. As Secretary of State, she oversees the Office of the Global AIDS Coordinator and the President's Emergency Plan for AIDS Relief (PEPFAR). The U.S. government's largest global health program, PEPFAR was reauthorized in 2008 for \$48 billion over five years. Secretary Clinton also oversees United States embassies in 162 countries, which implement a variety of diplomatic initiatives and other community-based HIV/AIDS programs.*

**TREAT Asia Report:** You have been an outspoken advocate of women's rights, including the right to sexual and reproductive health care. How will the needs of women living with HIV be supported as U.S. global health strategies evolve?

**Secretary of State Hillary Clinton:** First, I would like to thank amfAR for being such an important part of what we've been able to achieve through PEPFAR. We truly appreciate our partnership.

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## A Partnership that Pushes the Boundaries of Pediatric HIV Research

Children and adolescents living with HIV have unique healthcare needs, and many questions about pediatric HIV care remain unanswered. For example, which antiretroviral regimens—and at what doses—are most appropriate for young people? What are the long-term effects of antiretroviral therapy (ART) on growth and development? How can

communication between clinicians and HIV-positive adolescents be improved to produce better health outcomes? TREAT Asia is tackling these issues head on, thanks to its groundbreaking partnership with ViiV Healthcare.

Making the single largest award in the history of the TREAT Asia pediatric program, ViiV Healthcare first teamed

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Photo: Kevin Tachman

*A child having a blood sample taken in a pediatric HIV clinic in Malaysia.*

## TREAT Asia Report

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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](http://www.treatasia.org).

### TREAT Asia Report

Cassandra Gallese, Editor

#### Contributors

Nicolas Durier, M.D., M.P.H.  
Giten Khwairakpam  
Annette Sohn, M.D.

#### Publication Design

Raoul Norman-Tenazas  
Yolande Hunter

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120 Wall Street, 13th Floor  
New York, NY 10005-3908 USA  
tel: 1-212-806-1600  
[www.amfar.org](http://www.amfar.org)

### TREAT Asia Steering Committee

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## Leadership and Common Solutions: Talking → Walking



The International AIDS Conference in July will be a platform for many voices—forceful, pragmatic, angry, frustrated, excited. While more potent treatments are becoming available for use in resource-limited settings, and new prevention opportunities are opening up, we continue to struggle with ensuring access to basic first-line treatments and with sharing the ever shrinking pool of global health funding. But instead of collaborating on strategies that seek to increase the size of the “pie,” advocates for different groups at risk of HIV in Asia are still criticizing each other.

In this environment, the need for strong leadership is even greater. And, as noted by Secretary Clinton, achieving our common goal of an AIDS-free generation will require shared responsibility (see page 6). Our response must involve both governments and individuals, such as the growing, community-led effort to phase out the use of the antiretroviral stavudine (see page 5). With the drug options we have today, patients, clinicians, and program implementers should no longer accept that just being kept alive on a drug with serious side effects is good enough.

As the International AIDS Conference wraps up, our next steps must be to follow up on all the talk about what is not being done or is being done incorrectly, translating words into the collective action necessary to forge effective solutions.

Annette Sohn, M.D.

### PEDIATRIC HIV RESEARCH

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up with TREAT Asia in 2010 in an effort to fill critical data gaps and establish an evidence base from which to identify best practices for pediatric HIV management in Asia. With ViiV Healthcare’s support, TREAT Asia created the first pediatric HIV drug resistance monitoring program in the region. Currently operating in eight sites in three countries, the program focuses on children already on second-line ART regimens due to initial treatment failure.

In addition to the study of drug resistance, ViiV Healthcare’s award has supported pilot studies in Thailand and Malaysia of an audio computer-assisted survey instrument (ACASI) used to

interface with adolescents in an effort to obtain honest and accurate information regarding behavioral risk factors. ViiV Healthcare’s award is also funding ongoing analyses on the use of viral load testing in assessing treatment failure in children as well as the impact of orphanhood in HIV outcomes.

In December 2011, ViiV Healthcare sought to build on the core capacity developed through its partnership with TREAT Asia by awarding a second grant to address the healthcare challenges HIV-positive children face as they age into adolescence. Research supported by this funding will focus on integrating reproductive

# Access to Affordable HIV Medicines at Risk in Trade Negotiations

Many of the world's poorest countries are dependent on India's pharmaceutical industry for affordable medicines that keep millions of HIV-positive people alive and healthy every day. These lives will soon be at risk, however, if intellectual property demands proposed by the European Union in a draft Free Trade Agreement (FTA) with India are accepted.

Primarily as a result of competition from India's generic pharmaceutical companies, prices for standard antiretroviral drug regimens in low- and middle-income countries have fallen from US\$15,000 per person per year in 2001 to less than US\$70 in 2012. Today, India supplies more than 80 percent of all adult antiretroviral drugs and more than 90 percent of all pediatric antiretroviral formulations in use in developing countries. An estimated 6.6 million people in low- and middle-income countries are now on antiretroviral therapy, and the annual number of AIDS deaths has fallen by more than 18 percent since the middle of the last decade.

India's strict patent laws and public health safeguards have ensured its ability to manufacture safe, effective, and affordable medicines. Clauses proposed by the European

Union in its draft FTA with India would increase HIV drug prices, thereby diminishing access to these essential medicines. Specific clauses of concern include the following:

- Patent term extensions that extend patent life beyond 20 years;
- Data exclusivity provisions that delay the registration of generic medicines and prevent distribution and marketing of affordable versions of pediatric drug formulations and combinations of "off-patent" medicines;
- Investment rules that permit foreign companies to sue the Indian government in private courts to contest domestic health policies, such as reasonable measures to reduce drug prices;
- Border measures that would deny sales of medicines to patients in other countries by authorizing European customs officials and other countries to seize generic medicines in transit;

“Primarily as a result of competition from India's generic pharmaceutical companies, prices for standard antiretroviral drug regimens in low- and middle-income countries have fallen.”

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Photo: Kevin Tachman

*An HIV-positive child getting a check-up from a physician in a Cambodian clinic.*

healthcare, treatment adherence among teenagers, and studying the risk of bone damage due to lifelong ART.

“Barriers to HIV treatment and services are particularly significant for infants and children living across Asia and require urgent attention,” said Dr. Dominique Limet, CEO of ViiV

Healthcare. “Our ongoing partnerships with the TREAT Asia program have enabled treatment literacy work and evidence-based research to develop strategies to support lifelong pediatric care and inform optimal pediatric treatment guidelines. ViiV Healthcare is immensely proud to be a part of these efforts, and we thank the amfAR team for their hard work and dedication to adults and children living with HIV in Asia and across the rest of the world.”

From its beginnings, TREAT Asia's partnership with ViiV Healthcare has included a provider education component intended to train clinicians

at the provincial and referral levels in TREAT Asia network countries on the latest developments in pediatric HIV treatment. To date, TREAT Asia has conducted pediatric treatment failure and lipodystrophy management workshops in Cambodia, China, Indonesia, Thailand, and Vietnam. By turning innovative research into best practices, TREAT Asia is shaping pediatric HIV care in the region. Together ViiV Healthcare and TREAT Asia are pushing the boundaries of pediatric HIV research and making a difference in the lives of children living with HIV across Asia. ■

## The Clinical and Economic Benefits of Once-Daily Pills

Photo: Kevin Tachman



*A child in Cambodia takes her antiretrovirals.*

Antiretroviral therapy (ART) has come a long way in making HIV a manageable chronic infection. In the 30 years of the epidemic, more than 20 antiretroviral agents have been approved by the U.S. Food and Drug Administration. The broader availability of newer, safer drugs and studies reporting on side effects of older drugs led the World Health Organization (WHO) to change its treatment guidelines in 2010 to promote less toxic regimens and those requiring fewer pills each day.

Researchers in the U.S. recently evaluated differences in adherence and hospitalizations depending on the number of antiretroviral pills taken each day.<sup>1</sup> They assessed whether having to take fewer pills improved adherence and clinical outcomes in patients living with HIV.

The study found that patients taking a single pill each day had significantly better adherence when compared with patients taking multiple pills a day. Approximately 47 percent of patients taking a single daily pill achieved

adherence rates of 95 percent or more, compared to 41 percent of patients on two pills and 34 percent on three or more pills a day. Furthermore, patients with at least 95 percent adherence had significantly lower rates of hospitalization. As the results show, achieving high levels of adherence is difficult regardless of the treatment regimen. However, once-daily regimens correlate with the highest levels of adherence and therefore should be

## Cotrimoxazole Still Prevents Death in the Era of Antiretroviral Therapy in Asia

Cotrimoxazole (trimethoprim-sulfamethoxazole) is an antibiotic that is active against a wide range of bacteria, fungi, and parasites. In HIV-infected patients, it is recommended for all patients with severe immune suppression (CD4 counts below 200 cells/mm<sup>3</sup>) to prevent the occurrence of opportunistic infections such as *Pneumocystis jirovecii* pneumonia, or PCP. Using cotrimoxazole as a prophylactic medicine has also been shown to reduce deaths in patients who have severe immune suppression, even when antiretroviral therapy is available.

In spite of guidelines recommending cotrimoxazole prophylaxis and the wide availability and affordability of the

drug, it is not consistently used in resource-limited settings. TREAT Asia researchers investigated the use of this prophylaxis between 2003 and 2009 in the TREAT Asia HIV Observational Database (TAHOD).<sup>1</sup> The analysis included a total of 4,050 patients, of whom 90 percent were taking antiretroviral therapy. It was found that among those with CD4 levels below 200 who should have been receiving prophylaxis, only around 60 percent received it over the study period, although this proportion increased from 58 percent in 2007 to 72 percent in 2009. This varied also by clinical site, with prophylaxis coverage ranging from



as low as 30 percent in some centers to 100 percent in others.

During follow-up, 62 cases of PCP were diagnosed and 169 patients died. It was found that the risk of PCP diagnosis was not statistically different between patients receiving or not receiving prophylactic antibiotics. However, the risk of overall mortality was more than 10 times higher in patients not receiving prophylaxis. The survival benefit of prophylaxis was highest in patients with

prioritized to improve the effectiveness of ART.

Although the study was based in a high-income country, the results may be applicable for patients in Asia. Fixed-dose, once-daily combination antiretroviral pills are available in many Asian countries, with some in less expensive generic forms. Despite WHO recommendations and research findings validating the benefits of once-daily pills, many Asian countries continue to use regimens with twice-daily or multiple pills due to lower costs.

Asian countries need to make greater efforts to promote simpler once-daily ART regimens that can result in better long-term treatment outcomes. ■

1. Paul E. Sax, Juliana L. Meyers, Michael Mugavero, and Keith L. Davis. Adherence to Antiretroviral Treatment and Correlation with Risk of Hospitalization among Commercially Insured HIV Patients in the United States, PLoS One. 2012;7(2):e312591. Epub 2012 Feb 24.

## How Long Will People Be Forced to Deal with d4T?

“How many times will I have to explain, and to how many people, what is wrong with my looks, my face?” At their “Stavudine Festival” in May, the Delhi Network of Positive People (DNP+) gave people like Mr. Munna the chance to share their stories about the toxic effects of the antiretroviral drug stavudine (also known as d4T). d4T helped save Mr. Munna’s life as part of an antiretroviral treatment regimen, but after four years, this medicine has caused him peripheral neuropathy (nerve damage leading to weakness of his leg muscles) and lipoatrophy (thinning of the fat in his face and extremities). Mr. Munna is now having difficulty going to work because of the pain in his legs, risking his and his family’s livelihood.

DNP+ emphasized that the complaints regarding d4T are not solely about cosmetic appearances but also about how these side effects are directly leading to stigma and discrimination, thereby putting families at risk of economic insecurity. Community members asked why d4T continued to be used for the majority of patients in India, despite the wide availability of another low-cost antiretroviral, zidovudine (AZT), and research from India demonstrating how using more expensive generic options like tenofovir can be cost-effective over the long term.

In 2010, the World Health Organization advised national HIV programs to develop plans to phase out d4T, but the actual phase-out has been slow. Community groups like DNP+ have been advocating for programs to stop buying d4T, but purchases have continued despite these global recommendations, creating stockpiles of drugs that governments can argue will need to be used by people with HIV before country programs transition to other antiretrovirals.

The “Stavudine Festival” brought together the voices of people who have been forced to ask themselves whether they want to continue living with HIV on d4T or risk dying without it. One woman from the Delhi-based organization Nai Umang Positive Welfare Society disagreed with her doctor, who told her that these options were still good for her. Clinicians and policy makers should reconsider the false paradigm that requires people living with HIV to accept treatment that is considered too toxic in high-income countries when other feasible options exist. ■

“How many times will I have to explain, and to how many people, what is wrong with my looks, my face?”



DNP+ members work in groups to propose strategies for promoting d4T phase-out in their communities.

very low CD4 levels (below 50 cells/mm<sup>3</sup>), but remained significant for all patients with CD4 counts below 200 cells/mm<sup>3</sup>, and was also observed in patients with levels above 200 cells/mm<sup>3</sup>.

These findings confirm the importance of cotrimoxazole prophylaxis to prevent death in patients with immune suppression, even when taking antiretroviral therapy, and illustrate the need to continue efforts to offer this simple intervention to all eligible patients receiving HIV care in Asia. ■

1. Poh-Lian Lim, Jialun Zhou, Rossana A. Ditangco, Matthew G. Law, Thira Sirisanthana, Nagalingeswaran Kumarasamy, Yi-Ming A. Chen, Praphan Phanuphak, Christopher K.C. Lee, Vonthanak Saphonn, Shinichi Oka, Fujie Zhang, Jun Y. Choi, Sanjay Pujari, Adeeba Kamarulzaman, Patrick C.K. Li, Tuti P. Merati, Evy Yuniastuti, Liesl Messerschmidt and Somnuek Sungkanuparph for the TREAT Asia HIV Observational Database. Failure to prescribe pneumocystis prophylaxis is associated with increased mortality, even in the cART era: results from the TREAT Asia HIV observational database. J Int AIDS Soc. 2012 Jan 26; 15(1):1

As you are aware, in low- and middle-income countries worldwide, HIV is the leading cause of death and disease in women of reproductive age. In Africa, 60 percent of those living with HIV are women, and in some of these countries, prevalence among young women aged 15-24 years is about three times higher than among men of the same age. So PEPFAR is putting women front and center in the response. We're ensuring equitable access to services, addressing the tragedy of gender-based violence, keeping mothers alive through programs to prevent mother-to-child transmission of HIV, and making sure HIV programs are linked to our other women's health programs under the Global Health Initiative. There's a lot of work ahead because some of these issues go very deep, but we are working with countries to address them.

“ In low- and middle-income countries worldwide, HIV is the leading cause of death and disease in women of reproductive age. ”

**TA Report:** PEPFAR is arguably the most popular and successful foreign policy initiative in recent years, yet the President's fiscal year 2013 budget proposal calls for a nearly 12 percent reduction in funding for PEPFAR. How does the administration reconcile this with its ambitious commitment to achieving an “AIDS-free generation?”

**Clinton:** We define success in terms of results—saving lives is the most important metric. President Obama and I are committed to creating an AIDS-free generation, including reaching ambitious

*Secretary Clinton delivers remarks at the launch of a Global Partnership on Maternal and Child Health in Washington, D.C., on March 9, 2011.*



Photo: State Department

goals for treatment and prevention. PEPFAR has a history of success to draw on—this program has consistently met its goals, and I am confident it will continue to do so. But achieving an AIDS-free generation requires the shared responsibility of everyone—donor nations, partner countries, the Global Fund and the private sector.

**TA Report:** Programs like PEPFAR that deliver lifesaving antiretroviral treatment to millions of people in developing countries are heavily reliant on generic ARVs produced in India. How will the U.S. government's trade policies ensure that affordable medicines remain accessible to those who need them?

**Clinton:** PEPFAR, the State Department, and our other interagency partners are working with the U.S. Trade Representative to increase access to medicines and ensure that public health concerns are part of the conversation. We're very proud of the large reductions in per-patient costs PEPFAR has been able to achieve and we will continue to work to make medicines even more affordable.

**TA Report:** You made a historic commitment to the rights of LGBT people last year. As you know, gay men and other men who have sex with men are disproportionately affected by HIV in most parts of the world. How is the PEPFAR program expanding access to HIV services for MSM?

**Clinton:** This is a clear priority for PEPFAR because there is strong evidence of the higher risks faced by MSM. Last year, PEPFAR released guidance on providing services to MSM, explaining the evidence base and offering tools to help country programs respond. An important part of the effort is working with partner countries to help them see that a public health approach that makes HIV services available to marginalized groups, without the stigma or discrimination that can drive people underground, will advance the health of the nation as a whole. In addition to working with governments on a data-driven response that targets funding to key at-risk populations like MSM, PEPFAR is also working with community groups. By supporting efforts like the Purple Sky Network in Asia, PEPFAR has enabled MSM organizations to develop peer relationships and advocate on behalf of HIV and other health issues in their nations. So we're taking a comprehensive approach that works with governments and communities to get the services to the people in need.

**TA Report:** Through PEPFAR, the U.S. has focused primarily on AIDS in Africa. How does Asia—with its concentrated HIV/AIDS epidemics, harder-to-reach populations, and PMTCT challenges—fit into U.S. global health strategy?

**Clinton:** Asia requires very different approaches than Africa—and indeed there is great variety even within Asia. I think our PEPFAR programs in the region reflect the unique circumstances. Many of the countries have significant resources of their own to devote to fighting AIDS, but what we can offer is the technical support to maximize the impact of what they are doing. Because the epidemics are concentrated among population groups that face stigma—such as persons who inject drugs, MSM, and sex workers—we work directly with those groups in ways that will not put them at risk.

“ Any sense of complacency would be tremendously misguided and harmful—there is still significant unmet need in the world, and for our part the United States is going to keep the pressure on. ”

**TA Report:** In December 2011, you became the first U.S. Secretary of State to visit Burma in more than 50 years. How might closer diplomatic ties between the two countries impact support for Burma’s HIV response?

**Clinton:** The changes to date are fragile, but very encouraging. Following my visit, in April of this year, Burma’s Minister of Health led a delegation that visited a number of U.S. officials, including our PEPFAR leadership at the State Department and our implementing agencies. It’s too soon to make any definitive statements as to increased cooperation on HIV, but the fact that our governments are now in dialogue is certainly promising.



*Secretary Clinton visits Daw Aung San Suu Kyi at her house in Rangoon, Burma, on December 2, 2011.*

Photo: State Department

**TA Report:** As you travel the world, are you seeing any notable shifts—either dispiriting or encouraging—in country responses to AIDS?

**Clinton:** Compared with where we were in the recent past, I’m very encouraged by the leadership we’re seeing from many of the hardest-hit countries. More and more, they understand the importance of this issue, and want to grow both their commitment and their capacity to step up. I think a key to this transformation is that they now see that it’s something they can be successful doing—the past decade has proven that. It’s always easier to enlist people in a fight they can win, and I am confident that we can win this fight against AIDS.

**TA Report:** What do you see as the major impediments to achieving an “AIDS-free generation?”

**Clinton:** Any sense of complacency would be tremendously misguided and harmful—there is still significant unmet need in the world, and for our part the United States is going to keep the pressure on. But as I have said, it’s a shared responsibility, and we need other donor and partner countries to step up and meet the challenge as we are doing. Budget constraints and competing demands are issues everywhere, and always will be. But the vision of an AIDS-free generation is so compelling, and the science is behind us. I believe we will all rise to meet the challenge. ■

# Hepatitis C: National Governments Need to Respond

There are up to 170 million people living with hepatitis C infection worldwide. In March 2010 the World Health Assembly, the governing forum of the World Health Organization (WHO), adopted a viral hepatitis resolution urging member states to take steps to address this public health problem.

The U.S. Centers for Disease Control and Prevention reports that hepatitis C has superseded HIV as a cause of death in the United States. Between 1999 and 2007, deaths from hepatitis C increased to more than 15,000, whereas deaths from HIV declined to less than 13,000.<sup>1</sup> In the regional context, Southeast Asia and India also see more deaths from viral hepatitis infection than from HIV.<sup>2</sup>

In high-income countries, the standard of care for treating hepatitis C is combination therapy with pegylated interferon (an injectable medicine) and ribavirin (an oral pill), with some patients being treated by adding newer regimens of expensive oral pills to the standard of care. In most of Asia, treatment is not accessible, as pegylated interferon remains under patent in many countries and is without low-cost generic equivalents.

A standard course of pegylated interferon is 48 weeks, which costs approximately US\$18,000 in India and US\$14,000 in Malaysia but only US\$2,000 in Egypt. Depending on the country, price variations may be based on the availability of generic options and the involvement of governments in negotiating reductions for national procurement. These variations in pricing and the consequent burden to individual patients and governments reflect one of the central challenges



to implementing hepatitis C treatment, underscoring the need for more consistent global pricing mechanisms to allow broader access to these effective treatments.

Most low- and middle-income Asian countries do not include hepatitis C treatment as part of their public health programs, forcing patients to bear the burden of the expense or go without treatment. In India, which supplies more

than 80 percent of the developing world's HIV medication, patents preventing the generic production of pegylated interferon have been under challenge in courts since May 2007.

The global community has learned from the HIV epidemic that access to life-saving treatments is ensured only when governments intervene at the national level. A growing movement calls for policymakers to apply these lessons to overcome the pricing and political barriers currently limiting access to hepatitis C treatment.

After saving the lives of so many infected with HIV, we now risk losing them to liver diseases, which would undermine the advances that have been achieved in the HIV response. Asian governments urgently need to initiate national programs for prevention and treatment of hepatitis C and put the WHO's viral hepatitis resolution into action. ■

1. Kathleen N. Ly, Jian Xing, R. Monica Klevens, Ruth B. Jiles, John W. Ward and Scott D. Holmberg. The Increasing Burden of Mortality From Viral Hepatitis in the United States Between 1999 and 2007. *Annals of Internal Medicine*. 2012 Feb 21; 156 (4): 271-8.
2. Samlee Plianbangchang. Viral Hepatitis kills more than Malaria, Dengue and HIV/AIDS in South-East Asia. *The Dili Weekly*. 2011 Aug 24. <http://www.thediliweekly.com/tl/editorial/sikun-editores/116-viral-hepatitis-kills-more-than-malaria-dengue-and-hiv-aids-in-south-east-asia> (Accessed 14.4.2012)

## AFFORDABLE HIV MEDICINES CONTINUED FROM PAGE 3

- Injunctions that undermine the independence of the Indian judiciary to protect patients' right to health over private industry's pursuit of profits;
- Other enforcement mechanisms that would place third parties, such as health care providers, at risk of police action if they prescribe or distribute generic medicines.

While the European Union (E.U.) has stated that some measures—such as proposed patent term extensions and data exclusivity provisions—are no longer being proposed, others remain the subject of active negotiation. In protests in front of European country embassies around the world, people

living with HIV have been resisting the E.U.'s pressure on India to sign an FTA that would endanger their access to generic lifesaving medicines. amfAR has joined their voices, urging the Indian government to reject provisions that would undermine both Indian industry and the global fight against HIV. ■