

TREAT ASIA REPORT



Forcing a Retreat
PAGE 2

Disclosure and Consent
Among Adolescents with HIV
PAGE 4

"First-line Forever"
PAGE 8

ON THE INSIDE

New Directions for PEPFAR? Setting the Course of U.S. AIDS Efforts

The *TREAT Asia Report* Interview: Ambassador Eric Goosby



As U.S. Global AIDS Coordinator, Ambassador Eric Goosby leads the country's international HIV/AIDS efforts, including the President's Emergency Plan for AIDS Relief (PEPFAR). Ambassador Goosby has more than 25 years HIV/AIDS experience as a physician and policy maker, and is also professor of clinical medicine at the University of California, San Francisco.

TREAT Asia Report: PEPFAR is moving towards an approach to global health that strengthens health systems and emphasizes government ownership of health programs. But in Asia, it's the vulnerable and often hard-to-reach communities—sex workers, drug users, and men who have sex with men (MSM)—that are disproportionately affected by HIV. How do we make sure that these populations get the attention they need?

Ambassador Eric Goosby: Our goal is to create an opportunity to identify more difficult-to-reach populations, bring them into care, and keep them there by creating a safe space where they can reveal themselves to the authorities. For that to happen, a safe space needs to be explicitly understood as a spot where

CONTINUED ON PAGE 6

In Viet Nam, Global Partnerships Help Change the Course of AIDS

Intent on turning the tide against the AIDS epidemic in Viet Nam, international donors began to support a massive expansion of HIV prevention, treatment, and care in 2004. Taking up the challenge presented by this dramatic funding increase, Viet Nam has established increasingly sophisticated HIV programs that have achieved a sixfold increase in antiretroviral therapy (ART) and doubled the number of HIV-positive pregnant women on treatment.

CONTINUED ON PAGE 3



Dr. Bui Vu Huy (left) of Hanoi's National Hospital of Pediatrics reviews patient records for TREAT Asia's pediatric HIV database with a member of his team and data manager Azar Kariminia.

Forcing a Retreat

In Asia and Around the Globe, Funding Cuts Jeopardize Advances on HIV/AIDS



belief that HIV programs are overfunded.

Over and over again we have had to prove that dollars spent on prevention, treatment, and research are worth the investment today to save lives and dollars tomorrow. But this is an argument being lost daily in clinics around the world where patients are being turned away because of the lack of funding for antiretroviral drugs.

At TREAT Asia, we recently learned that we are losing one of our core programs. For the past five years, we have been part of a program funded by the government of the Netherlands to enhance the global response to HIV through the first regional-level HIV drug resistance monitoring programs in Asia and Africa. With a blanket rejection of our preliminary renewal proposal, all of our consortium partners have now lost this key source of funding, which will impact almost 100 community organizations that have been working to mitigate the impact of the HIV epidemic around the world.

"This is a disaster," said Ton Coenen, executive director of Aids Fonds and Stop AIDS Now in the Netherlands, "especially for those programs targeting the most vulnerable groups of people, such as injecting drug users, and men who have sex with men. The Dutch government is not allocating

Over the past year, newspaper reports, opinion pieces, editorials, and emails forwarded throughout the HIV community have been cautioning against growing cuts in funding for HIV/AIDS programs. An intense effort has been under way to mobilize all sectors of the HIV community to challenge the

the money anymore. Now the great work these programs are doing will have to stop."

Without support for innovative programs to deliver care and conduct research, it is unclear how health systems faced with decelerated funding can make the progress needed to stop this expanding epidemic. amfAR Vice President and Director of Public Policy Chris Collins recently wrote, "We cannot hope to establish sustainable health services in developing countries as waiting lines for AIDS treatment grow" (*Boston Globe*, 17 April 2010).

As TREAT Asia moves into its tenth year, we continue to see the positive results of our efforts to build a pipeline of innovation for HIV research, education, and community programs in the Asia-Pacific region. The novel approaches being led by Dr. Rossana Ditangco in the Philippines are just one example (see page 8). Dr. Ditangco took what she learned from the Dutch-funded HIV drug resistance monitoring

program and used it to implement a national system for improving the quality of HIV clinical management in the Philippines. Biostatistics mentoring that TREAT Asia is now providing to her staff will facilitate analysis of resistance data, which can then be used to help the Philippine government determine how to utilize the country's limited resources more efficiently. If we stop investing in these types of activities, how will it be possible to create the sustainable solutions that health systems so desperately need?

In recent years, there has been an effort to downplay the use of terms like "fight" and "battle" among some global HIV programs such as those of the United Nations. But as funding is cut, HIV/AIDS programs are closing. Communities are losing their access to care. Researchers are losing their grant support. People should not have to die before we recognize that the "war" is not over.

Annette Sohn, M.D.

Over and over, we have had to prove that dollars spent on prevention, treatment, and research are worth the investment. But this is an argument being lost every day in clinics where patients are being turned away because of the lack of funding.

The *TREAT Asia Report* is a newsletter published by amfAR on behalf of TREAT Asia—Therapeutics Research, Education, and AIDS Training in Asia.

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

Constance Herndon, Editor

Contributors

Chris Collins
Carolyn Hanson
Jennifer Ho
Kylie Johnston
Liesl Messerschmidt
Annette Sohn, M.D.

Publication Design
Raoul Norman-Tenazas
Yolande Hunter

© 2010 amfAR

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

TREAT Asia Steering Committee

Jintanat Ananworanich, M.D., Ph.D.
Thailand
Kulkanya Chokephaibulkit, M.D.
Thailand
David A. Cooper, M.D., D.Sc.
Australia
Nagalingeswaran Kumarasamy, M.D.
India
Poh Lian Lim, M.D. (Chair)
Singapore
Tuti Parwati Merati, M.D.
Indonesia
Robert Ruiz
Philippines
Annette H. Sohn, M.D.
Thailand
Somnuek Sungkanupraph, M.D. (Co-chair)
Thailand
Monica Thien, R.N.
Malaysia
Jorge Villacian, M.D.
Belgium
Fujie Zhang, M.D.
China

VIET NAM CONTINUED FROM PAGE 1

Although the epidemic continues to spread, particularly among injection drug users (IDUs) and men who have sex with men (MSM), the recent history of AIDS in Viet Nam illuminates some of the ways in which global partnerships can help change the landscape of public health.

From the earliest years of the epidemic in Viet Nam, HIV/AIDS has been concentrated within vulnerable populations. IDUs, for example, constitute up to 60 percent of the country's HIV-positive population. During the 1990s HIV prevalence rose sharply, yet the country lacked the resources to launch an aggressive campaign on its own against the epidemic. But this changed in 2004 when the U.S. partnered with Viet Nam under the umbrella of its global AIDS program, PEPFAR. In six years, the annual budget for HIV has increased 20-fold, to \$120 million.

"Having those resources has made a huge impact," said TREAT Asia Director Annette Sohn, M.D. "PEPFAR brought a concentration of scientific and technical resources to Viet Nam, including training for doctors, community organizations, and NGOs. And because core structures were being built that made expansion and success possible, other international donors came forward as well."

TREAT Asia's involvement in HIV research in Viet Nam began in 2005 when the National Hospital of Pediatrics in Hanoi and Children's Hospitals #1 and #2 in Ho Chi Minh City joined the newly formed TREAT Asia Pediatric Network. TREAT Asia has since expanded its research and education activities to include collaborations with five hospitals and two labs involving adult and pediatric clinical research, provider education, and laboratory quality assurance.

Dr. Bui Vu Huy of the National Hospital of Pediatrics in Hanoi attended TREAT Asia's annual network meeting for the first time in 2006 when it was held in Hanoi. "There we met many colleagues in other countries who had worked with us on other projects, including Professor Virat Sirisanthana from Chiang Mai University, who had been teaching me about HIV/AIDS since 1995," remembered Dr. Huy.

This year the National Hospital of Pediatrics is expected to join TREAT Asia's pediatric HIV observational database cohort along with two other hospitals. "In Viet Nam, doctors have conducted much HIV research in-country," said Dr. Huy, "but joining the TREAT Asia research collaboration will help us further these studies, which can have a big impact on the care and treatment of our patients."

TREAT Asia has recently begun conducting a physician education program in Viet Nam with the support of AusAID. In response to requests from local HIV/AIDS clinicians, TREAT Asia has organized three workshops on clinical epidemiology and research methods over the past eight months, with plans to expand these activities in the coming year.

Like many countries in the region, Viet Nam is now facing an uncertain future when it comes to ongoing international support for its HIV/AIDS programs. As the only PEPFAR focus country in Asia, it faces a significant challenge in determining how it will sustain treatment and infrastructure when PEPFAR begins to draw down its support. The growing involvement of Vietnamese clinical centers in research networks like TREAT Asia is creating links to technical support and facilitating collaborations that will help see their programs into the future. ■



A child under treatment at Sapa Provincial Hospital.

Disclosure and Consent Among Adolescents with HIV

The number of children under 15 living with HIV was estimated at 2.1 million worldwide in 2008.¹ As these children are becoming adolescents, issues of disclosing their HIV status to them and gaining consent for their participation in HIV care and research are increasingly important to providers, caregivers, and the adolescents themselves. Despite the impact of these issues, however, there is no standard practice within Asia for how and when to approach disclosure and consent.

The struggle to find appropriate approaches to disclosure and informed consent is growing as



A camp in Thailand for youth with HIV.

the pediatric epidemic in the region matures. A recent study exploring consent in resource-limited countries found that lack of autonomy, illiteracy, poverty, and socio-cultural and religious diversity complicate consent and disclosure practices.² Investigators emphasized the importance of involving families and communities in making decisions about participation in research. Particularly challenging is the need to protect the privacy

HIV and Syphilis Among MSM in China

A recent study including cross-sectional surveys conducted in seven provinces in China has revealed high prevalences of both syphilis and HIV in men who have sex with men (MSM). Although these findings have been previously documented among urban MSM in China, most studies focused on men living in large urban centers, including Beijing, Shanghai, and Guangzhou. This new study was conducted across 20 large and mid-size cities and districts in regions with low overall HIV prevalence.

The surveys showed that the average HIV prevalence among MSM was 2.9%, although in one district it was as high as 15.1%. Syphilis prevalence was also high, ranging from 1.3% to 29.3%, with an average rate of 9.8%. The study also documented behavioral information, including sexual practice, health-seeking behavior, and understanding of HIV transmission.¹ Knowledge of how HIV was transmitted was high at 72.9%. However, knowledge does not necessarily translate into safe sexual practice or health-seeking behavior, as was demonstrated by the finding that only 18% of participants reported having had an HIV test. Twenty-seven percent reported always using condoms during anal sex with men.¹

Although efforts have been made to scale up the response to HIV among MSM in China, less than 15% of this population is reported to be receiving comprehensive HIV prevention interventions or is covered by current health surveillance.² The rates of both HIV and syphilis among MSM in China highlight the risk of sexually transmitted infections among MSM and underline concerns about the relationship between HIV and syphilis because sexually transmitted infections that cause skin ulcers, like syphilis, have been shown to increase the risk of acquiring and transmitting HIV.³

This study, along with other research emerging from China, emphasizes the need to include information regarding a range of sexually transmitted infections and their impact on HIV transmission in standard health information and education targeted to MSM. ■

1.Xiao Y et al. Prevalence and correlates of HIV and syphilis infections among men who have sex with men in seven provinces in China with historically low HIV prevalence. *Journal of Acquired Immune Deficiency Syndrome*. 2010; 53: S66-S73.

2.Muessig KE et al. HIV and syphilis among men who have sex with men in China: the time to act is now. *Sexually Transmitted Diseases*. 2010; 37:214-216.

3.Yuhua R et al. Relationship between syphilis and HIV infections among men who have sex with men in Beijing, China. *Sexually Transmitted Diseases*. 2007; 34:592-597.

Evaluating the Need for Directly Observed Antiretroviral Therapy

rights of adolescents when obtaining consent from parents or guardians.

It is important for adolescents and their legal guardians to fully comprehend the research and understand who will have access to what information. Towards this end, the processes of disclosure and obtaining informed consent should be conducted in local languages, prepared and delivered in a manner that is culturally appropriate and reflects the sex and developmental age of the adolescent, and involves counselors with experience in information disclosure and methods of communication. The need to view the process of disclosure

The struggle to find appropriate approaches to disclosure and informed consent is growing as the pediatric epidemic in Asia matures.

as a continuous rather than a discrete event was emphasized, as was the importance of providing ongoing access to family counseling.

Disclosure and consent are critical issues for adolescents. As the need for HIV research involving adolescents increases, age-appropriate and culturally sensitive models are needed to more effectively support care providers in this complex process. ■

An approach known as directly observed therapy (DOT), in which a healthcare worker or someone else witnesses a patient taking medications, has been proposed as a possible strategy for improving adherence to antiretroviral therapy (ART). DOT has been of particular interest for populations judged to be at high risk for poor adherence, including injecting drug users. But questions and concerns have remained about the cost-effectiveness and benefit of such an intervention.

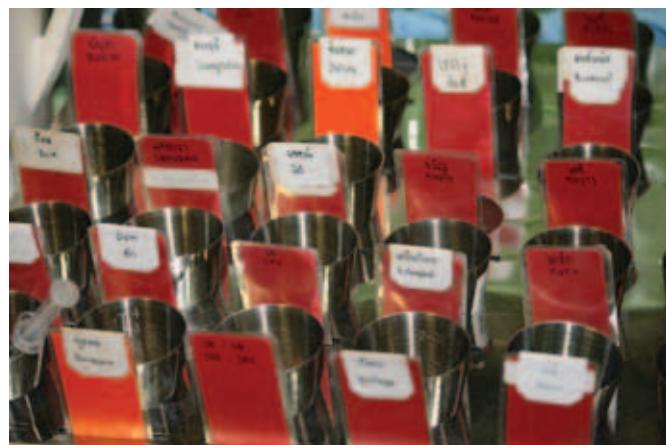
Recently, researchers from Médecins Sans Frontières gathered multiple studies on this issue and evaluated them as a group as part of a meta-analysis. They found that there was generally minimal patient benefit from the added supervision provided through DOT.¹

Using changes in viral load level as the measurement of a successful outcome, the study found that overall, patients on DOT did not have lower viral loads than those who took ART without additional supervision. However, there did appear to be some benefit from DOT in groups of patients considered to be at higher risk of poor adherence. The authors suggested that future studies should consider looking into the effectiveness of DOT for specific groups, rather than for all patients.

Although adherence support is a critical component of successful ART, the authors concluded that the limited added benefit of DOT, together with the extra burden it places on patients and health systems, is reducing confidence in this approach. In addition to the costs for travel, as well as patient and provider time, the rights and responsibilities of patients to manage their own care should also be considered. Efforts need to be made to prioritize patient-led and patient-controlled adherence strategies. ■

There was minimal patient benefit from the added supervision provided through directly observed therapy.

1. Ford N, Nachege JBE, Mark E, Mills EJ. Directly observed antiretroviral therapy: A systematic review and meta-analysis of randomized clinical trials. *The Lancet*. 2009 Dec. 19/26; 374.



Medicines are set aside for each patient at a Thai orphanage for HIV-positive children.

1.UNAIDS. Global Facts and Figures 2009. data.unaids.org/pub/FactSheet/2009/20091124_FS_global.en.pdf

2.Mystakidou K, et al. Ethical and practical challenges in implementing informed consent in HIV/AIDS clinical trials in developing or resource-limited countries. *SAHARA J*. 2009 Sep; 6(2):46-57.

they're not going to increase their chance of being arrested or identified by the police.

Creating safe zones for vulnerable groups requires that we make a concerted effort to educate the authorities—police departments, health departments, politicians. There needs to be a better understanding of how these communities are impacted by HIV and how they relate to the general population. But we also need to support leaders within civil society who can help us make our arguments about hidden populations.



Ambassador Goosby meeting with a physician during a trip to Africa. (Photo: PEPFAR)

The educational process is sometimes slow but it is a critical foundation on which a sustainable, durable response is based. So our approach is to have all of those fronts of activity concomitant with what often turns out to be—because of a lack of willingness to engage on the part of governments—a strategy that relies on NGOs as our primary interface with vulnerable communities. They can create safe spaces and at the same time work with public institutions, law enforcement in particular.

We have observed progress towards providing services for injection drug users and other vulnerable groups in Viet Nam, China, and Cambodia. These countries have, over a relatively short time, expanded their understanding of HIV among vulnerable groups, and that understanding is now reflected in programmatic changes.

Many challenges remain, however. I can't tell you the number of times we've heard people say that these issues with vulnerable communities are not a problem they have in their countries—with injection drug use in particular. There is also a lack of acknowledgment of the spectrum of human sexuality

and its expression. Here, too, governments insist that this is not something that they need to develop a response to. But just by working with country leadership in the clinical setting, you can demonstrate very quickly that these are real issues that need and deserve attention because of the disproportionate impact on all of these populations.

We have made this a big part of how we relate to governments that have epidemics in which socially marginalized groups are particularly vulnerable. We have made direct comments aimed at countries that have laws, or are considering laws, that could deter the ability to engage with vulnerable communities. That will continue. When I—or the President or the Secretary of State—come to a country, we make sure that we meet with representatives of vulnerable groups in conjunction with our partner countries so that our commitment to these communities is a clear priority.

TA Report: PEPFAR's new plans involve taking a strategic approach to HIV prevention. Can you tell us how prevention responses are progressing in Asia and around the world?

Ambassador Goosby: Because it's difficult to show results in prevention, I'm most interested in concentrating our activity on those interventions that we know have the greatest impact. We are internally assessing our approach to HIV prevention in all 30 of the PEPFAR target countries and we aim to have a core set of prevention interventions for each country reflecting its demographics and its risk groups.

Prevention plans have to acknowledge that there are populations such as MSM, injection drug users, and transgenders who are not well recognized and have no clear access points to testing, prevention services, and treatment. We must have special strategies for these groups. The shift in PEPFAR's prevention strategy is to increase the capacity to identify high-risk groups, matched with a core toolbox of high-impact interventions.

Needle exchange, as we know, is a major HIV prevention strategy among injection drug users, who constitute a significant segment of the HIV population in Viet Nam and in many Asian countries. The goal is to keep people from sharing syringes so that those who are infected with HIV and hepatitis don't spread them. This is an effective intervention that has a direct impact on seroprevalence, morbidity, and mortality among injection drug users. By preventing HIV transmission in this community, we can slow the virus's movement into the low-risk general population.

Pediatric HIV to Be a Major Focus for TREAT Asia at Vienna Conference

From improving pediatric HIV care to studying the differences in antiretroviral therapy outcomes between men and women, TREAT Asia and its members will address a wide range of topics at the XVIII International AIDS Conference in Vienna, Austria, 18–23 July.

Emphasizing its commitment to pediatric HIV/AIDS research and treatment, TREAT Asia will be a scientific co-sponsor of the 2nd International Workshop on HIV Pediatrics, which precedes the conference. While progress has been made in treating HIV among adults, many challenges remain for infants and children, including the

limited availability of pediatric HIV drug formulations. The workshop will bring together clinical experts to share their research and discuss the latest developments in pediatric HIV management, drug development, and prevention of perinatal transmission. It will also include an oral presentation on adverse events experienced by children in TREAT Asia's pediatric cohort.

During the International AIDS Conference itself, several TREAT Asia network members and partners will make presentations. Posters will be presented from the adult HIV cohort on the differences in long-term treatment outcomes between men and women,



Dr. Man Po Lee of Queen Elizabeth Hospital in Hong Kong will present TREAT Asia research in Vienna.

hepatitis B and C co-infection, and the TREAT Asia Studies to Evaluate Resistance program. In addition, an oral presentation of a multiregional pediatric mortality analysis conducted through the U.S. National Institutes of Health's International Epidemiologic Databases to Evaluate AIDS will include data from TREAT Asia's pediatric research program. ■

TA Report: Can you tell us what sorts of lessons have come out of PEPFAR's efforts in Viet Nam?

Ambassador Goosby: Injection drug users in Viet Nam present a challenge because the population is participating in behavior that is often illegal. As a result, governments frequently have a law enforcement strategy. But taking a law enforcement-dominated approach drives injection drug users underground. They don't reveal themselves to get tested, accept safe injection instruction or syringes, or receive diagnosis and treatment of HIV and hepatitis.

There has to be cooperation between public health and medical responses on the one hand and the law enforcement response on the other. These interests have to come to an agreement that will maximize the ability to identify, enter, and retain injection drug users into HIV care and services.

These issues have been highlighted in Viet Nam, along with an awareness of how important issues of trust and understanding are between the government and the public health sector, law enforcement, and the community. It has taken time to orchestrate a strong collaboration between these

groups but we are moving forward. Viet Nam is now planning to rapidly scale up medication assisted treatment along with needle and syringe programs.

TA Report: Recent reports suggest that PEPFAR may be decelerating the scale-up of AIDS treatment. What do you see for the pace of treatment and prevention scale-up over the next several years?

Ambassador Goosby: In the countries where PEPFAR is working, we are moving thousands of patients onto drugs every month. How rapidly we're scaling up is really specific to any given country, and requires understanding how that site is doing, what it is budgeted to be doing, and what resources are coming into that site for treatment support. Treatment will continue to be the central piece of many of PEPFAR's activities, especially in sub-Saharan Africa. We will not renege on the commitment we have made to those already on treatment. ■

This interview with Ambassador Goosby was conducted by amfAR Vice President and Director of Public Policy Chris Collins.

“First-line Forever”

In the Philippines, Stopping Drug Resistance Before It Starts

Approximately 950 people are on antiretroviral therapy (ART) in the Philippines, and Dr. Rossana Ditangco knows them all.

As head of the AIDS Research Group at the Research Institute for Tropical Medicine (RITM) near Manila, she may not have met them all in person but she has become familiar with key details of their lives: where and when they get their medications, what kind of support they receive from their healthcare providers, and how their immune systems are responding to treatment. This knowledge comes from an ambitious new program—inspired in part by RITM’s participation in the TREAT Asia Studies to Evaluate Resistance (TASER)—to enhance treatment adherence and monitor the emergence of drug resistance in the Philippines.

Preventing drug resistance, which can lead to failure of first-line treatment, is particularly important in countries like the Philippines where access to second-line drugs is limited due to cost. Dr. Ditangco began planning the resistance monitoring program several years ago when first-line ART became more widely available in the Philippines. “Thanks to my constant interaction with other clinicians and researchers in the region, I knew that drug resistance was one of the major challenges of scaling up treatment,” she explained.

Drug resistance is not widespread in the Philippines, which is how Dr. Ditangco and her colleagues want to keep it. “Our motto is First-line Forever,” she says. Among the small population of patients who are experiencing treatment failure as a result of resistance, most have been living with HIV for many years and began taking ART before the country had a systematic treatment and counseling program.

Dr. Ditangco and her colleagues spent more than two years developing the monitoring program, aided by the technical assistance they received through TASER. The program she has designed includes training for healthcare workers on treatment guidelines and adherence counseling, a physician guidebook, informational materials for patients, and standardized enrollment forms and adherence evaluation forms. It also includes a standard operating procedure for patient enrollment,



Staff at RITM’s AIDS Research Group (from left): Cresset Manucat, Elizabeth Navo, Laila Grace Marquez, Rosa Lyn Bantique, Ana Inocencio, and Dr. Rossana Ditangco.

monitoring, and laboratory testing, which includes regular CD4 and viral load testing, as well as resistance testing.

“TASER enabled me to bring the technology into the country, and then transfer the technology to the national program,” she said. “I’ve also been able to interact with top scientists in the area, which is very important. In developing countries like the Philippines, we would not have access to this technology and knowledge without joining a regional group like TREAT Asia.”

In addition to her role as a researcher, Dr. Ditangco is still a practicing physician, caring for patients at RITM who are enrolled in TASER and the TREAT Asia HIV Observational Database (TAHOD).

“Working in the field helps me see firsthand what is going on,” she explained. “Patients now are very educated when it comes to treatment. But they are still dealing with personal issues that interfere with adherence, and that’s very difficult to contend with. We have to do a lot of counseling.”

According to Dr. Ditangco, RITM acts as the “central nervous system” of the national treatment program, overseeing a network of treatment hubs—government hospitals that provide ART. For the monitoring program, Dr. Ditangco established a database into which HIV/AIDS clinicians across the country enter all their patients’ information, and then transfer the data to RITM for analysis.

Following the first data transfer this spring, most participating clinicians are enthusiastic about the program. “They are all in agreement that we cannot allow drug resistance to develop because we may not be able to provide second-line treatment to everyone,” said Dr. Ditangco. ■