

Therapeutics Research, Education, and AIDS Training in Asia (TREAT Asia)

A Cooperative Approach to Building Capacity
for the Broader Introduction of HIV/AIDS
Therapeutics in Asia and the Pacific Region

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Therapeutics Research • Education • AIDS Training

TREATASIA

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HIV/AIDS in Asia: An Overview

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I Vision

As part of a comprehensive response to an expanding and potentially catastrophic HIV/AIDS epidemic in Asia and the Pacific, the American Foundation for AIDS Research (amfAR) is launching a cooperative initiative in the region that aims to build capacity for the safe and effective administration of therapeutics for HIV/AIDS on a broad scale. Recent reductions in the price of HIV/AIDS therapeutics and the increasing availability of generic versions of some drugs have paved the way for expanded access to antiretroviral therapy across Asia and the Pacific region. The experience of many countries has shown, however, that the complexities of AIDS drug regimens and their safe and effective administration require specialized knowledge that is best acquired through education and training.

TREAT Asia seeks to increase the availability of high quality HIV/AIDS treatment and care by expanding the pool of physicians and health care professionals who are well qualified in the safe and effective delivery of therapeutics and the management of HIV infection and AIDS; develop and advance a coordinated clinical research agenda that is responsive to the needs of HIV-infected populations in the region; enhance health care infrastructure in preparation for expanded access to antiretroviral therapy and experimental therapeutics; and identify and address the major policy obstacles that hinder the expansion of access to drug treatments for HIV/AIDS across Asia and the Pacific region.

TREAT Asia is a narrowly defined initiative that seeks to complement the existing programs and activities of governmental and nongovernmental organizations (NGOs) operating in Asia and the Pacific region. By contributing a key element of a comprehensive response to the epidemic, the initiative will help to advance a holistic approach to confronting and containing it. It could also help to broaden the public's peripheral vision on HIV/AIDS, increasing awareness of the need for concerted action and for an infusion of resources to thwart the epidemic in this populous region.

Asia and the Pacific region will soon have more new HIV infections than any other part of the world and is expected to be the epicenter of the global AIDS pandemic in the coming decade. The need exists for a comprehensive response to the growing problem of HIV/AIDS in Asia and the Pacific—a response that includes treatment and prevention, care, research, education, and training, and that involves cooperation and partnership between the public and private sectors.

As an important component of this comprehensive response to HIV/AIDS in Asia and the Pacific, the American Foundation for AIDS Research (amfAR) is initiating a cooperative network that seeks to help in building capacity for therapeutics education, training, and research across the continent. The initiative aims to facilitate the sharing of clinical experience and expertise, the enhancement of necessary infrastructure for the design and implementation of cooperative clinical trials, and the creation of a network of health care professionals skilled in the treatment and management of HIV/AIDS that can be expanded across the region. It also aims to help identify and address major policy impediments to expanding access to HIV/AIDS therapies at both the local and the regional level.

TREAT Asia has the potential for producing significant direct benefits for the region. These could include increased access to high quality HIV/AIDS treatment and care through an expanded pool of physicians and health care professionals who are well qualified in the treatment and management of HIV infection and AIDS; development of standards of care that are specific to, and responsive to the needs of, the different epidemics in the region; and, over time, expanded access to experimental therapeutics. The synergistic relationship between the therapeutics education, training, and research components of the initiative could have a beneficial effect in the areas of HIV prevention, improved health care infrastructure, health-care technology transfer, increased government and private industry engagement in HIV/AIDS, and increased community involvement.

Much has been learned about expanding access to treatment and raising standards of care in resource-poor settings through the experience of NGOs and through government-led initiatives in parts of sub-Saharan Africa, Latin America, and some countries in Asia. In Brazil, for example, an aggressive government response to the spread of HIV infection and AIDS, whereby the primary strategy was to facilitate the free distribution of antiretroviral drugs, helped halve the country's AIDS death rate between 1996 and 1999. While drug pricing and access are crucial pieces of the puzzle, the need for a properly trained health care workforce is also well documented. Evaluation of a UNAIDS-sponsored Drug Access Initiative, launched in 1997 with pilot programs in Chile, Côte d'Ivoire, Uganda, and Vietnam, showed “an increased knowledge of the use of

antiretrovirals by health care workers as well as a successful transfer of know-how for a comprehensive follow-up of [people with AIDS] on anti-retroviral therapy.”

In addition to lessons learned on the ground, the international community is showing the first signs of a coherent and committed response to the pandemic of HIV/AIDS. In April 2002, the Global Fund to Fight AIDS, Tuberculosis and Malaria issued its first round of grants, distributing \$378 million to 40 programs in 31 countries. While this falls short of the expectations of many, it nonetheless represents a much-needed infusion of funds for treatment, prevention, and education programs in the developing world. These awards followed on the heels of the UN General Assembly’s historic Special Session on AIDS in June 2001. The Session produced a Declaration of Commitment that established a framework for national and international accountability on AIDS and set benchmark targets for prevention, care, support and treatment. The Declaration articulated the need “...to strengthen health care systems and address factors affecting the provision of HIV-related drugs, inter alia affordability and pricing...and technical and health care systems capacity. Also, in an urgent manner make every effort to: provide...the highest attainable standard of treatment for HIV/AIDS, including...effective use of quality-controlled antiretroviral therapy, in a careful and monitored manner to improve adherence and effectiveness and reduce the risk of developing resistance.”

This is an opportune time for coordinated action on HIV/AIDS in Asia and the Pacific for additional reasons. First, in spite of high infection rates in some areas, the epidemic in the region is still in its infancy and well-planned programs initiated now can help in containing the epidemic and managing its impact. Second, the devastation wrought by AIDS in sub-Saharan Africa has created a broader awareness and acceptance of the need for cooperative education, training, and research programs. Third, continued pressure on the pharmaceutical industry to lower prices, combined with greater access to generic drugs, increases the probability that the availability of antiretroviral treatments will gain further momentum across the developing world. And fourth, there are early signs of an emerging acceptance of the magnitude and the ramifications of the HIV/AIDS epidemic on the part of governments in the region—most notably China—that, for various reasons, were once reluctant officially to acknowledge HIV/AIDS as a significant public health issue.

amfAR has long been engaged in HIV/AIDS prevention, education, research, and training in the international arena. Historically, amfAR’s global initiatives have focused on providing technical assistance to AIDS organizations in developing countries and forming partnerships with non-governmental organizations (NGOs) and community-based organizations

to help them establish effective local education and prevention programs. In addition, amfAR has sought to help health care workers from developing countries maximize their local resources and to facilitate the transfer of proven prevention strategies and public health interventions from developed to developing countries.

With 90 percent of people with HIV/AIDS living in developing countries, amfAR and all concerned institutions in both the public and private sectors have a clear moral obligation to respond to the burgeoning epidemics in those countries. The challenge lies in deploying finite resources to maximum effect. TREAT Asia aims to make best use of existing resources and to generate necessary investment in therapeutics education, training, and research.

Given the vast size of the region and the scope of the problem, TREAT Asia represents one strategy among a constellation of programs and approaches to addressing HIV/AIDS in Asia and the Pacific region. Other groups and collaborations are active in the region in the areas of treatment, prevention, research, and education. The HIV Netherlands Australia Thailand Research Collaboration (HIV-NAT), for example, has been conducting multicenter HIV clinical trials in Thailand since the mid-1990s. In Vietnam, a UNAIDS-sponsored Drug Access Initiative has focused on reducing mother-to-infant transmission of HIV and has also included some training in the use of antiretrovirals and drugs for opportunistic infections. Médecins Sans Frontières operates treatment programs in some parts of Cambodia, Laos, and Thailand. The International AIDS Society's Clinical Trials Partnership is developing a framework within the IAS for exchanging information relating to HIV clinical trials in developing countries. And a disparate array of individual clinics, hospitals, and health care centers ministers to the needs of people with HIV/AIDS in both rural and urban settings.

A core principle underlying the TREAT Asia concept is that, by cooperating with existing programs and initiatives in the region, it will complement their efforts and avoid duplicating what is already being done. And by fostering collaboration among health care professionals and community

III Core Values

representatives with frontline clinical experience and firsthand knowledge of the needs of the region, TREAT Asia has the potential for creating a ripple effect that steadily expands outward across the region as the network grows and the benefits of education and training programs are replicated in regional and rural clinics and communities.

The development and operations of the cooperative will be guided by the following principles:

- **Inclusion**

Political, cultural, and other external concerns will not influence or govern the inclusion of participating individuals or organizations in the cooperative. amfAR firmly believes it is essential that the cooperative include members of the infected/affected community as an integral and critical component of all decision-making processes. In this way, the activities of the cooperative will be shaped in partnership with, and be responsive to, the needs, ideas, and aspirations of that community.

- **Transparency**

All activities and projects implemented by the cooperative, and the decision-making bodies and processes that govern such activities and projects, will be fully open to public scrutiny. In this way, the cooperative will be open to examination by the infected/affected community, the general public, the scientific community, the broader international community, and/or other interested parties.

- **Expansion**

The cooperative will be thoroughly committed to broadening and sharing the education, training, and research benefits derived from its activities with the infected/affected community, the scientific community, health care professionals, and the general public in the region.

- **Peer review**

The peer review process facilitates the evaluation of research projects by independent scientists, community representatives, and others, and helps to ensure the selection of projects based on scientific merit, originality, and potential for saving lives. Since its inception, amfAR has been committed to rigorous peer review as the most objective and credible method for the evaluation of research proposals.

1. **Develop the skills of the health care workforce in the safe and effective administration of drug treatments for HIV/AIDS.**

As has been made clear in Africa, mere access to therapeutics is only a small part of the challenge groups are facing as they come to terms with trying to extend the benefits of HIV/AIDS therapeutics to populations in the developing world. As access to antiretroviral treatment inevitably spreads across the region, the complexities of medical management will only increase. In many parts of Asia and the Pacific, there is a pressing need for greater experience in the management and treatment of HIV infection and AIDS among physicians and health care professionals. An expanded pool of experienced and highly trained health care providers, with knowledge of delivering therapeutics effectively and safely, is a necessary component of a comprehensive health care infrastructure that will be needed in the region.

TREAT Asia aims to initiate a systematic effort to broaden access to education and training in the management of HIV/AIDS and the safe and effective administration of antiretroviral therapy. The cooperative would undertake this incrementally. A core network of physicians, nurses, case-workers, home health aides, and study coordinators, trained and experienced in the treatment and management of HIV infection and AIDS, would provide the foundation for expanded training and education of health care providers across the region.

Objectives

- To develop, administer, and replicate training modules that could be used throughout the region to develop standards of clinical care. These would be based in large part on existing health care education and training programs in the region that have proven to be effective.
- To identify and support regional clinical “centers of excellence” that, with minimal investment in infrastructure, could administer education and training programs.
- To develop efficient methods of communication and consultation to facilitate the sharing of clinical expertise throughout the region. These could include regular meetings and workshops, teleconferences, electronic communications, a dedicated website, and newsletters.

2. Enhance existing infrastructure and formulate strategies for capacity building to prepare for expanded access to, and the safe and effective administration of, HIV/AIDS drug treatments.

Existing health care infrastructure varies widely across Asia and the Pacific, but many countries in the region have a relatively solid foundation for the provision of health care services. Nonetheless, well-orchestrated technology transfer will be pivotal to the success of TREAT Asia. This would involve the transfer and application of technologies for laboratory testing and monitoring, acquisition of laboratory and clinic equipment where necessary, and, crucially, developing and undertaking training programs for lab technicians, clinical study monitors, ancillary personnel, and community advocates.

In the laboratory setting, for example, there is typically little surplus capacity for providing anything beyond the most essential analysis and testing services. Large-scale administration of antiretroviral therapy may necessitate the development or acquisition of more sophisticated monitoring tools and techniques. Similarly, a coordinated therapeutics research effort will require some expansion of resources across a regional network of laboratories. In addition to the obvious benefits of improved infrastructure, it will also increase the potential for investment from the pharmaceutical industry.

Infrastructural needs will also extend to ancillary operations and services, such as database development and management, statistical analysis, electronic communications, and administrative support.

Objectives

- To identify and prioritize infrastructural needs relative to laboratory facilities, monitoring, statistical/data management, telecommunications, and administrative support.
- To identify training needs and develop training programs to upgrade skills where necessary.
- To identify potential funding sources and solicit funding from foundations, corporations, individual donors, government.

3. Develop a framework for regional collaboration on a therapeutics research agenda that is responsive to the needs of patient populations in the region.

Clinical research can be considered the most important part of translational research, as it seeks to understand the implications of therapeutic strategies in a “real world” setting. Essentially, the goal of clinical research is to develop and implement therapeutic strategies that are unique and relevant to the populations being studied. When conducted at a single site, the benefits of clinical research are largely confined to the populations represented at that particular site. Extrapolating study results to larger populations requires a corresponding expansion of the patient pool. Thus, a regional therapeutics research cooperative in the context of TREAT Asia will seek to foster the cooperation necessary for access to patient populations across the entire region. In the long term, this cooperation will help to define standards of care for patients throughout Asia and the Pacific—standards that may be strikingly different from those that have been established in the West.

amfAR’s experience with community-based clinical trials in the United States has shown that a cooperative therapeutics research network can also produce important indirect benefits. Essentially, the Foundation recognized the potential of community-based clinical research for “real world” testing of the efficacy, safety, and acceptability of new drugs and drug regimens among a large and diverse HIV-infected patient population. amfAR’s community-based clinical trials program, initiated in New York and San Francisco in 1988, significantly expanded access to both experimental and approved treatments by enabling many more people with HIV/AIDS to enroll in clinical trials. The program contributed to raising standards of HIV/AIDS treatment and care and gave primary care physicians opportunities to study new therapies and acquire much needed expertise in their use, efficacy, and side effects in a “real world” setting.

As with existing methods of conducting clinical research, the primary objective of community-based clinical research at the outset was to generate data from the study of new medical management strategies that could be used to improve treatment and care for people living with HIV/AIDS. This objective is valid for all parts of the world. Defining treatment regimens for any region is influenced by many factors, including overall health care funding, availability of therapeutics, and the performance of the therapeutics within the population for whom the standards are being developed, to name a few. It is important to note that, while the standards of care for people with HIV/AIDS that are broadly applied in the West can inform the development of a standard for Asia and the Pacific, there will likely be

significant differences between the two. As an example, it is well established that the range for normal body weight in Asians is less than in Caucasians. For that reason, the dosing of antiretrovirals, which is established through pharmacokinetic research studies, may well be different for Asians than for Caucasians. Only clinical research can establish the appropriate doses of medicines for people with HIV/AIDS in Asia and the Pacific.

Objectives

- To identify and build a core group of physicians and academics with clinical therapeutics research expertise from established clinical centers throughout the region.
- To develop a comprehensive understanding of the needs of the region relative to therapeutics research.
- To identify and prioritize therapeutics research projects that are regionally relevant, i.e., that have potential for benefiting patient populations in the region. These could include studies of new therapeutics, salvage therapy, HIV/tuberculosis co-infection, adherence issues, the impact of HIV on women and reproductive health, bioequivalent studies (generics), and investigation of cost-effective ways to monitor treatment regimens.
- To develop and execute a therapeutics research agenda that addresses regional needs and facilitates expanded access to approved and experimental therapeutics for patient populations in the region.

4. Define and address the national and regional policy issues that impede expanded access to drug treatments for HIV/AIDS.

The success or failure of a health care agenda is largely dependent on the priorities established by local and national governments and the corresponding allocation of resources. In general there is a correlation between the effective containment of the HIV/AIDS epidemic and the willingness of governments to assign a high priority to HIV/AIDS treatment and prevention and to work cooperatively with nongovernmental organizations. Increased government support of all HIV/AIDS research, treatment, prevention, and education programs is critically important, and TREAT Asia could be an effective vehicle for advocating the needs of people with HIV/AIDS and encouraging lawmakers across the region to assign the highest possible priority to HIV/AIDS programs.

Objectives

- To develop a forceful, collective voice for effective advocacy in the region.
- To develop mechanisms for increasing government support of HIV/AIDS research, prevention, treatment, and training programs.
- To build public support for HIV/AIDS programs in the region. Advocacy efforts and, thus, the likelihood of government support for the cooperative will be greatly enhanced by broad-based public awareness of the HIV/AIDS epidemic and its consequences and by public support for HIV/AIDS initiatives.

Planning Phases

With rates of HIV infection rising ominously in many countries in Asia, in December 2000 amfAR organized a special World AIDS Day conference at the United Nations in New York to call attention to the epidemic's eastward advance. This was followed by site visits to clinical centers in Thailand, China, Singapore, Malaysia, and India, and discussions with physicians, academics, and public health representatives to assess the opportunities for amfAR to play a role in addressing the epidemic in Asia and the Pacific region. amfAR's Global Initiatives Committee agreed that the Foundation could and should bring its experience and expertise to bear to contribute to some of the unmet needs of the region, and that the broad aims of TREAT Asia were consistent with the priorities of amfAR's Global Initiatives program. Discussions of the feasibility of a cooperative initiative in Asia were also held with representatives of UNAIDS and WHO.

In July 2001, amfAR convened a two-day meeting in Bangkok, Thailand, to further assess regional needs and to determine levels of interest in and commitment to a cooperative effort among clinicians and clinical

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researchers at HIV/AIDS centers across the region. Representatives attended from 13 countries, as well as the International AIDS Society, the HIV Netherlands Australia Thailand Research Collaboration (HIV-NAT), the Fogarty Institute, the U.S. National Institutes of Health (NIAID), the pharmaceutical industry, private foundations, and the community sector. The Bangkok meeting produced general agreement on the goals and objectives of TREAT Asia and its terms of reference. An *ad hoc* steering committee was formed to provide oversight and leadership for the cooperative.

Further fact-finding visits were subsequently undertaken in Cambodia, Taiwan, and Vietnam. In October 2001, the group met again in Australia, and the TREAT Asia steering committee met in Bangkok in January 2002.

Planning phases are proceeding on several tracks. Periodic meetings of the group will continue in order to build cohesion and to refine needs, goals, and objectives. Planning grants will be sought to secure a funding base from which to further develop the initiative. And, importantly, science-based information will be gathered to inform and support the goals and objectives of TREAT Asia and to provide objective measures of progress.

An observational database could be a key component of the data-gathering effort. It could help to develop capacity in HIV clinical data collection across the region, to evaluate the introduction of new HIV treatments, and to monitor patterns of antiretroviral and prophylactic treatment use relating to demographic factors and markers of HIV disease stage. As access to antiretroviral therapy expands across Asia and the Pacific, it will be critically important to monitor and evaluate its effect on morbidity and mortality, and to monitor issues such as therapeutic toxicity and adherence. In addition, a linked observational cohort study would provide a useful foundation from which to pursue further clinical research studies.

Oversight

Comprised of leaders in the medical and clinical research communities and with representation from the HIV/AIDS community, the TREAT Asia steering committee will be responsible for formulating criteria for participation in the cooperative and for roles and responsibilities of participating sites; reviewing and prioritizing projects; developing and overseeing budgets; and securing funding. Subcommittees will be established for communications/public relations, fund raising, and policy/advocacy.

Inclusion criteria

While precise membership criteria remain to be determined, the sites participating in the cooperative will represent varying levels of expertise, experience, and available resources. Given the central objective of building levels of expertise in HIV/AIDS treatment, however, site selection criteria and minimum standards will be aimed at raising the standard of all sites to the level of those at the upper end of the spectrum.

At a minimum, participation in TREAT Asia will require a commitment to engage the challenges that exist within the region, whether cultural, political, linguistic, demographic, or geographic, as well as a commitment to engage all sectors of society in advancing the goals and objectives of the cooperative, including government, private industry, NGOs, development assistance agencies, and people living with HIV/AIDS.

Role of amfAR

As catalyst for the cooperative, amfAR is committed to supporting and facilitating the development of structures and mechanisms that are necessary for the establishment of the cooperative and is thus initially committed to adopting a leadership role. With appropriate structures and a governing body in place, however, the Foundation's role will evolve into that of partner in, and advisor to, the cooperative, although it will have ongoing responsibility as fiscal agent for the cooperative.



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